

work, family & health study

Documentation of the Work, Family, & Health Network (WFHN) Field Operations

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# 1.1 Overview

Although the prevalence of "family-friendly" policies in US workplaces has increased dramatically in recent vears, few have been studied using scientifically sound designs. To address this critical gap, the National Institute of Health and the Center for Disease Control formed the Work, Family & Health Network (WFHN). During Phase 1, WFHN designed and conducted multiple pilot and feasibility studies. For Phase 2, the WFHN has been called upon to implement an innovative intervention based on Phase I pilot studies and to evaluate the intervention using a group randomized experimental design. The goal of the study is to assess the effects of a workplace intervention designed to reduce work-family conflict, and thereby improve the health and well-being of employees, their families, and their workplaces. The study intervention is grounded in theory from multiple disciplines and supported by findings from our pilot/feasibility studies on the importance of increasing familysupportive supervisor behaviors and employees' control over work. We are assessing the efficacy of the intervention via group-randomized field experiments, one at each of two employers representing different industries. Within the long-term care industry, 30 worksites of 30-89 (average of 51) employees each were randomly assigned to intervention or usual practice conditions. In the other industry, IT/telecommunications, 56 study groups were randomly assigned to intervention or usual practice conditions; study groups had 7-60 employees each (average of 28). All employee and supervisor participants were assessed at baseline and at 6-, 12-, and 18-months post baseline, including survey interviews and health assessments of cardiovascular risk and sleep dysregulation based on selected biomarkers and actigraphy. Employees' spouse/partners and/or children (one resident child per employee) aged 9-17 years were assessed to document the impact of the intervention on family functioning. In addition, to provide a more detailed perspective on the temporal relationship of work-family conflict and health, a sub-sample of 633 employee participants and their child participated in a daily diary assessment including telephone interviews and saliva sampling. Finally, our process evaluation documents details of intervention fidelity, implementation, and dose received by participants. The WFHN will also translate findings to business environments and other public media channels. The study holds areat promise for informing the implementation of evidence-based family-friendly policies, and therefore improving the health and well-being of employees and their families nationwide.

# 1.2 Changing Work and Changing Families

Technological, economic, and globalization forces are simultaneously reducing job security, particularly for lowwage earners, and increasing job demands by requiring longer and often "non-standard" hours (Presser, 2003). Increased cohabitation and delayed marriage and childbearing allow young adults more time to establish their careers. but also create more family demands at midcareer and beyond, when work responsibilities are the greatest (Casper & Bianchi, 2002; Moen, 2003; Moen & Chesley, 2008; Moen & Roehling, 2005). More mothers (and women in general) are in the labor force and they work more hours (Casper & Bianchi, 2002; Saver et al., 2004). Today, most employees must coordinate both job and home schedules with little backup at home. Demands have increased for the growing number of dual-earner families, single mothers, and "sandwich" families who must provide care for young and old (Casper & Bianchi, 2002; Moen, 2003; Moen & Chesley, 2008; Neal & Hammer, 2007). As the U.S. population ages, older workers in full-time jobs with little flexibility may experience both health and safety difficulties (National Research Council & the Institute of Medicine, 2004) or decide to retire early from these demanding jobs (Moen, 2007). Furthermore, employees are increasingly expected to be available to work all hours of the day and all days of the week, with no schedule consistency (Presser, 2003), resulting in higher job demands and less control over the time and timing of their work. Escalating time pressures and work-family conflict have negative business consequences, such as reduced worker productivity and higher employee turnover (Grandey & Cropanzano, 1999; Netemeyer et al., 1996; Kelly et al., 2008), and have negative long-term consequences for the economic health of organizations and, ultimately, the nation. Evidence suggests that individuals and families have exhausted their ability to rearrange their lives (including reducing fertility and delaying childbearing) to fit the existing social organization of work (Bianchi & Raley, 2005; Moen & Chesley, 2008; Moen & Roehling, 2005; Sayer et al., 2004). Thus, there is a clear need for initiatives that change current working conditions in ways that reduce these stressors and improve the health of workers, their families, and their employers.

# 1.3 Work-Family Conflict

Work-family conflict is defined as a type of interrole conflict where work and family roles are incompatible (Greenhaus & Beutell, 1985). Meta-analyses and reviews show that work-family conflict is significantly correlated with higher work stress, turnover intentions, absenteeism, and family stress; with lower family, marital, life, and job satisfaction; and with lower organizational commitment and productivity (see, e.g., Allen et al., 2000; Eby et al., 2005; Kossek & Ozeki, 1998; Melchior et al., 2007). Recent research also shows that work-family conflict is linked to lower levels of employee safety participation, with serious negative implications for family members affected by employee injuries (Cullen & Hammer, 2007).

Both lack of supervisor support for work-family balance and insufficient employee control over the time and timing of work have been linked to higher work-family conflict (Hammer et al., 2005a; Kelly & Moen, 2007; Kelly et al., 2008). Current work hour and supervisory policies and practices are outmoded because many of these were fashioned in the 1940s and '50s on the premise that employees have few non-work responsibilities, needs, or interests (Bianchi & Raley, 2005; Moen & Chesley, 2008; Neal & Hammer, 2007). Many organizations have adopted "family-friendly" or "work-life" policies, but these initiatives are differentially available to employees and implemented unevenly across and within organizations (Eaton, 2003; Kelly & Kalev, 2006; Kossek & Distelberg, 2009). Current work-family policies are also generally treated as "accommodations" available to some employees rather than adaptations of the work process that are broadly implemented (Lee et al., 2000; Williams, 2000). Employees' use of these policies is low, partly because workers fear and often experience career penalties (Blair-Loy & Wharton, 2002; Glass, 2004; Smock & Noonan, 2005) or because managers are not socialized to emphasize work-family support. Thus, workers face a variety of health- and safety-related stressors (e.g., deadlines, increased work loads and overloads) that lead to work-family conflict, parenting stress, and goals and expectations at work and at home that are often at odds with one another.

# 1.4 Work-Family Conflict and Health

Work-family conflict is linked to mental health problems and reduced self-reported health (Frone, Russel, & Cooper, 1997; Frone, 2000; Greenhaus, Allen, & Spector, 2006; Grzywacz & Bass, 2003; Melchior et al., 2007); more chronic physical symptoms; and higher levels of dysphoria, psychological distress, and sickness-related absence (Grzywacz, 2000; Vaananen et al., 2004). Related literature suggests that, over time, the effects of work-family conflict result in negative health outcomes among objectively measured indicators such as high blood pressure (Belkic et al., 2004; Landsbergis et al., 2002) and other mental and physical health problems (Ganster & Schaubroeck, 1991; Ganster et al., 2001; Macik-Frey et al., 2007; Melchior et al., 2007). Dmitrieva, Baytalskaya, and Almeida (2007) showed that increases in work-family conflict predicted increases in chronic health conditions and self-rated health problems over a 10-year period. We hypothesize that these effects work in much the same way as classical job strain measures based on high demand and low control; often, low workplace support has impacted a host of outcomes, especially cardiovascular-related outcomes (Karasek et al., 1998; Bosma et al., 1997). In the proposed study, we test whether the workplace intervention improves employees' health and spills over to improve their family relationships. We measure these health and family outcomes at the global level and, using a daily diary approach, we also take the innovative step of studying the effects of the intervention on work-family spillover on a daily level.

Grounding our work in an emotion transmission paradigm (Larson & Almeida, 1999), we also test whether employees' experiences at work cross over to affect the health and well-being of their partners and children. Within this paradigm, families are a nexus of social exchanges, and the emotional tone of family interactions varies in intensity and valence in ways that have implications for family members' individual well-being and family relationships (Repetti et al., 2002). Importantly, individuals bring experiences from the external world to bear on their family interactions (Crouter et al., 1989); in this way, employees' experiences at work can cross over to affect the health of spouses and children (Hammer et al., 1997; Almeida et al., 1999). We propose to examine the effects of the intervention on work-family cross-over processes on a global level, but also to study how parents' work experiences on a given day link, on that same day, to the health and family experiences of their children.

### 1.5 Workplace Policies and Management Practices

### 1.5.1 The Need for Policies and Management Practices That Support Families.

Low levels of governmental support for reconciling work and promoting work-family balance in the United States place the responsibility for providing support to working families with U.S. employers (Kelly, 2005; Ruhm, 2005; Waldfogel, 2005; Wertheimer et al., 2005). Only in the past few decades, however, have U.S. employers recognized that work and family are intertwined and that effective policies and practices for reducing work-family conflict are needed, both for the health of employees and their families and for fiscal health of organizations. Unfortunately, low-wage workers are less likely to have access to supportive work policies and practices that would benefit them and their families (Burton et al., 2005; Perry-Jenkins, 2005). There also is mounting evidence linking employees' stressors on the job with crossover effects to family members. Most of this research (e.g., Hammer et al., 1997; Westman, 2001; Westman et al., 2004) focuses on crossover to spouses, but there is some research (e.g., Almeida et al., 1999) that documents crossover effects to children.

### 1.5.2 The Need for Evaluation Research on Workplace Policies and Management Practices.

Few studies have systematically tested the effects of workplace policies and practices on work-family conflict, individual and family health and well-being, or organizational outcomes (Kelly et al., 2008). Furthermore, few studies have examined the same associations between work policies and health, and none, to our knowledge, has tested for a causal relation between the two. Rigorous evaluations of work-family programs and policies affecting work-family conflict that involve longitudinal data and appropriate comparison groups are virtually nonexistent (exceptions include Hammer et al., 2005; Thomas & Ganster, 1995). A recent review conducted by network researchers in Phase 1 (Kelly et al., 2008) suggests that supervisors' support for family and personal life and employees' control over work time are crucial components of interventions to reduce work-family conflict, but these studies provide little guidance on how organizations can effectively modify the work environment to promote control over work time or family-supportive supervision (Kristensen et al., 2005). Additionally, theory from a number of disciplines (e.g., Barrera, 1986; Bandura, 1988; Deci & Ryan, 1995; Karasek & Theorell, 1990; Landsbergis, 1988) also points to the importance of control and support for individual well-being. The conjunction of high control and high support in the context of reasonable demands produces healthy environments that encourage individual development and well-being. Our study rigorously evaluates a workplace intervention designed to reduce work-family conflict and improve health by increasing control over work time in the context of increasing supervisors' support for work-family issues. The intervention is innovative by incorporating principles of participatory work redesign and supervisor-focused training, reinforced by selfmonitoring, to increase family-supportive supervisory behaviors.

An innovation of the study is the use of objective biomarkers and assessments of health status, specifically focusing on cardiovascular risk and sleep disruption, as piloted successfully by the Harvard RU in Phase 1. For example, cholesterol levels are among the most important predictors of cardiovascular risk (including new cardiovascular disease, cardiac events, and mortality) (Lien et al., 2007; Ray et al., 2007). Blood sugar control (i.e., HbA1c levels), a central indicator of diabetes or diabetes risk, has been used in several studies to link socially stressful experiences to health outcomes, particularly those related to cardiovascular disease (McEwen & Seemen, 1999). In addition to these two biomarkers, we objectively assessed blood pressure and body mass index (BMI) and collected self-reports of cardiovascular disease, diabetes, and cigarette smoking. Furthermore, we objectively measured sleep dysregulation, defined as insufficient sleep duration or sleep disruption, as a health marker predictive of future diabetes (Ayas et al., 2003; Nilsson et al., 2004), cardiovascular disease (Wolk et al., 2005; Ayas et al., 2003; Meisinger et al., 2007), and early mortality (Wingard & Berkman, 1983; Mallon et al., 2002).

Another innovation of the proposed study is the use of a daily diary method to study the effects of the intervention. Work policies are not monolithic: Individuals can take advantage of some policies, such as a flexible schedule, on some days more than on others. Analyses in a daily diary design focus on variations around individuals' central tendencies. We used daily methods to examine how daily variations in workers' experiences of intervention-targeted workplace practices map to daily variations in physical and emotional health and family relationship experiences of employees and their children.

### **1.6** The Need to Translate and Disseminate Successful Interventions.

Effective workplace interventions to reduce work-family conflict are only useful if they are actually adopted by workplaces. We are assessing the conditions under which interventions achieve optimal results. These findings will then be disseminated through communication channels that appeal to business leaders, policy makers, and the public. Such dissemination requires more than publications in scholarly journals. It also requires active dissemination of results into readily accessible business journals, corporate business-to-business tools, and multimedia channels directed at human resource managers and senior business leaders. Research grounded in the science of translation is also needed to better understand the successful integration of an evidence-based intervention within specific work settings (Khoury et al., 2007). This means learning more about how new practices and policies are adopted and how barriers to adoption can be avoided (Glasgow & Emmons, 2007). Barriers to translating research findings into practice can be reduced by anticipating them (Glasgow & Emmons, 2007). Our approach incorporates the science of translation, from the beginning of Phase 2. Translational research will inform our intervention delivery methods, measures, and study design in ways that strengthen the research and facilitate its applicability to real-world practice and policy decisions.

#### References

- Allen, T.D., Herst, D.E.L., Bruck, C.S., & Sutton, M. (2000). Consequences associated with work-to-family conflict: A review and agenda for future research. *Journal of Occupational Health Psychology*, *5*, 278-308. doi: 10.1037//1076-8998.5.2.278
- Almeida, D.M., Wethington, E., & Chandler, A. (1999). Daily transmission of tensions between marital dyads and parent-child dyads. *Journal of Marriage and Family, 61,* 49-61. doi: 10.2307/353882
- Ayas, N.T., White, D.P., Manson, J.E., Stampfer, M.J., Speizer, F.E., Malhotra, A., Hu, F.B. (2003). A prospective study of sleep duration and coronary heart disease in women. *Archives of Internal Medicine*, *163*, 205-209. doi: 10.1001/archinte.163.2.205
- Bandura, A. (1988). Self-regulation of motivation and action through goal systems. In V. Hamilton, G.H. Bower, & N.H. Frijda (Eds.), *Cognitive perspectives on emotion and motivation* (pp. 37-61). Dordrecht, The Netherlands: Kluwer Academic Publishers.
- Barrera, M. (1986). Distinctions between social support concepts, measures, and models. *American Journal of Community Psychology, 14,* 413-445. doi: 10.1007/BF00922627
- Belkic, K., Landsbergis, P. A., Schnall, P. L., & Baker, D. (2004). Is job strain a major source of cardiovascular disease risk? *Scandinavian Journal of Work Environment & Health, 30*, 85-128. doi: 10.5271/sjweh.769
- Bianchi, S.M., & Raley, S. (2005). Time allocation in working families. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health, and well-being* (pp. 21-42). Mahwah, NJ: Erlbaum.
- Blair-Loy, M., & Wharton, A.S. (2002). Employees' use of work-family policies and the workplace social context. *Social Forces, 80,* 813-845. doi: 10.1353/sof.2002.0002
- Bosma, H., Marmot, M.G., Hemingway, H., Nicholson, A.C., Brunner, E., & Stansfeld, S.A. (1997). Low job control and risk of coronary heart disease in Whitehall II (prospective cohort) study. *British Medical Journal*, *314*, 558-565. doi: 10.1136/bmj.314.7080.558
- Burton, L. M., Lein, L., Kolak, A., Bianchi, S. M., Casper, L. M., & King, R. B. (2005). Health and mothers' employment in low income families. In S. Bianchi, L. Casper, & R. King (Eds.), *Work, family, health, and well-being* (pp. 493-509). Mahwah, NJ: Erlbaum.

- Casper, L. M., & Bianchi, S. M. (2002). *Continuiy and change in the American family: Anchoring the future.* Thousand Oaks, CA: Sage Publications.
- Crouter, A.C., Perry-Jenkins, M., Huston, T.L., & Crawford, D.W. (1989). The influence of work- induced psychological states on behavior at home. *Basic & Applied Social Psychology, 10,* 273-292. doi: 10.1207/s15324834basp1003\_5
- Cullen, J. C., & Hammer, L. B. (2007). Developing and testing a theoretical model linking work-family conflict to employee safety. *Journal of Occupational Health Psychology, 12*, 266-278. doi: 10.1037/1076-8998.12.3.266
- Deci, E.L., & Ryan, R.M. (1995). Human autonomy: The basis for true self-esteem. In M. Kemis (Ed.), *Efficacy, agency, and self-esteem* (pp. 31-49). New York: Plenum.
- Dmitrieva, N., Baytalskaya, N., & Almeida, D. M. (2007). Longitudinal changes in work-family conflict predict changes in health. Poster presented at the 60th Annual Scientific Meeting of the Gerontological Society of America, San Francisco, CA.
- Eaton, S.C. (2003). If you can use them: Flexibility policies, organizational commitment, and perceived performance. *Industrial Relations*, *65*, 145-167. doi: 10.1111/1468-232X.00285
- Eby, L. T., Casper, W. J., Lockwood, A., Bordeaux, C., & Brinley, A. (2005). Work and family research in IO/OB: Content analysis and review of the literature (1980–2002). *Journal of Vocational Behavior, 66*, 124-197. doi: 10.1016/j.jvb.2003.11.003
- Frone, M. (2000). Work-family conflict and employee psychiatric disorders: The national comorbidity survey. *Journal of Applied Psychology, 85,* 888-895. doi: 10.1037/0021-9010.85.6.888
- Frone, M., Russel, M., & Cooper, M. (1997). Relation of work-family conflict to health outcomes: A four-year longitudinal study of employed parents. *Journal of Occupational and Organizational Psychology*, 70, 325-335. doi: 10.1111/j.2044-8325.1997.tb00652.x
- Ganster, D.C., Fox, M.L., & Dwyer, D.J. (2001). Explaining employee health care costs: A prospective examination of stressful job demands, personal control, and physiological reactivity; *Journal of Applied Psychology, 86*, 954-964. doi: 10.1037//0021-9010.86.5.954
- Ganster, D.C., & Schaubroeck, J. (1991). Work stress and employee health. *Journal of Management*, *17*, 235-271. doi: 10.1177/014920639101700202
- Glasgow, R. E., & Emmons, K. M. (2007). How can we increase translation of research into practice? types of evidence needed. *Annual Review of Public Health*, 28, 413-433. doi: 10.1146/annurev.publhealth.28.021406.144145
- Glass, J. (2004). Blessing or curse? work-family policies and mother's wage growth over time. *Work and Occupations*, *31*, 367-394. doi: 10.1177/0730888404266364
- Grandey, A., & Cropanzano, R. (1999). The conservation of resources model applied to work-family conflict and strain. *Journal of Vocational Behavior, 54*, 350-370. doi: 10.1006/jvbe.1998.1666
- Greenhaus, J. H., Allen, T. D., & Spector, P. E. (2006). Health consequences of work-family conflict: The dark side of the work-family interface. In P. L. Perrewe & D. C. Ganster (Eds.), *Research in occupational stress and well-being* (Vol. 6, pp. 171-211). Amsterdam: JAI.
- Greenhaus, J.H., & Beutell, N.J. (1985). Sources of conflict between work and family roles. Academy of Management Review, 10, 76-88. doi: 10.2307/258214

- Grzywacz, J. (2000). Work-family spillover and health during midlife: Is managing conflict everything? *American Journal of Health Promotion, 14,* 236-243. doi: 10.4278/0890-1171-14.4.236
- Grzywacz, J., & Bass, B. (2003). Work, family, and mental health: Testing different models of work-family fit. *Journal of Marriage and Family, 65*, 248-262. doi: 10.1111/j.1741-3737.2003.00248.x
- Hammer, L.B., Allen, E., & Grigsby, T.D. (1997). Work-family conflict in dual-earner couples: Within-individual and crossover effects of work and family. *Journal of Vocational Behavior, 50*, 185-203. doi: 10.1006/jvbe.1996.1557
- Hammer, L.B., Cullen, J.C., Neal, M.B., Sinclair, R.R., & Shafiro, M.V. (2005a). The longitudinal effects of workfamily conflict and positive spillover on depressive symptoms among dual-earner couples. *Journal of Occupational Health Psychology*, 10, 138-154. doi: 10.1037/1076-8998.10.2.138
- Hammer, L.B., Neal, M.B., Newsom, J.T., Brockwood, K.J., & Colton, C.L. (2005b). A longitudinal study of the effects of dual-earner couples' utilization of family-friendly workplace supports on work and family outcomes. *Journal of Applied Psychology, 90*, 799-810. doi: 10.1037/0021-9010.90.4.799
- Karasek, R., Brisson, C., Kawakami, N., Houtman, I., Bongers, P., & Amick, B. (1998). The job content questionnaire (JCQ): An instrument for internationally comparative assessments of psychosocial job characteristics. *Journal of Occupational Health Psychology*, *3*, 322-355. doi: 10.1037//1076-8998.3.4.322
- Karasek, R.A., & Theorell, T. (1990). *Healthy work: Stress, productivity, and the reconstruction of working life.* New York: Basic Books.
- Kelly, E.L. (2005). Discrimination against caregivers? gendered family responsibilities, employer practices, and work rewards. In L. B. Nielsen, & R. L. Nelson (Eds.), *The handbook of employment discrimination research* (pp. 341-362). New York: Kluwer Academic Publishers.
- Kelly, E.L., & Kalev, A. (2006). Managing flexible work arrangements in US organizations: Formalized discretion or 'a right to ask'? *Socio-Economic Review, 4,* 379-416. doi: 10.1093/ser/mwl001
- Kelly, E.L., Kossek, E.E., Hammer, L.B., Durham, M., Bray, J., Chermack, K., Kaskubar, D. (2008). Getting there from here: Research on the effects of work-family initiatives on work-family conflict and business outcomes. Academy of Management Annals, 2, 305-349. doi: 10.1080/19416520802211610
- Kelly, E.L., & Moen, P. (2007). Rethinking the clockwork of work: Why schedule control may pay off at work and at home. *Advances in Developing Human Resources, 9,* 487-506. doi: 10.1177/1523422307305489
- Khoury, M. J., Gwinn, M., Yoon, P. W., Dowling, N., Moore, C. A., & Bradley, L. (2007). The continuum of translation research in genomic medicine: How can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention? *Genetics in Medicine, 9*, 665-674. doi: 10.1097/GIM.0b013e31815699d0
- Kossek, E. E., & Distelberg, B. (2009). Work and family employment policy for a transformed work force: Trends and themes. In N. Crouter & A. Booth (Eds.), *Work-life policies that make a real difference for individuals, families, and organizations.* Washington, DC: Urban Institute Press.
- Kossek, E. E., & Ozeki, C. (1998). Work-family conflict, policies, and the job-life satisfaction relationship: A review and directions for organizational behavior/human resources research. *Journal of Applied Psychology*, *83*, 139-149.
- Kristensen, T.S., Smith-Hansen, L., & Jansen, N. (2005). A systematic approach to the assessment of the psychological work environment and the associations with family-work conflict. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health and well-being* (pp. 433-450). Mahwah, NJ: Erlbaum.

- Landsbergis, P.A. (1988). Occupational stress among health care workers: A test of the job demands-control model. *Journal of Organizational Behavior, 9,* 217-239. doi: 10.1002/job.4030090303
- Landsbergis, P. A., Schnall, P. L., Belkic, K., Baker, D., Schwartz, J. E., Pickering, T. G., Quick, T.G. (2002). The workplace and cardiovascular disease: Relevance and potential role for occupational health psychology. In J. Campbell & L.E. Tetrick (Eds.), *Handbook of occupational health psychology* (pp. 265-288). Washington, DC: American Psychological Association.
- Larson, R.W., & Almeida, D.M. (1999). Emotional transmission in the daily lives of families: A new paradigm for studying family process. *Journal of Marriage and Family, 61,* 5-20. doi: 10.2307/353879
- Lee, M.D., MacDermid, S. M., & Buck, M.L. (2000). Organizational paradigms of reduced-load work: Accommodation, elaboration, and transformation. *Academy of Management Journal*, *43*, 1211-1226. doi: 10.2307/1556346
- Lien, L.F., Brown, A.J., Ard, J.D., Loria, C., Erlinger, T.P., Feldstein, A.C., Svetkey, L.P. (2007). Effects of PREMIER lifestyle modifications on participants with and without the metabolic syndrome. *Hypertension*, *50*, 609-616. doi: 10.1161/HYPERTENSIONAHA.107.089458
- Macik-Frey, M., Quick, J. C., & Nelson, D. L. (2007). Advances in occupational health: From a stressful beginning to a positive future. *Journal of Management, 33,* 809-840. doi: 10.1177/0149206307307634
- Mallon, L., Broman, J.E., Hetta, J. (2002). Sleep complaints predict coronary artery disease mortality in males: A 12-year follow-up study of a middle-aged Swedish population. *Journal of Internal Medicine, 251,* 207-216. doi: 10.1046/j.1365-2796.2002.00941.x
- McEwen, B.S., & Seemen, T.S. (1999). Protective and damaging effects of mediators of stress: Elaborating and testing the concepts of allostasis and allostatic load. *Annals of the New York Academy of Sciences*, *896*, 30-47. doi: 10.1111/j.1749-6632.1999.tb08103.x
- Meisinger, C., Heier, M., Lšwel, H., Schneider, A., & Doring, A. (2007). Sleep duration and sleep complaints and risk of myocardial infarction in middle-aged men and women from the general population: The monica/kora augsburg cohort study. *Sleep, 30*, 1121-1127.
- Melchior, M., Berkman, L.F., Niedhammer, I., Zins, M., & Goldberg, M. (2007). The mental health effects of multiple work and family demands. A prospective study of psychiatric sickness absence in the French GAZEL study. Social Psychiatry and Psychiatric Epidemiology, 42, 573-582. doi: 10.1007/s00127-007-0203-2
- Moen, P. (2003). It's about time: Couples and careers. Ithaca, NY: Cornell University Press.
- Moen, P. (2007). Not so big jobs and retirements: What workers (and retirees) really want. *Generations, 31*, 31-36.
- Moen, P., & Chesley, N. (2008). Toxic job ecologies, time convoys, and work-family conflict: Can families (re)gain control and life-course "fit." In K. Korabik, D.S. Lero, & D.L. Whitehead (Eds.), *Handbook of work family integration: Research, theory, and best practices* (pp. 95-121). New York: Elsevier.
- Moen, P., & Roehling, P. V. (2005). *The career mystique: Cracks in the American dream*. Lanham: Rowman and Littlefield.
- National Research Council, & the Institute of Medicine (2004). Health and safety needs of older workers. Committee on the Health and Safety Needs of older Workers. In D. H. Wegman & J. P. McGee (Eds.), *Division of Behavioral and Social Sciences and Education*. Washington D.C.: The National Academies Press.

- Neal, M.B., & Hammer, L.B. (2007). Working couples caring for children and aging parents: Effects on work and well-being. Mahwah, NJ: Lawrence Erlbaum Associates.
- Netemeyer, R.G., Boles, J.S., & McMurrian, R. (1996). Development and validation of work-family conflict and family-work conflict scales. *Journal of Applied Psychology, 81,* 400-410. doi: 10.1037/0021-9010.81.4.400.
- Nilsson, P., Rööst, M., Engström, G., Hedblad, B., & Berglund, G. (2004). Incidence of diabetes in middle-aged men is related to sleep disturbances. *Diabetes Care, 27,* 2464-2469. doi: 10.2337/diacare.27.10.2464
- Perry-Jenkins, M. (2005). Work in the working class: Challenges facing families. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds), *Work, family, health, and well-being* (pp. 453-472). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Presser, H. (2003). Working in a 24/7 economy: Challenges for American families. New York: Russell Sage.
- Ray, K.K., Cannon, C.P., & Braunwald, E. (2007). Recent trials of lipid lowering. *International Journal of Clinical Practice, 61,* 1145-1159. doi: 10.1111/j.1742-1241.2007.01425.x
- Repetti, R.L., Taylor, S.E., & Seeman, T.E. (2002). Risky families: Family social environments and the mental and physical health of offspring. *Psychological Bulletin, 128,* 330-366. doi: 10.1037/0033-2909.128.2.330
- Ruhm, C.J. (2005). How well do government and employer policies support working parents? In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health, and well-being (*pp. 313-328). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Sayer, L. C., Cohen, P. N., & Casper, L. M. (2004). *Women, men, and work*. Washington, DC: Population Reference Bureau.
- Smock, P.J., & Noonan, M. (2005). Gender, work, and family well-being in the United States. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), Work, family, health, and well-being (pp. 343-360). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Thomas, L.T., & Ganster, D.C. (1995). Impact of family-supportive work variables on work-family conflict and strain: A control perspective. *Journal of Applied Psychology, 80,* 6-15.doi: 10.1037/0021-9010.80.1.6
- Vaananen, A., Kevin, M.V., Ala-Mursula, L., Pentti, J., Kivimaki, M., & Vahtera, J. (2004). The double burden of and negative spillover between paid and domestic work: Associations with health among men and women. Women & Health, 40, 1-18. doi: 10.1300/J013v40n03\_01
- Waldfogel, J. (2005). Work and family research: A public policy perspective. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health, and well-being* (pp. 213-244). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Wertheimer, R., Jekielek, S., Moore, K.A., & Redd, Z. (2005). Government policies as external influences on work-family trade-offs. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health, and wellbeing* (pp. 157-168). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Westman, M. (2001). Stress and strain crossover. *Human Relations, 54*, 717-751. doi: 10.1177/0018726701546002
- Westman, M., Etzion, D., & Horovitz, S. (2004). The toll of unemployment does not stop with the unemployed. *Human Relations, 57,* 823-844. doi: 10.1177/0018726704045767

- Williams, J. (2000). Unbending gender: Why family and work conflict and what to do about it. New York: Oxford University Press.
- Wingard, D.B., & Berkman, L.F. (1983). Mortality risk associated with sleeping patterns among adults. *Sleep,* 6,102-107.
- Wolk, R., Gami, A.S., Garcia-Touchard A., & Somers, V.K. (2005). Sleep and cardiovascular disease. *Current Problems in Cardiology, 30*, 625-662. doi: 10.1016/j.cpcardiol.2005.07.002

#### 2.1 Overview

Managing work and family responsibilities in the United States is often difficult and impacts the health and wellbeing of employees, their families, and the workplace. While the prevalence of "family-friendly" or "work-life" policies in U.S. workplaces has increased dramatically in recent years (Bond et al., 2005; Holzer, 2005; Kelly, 2003; Kossek, 2005), there are few longitudinal studies using experimental designs to evaluate the effects of specific work-family interventions on work-family conflict and health outcomes (Kelly et al., 2008). To address this critical gap in the knowledge base supporting work-family policies, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) formed the Work, Family & Health Network (WFHN). Phase 1 of the WFHN consisted of pilot research by four developmental centers, a logistics coordinating center, and a methods coordinating center. For Phase 2, NIH and CDC called upon the WFHN to implement an innovative workplace intervention and to evaluate it using a group-randomized experimental design. The Work, Family and Health Study (WFHS) is the WFHN's response to this call. The WFHS assessed the effects of a workplace intervention designed to reduce work-family conflict, thereby improving the health and well-being of employees, their families, and the workplace. We conducted a randomized field experiment to achieve the following aims.

**Aim 1:** Test the effect of the intervention, compared with usual practice (UP), on employee's work-family conflict, cardiovascular risk, sleep disruption, and psychological distress.

**Aim 2:** Test whether the effects of the intervention, compared with UP, spill over to improve employees' global and daily family processes (e.g., marital satisfaction, daily parental involvement) and health (physical symptoms, self-reported and biological indicators of daily stress) and cross over to improve global and daily family processes and health in spouses/partners and children.

**Aim 3**: Test the effect of the intervention, compared with UP, on organizational outcomes such as job satisfaction, organizational commitment, absenteeism, safety/injuries, retention rates, and productivity.

**Aim 4:** Test whether work-family conflict mediates the effects of the intervention on employee health outcomes and whether employee, midlevel manager, and work-group characteristics moderate the effect of the intervention on work-family conflict and health outcomes.

**Aim 5:** Translate and disseminate the results of our research to the broader public and business community by drawing on process evaluations and dissemination research to make the intervention accessible and informative to a wider audience.

This research was designed to enhance understanding of the impact of workplace practices and policies on work, family life, and health outcomes and will illuminate the processes through which such practices and policies are adopted and implemented by employers. The intervention was aimed at increasing employees' control over their work time and supervisor support for managing work and family responsibilities. The intervention included both supervisory training on strategies to facilitate employees' control over work time and work redesign activities that identified new ways to work that meet business needs, while increasing employee control over work time. The intervention involved changing both the organization of work and the organizational culture (Bailyn et al., 2005; Thompson et al., 2005). It was tailored specifically to the needs of the participating workplaces, but conceptual fidelity was carefully monitored across sites (see Chapter 9).

Two employers from two different industries were recruited: long-term care, and IT/telecommunications industries. The long-term care industry provided 1524 employees, and the IT/telecommunications industry provided 823 employees. We also collected data from all consenting spouses/cohabiting partners of employees (386 for long-term care and 455 for IT/telecommunications) and from a child between the ages of 9 and 17 living with the participating employee parent (257 from long-term care and 148 from IT/telecommunications). Worksites were randomly allocated using a 1:1 allocation rule, with group-level randomization to intervention or UP. Outcomes were assessed at baseline and at 6, 12, and 18 months. We assessed change over multiple intervals to allow sufficient time for the intervention to be implemented; workplace change to occur and be sustained; and longitudinal assessment of intervention effects on individual work-family conflict and health, family health, and organizational health.

All centers from Phase 1 of the WFHN collaborated in Phase 2, each bringing unique expertise. The Portland State Research Unit (RU) has extensive experience designing, implementing, and evaluating worksite interventions and supervisor training within the retail/service industry, as well as expertise in occupational health psychology, organizational behavior, human resource and employer work-family policy implementation. and recruiting and maintenance of worksites in intervention work. The Minnesota RU has expertise in multimethod evaluations of workplace innovations and has conducted path-breaking research on work-family issues across the life course. The Pennsylvania State University (Penn State) RU has developed state-of-theart methods for collecting data on daily family processes, stress, and resilience in adults and children. The Harvard University RU has developed innovative methods for collecting biomarkers related to key health outcomes and has a history of worksite studies, both observational and experimental, most recently in longterm care (Berkman et al., 2004; Melchior et al., 2003; Sorensen et al., 1995, 1996, 2002). RTI serves as the DCC and contributes multidisciplinary expertise in statistics, evaluation design and methodology, and economic analyses. The Kaiser Permanente Center for Health Research serves as the Translation Coordinating Center (TCC) and has extensive experience conducting translational research and coordinating corporate groups to adapt best practices. Together, the six sites complement each other and were uniquely positioned to carry out the Work, Family Health Study.

# 2.2 Study Design

# 2.2.1 Overview of Design and Methods

As noted, the WFHN conducted group-randomized field experiments in two different industries. We recruited approximately 28 employees from each of 56 study groups for the IT/telecommunications industry. For long-term care, approximately 51 employees from each of 30 sites were recruited. Study groups and worksites were randomly assigned either to intervention or usual practice (up) conditions.

The intervention was designed to increase supervisor support for work-family integration and to increase employees' perceptions of control over their work time. It is delivered through supervisory training that included strategies to facilitate employees' control over work time in conjunction with work redesign activities that help employees and supervisors identify ways to increase employees' control over work time while meeting business goals. Random group assignment enhances internal validity while minimizing the opportunity for contamination. We chose UP as the control to directly address whether the intervention produced better outcomes than current practice, a high priority issue for companies, and because of feasibility concerns about implementing inert attention controls in workplaces. Recognizing the differential attention across conditions, we strengthened the experiment's inferential power by formulating *a priori* hypotheses about the mechanisms through which the intervention will produce changes in outcomes (i.e., its "active ingredients"), as a way of ruling out attention as an alternative explanation of the findings. A process evaluation accompanied the intervention as well as the assessment of individual, family and organizational outcomes.

The intervention was delivered using Phase 1 vendors experienced in supervisory training, self-monitoring and employee work redesign activities. These include Culture Rx (developers of Results-Only Oriented Work Environment [ROWE]), K. Anger (computer-based instruction [CBI]) with NwETA, and R. Olson (behavioral self-monitoring [BSM]) with the Oregon Health & Science University. ROWE is innovative, aiming to change both the organizational culture and the organization of work through the use of participatory work redesign training that focuses attention solely on the desired result of an assignment, not the employee's time spent at work (Bailyn, 2005; Rapoport et al., 2002). CBI training programs apply neurobehavioral test methods in human field research (e.g., Anger et al., 2006). Workplace interventions that incorporate BSM activities, where individuals repeatedly observe, evaluate, and record aspects of their own behavior, have been studied for over 35 years, and show particular promise for improving occupational health (e.g., Hickman & Geller, 2003a, 2003b; Jackson, 2003; Olson & Austin, 2001).

Data collection among employees, their families, and their employers corresponded to the study aims and associated hypotheses aimed at testing the effect of the intervention at each of those levels. All employee and supervisor participants were interviewed at baseline and at 6-, 12-, and 18-months post-baseline. Each of these assessments was critical to study the sustainability of the intervention effects on health outcomes. Health assessments supported a modified Framingham risk factor score and included: interviews, dried blood spots (for cholesterol and glycosylated hemoglobin), blood pressure, and height/weight. Sleep dysregulation based on 7 days of wrist actigraphy (an objective indicator of sleep quantity and quality) was collected at baseline and at 6 and 12 months post-baseline. We also collected additional dry blood spots to look at novel indicators including C-Reactive Protein (chronic inflammation) and Epstein Barr Virus antibodies (immunosuppressant) (McDade et al., 2007). Spouse/partners were interviewed by phone. Children of employees and their employee parents also were interviewed in their homes at baseline, 12, and 18 months to assess the impact of the intervention on family dynamics and child health. Child participants include biological, step and adopted children, aged 9-17 years, who were living with the employee; if there was more than one age-eligible child we targeted the child who was closest to 13 years of age. We focused on youth aged 9-17 years because this developmental period is a time of dramatic change, with unique demands on parents that may exacerbate workfamily conflict. Also, youth in this age group are able to provide reliable reports of family experiences. To provide a more detailed perspective on work to family spillover of employees and crossover to children, we recruited a sub-sample of employees with one participating child for the daily diary assessment, including nightly telephone interviews and saliva sample collection for measuring hormone biomarkers. On the next page is an overview of data collection.

# Work, Family & Health Study Data Elements



#### NOTES ON INTERPRETING THIS CHART:

--Each **color** represents a major content area --**Circles** indicate individual-level data --**Lines** indicates a current linking structure --There may be **significant content overlap** for the surveys in **green** all contain work, family and --Each shape is a data element

--Squares indicate group-level data --Line style is for visual effect only

--There may be **significant content overlap** for any individual element. For example, the surveys in **green** all contain work, family and health data elements. Data elements have been placed in the quadrant where they loosely make the most sense.



#### 2.2.2 Background and Logic Model of Intervention

The study intervention was based on our pilot work and on theory from a number of disciplines (e.g., Barrera, 1986; Bronfenbrenner, 2005; Karasek & Theorell, 1990; Landsbergis, 1988; Thomas & Ganster, 1995) that suggests the conjunction of high control and high social support. in the context of reasonable demands, produces healthy environments that encourage individual development and well-being. We targeted specific dimensions of control and support in the workplace: control over work time and supervisor support for work-family integration. We defined control over work time as employees' latitude over their schedules and the total number of hours they worked. Control over work time may involve the ability to choose one's hours and/or the predictability of schedules if shifts must be coordinated to ensure adequate coverage (Kelly & Moen, 2007). We defined supervisor support for work and personal and family life as supervisors' behaviors that convey emotional support, instrumental support including facilitating employees' flexibility and use of existing work-family policies, role modeling of work-family balance, and creatively managing the work process to address both the needs of the organization and the family and personal needs of employees (Hammer et al., 2007). Supervisory training motivates the move to new work practices and provides supervisors with the tools and strategies they need to assist employees as they gain more control over their work time. Previous research has found wide variability in supervisors' implementation of traditional flexible work and scheduling policies (Blair-Loy & Wharton, 2002; Hammer et al., 2007; Kelly & Kalev, 2006; Kossek, 2005) and therefore it is essential to teach supervisors how to facilitate work-time control.

The intervention drew on principles and expertise related to supervisory training and employee work redesign activities from our Phase 1 research projects. The intervention was delivered by organizational development facilitators who were hired by Culture Rx, an organizational development company. As described below in section 2.3 "Intervention Activities," the facilitators worked with supervisors in three face-to-face training sessions, facilitated supervisors' completion of a computer-based training session (using the cTRAIN program), and introduced two behavioral self-monitoring activities where supervisors repeatedly observed. evaluated, and recorded aspects of their own behavior. The intervention drew on the expertise of Dr. Anger, an experimental psychologist with expertise in workplace interventions who developed cTRAIN, and Dr. Olson, who has experience with behavioral interventions and has demonstrated that such behavioral workplace interventions produce large effects (Olson & Winchester, 2008). Facilitators also conducted four face-to-face sessions that involved both employees and supervisors in work redesign activities. The intervention was not a one-size-fitsall or one-time "treatment" but, rather, a facilitated process in which supervisors and employees looked carefully at current supervisory and temporal practices and identified concrete changes that might improve their work conditions and ameliorate work-family conflict. The intervention was designed to prompt reflection on and improved workplace practices regarding two questions: What concrete actions can supervisors take to demonstrate their support of employees' lives and family responsibilities? What concrete actions can work groups take to increase the control they have over their schedules and work time while simultaneously meeting business goals?

Figure 2.1 presents the logic model for the intervention. We hypothesized a mediational model through which the intervention affects outcomes via work-family conflict, but the model allow for direct effects of the intervention on key outcomes.

Figure 2.1. Logic Model of the Intervention



### 2.2.3 Intervention Activities

Table 2.1 outlines the proposed intervention activities. Over a 4-month period, employees spent 4 hours, and supervisors spent about 9 nine hours in intervention activities. The facilitators guided employees and supervisors through face-to-face sessions using scripts and structured, but interactive, activities (including role plays, games, etc.). These participatory sessions encouraged supervisors and employees to reflect on current practices and identify strategies to increase supervisor support, increase work-time control, and reduce work-family conflict, while continuing to meet or exceed business goals. Additionally, supervisors completed computerbased training early in the intervention process and completed two self-monitoring activities designed to transfer the training to practice. The intervention involved multiple modes of delivery (including participatory sessions, computer-based training, and behavioral self-monitoring) that were sequenced to build on each other, reinforce the core messages, and address different learning styles.

Intervention Activity	Key Content / Messages	Time
Activity #1 for	Provide overview of intervention and answer questions;	1
supervisors (Face-	solicit and provide examples of how to enact family-	hour
to-face, facilitated)	supportive supervisor behaviors that facilitate employee	
	work-time control in this setting; encourage peer support	
	during change period.	
Activity #2 for	Provide standardized information on the importance of	1
supervisors	addressing work-family conflicts and existing policies and	hour
(Computer-Based	regulations related to schedules, leaves, etc.; introduce	
Training via	family-supportive supervisor behaviors that facilitate	
cTRAIN)	employee work-time control; encourage learning with	
	frequent quizzes, immediate feedback, self-paced.	
Activity #3 for	Transfer training to practice by encouraging regular	<30
supervisors	attention, goal setting, and feedback on family-supportive	min.
(Behavioral Self-	supervisor behaviors and facilitating employee control	
Monitoring)	over work time. Involves brief but regular self-monitoring	
	of supportive behaviors over 1 week.	
Activity #1 for	Provide peer and expert support on managing employees	1
Employees (Face-	who expect more control over work time; reflect on	hour
to-face, facilitated)	enactment of family-supportive supervisor behaviors	
	based on feedback from self-monitoring. Provide	
	overview of intervention to participating employees and	
	answer questions; motivate engaged participation in	
	other sessions by discussing possible benefits to	
	employees, families, and the organization; encourage	
	peer support during change period.	
Activity #2 for	Review changes in their supportive behaviors and work	1
Employees (Face-	unit processes since previous sessions (4-–6 weeks	hour
to-face, facilitated)	ago); reflect on facilitation of employee control over work	
	time based on feedback from self-monitoring; discuss	
	challenges and brainstorm solutions with peers. Guide	
	work units through assessment of current expectations	
	and practices to identify current stressors related to	
	support or work-time control, current best practices, and	
	key measures of productivity for individuals and the work	
	unit.	
Activity #3 for	Guide work units through identification of concrete	1
Employees (Face-	strategies to increase work-time control and/or	hour
to-face, facilitated)	demonstrate support for family and personal life while	
	meeting business goals.	

Intervention Activity	Key Content / Messages	Time
Activity #4 for	Transfer training to practice by encouraging regular	<30
supervisors (Behavioral Self- Monitoring)	attention, goal setting, and feedback on family-supportive supervisor behaviors and facilitating employee control over work time. Involves brief but regular self-monitoring of supportive behaviors over a 1 week period. This second event will occur about 4 months after the start of the intervention.	min.
Activity #4 for	Review changes in work unit processes since previous	1
Employees (Face-	sessions (6-–8 weeks ago); discuss challenges and	hour
to-face, facilitated)	brainstorm solutions with peers.	

Supervisor strategies to provide more support for employees' family and personal lives and to facilitate employees' control over work time included: expressing appropriate and genuine interest in employees' lives outside of work; sharing accurate information on the company's work-life policies and benefits; modeling work-life balance in their own work patterns; establishing standard procedures for managing scheduling conflicts in a fair and transparent manner; posting schedules as far in advance as is feasible; and facilitating cross-training that will allow for easier management of schedules. Employee strategies to maximize work-time control while still meeting business goals included self-scheduling systems; establishing standard procedures for requesting schedule changes or trading shifts; cross-training to increase back-ups within the work group; standard procedures for requesting an experienced floater/utility person; designated "no meeting hours" policies; or a shift to laptop computers, when feasible, to allow more work to be done remotely.

#### References

- Anger, W.K., Stupfel J., Ammerman, T., Tamulinas, A., Bodner, T., & Rohlman, D.S. (2006). The suitability of computer-based training for workers with limited formal education: A case study from the US agricultural sector. *International Journal of Training and Development, 10*, 269-284. doi: 10.1111/j.1468-2419.2006.00260.x
- Bailyn, L. (2005). Filling the gap by redesigning work. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), Work, family, health, and well-being (pp. 131-138). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Barrera, M. (1986). Distinctions between social support concepts, measures, and models. *American Journal of Community Psychology, 14,* 413-445. doi: 10.1007/BF00922627
- Berkman, L.F., Melchior, M., Chastang, J.F., Niedhammer, I., Leclerc, A., & Goldberg, M. (2004). Social integration and mortality: A prospective study of French employees of electricity of France-gas of France: The GAZEL cohort. *American Journal of Epidemiology*, 159,167-74. doi: 10.1093/aje/kwh020
- Blair-Loy, M., & Wharton, A.S. (2002). Employees' use of work-family policies and the workplace social context. *Social Forces, 80,* 813-845. doi: 10.1353/sof.2002.0002

- Bond, J.T., Galinsky, E., Kim, S.S., & Brownfield, E. (2005). *National study of employers*. New York: Families and Work Institute.
- Bronfenbrenner, U. (2005). Strengthening family systems. In U. Bronfenbrenner (Ed.), *Making human beings human: Bioecological perspectives on human development* (pp. 260-273). Thousand Oaks, CA: Sage Publications.
- Hammer, L. B., Kossek, E. E., Zimmerman, K., & Daniels, R. (2007). Clarifying the construct of family supportive supervisory behaviors: A multilevel perspective. In P. L. Perrewe & D. C. Ganster (Eds.), *Research in occupational stress and well-being* (Vol. 6, pp. 171-211). Amsterdam: Elsevier Ltd.
- Hickman, J. S., & Geller, E. S. (2003a). A safety self-management intervention for mining operations. *Journal of Safety Research*, 34, 299-308. doi: 10.1016/S0022-4375(03)00032-X
- Hickman, J. S., & Geller, E. S. (2003b). Self-management to increase safe driving among shorthaul truck drivers. *Journal of Organizational Behavior Management, 23*, 1-20. doi: 10.1300/J075v23n04\_01
- Holzer, H. (2005). Work and family life: The perspective of employers. In S.M. Bianchi, L.M. Casper, & R.B. King (Eds.), *Work, family, health, and well-being* (pp. 81-94). Mahwah, NJ: Lawrence Erlbaum Associates Inc.
- Jackson, A. (2003). Effectiveness of self-monitoring interventions: The effects on safe bus operation. (Unpublished master's thesis). Florida State University, Tallahassee, FL.
- Karasek, R.A., & Theorell, T. (1990). *Healthy work: Stress, productivity, and the reconstruction of working life.* New York: Basic Books.
- Kelly, E.L. (2003). The strange history of employer-sponsored childcare: Interested actors, uncertainty, and the transformation of law in organizational fields. *American Journal of Sociology, 109*, 606-649. doi: 10.1086/379631
- Kelly, E.L., & Kalev, A. (2006). Managing flexible work arrangements in US organizations: Formalized discretion or 'a right to ask'? Socio-Economic Review, 4, 379-416. doi:10.1093/ser/mwl001
- Kelly, E.L., Kossek, E.E., Hammer, L.B., Durham, M., Bray, J., Chermack, K., Kaskubar, D. (2008). Getting there from here: Research on the effects of work-family initiatives on work-family conflict and business outcomes. *Academy of Management Annals, 2,* 305-349. doi: 10.1080/19416520802211610
- Kelly, E.L., & Moen, P. (2007). Rethinking the clockwork of work: Why schedule control may pay off at work and at home. Advances in Developing Human Resources, 9, 487-506. doi: 10.1177/1523422307305489
- Kossek, E. E. (2005). Workplace policies and practices to support work and families: Gaps in implementation and linkages to individual and organizational effectiveness. In S. Bianchi, L. Casper, & R. King (Eds.), *Workforce/workplace mismatch? work, family, health, and well-being* (pp. 95-114). Mahwah, NJ: Erlbaum Press.

- Landsbergis, P.A. (1988). Occupational stress among health care workers: A test of the job demands-control model. *Journal of Organizational Behavior, 9,* 217-239. doi: 10.1002/job.4030090303
- McDade, T., Williams, S., & Snodgrass, J. (2007). What a drop can do: Dried blood spots as a minimally invasive method for integrating biomarkers into population-based research. *Demography, 44*, 899-925. doi: 10.1353/dem.2007.0038
- Melchior, M., Berkman, L.F., Niedhammer, I., Chea, M., & Goldberg, M. (2003). Social relations and self-reported health: A prospective analysis of the French gazel cohort. *Social Science & Medicine, 56,* 1817-1830. doi: 10.1016/S0277-9536(02)00181-8
- Olson, R., & Austin, J. (2001). Behavior-based safety and working alone: The effects of selfmonitoring package on the safe performance of bus operators. *Journal of Organizational Behavior Management, 21*, 5-43. doi: 10.1300/J075v21n03\_02
- Olson, R., & Winchester, J. (2008). Behavioral self-monitoring of safety and productivity in the workplace: A methodological primer and quantitative literature review. *Journal of Organizational Behavior Management, 28,* 9-75. doi: 10.1080/01608060802006823
- Rapoport, R., Bailyn, L., Fletcher, J. K., & Pruitt, B. H. (2002). *Beyond work-family balance: Advancing gender equity and workplace performance*. San Francisco: Jossey-Bass.
- Sorensen, G., Himmelstein, J.S., Hunt, M.K., Youngstrom, R., Hebert, J.R., Hammond, S.K., Ockene, J.K. (1995). A model for worksite cancer prevention: Integration of health protection and health promotion in the wellworks project. *American Journal of Health Promotion, 10,* 55-62. doi: 10.4278/0890-1171-10.1.55
- Sorensen, G., Thompson, B., Glanz, K., Feng, Z., Kinne, S., DiClemente, Lichtenstein, E. (1996). Worksite-based cancer prevention: Primary results from the working well trial. *American Journal of Public Health, 86*, 939-947.
- Sorensen, G., Stoddard, A.M., LaMontagne, A.D., Emmons, K., Hunt, M.K., Youngstrom, R. Christiani, D.C. (2002). A comprehensive worksite cancer prevention intervention: Behavior change results from a randomized controlled trial (United States). *Cancer Causes & Control, 13,* 493-502. doi: 10.1023/A:1016385001695
- Thomas, L.T., & Ganster, D.C. (1995). Impact of family-supportive work variables on workfamily conflict and strain: A control perspective. *Journal of Applied Psychology, 80*, 6-15. doi: 10.1037/0021-9010.80.1.6
- Thompson, C. A., Adreassi, J. K., & Prottas, D. J. (2005). Work-family culture: Key to reducing workforce-workplace mismatch? In S. M. Bianchi, L. M. Casper, & R. B. King (Eds.), *Work, family, health, and well-being* (pp. 117-132). Mahwah, NJ: Erlbaum.

# **Chapter 3: Industry Recruitment & Communication**

### 3.1 Selection of Industry Partners: Background

In mid-2007 WFHN began recruiting company partners in two disparate organizations for Phase II of the research grant. Replication of a successful work-time control program in the white-collar setting would be contrasted with findings from the intervention in nursing homes. WFHN assembled a recruitment brochure to explain the study and partnership.

### 3.2. Selection and Recruitment of White Collar Industry

Results Only Work Environment (ROWE) program, developed by CultureRx, was the basis for the Phase II intervention. The University of Minnesota (UMN) worked with CultureRx for the entirety of Phase I, and secured a list of companies who had contacted them about implementing ROWE in their business. Recruitment material was send to 18 companies; recruitment conversations over 8 months identified the most likely industry partner company; their involvement was negotiated over the next 12 months.

### Chapter 4: Site Recruitment

### 4.1 Selecting Worksites

After selecting industry partners, WFHN recruited worksites. Worksite recruitment was done in conjunction with the Industry Advisory Board for each industry and was managed by the intervention investigators. Selection criteria included adequate support from local management, worksite size and geographic proximity to other study sites, and ability to support logistically the intervention delivery and data collection.

### 4.2 TOMO Worksite Selection

The University of Minnesota and TOMO began discussions of site selection late 2008. It was decided during company recruitment that the IT department within TOMO would most likely be the only department participating in the study. TOMO HR shared the total sample within the IT department that could be chosen from. We narrowed this original IT sample by excluding contractors or any temporary workers. This reduced sample contained TOMO IT employees all over the country with the bulk of employees located in Colorado and Ohio. An analysis of travel cost determined that the small number of employees in remote groups would be excluded.

WFHN worked with TOMO HR to arrive at the final scheme of 56 groups that consistently worked together, each group comprised of smaller work groups. Within the 56 groups there are 115 smaller work groups with individual managers – managing anywhere from 2 to 41 employees and supervisors. Within these work groups, there are also additional supervisors and smaller teams. The 56 study groups were each given a number and then randomized to either a control group or intervention group.

# 4.3 LEEF Worksite Selection

This Network partner managed 55 extended-care facilities in the Northeast region, spanning all six New England states. Thirty prospective facilities were identified by the industry's Vice-President of Development. Inclusion criteria for consideration in the study ranged from facility size (< 30 nursing staff), how recently the site was acquired (if relevant), and stability of the management structure. Extended-care facilities which were currently engaged in other research studies were removed from consideration.

These worksites were paired into 15 groups and were assigned as a control or treatment site (see adaptive randomization procedures, Chapter 6).

Site recruitment used a multi-faceted approach, designed to obtain management support and generate interest among the eligible employees in the nursing department of each facility, while also engaging the worksite with information necessary for effective preparation for data collection. Upper management (Administrators, Directors of Nursing), middle management (Unit Managers/Charge Nurses) and direct care staff were provided detailed information to describe the study components and purpose prior to the beginning of data collection to allow an educated decision to participate, as described below.

To identify eligible employees, the Site Manager worked with the facility scheduler to find those that fit the following criteria: must have worked directly for the facility; worked a minimum of 22.5

hours per week; must have worked primarily on the day and/or evening shift. Primary night, or 3<sup>rd</sup> Shift, workers were not eligible to participate.

### 4.4 Naming Conventions Across Industries

### **Organization**

*Organization* here means the study partner – TOMO or LEEF. At TOMO, people use the term "organization" to refer to all the employees under a VP (e.g., Julie's organization) but that is not our usage.

### **Bundles**

*Bundles* are artificial, logistical units that were created only for the ease of completing and scheduling the CAPI data collection and STAR training at TOMO. There are 13 bundles, each bundle includes 1 or more intervention study groups and 1 or more control study groups. Each bundle was put together to include around 100 employees. Each bundle has a study launch date on the timeline. At LEEF, bundles are two sites which are paired together based on geography and size. Although the size of each site/facility varies, the average size is about 55, so a total of 110 for each bundle/pairing.

#### Study Groups/Sites

*Study groups* at TOMO are corollary with sites at LEEF. The 56 study groups in TOMO are the randomizing units. The study groups were compiled based on the organizational hierarchy (see Director and Manager Levels in groups spreadsheet). When there were multiple managers' work groups put together to be a single study group, we consulted with TOMO HR and the relevant executives to be sure that the employees did similar enough work and/or worked together so that we could treat them as a single study group. The site managers kept detailed site/study group profiles.

For LEEF, a *site* or *facility* is the self-contained nursing home facility. They are fairly autonomous units, where the Administrator is the top manager.

#### Work Groups/Units

The term *work group* refers to TOMO employees who share the same Manager Level. Some study groups (above) have multiple work groups and a few study groups have just 1 larger work group. Note that this usage of work group does NOT match up with everyday usage by TOMO employees, where they may talk about a work group as people working together on the same project (e.g. Softech group). This is because the testers/QA and project manager for that project will be in the work group and study group under their hierarchy. Site managers investigated variation across work groups within a study group and documented that with the site/study group profiles.

*Units* in LEEF are subgroups within a facility, often defined by the type of care provided (e.g., long-versus short-term care and dementia units). Depending on the size of the facility, there are 2-4 units, cutting across all three shifts and headed by a unit manager who reports to the Director of Nursing Services (DNS). Staff can float between units occasionally to ensure proper coverage, but have a primary assignment in one unit.

There are supervisors for the entire facility for Evening, Night and Weekend Shift

### Chapter 5: Subject Recruitment

### 5.1 Overview of Subject Recruitment

Within each participating study group in TOMO (telecommunications) and worksite in LEEF (extended-care), we recruited approximately 50 employees and up to 8 managers to participate in data collection. Employees and supervisors in TOMO were eligible to participate if they were employed by the company in the two cities where data collection occurred and were classified as employees, rather than independent contractors, of the company. In general, study groups in TOMO were comprised of people who worked together under the same director or manager depending on the size of the director's group. More specific discussion on study groups is included in Chapter 4. Worksites in LEEF were individual extended-care facilities. Employees and supervisors in LEEF were eligible to participate if they were normally scheduled to work 22.5 or more hours per week in direct patient care or in relevant positions within the nursing department, and they worked on the day or evening shifts (thus excluding night shift workers). All spouses and cohabiting partners of eligible employees were eligible for study participation. Child participants (ages 9 to 17 years) including biological, step, and adopted children who lived with the employee for 4 or more days per week were also eligible. If there was more than one age-eligible child, the child closest to age 13 was selected. All subjects recruited for the study were given sufficient information through recruiting materials and informed consent documents to make a fully informed decision to participate in the research activities, and understood that no penalties or negative outcomes would be imposed for participating or declining participation.

### 5.2 Recruitment of Employees and Managers for Worksite Interviews

Industry representatives worked with network study staff to identify the best recruiting methods for gaining employee and manager participation. The recruiting methods were customized for each industry as described below. Recruitment materials included memos of endorsement from top leadership within each industry, study fact sheets, e-mail messaging, and letters and brochures.

# 5.2.1 Recruitment within Telecommunications Industry

At the beginning of data collection for the entire company, an email was sent by the upper level administrator announcing participation in the study and encouraging managers and employees to take part. Study groups were sent another email from the upper level administration about 6 weeks prior to their data collection window to remind them of the study. Four to six weeks before data collection was slated to start, the field site managers obtained company rosters of employee and manager work e-mail addresses from each group.

A few weeks before the first wave of the study began, field site managers held meetings with study group managers and work teams to provide in-depth information, answer questions and encourage participation. Study brochures, frequently asked question handouts and information pertaining to the spouse and child components of the study were distributed during these meetings. Lead letters were then sent by email to employees and managers from field site managers and RTI field interviewers followed up with individually assigned employees and managers by email to schedule the in-person data collection appointments. When necessary, refusal conversion letters were also sent to employees and managers from RTI's field supervisor by email. Managers who did not work on-site in the two cities where data collection occurred were recruited to complete a telephone interview.

# 5.2.2 Recruitment within Extended-care Industry

A series of meetings were completed by the Industry Coordinator with key staff at each care facility (Administrator, Director of Nursing, Scheduler) to review the study purpose, develop the roster of employees and managers to interview, discuss plans for providing study information to employees/managers, and plan for scheduling and completing data collection activities at the facility.

The recruitment strategy employed the following techniques: providing letters and brochures to subjects as an insert with their paycheck, placing study posters and informational material in convenient locations within the facility, participating in the facilities' "Morning Meeting", and holding several "Meet & Greet" sessions.

Approximately three weeks prior to the launch of data collection at each facility, a study team (industry coordinator, site manager, and field supervisor) attended and participated in the "Morning Meeting" where the facilities' department heads, nursing management, and HR representative gather to discuss the current affairs of the facility. During this meeting, the study team provided an overview of the study's purpose and components while describing the next steps – the "Meet & Greet", which allowed the study team to communicate with the direct care staff.

The "Meet & Greet" sessions were conducted over a period of three days, typically Tuesday through Thursday, one week prior to the scheduled launch of data collection, to allow the study team to meet as many study-eligible employees as possible. On the first two days of these sessions, the facility's management allowed the industry coordinator, the site manager, and/or the field supervisor to gather eligible employees into small groups and present an overview of the study, distribute study materials, and answer questions about the study. The sessions, which lasted each about 20 minutes, were conducted either at the nurse's station of each "neighborhood" (unit), a conference room, or a quiet location in the facility. Sessions were conducted for all of the eligible employees in the first and second shifts working on those days. Depending on the size of the facility, 4 to 8 sessions were held each of the first two days. On the third day, facility management gave the employees the opportunity to visit project staff at their leisure to learn more about the study, and have questions or concerns addressed. Study staff set up a station for the last two hours of the first shift and the first two hours of the second shift at a location convenient to the staff. Snacks and beverages were distributed to all those who participated in the informational sessions.

#### 5.3 Recruitment for Blood and Actigraphy Collection

All employee respondents (both companies) and LEEF managers were invited to participate in two additional components conducted at the workplace: blood collection and wrist actigraphy. The interviewer introduced the blood collection and actigraphy components using detailed CAPI scripts, frequently asked question documents, and consent forms. Eligible employees in TOMO were recruited into these sub-studies during the worksite interview appointment. Employees and managers in LEEF were recruited either as part of the worksite interview appointment or in a separate appointment. The blood collection involved a finger stick to collect 5 droplets of blood on a special protein card and a small droplet of blood the interviewer used to obtain an HbA1c reading. If requested, the interviewer walked the respondent through steps of the blood collection and a 30 g actigraph with on-wrist detection and a

watch face to discretely record wrist movement activity patterns and ambient light exposure for 1 week.

# 5.4 Recruitment of Spouse/Partners and Children for Interviews

At baseline, employees were asked to provide information on current household composition within the survey, including whether the employee lives with a spouse or partner and the ages of his/her children. Based on the data collected on household composition, an employee's spouse or partner (who has lived with the employee for at least one year) and one child from the household in the target age range of 9 to 17 years (child closest to the age of 13) was recruited to participate in the study. A child / youth information card and wave-specific child gift was given to the employee to give to the child directly. Separate consent and assent procedures were followed for each family participant. Spouses or partners were recruited to participate in a telephone interview through contact information provided by the employee, and through recruitment communication given to the employee to provide to the spouse or partner directly. Contact information was collected from the employee to conduct the child interview and health assessment at the home, along with an employee home interview.

Interviews with other family members at 12- and 18-months follow-up were dependent on employee participation in the worksite interview. At 12- and 18-month worksite follow-up interview, employees were asked for information on their current household composition, including the status of spouse/partners and children selected for the baseline interview. Spouse/partners who completed the baseline interview and were still living with the employee at 12-months were asked to participate in a 12-month spouse/partner interview by telephone. Additional home interviews at 12- and 18-month follow-up were attempted with all employees and children who were selected to participant in the home interviews at baseline, regardless of the outcome of participation in earlier survey rounds. If we learned at post-baseline follow-up that the child selected for interview at baseline was now living more than 50 miles from the closest field data collector, his/her interview was conducted by telephone using contact information provided by the employee. For children still living local to field data collectors, the post-baseline interview was completed in-person.

In TOMO at the 18-month wave only, the study attempted to collect survey information from children via an anonymous web survey in situations where the employee refused the request for the child to participate in the child home interview. In these situations the RTI field interviewer offered the anonymous web survey as a means of collecting information that could be not specifically be linked back to the child, and provided the employee with an information sheet to give to the child with instructions on how to access and complete the anonymous web survey.

# 5.5 Recruitment for Daily Diary Sub-study (Employee and Child)

To learn how the workplace intervention affects the daily life of employees and their children, a subset of employees and their children were recruited to participate in a daily diary study at baseline and 12-month follow-up, as conducted by Penn State. The daily diary study included a series of eight consecutive nightly telephone interviews. During these nightly calls, parent and child were asked, in individual interviews lasting about 20 minutes for the parent and 15 minutes for the child, about their family experiences, physical and emotional well-being, and experiences of stress during the day of the call. During four of the call days, parents and children were also asked to provide saliva samples over the course of the day; parents provided five samples per day and children provided four samples per day. The samples were assayed for a biomarker of

stress, diurnal cortisol. More detailed information on the daily diary study and saliva collection process is included in Section 7.9.

To initiate the Daily Diary data collection, the household contact information was uploaded daily via secure FTP to the Penn State research team. All consenting families were contacted by the Penn State survey group leading this data collection activity to complete the *Daily Diary Study*.

Daily diary recruitment at 12-month follow-up was dependent on two factors: a) the employee completing the 12-month worksite interview, and b) the employee and his/her child being selected at baseline for the daily diary study. Recruitment was consistent with the baseline procedures. Employee recruitment was administered immediately following the 12-month worksite interview. Child recruitment occurred immediately following his/her 12-month interview. The field interviewer provided saliva kits and home saliva collection instructions for the employee and child during the home visit along with a pre-incentive. The interviewer also provided a brief training on the saliva collection, and obtained incentive receipts for the small pre-incentives provided in the saliva kits by Penn State. In the situation where the 12-month child interview was conducted over the phone, the child's daily diary recruitment also took place over the phone. Once verbal assent was given, the interviewer recruited the child into the daily diary component and a saliva kit was be mailed to him/her. In this scenario, consenting employees were also mailed a saliva kit.

### **Chapter 6: Combined Randomization Protocol**

### 6.1 Selection of Randomization Units

## 6.1.1 TOMO

TOMO's randomization units (or groups) were selected through a series of conversations between TOMO HR, University of Minnesota team members, and RTI staff. There were several concerns that were balanced during the selection of randomization groups. First, the study team wanted to create as many groups as possible to increase the statistical power of the study to detect the intervention effect (ceteris paribus, more groups yields more statistical power). In the IT division of TOMO, there were 6 potential levels of management in the organizational hierarchy. The highest level was a level 1 VP and there were up to 5 levels of managers of decreasing authority below each of those VPs. The need for as many groups as possible created a desire to form groups at the lowest level of manager, so there would be as many groups as possible given the selected employee pool (the IT division of TOMO). However, from an intervention standpoint, the manager needed to have the authority to implement the intervention policies and protocols. Therefore, the study could not simply select the lowest manager level; instead the team had to find the lowest level of manager that could implement the changes necessary for the intervention's success.

Additionally, TOMO had a matrix organizational structure, meaning that individuals under different administrative supervisors frequently worked collaboratively in work or project groups. The team considered trying to organize groups based on this work group structure instead of the administrative hierarchy. However, this approach was abandoned for two primary reasons: (1) work groups fluctuated as project needs changed, thus it was anticipated that there would be significant reorganization of work groups over the course of the study and (2) TOMO HR was concerned about the potential for problems if employees tried to implement intervention policies when their administrative supervisors were not trained in the intervention. Taking all of the aforementioned considerations into account, the team identified 56 study groups containing an average of ~22 study eligible employees. The intervention team determined that study eligible employees were those working within the IT division at TOMO, who were located at either the Colorado or Ohio offices and were not contractors.

# 6.1.2 LEEF

It was easier to determine the unit of randomization for LEEF: individual nursing homes were a natural choice. The intervention team determined that direct care employees, those that actually cared for patients, who worked 22.5 or more hours a week would be eligible to participate in data collection. Third shift employees were excluded because third shift working environment was a very poor fit for the intervention protocols.

#### 6.2 Selection of Randomization Covariates

#### 6.2.1 TOMO

As a next step in the process, the intervention team identified characteristics of the groups that would be important to balance across study conditions. These were characteristics that the intervention team thought could have a significant effect on the outcomes of interest. The goal in balancing these characteristics was to increase the homogeneity of outcome variance across conditions; this means that the study attempted to standardize characteristics that might be correlated with baseline measures of outcomes across conditions. With greater similarity in baseline values, the study's analysis would have greater statistical power to detect the

intervention effects. The intervention team determined that that key characteristics to balance were the groups' "level 1" vice president and the groups' functions, either core development or support. Also, the team decided to balance the number of employees in each condition to further maximize statistical power.

# 6.2.2 LEEF

There were 33 LEEF nursing homes that were identified as being eligible to participate in the study. These homes were geographically distributed across a 5 state region in the New England area (Massachusetts, Maine, New Hampshire, Connecticut, and Rhode Island). These homes had anywhere from 31 to 117 direct care employees that worked more than 22.5 hours a week. The average was about 53 study eligible employees per nursing home site.

The intervention team identified three relevant criteria to balance across the intervention and control conditions. The first of these was the baseline retention rate of direct care employees. The targeted nursing homes' baseline retention rates ranged from ~52% to 84% per annum, with an average annual turnover of about 74%. Retention rate was identified as an important balancing criterion at LEEF for three reasons. The first reason was that turnover was an outcome of interest for the study. Turnover was much higher at LEEF than at TOMO; TOMO's workforce was generally guite stable. The intervention was expected to lower the turnover rate, which would increase the retention rate. Retention rate was used instead of turnover rate to minimize the effect of the "churn" (constant turnover) of part-time employees, who were not eligible to participate in the study. Also, the retention rate was thought to be a proxy for unobserved working conditions (lower retention rate being associated with worse working conditions). Finally retention rate would have an effect on follow-up sample sizes. The state in which the site was located was also chosen as a balancing criterion. Nursing home regulations varied significantly on a state by state basis. Thus, state might become a confounder if left unbalanced. Finally, to keep an approximately equal number of employees in each condition, the study chose to balance on the number of employees in each site.

There were also two logistical issues that needed to be considered during randomization. First, the study needed to group facilities that were relatively close to each other in order to reduce the travel burden on field interviewers and, consequently, data collection costs. Also, the nursing homes were subject to random audits during recertification periods. Data collection could not occur during these audit "black out" periods because the audit required the nursing home's full attention. Thus, in addition to geographic proximity, the team grouped sites that were ready to begin data collection and not currently in an audit blackout period.

#### 6.3 Selection of Randomization Strategy

#### 6.3.1 TOMO

Initially the study team selected a stratified randomization plan for TOMO. The study placed groups into strata based on the characteristics detailed above in section 6.2.1. Strata can be thought of as "meta"-groups of working groups that are similar across various traits. Each work group within a given stratum would have the same job function, the same level 1 VP, and be in the same size category based on its number of employees in CO and OH. Randomization to intervention and control conditions would occur within each stratum, with an equal number of groups within that stratum being assigned to each condition. This method of randomization would ensure balance across the stratifying characteristics. Since groups were going to be randomized to control and intervention within each stratum, there could be no "singletons" (i.e. strata containing only one group). For strata that contained only one group, the intervention

team matched the singleton group to the stratum which contained the most similar groups and the group was moved to that stratum.

Once these 56 groups were randomized, the intervention team took the lead in organizing the groups into "bundles" of groups that would rollout the data collection and intervention process over time. The bundles were created to number about 100 total employees per bundle with roughly 50 intervention employees and 50 control employees. The timeline or order in which bundles would move through data collection and intervention was then created so that the employees under a VP would move through the process together and so that bundles with Ohio employees would move through at approximately the same time. The proposed bundling and timeline was than shared with TOMO HR, who recommended some changes in order to avoid release dates in the organization.

However, during the break between initial data collection in Fall of 2009 and the start of the main data collection in January of 2010, the study's TOMO site manager, noted several changes in group structure. When the initial stratified randomization design was chosen, it was thought that there would not be significant changes to group structure over the course of the study period. Group membership might change somewhat as employees were hired, retired, or switched groups, but the groups as identifiable entities were thought to be quite stable. However, this early experience made the study team concerned that this assumption might not be true and that there might be significant changes to group structure during the course of data collection rollout. Since it did not make sense to have randomized groups that might not be in existence when data collection started, an alternative randomization method was needed to give the study the flexibility to handle the shifting nature of groups.

The new randomization scheme needed to balance on the criteria identified for use in the stratified randomization scheme: number of employees, the group's function (as core or support) and the group's level 1 vice president. The new scheme would also need to allow for the same general rollout plan that the intervention team had identified, as the data collection rollout had been planned around specific groups' release dates and the groups' management had already been informed of the rollout schedule. The team also wanted a design that would give them as much power as possible when using the intent-to-treat analysis that many Network members wanted to eventually perform.

After additional discussion, an adaptive randomization scheme, similar to the one already being employed at LEEF, was considered to be the most appropriate randomization algorithm. Randomization via that method allowed groups to be randomized near the beginning of their data collection instead of months or years in advance, so that previously randomized groups would be much more likely to be in existence when data collection started. Adaptive randomization allowed the groups to be balanced across all of the previously identified criteria. Conveniently, the adaptive randomization process required that the first 4 groups be simply randomized and the first two sites had already simply been randomized (within their cluster). Thus, we were able to integrate their previous randomization without additional design or analytical complications.

#### 6.3.2 LEEF

We implemented a just-in-time adaptive randomization, design that would allow the study to balance the conditions across multiple criteria while avoiding the previously encountered pitfalls. Nursing homes were only randomized into a condition as they were ready to begin data

collection. This "just-in-time" randomization reduced the lag between randomization and data collection. The reduction in lag, in turn, reduced the likelihood of a randomized site dropping out before the first wave of data collection began. Adaptive baseline randomization also allowed the study to use logistical concerns, such as geographical proximity and readiness to start data collection for blocking purposes without further complicating the design of the randomization.

### 6.4 Implementation of Adaptive Randomization Scheme

Randomization for both industries was implemented using a modified version of the adaptive randomization discussed by Frane in "A Method of Biased Coin Randomization, its Implementation, and its Validation" (1998). The study's modifications centered on implementing Frane's method in a block randomization environment (1998).

As discussed above, the three criteria that the randomization attempts to balance between control and intervention in TOMO were (1) the group's number of employees, (2) the group's function (core or support), and (3) the group's level 1 vice president. At LEEF the three variables were (1) the nursing home's retention rate, (2) the nursing home's state, and (3) the nursing home's number of study eligible employees. The randomization balanced the total number of groups assigned to each condition.

As previously mentioned, the intervention team blocked the workgroups at TOMO into data collection sites after the stratification of groups in the fall of 2009 for logistical management of the study rollout. The 56 groups were collapsed into 12 sites containing roughly 100 total employees. This site structure allowed for a manageable number of employees to undergo the intervention at one time, it also allowed the study to control the flow of groups with Ohio employees from a data collection standpoint; we needed to keep an appropriate case flow for a smaller pool of field interviewers that the study employed at the Ohio location. Finally the blocking accounted for the groups' project release dates (determined in cooperation with TOMO HR), which were work intensive periods of time that would prevent the group from participating in data collection or intervention activities. The study team made a decision to keep these general blockings for groups and to use them within the adaptive randomization process. The study added in newly formed groups and removed defunct groups prior to randomization within a specific block.

At LEEF, the blocking for randomization was based on two conditions (1) logistical feasibility and (2) readiness to begin data collection. Logistical feasibility was determined by the data collection team by examining the geographical proximity of nursing homes and the availability of nearby field staff. The goal of this assessment was to minimize the travel and logistical expenses of data collection. Readiness to begin data collection was determined by the intervention team through conversations with LEEF corporate management. This determination was to make sure the nursing home was not in an audit "blackout window" and could actually begin the data collection/intervention.

Once a block was ready to begin data collection, it was fed into the randomization algorithm. The baseline adaptive randomization method randomized one group at a time. This process made it sensitive to the order that groups were presented. Thus, the order that groups are randomized within a block is determined randomly (sorting within the block by an electronically assigned random number).

The first two groups in each industry that were randomized were the two pilot 1.0 sites. These sites were chosen based on logistical criteria by the intervention teams. At TOMO, one of these

sites was already randomized to each condition, using the previous stratified randomization scheme. Since this equated to a simple coin flip (as the 1.0 strata contained only two groups) we were able to keep the previous randomization results without change. Likewise, the two sites selected by the intervention team to be a part of 1.0 at LEEF were simply randomized.

Once the next logistical block was ready for randomization, the order of randomization within the block was determined randomly. The first 2 groups were randomized using simple randomization. The remaining groups (n-2) of that block were then randomized using the baseline adaptive randomization method described below. Also, all subsequent groups were then randomized using the baseline adaptive randomization method.

The baseline adaptive randomization technique used an intuitive method for maintaining balance across chosen criteria. It weighted the probabilities so that the randomization was biased towards the outcome that provided the most balance between the conditions (on the selected criteria). When it was a group or home's turn to be randomized, the probability that it would be assigned to each condition was determined in the following manner. First, the group was hypothetically assigned to one condition (e.g. intervention). A t-test<sup>1</sup> was then computed using the covariate values for all groups that had been previously randomized and the group currently being randomized. The corresponding p-value for each t-test was then recorded. Secondly, the group or home was then hypothetically re-assigned to the other condition and the t-tests were repeated with their corresponding p-values being noted. A hypothetical example is given in *Table 6.1* below<sup>2</sup>

	Intervention	Control
Group Function	0.451	0.878
Number of Employees	0.615	0.311
VP	0.095	0.554
Minimum p	0.095	0.311
Randomization p	0.146	0.854

Table	<del>2</del> 6.1	/—Exam	ple	p-values
1 0.010		-///	P	p

In this context, the t-test was testing the hypothesis that the intervention and control conditions had the same mean on the selected criteria (such as number of employees or retention rate). A lower p-value was indicative of it being more statistically likely that the hypothesis that they had the same mean could be rejected. Thus, a lower p-value indicated that the conditions were more likely to be significantly different on that criterion. Comparing the reported p-values for the randomization covariates (VP, number of employees, and group function) in the intervention column of the table above shows you that assigning the group to intervention would make the conditions most unbalanced on the VP criterion.

<sup>&</sup>lt;sup>1</sup> Please note that a Fisher's Exact test was used in place of a t-test on categorical variables such as VP group function, or state; however, for simplicity, all tests will be referred to as t-tests through the remainder of the document.

<sup>&</sup>lt;sup>2</sup> Modeled on the example presented by James W. Frane in "A Method of Biased Coin Randomization, its Implementation, and its Validation" *Drug Information Journal* (1998).

Once the t-tests had been performed, the minimum p-value for each condition (since the category with the lowest p-value was the least balanced) was then selected. In the above example, it would be  $p_1=0.095$  for intervention and  $p_2=0.311$  for control. The probability that the group is assigned to intervention would be  $p_1/(p_1+p_2)$ , while the probability that the group would be assigned to control is  $p_2/(p_1+p_2)$ . For this example, the probability that the group would be assigned to intervention is .095/(.095+.554)=.146 and the probability that the group would be assigned to control is .554/(.095+.554)=.854. This method of determining the probabilities of assignment to each condition weighted the probabilities so that the group was less likely to be assigned to the condition where it would cause the most imbalance. This weighting was also determined by the relative imbalance the group would cause in each condition (i.e. if the minimum p-value for one condition was much smaller than the minimum p-value in the other condition, the group was much less likely to be assigned to it). The randomization for that group was then made with the weighted probabilities determined above. This process was then repeated for the next group within the block.

A constraint placed on the randomization process was that an equal number of groups within each block were assigned to each condition. For example, consider a logistical block containing four groups. If the first two were assigned to intervention via the process detailed above, the remaining two would be automatically assigned to control without any further randomization within that block. Likewise if the block contained four groups, and of the first 3, two were assigned to control and 1 to intervention, the final group would be automatically assigned to intervention to maintain balance. Since logistical blocks contained an even number of groups, this process maintained an overall balance between the numbers of groups in each condition

#### References

Frane, J.W. (1998). A method of biased coin randomization, its implementation, and its validation. *Drug Information Journal, 32,* 423-432. doi: 10.1177/009286159803200213

#### **Chapter 7: Data Collection Process**

#### 7.1 Data Collection Procedures

Computer Assisted Interview (CAI) instruments were developed for workplace employees and managers, employees' spouses/partners, home interviews with employees and children, and for employees/managers at post-baseline no longer working for the industries (attriters). These were used for in-person interviews and health assessments with employees and managers at the worksite, and with employees and children in the home, and for telephonic interviews with employee's spouses/partners, and attriters at follow-up. The RTI Data Coordinating Center oversaw the instrument development process. The average administration time for each instrument is displayed in **Table 7.1** below. Instrument content was consistent across data collection waves and across participants from each industry. Trained field interviewers conducted the in-person interviews, and administered an informed consent or assent for participation including Computer Assisted Personal Interview (CAPI) scripts read to respondents and a corresponding hard-copy consent or assent form the respondent was asked to review. sign, and keep. Field interviewers also completed the spouse/partner interviews by telephone. Trained telephone interviewers within the RTI Call Center administered and obtained verbal consent for participation using CAPI scripts read to respondents, and completed the interviews with attriters by telephone.

Interview	Average		
	Administration Time		
Employee Workplace	58 minutes		
Manager Workplace	56 minutes		
Employee Home	24 minutes		
Child	59 minutes		
Spouse	32 minutes		
Attriter	38 minutes		

#### Table 7.1 Interview Administration Time

Data collection was completed in person with employees and managers at intervention and usual practice worksites at baseline and 6, 12, and 18 months post-baseline. Interview content included self-reported measures of workplace outcomes, physical and mental health outcomes, household demographic information and family relationships. Children's data was collected in the home at a time scheduled by the employee at baseline, 12 months, and 18 months postbaseline. For employees, managers, and children completing in-person CAPI interviews, blood pressure, height, and weight was also collected. Consenting employees (both industries) and managers (LEEF only) were also asked to provide dried blood spots (DBS) by a finger stick and to wear an actigraph watch to record sleep and wake behavior for a period of 1 week. Spouse/partner data was collected by telephone at baseline and 12 months post baseline. For a subset of employees and their children in our target age range, field interviewers introduced and enrolled participants into the daily diary study; collected information on the family's availability for daily diary calls; and provided saliva data collection kits and instructions. Information on enrolled families was transmitted to Penn State University, who completed the daily diary component at baseline and 12 months post-baseline. Data collection was completed by telephone interviewers in the RTI Call Center (through CATI) with employees and managers that were identified during the 6, 12, and 18-months post-baseline follow-up as no longer

working at the industries (referred to as Attriters). *Table 7.2* summarizes completion counts by participant group and industry (TOMO = telecommunications, LEEF = extended-care).

Participant Group	Industry	Baseline	6 Months	12 Months	18 Months	Total
Manager Interview	TOMO	221	196	188	187	792
(worksite)	LEEF	184	154	145	95	
	Total	405	350	333	282	
Employee Interview	TOMO	823	717	701	651	2,892
(worksite)	LEEF	1,525	1,275	1,083	774	
	Total	2,348	1,992	1,784	1,425	
Dried Blood Spots	TOMO	762	668	658	565	2,653
(worksite)	LEEF	1,545	1,384	1,201	760	
	Total	2,307	2,052	1,859	1,325	
Actigraphy	TOMO	716	621	594	503	2,434
	LEEF	1,452	1,244	1,086	699	
	Total	2,168	1,865	1,680	1,202	
Spouse	TOMO	455	NA	334	NA	789
(by telephone)	LEEF	404	NA	184	NA	
	Total	859		518		
Child Interview	TOMO	148	NA	141	137	426
(in home)	LEEF	257	NA	185	134	
	Total	405		326	271	
Employee Interview	TOMO	147	NA	147	151	445
(in home)	LEEF	257	NA	207	159	
	Total	404		354	310	
Daily diary collection	TOMO	131	NA	114	NA	245
	LEEF	173	NA	121	NA	
	Total	304		235		
Attriter Survey	ТОМО	NA	26	36	39	101
(by telephone)	LEEF	NA	78	101	59	
	Total		104	137	98	

Table 7.2 Completion Counts by Participant Group, Wave, and Industry

**Table 7.3** below shows the schedule for the data collection work for WFHS. Data collection for this study began in September 2009 and ended in December 2012. Data collection sites were activated on a rolling basis.

 Table 7.3 Schedule for WFHS Data Collection Activities

Activity	Date
Baseline Data Collection	September 2009 — July 2011
6-Month Follow-Up Data Collection	March 2010 — December 2011
12-Month Follow-Up Data Collection	October 2010 — June 2012
18-Month Follow-Up Data Collection	March 2011 — December 2012
# 7.2 Field Data Collection Teams

The field data collection teams (one per industry) included an industry coordinator, site managers (as previously discussed), a field manager, a field supervisor, field data collection team leaders, and field interviewers. To support data collection, the industry coordinator's primary responsibility was to obtain initial acceptance of each facility's participation in the study. The site managers had primary responsibility to coordinate the data collection schedule and obtain necessary documentation and rosters for sample selection. The site managers led employee recruitment and served as the liaison between the workplace and the field data collection teams to schedule and implement baseline and follow-up data collection. The field manager had primary oversight of the field data collection activities and the field personnel including the field supervisors, data collection team leaders, and interviewers. Field supervisors (one per industry) coordinated and organized the work, and managed the day-to-day activities of the data collection team leaders and interviewers. The field supervisor also provided support and re-training to field interviewers; served as the point of contact with the site manager for all data operations; and interfaced with Penn State staff regarding assignment of participants into the daily diary study. The data collection team leaders shared responsibilities for completing workplace, telephone and home-based CAPI interviews and collecting biometric measures, along with other field interviewers; however, the team leaders also performed other important administrative and quality control functions as the team lead at the site. These activities included managing and maintaining biometric supplies and equipment; configuring, organizing, and downloading actigraphy watches; serving as the point of contact with the site manager for site logistics; and arranging shipments of the collected blood specimens through interface with the Harvard team. Data collection teams spent approximately 3-4 weeks at each site for each wave of data collection.

# 7.3 Field Preparation and Training

Across the life of the project, the field management team recruited, hired and trained field interviewers to complete data collection in the various geographic study regions. Study materials including a training information sheet, field interviewer manual, homestudy quiz, and IRB module and quiz were mailed to each interviewer about a week before the in-person training to review and complete. All field staff attended an 8-day project-specific training session utilizing multiple training techniques (e.g., lecture, hands-on practice) to prepare staff for interview and biomarker collection activities. To protect field interviewers from blood borne pathogens prior to potential exposure while performing a finger stick, interviewers completed the OSHA mandated Bloodborne Pathogen training module. Interviewers were also trained on how to wear all personal protective equipment (PPE), such as gloves or gown, when collecting or handling all biospecimens. Interviewers also either began a series of 3 Hepatitis B vaccinations prior to collecting blood spots or actively decline to be vaccinated.

Throughout the study, the RTI and/or Harvard team also lead in-person refresher trainings for field staff on an as-needed basis to review WFHS procedures or demonstrate new blood collection protocols (i.e., new lancet).

# 7.4 Participant Compensation

As a token of appreciation to thank respondents for participating in WFHS, they were offered a monetary gift of a pre-determined amount. For components completed in-person cash was offered to the respondent; for components completed over the telephone a check incentive was

mailed to the subject. See **Table 7.4** below for participant compensation broken out by component. Once data collection was underway, the study made incentive amount adjustments for select components in efforts to encourage participation. The initial and final compensation amounts are included in the table.

Component	TOMO / LEEF / Both	Initial Compensation Amount	Final Compensation Amount
Employee CAPI Interview and Health Assessments	Both	\$20	\$20
Employee Blood Spot Collection	Both	\$20	\$20
Employee Actigraphy	Both	\$20	\$20*
Employee Second CAPI Interview	Both	\$20	\$30
Manager CAPI Interview and Health Assessments	Both	\$20	\$20
Manager Blood Spot Collection	LEEF Only	\$20	\$20
Manager Actigraphy	LEEF Only	\$20	\$20*
Spouse Telephone Interview	Both	\$20	\$20
Child CAPI Interview and Health Assessments	Both	\$20	\$50
Daily Diary Study	Both	\$150**	\$250**
Qualitative Interview (for Process Evaluation)	Both	\$15***	\$15***

Table 7.4 Participant compensation by Component

\* At the 18-month wave for LEEF, extended-care employee and manager respondents were offered an additional \$20 (total \$40) contingent upon their wearing the actigraphy watch for the full 7 days.

- \*\* Total incentive for the Daily Diary study was \$150 at baseline, and \$250 at 12-month follow-up.
- \*\*\* Participants who completed the qualitative interview were the only study respondents to receive an incentive in the form of a gift card.

# 7.5 Scheduling and Completing Employee and Manager Workplace Interviews

RTI field interviewers completed workplace CAPI interviews, blood collection and actigraphy with sampled employee and manager respondents at the industry's site. The interviews and biospecimen collection were completed in space reserved specifically for WFHS. Site space had to meet certain criteria: reasonable privacy, comfortable room temperature (especially for blood collection), an electrical outlet for equipment, and a safe environment for both the field interviewer and respondent.

In both industries, site managers communicated with the company's management staff (at various levels) beginning several weeks prior to the data collection launch date. This allowed the study team an opportunity to discuss the upcoming data collection window, any pressing demands on the employees' time, and to obtain a sample roster for the upcoming site.

For the worksite interviews, field staff worked with the industries' staff to set up individual appointments with employees and managers to introduce the study, obtain consent, and complete the interview experience. The data collection team maintained flexibility when scheduling workplace appointments, as employees and managers would be taking time during working hours to complete the WFHS study activities. The window of time to complete data collection in each worksite was typically 3-4 weeks.

# 7.6 Completing Blood Collection and Actigraphy at the Worksite

In the telecommunications industry a single appointment was set up to complete the CAPI interview first immediately followed by the DBS and actigraphy modules. In the extended-care industry flexibility was built into the protocol due to the limited time employees could come off the floor at a given time. Interviewers working this industry could complete all activities in a single setting, or could complete either the DBS and Actigraphy or the CAPI interview first and schedule an additional appointment to complete the remaining activities. The on-the-ground project staff determined the logistics for best scheduling and completing the study activities during meetings with extended-care facility staff several weeks before the launch of the site's data collection.

# 7.6.1 Dried Blood Spot Collection

As part of the pre-data collection meetings at each worksite, project staff and industry staff discussed and pinpointed suitable location(s) that could be reserved for WFHS study use to safely set up and complete the blood collection in a sanitary environment, and possibilities for secure storage of the materials and equipment at the worksite during the data collection period. On each day of fieldwork involving blood collection, field interviewers were required to set up and pack up the lab area. Checklists were provided and used by field staff to guide this process.

# 7.6.2 Actigraphy Collection

Following the dried blood spot collection, employees (both industries) and managers (extendedcare industry only) were asked to wear an actigaphy spectrum or "sleep watch" for a period of 7 days to measure wrist movement activity to quantify sleep and wake patterns. The "sleep watch" is worn on the respondent's wrist and displays the current date/time. Team leaders were trained to use Actiware software at the worksite to properly set up and prepare the Actiwatches to be worn for 7 days. Once watches were returned, team leaders used the same software to download data off the watches which was uploaded to the Harvard team for analysis of the sleep data.

# 7.7 Interviews with Spouse/Partners and in the Employee's Home

In addition to the worksite data collection activities described above, spouses and cohabitating partners, and children (ages 9 to 17 years) of employees who completed the worksite interview were also eligible for study participation. The employee baseline worksite interview collected detailed information on current household composition including if currently married or living with a permanent romantic partner, and the names, ages and gender of all children (biological,

step, and adopted) living in the subject's home for 4 or more days a week. Based on the data collected on household composition, an employee's spouse or partner and one child from the household in the target age range of 9 to 17 years were recruited to participate in the study. If there was more than one age-eligible child living in the household, the child closest to age 13 was selected to participate. The WFHS focused on youth ages 9 to 17 because this developmental period is a time of dramatic change, with unique demands on parents that may exacerbate work-family conflict. Also, youth in this age group are able to provide more reliable and nuanced reports of family experiences than are younger children.

Spouses or partners were recruited at baseline to participate in a 30-minute telephone interview through contact information provided by the employee, and through recruitment material given to the employee to provide directly to the spouse or partner. Spouse/partners who completed the baseline interview and were still living with the employee at 12-months were also eligible to complete a 12-month spouse/partner interview by telephone.

For households with age-eligible children only, the field interviewer followed CAPI scripts to introduce two home-based survey activities to the employee: a child 60-minute home interview and assessment; and an additional 25-minute employee home interview. Contact information (and best times to visit the home) was collected from employees, and interviewers scheduled the employee home and child interview during the same visit. The child interview included an ACASI (Audio Computer-Assisted Self-Interviewing) section for some of the more sensitive items in the survey, and the health assessment included blood pressure, height, and weight. With ACASI, the respondent wears headphones connected to the laptop computer and listens to the questions in private after being trained how to enter their answers directly into the computer. The privacy ACASI affords provides for more accurate reporting of sensitive behaviors.

For employees and children who completed home interviews at baseline, we attempted to complete home interviews at 12- and 18-months post baseline, provided the employee worksite interview was completed. During the 12- and 18-month worksite interview we followed the same procedures as at baseline to obtain contact information, and attempt to schedule and complete the home interviews.

# 7.8 Daily Diary Study Recruitment and Collection Activities

To learn how the workplace intervention impacts the daily life, the employees and children who completed the home interview at baseline and at the 12-month follow-up were also asked to complete data collection activities for the Daily Diary study. Participation in the Daily Diary study involved two activities for both the employee and the child – telephone calls on 8 consecutive days to complete short telephone interviews, and the collection of saliva specimens.

The Daily Diary study was led by researchers at Penn State University, and RTI field interviewers were responsible for recruiting and consenting families to participate, and providing adult and child saliva kits with instructions to each recruited family. For eligible families, the field interviewer was prompted at the end of the employee workplace interview to follow CAPI scripts to introduce the Daily Diary study and request participation. The employee was provided with a Daily Diary brochure to review that provided detailed information on the collection activities. For families who agreed to participate in the Daily Diary study, the RTI field interviewer obtained

written consent from the parent and written assent from the child, and collected information in CAPI including employee and child telephone contact information and general availability during the week to complete daily diary telephone interviews.

RTI field interviewers also provided saliva kits to the respondents (one for the employee, one for the child). The kits included instructions and a DVD on how to collect and ship the saliva samples. Adults and children were asked to provide saliva samples for four days (on days 2-5) during the daily diary portion of the study. Adults provided saliva 5 times a day—before they get out of bed in the morning, a half hour after they were out of bed, before lunch, before dinner, and before bed. Children provided saliva only 4 times a day—before they get out of bed, a half hour after they were out of bed. Respondents were instructed to put saliva samples into the refrigerator immediately if the samples were taken at home, or to refrigerate the samples as soon as they arrive home if the samples were taken outside the home.

The Daily Diary telephone interviews were completed by Penn State's Survey Research Center. The calls lasted about 15 minutes, on average, and occurred on 8 consecutive days. The employee and child each completed a separate interview on the same 8 days. The second component of the daily diary was the collection of saliva from both the employee and child on 4 of the 8 diary days. Participants were reminded by Penn State about the saliva data collection on the evenings prior to scheduled collections and asked a short set of questions (i.e., about the timing of collections, about medications) on the days when saliva samples were collected. The morning after all saliva samples had been collected from the adult and child, they were instructed to mail back all salivettes, data collection sheet(s), and the medication use form in the pre-paid UPS Next Day mailing bag provided in the adult kit.

# 7.9 Study Materials and Supplies for Field Data Collection

WFHS provided RTI field interviewers with the necessary study materials and equipment needed to collect study data. Interviewers were informed at training they are the only person authorized to use the study materials and equipment. Each interviewer was required to sign for hard-copy materials and equipment (computer, scale, stadiometer and blood pressure cuff) when he/she received them indicating an understanding and acknowledging that all provided materials belong to the WFHS and are intended for study use only.

# 7.10 Quality Control Measures

Quality control was important at all stages of the data collection process. This section discusses some of the quality control measures put into place for field interviewer training, field edits, interview edits, the collection of biospecimen and health measures, field observations and field verifications.

# 7.10.1 Evaluation of Training

At the end of each training day, the interviewers were asked to complete an evaluation form to assess the training program and materials, the trainers, and the training facilities. Their feedback on the effectiveness of the interviewer training program was important for letting the study team know whether the training program was thorough and effective. The study used this feedback to improve preparations for additional training sessions.

#### 7.10.2 Field Edits

Editing case materials was an important aspect of maintaining data quality throughout the field period. The edits interviewers and their field supervisors performed in the field were crucial in identifying missing or incorrectly completed materials. This section focuses on some of the editing procedures put in place to strengthen the quality of the data for case folders, Record of Action forms (ROAs), and interview data.

# 7.10.3 Case Folder Edits

Before submitting case documentation, the interviewer was required to review the case folder carefully and ensure all required forms were included and fully completed. RTI provided tools including a Case Folder Inventory Sheet and a case folder transmittal form to assist field staff in submitting their completed case materials. A case was complete when all interviews and health measures for each selected person associated with a household ID had been completed. For employees, this could consist of the employee worksite and home interviews and health measures, the spouse/partner interview, and the child interview and health measures. For managers, this included the manager worksite interview and health measures; for the managers in the extended-care industry, this also included dried blood spot and actigraphy collection.

It was critical that interviewers collected the correct consent/assent forms and that they were filled out completely (with printed names, signatures, dates and barcodes or ID numbers), and that all incentive receipts were accounted for and filled out properly. Failure to collect a form, or using the incorrect version of a form (having an employee sign a manager consent form, for example) resulted in field management staff having to complete and submit an incident report to the IRB, and to make additional contacts with the respondent to get the correct form. If we are unable to do so, the data were unusable.

As interviewers worked on and made progress with cases in their assignments, they were required to make daily updates to the paper Record of Actions Forms (ROA) included in the case folder, and to also update the case status electronically in the Case Management System. Each entry made accounted for an action taken towards completing a case.

#### 7.10.4 Supervisor Edits

Each week, the interviewers sent all completed case folders via Federal Express to their field supervisor. Once received, the field supervisor reviewed each case folder and its contents for completeness. Any incomplete folders (i.e., a consent form is missing, a form is missing a signature, FI administered incorrect version of consent/assent form, etc.) were flagged and addressed immediately. If there was a case folder error involving a consent/assent form the field supervisor filled out an incident report, notified RTI's field management team, and submitted the incident report to the IRB for review. Any follow-up action recommended by the IRB was completed as soon as possible.

All correct case folders were then shipped to the RTI Data Processing Unit for receipt and proper storage. In the first few weeks of fieldwork, the interviewer submitted cases as they were completed for supervisor review and immediate feedback.

#### 7.10.5 Interview Edits

Most information collected for WFHS is entered directly into the laptop computer, so the traditional editing of completed hard-copy is eliminated. Instead, the computer edits as the interviewer conducts the interview, such as checking skip patterns for missing or inconsistent data. All CAPI interview files transmitted to RTI were reviewed and evaluated to ensure the interviewer was administering the study correctly. The field supervisor shared any provided feedback with the interviewer.

# 7.10.6 Quality Control of Health Measures

Special attention was given to properly following all protocols for collecting the health measures to ensure the safety of the interviewers, accuracy of all measures collected, and the quality of blood samples obtained. Detailed information on the protocols and procedures for health measures is included in *Chapter 8* of this manual. The information provided below references specific quality control activities followed when the interviewers completed health measures.

### Dried Blood Spot Collection

The finger stick procedure, when done properly, is a very clean and very safe procedure. As with all body fluids, universal (safety) precautions must be strictly observed at all times.

- 1. Proper housekeeping and use of Personal Protective Equipment (PPE) will reduce the risk of infection.
- 2. Before and after physical contact with each subject, interviewers must wash their hands with soap and water for 20 seconds; rinse and then use a towel to turn off the water.
- 3. If there is not a sink accessible, interviewers must use Purell before and after applying gloves. Apply enough to cover all surfaces of both hands.
- 4. Interviewers must wear gloves on both hands throughout the blood collection procedure until the filter paper cards are secured and used supplies are disposed of in the biohazard waste bag.
- 5. Any misplaced blood drops must be cleaned up immediately with Asepti-Wipes or bleach solution towelettes.
- 6. Interviewers must dispose of Sharps in proper containers using lancets only once.
- 7. Interviewers must not eat or drink in contaminated areas, or apply makeup or contact lenses where exposure could occur.

#### Calibrating Reagents before Using in DCA Vantage System

The reagents cartridges used with the DCA machine came in a product box, and each box / batch of reagents had a lot number. Lot numbers are batches of a product that are made at the same time using the same "recipe." Lot numbers were noted on the box and packages. For the DCA machine to work properly, information on the lot number of reagents being used needed to be inputted by swiping a calibration card included in the product box. All interviewers were trained on how to properly calibrate a new batch of reagents before using them with the DCA machine.

#### Preparing the Blood Samples for Shipment

As part of preparing the samples for shipment, the team leader also performed QC of the completed and bagged samples. If the team leader noticed a pattern of substandard blood collections from a particular interviewer or if an interviewer was not following protocols as it related to drying and packaging the sample protein card, s/he discussed this with the field supervisor who provided feedback to or request re-training for the interviewer.

Once team leader completed the additional check of the samples, s/he sealed them into a shipper, and notified the field supervisor of details of the shipment. Such details included the identification numbers listed on all of the protein cards being shipped as well as the date shipped and FedEx tracking number. Samples being shipped were never left in a FedEx dropbox; they were physically handed off to a FedEx delivery person or personnel.

#### **Blood Sample Shipment Tracking and Quality Monitoring**

Tracking specimens from the field to the Harvard Team required active involvement by field interviewers, field team leaders, the field supervisor, project staff and Harvard personnel. Field interviewers were required to transmit every day that they completed an interview or blood specimen collection. Internal reports monitored blood specimens collected (per transmitted CAPI data), specimens in transit, specimens received by the Harvard Team, and delinquencies (specimens that were shipped, but had not been reported as received).

#### **Disposing of Bio-hazard Waste and Sharps**

Special attention was given to making sure all bio-hazardous materials were properly disposed of in approved containers provided to the field staff. Bio-hazardous waste was never to be left in an area that could be accessed by untrained personnel. The procedures for properly disposing of hazardous waste bags or containers were different in the two industries.

At the telecommunication industry worksites, no on-site disposal of medical waste was available. Instead, field staff were provided with hazardous waste container buckets that (when full) were mailed to a medical waste vendor for proper disposal. The key steps the interviewers followed in the telecommunications industry included:

- NEVER putting hazardous waste into ordinary trash.
- NEVER leaving the hazardous waste container in a common area unattended, it was sealed and locked up with the DCA machine and bloodspots at the end of each day.
- When a hazardous waste container was full, it was packaged in the supplied postage-paid box, and dropped off at the appropriate location to be mailed back to the waste disposal vendor.
- Field interviewers working at the worksites were notified of the local FedEx locations for drop-off.

In the extended-care worksites, on-site medical waste disposal was made available to the field team. The key steps the interviewers followed in the extended-care industry included:

- NEVER putting hazardous waste into ordinary trash.
- Place all hazardous waste in provided sharps containers and bio-hazardous waste barrels.

- At each worksite, interviewers were instructed as to where all the bio-hazardous waste should be disposed of on-site.
- As standard practice, the medical waste was disposed of on-site at the end of each day.

# **Monitoring Blood Specimen Quality**

Blood sample specimen quality was monitored by the team leader when packaging the specimens for weekly shipments, and also by Harvard Team upon receipt. Harvard staff graded the quality and completeness of samples as they were checked in for storage, and this information was provided electronically to RTI in a DBS quality report. RTI field management monitored this report for quality issues, and the field supervisor addressed the issues with individual interviewers in a timely manner to correct any problems or concerns.

# 7.10.7 Field Verifications

To ensure data quality and study integrity, RTI also completed telephone verifications on 10% of all completed manager and employee interviews, including the associated family components for the employee (spouse/partner, child, employee home). Trained telephone interviewers (located at RTI's call center in Raleigh, NC) performed the interview verifications by telephone. In the verification interview we asked questions on the mode of administration, length of time to complete the activities associated with the survey, activities completed by the participant, incentives received, and interviewer professionalism. For employee verifications we asked questions to verify all components completed by the employee (worksite interview, basic health measures, collection of DBS, Actigraphy collection, second interview in the home), the employee's spouse/partner (interview by phone), and the employee's child (interview and basic health measures). If the employee was eligible for the daily diary component, we also asked questions about the daily diary enrollment. The verification instrument provided the telephone interviewer with the proper questions to ask based on which study components were reported to be completed in the field. Verifications with employees lasted from 5 to 10 minutes. For manager verifications, we attempted to verify all components completed by the manager in the field including the worksite interview, basic health measures, collection of DBS and Actigraphy (in extended-care industry only). Verifications with managers were shorter and took about 5 minutes to complete. Checks were programmed into the verification instrument to flag discrepancies between the respondent's account of the interview and what was reported in the field. Daily reports were generated with all discrepancies for project review and resolution. Field interviewers received feedback on their performance per information reported on the verification calls.

# 7.10.8 Field Observations

After completing training, all WFHS interviewers were observed in the field. The field supervisors, Site Managers, other RTI project staff, and Harvard team members observed each field interviewer throughout the data collection period. About 2% of all completed workplace interviews were observed by the Network.

Observers used the WFH Field Interview Observation Form (<u>Appendix 7.4</u>). This form included interviewer and observer names and scoring of the interviewer's performance according to study protocol but left no identifying information on the participants.

Observation feedback data was sent within 24 hours of collection to the Field Supervisor (FS) and RTI Field Manager. For serious problems with data collection, FS follow up with FI --after consultation with the field management staff (FMS)-- should occur within 24 hours. With respect to the biomarker data collection, observations also may be followed upon completion of the interview--after the participant has left--with immediate retraining on biomarker data collection and group retraining as needed. Otherwise feedback will be provided to the FI within one week of the observation appointment.

Operations Subcommittee was updated weekly by the FMS with the observation as well as other relevant data. No identifying information (FI, participant) was included in the data provided to the Operations Committee. Operations regularly discussed the performance of individual FIs as well as any associated revisions to training or to the interview protocol and will make regular updates to the Network.

# 7.11 WFHS Attriter Survey

For baseline employee and manager participants no longer actively employed with the two industries during the 6-, 12- and 18-month follow-up waves, the study received Administration for Child and Families (ACF) funding to locate and contact the employee or manager by telephone to complete a 45-minute Attriter Survey. During each wave of follow-up with each worksite we confirmed the work status of all employees and managers interviewed at baseline to determine if they were still actively employed with the industry. Those identified as no longer working with the industry were classified as *Attriters*, eligible for the Attriter survey.

The telephone Attriter Survey collected information from the employee about:

- Why she/he left her/his previous job;
- Current employment status;
- Family demographics;
- Current workplace environment (perceived control of activities, experiences with supervisor and employer as a whole);
- Physical Health;
- Mental Health
- Family Composition.

Table 7.10 shows the schedule for the implementation of the Attriter Survey.

Event	Date
First RTI Call Center Training	July 2010
Refresher RTI Call Center Training	February 2012
Attriter Survey (Tracing and Data Collection)	July 2010 — December 2012

# Table 7.10 Schedule of Attriter Survey Activities

Similar to the multiple waves of interviews conducted in-person with employees and managers still employed at the industries, participants identified as attriters were administered the same survey for up to 3 times (at approximately 6-, 12-, and 18-months from the baseline survey date) dependent on the point at which we determined they were no longer employed at the industry. Sample members were given a unique ID for each Attriter interview. The box that follows illustrates the unique nature of the ID scheme used on the study.

2 <sup>nd</sup> digit of case ID	Last digit of case ID E or M = first Attriter survey
1 Telecommunications group	E= Employee (e.g., U11AF21 <u>E</u> )
e.g. U <u>1</u> 1AF21B	M= Manager (e.g., U11AF21 <u>M</u> )
2 Extended-care group	A= Second time Attriter survey (e.g.,
e.g. U <u>2</u> 1AA21E	U11AF21 <u>A</u> )
	B = Third time Attriter survey (e.g., U11AF21 <u>B</u> )

The process of identifying and interviewing employees who were no longer employed at the industries included several steps. The main steps of the process will consist of:

- Identification of employees and managers no longer working for the industry During site preparation activities for follow-up field data collection, project staff confirmed the work status of all employees and managers interviewed at baseline to determine if they were still actively employed with the industry. Those identified as no longer working with the industry were classified as *Attriters*, and added to the list to be contacted for the ACF Attriter Survey. Project staff also reviewed the batch of Attriters associated with the worksite from earlier waves and determined which of these cases were eligible for a 2<sup>nd</sup> or 3<sup>rd</sup> Attriter survey. Such cases were added to the list of cases to work and assigned an Attriter case ID for the next round.
- Load locator data for subject in tracking database For attriter subjects, all available contact information from the previous interview was provided to Tracing Specialists in RTI's internal tracing unit for use in tracing.
- Attempt to confirm accuracy of last known address and phone number via interactive tracing – Using provided contact information for interactive tracing, a tracing specialist attempted to verify the accuracy of the employee/manager's address/phone number or obtained updated information. Once tracing was completed, all address and phone updates were added to the subject's file in the project control system.
- Prepare and send lead letter in advance of calling Using the best known address, project staff prepared and sent lead letters to the employee/manager approximately one week prior to beginning Attriter Survey calls. The lead letter provided the participant with contact information (toll-free telephone number and e-mail address) for the WFHS telephone survey manager should he/she have any questions or like to set up an appointment. In addition to sending a hard-copy lead letter, an electronic version of the letter was e-mailed to any respondent that had provided a personal e-mail address as a mode of contact.

- Telephone interviewer contacts phone number(s) to reach employees and managers One week after the lead letter was mailed, telephone interviewers placed calls to reach employees/managers. Initial questions in the Attriter survey verified that we were speaking with the correct person, and that he/she was no longer working for the study industry. If the participant indicated that she/he was still employed with the industry, the interviewer explained that the subject was not eligible for the Attriter survey and stopped the interview. Otherwise, the interviewer continued through the CATI instrument and completed the Attriter survey.
- **Conduct next telephone interview of the same ACF survey -** Four to six months after the sample member completed the first Attriter interview, project staff identified and pulled the case for the next round's Attriter interview. The survey questions stayed the same as in the previous survey. At the end of the survey we verified the participant's correct mailing address, and mailed a \$20 incentive check to her/him.

# 7.11.1 Additional Activities for Attriter Cases

For the Attriter survey we quickly discovered a significant difference in our ability to reach subjects who had been employed within the two industries. The study was readily able to reach the employees and managers by telephone who had been working within the telecommunications industry. These individuals were highly educated, had white-collar jobs with high income, and were fairly stable with their living arrangements. The study's ability to reach the employees and managers who had been working in the extended-care industry was much more problematic. These individuals were working blue collar jobs with a much lower income, many participants working two jobs to make ends meet, and were less stable with their living arrangements. Given the hectic and chaotic schedules of the extended-care attriters, we implemented some additional rules to increase our ability to reach them and complete the survey.

# • Second Round of Tracing with SSNs

For all subjects, the project completed an initial round of tracing to confirm best known address and telephone number(s) by using the subject's last reported address and telephone information, and the names of other contacts they provided to us who would know how to reach them. From this tracing activity, all known phone numbers for the subject were loaded into CATI, and telephone interviewers called the numbers to attempt to reach the subject.

We closely monitored attempts to reach the subject, including indications that the numbers dialed were for the subject (e.g. answering machine with subject's name). For cases where we maxed out call attempts without reaching and talking with our subject, we attempted a second round of tracing using the subjects social security number (if she/he had provided it to us in an earlier interview) to attempt to uncover address and telephone information. If new telephone information was uncovered, we attempted additional calls to reach the subject using the new information. Otherwise, we coded out the case as "unlocatable".

#### • Refusal Cases (Extended-care subjects)

With subjects in the extended-care industry, we encountered a much higher rate of refusal for the Attriter Survey due to their hectic schedules and heavy demands on their time. We received IRB approval to offer an increase in incentive of **\$50** to these extended-care subjects who refused the telephone interview request. Once a extended-care case was coded as a refusal, project staff sent a letter offering the \$50 incentive and request to reconsider to the subject, with information on how to contact the study to set up an appointment. Similar to the lead letter, an electronic version of this follow-up letter was also e-mailed to subjects for whom we had an e-mail address.

The additional round of tracing and the letter with increased incentive had a small impact on increasing participation in the Attriter Survey with the long-term industry group.

### 7.11.2 Attriter Compensation

As a token of appreciation, employees and managers who completed the Attriter survey received a **\$20** or **\$50** check for their participation. At the end of the Attriter interview, CATI prompted the interviewer to verify the correct spelling of the subject's name, and her/his mailing address. Using the information every other week, project staff provided and mailed checks in the subject's name along with a thank you letter to the attriter.

### 7.11.3 Description of Telephone Security Measures

All telephone interviews were conducted following strict confidentiality procedures to ensure that the identity of individuals was kept completely confidential. To be certain that interviewers understood and agreed with the confidentiality requirements of this study, they were required to review and sign a WFHS Confidentiality Pledge at their project training session.

Telephone interviewers conducted the interviews at workstations within RTI's call center that had controlled access. All computers at the workstations are password protected. Telephone interviewers did not have access to project cases until study management had authorized case assignment. All case information and data were kept within encrypted electronic systems, including the CATI system and the Control System. Telephone staff were trained not to record any case information on hard copy paper.

# 7.11.4 Data Collection Training for Attriter Survey

Throughout the duration of the Attriter study, two telephone trainings were held at RTI's call center training a total of 16 telephone staff (both interviewers and supervisors). The various telephone staff were spread across various work shifts to ensure WFHS interviewers were available and working in every working shift in RTI's call center. **Table 7.11** summarizes the schedule for the call center trainings and the number of hired telephone staff (interviewers and supervisors) who attended that training session.

Table 7.11	

Training	Training Date	Number of Attending Telephone Staff Persons
First Training	7/12/2010	8
Second Training	2/1/2012	8

To ensure standardization of staff training, a comprehensive telephone interviewer manual was prepared describing the study objectives, instructions for telephone data collection, and instructions for completing CATI instruments. For cost efficiency and scheduling constraints, the attriter trainings were combined with the verification trainings.

All telephone staff attended a 4-hour, 1-evening project-specific training session utilizing multiple training techniques (e.g., lecture, hands-on practice) to prepare staff for interview collection activities. *Table 7.12* is the telephone interviewer training agenda broken out by modules covered.

# Table 7.12 – WFHS Telephone Interviewer Training Agenda

### Welcome/Introductions (10 minutes)

- Introduce project staff
- Ask others to introduce self / experience with RTI
- Pass out and sign confidentiality agreement

#### WFHS Study Background and Overview (10 minutes)

- Introduce how sites are being rolled out on a rolling basis
- Discuss what this means for each industry
- Introduce case ID rules
- Explain points of contact for each component (verifications and attriters)

# **Description of Verification Telephone Interview** (20 minutes)

- Two types of Verification interviews
- Employee verification and its contents
- Manager verification and its contents
- Probing Introduction
- Verification FAQs

#### **Description of ACF Attriter Study** (40 minutes)

- Overview of ACF Attriter survey
- Review flowchart of ACF Attriter Survey
- Attriter FAQs
- Additional rules for Attriter data collection

# Preloaded and Locator Information from Tracing (15 minutes)

• Preload information for tracing

Locator information from tracing to load in CATI

#### Administrative Procedures and Interview Strategies (25 minutes)

- Informed Consent Procedures
- Interviewing Techniques
- General Questionnaire Conventions
- Incentive Payments for the ACF Attriter Study

#### Policy on Distressed Respondents (25 minutes)

#### Round-Robin practice with survey (1 hr and 10 minutes)

#### 7.11.5 Telephone Quality Control Measures

The WFHS Telephone Study Manager (TSM) was responsible for overseeing the implementation of quality control measures for the Attriter Survey and Verification interviews. She worked closely with Call Center supervisors and Call Center monitors to implement quality control activities.

Several project reports were utilized to inform quality measures including summary status reports, refusal reports, case detail reports, and hours, cost and efficiency reports. The TSM implemented quality control measures by monitoring daily production reports, and completing weekly reviews of 1) case detail reports to monitor actions taken to complete pending cases, 2) actions taken on all refusal cases to determine next steps, and 3) call notes for high call count cases to determine if additional tracing was warranted, guide additional calling attempts, and decide when cases should be final coded as non-interviews.

A project-specific toll-free call-in line was used for the telephone study activities to address subject questions and concerns, and allow subjects to call in to complete survey activities or provide best dates/times to call to reach them. The toll-free number was included in letters and e-mails sent to telephone subjects, and also in project voice-mail messages. This call-in line proved to be effective in conjunction with the refusal letters we sent to extended-care subjects as a means of setting up hard appointments to complete interviews with the higher incentive.

RTI Call Center monitors also completed on-going quality control monitoring on 10% of all telephone interviewer calls where the monitor listened to the interviewer and respondent interaction, and also viewed what the interviewer was entering as responses in the CATI system. All subjects were asked at the start of the interview if QC monitoring could take place, and the monitoring was "blind," meaning that neither the interviewer nor the respondent was aware of which cases were being monitored. The QC monitoring allowed for validation of interview activities, and for gauging interviewer performance with the initial contact with household members, gaining cooperation skills, proper use of interviewing conventions, and adherence to project protocols. Regular feedback was provided to interviewers based on the monitoring activities.

# 7.12 Maintaining Confidentiality

To mitigate potential risks related to study participation, agreements were obtained with each worksite or work group manager that provided assurance to support all research activities and impose no negative consequences for study participants. Additionally, no individual identifiable

data was shared with the worksite or any entity outside of the WFHN research team directly involved with the study. Careful consideration of sharing any aggregate-level data with the workplace that might pose any risk to participants was also part of our data sharing agreements. RTI also obtained an NIH Certificate of Confidentiality to protect the data and the identity of respondents from court order or subpoena.

To minimize breaches of confidentiality, the CAPI data collection and transmission procedures followed RTI's strict protocols for maintaining field equipment and data confidentially at all times during the study period. Interviewers were trained on the meaning and importance of confidentiality and signed Confidentiality Agreements. All in-person data collection was conducted in private settings either in the workplace (e.g., library, private office, room off dining hall) or in the home, such that responses would not be overheard by others. For telephone interviewes, interviewers also ensured that respondents were answering in a private setting during telephone data collection.

# 7.13 Distressed Respondent Protocols

To mitigate risks to potential distress related to the psychological well-being survey items, a distressed respondent protocol was developed and approved by the IRB (see <u>Appendix 7.5</u>). The protocol included procedures for trained interviewers to be able to detect possible respondent distress based on participant responses to interview questions, statements made by the respondent during the interview process, and physical cues that might suggest possible distress. The protocol provided clear guidance on triage approaches related to the severity of the potential distress, including emergency contacts, referrals to appropriate workplace or local resources (e.g., employee assistance programs, workplace medical providers), and other local treatment providers outside the workplace. Respondents were informed that reports of abuse of a child or elderly person would result in mandatory reporting to appropriate authorities.

The IRB-approved protocols interviewers followed during the interview and lab experience include:

# **Respondents Exhibiting Psychological Distress**

A respondent could become distressed during the conduct of the interview if a question(s) evoked bad memories or unpleasant experiences. It was important to distinguish between distress and discomfort. While the interview was not designed to discuss sensitive topics with the respondent, it was possible that questions about physical health, stress, or family relations could create emotional discomfort for the respondent. Respondent distress was identified through emotional reaction (such as crying or anger), statements about extreme worry or anxiousness (such as concern about the respondent's own parenting skills or very high amounts of work related stress), and/or statements indicating hopelessness, sadness, or depression.

# Examples of respondent discomfort.

- Respondent says they do not want to answer a question
- Respondent states that the information is too personal to disclose

#### Interviewer responses to respondent discomfort.

- Interviewer reminds respondent that participation is voluntary
- Interviewer reminds the respondent that he/she can skip any question or stop the interview at any time

 Interviewer monitors the respondent closely to react properly if discomfort were to worsen to distress

#### Potential signs or indications of respondent distress

- Respondent becomes tearful and/or reports that he/she feels badly or is sad
- Respondent shows signs of being considerably more nervous or anxious (e.g. very nervous speech)

#### Interviewer responses to respondent distress

- Interviewer evaluates whether distress is extreme (see below)
- Interviewer reminds respondent that participation is voluntary
- Interviewer reminds the respondent that he/she can skip any question or stop the interview at any time.
- Interviewer asks the respondent "Would you like to take a short break?" and allows the respondent time to regain composure before finishing the interview
- Interviewer provides a list of local health care resources to the respondent (or a parent if the respondent is a child). If the interview takes place by phone (i.e., with spouse/partner), interviewer provides relevant phone numbers to the respondent by phone and mentions the resource guide that will be included in the incentive mailing.
- If the respondent expresses distress during the interview, the interviewer will complete an incident report and submit it to their Field Supervisor within 24 hours. The report will be distributed to the WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor.

#### Potential signs or indications of respondents with extreme distress:

- Respondent exhibits an extreme emotional reaction (e.g. the respondent cannot stop crying, the respondent cries to the point that the interviewer is worried about the respondent, the respondent becomes and stays angry, the respondent becomes angry to the point the interviewer is worried about the respondent's and/or the interviewer's safety)
- Respondent makes statements indicating that the respondent is consumed with worry or anxiety about their family or work situation
- Respondent makes statements indicating extreme hopelessness, sadness, or depression (e.g. repeating over and over that he/she is hopeless, statements about sadness that become increasingly severe, the respondent volunteers information about depressive symptoms)

#### Interviewer responses to respondents with extreme distress:

• In all cases of extreme distress the interviewer immediately stopped administering the interview. The interviewer provided a list of local health care resources to the respondent (or a parent if the respondent is a child). If the interview took place by phone (i.e., with spouse/partner), the interviewer provided relevant phone numbers to the respondent by phone and mentioned the resource guide that was included in the incentive mailing. The interviewer also offered to help the respondent seek immediate assistance, such as by calling an appropriate resource from the list provided or by calling 911. The interviewer immediately filled out an incident report and submitted it to their supervisor.

#### Suicidal Risks for Child Respondents

Although child respondents were not asked directly about suicidal feelings or intent, it was possible that a respondent would spontaneously report suicidal intent outside the course of the interview. If this situation occurred with a child respondent, the interviewer was trained to proceed in a calm, matter-of-fact fashion, without appearing shocked or upset in front of the child. The interviewer was trained to then follow these procedures:

- 1. At the end of the interview, the interviewer said to the respondent: "When you agreed to participate in this interview I told you that I would not tell anyone about anything you told me unless I was required to tell someone to prevent harm from coming to you. What you have told me about hurting yourself (i.e., suicide) has me concerned about your safety and well being. I have to tell your [parent/caregiver] about what you told me so they can make sure that you are safe. Would you like to be with us when we talk about it? I will also have to tell my supervisor."
- 2. The interviewer would then find the parent or other responsible adult in the home and inform them. The interviewer would say: "During the interview \_\_\_\_\_\_ told me that he/she (DESCRIPTION OF THE THREAT OR INTENT). I am not a trained counselor so I cannot tell you more about what this means. In the case of an emergency, we suggest taking your child to the emergency room immediately. If you are physically unable to get your child to the emergency room without help, you should call 911 for assistance. It is important not to let your child out of your sight or the sight of another responsible adult during this time if you feel that (he/she) is going to hurt (himself/herself). You should also contact (his/her) doctor or health care provider."
- 3. The interviewer would immediately file an incident report with the Field Supervisor.

# Suicidal Risks for Adult/Young Adult Respondents

- If an adult/young adult respondent stated that he or she was thinking about, feeling like, or planning *suicide*, the interviewer was trained to follow steps similar to those outlined for child respondents. First, the interviewer would tell the respondent of their concern for his/her safety, and remind him/her that you are required to contact the appropriate authorities as discussed before the interview. The interviewer would offer to assist the respondent with a call to the National Suicide Prevention Hotline (1-800-SUICIDE). Should the interviewer feel that the respondent is in immediate danger of self-harm, the interviewer would immediately call 911.
- 2. The interviewer would also suggest to the adult respondent that he/she would stay with him/her until professional help (e.g., EMS professional, agency mental health provider, local hospital staff, and caseworker) has taken responsibility for the situation either on the phone or in person. The interviewer may also ask another adult in the home to come sit with the respondent while they wait. Should the respondent ask the interviewer to leave them alone, the interviewer will respect their wishes. However, as mentioned above, if the interviewer believed the respondent is in immediate danger of self-harm, he/she should let them know that you he/she is required to call someone who can help them. The interviewer would leave and call 911.
- 3. The interviewer would immediately file an incident report with the Field Supervisor.

#### Suspected Child Abuse or Neglect

Although the questions in the interviews did not ask respondents specifically about child abuse or neglect, a respondent may voluntarily disclose such information during or after the interview process. Interviewers may have also observed abusive behavior or situations when they were doing home interviews.

All interviewers were required to report when they suspected a child younger than age 18 is abused or neglected by his/her parent, guardian, custodian, or caretaker. "Abused" means that a child has been inflicted with physical injury or injuries other than by accidental means or is in a condition which is the result of maltreatment such as: malnutrition, sexual molestation or exploitation, deprivation of necessities, or cruel punishment. It also includes living in an environment injurious to the juvenile's welfare (for example, in a home which is physically deteriorated to the point where it is dangerous or lives in an unsuitable /dirty environment). The child suspected of being abused or neglected may be a youth respondent, may be a respondent's child, or may be another child the respondent identifies.

All consent/assent forms included language to inform the respondent that if the project staff learned that harm or danger of a child is suspected, then this will be reported to someone who can check to see if the child is safe and protected. Therefore, all respondents were informed about potential actions that may follow disclosure of such information or observation of events that may require reporting or notification and can agree to those terms before participating in the interview or conversely, choose not to participate.

In the case of suspected child abuse or neglect, the field interviewer was trained to immediately file an incident report with the Field Supervisor. The report will be distributed to WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. If deemed necessary, the interviewer and Field Supervisor placed a call to the appropriate authorities, such as the Department of Child and Family Services for the county in which the respondent resides. If the field interviewer felt that a child was in imminent danger, he/she would call the appropriate authorities and attempt to stay in the home until professional help has taken responsibility for the situation either on the phone or in person. Should the field interviewer feel that his/her own safety would be endangered by staying in the home, he/she will leave and call 911.

#### **Distress Related to Biospecimen Collection**

Due to the potential for discomfort from the finger prick for the blood spot collection, procedures were developed in case a respondent became distressed during the blood spot collection process. During the collection of health measures, interviewers were trained to be alert for signs such as pallor, perspiration on the face and forehead, complaints of blurring vision, drooping or fluttering eyelids, or complaints of nausea. If this occurred, the interviewer was trained to implement the following procedures:

If a respondent was feeling faint, lightheaded, dizzy, or shows any signs of impending faint:

- Take care that the respondent does not fall or become injured.
- Calmly reassure the respondent and if necessary, ask the respondent to bend at the waist and put his/her head between his/her legs.

- Have the respondent rest for 10 minutes.
- Resume the procedure if the respondent consents to continue.

If the respondent fainted:

- Take care that the respondent does not fall or become injured.
- Have the respondent lie on his/her back as quickly as possible with feet elevated. The respondent will be instructed to lie down directly from the seated position without standing up.
- Ask the respondent to loosen any tight clothing.
- Have the respondent rest for 10 minutes.
- The interviewer will not resume blood spot collection, but if the respondent consents, the interviewer will skip to the introduction to the actigraphy study.
- If the respondent does not respond after one minute, the interviewer will call 911.

There was no physical risk or discomfort associated with the saliva or the anthropometric measures (blood pressure, height, weight). However, for adults, if a very high blood pressure value was obtained during the blood pressure readings (average systolic pressure > 210 or diastolic pressure > 120), interviewers were prompted by CAPI to indicate on the respondent's health feedback card that their blood pressure is very high and that they should seek medical attention within the next few days. A resource list was provided to the respondent with information about urgent medical care providers in their local area. The interviewer was trained to ask if the respondent wishes to continue with the data collection after this point. For children, CDC guidelines based on the child's age, sex, and height were used to determine whether the respondent's blood pressure is very high, and the feedback form given to the child's parent or guardian indicated that the parent should take the child to a doctor in the next few days. The resource list was given to the parent.

If any adverse events or any other unanticipated event occurred, the interviewer was trained to complete an incident report (Appendix 7.6) and submit it to RTI project team within 24 hours. The report was distributed to WFHN Coordinating Center Data Collection Study Leader and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. Potential adverse or unanticipated events reported outside of data collection appointments to a member of the study team were investigated by the field supervisor and reported to the IRB within 2 business days of obtaining enough firsthand information to be able to complete an incident report. For all incidents of physical distress related to study participation, the interviewer provided the respondent with a list of local health care resources and the Field Supervisor followed up with the respondent within 2 to 3 weeks to ensure that symptoms had resolved. Any instances of these events would be reported to the DSMB.

#### **Chapter 8: Data Measurements**

#### 8.1 Overview of the WFHS Data Collection

Data collection for managers, employees, spouse/partners, and children was conducted through a computer-assisted personal interview (CAPI) that included a self-report survey and biometric health measurements. Biometric health measures were collected only for managers, employees and children. The child health assessment included measures of blood pressure, height, and weight. The employee health assessment in both industries included these measures plus blood spot and actigraphy data collection. Within the extended-care care industry only, the blood spot and actigraphy data collection was also completed with managers.

Employee and manager participants received a \$20 incentive for each completed worksite interview including basic health assessment, and an additional \$20 each for the blood spot collection and actigraphy. Employees received a \$30 incentive for completing the additional home interview, and children received a \$50 incentive for their interview with health assessment. Spouses/partners received a \$20 incentive for each completed interview by telephone. Employee, manager, and child participants were also given information on their computed BMI, blood pressure and HbA1c levels (for those with blood collected), on a feedback card, which included an interpretation of the readings and recommended follow-up guidelines with a physician as needed.

Field interviewers were issued laptop computers to conduct all WFHS interviews. Interviews were conducted in a private location in the workplace for managers and employees and in a private location in the home for children. A CAPI module (administered by the RTI field interviewer) was also used to conduct the spouse / partner telephone interviews. In all cases, the interviewer read the survey questions as scripted to the participants and recorded responses directly into the computer. Respondents were provided with a response card booklet for the survey portion of the interview. At three pre-established points during the in-person interviews, interviewers were prompted to collect blood pressure readings with a wrist blood pressure monitor (Omron HEM-650), which uses the oscillometric method to obtain systolic and diastolic blood pressure readings, as well as pulse. Upon completion of the survey, interviewers were also prompted to collect height and weight measurements. Height was measured in centimeters using standard techniques and a Seca 214 stadiometer. Weight was measured in kilograms using a Health-O-Meter digital scale capable of weighing respondents up to 390 pounds. In cases where the manager or child interview was conducted over the telephone, the health assessments were not collected.

Interviewers were required to double enter blood pressure, height, and weight values into the computer. CAPI automatically calculated BMI and average blood pressure. Range and consistency checks were built into CAPI for the blood pressure, height, and weight values, and inconsistent and outlier values were flagged for resolution by the interviewer as a means of validating the accuracy of field entries. Additional checks and scripts were programmed into the interview to handle instances of dangerously high blood pressure.

Consenting employees (both industries) and managers (extended-care only) were also asked to provide dried blood spots by a finger stick. Interviewers wore latex-free gloves; cleansed the participant's finger with an alcohol swab; pricked the finger with a sterile, disposable micro-lancet; attempted to collect up to five blood spots on filter paper; collected a tiny (1 µI) blood droplet in a capillary tube for assay during interview of HbA1c levels using a simple DCA point-

of-care device; and then applied a small bandage to the finger. These subjects were also asked to wear an actigraph (Actiwatch Spectrum, Philips/Respironics, Murrysville, PA) to record sleep and wake behavior for a period of 7 days. The Spectrum is a small wrist-worn device (30 grams) that measures activity and ambient light exposure over extended periods in a noninvasive and discreet manner.

*Table 8.1* summarizes the specific health measures collected per participant type. The computer was programmed with prompts to guide the health measure collection process with each respondent.

Health Measure	Employee	Manager	Child
Blood pressure	Yes	Yes	Yes
Height*	Yes	Yes	Yes
Weight*	Yes	Yes	Yes
Dried blood spots**	Yes	Yes (extended- care care only)	_
Actigraphy**	Yes	Yes (extended- care care only)	_
Saliva***	Yes	_	Yes

Table 8.1 Health Measures by Participant Type

- \* Height and weight were collected on respondents able to stand unassisted.
- \*\* Dried blood spots and actigraphy were collected from employees and managers at the worksite.
- \*\*\* Employees / child (9-17) pairs who completed the interview were also asked to complete the Daily Diary study component led by Penn State, which included saliva collection. Interviewers recruited and enrolled subjects, and provided saliva kits to complete. (See Section 8.6 for more detail.)

# 8.2 Computer Assisted Personal Interview (CAPI) and Biometric Data Measures

Tables 8.2, 8.3, 8.4 and 8.5 describe the measures collected for each type of CAPI. A reference for measures was also provided. Details on the question text and survey instrumentation were made available on the WFHN Data Documentation Directory. These tables are included in the second flagship paper which contain the detailed references:

Bray, J., Buxton, O., Kelly, E., Hammer, L., Almeida, D., & Dearing, J.W. (2013). *An integrative, transdisciplinary, and multi-level research design: The work, family, and health network.* RTI Press.

Table 8.2 Employee and Supervising Manager	Workplace Interview Measures
Measure	Source/Adapted from

Outcomes/Mediators

Work-family conflict
Organization Work-Family Climate
Work-to-Family Conflict
Work-Family Positive Spillover
Time Adequacy
Psychosocial Work Environment
Control over work time
Job Control
Job Demands
Role Clarity
Low-Value Work
Family-Supportive Supervisor Behaviors
Organizational Citizenship
Task Interdependence
Obligation to Come to Work When Sick
Physical health
Chronic Conditions
Health Behaviors
Functional Disability (Employee Only)
Cardiometabolic Disease Risk
Chronic Inflammation (C-reactive protein) Stress-mediated immunosupression (Epstein- Barr Virus anti-body titers) Diabetes risk (Hb1Ac)
Sleep duration and disruption (Wrist actigraphy)
Sleep quality self-report (adapted from)
Sieep Aprica lisk (adapted from)
Nen Specific Boychological Distress KC Seele
Received Stress (Employee Only)
Perceived Siless (Employee Only)
Social Support
Family Processes
Spouse Support & Strain
Internage/Life Partner Expectations
Parent-Unid Conflict
Parental Knowledge

Kossek, 2001 Netemeyer et al, 1996 Hanson et al, 2006 Van Horn et al, 2001

Thomas and Ganster, 1995 Karasek et al. 1998 Karasek et al. 1998 Cammann et al. 1983 Rizzo et al. 1970 Hammer et al. 2009 Lambert 2000 Pearce and Gregersen 1991 WFHN Pilot Work

Seeman and Berkman 1988; Wilson et al. 1998 NCHS 2005; Bray et al. 2007; French et al. 2007 Garrat et al. 2002; Turner-Bowker et al. 2002 Modified Framingham risk factor score; Wilson et al. 1998; Berkman et al. 2010 McDade 2007 McDade 2007

Edelman et al. 2004; Norberg et al. 2006

Ancoli-Israel et al. 2003; Morgenthaler et al. 2007, Berkman et al JOHP 2010; Ertel et al Sleep 2011 PSQI (Buysse et al. 1989); Buxton et al. 2009 Maislin et al. 1995

Kessler et al. 2003; Mroczek and Kolarz 1998 Cohen, Kamarck, and Mermelstien 1983; Cohen and Williamson 1991 Seeman and Berkman 1988

Grzywacz and Marks 2000, 1999; Schuster, Kessler, and Aseltine, 1990; Whalen and Lachman 2000 WFHN Pilot Work Smetana 1988; Harris 1992 Stattin and Kerr 2000

#### Measure

#### Source/Adapted from

Parenting Time with Child(ren) Parenthood Expectations

#### **Organizational Outcomes**

**Burnout** Job Satisfaction Intention to Quit Job Security Safety Compliance Accidents and Injuries Productivity Health Care Utilization

Moderators/Confounds **Basic demographics** Gender Age Education Race/Ethnicity/Nativity Work Characteristics Job title Tenure Schedule Telecommuting Night/Weekend Work Multiple Jobs **Commuting Time** Number of Supervisees Family demographics Spouse/partner demographics Child roster Time spent caring for other adults Income Adequacy Neal and Hammer 2007 Adaptability/Readiness for Change (Manager only) Cunningham et al. 2002; Prochaska et al. 1994 Leadership Style (Manager only) Avolio et al. 1999 Management Trust Scale (Manager only) Cook and Wall 1980 Manager Views of Flexible Work Arrangements on Kossek, Barber, and Winters 1999 Productivity (Manager only)

Arnold et al. 1993 Novel WFHN Pilot Work

Maslach and Jackson 1986 Cammann et al. 1983 Boroff and Lewin, 1997 MIDUS Neal, Griffin, and Hart 2000 Hemingway and Smith 1999 Kessler et al. 2003 Bray et al. 2007

# Table 8.3 Employee Home Interview MeasuresMeasure

Source/Adapted from

Outcomes/Mediators		
Psychosocial Work Environment		
Team Cohesion	Podsakoff and MacKenzie 1994	
Family Specific Coworker Support	Hammer et al. 2009	
General Coworker Support	Caplan, Cobb, and French 1975	
Supervisor Support	Hammer et al. 2009	
Psychological distress		
Daily Discrimination	Williams et al. 1997	
Family Processes		
School Grade and Status (Employee report on Child)	Novel	
Relationship Satisfaction	Huston, McHale, and Crouter 1997	
Parental Stress	Stephens and Townsend 1997	
Parent-Child Warmth and Acceptance	Schaefer 1965; Schluderman and Schluderman 1970; Schwarz, Barton-Henry, and Pruzinsky 1985	
Parental Solicitation & Disclosure	Stattin and Kerr 2000	
Preparation for Bias	Hughes and Chen 1997	
Behavior Problems Index (BPI)	Peterson and Zill 1986;	
Child Adjustment	Dotterer et al. 2009	
Elder Care	Neal and Hammer 1998	
Child Care Arrangements	WFHN Pilot Work	

# Table 8.4 Spouse Telephone Interview Measures

Measure	Source/Adapted from		
Outcomes/Mediators			
Work-family conflict			
Work Characteristics	Job title, Schedule, Multiple Jobs, Hours Worked		
Work Schedule Flexibility	Novel		
Work-to-Family Conflict	Netemeyer et al. 1996		
Work-Family Positive Spillover	Hanson et al. 2006		
Time Adequacy	Van Horn et al. 2001		
Work-to-Family Conflict (Spouse report on Employee)	Netemeyer et al. 1996		
Time with Child(ren)	Novel		
Physical health			
Physical Health Symptoms	Almeida 1998; Charles and Almeida 2006;		
	Larsen and Kasimatis 1991		
Health Behaviors	NCHS 2005; Bray et al. 2007; French et al. 2007		
Health Behaviors (Spouse report on Employee)	NCHS 2005; Bray et al. 2007; French et al. 2007		
Physical Health Symptoms (Spouse report on Child)	Almeida 1998; Larsen and Kasimatis 1991		
Sleep			
Sleep quality self-report (adapted from)	Buysse et al. 1989; Buxton et al 2009		
Snoring (Spouse report on Employee)	Maislin et al. 1995		
Psychological distress			
Psychological Distress	Kessler et al. 2003; Mroczek and Kolarz 1998		
Perceived Stress	Cohen et al. 1983; Cohen and Williamson 1991;		
Positive and Negative Affect	Laurent et al. 1999; Watson et al. 1988		
(Spouse report on Child)			
Family Processes			
Relationship Satisfaction	Huston et al. 1997		
Spouse Support & Strain	Grzywacz and Marks 1999,; Schuster et al. 1990;		
Co-parenting	Margolin Gordis and John 2001		
Household Chaos	Matheny et al. 1995		
Time Spent Caring for Adults	Novel		
Parent-Child Conflict	Smetana 1998: Harris 1992		
Parental Knowledge	Stattin and Kerr 2000		
Parenting	Arnold et al. 1993		
Parenthood Expectations	WEHN Pilot Work		
Organizational Outcomes			
Productivity	Kosslor at al. 2003		
Job Security	MIDUS		
Insurance and Hospital Visits	Brav et al. 2007		
Moderators/Co	onfounds		
Basic demographics			

Gender

Age Socioeconomic Status Race/Ethnicity/Nativity Income Adequacy

Neal and Hammer 2007

Table 8.5 Child Home Interview Measures		
Measure	Source/Adapted from	
Outcomes/Mediators		
Work-family conflict		
Time Use	McHale, Crouter, and Tucker 2001	
Time Adequacy	Van Horn et al. 2001	
School and Work Situation	Novel	
Physical health		
Physical Health Symptoms	Almeida 1998; Charles and Almeida, 2006; Larsen and Kasimatis 1991	
Sleep		
Sleep duration and quality (self-report)	Adapted from Buysse et al. 1989; Buxton et al 2009	
Psychological distress		
Risky Behaviors	Dishion et al. 1991; Eccles and Barber 1990; Huizinga, Esbensen, Wieher 1991; Mason et al. 1994	
Depressive Symptoms	Kovacs 2001	
Psychological Well-Being	Keyes 2006;	
Family Processes		
Parent-Child Warmth and Acceptance	Schaefer 1965; Schluderman and Schluderman 1970; Schwarz et al. 1985	
Parent-Child Conflict	Smetana 1998; Harris 1992	
Parent-Child Time Together	McHale et al. 2001	
Parental Knowledge	Stattin and Kerr 2000	
Household Chaos	Matheny et al. 1995	
School Bonding	AddHealth; Dotterer, McHale, and Crouter 2007; McNeely 2005; Voelkl 1997; Fine 1991	
Social Competence	Search Institute 2001	
Routines	Jensen et al. 1983	
Parental Involvement in School	Phillips Smith et al, 1997	
Solicitation & Disclosure	Stattin and Kerr 2000	
Lax discipline	Schaefer 1965; Schluderman and	
	Schluderman 1970; Schwarz et al. 1985	
Moderate	ors/Confounds	
Economic Insecurity	WFHN Phase 2	
Pubertal Development	Petersen et al. 1988	

### 8.3 Biometric health assessment procedures

# 8.3.1 Height

Interviewers measured standing height of employee, manager, and child respondents who were able to safely stand unassisted, using a Seca 214 stadiometer. Interviewers were trained and certified to properly assemble the measuring device and measure height in centimeters (see <u>Appendix 8.1</u>). The assembled stadiometer was placed on a firm surface (an uncarpeted floor and near a wall or doorframe for support) for an accurate measure. In situations where a carpeted surface was the only available option, the field staff placed the stadiometer on top of a large ceramic tile. Participants were asked to remove shoes, headgear, and hairpieces that may have interfered with obtaining an accurate measurement. The height was measured and recorded to the nearest tenth of a centimeter. Interviewers were required to double enter measurements directly into the laptop.

We programmed consistency checks in CAPI on the height values entered, by using the following centimeter ranges by participant type:

- Adult male range for height: (158 to 194 centimeters) U.S. equivalent 5'2" 6'4"
- Adult female range for height: (146 to 178 centimeters) U.S. equivalent 4'8" 5'8"
- Male child range for height (recognizing children can be 9-17 years of age): (124 to 194 centimeters) U.S. equivalent 4'0" 6'4"
- Female child range for height (recognizing children can be 9-17 years of age): (124 to 178 centimeters) – U.S. equivalent 4'0" – 5'8"

Height values that fell outside of the above ranges generated a soft check prompt on the computer requesting the interviewer to double check the accuracy of their entry and make corrections where needed.

# 8.3.2 Weight

Interviewers collected weight measurements from employee, manager, and child respondents who were capable of standing unassisted. The study used a Health-O-Meter 800KL digital electronic scale capable of weighing respondents up to 390 pounds or 180 kilograms (kg). Interviewers were trained and certified on the proper setup and use of the scale to obtain weight measurements and on the process for calibrating the scale (see <u>Appendix 8.2</u>). The scale was placed on a firm surface (an uncarpeted floor) for an accurate measure. In situations where a carpeted surface was the only available option, the field staff placed the scale on top of a large ceramic tile. Participants were asked to remove heavy outer garments and shoes and to empty pockets during the weight measurement. Immediately after a successful measurement, the interviewer was required to double enter the value into the computer. Weight was measured and recorded to the nearest 0.1 kilogram. If the weight of the respondent exceeded the capacity of the scale, the interviewer noted this in CAPI.

We programmed consistency checks in CAPI on the weight values entered, by using the following kilogram ranges by participant type:

- Adult male range for weight: (53 to 150 kilograms) U.S. equivalent 117 331 pounds
- Adult female range for weight: (44 to 134 kilograms) U.S. equivalent 97 295 pounds
- Male child range for weight (recognizing children can be 9-17 years of age): (18 to 94 kilograms) U.S. equivalent 40 207 pounds
- Female child range for weight (recognizing children can be 9-17 years of age): (17 to 87 kilograms) U.S. equivalent 37 192 pounds

Weight values that fell outside of the ranges generated a soft check prompt on the computer requesting the interviewer to double check the accuracy of their entry and make corrections where needed.

Once a week interviewers were required to test and calibrate their scale using specific procedures and a 5-lb calibration weight. Interviewers were required to immediately notify their supervisor of any issues, and a replacement scale was shipped overnight as needed.

### 8.3.3 Blood Pressure

Interviewers attempted to obtain three complete measurements of systolic and diastolic blood pressure from each employee, manager, and child respondent. The left wrist was the wrist of choice for measuring blood pressure. However, if the left wrist could not be used, then the blood pressure procedure was performed using the right wrist. The study used a Wrist Blood Pressure Monitor with Advanced Positioning Sensor (APS) Model HEM-650 to collect the blood pressure readings (see <u>Appendix 8.3</u>). Interviewers were trained and certified on the proper setup and use of the blood pressure monitor.

The ideal environment to collect the blood pressure was a quiet room with a comfortable temperature and good lighting. The CAPI instrument directed the interviewer to place the cuff on the subject's wrist at the start of the interview (so the subject would be at rest for 5 minutes before collecting the first reading). The CAPI instrument also prompted the interviewer to collect each of the three readings at different points during the interview. The participant was directed to sit comfortably upright with both feet on the floor, legs uncrossed for each reading. The cuff was positioned on skin over the participant's left wrist with left thumb facing upward. In placing the cuff, FIs left a clearance of 1 inch between the edge of the wrist cuff and the bottom of the palm. For each collection the interviewer guided the subject on proper placement of the device at heart level. Once sensors in the device detected proper placement, the device inflated and automatically measured the blood pressure and pulse and displayed the readings. After each successful measure, interviewers were prompted to double enter the blood pressure and pulse of the participant (as displayed on the BP device) in the CAPI instrument.

Respondents were provided an average of their three blood pressure results on a feedback form at the end of the interview. Different versions were created for adults and children (See Appendices 8.4 and 8.4.1).

We programmed consistency checks in CAPI on the blood pressure and pulse values entered, by using the following ranges:

• Systolic blood pressure value range: 60 to 250 mmHG (millimeters of mercury)

- Diastolic blood pressure value range: 40 to 160 mmHG (millimeters of mercury)
- Pulse reading range: 40 to 200 beats per minute

Values that fell outside of the ranges generated a soft check prompt on the computer requesting the interviewer to double check the accuracy of their entry and make corrections where needed.

# 8.3.4 Dried Blood Spots

For the dried blood spot collection, interviewers accessed and completed the blood collection and actigraphy module for the particular respondent. The module included scripted text to guide the consent process and various prompts and instructions for obtaining and entering blood collection results. Consenting employees (both industries) and managers (extended-care only) were asked to provide up to five blood spots by finger stick(s). All five drops were placed on a Whatman 903 filter paper. For blood spot collection, the interviewers were trained to allow the blood to form a drop and fall of its own weight or to use capillary action to gather the samples. If blood flow was not sufficient for collecting all spots with one fingerstick, we allowed for the skin puncture to be repeated up to two times per hand and using a new finger for each finger stick. Blood spots placed on the filter paper were allowed to air dry a minimum of 15 minutes, were packaged in individual bio-hazard specimen bags with a desiccant sack, and placed in a storage cooler. The storage cooler was kept in a secure location at the worksite, and the collected specimens were shipped at least weekly to Harvard University using special bio-hazard shipping boxes. Once received, Harvard staff performed quality assessment measures on the blood spot cards for size, saturation, desiccation and documentation. After quality assessment, the samples were stored in a locked -80 °C Revco freezer until they were shipped frozen to the external laboratory for assay. The collected dried blood spots (or DBS) were analyzed to identify certain biomarkers that are associated with health outcomes. The biomarkers measure how well organs are functioning by examining levels of C-reactive protein levels (CRP; inflammation response), and total and HDL cholesterol (total; heart disease risk). Dried blood spots for C-Reactive Protein were collected and frozen for later assay using standard techniques (McDade et al., 2007).

In addition to the blood spots, interviewers also collected a tiny (1 µl) blood droplet on a capillary tube for immediate measurement of HbA1c levels (glycosylated hemoglobin) using a simple DCA Vantage Analyzer point-of-care device (DCA Vantage ™ Analyzer, Siemens Healthcare Diagnostics; Frimley, Camberley, UK). The interviewer snapped the capillary tube into a reagent cartridge which was loaded into the DCA device. The HbA1c assay took 6-7 minutes to run, and the interviewer printed the HBA1c score results. These results were double keyed into CAPI, and were also written on a feedback card provided to the participant. In sharing the results, the interviewer noted that results were for research purposes and should not be used as a clinical diagnosis. If the participant's score was outside of the range of 4.0%-7.0% the interviewer suggested the participant be retested by their own doctor or other medical provider.

Researchers at Harvard have been able to obtain results for three tests (Total Cholesterol, HDL, and C-Reactive Protein) from dried blood spot samples. *Table 8.6* shows the percentages of DBS samples for which study test results were obtained across 4 waves.

Test	Percentage of DBS Samples Results Obtained
Total Cholesterol	98.2%
HDL ("Good" Cholesterol)	99.2%
C-Reactive Protein	99.1%

### 8.3.5 Actigraphy

Employees (both industries) and managers (extended-care only from LEEF 7.0 forward from baseline) were asked to wear an actigraph (Actiwatch Spectrum) to record sleep and wake patterns for a period of 7 days. The Spectrum is a small wrist-worn device (30 grams) that measures activity and ambient light exposure over extended periods in a noninvasive and discreet manner. Because activity and sleep habits may vary from day to day, it is important to get a full week of information on the watch. This includes days when the employee did and did not go to work but excluded vacation and leave periods.

For the actigraphy collection, interviewers accessed and completed the blood collection and actigraphy module for the particular respondent. The module included scripted text to guide the actigraphy consent process, and guide the assignment and placement of the actigraphy device on consenting subjects (see <u>Appendix 8.5</u>). Interviewers were prompted to capture in CAPI the date assigned and watch serial number by using a bar code reader. Interviewers then placed the device on the subject's non-dominant wrist, checking that the watch was not too tight and was working properly. When given the Actiwatch, subjects also received an instruction card explaining how to wear and care for the Actiwatch. The interviewer reviewed each point listed on the card, and also printed the date, time, and location of the watch's return on the card. After a period of about 7 days, the interviewer met with the subject to retrieve the actiwatch and to provide the actigraphy \$20 incentive. Once returned, the data from the retrieved watch was downloaded by the team leader. An interface reader was attached to the team leader's laptop computer for the purpose of transferring data from the actiwatch telemetrically. The actigraph data was transmitted to RTI, and then provided de-identified to the Harvard team to be scored using Actiware-Sleep Software (Respironics/Philips, Murrysville, PA). Once the watch data was downloaded by the team leader, each watch was cleaned with mild soap and warm water before being set up and handed out to another subject.

#### 8.3.6 Daily Diary and Saliva Collection

The WFHS also included a daily diary study with eligible employees and their children, aged 9 through 17 (biologically or legally related and living with employee at least 4 days a week), at baseline and again at the 12-month follow-up. Employees with children in the target age range were recruited during the baseline workplace interviews for participation. They were asked to participate, along with a child in the target age range (their child closest to age 13), in a series of eight nightly telephone interviews and the collection of saliva.

The telephone interviews were completed by Penn State's Survey Research Center. The calls lasted about 20 minutes, on average, and occurred on 8 consecutive days. The first call (on Day 1) lasted a little longer (about 30 minutes) than the subsequent daily calls. The employee and child each completed a separate interview on the *same* 8 days. The second component of the daily diary was the collection of saliva from both the employee and child on 4 of the 8 diary days (Days 2-5).

The diagram below describes exactly how the daily diary data collection unfolded.

Figure 8.1 Overview of the Daily Diary Data Collection



**Daily Diary Interview Days** 

Across the top were the 8 daily diary collection days. Days 1-8 could fall on any day of the week and were not expected to start on the same days for all families. On Days 2-5, employees and children were asked to provide saliva, on 4 days of the total 8 diary days. As shown here, adults were asked to provide saliva at 5 different times during the day. Children were asked to provide saliva at 5 different times during the day. Children were asked to provide saliva at 5 different times during the day.

# 8.4 Daily Diary Telephone Interviews

During the consent process for the Daily Diary Study, the RTI field interviewer asked for the employee and child telephone contact information and general availability during the week for the Survey Research Center at Penn State to make contact by telephone. This information was keyed in CAPI, transmitted nightly to RTI. RTI packaged and transferred the contacting and availability information to Penn State, who has carried out a number of telephone diary studies, to follow up with subjects to schedule and complete the daily diary calls on 8 consecutive days.

During these nightly calls, the parent and child were asked to complete individual interviews lasting about 20 minutes for parents and about15 minutes for children. Questions were about daily health, affect, time use, stressors, positive events, and interactions with supervisors and family members. Participants were also reminded about the saliva data collection on the evenings prior to scheduled collections and asked a short set of questions (i.e., about the timing of collections, about medications) on the days when saliva samples were collected.

Employees and children were provided a pre-incentive of \$25 each at baseline, and \$50 each at 12-months along with the saliva kits. Families were sent an additional \$100 at baseline and \$150 at the 12-month follow-up upon completing the phone interviews and mailing in saliva samples.

# Table 8.7 Employee Daily Diary Measures

#### Measure

# **Outcomes/Mediators**

Daily Experiences	
Time Use (work hrs, household tasks)	Almeida & McDonald, 2005
Work Shifts (timing, location)	Novel
Social Support	Almeida et al., 2001
Daily Stressful Experiences	Almeida, Wethington, Kessler, 2002
Daily Positive Events	Almeida et al., 2002
Discrimination (Day 8 only)	Almeida et al., 2002
Work-family conflict	
Work-to-Family Conflict	Netemever et al. 1996
Time Adequacy (adapted)	Van Horn et al. 2001
Psychosocial Work Environment	
Control over work time	Thomas and Ganster, 1995
Job Demands	Karasek et al. 1998
Family-Supportive Supervisor Behaviors	Hammer et al. 2009
Supervisor Support – general, for work-	Novel
family	
Physical health	
Physical Health Symptoms	Larsen & Kasimatis, 1991
Alcoholic and Caffeinated Drinks	MIDUS
Tobacco Use	Heatherton et al., 1991
Yoga and Meditation	Novel
Sleep	
Sleep duration and disruption	PSQI (Buysse et al. 1989)
Sleep quality (adapted from)	PSQI (Buysse et al. 1989; Buxton et al. 2009)
Psychological distress	
Non-Specific Psychological Distress K6	Kessier et al. 2003; Watson et al., 1988
Dositivo Affoct	Watson Clark & Tollogon 1988
Fosilive Aneco	Walson, Clark, & Tellegen, 1900
Experiences with Target child	Spoth Redmond & Shin 1998
Target Child's Care Arrangements	WEHN Phase I
Parental Knowledge	Stattin & Kerr 2000
Parental Worry	Barnett & Gareis, 2006
Time with Partner and Child	Almeida et al., 2002
Organizational Outcomes	
- Cutbacks/Impairment at Work	MIDUS
Cognitive Interference	Mogle, Stawski, & Sliwinski, 2008; Stawski, Mogle, & Sliwinski, 2009

#### Measure

Memory Failure

#### Source/Adapted from

Sliwinski & Smyth (2009)

Table 8.8	Child Daily Diary Measures				
Measure		Source/Adapted from			
	Outcomes/Mediators				
Daily Expe	riences				
Time Use (homework, hobbies, work)		Almeida & McDonald, 2005			
Daily Stressful Experiences		Almeida, Wethington, Kessler, 2002			
Daily Positive Events		Almeida et al., 2002; Charles et al., 2010; Seltzer et al., 2009			
Work-fami	ly conflict				
Time Adequacy (adapted)		Van Horn et al, 2001			
Physical h	ealth				
Physical Health Symptoms		Larsen & Kasimatis, 1991			
Alcoholic and Caffeinated Drinks		MIDUS			
Tobacco Use		Heatherton et al., 1991			
Sleep					
Sleep du	ration and disruption	PSQI (Buysse et al. 1989); Lawson et al., 2014			
Sleep qu	ality (adapted from)	PSQI (Buysse et al. 1989); Buxton et al 2009; Lawson et al., 2014			
Psycholog	ical distress				
Non-Spe	cific Psychological Distress K6	Kessler et al. 2003; Watson et al., 1988			
Scale					
Positive A	Affect	Watson, Clark, & Tellegen, 1988			
Parent's	Mood After Work	WFHN Phase I			
Family Pro	Cesses				
Contact v	vith Working Parent	WFHN Phase I			
Experien	ces with Target child	Spoth, Redmond, & Shin, 1998			
Parental Knowledge		Stattin & Kerr, 2000			
Time with	n Parent	Almeida et al., 2002			

#### 8.4.1 Daily Diary Saliva Collection

Field interviewers provided saliva kits to the respondents (one for the employee, one for the child) following the child's home CAPI interview. The kits included instructions and a DVD on how to collect and ship the saliva samples. Adults and children were asked to provide saliva samples for four days (on Days 2-5) during the daily diary portion of the study by rolling a cotton swab around their tongue until saturated. Adults provided saliva 5 times a day—before they get out of bed in the morning, a half hour after they were out of bed, before lunch, before dinner, and before bed. Children provided saliva only 4 times a day—before they get out of bed, a half hour after they were out of bed, before they get out of bed, a samples were assayed for a biomarkers of stress-diurnal cortisol, a hormone that has been implicated in

the stress response of the hypothalamic-pituitary-adrenal (HPA) axis. Respondents were instructed to write the date and time of data collection on the salivettes, which contain the cotton swabs, and on the Saliva Home Collection Sheet. Ten percent of the sample received time stampers; this group were instructed to use the time stamper instead of hand-writing dates and times of collection on the sheet.

# 8.4.2 Saliva Sample Storage and Shipment

Respondents were instructed to put samples into the refrigerator immediately if the samples were taken at home, or to refrigerate the samples as soon as they arrive home if the samples were taken outside the home. Keeping samples refrigerated after collection is important. When samples remain at room temperature for periods of time longer than two hours, bacteria can grow, which will compromise assay validity.

The morning after all saliva samples had been collected from the adult and child, they were instructed to mail back all salivettes, data collection sheet(s), and the medication use form in the pre-paid UPS Next Day mailing bag provided in the adult kit. This package was shipped to project staff at Penn State. The adult kit contained instructions for respondents on how to prepare their shipment and how to schedule a pick up time. We asked for both the child and adult kits to be mailed back together.

# 8.5 Administrative and Organizational Data Measures

WFHS investigators worked with the two participating industries to gain access to employee administrative records that could be merged with data collected through CAPI at both the individual- and group-level. Individual-level data were abstracted when possible to be integrated with employee and manager survey data, but in some cases, the data were only available at a group-level. We defined 2 types of records: administrative and organizational. Administrative data consisted of human resources information system (HRIS) records and health care claims records from employee-sponsored health plans – both requiring consent from the employee/manager to collect. The other type of data, organizational data, did not require consent from individuals. Organizational data was collected for all potentially eligible respondents and worksites to inform randomization and to populate work site rosters for subject recruitment.

#### Administrative data

Individual-level administrative data from the industry partners included:

- Respondent's basic demographics
- Respondent's title, terms of employment, and job information
- Respondent's salary and performance records (telecommunications-only)
- Respondent's use of time off (both industries) and benefits (extended-care only)

# 8.5.1 Terms of employment

Both industries provided information about term of employment, hire date, and years of service. The telecommunications industry also provided data for the employee's earliest retirement date. The extended-care care industry also provided a re-hire date if the employee or manager had ever left the company and then returned for employment, an indicator if an employee had been terminated, the date of termination, and an indicator of whether the termination was voluntary or involuntary.

# 8.5.2 Job Information

Both industries provided the employee's job title and exempt/non-exempt status and income information (salary in telecommunications industry, hourly rate of pay in extended-care care industry), standard hours worked (calculated quarterly for extended-care care industry), last pay increase (%) and last pay increase date. The telecommunications industry also provided department name/ID, job code, regular or temporary status, full or part-time status, supervisor or non-supervisor status, salary grade, survey salary (industry comparison salary), and the minimum, midpoint, and maximum salaries for that grade. The extended-care care industry provided overtime hours (calculated quarterly) and productive hours (calculated quarterly from pay-period base).

# 8.5.3 Performance

The telecommunications industry also provided information, when available, on the last performance rating and the effective date of that rating, as well as the previous rating and its effective date.

# 8.5.4 Time-off

Both industries provided information on total paid time earned, paid time off remaining, and how much has been taken. For the extended-care care industry, time taken was separated into sick time, personal time, and vacation time, and information was also provided on unpaid time off, and on whether an employee had cashed-out or bought-back either sick time or vacation time. The telecommunications industry provided information on their time off accrual rate and last process date of time off.

# 8.5.5 Benefits

The extended-care care industry provided information on whether an employee is eligible for healthcare coverage, conditional of eligibility whether they are enrolled in healthcare coverage, and whether the employee elected modified compensation.

# 8.6 Group-level administrative data

Group-level administrative data from the telecommunications industry partner included internal performance metrics.

Group-level administrative data from the extended-care industry partner included:

- MyInnerview satisfaction surveys
- Nursing Home Quality Indicators
- Site-level average wages and turnover/retention rates
- Census vs. Budget admissions reports

At the telecommunications industry, employees and managers were also asked to sign an Authorization for the Release of Health Information during their interview. By consenting, the employee or manager agreed to allow the release of health care claims records to the WFHS for
research purposes. Due to logistical constraints, we have been unable to obtain health care claims records.

At the extended-care care industry, we will not collect individual-level health care claims records by request of the study partner. We have attempted to collect these records at the site-level, but have been unable to collect these so far due to logistical constraints.

# 8.6.1 Organizational Data measures

There are 2 types of organizational data: individual-level data used to populate study rosters; group-level data used for randomization to document organizational hierarchy and to describe the full sample.

# 8.6.2 Employee Roster Information

The industry partners provided a roster of employee names and basic demographic information, including: age, race and ethnicity (telecommunications industry-only), gender, management status, and several variables related to the respondent's business unit/floor/shift. This information was used to determine study eligibility, to pre-load information into CAPI, and for the use of scheduling interviews.

# 8.6.3 Randomization Information

Randomization variables were different for the industries. For the telecommunications industry, randomization variables included: number of employee in a cluster, the Level 1 vice president assigned to that cluster, and the cluster's job function (core or support). For the extended-care industry, randomization variables included: number of employees in a facility, the geographical state of the facility, and the facility's turnover/retention rate.

# 8.6.4 Management Hierarchy Information

At the telecommunications industry, there were 5 levels of management. That means, for any one employee, there were up to 5 managers above that employee. The WFHS study team worked with the HR department to create an organizational chart to capture the management hierarchy. This organizational chart was converted into linkable data.

At the extended-care industry, a similar organizational chart was drafted at the facility-level. The maximum number of management levels above in an employee is 4.

# 8.6.5 Full-sample descriptive information

For both industries, we collected demographic information (age, gender, race, etc.) for the full sample of eligible participants to be able to examine non-response and self-selection bias. These variables were available at the group-level. For the telecommunications industry, "group" had 3 different meanings: team, work group, and study group.

- Team: Teams were the lowest-level, or finest-level of employees that all reported to the same supervisor.
- Work group: Work groups comprised of a single team or teams that reported to a higher-level manager.

• Study group: Study groups were the highest-level unit, consisting of one or more work groups. This industry was randomized at the study group-level.

For the extended-care industry, there were 2 levels of descriptive demographic information obtained: eligible employees, and full roster. Several types of employees at the extended-care facilities were not eligible to participate in the study. We therefore compiled this descriptive information at the facility level with the number of eligible employees as a denominator, and with the full number of employees as a denominator (eligible and non-eligible).

### **Chapter 9: Formative Research**

### 9.1 Introduction

The following protocol provides a general overview of the formative research data collection for the Work, Family & Health Network. The formative research component was conducted before any formal data collection for the Work, Family & Health Study or any Intervention activities occurred. Formative research was conducted in both industries and the same protocol was followed for each, with some small variation.

The purpose of the formative research was to inform all aspects of the study, including both the data collection and the intervention, as to the context of the industries and the specific organizations. Measures and Analysis used the information to make decisions regarding which constructs would be most critical to measure in the study. The Family Study team gained a better understanding of the types of families (e.g., ages of children, elder care issues) and what specific issues were faced by parents in each industry. The Intervention team analyzed the formative data extensively to customize the intervention to make it more relevant to the specific types of work done in each organization. The Operations Committee focused information that shed light on the logistical constraints faced while rolling out the data collection and the intervention.

We used three primary methods of data collection for the formative research: job shadowing, manager interviews, and employee focus groups. In addition to these 3 formal data collection techniques, researchers also took ethnographic fieldnotes (and occasionally recorded and transcribed) of the many meetings we sat in on with our company partners as part of the study planning phase. The information presented in this protocol is taken primarily from a training document created for our research staff.

It is critically important that the formative research process was standardized in order to protect the scientific validity of the study.

The Formative Research Phase, including meetings with Industry Partners, took place between September 2008 and May of 2009. The bulk of TOMO's research was completed between September and December 2008 (some shadows and interviews conducted until March 2009); LEEF was completed between November 2008 and end of February 2009. Both UMN and PDX had applications accepted by both of our Institutional Review Boards before beginning formative research.

### 9.1.1 Formative Research Participants

Although TOMO's headquarters is in Denver, it has satellite offices all of over the country. Our HR partners at TOMO informed the University of Minnesota that the satellite office in Minneapolis was a representative office and they would be a typical and convenient site to participate in the formative research. Although UMN did complete some formative research in Denver, the bulk of the research took place in the Minneapolis satellite office. In addition, by using a sample outside of Denver where the majority of the study and intervention would take place, contamination of that sample was minimized. Demographic information was collected from all participants in the formative research phase to gauge the background and representativeness of the sample (see <u>Appendix 9.1</u>).

In LEEF, the extended-care industry, two very different extended care facilities were selected in cooperation with the corporate partners. The facilities chosen were not included in the list of possible facilities in the larger study. One site was larger, urban, and had a very racially and ethnically diverse staff, many of whom did not speak English as their primary language. The other was smaller, more rural, and almost all White. This provided our research team with a wider range of experiences to understand some of the issues we would be facing during the study. Demographic information was collected from all participants in the formative research phase to gauge the background and representativeness of the sample (see <u>Appendix 9.2</u>).

# 9.2 Meetings with Corporate-Level Industry Partners

In each industry, there were several meetings with our partners at the Corporate level. This not only provided information about the structure of the organization, but assisted us in the recruitment of participants for the Formative Research, as well as allowing us to further build a relationship for the study as a whole.

# томо

Below is a timeline and list of meetings that occurred in the IT industry\*:

- September 15, 2008: University of Minnesota Team met with TOMO Managers to explain the Formative Research portion and to recruit participants for data collection in October.
- September 23rd, 2008- UMN team attended a different TOMO staff meeting to schedule/recruit for shadows and focus groups.
- October 6-7, 2008- Several investigators meet with the TOMO Study Advisory board, and Human Resources representatives. We recorded, transcribed and deidentified 7 meetings from that trip.
- October 9<sup>th</sup>, 2008- UMN team attended another TOMO staff meeting to introduce the study and recruit participants.
- December 8-9, 2008- Formative Research begins. Several investigators meet with HR representatives as well as conduct interviews with TOMO staff. We recorded, transcribed and deidentified 3 meetings from that trip.

\* Powerpoint presentations, handouts, agendas, notes and transcripts from these meetings exist but were not included in the appendices. Contact the UMN if needed.

# LEEF

The addition of LEEF as an industry partner occurred a little later than TOMO. Below is a list of meetings that occurred with LEEF Corporate partners to discuss the study as a whole, as well as the Formative Research element.

- November 8, 2008 Harvard team members scheduled initial meeting with LEEF representatives .
- December 11, 2008 Developed a timeline for the Formative research and discuss more contextual issues related to LEEF organizational structure
- January 8, 2009 Preliminary discussion with LEEF Leadership Team about who would be included in Formative research (i.e., which facilities) and more specific about when.
- January 15, 2009 Several investigators gave a presentation on the WFHN study. After this larger meeting, VPQ and VPHR discussed the proposed intervention in more detail with investigators.

- January 22, 2009 Meeting with LEEF HR Group Presented study and discussed some of the logistical issues we might encounter for both the data collection and the intervention, particularly around scheduling.
- January 27, 2009 Meeting with Formative Facility #1. and presented the information about the Formative Study.
- February 23, 2009 –Meeting with Formative Facility #2 . Attended regular morning meeting with management team.
- February 26, 2009 Meeting with LEEF Advisory Board.

# 9.3 Job Shadowing and Team Observations

In order to better understand some of the everyday issues faced by employees and managers during the course of the workday, a research assistant followed the participant for an entire shift when possible. For some participants, only a partial shift was possible or desired. At LEEF, we handed out recruitment letters to employees and managers at each of the extended care facilities where we conducted our formative research.

For both industries, the general objective and procedure was the same. The researcher met with the participant at the scheduled time and went over the expectations and Informed Consent form (see <u>Appendix 9.3</u>). Participants were told that they could ask the researcher to leave at any time if there was a delicate and/or confidential matter to be discussed or dealt with. The researcher would ask questions if time and the situation allowed, but otherwise would just observe. Any notes that were taken would not identify anyone directly; any names would be changed so the information could not be linked back to an individual.

The researchers were given instructions of what to look for and what questions to ask, when possible (see Appendices 9.4, 9.5, and 9.6).

After the shadowing was completed, participants received a \$10 gift card in LEEF and \$15 in TOMO as a thank you for their participation. The researcher typed up a full set of notes, as well as a summary sheet focusing on specific intervention-related topics (see Appendices <u>9.7</u> and <u>9.8</u>). All notes were de-identified and coded, then stored on the Flexwork server at the University of Minnesota.

A total of 15 job shadows were completed in TOMO. In LEEF, 8 job shadows were completed – 4 at each formative research facility.

It was suggested to the UMN team that we have some researchers come in and observe the teams leading up to a release date. It was told to us this is a busy, stressful time and it would be a valuable learning experience for us to see what goes on minute to minute in the weeks and then days leading up to a release. Two researchers observed the teams for several hour chunks including their stand up meetings for the 2 weeks prior to the release date.

### 9.4 Focus Groups

The focus group format allowed us to talk with several employees and managers representing various departments, functions, units and shifts from across the facility and to observe how people tend to interact with one another (see Appendices <u>9.9</u> and <u>9.10</u>). Focus groups were comprised of 4-10 employees and lasted 1 to 1.5 hours. Participants received a gift card for

participating (\$15 in TOMO and \$10 in LEEF). See <u>Appendix 9.11</u> for the recruitment letter we gave to potential participants.

In TOMO, a total of 2 focus groups were held. In LEEF, there were a total of 6 employee focus groups

In addition to the employee focus groups, separate focus groups were held in LEEF with just managers to discuss the particular issues faced by this group. In LEEF, manager focus groups were held in each formative facility, with a total of 17 managers.

Scripts for each focus group were tailored to find out specific information from each industry. For instance, at TOMO, questions were asked about policies and attitudes about taking late-night phone calls with coworkers in India. In LEEF, information was gathered about scheduling policies and procedures. Complete scripts for focus groups in each industry can be found in Appendices <u>9.12</u> (TOMO) and <u>9.13</u> (LEEF).

In addition, after the focus group, the participants were asked to complete two ranking exercises. In the first, participants noted the top 3 supervisory behaviors that were most helpful to them personally to improve their work-life balance or fit. In the second, participants chose the top 3 aspects of work schedule flexibility that enable work-life balance or fit. Both exercises can be found in full in Appendices 9.14 and 9.15. We also collected demographic information from all participants in order to gauge the representativeness and background of our sample (see Appendices 9.16 and 9.17).

All focus groups were recorded, once informed consent was obtained, transcribed, de-identified and coded. TOMO data were stored in an Atlas ti database on the secure Flexwork server at the University of Minnesota. Similarly, LEEF data were stored in an Atlas.ti database on the secure server at Portland State University.

### 9.5 In-depth Interviews

We conducted individual interviews with employees and managers at various levels in order to get their candid responses and evaluations of issues in each industry (see Appendices <u>9.18</u>, <u>9.19</u>, and <u>9.20</u>). In TOMO, 11 interviews were completed and 20 in LEEF (11 in Facility #1 and 9 in Facility #2). In LEEF, we recruited managers at all levels and functions within a facility (see <u>Appendix 9.21</u> for the recruitment letter).

Interviews lasted for 1 to 1.5 hours and interviewers asked questions regarding the supervisor's personal background, the organizational culture, policies that effect work-life fit, performance measurement, and possible barriers to change. See Appendices <u>9.22</u> and <u>9.23</u> for interview guides for TOMO and LEEF managers respectively (see <u>Appendix 9.24</u> for the manager interview summary guide).

All manager interviews were recorded, once informed consent was obtained, transcribed, deidentified and coded. TOMO data were stored in an Atlas ti database on the secure Flexwork server at the University of Minnesota. LEEF data were stored in an Atlas.ti database on the secure server at Portland State University.

### **Chapter 10: Intervention**

### **10.1** Overview of the Intervention

The goal of the study was to assess the effects of a workplace intervention designed to reduce work-family conflict and thereby improve the health and well being of employees, their families, and their workplaces. The study intervention was grounded in theory from multiple disciplines and supported by findings from our Phase I pilot/feasibility studies on the importance of increasing family-supportive supervisor behaviors and employees' control over work time. Summaries of this Phase I work can be found at: Hammer, Kossek, Anger, Bodner, and Zimmerman (2011) and Kelly, Moen, and Tranby (2011).

The intervention drew on principles and expertise related to supervisory training and employee work redesign activities from these Phase I research projects. The intervention was not a one-size-fits-all or one-time "treatment" but, rather, a facilitated and adaptive process in which supervisors and employees looked carefully at their current supervisory and temporal practices and identified concrete changes that may improve their work conditions and ameliorate work-family conflict. The intervention was designed to prompt reflection on and improve workplace practices regarding two questions: What concrete actions can supervisors take to demonstrate their support of employees' lives and family responsibilities? What concrete actions can employees and work groups take to increase the control they have over their schedules, work time and work processes while simultaneously meeting business goals?

The intervention was delivered in two industries and consisted of: 1) participatory sessions, 2) employee outside activities, and 3) supervisor computer-based training and behavior tracking. The participatory sessions were delivered by facilitators hired by CultureRx, an organizational development company who also worked on one aspect of Phase I. The supervisor computer-based training and behavior tracking (that became known as the "weSupport" component of the intervention) was delivered by STAR/T Coordinators, researchers hired specifically for this intervention.

The facilitators provided two types of <u>participatory sessions</u>: 1) supervisors/managers only, and 2) both supervisors/managers and employees. Working with supervisors only, the facilitators conducted face-to-face, participatory sessions that introduced the supervisors to the main concepts of the intervention, what to expect of themselves and their employees as they experience the intervention, and instruction and coaching focused on family/personal support as well as performance support. The facilitators also conducted face-to-face, participatory sessions with supervisors and employees together. At these sessions, the facilitators imparted the basic tenets of the work redesign intervention and introduced <u>two employee outside activities</u> that took place between sessions. In these two outside activities, participants put into practice what they had learned.

In addition to attending the sessions conducted by facilitators, supervisors also completed a one hour <u>computer-based training</u> that reinforced the learning from the sessions and taught them more specifically how they can provide family and personal support as well as performance support to their employees. The computer training also introduced them to a <u>behavioral self-monitoring activity</u> where supervisors observed and

recorded their supportive behaviors. Supervisors conducted this behavioral selfmonitoring activity twice during the intervention.

The intervention was known as STAR – which stands for *Support. Transform. Achieve. Results.* The name STAR was modified to include an ending "T" for "Today" for LEEF, the employer of the hourly, long-term care workforce, to differentiate it from another employer training in that workplace. We use the term "STAR/T" throughout this document, and others, to signify the development of the intervention as applicable to both employers and industries.

The three components of STAR/T were more clearly defined: participatory sessions, employee outside activities, and separate training for supervisors. STAR/T was designed to take place over a 4-month period of time and the facilitators would guide employees and supervisors through the face-to-face, participatory sessions using structured and interactive activities (including role plays, games, etc.). The participatory sessions and outside activities were sequenced to build on each other and to reinforce the lessons learned.

There were six proposed participatory sessions: Leadership Education, Kick Off, Sludge, Culture Clinic, Managers Only, and Forum. These six sessions were adapted from Phase I and two of the six sessions were intended for managers only: Leadership Education and Managers Only. The big-picture customization from Phase I involved emphasizing the messages around supervisor support and coworker support. Phrases and reminders were developed for these support messages and discussions to foster the development of support within work groups (or sites in the case of LEEF) became built-in aspects of the training. In the sessions designed specifically for managers/supervisors, we focused on illustrative examples of performance support, as well as personal and family support, and developed strategies to return to these messages throughout the session.

At this time, we also began to further design and integrate two employee outside activities into the intervention process that were designed to reinforce what was learned in the participatory sessions. In these outside activities, employees and managers were asked to participate in specifically-designed activities between the participatory sessions. One activity, the "Sludge Poll," was designed to occur after the Sludge session and the second activity, "Do Something Scary" (renamed "Do Something Different" in LEEF), was designed to occur after the Culture Clinic session. Incorporating these outside activities into the learning process helped to strengthen the messaging from the sessions and move the training from learning to application.

In addition to the participatory sessions and employee outside activities, there was a concerted effort, at this time in the development stage, to focus on providing supervisors and managers with additional tools to educate them about what it means to be a supportive supervisor and why it is essential that they take measures to become more supportive. Adapted from Phase I and described briefly above, a one-hour computer training and a follow-up tracking activity for supervisors were added to the intervention process. Loosely defined at this point, Dr. Kent Anger from Oregon Health Sciences University began to develop the early versions of what we called the computer-based training (CBT) using cTRAIN training software, a field-tested product licensed by Northwest Education, Training and Assessment (NwETA).

A tracking system that, early on, became known as the Behavioral Self-Monitoring (BSM) and then Supportive Behavior Tracking (SBT) was provided to supervisors twice during the intervention process to gauge learning over time and reinforce lessons learned throughout the intervention process.

This manager computer training, combined with the behavior tracking (previously referred to as SBT),d eventually became officially known as the weSupport Training and Tracking.

Chart 10.1 and Table 10.1 show the components of the STAR/T process at this time. While the specifics of the components changed over time, these summaries provide the reader with a good understanding of the main elements of the intervention. Below these is a summary description of the goals of the various components.



### Chart 10.1: Initial Design of STAR/T Implementation and Timing

<u>Audience</u>	Participatory session	Manager Training and	<u>Time</u>
	(each type of session	Employee Outside	
	has been numbered)	<u>Activities</u>	
Managers	Leadership Education		2 hours
	(1)		
Managers		Computer-Based	1 hour
		Training	
Managers		Supportive Behavior	2 weeks
U U		Tracking (Trial #1)	
All employees	Kick Off (2)		2 hours
All employees	Sludge (3)		2 hours
All employees		Sludge Poll	2 weeks
All employees	Culture Clinic (4)		2 hours
All employees		Do Something Scary	2 weeks
Managers	Managers Only (5)		2 hours
Managers		Supportive Behavior	2 weeks
-		Tracking (Trial #2)	
All employees	Forum (6)	/	1.5 hours

### Table 10.1: Initial List of STAR/T Components

### **10.2.1 Brief Introduction to Participatory Sessions**

Each participatory session was originally grounded in ROWE and designed to provide the participants with knowledge of the work redesign and overall ideas of a STAR/T work environment. These participatory sessions encouraged supervisors/managers and employees to reflect on current practices and identify strategies to increase supervisor support, increase work-time control, and reduce work-family conflict, while continuing to meet or exceed business goals. At this time, six sessions were proposed and these six sessions, along with their goals, became the keystone elements of the participatory session component used throughout the intervention in both industries. Knowing that each session would have to be further developed and customized, the group agreed on the original ROWE outline of sessions and the general information covered in each session. The flow of the sessions and the goals set forth for each were described as follows:

Leadership Education Session: The supervisors and managers are exposed to the STAR/T philosophy and business case. This session provides them with an overview of the program, its key elements, and an open forum to ask questions. *Kick Off Session*: In this session for employees, the STAR/T philosophy and business case is reviewed as well as an overview of the program, its key elements, and an open forum to ask questions.

*Sludge Session*: In this session for employees, key cultural concepts are learned that reinforce the STAR/T philosophy. Employees learn about 'sludge' - a negative way to talking about coworkers and their work time habits – and how to eradicate it from their everyday language.

*Culture Clinic Session*: In this session for employees, employees work on issues and challenges that are in their work environment using a STAR/T mindset, focusing on the key elements of control over work and support of employees.

*Manager-Only Session*: Managers discuss and learn about supportive supervisory behaviors and they are provided with coaching and opportunities to practice typical manager-employee situations.

*Forums*: A session for all employees to review and discuss the STAR/T mindset and to identify challenges and develop solutions and action plans.

### **10.2.2 Employee Outside Activities**

The goal with these outside activities was to reinforce what is learned in participatory sessions. The overall plan for these employee activities and the goals for learning were:

Sludge Poll: During the Sludge session, employees and managers were introduced to the concept of Sludge, the toxic language used to make judgments about how employees spend their work time. The first outside activity was the Sludge Poll where employees were asked to respond to a few questions about how often they heard this Sludge language, used it themselves, and stoped others from using it. Participants were asked to reflect on the Sludge Poll activity each day for two weeks. Feedback on how employees responded to this poll was presented in the Culture Clinic Session.

Do Something Scary: In the Culture Clinic session, employees were challenged to do something new and different during their workdays. Employees were handed a list of activities like "I will not set my alarm this week," or "I will take an afternoon off to spend with my child at the park," and they were asked to try one or more of these activities as a way to put into practice the things they were learning. The Do Something Scary activity lasted for two weeks. Feedback on how employees responded to this activity was shared during the Forum sessions.

### 10.2.3 Computer-Based Training and Supportive Behavior Tracking: weSupport

The computer-based training and supportive behavior tracking were intended to provide supervisors and managers with information about the relationships between work and non-work aspects of their employees' lives. The goal was for managers and supervisors to learn new supportive behaviors through the computer training, which would provide them with discussions, behaviors, and suggestions for how to be more supportive of their employees' work and personal lives. The tracking component was intended to encourage managers and supervisors to reflect on what they had learned and track their own behaviors for two weeks. The plan was for this tracking exercise to be repeated a second time at a later point in the implementation.

The computer-based training, more specifically, provided standardized information on the importance of addressing work-family conflicts and existing policies and regulations related to schedules, leaves, etc.; introduced family-supportive supervisor behaviors that facilitate employee work-time control; and encouraged learning with frequent quizzes that provided immediate feedback. This training also included a section tailored to the specific organization, with information gleaned during the formative phase of the study. In addition, a brief video was also developed from a person or persons in upper management supporting STAR/T and its goals. The training was self-paced, and lasted anywhere from 30 minutes to 1 hour.

The supportive behavior tracking, subsequently, provided managers with the opportunity to transfer training to practice by encouraging regular attention and feedback on family-supportive supervisor behaviors and facilitating employee control over work time. The activity involved setting goals for supportive behaviors and then tracking the completion of the various types over two weeks.

# 10.3 Development and Customization through 1.0 – Fall 2009

This next section describes the 1.0 implementation more specifically, including more details about the timing of the components and exactly what these "final" 1.0 versions entailed.

The strategy taken by the overall Network was to begin baseline data collection and then implement STAR/T in a single industry first, and then after a short interval, begin the implementation in the second industry. This decision reflected the fact that the TOMO partnership was finalized first and that TOMO was eager to begin the study and STAR/T as soon as possible. The staggered start benefitted the intervention implementation in several ways. First, it gave all parties some time to concentrate on the newly-designed components of the intervention while maintaining a focus on the specific needs of only one industry. The potential distractions of competing challenges from a second industry could have had deleterious effects on the quality of the initial implementation. Second, the ramping up of the resources required by all parties benefitted from the staggered start by allowing resources to be more slowly added, as needed. The interval between the first sessions in TOMO and LEEF was one month.

Another strategy developed was to implement the interventions in only one study group at TOMO and one facility at LEEF and then pause prior to continuing with more implementations. This allowed us time to carefully monitor and reflect on how well the intervention was received in both industries and make adjustments before the number of work groups participating was too high.

TOMO was selected as the industry to begin first and the intervention components were modified to ensure that they were compatible with TOMO's workforce and work environment. Thus, the intervention was primarily developed in TOMO and then was customized for the LEEF environment. The intervention components for LEEF were modified as learning from TOMO occurred and then further tailored given the specific needs of its workforce and work environment.

### 10.3.1 Customization of LEEF and TOMO Participatory Sessions for 1.0

While the participatory sessions underwent a significant number of changes to how they would be delivered in the two industries, the central themes and goals did not change. Building on CultureRx's design of the sessions, we further customized the training by incorporating more messages and examples that illustrated supervisor support and coworker support, as well as the importance of schedule control. Below is a more specific summary of each of the six sessions and their objectives.

**Leadership Education Session:** The supervisors and managers were exposed to the STAR/T philosophy and business case. This session provided them with an overview of the program, its key elements, and an open forum to ask questions.

**Kick Off Session:** In this session for all employees, participants learned about STAR/T – what it was, how it worked, and why it was important for their organization. The facilitator provided an overview of the intervention and answered questions; motivated participation in sessions by discussing possible benefits to employees, families, and the organization; and encouraged peer support.

**Sludge Session:** This session for all employees addressed the need to eliminate language that was typical in a 'time-focused' work environment, and replaced it with the language of a STAR/T mindset. Participants learned how to manage the factors that impeded the adoption of a STAR/T work environment. Participants learned about their role in 'Sludge removal,' a critical component that increased the probability of a successful adoption of STAR/T.

**Culture Clinic Session:** In this interactive session for all employees, participants continued their education and learned how to: 1) operate effectively within a counter-culture environment, 2) resist implementing traditional guidelines within the counter-culture, and 3) solidify their feelings as part of a new team or community. At the end of this session, employees had the framework they need to operate in a STAR/T environment. The group reviewsed changes in their supportive behaviors and work unit processes since the previous sessions; reflected on facilitation of employee control over work time based on feedback from activity between sessions; discussed challenges and brainstormed solutions with peers. Participants were guided through an assessment of expectations and practices to identify current stressors related to support or work-time control, current best practices, and key measures of productivity for individuals and the work unit. They were then guided through identification of concrete strategies to increase work-time control and/or demonstrate support for family and personal life while meeting business goals.

**Manager-Only Session:** The Manager-Only session was a necessary checkpoint to ensure managers did not feel the need to issue workplace guidelines as the process evolves. The session included on-the-spot coaching, confidence-building, situational role-plays, and review of management practices using the new framework. The session allowed for frank and open dialog about managing without the old workplace rules and regulations. These intense coaching sessions helped managers accept the challenge and operate effectively while the culture was evolving. Feeling 'out of control' and 'confused' at times was normal during this period of the migration to a STAR/T work environment. Managers shared wins and challenges that reinforced their support system. **Forum**: Participants came back together to share wins and challenges that they experienced in a STAR/T. At these sessions, facilitators provided on-the-spot coaching and encouragement to keep managers and employees going in the right direction. Robust discussions keet old beliefs and behaviors from creeping back in.

By the early fall of 2009 on the heels of our formative research in LEEF, it was clear the participatory sessions for the industries needed to be adjusted to account for significant differences between the workplaces. Due to the differences in the culture and workforce, we decided that the sessions needed to be tailored more specifically to each audience. We revamped the examples and illustrations in the training sessions to incorporate more industry-specific themes, language, and specific behaviors. We modified the examples, and more specifically, the terms of the structure of the work, the culture of employee-management interactions, and the experiences of the employee populations. Aspects of the workplace and work culture at TOMO were not the same or as relevant at LEEF, and vice versa. Although the training differed slightly by industry (due to this degree of customization needed), the sessions, the delivery of information, and the core message (i.e., control over time and support) were essentially the same for LEEF and TOMO.

For TOMO, shifting from the University of Minnesota's Phase I intervention to STAR in Phase II was not a difficult transition. TOMO and the white-collar population from the University of Minnesota study in Phase I share many of the same corporate values and characteristics. The focus on face-time, immediate urgency of work, feeling overworked, constant work interruptions, and sense of limited time were all factors that the University of Minnesota's Phase I population described as characteristics of their work environment. These characteristics were also evident from early research experiences at TOMO. Thus, a complete overhaul of the language and cultural nuances in the facilitators' scripts was not necessary in this industry/organization; however, smallerscale adjustments were essential.

The presence of off-shore workers at TOMO was one of the first aspects of the work environment that required customization. Since the Phase I projects did not deal directly with a workforce that had overseas counterparts, this was a new element. The University of Minnesota team suggested that the facilitators use off-shore workers as an example in many of the sessions and outside activities (Sludge cards, Culture Clinic brainstorming). Because TOMO work groups in the U.S. were also geographically dispersed, arrangements were made to allow remote workers in the U.S. to participate in the sessions. These workers were teleconferenced in and they were given access to slide presentations as they were happening.

Another common aspect of their culture was the use of Instant Messenger (IM). Many employees in this organization (as well as managers) use this tool very frequently during the "official" work day and also at night to keep in contact and respond to questions. There were also expectations built around who used it, when, and what his or her 'status' was while logged into the program. Additionally, some TOMO work groups had pagers and established protocols for responding to emergencies (e.g., network outages). This meant some groups knew exactly how to reach each other in emergencies, how quickly they were expected to respond to emergency pages, and who backed each other up if someone was away and not able to respond to emergencies. These protocols, especially the formal back-ups, were then used as examples that could be modified to handle non-emergencies in STAR. These aspects of the STAR customization for TOMO were first written in detail and noted in the facilitator scripts, but they also came up routinely when employees and managers raised them as issues and facilitators were oriented to them as well.

The LEEF workforce had no remote workers; however, other accommodations needed to be made for its workforce including adding multiple offerings of each session, customizing language, and reducing the length of session times. Because all employees could not attend a single session offering (for example, one offering of Sludge) given the nature of their work, multiple time offerings of each type of session were held. The multiple offerings occurred over several days and were scheduled by management in collaboration with the START Coordinator.

Other changes were discussed and made to account for differences in language and culture. Changes to session names were made including from "Leadership Education" to "Management Education" because the term "leadership" and its derivatives are not as relevant in the LEEF work environment as they are in TOMO. Any form of the word "leader" was modified to "manager or supervisor" in the LEEF implementation and "Kick Off" was changed to "Team Induction."

In addition, during the pilot test in LEEF, prior to the 1.0 launch, it quickly became clear that holding sessions during the night shift (typically from 11 p.m. to 7 a.m.) was untenable. First, night shift staffing was generally a skeleton crew designed to attend to any emergency matters that might arise since the vast majority of patients were sleeping during this time. Taking people off the floor for these trainings was extremely difficult since there was little to no back up for them. Second, due to the number of sessions that were offered over the week, asking a facilitator to do sessions during the night time as well as several during the day was not feasible. Night shift workers were told they could come to sessions but none were scheduled during that particular shift.

When LEEF Corporate reviewed the initial implementation schedule, they suggested reducing the time employees would be scheduled to be away from their responsibilities and in sessions. This request was agreed to and with the exception of the initial session with managers, no session was scheduled to last longer than one hour. Table 2 shows the results of these changes and how TOMO 1.0 differed from LEEF 1.0. The number of participatory sessions remained at six for TOMO but increased to eight for LEEF. The allotment of time for the Management Education session was reduced in LEEF from 2 hours to 1.5 hours. The time allotments for LEEF Team Induction sessions and Sludge sessions were reduced by half and CultureRx made adjustments in the material delivered. For the LEEF Culture Clinic session and Managers Only session, these were split into two sessions each lasting for one hour and thus all of the material was kept. LEEF Forums were reduced from 1.5 hours to 1 hour. The LEEF reductions in the time commitments of individual sessions decreased the time managers and employees spent in sessions as compared to their TOMO counterparts (26% decrease for managers and 33% for employees).

TOMO 1.0 – Launch October 1, 2009		LEEF 1.0 – Launch November 4, 2009	
Session	Time	Session	Time
Leadership Education (1)	2 hours	Management Education (1)	1.5 hours
Kickoff (2)	2 hours	Team Induction (2)	1 hour
Sludge (3)	2 hours	Sludge (3)	1 hour
		Managers Only #1 (4)	1 hour
Culture Clinic (4)	2 hours	Culture Clinic #1 (5)	1 hour
		Culture Clinic #2 (6)	1 hour
Managers Only (5)	2 hours	Managers Only #2 (7)	1 hour
Forum (6)	1.5 hours	Forum (8)	1 hour
TOTALS		TOTALS	
Managers	11.5	Managers	8.5
Employees	7.5	Employees	5.0

### Table 10.2: Comparison of TOMO 1.0 versus LEEF 1.0 Participatory Sessions

### **10.3.2 Scripts for LEEF and TOMO Participatory Sessions**

Most of these aspects of LEEF and TOMO customization were created and agreed upon during face-to-face meetings and in the development and revision of "scripts" that detailed each session for each industry. In the summer and fall of 2009, the University of Minnesota and CultureRx used a dynamic process to customize the content of the participatory sessions from Phase 1 to TOMO's work environment and the time allotment allowed by TOMO. CultureRx developed scripts for each of the six participatory sessions describing not so much word-for-word how the sessions would be conducted, but fairly detailed instructions of what should be covered during each session. TOMO scripts were finalized for 1.0 starting in September of 2009 in preparation for the October launch. About the same time, a similar dynamic process took place between Portland State University/Michigan State University and CultureRx with the LEEF scripts in preparation for its November launch.

As the scripts were developed, modifications were made to tailor the messaging and the activities to the industries and workforces. The major areas of differences between the two industries included:

- Mission statements
- Definition of STAR/T
- o Guideposts
- Key activities

<u>Mission statements</u> were used by CultureRx to show participants the overarching goal of the STAR/T program given the products and services of each of the industries. TOMO did not have a mission-statement, per say, since the goals around workplace flexibility and support were clearly evident for their workforce. LEEF, however, needed more elaboration on the goals of the intervention and an explanation of why STAR/T was important to this industry. The group designed the mission statement was: "Create a people-centered care facility where everyone feels equally supported to live and work in a healthy and successful manner." While this mission statement was used for LEEF 1.0, it was not used after that time.

Each industry also had a <u>definition of the STAR/T</u> work environment. For TOMO, the definition was: "Each person is free to do whatever they want, whenever they want, as long as the works get done." The LEEF definition was: "Each person has the support they need to have control over their work and life as long as the work gets done."

CultureRx used a number of <u>Guideposts</u> that they have developed to further employees' understanding of the type of work environment they were striving to create. These Guideposts were meant to assist in employee behavior change that would evolve the current culture to align with the STAR/T mission. The Guideposts for STAR and START were adapted from the 13 Guideposts used in Phase 1. For TOMO, the modifications were minor and included some language changes. For LEEF, the changes were more significant, as many Guideposts were not appropriate for the industry or the predominantly hourly workforce and thus, the number of Guideposts was reduced to six. Table 10.3 shows a comparison of the Guideposts used in the two industries.

There were also <u>key activities</u> that were part of each type of participatory session and we also chose to modify these based on industry, workforce, and time constraints. Below we compare by industry key activities for each of the participatory sessions.

 Table 10.3: Comparison of Guideposts used in TOMO 1.0 and LEEF 1.0.

Guideposts	<b>TOMO 1.0</b>	LEEF 1.0
People at all levels stop doing any activity that is a waste of their		al
time, the customer's (resident's) time, or the company's money.*	N	v
Employees have the freedom to work any way they want.		$\checkmark$
Every day feels like Saturday (my day off).*		$\checkmark$
Work isn't a place you go, it's something you do.		$\checkmark$
Nobody feels guilty, overworked or stressed out.		$\checkmark$
There is no judgment about how you spend your time.		$\checkmark$
People have an unlimited amount of "paid time off" as long as the		
work gets done.		
Arriving at the workplace at 2 p.m. is not considered coming in late.	$\checkmark$	
Leaving the workplace at 2 p.m. is not considered leaving early.		
Nobody talks about how many hours they work.		
Every meeting is optional.		
There aren't any last-minute fire drills.		
There are no work schedules.		
It's OK to grocery shop on a Wednesday morning, catch a movie on		
a Tuesday afternoon or take a nap on a Thursday afternoon.		

\*Small wording modifications are made for each industry.

# 10.3.3 Leadership/Management Education.

Most of the activities and ideas in the Leadership Education/Management Education sessions were similar (see Table 4 which compares the key activities from the two industries). Because of the medical environment of LEEF, LEEF Corporate put in additional guidelines that employees should use when they were considering changes to their work environment. LEEF Corporate requested that all changes be "*safe, legal, and cost neutral*" to ensure the changes are in the best interest of residents/patients, employees, and headquarters. These guidelines of "*safe, legal, and cost neutral*" were also communicated to all employees in the Team Induction session.

In TOMO, employees were required to sign a telecommuting agreement with the company. During TOMO's Leadership Education, this idea was introduced to managers; Culture Rx described the processes for employees consenting to this agreement.

TOMO 1.0 Leadership Education (2	LEEF 1.0 Management Education (1.5	
hours)	hours)	
Overview and Definition of STAR	Overview and Definition of START	
Impediments to STAR	Impediments to START/Beliefs Activity	
Socially Acceptable/Unacceptable Activity	Socially Acceptable/Unacceptable Activity	
	Safe, Legal, Cost Neutral	
Guideposts	Guideposts	
Management Concerns	Management Concerns	
Overview of Computer-Based Training &	Overview of Computer-Based Training &	
Supportive Behavior Tracking	Supportive Behavior Tracking	

### Table 10.4: Comparison of Leadership/Management Education Key Activities for 1.0

### 10.3.4 Kick Off/Team Induction.

Most of the activities and ideas in the Kick Off and Team Induction sessions were similar (see Table 10.5 which compares the key activities from the two industries). Similar to the Leadership/Management Education session, LEEF had an additional discussion about Corporate guidelines of *"safe, legal, and cost neutral."* The real focus during the session was on helping people see that we should reward productivity and not on the amount of time spent completing a task. An activity was added to demonstrate this principle.

In TOMO, employees were introduced to the telecommuting agreement that they were required to sign. CultureRx and the STAR Coordinator described the agreement and the processes for filing the paperwork.

TOMO 1.0 Kick Off (2 hours)	LEEF 1.0 Team Induction (1 hour)
Overview and Definition of STAR	Overview and Definition of START
Impediments to STAR	Impediments to START/ Beliefs Activity
Socially Acceptable/Unacceptable Activity	Socially Acceptable/Unacceptable Activity
	Safe, Legal, Cost Neutral
Guideposts	Guideposts
Time Activity	Time Activity

Table 10.5: Comparison of Kick Off/Team Induction Key Activities for 1.0

### 10.3.5 Sludge

The activities and ideas in the Sludge sessions were identical, although the time to cover the topics differed. Table 10.6 compares the key activities from the two industries.

### Table 10.6: Comparison of Sludge Key Activities for 1.0

TOMO 1.0 Sludge (2 hours)	LEEF 1.0 Sludge (1 hour)
Definition of Sludge	Definition of Sludge
Supervisor Support Discussed	Supervisor Support Discussed
Gap Activity	Gap Activity
Sludge Role Plays	Sludge Role Plays
Sludge Definitions	Sludge Definitions
Sludge Eradication	Sludge Eradication
Rating of Sludge Knowledge	Rating of Sludge Knowledge

### 10.3.6 Culture Clinic.

While some of the activities and ideas in the Culture Clinic sessions were similar, many were different (see Table 10.7 compares the key activities from the two industries). LEEF had activities that focused on the type of scheduling and communication that would be required in the type of work environment that they were striving to create. These activities were not relevant for the TOMO work environment. In the Culture Clinic session at TOMO, the Group Brainstorming Time was literally working on team issues.

TOMO 1.0 Culture Clinic (2 hours)	LEEF 1.0 Culture Clinic #1 and #2 (2	
	hours)	
Sludge Eradication Update	Sludge Eradication Update	
	Vision Activity	
	Calendar Activity - People-Centered Staffing	
	Calendar and Scenarios	
	Message in a Bottle Activity	
Feud Game/Discussion	Feud Game/Discussion	
Group Brainstorming Time		
Action Plan and Identified Volunteers	Action Plan and Identified Volunteers	

# Table 10.7: Comparison of Culture Clinic Key Activities for 1.0

# 10.3.7 Manager Only

There was some overlap between the industries with the activities and ideas in the Manager Only sessions, but some activities were unique. Table 10.8 compares the key activities from the two industries.

TOMO 1.0 Manager Only (2 hours)	LEEF 1.0 Manager Only #1 and #2 (2	
	<u>hours)</u>	
Feelings and Concerns	Feelings and Concerns	
Wins and challenges	Wins and challenges	
	Review employee feedback from Sludge	
	session	
Activity: STAR situation practice and	Activity: START situation practice and	
feedback	feedback	
Activity – Large-group discussion of		
scenarios and solutions		
Overview – Key behavior indicators		
Overview – Leadership call to action		
Discussion about having performance		
conversations with employees		
Handout: Tips for Managing in STAR	Handout: Tips for Managing in START	
Environment	Environment	
	Handout: EMR Plan	

### Table 10.8: Comparison of Manager-Only Key Activities for 1.0

### 10.3.8 Forum

Most of the activities and ideas in the Forum sessions were similar. Table 10.9 compares the key activities from the two industries.

### Table 10.9: Comparison of Forum Key Activities for 1.0

TOMO 1.0 Forum (2 hours)	LEEF 1.0 Forum (1 hours)
Rating of Control & Support	Rating of Control & Support
Card Activity—wins for control and support	Card Activity – wins for control and support
35 Game Activity—discuss challenges	Activity – Support for Roles When Absent
	Activity – Hurdles and Challenges to START

### **10.3.9 Employee Outside Activities for 1.0**

**Sludge Poll Activity:** As noted above, during the Sludge session employees learned about Sludge and how to eradicate it. The first outside activity was the Sludge Poll, where employees were asked to indicate how often they heard Sludge language, used Sludge eradication strategies, and stoped themselves from Sludging others. The statements were: 1) "I used the Sludge Eradication strategy!", 2) "I thought about saying something Sludgey but stopped myself", and 3) "I had a Sludge-Free day!". The Sludge Poll activity lasted for two weeks and the results on how employees did were presented in the Culture Clinic Session.

In TOMO, this activity was conducted electronically. Using SurveyMonkey, employees responded to the questions above via the web. The STAR Coordinator sent participants a link to the SurveyMonkey page, requesting they fill out the survey and provided the

instructions to do so. The STAR Coordinator was also responsible for sending reminders to employees via email.

In LEEF, given that the vast majority of employees did not have access to or use a computer on a daily basis, the activity process was changed from an electronic method to a hard copy poster and stamping method. The activity was conducted using large posters with marker stamps (magic markers with stamps of various shapes). The posters and marker stamps were placed in the break room and participants were encouraged to go to the posters each day to use the stamp to mark the posters with their responses to the Sludge questions.

**Do Something Scary/Different:** In the Culture Clinic session, employees were challenged to do something new and different at work. At this session, employees were encouraged to do activities like "I will not set my alarm this week," or "I will take an afternoon off to spend with my child at the park," and they were asked to try one or more of these activities as a way to put into practice the things they learned in the sessions. While there were some activities that were used for both LEEF and TOMO, others were customized for the industry. The Do Something Scary/Different activity lasted for two weeks. Feedback on how employees responded to this activity was shared during the Forum sessions.

The administration of the two outside activities in TOMO for 1.0 used SurveyMonkey. The STAR Coordinator created, and send via email, a repeating daily Outlook calendar event (lasting for two weeks) with a link to the web polls. If employees accepted the events, their calendars showed a daily event with a reminder to follow the link to do the polls. Electronic reminders were sent out as well as the feedback on the results. Participants received a handout at the Culture Clinic with a list of activities could try.

In LEEF, the activity name was changed from "Do Something Scary" to "Do Something Different." The word "scary" was thought to be too difficult for a health care environment and thus a modification was made. In addition, given that the vast majority of employees did not have access to or use a computer on a daily basis, the activity process was changed from an electronic method to a hard copy poster and stamping method. The activity was conducted using large posters with Post-It notes (and pencils) set up in the break room. In the Culture Clinic session, the facilitator offered participants two or three dozen 4"x6" cards with a single activity listed on each card. Participants selected one card listing an activity to do something supportive and one card listing an activity to take more control. Participants took the cards with them when leaving the session and they were asked to do the activity during the following two weeks. Once the participants completed the activity/activities, they were encouraged to go to the posters and use a Post-It note to summarize the activity and place it on the poster.

# **10.3.10** Supervisor Supportive Behavior Training and Tracking: Computer-Based Training and Supportive Behavior Tracking for 1.0 (Renamed "weSupport" Training and Tracking after 2.0).

### **Computer-Based Training**

As the STAR/T initiative became more developed through 2009, the manager computerbased training was also further developed (and then further customized by industry later, see below). The computer-based training was designed to provide managers with information about the relationship between work and non-work and how this relationship can impact the health and performance of supervisors and their employees. It provided guidance on how to enact the four domains of Family Supportive Supervisor Behaviors (FSSB): (1) emotional support, (2) instrumental support, (3) role modeling, and (4) creative work-family management, all related to the construct developed by Hammer and colleagues (2009). At periodic intervals during this training, supervisors completed a short quiz assessing what they had learned. At the initial deployments of 1.0, a post-test was included but not a pre-test.

Initial versions of the computer-based training were over 100 slides long and would have taken well over an hour for managers to complete given the slides and the quiz questions. Over the next year, TOMO and LEEF project representatives along with Dr. Kent Anger, went through several iterations of the STAR and START computer-based training, trimming and reorganizing. These versions were also tested periodically with organizational representatives and with members of the research teams to resolve issues of timing, content, and the overall flow of the training. As we progressed toward more specified and customized versions of the overall intervention, these computer-based trainings became equally as customized. In addition, this training was branded "weSupport Training" starting with the 2.0 site. Table 10.10 compares the topic areas and sequencing for the first trainings in each industry.

<u>TOMO 1.0</u>	LEEF 1.0
Introduction – Review Major Concepts	Introduction – Review Major Concepts
Why Work Needs to Change	Why Work Needs to Change
What We've Learned at TOMO	What We've Learned at LEEF
The Research Behind STAR	The Research Behind START
Supervisor Support	Supervisor Support
<ul> <li>4 Types of Family/Personal</li> </ul>	<ul> <li>4 types of Family/Personal Support</li> </ul>
Support	
<ul> <li>4 Types of Performance Support</li> </ul>	<ul> <li>4 types of Performance Support</li> </ul>
What to Expect Next	What to Expect Next
<ul> <li>Video of Support from TOMO</li> </ul>	<ul> <li>Video of Support from LEEF</li> </ul>
Corporate	Corporate
<ul> <li>Review Overall Program</li> </ul>	- Review Overall Program
Introduction to Supportive Behavior	Introduction to Supportive Behavior
Tracking	Tracking
<ul> <li>Video of tracking* Software</li> </ul>	<ul> <li>Video of tracking* Software</li> </ul>
Rationale	Rationale
<ul> <li>Video of tracking* Instructions</li> </ul>	<ul> <li>Video of tracking* Instructions</li> </ul>
Post Test	Post Test

|--|

\* "Habitrak" was the initial name given to the supportive behavior tracking exercise which was later changed to weSupport Tracking.

The versions of the computer-based training that were used for 1.0 in each industry do not vary much, although some customization was done. In the introduction and review of major concepts, these sections reflected the changes made in the participatory sessions for each industry both in terms of content as well as the rollout of the sessions.

For example, the TOMO training mentioned the Manager Only session after the Culture Clinic session while the LEEF training mentioned a Manager Only session both before and after the Culture Clinic. An example of content difference is that the Guideposts used in the participatory sessions varied by industry and this difference was echoed in the training. In addition, each training session had a summary of the formative research done in each industry to show participants the knowledge gained to customize the training to their work environments. This summary was a brief review of the challenges and stressors in their work environments as well as various personnel policies of each organization. Embedded items throughout the trainings and the post-test items were customized to each industry and repeated the differences noted.

Throughout both trainings, pictures were included and these also varied by industry to demonstrate their unique environments.

### **Supportive Behavior Tracking**

The Supportive Behavior tracking exercise was designed to help supervisors examine the ways they provide family/personal support and performance support to their employees. This was done to help managers become more aware of their actions versus their intentions. Software developers at OHSU under the direction of Dr. Ryan Olson developed an app for the iPod Touch, initially called "Habitrak" and eventually revised to "WeSupport Tracking" in 2.0 with the branding of the training/tracking exercises. Each manager who participated was given an iPod Touch and they used it for 2 separate two-week periods.

### Computer-Based Training (CBT) at 1.0 Sites

The computer-based training and behavior tracking activities were administered during one hour training sessions. The STAR/T Coordinator worked with managers, usually one-on-one but occasionally in pairs, to go through the computer training and then to be trained to use the iPod. The computer portion of the session required approximately 30-45 minutes leaving the remainder of the time for learning the specifics of the behavior tracking and the iPod, as well as time for questions.

In LEEF, all of these sessions were conducted in person. In TOMO, the majority of them were also conducted in person, with the occasional need to train a TOMO manager who was off site. Due to the company's geographic dispersion, there were several occasions where the STAR Coordinator needed to train a manager in another state. These remote training sessions were conducted in the same manner as the in-person training, except over the phone. Between 2 and 7 days before the remote training was scheduled, the STAR Coordinator was responsible for shipping a laptop, handouts, consent forms, and an iPod touch to the remote manager. The Minnesota team developed a protocol for conducting these remote training sessions that included introductions, a description of the training and tracking, instructions for completing the computer training and the appropriate handouts. The STAR Coordinator also included shipping return packaging and labels for the laptop, iPod, and required forms. The first step was for the manager to complete the training. Sometimes the STAR Coordinator remained on the phone line while the manager proceeded with the training in case the manager had questions, but generally they left their phone number with the manager who was asked to call if they had questions or once they had completed the computer portion of the training. Once the training was completed, the STAR Coordinator walked the manager through the iPod set up and goal setting for the tracking activity.

Managers in both industries received information about the trainings and were asked to sign consent forms so the research team could use data gathered during the training and tracking. Managers retained a copy of the consent form which included contact

information if they had questions. Managers were also asked to fill out a short demographics form. To facilitate their learning, managers in both industries were given a handout summarizing the eight types of supportive behaviors they learned about in the computer training. Because it was thought LEEF managers might be new to the iPod technology, these managers were also given a handout summarizing the basic functions of the iPod and instructions to use the training software. Participants at TOMO were also given a 'Wellness Information' sheet that covered the company's current policies and programs around employee health and wellness. TOMO wanted employees to be aware that the company already offered several health and wellness programs (diet counselors, smoking cessation programs, etc.) in addition to rolling out STAR, a health-focused concept. This information was also presented to managers during the actual training as well, at TOMO's request. See Table 10.11 for a summary of industry differences in materials used for the training and tracking exercises.

# Table 10.11: Comparison of Materials and Resources used in the computertraining and behavior tracking training at TOMO 1.0 and LEEF 1.0.

\*Small wording modifications are made for each industry.

	<b>TOMO 1.0</b>	<b>LEEF 1.0</b>
Consent Form*	$\checkmark$	$\checkmark$
Demographics Form	$\checkmark$	$\checkmark$
Handout Summary of Family/Personal Support and Performance	$\checkmark$	$\checkmark$
Corporate Wellness Form		
Handout User Instructions for iPod		$\checkmark$

# 10.5 Continued Development and Customization: Refining the process after 1.0, preparing for 2.0

After the completion of 1.0 at both TOMO and LEEF, the intervention team met in person at the University of Minnesota to review these earliest interventions. This review was held in January of 2010 and modifications were made to the interventions in both industries.

In February 2010, the CultureRx scripts for the participatory sessions were shortened into outlines. These outlines contained the same basic information, but in a condensed format. The outlines were rarely used in the project after this point although they often served as a check during the development of the grids. The grids were developed during the winter and spring of 2010 to track the customization and activities, as well as the larger delivery of the sessions as a whole and solidified the involvement and responsibilities of all contributors moving forward to 2.0.

The computer-based training and supportive behavior tracking terminology was changed after the January 2010 meetings. In order to provide a "branding" for the training that allowed STAR/T Coordinators to more easily communicate the activity, the term *"weSupport Training and Tracking"* was used.

# 10.4 Final Intervention Components TOMO and LEEF

The next sections describe the FINAL intervention components for both TOMO and LEEF. Given the high number of adjustments and changes made after these earliest intervention sites (especially in LEEF) and before final component elements became accepted, we provide information on these historical changes in the appendices. This allows the reader to understand the final components of the intervention here without having to review all of the historical changes.

# 10.4.1 Final Participatory Sessions: 2.0 and Beyond

The facilitator guides for the participatory sessions, as well as the handouts and other materials provided in the sessions, can be found in Appendices <u>10.1.1</u>, <u>10.1.1a</u>, <u>10.1.1b</u>, <u>10.1.1c</u>, <u>10.1.2</u>, <u>10.1.2a</u>, <u>10.1.3</u>, <u>10.1.3a</u>, <u>10.1.3b</u>, <u>10.1.4</u>, <u>10.1.4a</u>, <u>10.1.4b</u>, <u>10.1.4c</u>, <u>10.1.4d</u>, <u>10.1.5</u>, <u>10.1.5a</u>, <u>10.1.6</u>, <u>10.1a</u>, <u>10.1b</u>, <u>10.2</u>, <u>10.2.1a</u>, <u>10.2.2</u>, <u>10.2.2a</u>, <u>10.2.2b</u>, <u>10.2.3a</u>, <u>10.2.3b</u>, <u>10.2.4c}</u>, <u>10.2.4c</u>, <u>10.2.4c</u>, <u>10.2.5c</u>, <u>10.2.5a</u>, <u>10.2.5a</u>, <u>10.2a</u>, <u>10.2b</u>, <u>10.2c</u>, and <u>10.2d</u>.

The final components for LEEF excluded the earlier-used mission statement (TOMO did not have a mission statement). Because of the complexity and large amount of the material, the group felt that it was too much for participants to remember a STAR/T definition as well as a mission. The definitions and Guideposts remained the same in each industry from the earliest interventions to the final components.

# томо

KnowledgeQ provided as intranet resource at TOMO:

TOMO's internal site, KnowledgeQ, became a house for many STAR resources. Although employees rarely took advantage of this accessibility, many documents, such as the guideposts and DSS handouts, were made available to everyone. Handouts were avoided except for DSS handout.

### Other changes:

Some of the later groups at TOMO had many people located in areas other than the 2 primary sites, and so many participants attended the session via conference call. In those cases, remote participants were able to view the slides as the facilitator moved through them and could also "chat" via instant messaging (built into the meeting software) with other remote participants. Some activities were adapted to cover the large number of people on the phone. For example, sometimes the phone participants were one team for the Feud and these participants would confer via instant messaging on their team's answer to a question. The participants in the room acted as the other team. Facilitators were able to see the names of remote participants and so could call on those employees to answer questions or participate in a role play activity as needed. Also, when forum attendance was quite small (<15 participants), the facilitators helped participants brainstorm responses to all of the challenged identified by participants, rather than ranking the top challenges with a game and then just brainstorming the top few.

### LEEF

One of the most significant changes to the LEEF intervention after 1.0 occurred as a result of a need in LEEF to address industry concerns about the amount of time employees needed to spend off the floor (i.e., attending to patient needs). Also as a result of this difficulty, attendance during sessions was negatively impacted. Three major changes were enacted to deal with this challenge. First, it was recognized that not

everyone would be able to attend all sessions so a "Steering Team" approach was adopted. This Steering Team was comprised of a cross section of the facility, including managers and front line staff from all departments, acting as "peer leaders" for the intervention. Peer leaders were charged with conveying information about each session to their coworkers or employees who may have been unable to attend in person. This was an attempt to bolster support at all levels of the organization and to ensure all employees had exposure to the material provided in the participatory sessions. The Steering Team met at the beginning of START and at the onset of the Culture Clinic sessions.

The second major change to START was the reorganization of the session roll out. Because much of the information and onus of the momentum of START was not on the Steering Team, the total number of sessions for employees was reduced to three. The Team Induction and Sludge sessions were combined into one session, but 1.5 hours instead of just 1. Culture Clinic was extended to 1.5 hours as well, and Forums remained at one hour. The Manager Education and Manager Only sessions were replaced with a manager-only component at the end of each Steering Team meeting. Finally, two new participatory sessions were added: a) START Readiness and b) "START Moving Forward." START Readiness was created to help sites prepare for the START initiative and it was delivered by a LEEF Corporate representative to the management team at the facility prior to the first Steering Team session (see Appendix 10.3.1). A START Coordinator observed each START Readiness session, either in person or on the phone. This purpose of this additional session was manifold. First, it introduced the key decision makers at a facility to what was coming and why they were chosen to participate. Second, it demonstrated corporate support for START. Third, the need for a culture change initiative was highlighted and how it could benefit the facility if they embraced it.

The START Moving Forward session was created to help the sites continue to do work on their culture upon completion of the Forum sessions. The session was designed to be facilitated by a senior manager and all members of the Steering Team were invited to join, in addition to others who had taken a significant interest in START (see <u>Appendix</u> <u>10.3.2</u>). For most sites, the CultureRx facilitator was available on the telephone for coaching and to answer any questions. A START Coordinator was also on the phone for each session. The research team provided an outline for guidance, but let the Steering Team take ownership of the session and for how START would be sustained at the facility.

In sum, the changes in START were designed to minimize the amount of time each individual employee was off the floor for START activities while increasing exposure to and ownership of the intiative for a smaller group of individuals, the Steering Team. A summary of the final changes in START can be seen in Table 12. To encourage attendance, LEEF introduced an incentive program in 2.0 for attending participatory sessions. Initially the incentive was for \$50 but it was increased to \$100 shortly after implementation. Employees received a chance to win a single prize of a \$100 Visa gift card each time they attended sessions. At the end of all the sessions, a winner of the \$100 gift card was randomly drawn from all those who attended sessions. The prize money came from OHSU. See <u>Appendix 10.4.3a</u> for the Incentive Flyer that was distributed at each site.

The LEEF handouts included:

- All participants: a) START Overview Workplace Guideposts and Checklist, b) Sludge Overview - Attention Sludge Eradicators, and c) Identification of Peer Leaders at Team Induction/Sludge; and d) Do Something Different Activity handout at Culture Clinic.
- Steering Team members: Peer Leader Role/Activities at Steering Team #1.
- Managers: a) Tips for Managing in a START Workplace at Steering Team #1 -Manager Only; and b) the Managers' Express/Model/Reinforce (EMR) Plan at Steering Team #2 - Manager Only.

# Table 10.12: Comparison of TOMO versus LEEF Final Participatory Sessions: 2.0 and Beyond

ТОМО		LEEF	
Session	Time	Session	Time
		START Readiness (1)	1 hour
		Steering Team #1 Overview	20
		(2)	minutes
Leadership Education	2 hours	Management Team	2 hours 40
(1)		Induction/Sludge and	minutes
		Manager Only (3)	
Kickoff (2)	2 hours	Team Induction/Sludge (4)	1hour 30
Sludge (3)	2 hours		minutes
		Steering Team #2 Review	20
		(5)	minutes
		Management Culture Clinic	2 hours 40
		and Manager Only (6)	minutes
Culture Clinic (4)	2 hours	Culture Clinic (7)	1hour 30
			minutes
Managers Only (5)	2 hours		
Forum (6)	1hour 30	Forum (8)	1 hour
	minutes		
		START Moving Forward (9)	1hour 30
			minutes
TOTALS		TOTALS	
Managers	11 hours 30	Managers	9 hours 30
Employees	minutes	Employees	minutes
	7 hours 30	Steering Team (non-	4 hours
	minutes	managers)	6 hours 10
			minutes

# 10.4.2 Final Employee Outside Activities: 2.0 and Beyond

# томо

Depictions of the materials used for the TOMO employee outside activities can be found in <u>Appendix 10.4.2a</u> and <u>Appendix 10.4.2b</u>. The administration of the two outside activities in TOMO was changed from 1.0 to 2.0. Starting with 2.0, the polls were customized for each site instead of using SurveyMonkey. There were minor changes to the web polls over time, but little that affected the intent or content of the activities. The basic procedure starting with 2.0 was that the STAR Coordinator would create and send via email a repeating daily Outlook calendar event (lasting for two weeks) with a link to the web polls. If employees accepted the events, their calendars showed a daily event with a reminder to follow the link at do the polls.

### Final Sludge Poll activity

No changes other than moving from a SurveyMonkey platform to a customized platform.

#### Final Do Something Scary Activity

No changes other than moving from a SurveyMonkey platform to a customized platform.

### LEEF

Depictions of the materials used for the LEEF employee outside activities can be found in Appendices <u>10.4.3b</u>, <u>10.4.3c</u>, <u>10.4.3d</u>, and <u>10.4.3e</u>. The administration of the two outside activities in LEEF was changed from 1.0 to 2.0.

### Final Sludge Poll Activity

Sludge posters continued to be used throughout the LEEF rollout, but the magic marker stamps were changed to actual stamps in 2.0. These new stamps performed the same function as the magic markers, but they could be attached to the posters to allow for ease of use and they could not be as readily lost. In addition, because of the limited space in the LEEF sites, the posters were reduced in size to 2' x 3'. Slight wording changes were made from 1.0 to the final posters used. Participation lanyard cards were created that allowed participants to record their own behavior and also collection boxes were used to help gather these cards after the Activities were finished. An 8.5" x 11" flyer was created at each site to post the results of the activity and this was shown in the Culture Clinic sessions. See Appendices 10.4.3a, 10.4.3b, 10.4.3c, 10.4.3d, and 10.4.3e for representation of final poster, final lanyard card, and final results flyer.

LEEF also introduced incentives in 2.0 for both outside activities. All employees participating in the Sludge Poll Activity had a chance to win a single prize of a Visa \$100 gift card (this prize started at \$50 but was later changed to \$100). A winner was randomly drawn from all those who participated and was given a \$100 gift card. The prize money came from OHSU. Participation lanyard cards were created and collection boxes were used to help gather cards.

### **Final Do Something Different Activity**

Do Something Different posters continued to be used throughout the LEEF rollout, but handouts eventually replaced the cards, and stamps (like those used for the Sludge Poll eventually) replaced the Post-It notes. In addition, similar to the Sludge posters, the posters were reduced in size to 2' x 3'. Slight wording changes were made from 1.0 to the final posters used. Participation lanyard cards were created that allowed participants to record their own behavior and also collection boxes were used to help gather these cards. An 8.5" x 11" flyer was created at each site to post the results of the activity and this was shown in the Forum sessions. See Appendices <u>10.4.3a</u>, <u>10.4.3b</u>, <u>10.4.3c</u>, <u>10.4.3d</u>, and <u>10.4.3e</u> for representation of final poster, final lanyard card, and final results flyer.

As with the Sludge Poll activity, an incentive was introduced in 2.0. All employees participating in the Do Something Different Activity had a chance to

win a single prize of a \$100 Visa gift card (this prize started at \$50 but was later changed to \$100). A winner was randomly drawn from all those who participated and was given a \$100 gift card. The prize money came from OHSU.

# 10.4.3 Final Computer-Based Training and Supportive Behavior Tracking

The computer-based training and tracking terminology was changed after the 1.0 implementations in order to provide a branding for the training that allowed STAR/T Coordinators to more easily communicate the activity. The term "weSupport" was used to characterize the entire training (both training and tracking components) and "weSupport Training" used to identify the computer-based training and "weSupport Tracking" used to identify the two-week iPod exercises.

# 10.4.4 Final weSupport Training

After the 1.0 implementations, a pre-test was added to the training for both TOMO and LEEF. This provided researchers with participants' baseline knowledge prior to the training so they could better evaluate the effectiveness of the training by comparing this to the post-test. Also, "Daily job and personal problem solving" was changed from the term "Functional Support" at 2.0 because of the high number of participants who got question items about Functional Support incorrect.

Few changes to the weSupport training occurred in TOMO after 1.0 implementation because they didn't want to make significant changes. While the two industries used the same basic consent form, demographic form, and handout of Summary of Family/Personal Support and Performance Support, small industry-specific differences are acknowledged. These can be found in Appendices <u>10.5.1a</u>, <u>10.5.1b</u>, <u>10.5.1c</u>, <u>10.5.2a</u>, <u>10.5.2b</u>, <u>10.5.2c</u>, <u>10.5.2d</u>, <u>10.5.2e</u>, <u>10.5.2f</u>, <u>10.5.2g</u>, <u>10.5.3a</u>, <u>10.5.3b</u>, <u>10.5.3c</u>, <u>10.5.3d</u>, <u>10.5.3e</u>, and <u>10.5.3f</u> with the Corporate Wellness Form that was used in TOMO. Also included in this appendix is the script of the actual computer training and the instructions used for the remote employees.

LEEF took advantage of the time before the 2.0 rollout to refine and develop the most user-friendly training possible. Minor word changes were made and some reorganization of slides was done, but the overall content was not changed. Also, because of the severe time constraints of the managers, LEEF needed to review the training to ensure participants could get through the material as efficiently as possible and finish the training in one hour or less. One change that was made for LEEF was that the video describing why the app was developed was removed. It was felt that the video was redundant with material presented in the screen shots and thus removing it would save time. In addition to this change, the LEEF training was modified several times after 1.0 to improve comprehension of the content. See Appendices 10.5.3a, 10.5.3b, 10.5.3c, 10.5.3d, 10.5.3e, and 10.5.3f for the consent form, demographics form, handout of Summary of Family/Personal Support and Performance Support, and script of the training.

### Table 10.13: Comparison of Final weSupport Training

TOMO	LEEF
Pre-Test	Pre-Test
Introduction – Review Major Concepts	Introduction – Review major concepts
Why Work Needs to Change	Why Work Needs to Change

TOMO	LEEF	
What We've Learned at TOMO	What We've Learned at LEEF	
The Research Behind STAR	The Research Behind START	
Supervisor Support	Supervisor Support	
<ul> <li>4 Types of Family/Personal</li> </ul>	<ul> <li>4 types of Family/Personal Support</li> </ul>	
Support		
- 4 Types of Performance Support	<ul> <li>4 types of Performance Support</li> </ul>	
What to Expect Next	What to Expect Next	
<ul> <li>Video of Support from TOMO</li> </ul>	<ul> <li>Video of Support from LEEF</li> </ul>	
Corporate	Corporate	
<ul> <li>Review Overall Program</li> </ul>	<ul> <li>Review Overall Program</li> </ul>	
Introduction to Supportive Behavior	Introduction to Supportive Behavior	
Tracking	Tracking	
<ul> <li>Video of weSupport Software</li> </ul>	<ul> <li>Video of weSupport Software</li> </ul>	
Rationale	Rationale	
<ul> <li>Video of weSupport Instructions</li> </ul>	<ul> <li>Video of weSupport Instructions</li> </ul>	
Post-Test	Post-Test	

# 10.4.5 Final weSupport Tracking

The use of the iPod technology for weSupport required that the app be updated to ensure that it worked with software revisions by Apple. In addition, as feedback was received from the field, small changes were made to the placement of buttons or how the app moved the user within the software. For example, it was noted that some participants were having difficulty with finishing the Exit Survey and thus an improvement was made to make completion easier. Another example of an enhancement was that early versions had countdown features that were not user-friendly and at times, required the user to take action. An enhancement was programmed to allow the countdown feature to work more automatically and not require the user to do anything. All of the improvements to the weSupport app enhanced the experience for the user or made the program more efficient, but the essence and content of the tracking exercise was not changed. We kept the materials and screen shots used in the tracking exercise together with the materials used for the training. For TOMO, see previously listed Appendices 10.5.2a, 10.5.2b, 10.5.2c, 10.5.2d, 10.5.2e, 10.5.2f, and 10.5.3d, 10.5.3e, and 10.5.3f.

### 10.5 Final Note

Changes to the intervention occurred throughout the life of the project. We provided summaries of the key activities and elements for each of the work groups and sites in <u>Appendix 10.6</u> TOMO History of Implementation and <u>Appendix 10.7</u> LEEF History of Implementation.

### References

Hammer, L.B., Kossek, E.E., Anger, W.K., Bodner, T., & Zimmerman, K. (2011). Clarifying work-family intervention processes: The roles of work-family conflict and family supportive supervisor behaviors. *Journal of Applied Psychology, 96,* 134-150. doi: 10.1037/a0020927 Kelly, E.L., Moen, P., & Tranby, E. (2011). Changing workplaces to reduce work-family conflict: Schedule control in a white-collar organization. *American Sociological Review, 76,* 265-290. doi: 10.1177/0003122411400056

### **Chapter 11: Process Evaluation of the Intervention**

### 11.1 Overview

The process evaluation study of the Work, Family & Health Study has three main goals: 1) to gather contextual data in each site to help anticipate and appropriately respond to any issues regarding the data collection, intervention, or relationship between partner organizations and the Network, 2) to provide information about exposure to the intervention, fidelity of the intervention as delivered, and confounding events to inform the analysis of other data collected in the study and 3) to collect data that allows for a more nuanced analysis of the change process in intervention work sites in order to guide the dissemination and translation of STAR/T to other organizations and employee populations. The third goal includes cross-site analysis of initial reactions to STAR such as managerial resistance or buy-in, where changes are larger or smaller (for employees and for the business), and where changes are sustained or abandoned over the 18 month study period.

# Chapter 12: Participant Safety & Data Monitoring

# 12.1 Protocol Review and Study Monitoring (DSMB)

A data safety and monitoring board (DSMB) was convened to provide input and oversight related to study procedures, data management, and safety on a periodic basis. The DSMB membership included experts external to the study team and met bi-yearly, as was deemed appropriate by the board based on the study's timeline, enrollment rate, and determination of potential risks to subjects. Following meeting sessions, the DSMB recommended modifications for study procedures to the WFHN Steering Committee, representatives of NIH, and/or governing IRBs. As part of the data safety and monitoring plan, the DSMB coordinated with the study team for appropriate access to materials and data. The role of the DSMB was tailored to best meet the requirements for oversight of the WFHN, but had special focus on coordinating safety and human subjects' protection procedures across all data collection sites and WFHN members. The DSMB also paid special attention to issues concerning the safety and wellbeing of child respondents. DSMB procedures included review of protocols before implementation by the investigators, review of implementation and progress of the study, and ongoing reviews of the data to detect evidence of significant benefit or harm for subjects while the study was in progress. This latter review, beyond that provided by the IRB, served as a means of additional human subjects' protection, but did not supplant the regulatory requirement for the investigator(s) to report serious and unanticipated adverse events to all relevant IRBs.

# 12.2 Institutional Review Boards

Prior to implementation of the study, the recruitment scripts, procedures, and informed consent/assent forms were approved by the IRB of the data coordinating center and by the IRB of each relevant center. All amendments to these approved items, as well as other amends in response to issues affecting the safety and welfare of study participants were approved during the course of the study by the data coordinating center IRB and other relevant center IRBs. The study center PI was responsible for preparation of all submission documents and for their continuing, periodic review. Each center had approval to collect data they were responsible for and approval to receive de-identified data from the data coordinating center.

Appendix 12.1 contains IRB approvals of materials and amendments for each study center.

# 12.3 Informed Consent / Assent

As part of study enrollment, the RTI Field Interviewer administered an in-person study consent at the workplace for employees and managers. The study consent provided information related to all elements of study participation and data collection conducted by the RTI Field Interviewers. Informed consent procedures for employees included separate consent forms (and acknowledgements) for the CAPI survey and health assessments, dried blood spot (DBS) collection, wearing an actigraph watch, and access to administrative company data and employer-sponsored health care claims. Separate employee consent forms were used for the employee home interview, child participation in the home interview and health assessment, and for employee and child participation in the daily diary study. Informed consent for managers also included a separate consent form (or oral confirmation for telephone interviews) for access to administrative data and health care claims. Consent for the spouse/partner interviews was obtained orally over the telephone. In some follow-up interviews, child consent/assent was also obtained orally. The respondent's reply to the request for oral consent was entered into the interviewer's computer. Only the administrative records consent obtained at baseline covered the entire study period. All other consent elements were re-obtained at each wave of data collection.

# 12.3.1 Informed Consent Procedures for Basic Health Measures

For the employee and manager worksite interviews and for the child home interview, interviewers followed scripted text in CAPI to explain the procedures for the survey and for the collection of the basic health measures. Interviewers obtained <u>written</u> consent from the employee and manager, <u>written</u> parental consent and written child assent for the child objective health measures. There were different consent and assent forms for the WFHS, dependent on the type of participant. The computer guided the collection process and told the interviewer which form(s) to use.

Once consent or assent was obtained, the interviewer performed the basic health measures as part of the interview process—blood pressure at three points during the interview, height using a stadiometer, and weight using a digital scale.

In some cases, the manager worksite interview and child home interview (12- and 18-month follow-up only) were conducted over the telephone, and the objective health measures were skipped.

# 12.3.2 Employee Informed Consent Procedures for Dried Blood Spots and Actigraphy

The field interviewers followed scripted text in CAPI to explain procedures for the collection of dried blood spots and for wearing an actigraph watch, and obtained separate <u>written</u> consent for each activity from the employee (both industries) and manager (Extended-care only). At the start of the dried blood spot collection, the interviewer read the scripted text to participants to explain the collection procedures, and asked the employee to review and sign the form, *Workplace Informed Consent: Blood Spot Sample.* Likewise, at the start of the actigraphy module, the interviewer read the scripted text to participants to explain the actigraphy collection procedures, and asked the employee to review and sign the form, *Workplace Informed Consent: Blood Spot Sample.* Likewise, at the start of the actigraphy collection procedures, and asked the employee to review and sign the form, *Workplace Informed Consent: Blood Spot Sample.* Likewise, at the start of the actigraphy collection procedures, and asked the employee to review and sign the form, *Workplace Informed Consent: Activity Monitor.* The interviewer received a supply of *Frequently Asked Questions: Blood Sample Collection* sheets to give to respondents to provide information on the purpose of the DBS collection and overview of the procedure.

# 12.3.3 Employee and Child Informed Consent/Assent Procedures for Daily Diary Study

A subset of employee / child pairs who completed the workplace and home interviews were also asked to complete the Daily Diary study component conducted by the Penn State Center, which included a daily telephone interview and saliva collection. RTI Field Interviewers recruited and enrolled subjects, and provided saliva kits. Recruitment procedures for employee participation in the daily diary portion of the study were administered immediately following the worksite interview. Interviewers provided the employee with a brochure that described the daily diary study, read scripted text to introduce the objectives and procedures for the daily diary, and consented the employee to participate alongside his/her child. The child was recruited into the daily diary study immediately following the child home interview. Interviewers read scripted text in CAPI to explain the daily diary study to the child, and to obtain the child's written assent (see <u>Appendix 12.1</u>). After written child assent was obtained, interviewers provided 2 sets of saliva kits and instructions for the employee and child.

At 12-month follow-up, the employee and child did not need to participate as a pair. Thus, written or oral consent was obtained and saliva kits distributed separately for the employee and child.

# 12.3.4 Informed Consent for Administrative and Health Claims Records

At the very end of the interview process, the interviewer read scripted text in CAPI to ask employees and managers in both industries for consent to collect administrative records on them from their company's Human Resources systems. At the telecommunications industry, the interviewer also asked the employee to sign an authorization to release their employersponsored health claims records. Duplicate copies of signed consent forms and authorizations were sent to each industry so that they have a record for their files.

# 12.4 Resources for Participants

# 12.4.1 Providing Feedback on Health Measures

Child, manager, and employee participants received feedback on their health measure readings following completion of the interview. From the collection of height and weight (as reported earlier in this chapter), the computer was programmed to calculate the participant's body mass index (BMI). From the collection of the three blood pressure and pulse readings, the computer was also programmed to calculate the average blood pressure for the participant.

At the end of the child interview, the computer prompted interviewers to provide feedback to the child's parent or guardian on the objective health measures that had been obtained. The computer displayed information on the child's average blood pressure reading and BMI, and the category box to check for each. Interviewers needed to carefully and accurately record this information on a Child Health Results feedback form to provide to the participant's parent or guardian. The form offered an interpretation of the readings and recommended guidelines for the participant's parent to follow up with a physician as needed.

Likewise, at the end of the Manager Employee interviews, the computer prompted interviewers to provide feedback to the Manager or Employee participant on the health measures that had been obtained. Information pertaining to the participant's average blood pressure reading and BMI was displayed. For employees and extended-care industry managers, results for the measure of blood sugar control (HbA1c) measured during the employee blood spot collection were also displayed if the participant agreed to participate in the blood spot collection. Interviewers needed to carefully and accurately record this information on the appropriate feedback form to provide to the participant. There were two feedback cards for adults, one for results when HbA1c was not obtained, and one for results that included the HbA1c reading (<u>Appendix 12.1</u>). These cards offered an interpretation of the readings and recommended guidelines for the participant to follow up with a physician as needed.

# 12.4.2 Resource Lists

For each participating industry, a resource list was developed and distributed with the health feedback forms. Because some of the survey questions or health feedback forms could have caused emotional distress, this list was developed to connect participants with the appropriate program or provider.

Two separate resource lists were developed for the telecommunications industry: a list of company-sponsored wellness programs and a list of local health care programs and resources. For the extended-care industry, a list of local health care and other wellness resources was developed and tailored to each site. For in-person employee, manager and child interviews, the relevant resource list was handed out at the end of the interview with the health feedback form. For spouses and for telephone interviews, the resource list was mailed with the incentive check.

See <u>Appendix 12.1</u> for copies of the resource lists.

# 12.5 Participant Issues Reporting Protocol

# 12.5.1 Participant Issues Committee

Given the complex, multi-center data collection implemented in this study, a Participant Issues Committee (PIC) was formed to respond to facilitate a timely and appropriate response to issues affecting study partners and participants. Because any specific issue could require guidance and input from multiple centers or staff, the primary function of this committee was to serve as a centralized facilitator for gathering and reporting information for all participant issues. A secondary function of the PIC was to advise the Operations Subcommittee on protocol changes resulting from the PIC's monitoring of participants issues.

The PIC was comprised of the 2 WFHN Steering Committee Co-Chairs, the Operations Subcommittee Chair, the IRB Subcommittee Chair, and the Federal government project scientist. The 5 PIC members had a standing weekly meeting. A Consultant Board was also established; comprising representatives from 9 major areas of the study (refer to Figure 12.1). Members from the Consultant Board attended PIC meetings on an as-needed basis.

# 12.5.2 Participant Issues Reporting Flow- Timing Guide

There were two categories of participant issues:

- Urgent issues
  - New issues that had not come up before
  - Issues that prompted the use of distressed respondent protocol (psychological or physical distress including injury, statement of intent to harm, disclosure of child abuse/neglect)
  - Issues that put site or industry participation at risk
  - Workplace consequences (to respondents) of participating in the study
  - Events that invoked legal issues (e.g., violence toward respondents or study staff, respondent reports of custody issues involving study information)
- Non-urgent issues
  - Issues that had come up before and did not otherwise qualify as urgent
  - IRB protocol violations that did not qualify as urgent issues (e.g., related to consent, data security, incentive distribution)
  - Respondent return of study materials (e.g., watches, time stampers)

Urgent issues were reported to the Participant Issues committee within **1 business day** by email to all members. These issues were reported at the same time or shortly thereafter to the relevant Industry PIs.
- For issues that required use of the distressed respondent protocol, if enough information had been gathered to submit an IRB incident report (and this was determined to be the appropriate course of action), the incident report was submitted within **1 business day** of being received by the Participant Issues committee.
- For urgent issues that did not reflect respondent distress, an incident report was submitted to the appropriate IRB within **2 business days** from the point at which the Participant issues committee determined this was needed and at which adequate information about the issue had been collected.
- If additional information was needed to determine whether to submit an incident report and/or how to describe the event and follow-up steps, this information was collected within **3 business days** of the initial report of the event. If an incident report was necessary, it was submitted within **2 business days** to the appropriate IRB.
- At least one member of the Participant Issues committee reviewed and approved each incident report prior to submission. Incident reports were shared with relevant industry PIs after submission to ensure all relevant parties had documentation of the report.

Non-urgent issues were reported to the Participant Issues committee as soon as possible, but within **5 business days** by email to all members

- In the case of repeat issues, reporting followed the established procedure for that particular issue, including follow-up as needed to collect complete information, and as needed, expedited communication with the Participant Issues committee.
- Reporting to Participant Issues committee was often concurrent with IRB reporting in the case of repeat issues where a prior incident report for the same issue had been reviewed.

The Participant Issues committee kept a cumulative record of issues reported, including what happened and which study staff were involved. This record was reviewed regularly in order to inform recommendations about changes to study protocols. Copies of all incident reports were uploaded to the secure website for reference.

Table 12.1 displays examples of participant issues and how they should be reported; Figure 12.1 shows the reporting flow that was used.

Event or Issue	Follow up steps	Reporting and Timing	
Data collection issues			
<b>Urgent:</b> Respondent faints during blood collection; Respondent becomes upset during interview; Child discloses abuse during interview	FI uses distressed respondent protocol and notifies FS immediately after the interview to prepare incident report (or Penn State project coordinator informed if during daily diary)	Reported by FS or Penn State project coordinator to Participant Issues committee (and incident report shared) within 1 business day; report submitted to appropriate IRB within 1 business day of being received by Participant Issues committee Industry coordinator / site manager and industry PI notified within 1 business day to follow-up with workplace as needed	

# Table 12.1Examples of Participant Issues

Event or Issue	Follow up steps	Reporting and Timing
<b>Urgent:</b> Respondent reports workplace consequence (e.g., job loss, discipline) as result of participation in study	Person reported to asks for complete information if firsthand; FS contacts respondent to collect information if not firsthand	Reported to Participant Issues committee within 1 business day; Participant Issues committee discusses with Industry PIs to determine appropriate follow-up actions; incident report submitted to RTI IRB with 2 business days of complete information collected and follow-up decisions made
Urgent (first time and/or if site risk): Confidentiality breach by FI (e.g. lost/stolen equipment or case materials, breach of subject identity or responses)	Person reporting (FI or other) to notify FS immediately by e- mail or phone with details of incident; FS prepares incident report and continues to collect more information if needed	Participant Issues committee notified by within 1 business day (first time and/or is site risk); FS collects additional informat if needed within 3 business days and incident report made to the RTI IRB with business days
Urgent: Violence toward study staff	Law enforcement contacted as needed	Reported to Participant Issues committee within 1 business day; Participant Issues committee discusses with Industry PIs to determine appropriate follow-up actions
Urgent (first time and/or if site risk): Complaint from respondent or administrator about some aspect of data collection (e.g. burden, discomfort, accusation of staff problem such as tardiness, poor attitude, violence)	Person reporting (FI or other) to notify FS immediately; FS contacts respondent to collect more information if not firsthand	Participant Issues committee notified by within 1 business day (first time and/or it site risk); committee determines what if follow up steps are needed (e.g., incider report, change in study protocol, staff re training or discipline, discussion with industry partner)
Non-urgent (unless new issue): Report of rash from actigraphy watch; Report of reaction/infection from finger stick	Person reported to asks for complete information if firsthand; FS contacts respondent to collect information if not firsthand	Incident report prepared for RTI IRB with 2 business days of collecting information about problem; report shared with Participant Issues committee before submission (for first instance) and concurrent with submission (for subsequinstances)
<b>Non-urgent:</b> Missing consent form	FS confirms whether consent was obtained and if so, attempts to collect consent form again:	Incident report prepared for RTI IRB with 2 business days of learning about missin consent; report shared with Participant Issues committee before submission (for first instance) and concurrent with

Event or Issue	Follow up steps	Reporting and Timing	
	FI re-trained	submission (for subsequent instances)	
<b>Non-urgent:</b> Data transfer/storage procedures incorrectly followed, resulting in compromised data security	FI or project staff re- trained or disciplined	Participant Issues Committee notified within 5 business days (assuming no site risk) and incident report for RTI IRB shared with committee before submission	
	Interventio	on issues	
<b>Urgent:</b> A participant is angry, disrespectful, and unruly towards the facilitators and others and is asked to leave by the session by the facilitator or another participant.	CRX notifies site contact directly (i.e., Director or Administrator)	Reported by CRX to Intervention Coordinator and/or Industry PI within 1 business day; report submitted to Participant Issues committee by Intervention Coordinator or Industry PI within 1 business day to follow-up with workplace as needed	
Non-urgent: A participant is forced by a manager to work overtime without pay because she was not able to get her work done because she attended a STAR/T session.	CRX communicates with Intervention Coordinator who then follows up with participant to collect information if not firsthand	Reported by CRX to Intervention Coordinator and/or Industry PI within 5 business days; report submitted to Participant Issues committee by Intervention Coordinator or Industry PI within 1 business day to follow-up with workplace as needed	
Non-urgent: Participant reports reprimand or retaliation by coworker or manager for implementing STAR/T	CRX communicates with Intervention Coordinator who then follows up with participant to collect information if not firsthand	Reported by CRX to Intervention Coordinator and/or Industry PI within 5 business days; report submitted to Participant Issues committee by Intervention Coordinator or Industry PI within 1 business day to follow-up with workplace as needed	
<b>Non-urgent:</b> A participant is verbally mistreated by a coworker for not participating in the Sludge	CRX communicates with Intervention Coordinator who then follows up with participant to collect information if not	Reported by CRX to Intervention Coordinator and/or Industry PI within 5 business days; report submitted to Participant Issues committee by Intervention Coordinator or Industry PI within 1 business day to follow-up with	

Event or Issue	Follow up steps	Reporting and Timing
Eradication Activity.	firsthand	workplace as needed
Non-urgent: A	CRX communicates	Reported by CRX to Intervention
participant	with Intervention	Coordinator and/or Industry PI within 5
expresses distress	Coordinator who then	business days; report submitted to
in the context of	follows up with	Participant Issues committee by
intervention activities	participant to collect	Intervention Coordinator or Industry PI
	information if not	within 1 business day to follow-up with
	firsthand	workplace as needed





## 12.6 Adverse Events and the Distressed Respondent Protocol

This protocol was designed to provide guidance to interviewers in identifying and reacting to adverse events that might occur during the data collection process. While these events were expected to be extraordinarily unlikely, interviewers were prepared to correctly respond to them in the rare event such situations arose.

#### 12.6.1 Respondents Exhibiting Psychological Distress

A respondent could have become distressed during the conduct of the interview if a question(s) evoked bad memories or unpleasant experiences. It was important to distinguish between distresses and discomfort (see below). While the interview was not designed to discuss sensitive topics with the respondent, it is possible that questions about physical health, stress, or family relations could have created emotional discomfort for the respondent. Respondent distress was identified through emotional reaction (such as crying or anger), statements about extreme worry or anxiousness (such as concern about the respondent's own parenting skills or very high amounts of work related stress), and/or statements indicating hopelessness, sadness, or depression.

#### Examples of respondent discomfort.

- Respondent said they do not want to answer a question
- Respondent stated that the information was too personal to disclose

#### Interviewer responses to respondent discomfort:

- Interviewer reminded respondent that participation is voluntary
- Interviewer reminded the respondent that he/she could skip any question or stop the interview at any time
- Interviewer monitored the respondent closely to be able to react properly if discomfort were to worsen to distress

#### Potential signs or indications of respondent distress

- Respondent became tearful and/or reported that he/she felt badly or was sad
- Respondent showed signs of being considerably more nervous or anxious (e.g. very nervous speech)

#### Interviewer responses to respondent distress

- Interviewer evaluated whether distress was extreme (see below)
- Interviewer reminded respondent that participation is voluntary
- Interviewer reminded the respondent that he/she could skip any question or stop the interview at any time.
- Interviewer asked the respondent "Would you like to take a short break?" and allowed the respondent time to regain composure before finishing the interview
- Interviewer provided a list of local health care resources to the respondent (or a parent if the respondent is a child). If the interview took place by phone (i.e., with spouse/partner), interviewer provided relevant phone numbers to the respondent by phone and mentioned the resource guide that will be included in the incentive mailing.
- If the respondent expressed distress during the interview, the interviewer completed an incident report and submitted it to their Field Supervisor within 24 hours. The report was distributed to the WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor.

#### Potential signs or indications of respondents with extreme distress:

- Respondent exhibited an extreme emotional reaction (e.g. the respondent could not stop crying, the respondent cried to the point that the interviewer was worried about the respondent, the respondent became and stayed angry, the respondent became angry to the point the interviewer was worried about the respondent's and/or the interviewer's safety)
- Respondent made statements indicating that he/she was consumed with worry or anxiety about their family or work situation
- Respondent made statements indicating extreme hopelessness, sadness, or depression (e.g. repeating over and over that he/she was hopeless, statements about sadness that became increasingly severe, the respondent volunteered information about depressive symptoms)

## Interviewer responses to respondents with extreme distress:

In all cases of extreme distress the interviewer immediately stopped the interview. The interviewer provided a list of local health care resources to the respondent (or a parent if the respondent is a child). If the interview took place by phone (i.e., with spouse/partner), the interviewer provided relevant phone numbers to the respondent by phone and mentioned the resource guide that was to be included in the incentive mailing. The interviewer offered to help the respondent seek immediate assistance, such as calling an appropriate resource from the list provided or by calling 911. The interviewer also completed an incident report and submitted it to their Field Supervisor within 24 hours. As deemed necessary, the interviewer and Field Supervisor made a referral to appropriate support services. The report was distributed to the WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor.

## 12.6.2 Suicidal Risks

## 12.6.2.1 Child Respondents

Although child respondents were not asked directly about suicidal feelings or intent, it is possible that a respondent could have spontaneously report suicidal intent outside the course of the interview. If this situation occurred with a child respondent, the interviewer proceeded in a calm, matter-of-fact fashion, without appearing shocked or upset in front of the child. The interviewer then followed these procedures:

- 4. At the end of the interview, the interviewer said to the respondent: "When you agreed to participate in this interview I told you that I would not tell anyone about anything you told me unless I was required to tell someone to prevent harm from coming to you. What you have told me about hurting yourself (i.e., suicide) has me concerned about your safety and well being. I have to tell your [parent/caregiver] about what you told me so they can make sure that you are safe. Would you like to be with us when we talk about it? I will also have to tell my supervisor."
- 5. The interviewer found the parent or other responsible adult in the home and informed them. The interviewer said: "During the interview \_\_\_\_\_\_\_ told me that he/she (DESCRIPTION OF THE THREAT OR INTENT). I am not a trained counselor so I cannot tell you more about what this means. In the case of an emergency, we suggest taking your child to the emergency room immediately. If you are physically unable to get your child to the emergency room without help, you should call 911 for assistance. It is important not to let your child out of your sight or the sight of another

responsible adult during this time if you feel that (he/she) is going to hurt (himself/herself). You should also contact (his/her) doctor or health care provider."

6. The interviewer immediately filed an incident report with the Field Supervisor. The report was distributed to WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. The IRB Subcommittee chair then alerted the PIC.

## 12.6.2.2 Adult/Young Adult Respondents

- 4. If an adult/young adult respondent stated that he or she was thinking about, feeling like, or planning *suicide*, the interviewer was expected to follow steps similar to those outlined for child respondents. First, the interviewer would tell the respondent of their concern for his/her safety, and reminded him/her that the FI is required to contact the appropriate authorities as discussed before the interview. The interviewer also would offered to assist the respondent with a call to the National Suicide Prevention Hotline (1-800-SUICIDE). If the interviewer felt that the respondent was in immediate danger of self-harm, the interviewer immediately would call 911.
- 5. The interviewer would suggest to the adult respondent that the FI would stay with him/her until professional help (e.g., EMS professional, agency mental health provider, local hospital staff, caseworker) has taken responsibility for the situation either on the phone or in person. The interviewer may have also asked another adult in the home to stay with the respondent while the respondent waits. If the respondent asked the interviewer to leave the respondent alone, the interviewer respected this wish. However, as mentioned above, if the interviewer believed the respondent was in immediate danger of self-harm, the FI would tell the respondent know that the FI was required to call someone who could help the respondent. The interviewer would have left and called 911.
- 6. The interviewer would immediately file an incident report with the Field Supervisor. The report would be distributed to WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. The IRB Subcommittee chair then alerted the PIC.

#### 12.6.3 Suspected Child Abuse or Neglect

Although the questions asked in the Work, Family and Health Study did not ask respondents specifically about child abuse or neglect, a respondent may have voluntarily disclosed such information during or after the interview process. Interviewers may also have observed abusive behavior or situations when they were doing home interviews.

All interviewers were required to report when they suspected a child younger than age 18 was abused or neglected by his/her parent, guardian, custodian, or caretaker (see below for reporting protocol). "Abused" meant that a child had been inflicted with physical injury or injuries other than by accidental means or was in a condition which was the result of maltreatment such as malnutrition, sexual molestation or exploitation, deprivation of necessities, or cruel punishment. It also included living in an environment injurious to the juvenile's welfare (for example, in a home which was physically deteriorated to the point where it was dangerous, or lived in a "crack house"). The child suspected of being abused or neglected may have been a youth respondent, may have been a respondent's child, or may have been another child the respondent identifies.

All consent/assent forms included language to inform the respondent that if the project staff learned that harm or danger of a child was suspected, then this would be reported to someone who could check to see if the child is safe and protected. Therefore, all respondents would have been informed about potential actions that would have followed disclosure of such information or observation of events that would have required reporting or notification and would have agreed to those terms before participating in the interview or conversely, chosen not to participate.

In the case of suspected child abuse or neglect, the field interviewer immediately filed an incident report with the Field Supervisor. The report was distributed to WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. The IRB Subcommittee chair then alerted the PIC. As deemed necessary, the interviewer and Field Supervisor placed a call to the appropriate authorities, such as the Department of Child and Family Services for the county in which the respondent resided. If the field interviewer felt that a child was in imminent danger, he/she called the appropriate authorities and attempted to stay in the home until professional help had taken responsibility for the situation either on the phone or in person. Should the field interviewer have felt that his/her own safety would be endangered by staying in the home, he/she left and called 911.

## 12.6.4 Distress Related to Biospecimen Collection

While extremely unlikely, a respondent may become dizzy, lightheaded or faint during or after the finger stick. Interviewers were instructed to be alert for signs such as pallor, perspiration on the face and forehead, complaints of blurring vision, drooping or fluttering eyelids, or complaints of nausea.

If any of these symptoms were present at any point during the interview, the interviewer reacted according to the following procedures:

If a respondent felt faint, lightheaded, dizzy, or showed any signs of impending faint, the interviewer stopped the procedure and took the following actions:

- Took care that the respondent did not fall or become injured.
- Calmly reassured the respondent and as necessary, asked the respondent to bend at the waist and put his/her head between his/her legs.
- Had the respondent rest for 10 minutes.
- Resumed the procedure if the respondent consented to continue.

If the respondent fainted, the interviewer took the following actions:

- Took care that the respondent did not fall or become injured.
- Had the respondent lie on his/her back as quickly as possible with feet elevated. The
  respondent was instructed to lie down directly from the seated position without standing
  up.
- Asked the respondent to loosen any tight clothing.
- Had the respondent rest for 10 minutes.
- The interviewer did not resume blood spot collection, but if the respondent consented, the interviewer skipped to the introduction of the actigraphy study.
- If the respondent did not respond after one minute, the interviewer called 911.

If either of these events occurred in response to the finger stick or at any time during the interview, the interviewer completed an incident report and submitted it to their Field Supervisor

within 24 hours. The report was distributed to WFHN Data Collection Manager and the chair of the RTI IRB Committee within 2 business days of being received from the Field Supervisor. The IRB Subcommittee chair then alerted the PIC. For any incidents of physical distress related to study participation, the interviewer provided the respondent (or a parent if the respondent is a child) with a list of local health care resources and the Field Supervisor followed up with the respondent within 2 to 3 weeks to ensure that symptoms had resolved.

To protect field interviewers from blood borne pathogens, prior to performing a finger stick, interviewers completed the Bloodborne Pathogen training module. Interviewers were also trained to wear gloves when collecting or handling all biospecimens. Finally, interviewers began a series of 3 Hepatitis B vaccinations prior to collecting blood spots, or actively declined to be vaccinated.

There was no physical risk or discomfort associated with the saliva or the anthropometric measures (blood pressure, height, weight). However, for adults, if a very high blood pressure value was obtained during the blood pressure readings (average systolic pressure > 210 or diastolic pressure > 120), interviewers indicated on the respondent's health feedback card (<u>Appendix 12.1</u>) that their blood pressure was very high and that they should seek medical attention within the next few days (<u>Appendix 12.1</u>). A resource list was also provided to the respondent with information about urgent medical care providers in their local area. The interviewer asked if the respondent wished to continue with the data collection after this point. For children, CDC guidelines based on the child's age, sex, and height were used to determine whether the respondent's blood pressure was very high, and the feedback form given to the child's parent or guardian indicated that the parent should take the child to a doctor in the next few days. The resource list was given to the parent.

## 12.7 Protection of Participant Privacy

Privacy refers to the confidentiality of data and personal information both at the interview site and in the handling and reporting of data by the Coordinating Center. It also includes discretion on the part of interviewers and the arrangement for physical privacy during interviews and health measure collections. Each interviewer/data collection coordinator was responsible for ensuring the physical privacy of participants and ensuring that data were stored in a secure area accessible only to WFHS staff. This was monitored through periodic visits by the Coordinating Center staff. All in-person data collection was conducted in private settings either in the workplace (e.g., library, private office, room off dining hall) or in the home, such that responses would not be overheard by others. Interviewers ensured that respondents could not be overheard during telephone data collection.

A certificate of confidentiality was held to protect against the involuntary disclosure of the identities of research participants.

## 12.8 Data Security and Confidentiality

To minimize breaches of confidentiality, the CAPI data collection and transmission procedures followed RTI's strict protocols for maintaining field equipment and data confidentially at all times during the study period. Field interviewers were trained on the meaning and importance of confidentiality and signed Confidentiality Agreements.

Interview data collected by field interviewers used computer-assisted technology, allowing for direct entry of data into a secure password-protected computer. In addition, the hard drives of all

computers were encrypted using Pointsec, a hard disk encryption application. Any computer files were inaccessible without the appropriate passwords, even if the hard disk was removed and connected to another computer. The collected health measure readings were also entered directly into the computer as part of the interview data collection process. Computers were configured to require three levels of passwords: a login and password at startup, a login and password to log in to Windows, and a third password to get into the Case Management System (CMS). The three passwords were required to be different from each other. The startup password was a "strong" password that contained letters, digits, and a special character. The Windows login and CMS passwords contained a combination of letters and special characters. Field staff were instructed never to write down the passwords anywhere. To reduce the risk of intrusion should a computer be obtained by an unauthorized person, communications software on field computers were configured to connect to RTI's network for data transfer. Completed case data files were removed from the computer PCs during transmission, after the data had been verified as having been received intact at RTI. Field staff transmitted data daily as interviews were completed or cases were updated. The field team leaders monitored field staff adherence to the protocol using daily transmission reports.

SecureZip software was used to encrypt data on computers. SecureZip used triple-DES encryption and, based on RTI ITS review, met FIPS 140-2 requirements. Field interviewers signed a document upon employment agreeing that they would not use RTI computers for anything unrelated to RTI field data collection work. Field staff were able to use the computers to connect to the Internet to access an online scheduling calendar and to send email directly to study participants; Internet usage was explicitly covered in the computer authorization document. The transmission program on the computers created a connection to transfer data between RTI and computers in both dialup and broadband connections. The risk of computers becoming infected with a virus was minimal. Nonetheless, to install anti-virus software updates on computers, automatic updates were downloaded during transmission as they were available.

Data transfer outside of RTI's network took place via secure ftp with computers calling into dedicated servers at RTI. The zipped and encrypted files transmitted from computer were stored in secure file servers until nightly processes extracted that data into secure databases within RTI intranet. The SQL server database used for data transfer contained only case assignment and status data, including name and locating information. Case assignment, status data, and interview data were stored in secured separate files. All data was retrieved from the computers and stored in a restricted project share. Case assignment and status data was transmitted separately and stored in separate network locations from study data. Data being sent to and from field computers was stored in a domain of the RTI network that is behind the RTI firewall but allowed access, with appropriate credentials, to users accessing RTI resources while physically outside the private domain (i.e., the innermost security login level accessible only by internal RTI staff). The particular file share in which the ingoing and outgoing data were housed was protected by NT security, which allowed access to the data only by RTI system administrators, field system programmers, and the controlled programs that were invoked when field interviewers' computers connected via direct dial-up to RTI's modems and communicated with the Integrated Field Management System (IFMS). Specific data management and data sharing protocols were followed for all access to stored data.

Qualitative process data was collected by trained site managers and investigators from the Minnesota and Portland State/Michigan State centers. Consent forms and notes from interviews were kept in a locked file cabinet in the home office of the site manager until he/she mailed those documents to the Flexible Work & Well-Being Center (at least monthly, by registered mail, FedEx, or UPS). These documents were then kept in a locked cabinet at the Flexible Work &

Well-Being Center (within the Minnesota Population Center). Audio files and other electronic documents were uploaded to a shared drive (limited to project staff) on a secure CLA-OIT server using VPN that provided encryption of documents during the transfer. These files were stored on a shared drive (limited to project staff) on a secure CLA-OIT server. Computers used by site managers had full disk encryption, which meant that a password was required to turn the machine on and to access any files (even if the computer was stolen and the hard drive was removed and put into a new machine).

Data from semi-structured interviews and non-participant observation of intervention activities was summarized in such a way that individuals were not likely to be identified even by others in the workplace. These processes included the use of pseudonyms and the masking of identifying information (e.g., slight alterations in age, role in organization) if quotes or other descriptions of a particular person were used as examples in reports or publications. RTI had access only to de-identified data from the process evaluation.

Devices (including wrist monitors, actigraphy watches, blood spot collection materials, and saliva kits) were labeled with scannable bar codes to indicate respondent identification numbers. All hardcopy case materials (i.e., screening forms, consent and assent forms, and incentive receipts) collected by RTI were stored in locked cabinets when not in use in the field. Upon completion of each case, case folders with hardcopy materials were sent to the RTI Fulfillment Center (FC) at Regent Place via Federal Express, signature required for receipt. Access to the building was by key-card entry. RTI employees had access to the building at all times; however, temporary agency employees only had access during their shift, plus 30 minutes before and after. The Fulfillment area within the building was locked at all times with a combination lock. No temporary agency employee was allowed in that area unless an RTI supervisor was present.

A Fulfillment Department Document Control Clerk (DCC) was assigned the responsibility of receiving and opening incoming packages with case folders each business day. Each incoming package consisted of case folders and a transmittal form designating the Case IDs of the included folders. For each case folder received, the DCC recorded an electronic "hit the door" receipt event in the project control system. The Case IDs of case folders within incoming packages were then compared to the transmittal form included with each shipment. Missing items were flagged, and tracking was immediately initiated with the field staff. Once the folder had been noted as received, the DCC opened the case folder for purposes of review and documenting within the project control system all of the contents (e.g. consent forms, incentive receipts) included within the folder. Once case folders and their contents were receipted as received within the control system, the folders were next batched for secure storage. In general, case folders were stored in batches of 20. For each set of folders to be stored, the DCC utilized the project control system to create a batch. The DCC entered the Case IDs of case folders to a batch and printed a batch header sheet. This batch header sheet was placed on top of the batch, which was rubber-banded and stored securely within designated WFHN project shelf space within the secure FC facility. This daily process of receipting and batching case folders and materials was repeated throughout the duration of the project. Only authorized project staff had access to study materials within the secure FC facility.

At the conclusion of the project, RTI archived the project share (allowing read-only access to designated project staff) but, as the Data Coordinating Center for the Network, ensured that Network collaborators had a final copy of the de-identified data to analyze beyond the end of the project. Unless needed for archival purposes, all sensitive hardcopy materials were shredded at the end of the project. Any such materials to be kept were stored in a secure room until

scheduled for disposal by shredding. If RTI obtained funding to conduct additional follow-up data collection with respondents enrolled in this study, identifying information would have been retained for as long as RTI had additional funding for the purpose of re-contacting and collecting data from these respondents. Biomarker samples were stored indefinitely at Penn State and Harvard but were de-identified. Computers were shipped back to RTI via a secure carrier at the end of the project, for final transmission and decommissioning. Once successful final transmission had been verified, each computer's hard drive would have been purged of project data by use of multi-pass overwriting secure erasure software.

## 12.9 Data Sharing and Transfer

All data sharing and transfer between RTI and other network centers took place via a secure website. The website was password protected, and passwords were only given to approved users. Data were encrypted using Secure Socket Layer (SSL) encryption. Specific folders were created for each type of data and access to each folder was restricted to approved users at the center involved in transmitting that type of data. This secure website was also used for sharing identified and de-identified study data with all network centers. All data were de-identified before making them available to network centers outside of RTI at the end of data collection. Access to the study data was restricted to approved users. Data were shared via the secure website and each network center signed a Data Transfer Agreement to maintain data security.

The collected dried blood spot data were labeled with study identification numbers only and shipped directly to the Harvard Research Unit for analysis. The de-identified specimens were stored in a secure location within a locked freezer. The sleep data (actigraphy) was downloaded from the wrist monitors directly into field computers, and transmitted to RTI per the process described above. Once at RTI, the sleep data were packaged and transmitted using the secure website to Harvard for analysis. No identifying information was shared with Harvard. The analyzed blood spot and sleep data were transmitted and maintained in de-identified fashion and transmitted securely between Harvard and RTI using the secure website.

Identifying information for participants recruited into the daily diary study was uploaded daily via the secure website for the Penn State research team. Penn State destroyed respondent contact information at the end of the study. Identification numbers unique to the daily diary study were assigned. Penn State maintained the link between these numbers and the main study identification numbers separately from the respondent contact information. Only project staff directly involved in cleaning and merging daily diary and main study data would have had access to the link file. Once collected and analyzed, de-identified daily diary data and saliva data were transmitted via the secure website from Penn State to RTI.

Quantitative data collected from intervention participants about workplace context, completion of intervention activities, and attendance at intervention sessions were uploaded to the secure website by the Minnesota and Portland State/Michigan State centers. These data included study IDs unique to the intervention data and did not include identifying information. A separate list of names of employees in the intervention, employee IDs, and study IDs unique to the intervention data was uploaded to the secure website to enable linking with main study data. The link between the intervention data IDs and the main study identification numbers was maintained at RTI so that identifying information for intervention participants could not have been linked to their main study data by Minnesota and Portland State.

#### Chapter 13: Data Management

#### 13.1 Introduction

Since this study provides a variety of data sources, including interviews, health measures, and lab reports, the data management systems used required flexibility to mesh with the variety of operational procedures implemented at the participating centers across the WFHN, while providing standardization and quality assurance in data collection and processing.

## 13.2 Data Entry

Field interview data from managers, employees, spouse/partners and children was collected by RTI field interviewers using computer-assisted technology, allowing for direct entry of data into a secure password-protected laptop. Attriter interview data were collected by RTI telephone interviewers using computer-assisted technology, with direct entry into electronic instruments on the RTI secure network. The WFHS electronic instruments were programmed with skip logic, defined range values and consistency checks, and the data were validated during entry with check-value flags requiring interviewer resolution when needed. During the data entry, interviewers were able to move back to previous questions and change data (if miskeyed), and for important health measure values (e.g. blood pressure readings, height, weight, blood collection readings) the study required double entry of values as a means of confirming the accuracy of entries.

## 13.3 Data Transfer

On each day they conducted fieldwork, field interviewers were required to update the event codes electronically for their cases to document each activity taken to contact and interview respondents, and transmit data from interview contact attempts and completed interviews to the RTI Data Coordinating Center (DCC). Interviewers were trained to complete these "housekeeping" activities, such as completing the "close-out" screens for interviews, at the worksite/respondent's home, or as soon as they arrived home, so that they could transmit all data updates on the same day. In some instances, field supervisors required interviewers to transmit more than once in one day, to receive electronic cases assigned to them or to pick up instrument updates. To ensure that all interviewers were transmitting to send or receive data as required, the project closely monitored transmission reports to confirm that field staff had the latest instrument updates on their laptops, and that they were transmitting data regularly.

Data transfer outside of RTI's network takes place via secure ftp with laptops calling into dedicated servers at RTI. The zipped and encrypted files transmitted from interviewer laptops are stored in secure file servers until nightly processes extract the data into secure databases within RTI intranet. The SQL server database used for data transfer contains only case assignment and status data, including name and locating information. Case assignment, status data, and interview data are stored in secured separate files. All data retrieved from the laptops are stored in a restricted project share. Case assignment and status data are transmitted separately and stored in separate network locations from study data. Data sent to and from field laptops are stored in a domain of the RTI network behind the firewall but allowing access, with appropriate credentials, to users accessing RTI resources while physically outside the private domain (i.e., the innermost security login level accessible only by internal RTI staff). The particular file share in which the ingoing and outgoing data are housed is protected by NT security, which allows access to the data only by RTI system administrators, field system

programmers, and the controlled programs that are invoked when field interviewers' laptops connect via direct dial-up to RTI's modems and communicate with the Integrated Field Management System (IFMS). Specific data management and data sharing protocols are followed for all access to stored data.

All data sharing and transfer between RTI and other network centers takes place via a secure website. The website is password protected, with passwords only given to approved users. Data are encrypted using Secure Socket Layer (SSL) encryption. Specific folders are created for each type of data and access to each folder is restricted to approved users at the center involved in transmitting that type of data. This secure website is also be used for sharing deidentified study data with all network centers. Access to the study data is restricted to approved users.

The collected dried blood spot data were labeled with the field interviewer's name, collection date and unique study identification number and shipped weekly via Federal Express to the Harvard Research Team for analysis. The de-identified specimens were stored in a secure location within a locked freezer. The sleep data (actigraphy) were downloaded from the wrist monitors directly into actiware databases on field laptops, and transmitted to RTI per the process described above. Once at RTI, the sleep data were packaged and transmitted using the secure website to Harvard for analysis. No subject identifying information was shared with Harvard. The analyzed blood spot and sleep data were maintained at Harvard in de-identified fashion and transmitted to RTI using the secure website.

Special care was taken to ensure that RTI could establish the link between the subject's CAPI data and the de-identified results from Harvard. For the dried blood spot data, the RTI field interviewer entered the unique study identification number from the blood spot card into the CAPI case for the subject, and for the actigraphy, the watch's serial number, date watch was assigned to the subject, and date the watch was returned were entered into CAPI. A unique watch ID per the subject's case ID was created at RTI for submission to Harvard. The blood spot and actigraphy results data, back from Harvard, included the identification number from the blood spot card (for blood results) and for actigraphy, the watch ID, watch serial number, dates the subject wore the watch and associated sleep results data. As the DCC, RTI was able to use the information captured in the CAPI instrument to link the analyzed blood spot and sleep data results from Harvard to the appropriate subjects.

In addition to the electronic entry of blood and actigraphy information in CAPI, the project also utilized hard-copy log sheets in the field to track the blood samples as collected, and the assignment and return of watches. This information was tracked by the subject's case ID and securely maintained in a 3-ring site binder by field staff. These log sheets provided an additional mechanism for RTI to link DBS and actigraphy data with subjects in the few situations where data were mis-keyed by the field interviewer in CAPI. At the end of data collection at each site, the paper logs were sent to RTI where they were securely stored for reference as needed.

Participants recruited into the daily diary study were assigned a unique family ID for Penn State use. As new families were recruited into the daily diary study, the RTI field interviewer captured names and contact information in CAPI, which was transmitted daily to RTI as described above. This information was extracted and packaged with the unique family ID, and the de-identified encrypted data were uploaded daily via the secure website for the Penn State research team. Also during the daily diary recruitment, the field interviewer assigned out an adult and child saliva kit to the family. Each saliva kit was labeled with a unique ID which the field interviewer

was required to enter in the CAPI case. Penn State used the family ID and respondent contact information to make contact with the adult and child in the family to complete the daily diary activities, and reported case outcome data back to RTI according to the family ID. Also, once collected, the daily diary interview data were transmitted with the associated family ID, from Penn State to RTI via the secure website. Penn State also processed the saliva samples and provided RTI with the saliva analysis results according to saliva kit ID via the secure website. As the DCC, RTI maintained the main study identification numbers, the family IDs, and saliva kit IDs, and was able to link the de-identified daily data and saliva results from Penn State to the appropriate subjects.

Qualitative process data were collected by trained site managers and investigators from the Minnesota and Portland State centers. Completed consent forms and notes from interviews were mailed monthly to the Flexible Work & Well-Being Center (within the Minnesota Population Center) where they are securely stored in a locked cabinet. Audio files and other electronic documents were uploaded to and are being stored on a shared drive (limited to project staff) on a secure CLA-OIT server at Minnesota using VPN that provided encryption of documents during the transfer. Laptops used by site managers to collect the process data had full disk encryption, meaning a password was required to turn the machine on and to access any files.

Devices and materials used to collect biomeasures (including actigraphy watches, blood spot collection cards, and saliva kits) were labeled with scannable bar code IDs, and field staff used bar code scanners to capture the ID information in CAPI instead of keying it in, to reduce entry error. As described above, the capture of the bar code ID information in the CAPI instrument that included the subject's study ID allowed for the study to provide Harvard and Penn State with de-identified data, and to link the de-identified results received back to the proper study subject.

As the DCC for the network, RTI de-identifies all data before making them available to network centers outside of RTI. Each network center was required to sign a Data Transfer Agreement to maintain data security, and the data are shared with the centers via a secure website.

At the conclusion of the project, RTI will archive the project share (allowing read-only access to designated project staff) but, as the Data Coordinating Center for the network, will ensure that network collaborators are able to continue to access and analyze de-identified data beyond the end of the project. Unless needed for archival purposes, all sensitive hardcopy materials will be shredded at the end of the project. Any such materials to be kept will be stored locked in a secure room until scheduled for disposal by shredding. If RTI obtains funding to conduct additional follow-up data collection with respondents enrolled in this study, identifying information will be retained for as long as RTI has additional funding for the purpose of recontacting and collecting data from these respondents. Biomarker samples will be stored indefinitely at Penn State and Harvard but will be de-identified. Laptop computers will be shipped back to RTI via a secure carrier at the end of the project, for final transmission and decommissioning. Once successful final transmission has been verified, each laptop's hard drive will be purged of project data by use of multi-pass overwriting secure erasure software.

#### 13.4 Database Reports

The RTI Data Coordinating Center developed and utilized several reports for project management use during the data collection period to monitor the status of field production and costs, field response rates, quality control with fieldwork, and status of health measure, biomarker collection and daily diary activities.

The reports can be classified into four types:

- Production reports by case type, wave, interviewer and industry
- Custom reports for tracking biomarkers, health measures, status of family interviews (home and child), and the daily diary study
- Quality control reports
- Field hours and cost reports

Table 13.1 provides a listing of the project reports used on the WFHS.

Table 13.1	WFHS	Database	<b>Reports</b>
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Reports Type	Report Name	
	Attriter Status Report	
	Completed Interviews by Wave	
Production Reports	Completed Interviews by FI	
	Completed Interviews by Industry	
	Completion Counts for All Samples	
	Pending Cases Report	
	Verification Status Report	
	Actigraphy Watches On Hand Report	
	Basic Health Measures Report	
Custom Reports	BP collected Report	
(Tracking Health Measures, Biomarkers,	Biomarkers Report	
Status of Family Pieces)	DBS and Actigraphy Cases Report	
	Family Status Report	
	Families Who Enroll in Daily Diary	
	Daily Diary Status Report	
	Weekly Dashboard Report	
	Aging Cases Report	
	Case Detail Reports	
	Case Folder Delinquency Report	
	Consent Report	
Quality Control Reports	DBS Detail Report for Processed Samples	
	Interview Timing Reports	
	Transmission Log Report	
	Transmission Receipt Report	
	Timing Outlier Reports (CAPI administration)	
	Untimely Transmission Report	
	Verification Problem Report	
	Average Hours and Miles (Weekly)	
	Field Cost and Production (Weekly)	
Field Hours and Cost Reports	Field Hours and Miles (Weekly)	
	Average Hours and Miles (Summary all	
	weeks)	
	Field Cost and Production (Summary all	
	weeks)	
	Field Hours and Miles (Summary all weeks)	

## 13.5 Database Closure

Before each major analysis, the database goes through a series of closure checks to insure the completeness and correctness of data collection and processing. These checks are performed on a "frozen" version of the database defined by a specific time cut point. The classes of checks done at closure include:

- Determining the status (excluded, ongoing, completed, withdrawn, etc.) of each participant entered.
- Assuring all expected forms have been received.
- Assuring all received forms have been processed.
- Assuring all queries generated have been resolved.

## 13.6 Data Retrieval and Statistical Computing

Data are retrieved from the study database and converted into SAS files on a regular schedule tied to the production of the study status report and data closure checks. Additional retrievals are done as needed for the production of other reports. These retrieval files are stored as SAS datasets within a SAS data library. The SAS database created for each report is permanently archived on magnetic tape cartridge or CD-ROM. All statistical analysis is done using validated statistical software.

## 13.7 Data Security and Confidentiality

## 13.7.1 Introduction

Data collected through the Work, Family & Health Study (WFHS) study are confidential. It was the responsibility of the field interviewers (FI) to maintain the integrity and confidentiality of the data entrusted to them. At training, they were asked to sign a Headway Corporate Resources Data Collection Agreement, which certified that they would carry out all project procedures precisely. Interviewers' signatures on this agreement affirmed their understanding of WFHS project policies and their agreement to comply with all of them. This section describes the protocols the study implemented to ensure that all papers, forms, data, materials, and equipment in interviewer possession were secure and confidential at all times.

#### 13.7.2 Safeguarding Materials in the Field

The WFHS collected data from employees and their families through a relationship of trust. Field interviewers had the <u>legal</u> and <u>ethical</u> obligation at all times to safeguard participant confidentiality and secure materials and equipment from unauthorized access or use. There were two different forms of confidential data used or acquired for the WFHS:

- Information found in hardcopy case records (e.g., case folders and their contents, such as consent forms and address history sheets).
- Computer equipment (e.g., data residing on the hard drive).

The interviewers were required to store all confidential project materials when not in use in a locked briefcase, or overnight in a locked cabinet, if available, <u>even at home</u>. Interviewers were trained to never store laptops, case folders, dried blood spot specimens, or other study

materials or equipment in a car overnight, **even in a locked trunk**. Also, laptops could only be used by authorized WFHS field staff and only for intended purposes.

## 13.7.3 Safeguarding Materials in the Interviewer's Home

At home, the interviewer securely stored materials in a locked briefcase or cabinet out of sight of family members and visitors. Additionally, laptops and other study equipment were not allowed to be used by anyone but the interviewer. Interviewers were not allowed to write down laptop passwords or make them available to anyone else.

### 13.7.4 Safeguarding Materials at the Worksite

When working at the site office, interviewers needed access to all of their pending case folders, in case they made contact with a respondent (for example, a respondent may suddenly be available to do the interview, or drop by to turn in the actigraphy watch). Interviewers were required to keep all case materials secure and out of sight in their briefcase when not in use. Also, interviewers were not allowed to discuss specific cases or participants with anyone other than their FS or other authorized project personnel.

When interviewers took breaks or stepped away from their workspace at the worksite, they were required to lock up all equipment and materials securely. Also, interviewers took care to not allow respondents to view the case management system (CMS) display on the laptop, which listed participant-specific information for all cases assigned to the interviewer. Also, they did not allow participants or other household members to see other case folders or participant information in their possession.

When preparing to leave the worksite for the day, interviewers conducted a careful check of all the case materials and belongings to ensure they were leaving with all case folders and their contents in their possession, and also locked up all materials and equipment being stored at the worksite.

As part of breaking down the lab at the end of the day, an interviewer decontaminated the area to prepare the blood collection and Actigraphy equipment and materials for storage. The DCA machine, travel cart, Actigraphy watches, 3-ring site binder and all health measurement supplies were stored on-site with the collected blood samples in a secure, locked area at the worksite.

#### 13.7.5 Safeguarding Materials in the Respondent's Home

If interviewers worked multiple cases during one day, they were required to either (1) carry all case folders and confidential information with them as they interview study participants, or (2) lock them out of sight in the trunk of their car while in the field for the day. They used common sense in deciding which of these approaches to use in a given neighborhood to keep case materials secure. When in the respondent's home, interviewers did not let study participants view the case management system (CMS) display, which lists participant-specific information. If they carried confidential information for other cases into homes, these were stored securely in their briefcase, out of the respondent's or other household members' sight. Also, they were not allowed to discuss specific cases or participants with anyone other than their FS or other authorized project personnel.

When preparing to leave the respondent's home, interviewers conducted a careful check of all the case materials and belongings to ensure they were leaving with all materials and paperwork,

including the case folder, the laptop, other equipment, and completed study materials generated during the home visit (e.g., consent forms).

## 13.7.6 Protocol for Safeguarding Materials When Moving Residences

If interviewers moved residences during the data collection period, they needed to notify their FS at least one week prior to the move. Their FS worked with them to conduct an inventory of all case materials and project supplies and equipment in their possession before the move and discussed procedures for safeguarding the laptop and hard copy materials during the move. The FS helped the interviewer conduct another inventory when they arrive at their new residence.

Interviewers were required to keep the laptop, project equipment, supplies, and case materials in their possession during the move. Interviewers were required to also transmit all interview data before the move. Hard copy materials could either be kept in their possession or shipped to their FS for safekeeping until the move was completed. The interviewers' laptops, equipment, and case folders were not to be placed in moving boxes and handled by movers or family members. They treated case materials, folders, equipment and their laptop as they would with their wallet, pocketbook, or other sensitive materials.

## 13.7.7 Shipping Materials

Another way we protected against data loss was by checking the timeliness of case materials received by RTI from the field, and the timeliness of case materials transferred across field interviewers. This alerted us to items that may have been misplaced or lost. Being able to quickly identify these items improved the likelihood of recovery and enabled us to notify affected persons as soon as possible.

## 13.7.7.1 Protocol for Shipping Dried Blood Spot (DBS) Samples to Harvard

Each week the designated team leader prepared, packaged, and shipped the completed and dried blood spot cards to the Harvard team for storage and analysis.

At the end of the interviewer's shift or when there was sufficient down time, the interviewer prepared the blood samples for storage until transport. The dried blood spot cards were required to be completely dry before packaging. At a minimum, interviewers had to wait 15 minutes, and with saturated cards as many as 30 minutes for the card to be completely dry. It was important for the interviewer not to fold and close the collection card cover on a saturated card. Once the card was completely dry, the sample was placed in a bio-hazard specimen bag with a desiccant sack and sealed tightly. Each DBS card, once dry, was placed in its own specimen bag with desiccant. The bagged specimens were placed in the designated storage cooler kept in a secure location with the DCA machine and travel cart until they were shipped.

Samples were shipped weekly to Harvard where they were frozen until analyzed. Team leaders were provided with two different sizes of boxes for shipping the bloodspots. The larger box was used if there were more than 15 samples to ship; the smaller box was used if there were less than 15 samples to ship. Samples were only shipped from the field on Monday, Tuesday or Wednesday. This was to ensure that the samples would be physically received at Harvard prior to the weekend so that they were not sitting on a loading dock unattended. The team leader completed a 3-part NCR DBS Transmittal Form listing all samples included in the shipment, and

included one copy in the shipment. The team leader had to apply a provided pre-addressed, pre-paid mailing label to the package prior to providing FedEx the samples to be shipped.

## 13.7.7.2 Protocol for Shipping Actiwatches

The team leader prepared and shipped watches as requested by the Harvard team. Depending on the need, watches were either shipped from one team leader to another (working a different site) or back to the Harvard team for maintenance. To prepare watches for shipment, the team leader downloaded all watch data that may be on the watch and put the watch to sleep. Like shipping the blood samples, the watches were enclosed in a special shipper box to be shipped via Federal Express 2-day delivery. Shipping information was provided to the Harvard team and FS by e-mail for watch packages. The e-mail included information on 1) package contents (i.e., watch IDs of the shipped watches), 2) the shipping date, 3) the expected receipt date, and 4) the FedEx tracking number. The team leader also completed an Actigraphy watch transmittal form to include with the shipment. The watch package was never left in a FedEx drop box, but physically handed to a FedEx representative.

## 13.7.7.3 Protocol for Shipping Completed Case Folders

Case folders for completed cases were submitted to the FS on a weekly basis, once all components of the case had been finalized. Case folders for completed cases were subject to quality control review by the FS before submission to RTI. The FS checked the quality and completeness of materials and addressed any problems before the folders were sent to RTI. Case folders were due at RTI within 7 days of finalization of all required case components. Delinquent folders were monitored and tracked on a daily basis.

A Case Folder Transmittal form was included in the shipment to the FS. To complete this form, interviewers specified the 8-digit case ID of each folder included in the shipment. They were also required to write the FedEx tracking number used for the shipment, and the shipment date on this form. If an item was missing in a listed folder, interviewers explain the reasons why on the comment line. Interviewers kept a copy of the transmittal form to reference as needed.

Shipping was done via FedEx overnight delivery. Interviewers placed packages containing case folders in a FedEx drop box, or handed them directly to a FedEx employee. Interviewers could not leave packages at their door for pick-up, or allow FedEx to leave packages for them if they were not home. Interviewers were also required to sign for packages themselves.

Interviewers did not write the study's name or acronym on the outside of packaging. Shipping information was provided to their FS by e-mail, and included 1) the package contents including case IDs, 2) the shipping date, 3) the expected receipt date, and 4) the FedEx tracking number.

## 13.7.7.4 Protocol for Shipping Daily Diary Incentive Receipts

For accounting purposes, the Penn State team required a copy of each completed daily diary incentive receipt (from eligible families). Field interviewers were asked to ship completed daily diary incentive receipts to their FS each week. The FS tracked that all required receipts were received, and shipped these incentive receipts in batches to Penn State.

## 13.7.8 Security of Electronic Data

Field interviewers were responsible for securing all electronic equipment used in their work for this study. We had several methods of helping interviewers protect these data and equipment.

## 13.7.8.1 Password Protections

All WFHS laptops and case management and data collection applications were password protected. Laptops were secured with three levels of passwords: one for the encryption system (PointSec), one for Windows, and one for the CMS. Only authorized FSs and FIs could use the laptops. Interviewers had to carefully protect the password information, and were not allowed to carry a written copy of the passwords in the laptop bag, give the passwords to others, or leave the passwords where others could find them.

## 13.7.8.2 Use of Project E-mail Accounts

All WFHS e-mail communications were done using the field staff e-mail accounts established for the project. Interviewers were not allowed to use personal e-mail accounts to send/receive confidential study information. Only if absolutely necessary did FSs send e-mail with nonconfidential information to an FI's personal account as a back-up (for communication time-sensitive or urgent matters). If a personal e-mail account was used, the message could not contain any confidential information.

# 13.7.8.3 Protocol for Data Transmissions

Field interviewers were required to transmit every day they worked and at least three times each week (unless on vacation, ill, or unable to transmit for some other justifiable reason). All interview data was transmitted the same day the interview was completed. For additional security, completed interviews and transferred cases were removed from laptops once receipt was verified in-house and 24-hour back-ups occurred.

## 13.7.8.4 Security of Other Project Equipment

All other pieces of equipment (such as DCA machines, blood pressure monitors, scales, stadiometers, actigraphy watches, and barcode readers) were also handled with care. These items were purchased by the Work, Family & Health Network partners and/or RTI for the purpose of this study. Interviewers were responsible for ensuring their field equipment was used only by authorized persons for the intended purpose. These materials were stored securely in their home or at the worksite.

## 13.7.9 Protocol for Reporting Unanticipated Problems Involving Data Security and Confidentiality

An unanticipated problem was defined as any activity that potentially compromised the confidentiality of the study participants and/or the security of the data. This included problems such as the loss or theft of any confidential information, including case folders and signed consent forms, loss/theft of the laptop containing interviews or preloaded information, and the electronic transmission of any confidential information through any means other than their RTI account was also considered an unanticipated problem.

Chapter 14: Publications and Presentations Policy; Ancillary and Adjunct Studies Policy and Procedure

#### 14.6.1 Standard Acknowledgments

#### 14.6.2 Acknowledgement of the Network

The Work, Family & Health Network has been created based on the intellectual conceptualization and input of key federal staff (past and present) and the investigator teams of the Network. Although additional investigators may use our ideas or future data to test a variety of innovative projects and interventions, their capacity to do so will rely on the initial conceptualization constructed by the original Network members. In order to recognize this contribution, as well as to unite the various publications that stem from this valuable work, a standard attribution will be added to <u>ALL PUBLICATIONS</u> from <u>INDIVIDUAL AND COLLABORATIVE</u> projects associated with the Network. The following statement will be used:

This research was conducted as part of the Work, Family & Health Network (www.WorkFamilyHealthNetwork.org), which is funded by a cooperative agreement through the National Institutes of Health and the Centers for Disease Control and Prevention: Eunice Kennedy Shriver National Institute of Child Health and Human Development (Grant # U01HD051217, U01HD051218, U01HD051256, U01HD051276), National Institute on Aging (Grant # U01AG027669), Office of Behavioral and Science Sciences Research, and National Institute for Occupational Safety and Health (Grant # U01OH008788, U01HD059773). Grants from the William T. Grant Foundation, Alfred P Sloan Foundation, and the Administration for Children and Families have provided additional funding. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of these institutes and offices. Special acknowledgement goes to Extramural Staff Science Collaborator, Rosalind Berkowitz King, Ph.D. and Lynne Casper, Ph.D. for design of the original Workplace, Family, Health and Well-Being Network Initiative.

#### 14.6.3 Logo

Every individual and collaborative publication that can accommodate a graphic (e.g., posters, websites, at least the first page of PowerPoint presentations, etc.) should include the Network logo, located at www.WorkFamilyHealthNetwork.org

#### 14.6.4 Acknowledgement of our worksite partners

If allowable by the editors, publications should include the following statement:

We wish to express our gratitude to the worksites, employers, and employees who participated in this research and made this publication possible.

## 14.9 Intellectual Property Considerations

The Network holds public domain research as a primary value and usually places its intellectual products in the public domain. The Network may create intellectual property through its collaborative work (e.g., data collection instruments and measures, books) and all federal regulations apply to its ownership. In the event that commercial value is created by the intellectual property of the collaborative, grantee institutions that have participated in the collaborative will have joint ownership of the property. Anything of value created in the future should be distributed among the parties through an equitable process. Contractual arrangements should be made prior to distribution as far in advance as possible.

## 14.10 Conflicts of Interest

## 14.10.1 Conflict of Interest and Network Credibility

Public and employer trust in the research conducted by the Network and the credibility of our published work depends in part on how well conflict of interest is handled during all of our individual and collaborative work. Conflict of interest exists when a Network member (or Network member's institution) has financial or personal relationships that inappropriately influence (bias) his/her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his/her scientific judgment

### 14.10.2 Declaration of Potential Conflicts of Interest Related to Individual Network Member Commitments

When Network members or outside authors submit manuscripts, abstracts or presentations to the Publication Subcommittee, all authors must submit a statement disclosing all financial and personal relationships that might bias their work. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) should be identified because they have the potential to undermine the credibility of the Network's research. Conflicts can also occur due to personal relationships between researcher and the company and/or the researcher's university and the company. To prevent ambiguity, all authors must state explicitly (in writing) whether potential conflicts do or do not exist.

# 14.10.3 Potential Conflicts of Interest Related to Project Support or Agreements with Employer Partners

Due to the nature of our work, employers are often our research partners. They have allowed access into their workplace and have sometimes made changes in their workplace policies and practices due to our involvement. All have approved our presence in the workplace and some interests at stake in the outcome of the research. Furthermore, the companies may partially or fully subsidize the workplace intervention of interest to the Network.

In order to prevent conflict of interest, the following practices have been adopted by the Network:

1. Employers cannot provide financial compensation to investigators or research staff.

- 2. Employers cannot control the results of the study or its findings nor can they suppress findings prior to publication.
- 3. Clear understanding from the company of the independent right of the researcher to publish uncensored results will be documented prior to the beginning of all studies begun after the adoption of this policy.
- 4. Employers have the right to review manuscripts prior to publication and may withdraw authors employed by the company from the manuscript at any time prior to the publication of an article.
- 5. If authors disagree on interpretation of findings from a study and this disagreement causes the submission of the article to be significantly delayed, the first author on the article may remove an author from the byline.

## 14.11 Informed Consent

All projects within the Network obtain approval or waiver by all appropriate Institutional Review Boards prior to start up. This includes appropriate sign offs by employer-partner companies that require approval/waiver by ethics, privacy or institutional review boards.