

## **Proposal to Robert Wood Johnson Foundation For Investigator Award**

**Jennifer L. Hochschild  
Maya Sen**

**Harvard University  
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“There is in biology ... a sense of barely contained expectations reminiscent of the physical sciences at the beginning of the 20th century. It is a feeling of advancing into the unknown and [a recognition] that where this advance will lead is both exciting and mysterious” (Economist 2007). We propose to focus on one aspect of that advance into the unknown – the growth of politics, values, and policies in the United States around the use of genomic science in medicine and racial identity. We will examine three emerging phenomena: (1) links between genetics-based medicine and the social practice of race, (2) links between medicine and individuals’ access to genetics-based medical testing, and (3) the impact of individuals’ access to genetic information on their racial and ethnic identity. What is government’s role in managing the relationship between genetics-based medicine and race, or between medical professionals and individuals who have attained genetic information about their own health? Should governments regulate direct-to-consumer sales of DNA tests? What ideological and partisan valences are developing around this science, and why? Most importantly, how can government (and which levels or branches of government) support genomic research while protecting citizens from potential risks? We will examine how American elected officials and policy-makers address these questions.

### **I. Purpose and Orientation of the Study**

If research continues at its current breakneck pace, genomic science may change the way medicine is practiced in the United States. “Genotyping cost is asymptoting to free;” within a generation “it will be easier to know someone’s genome than their name” (Altman 2008). Under those conditions, medical treatment could become individualized, such that a doctor will tailor treatments to each patient’s genome. In that scenario, “race” – whether chosen by the patient or attributed to the patient by the doctor – becomes irrelevant. An alternative scenario, however, is suggested by the fact that in 2005 the federal Food and Drug Administration (FDA) approved the use of the drug BiDil for treating congestive heart failure – but only for self-identified African Americans. Other race-inflected medicines might follow.<sup>1</sup> In short, the use of genomic science in medicine may make race immaterial, highly salient, or possibly both.

Genomic science is also developing links to racial identity and ancestry in a different arena. Individuals can purchase knowledge of their genealogy through tests that purport to match their mitochondrial or Y DNA to those of a geographically identified sample. These “recreational DNA tests” provide eagerly-sought knowledge about hereditary links to a contemporary tribe or ethnic group, thereby permitting “affiliative self-fashioning” (Nelson 2008). However, they can also challenge a person’s beliefs about his or her racial or ethnic heritage. Newspapers are full of stories

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<sup>1</sup> The drug Iressa “is already an established therapy for pre-treated NSCLC [non-small cell lung cancer] in the Asia-Pacific region” – that is, it is a drug now being marketed to Asians. Iressa has very recently been approved for sale in western Europe ( <http://www.iressa.com/>).

about people such as Danny Villarreal, a Hispanic Texan who believed himself to be of Spanish descent. A DNA test showed him to be more closely related to Jewish populations in Hungary and Poland, thereby calling into question his Hispanic identification (Lomax 2005). Such challenges might variously foster multiracial bridge-building or lead to the “further politicization of ethnicity and further fragmentation of the African American community” (Rotimi 2003): 157) – or both.

In addition, direct-to-consumer DNA tests can call into question long-standing assumptions about familial relationships. An email forwarded over a genetic genealogy listserv suggests some of the issues at stake:

A female project member inquired about ... DNA testing resolving a paternity issue involving one of her brothers. It seems there is a possibility that this one brother may have been sired by her paternal grandfather, rather than her father. ... This member has results from Autosomal-STR Panels 1 & 2, with Panel 3 on order. [W]ould [it] be worthwhile to have the brother in question order the Autosomal-STR Panels? Also, would it be worthwhile to test additional siblings?

This scenario is, of course, private and not an issue relevant for policy makers or the public arena. But increased regulation, and its opponents, are not far away: “A small but vocal group of scientists and legislators are clamoring for government regulation of DNA testing. A few states have already succumbed to this hysteria, and Washington has dipped its toe into the murky waters” [(Wheeler 2009); see also (Lee et al. 2009); (House of Lords Science and Technology Committee 2009)].

Other issues of knowledge and privacy quickly arise, especially as “genotyping is asymptoting to free.” A few hundred dollars gives a consumer information – correct, complete, or not -- about her risk of developing Huntington’s or Tay-Sach’s disease, or breast, ovarian or colon cancer. Similar tests can provide information – again, correct, complete, or not -- on a fetus’s genetic abnormalities or risk for certain diseases. A patient’s right to know, or even her responsibility to obtain, such potentially frightening information is itself contentious and uncertain. This right (or responsibility) to know will be even more complex in cases involving disputes with family members, employers, physicians, or insurance companies; questions will continue to rise about who must, may, or may not have access to this information.<sup>2</sup>

Up to now, use of genetic information has been lightly regulated. The new Genetic Information Nondiscrimination Act of 2008 (GINA) is just taking effect, and its eventual impact remains unknown. Neither political party has taken ownership of the issue: GINA passed the Senate unanimously and the House of Representatives with only one dissent. The FDA’s approval of BiDiL garnered both strong support and furious opposition from those focused on American racial dynamics. Genealogical DNA testing and the use of DNA testing to study human diversity evoke similar enthusiasm and anxiety [(Gates 2008); (Reardon 2001); (Rimmer 2007)]. Court cases addressing medical or individual uses of genomics are rare, and politicians’ comments even rarer. Francis Collins’ nomination as director of the National Institutes of Health clearly signals the Obama Administration’s support for genomics research, but Collins has yet to take office and the extent of his influence has yet to be felt.

Nevertheless, any phenomenon as important as genomic science will develop a partisan valence, normative dimensionality, and policy and regulatory structure. Consider the growth of

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<sup>2</sup> The genomics revolution has other societal manifestations. Courts use DNA evidence to re-open criminal cases and exonerate those wrongfully convicted. Forensics investigators have used genetic information to identify victims of political events such as the Srebrenica massacre and tragedies such as the felled Air France Flight 447. Private individuals and firms are using DNA evidence to breed animals, test the quality of fish in sushi, engage in matchmaking, and produce “personalized artwork.” These uses of DNA will themselves develop political valences and evoke regulatory policies. Since they are outside the arenas of health care and health policy, however, we do not address them here.

embryonic stem cell research; opinions about stem cell research quickly became linked to views on abortion and family dynamics, with subsequent policy impact. Genomics research is equally important for society and just as personal, but its political, ethical, and policy ramifications are only now beginning to take shape. This slow development permits us to explore how innovations in genomics research are moving into the public arena. Rarely do scholars have the chance to watch a new policy regime emerge, especially in a field so important to Americans' health and self-understanding.

To benefit from this opportunity, we will examine the growth of normative and partisan positions on 1) the simultaneous expansion of race-based and individualized medicine, 2) firms' and organizations' direct provision of ancestral genomics information to consumers, and 3) various actors' access to genetic medical information. We will then analyze the trajectory of policies and regulations in these areas, as well as relevant court cases. Finally, we will examine the emergence of public opinion about the links between genomics and medical care, genomics and racial identity, and genomics and health-related information. By tying public opinion back to partisan and normative developments, we can bring the analysis full circle.

This is an expansive agenda, and our ability to accomplish it rests on two pillars. The first is that we will address all three substantive issues through the same analytic lenses, explained below. The second pillar, ironically, is the fact that there has been little social science research or political and policy action. We are in the enviable position of studying an emerging policy area.

*Conceptual Framework:* Each of the three emerging phenomena demonstrates distinct tensions, policy questions, and plausible political valences.

*1) The simultaneous expansion of race-based and individualized medicine:* The benefits of physicians' eventual capacity to ignore "race" and focus directly on a patient's individual genetic profile are obvious for everything ranging from an infant's response to jaundice treatments ((Beal et al. 2006) to an adult's response to cancer treatments (Nathan 2007). But there are potential drawbacks. Some scholars fear that focusing on a patient's genome will lead physicians to pay insufficient attention to the patient's racialized social environment – which might be just as important in disease etiology and cure as are genetics (Krieger 2005). Ignoring race thus could lead doctors to overlook the role of racism in causing (or maintaining) poor health.

Conversely, if BiDiI is any indication, medicine might simultaneously become increasingly racialized. Some experts warn that this innovation might imply government endorsement of the biologization of race, bringing with it connotations of eugenics, the risk of claims to finding a "gene for violence," and inattention to social causes of disease [(Kahn 2005; Journal of Law Medicine and Ethics 2008)]. But others dismiss such fears on the grounds that "passion directed against this paradigm ["race as a descriptor of drug efficacy"] is misguided, as the consequences of persistent argument and debate unfortunately are persistent disease and premature death" of African American heart patients (Yancy 2007). So far at least, political configurations in this arena cut across conventional partisan and advocacy lines. Normative positions on the connections between race and medicine are underdeveloped and uncongealed. There is no convergence yet on the "liberal" (or "conservative") stance on the relationship between race and medicine [(Epstein 2007); (Roberts, D. 2006)] and no cohesive "white" or "minority" viewpoint (Singer et al. 2004).

Policies are similarly underdeveloped. The FDA defends its approval of BiDiI (Temple and Stockbridge 2007), but has yet to approve other race-specific medications. The National Institutes of Health sponsor research on genome sequencing, while seeking investigators' advice on "how should funding agencies encourage the application of [genome] sequencing and sequence data to the study of human health issues?" (Guyer and Felsenfeld 2009). Then-Senator Barack Obama twice introduced the Genomics and Personalized Medicine Act, which would have allocated funds to

genomics research and modernized the FDA's review of genomic tests. The bill had no co-sponsors the first time, and only one (a Republican) the second time; no committee held hearings. This policy arena will eventually become dense as its impact on health care deepens; we seek to study its early stages.

*2) Firms' and organizations' direct provision of ancestral genomics information to consumers:*

DNA tests are enabling people to find ancestral groups, to discover their mixed and unknown racial heritages, and to find genetic links to previously unrecognized family members. Some argue that these new capacities are or could be prying open Americans' artificial and debilitating racial categories, deconstructing the concept of race and pushing us to recognize our shared ancestry (Hitt 2005). Others, however, fear that "the use of markers for individual identification" risks "the subtle, sometimes inadvertent, reinscription of race at the molecular level" [(Duster 2006); see also (Palmie 2007); (El-Haj 2007)] . Not only "race" in the abstract, but extant racial categories might be further reified (Fullwiley 2007) – or, conversely, dangerously undermined. In short, ancestry testing might re-biologize race, reify racial categories, harmfully dissolve group solidarity, beneficially soften group boundaries, permit emotional attachments to one's ancestral roots and/or provide a distorted sense of a historical linkage. Liberals and conservatives, whites and non-whites, scholars and activists currently espouse all of these positions – while the voices of politicians or policy-makers are scarce.

But not for long. A recent article in *Science* urges regulation on the grounds that "direct-to-consumer genetic ancestry tests ...[have] little oversight and few industry guidelines to ensure the quality, validity and interpretation of information sold" (Lee et al. 2009) . The states of New York and California have used existing medical practice regulations to send cease-and-desist letters to commercial genetics testing firms on the grounds that the commercial firms are beginning to merge medical testing with ancestry testing. Intense debate immediately ensued over the normative standing of genetic information and the polity's appropriate regulatory role (Madrigal 2008) . The legal status of regulation is uncertain (Genomics Law Report 2009) and public opinion on the topic is not settled.

*3) Various actors' access to genetic medical information:* Although this issue has the most developed policies and cohesive normative structure of our three substantive arenas,<sup>3</sup> it is both intrinsically important and a useful comparison for the first two substantive areas. The issue of individual access to genetic medical information is linked to the issue of race in medicine because it directly involves health care, and it is linked to the issue of ancestral testing because it involves individuals garnering information outside any institution or set of consolidated practices. Whether policies in the other arenas will follow the path set by policies already being developed in the area of personal genetic medical information will be an important focus of our research.

Nevertheless, this arena has its own distinctive tensions and unsettled features. Individuals are likely to be torn between the desire to know their genetic medical profile and the fear of that knowledge, between seeking all information that could enhance the health of family members and resisting pressures from or about family members. They may simply not understand "complex, uncertain information" (Lee et al. 2001): 35). Public officials or courts will need to clarify if parents have full rights to obtain and use genetic medical information about their children or fetuses, or whether offspring have countervailing rights. Physicians may need guidance, and even legal protection, in treating patients with a great deal of (perhaps false, incomplete, or misunderstood) information [(Hunter et al. 2008); (Board on Health Sciences Policy 2009)]. GINA is unlikely to be

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<sup>3</sup> For an overview of laws and regulations, see NHGRI's Policy and Legislation Database, <http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>.

the last word on the use of genetic information in health insurance and employment contexts, or on the balance between federal and state protection [(Roberts, J. forthcoming 2010); (Tobin 2009)].

Political ownership of and normative valences in the issue are, as in the other two arenas, only beginning to emerge. For example, libertarians and political liberals presumably agree in supporting individuals' right to attain genetic information, but disagree on whether and how the government should regulate employers, insurance companies, and firms selling DNA tests. Conservatives may be torn between religiously-based opposition to interfering with genetic inheritances and ideologically-based opposition to government regulation of personal decisions. As before, public opinion is still too nebulous to influence politicians' decisions.

Each research arena, in short, will generate distinct political configurations, policy debates, and normative concerns. The arenas are nevertheless substantively connected through their shared focus on the personal and medical impact of genomics research. We will also link them thematically with three analytic questions:

a) *What are actors' attitudes toward genetic research and innovation?* One possible stance is "technology optimism," defined as "underestimation and neglect of uncertainty" in favor of "widely shared speculative promise" (Hjorleifsson et al. 2008): 379). Scientists are enthusiastic about their discoveries – Mary Claire King describes her laboratory researchers as "banging down the doors at 7 a.m. so they can get to work" – and potential users may be close behind. Entrepreneurs seek profit; doctors seek diagnostic and prescriptive information; patients seek cures; individuals seek roots and family ties. Technology optimism will lead public officials to provide financial resources as with NHGRI, licensing as with the FDA, and innovative laws as in Obama's Genomics bill.

The other end of this attitudinal continuum is "technology pessimism," defined as overestimation of risk and harmful impact, and insufficient attention either to benefits or to people's ability to respond appropriately to risk. Pessimism may be as appropriate as optimism; genomics science is more complex than initially anticipated, the medical benefits much farther off [(Wade 2009); (Carey 2009)] and arguably inappropriate uses already documented [(Council for Responsible Genetics 2008); but see (Otlowski et al. 2003)].

Technology pessimism might lead officials to emphasize regulation, to withhold approval of controversial new drugs, and to move cautiously in reconfiguring relevant federal or state agencies. It will also lead courts or regulatory bodies to limit misuse of genetic information, as in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* [135 F.3d 1260 (9<sup>th</sup> Cir. 1998)] or *EEOC v. BNSF* (no published case).

b) *How are attitudes, normative values, and political commitments diffused?* One possible dynamic is that attitudes and information flow from experts to nonexperts. Researchers, doctors, and genealogists will inform citizens and policy actors about the genomics revolution. They will explain what is known and hypothesized; they will explicate what they see as appropriate controversies and deflect attention from what they see as mistaken presumptions. Most generally, experts will provide enough useful information so that nonexperts will have consistent normative positions, grounds for their degree of technology optimism, and coherent policy goals. From this starting point, political and partisan alliances would develop in predictable ways.

At the other end of this continuum lies the possibility that idiosyncratic circumstances will shape initial attitudes, which in turn would be diffused through political channels. A particular court case, a patient's publicized dilemma, an ancestral discovery, or a family dispute will capture the public's or an advocacy group's attention. Elected officials and perhaps even policy makers and judges will follow suit (Grossback et al. 2004). Biomedical experts will try to show that this is the wrong concern, or that the inferences drawn from what is arguably a legitimate concern are mistaken. This kind of diffusion may lead to a different policy agenda, partisan configuration, or set of

normative judgments than the expertise-driven diffusion described above. It will not necessarily be less rational or even less appropriate, but it will be different -- following a democratic political logic rather than an elite-framed scientific logic.

*c) Links to other issues, policies, and values:* We have so far emphasized the innovative nature of genomics research and its possible implications for new forms of health care, health policy, and racial dynamics. But no policy arena or political dispute is completely new, and no normative commitment stands alone. People reason through analogy and experience. So the third theme cutting across all three substantive arenas of research is the ways in which the issue is understood as “like” or “not like” a more fully established issue.

A thematic continuum is once again useful. On one end, people will see genetic information as transformative. Doctors will change their diagnosis or prescription; individuals will shift their identities to accommodate a more multiracial ancestry or a deeper link to a particular tribe or ethnic group; people will make medical or family decisions in response to new knowledge about their genetic risk factors (Elton 2009). Politicians and policy-makers will emphasize their break with the past, as did then-Senator Obama with his Genomics bill and as Francis Collins might do in setting funding priorities at the NIH.

On the other end of this continuum, people will assimilate biomedical genomics research and ancestry information into extant practices, values, and understandings (Singer et al. 2005). Doctors will use genetic information only insofar as it dovetails with established medical practices (Paradies et al. 2007). Individuals will assimilate DNA-based genealogical information into rooted identities. Parents will decide about bringing a fetus to term in accord with religious convictions regardless of new medical knowledge. Politicians and policy-makers will rely on precedent to make only incremental policy changes, as agencies in California and New York apparently did in regulating direct-to-consumer DNA testing firms. At a more global level, both the public and policy actors will come to understand genomic science in terms of extant categories – for example, through the lens of debates over stem cell research or extant laws on privacy and patients’ rights.

*Products and Dissemination:* We will write 1) several conference presentations, and eventually peer-reviewed articles, for an academic audience, 2) a full-length book aimed at a broader audience of policy actors and the informed public, and 3) intermittent essays and articles for a general audience. As we develop policy recommendations, we will be available to consult with policy makers, elected officials, research organizations, journalists, and others.

The conference presentations and journal articles are likely to be methodologically framed, as described below (that is, an article on results from the public opinion survey, an article on interviews with one or several sets of actors, etc.). Each will analyze one substantive issue (race and medicine, ancestral searches, individual medical information) in terms of the three themes (technology optimism, diffusion of views, and links to other issues). One or more articles will directly discuss health policy recommendations.

In contrast, book chapters will be substantively framed, with one chapter each on the politics and policies of race and medicine, ancestral searches, and individual genetic medical knowledge. Two additional chapters will explore the politics and policies involved in using genomics in forensics and the criminal justice system, and in the more exotic or frivolous uses of genomics in society. Each substantive chapter will be organized in terms of the three analytic themes, and they will use mixed methods. The book will conclude with recommendations for health policy and their justifications.

## **B. Research Design**

We propose a mixture of quantitative and qualitative methods:

(1) *Public opinion surveys.* The General Social Survey (GSS) is currently conducting pretests on thirteen new items on genomics, proposed earlier this year by Jennifer Hochschild, Eleanor Singer, and Gail Henderson. (Four additional items were used in earlier years, so have no need for pretesting.) Final decisions on items for the 2010 (and later) GSS depend on funding and pretest results, but these questions will probably be included (see Appendix A). Previously asked questions on genetics are also available for analysis.

Jennifer Hochschild has also submitted a proposal to the Time-sharing Experiments for the Social Sciences (TESS) for two survey experiments. The first will explore public attitudes toward various uses, and users, of genetic information, particularly in the medical arena. The second will examine respondents' views about racial boundary blurring and strengthening through recreational DNA tests. The proposal has received an encouraging offer of "revise and resubmit." Appendix B provides the first version of proposed TESS items.

We propose to use RWJF support to mount a survey following up on these two initiatives. Building from the GSS and TESS results, it will focus on the particular substantive arenas and thematic questions developed in this proposal. For example, the 2010 GSS will presumably include two policy questions, asking if the government should regulate and/or provide financial incentives to encourage genomic science. Our new survey will include a wider array of policy questions, probing respondents' views on governmental regulation or encouragement of individual medical genetic testing, social or ancestral testing, medical professionals' use of genetic information for diagnosis and treatment, and so on. It will probe views about who has the right and responsibility to obtain and use genetic medical information – the individual, his or her family members, employers, the courts, etc. It will examine more fully than previous surveys have done respondents' knowledge about genetic medical research and use [(Lanie et al. 2004); (Sheldon et al. 2007)], and their expectations or experience of use. Probably through a series of individually tailored vignettes, the survey will explore ways in which respondents' racial or ethnic identity might be reinforced, changed, or expanded as a result of ancestral testing. The survey will include items about technology optimism and pessimism, and about respondents' perceptions of appropriate analogies or comparisons in the medical, social, and scientific arenas.

We anticipate about 30 questions. We do not include specific items in this proposal because we want to use the results from GSS and TESS, as well as from other genetics-related surveys in the U.S. and Great Britain, as a starting point for the new survey. The sample will be a nationally representative sample of adult Americans, in English and Spanish, with oversamples of blacks, Asians, Latinos, and Native Americans. The survey will include sufficient demographic, political, religious, and normative items so that we can link respondents' views on genomics and health policy to their broad concerns and circumstances. (Some of these data will be provided independently of our own 30-item module. See Appendix C for Letter of Intent from Knowledge Networks; it contains additional information about the survey.)

(2) *Interviews with scientific and public elites:* We will conduct interviews with approximately 100 experts, divided as follows: ten medical genetics researchers or physicians leading relevant associations; ten representatives of insurance companies or employers and managers or owners of direct-to-consumer firms; ten journalists, journal editors, or academic center directors; ten actors in the legal system; thirty elected officials (or members of their staffs); and thirty appointed officials. Interviews of elected officials and policymakers will be divided among the federal government and three states (California, New York, and Massachusetts) in which regulation has been enacted or is under consideration.

Precise questions will be tailored to the respondent, but interviews will explore knowledge of and views about:

- current and foreseeable uses of patients' genomic profiles in medical diagnosis and prescription, including the relationship between these profiles and other information on the person's race or ethnicity
- current and foreseeable licensing and use of race-specific medications;
- quality and quality control of direct-to-consumer DNA testing firms;
- relevant laws, regulations, and legal decisions in all three arenas;
- content and quality of information disseminated to the public by the media, medical professionals, and government officials;
- individuals' rights and responsibilities with regard to genetic information about themselves, fetuses, and family members;
- employers' and insurance companies' rights and responsibilities with regard to genetic information of current or potential workers and clients;
- current and foreseeable political configurations for using genomics research in medicine and by private consumers;
- their own and others' normative underpinnings in evaluating use of genomics research in medicine and by private consumers; and
- their own policy preferences with regard to our three substantive issues.

In addition to direct questions, we will leave time for more speculative or ruminative comments; in our experience, free-wheeling conversation (often at the end of an interview) can produce intriguing and important observations. Each interview will be taped (with the cooperation of the respondent), transcribed, and analyzed qualitatively and with appropriate content-analysis software.

*(3) Media treatment of uses of genomics research:* We are not requesting RWJF support for this analysis, but we want to note a current research project that will inform the two research procedures just described. In a paper now being revised for journal submission, we examine media treatment of the developing politics and ideology of racialized versus individualized medicine, and the politics and ideology of racial boundary-blurring versus solidification in DNA ancestry tests. We treat media reports as the vehicle for shared public communication and education. We have collected every article in Lexis-Nexis through 2007 using keywords "DNA and medicine" and "DNA and race" (and similar terms). We are conducting content analyses and cluster analyses of these approximately 60,000 unique articles, using new software being developed in Harvard's Institute for Quantitative Social Science. An early version of the paper was presented at the Midwest Political Science Association's annual meeting in April 2009, evoking comments such as "fascinating" and "wow." Results from the media analysis will be woven into the articles, essays, and book emerging from the RWJF project.

*(4) Advisory Committee:* Because we are social scientists, not medical professionals or geneticists, we plan to convene an advisory committee composed of genomics experts. The committee will provide advice on the direction, research methodology, and scientifically grounded conclusions of this project. It will include approximately eight members -- roughly half from within the Harvard community and half from other universities and research centers. We will ask the advisory committee to meet twice, after the elite interviews have been completed and after article drafts or the book manuscript have been prepared. We will also solicit their advice informally along the way, for issues such as who else to interview or whether proposed survey items are scientifically valid. We are waiting to contact potential advisory committee members until after the decision by RWJF, but we envision scholars such as Mary Clare King, David Altshuler, Eric Lander, Allen Counter, Nancy Krieger, Hank Greely, Richard Kittles, and George Church.



### **C. Policy Contributions**

In addition to the political and normative framing of each substantive arena, we envision three contributions to health policy:

*Policies regarding the appropriate role of race in drug approval and medical diagnosis or prescription:* Our research will seek ways in which public officials can help medical practitioners best link patients' individual genetic profile with their racial and ethnic identification, social setting, and treatment plan. At one end of the policy spectrum, we will propose guidelines for FDA approval of race-specific medications, focusing on the question of how much impact should "the intersection of racial consciousness and sub-population methods" have in "allowing a drug to be approved that otherwise would not have been approved" (personal communication with authors, 7/21/09). On the other end of the policy spectrum, we will propose guidelines for hospitals and medical practices in engaging with patients' often complicatedly mixed racial and ethnic ancestry. We will suggest regulations and incentives to help medical professionals link individual genomic information to the situation of patients in their social settings, such as promoting systematic communications about community racial dynamics between medical personnel and local authorities, clergy, and neighborhood associations. The goal will be to promote full use of a patient's genomic information while avoiding the many concerns that have been expressed about either reifying race or ignoring racial dynamics in society.

*Education and training:* That a well-functioning democracy requires citizens and decision makers to be reasonably scientifically literate is a cliché – but nevertheless an appropriate aspiration. We cannot develop specific curricula for the varied users of the new biomedical science. But we will propose policies to promote or mandate acquisition of essential knowledge in genomic science in medical schools, law schools, K-12 schools, and universities. We will also propose policies to help educate currently practicing judges, doctors, journalists, agency staffers, and politicians on the ways in which genomic science affects the public's understanding and practice of race, and individuals' relationships with doctors, family members, employers, and health insurance companies. To choose only one example, how do people in various positions need to reorient their understanding of medical treatment and health care policy if we move away from a focus on "the generic patient" or population averages, and move toward group-specific medicine, individualized treatment, or engagement with patients who have independent access to their own genetic profile?

*Policies regarding the use of information about individual DNA profiles:* Extant laws and regulations regarding privacy rights leave out some issues. Building on current proposals and a few states' experience, we will formulate policies for how or how much government agencies should regulate consumers' access to information about themselves, fetuses, or family members. We will develop similar guidelines for promoting appropriate responses by medical professionals' to individuals who attain genetic information and want it to be used in diagnosis or prescription. We will focus partly on guidelines for courts, since this set of issues will surely involve judicial adjudication.

### **D. Principal Investigators' Qualifications**

Jennifer Hochschild conducts research in American politics, social policy, normative political philosophy, and race and ethnicity. She holds the Henry LaBarre Jayne Chair in Harvard University's Department of Government, a joint appointment in the Department of African and African American Studies, and a lectureship at the Harvard Kennedy School. She is also a Harvard College Professor.

Previously, Hochschild held joint appointments for almost twenty years in Princeton University's Politics Department and Woodrow Wilson School of Public and International Affairs. She has written and taught extensively on school desegregation, education reform, social welfare policy for children, race policy, and policies for incorporating immigrants.

Hochschild's most relevant professional appointments are memberships on the Board of Trustees of the Russell Sage Foundation for a decade, and on the Board of Overseers of the General Social Survey for two terms. She has extensive experience in designing and overseeing survey research, and in evaluating policy-relevant research. Hochschild also has considerable experience in conducting elite interviews. She was a commentator on Professor Mary Claire King's Harvard Tanner Lectures on the ethics of the genomics revolution, and a chapter in her current book manuscript addresses the role of genomics in constructing and deconstructing American racial classifications and identities. Finally, in 2011, Hochschild will occupy the Library of Congress's John R. Kluge Chair in American Law and Governance, allowing her to conduct interviews with federal officials and participate in relevant events in Washington D.C.

Maya Sen is a doctoral candidate in the Department of Government at Harvard. She graduated in 2004 from the Stanford Law School, and brings legal experience to the project. Her published work includes a legal analysis of a key federal court case, *Rainier v. Union Carbide*, involving genomics issues. Sen's research focuses on race and politics, judicial politics, and political methodology. She is an affiliate of Harvard's Institute for Quantitative Social Science and holds the Terrence M. Considine Fellowship in Law and Social Sciences. Along with Hochschild, she is the co-author of the project on media treatment of race and medicine.

## **E. Project Schedule**

*Rest of 2009 and spring 2010* (not covered by RWJF award): continue literature review; submit article draft on media treatment of race, medicine, and genomics.

*Summer 2010*: analyze GSS and TESS surveys

*Fall 2010*: develop interview schedules and new survey items. Conduct state-level interviews, and begin interviews with genomics researchers and physicians.

*Winter and spring 2011*: conduct rest of interviews and oversee professional implementation of survey.

*Summer 2011*: transcribe interviews, and develop coding schemes and software. Begin analysis of survey results.

*Fall 2011 through fall 2012*: Complete analyses, and draft articles, essays, and book chapters. If possible, we will complete the non-RWJF research on courts' and forensic use of genomics research, and on popular uses.

*2013*: complete book draft and submit it for publication

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## **Appendix D: Examples of individuals or positions for elite interviews**

### *1. Medical genetics researchers or physicians leading relevant associations*

Eric Lander, Founding Director, Broad Institute of MIT and Harvard  
David Altshuler, Founding Director, Broad Institute of MIT and Harvard  
Mary Claire King, Professor of Genome Sciences and of Medicine (Medical Genetics),  
University of Washington  
George Church, Professor of Genetics and Director of the Center for Computational  
Genetics, Harvard Medical School  
Kim Allan Williams, Chair of the Board, Association of Black Cardiologists  
Edward McCabe, President, American Society of Human Genetics  
Christopher Cunniff, Director, Vice-President/President-Elect, American Board of  
Medical Genetics  
Heather Hampel, President, American Board of Genetics Counselors  
Bruce Korf, President, American College of Medical Genetics

### *2. Representatives of insurance companies or employers, and managers or owners of direct-to-consumer enterprises*

Michael Eastman, Executive Director for Labor Policy, U.S. Chamber of Commerce  
Matthew Rose, Chairman, President & CEO, Burlington Northern Santa Fe Railway  
Linda Avey and Anne Wojcicki, Co-Founders, 23andMe  
Rick Kittles, Founder, African-American Ancestry, and Associate Professor of Medicine,  
Ohio State University  
Spencer Wells, Director, Genographic Project, National Geographic Society

### *3. Journalists, journal editors, or academic center directors*

Amy Harmon, National Science Correspondent, *New York Times*  
Gina Kolata, Health Correspondent, *New York Times*  
Cynthia Morton, Editor, *American Journal of Human Genetics*  
Emily Niemitz, Senior Editor, *Nature Genetics*  
John Carey, Editor-in-Chief, *American Journal of Medical Genetics*  
Edward Hutchinson, Publications Director, *Journal of Law, Medicine, and Ethics*  
Kathy Hudson, Director, Genetics and Public Policy Center, Johns Hopkins University  
Georgia Dunston, Founding Director, National Human Genome Center, Howard  
University  
David Magnus, Director, Center for Biomedical Ethics, Stanford University  
Mark Rothstein, Director, Bioethics Institute, University of Louisville School of  
Medicine

### *4. Actors in the legal system*

Hank Greely, Professor of Law and Professor, by courtesy, of Genetics, Stanford  
University  
James Evans, Professor of Genetics and of Medicine, University of North Carolina  
School of Medicine  
Barry Schenck and Peter Neufeld, Co-Directors, Innocence Project

Hon. Gladys Kessler, Judge, U.S. District Court for the District of Columbia  
Paul Miller, Professor, University of Washington School of Law (and former  
Commissioner, Equal Employment Opportunity Commission)  
Adam Doerr and Kate Payerle, attorneys at Robinson Bradshaw & Hinson, and  
contributors to “Genomics Law Report” (blog)  
Jeremy Gruber, President, Council for Responsible Genetics

## *5. Government officials*

### *Federal:*

Rep. Louise Slaughter, U.S. House of Representatives, D-NY, GINA Sponsor  
Sen. Olympia Snowe, U.S. Senate, R-ME, GINA Sponsor  
Francis Collins, Director (Nominee), National Institutes of Health (and former Director,  
National Human Genome Research Institute [NHGRI])  
Alan Guttmacher, Acting Director, NHGRI  
Mark Guyer, Director, NHGRI, Division of Extramural Research  
Eric Green, Scientific Director, NHGRI  
Vence Bonham, Senior Consultant to the Director on Health Disparities, NHGRI  
Elizabeth Thomson, Program Director, Ethical Legal, and Social Implications Research,  
NHGRI  
Munir Khoury, Chair, Office of Public Health Genomics, Centers for Disease Control  
Joshua Sharfstein, Deputy Director, FDA Center for Drug Evaluation and Research  
Division  
Jesse Goodman, FDA Acting Chief Scientist  
David Blumenthal, National Coordinator for Health Information Technology

### *State:*

Karen Nickel, Chief, Laboratory Field Services, California Department of Public Health  
Bea O’Keefe, Section Chief, Facility Licensing, California Department of Public Health  
Steve Teutsch, Chair, Secretary of Health and Human Service’s Advisory Committee on  
Genetics, Health, and Society, and Chief Science Officer, Los Angeles County  
Department of Public Health  
Ann Willey, Director, New York State Department of Health Office of Laboratory Policy