

Relevant Training at HMS to Address Requirements for Formal Instruction in Rigorous Experimental Design and Transparency to Enhance Reproducibility

NOT-OD-16-034 provides notice of NIH's new Requirements for Formal Instruction in Rigorous Experimental Design and Transparency to Enhance Reproducibility for training grants, career development awards, and individual fellowships. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-034.html>

For Fellowships a "more detailed description of instruction in rigorous experimental design to ensure reproducibility will be required in the section on Institutional Environment and Commitment to Training" Thus, the requirement for formal instruction also applies to postdoctoral fellows applying for an F32, and thus, departments will need to have formal instruction if the school or University does not provide a generalized training course.

Relevant Annual Workshops for HMS Postdoctoral Fellows

Experimental Design for Postdocs (4h)

Workshop Speaker: David Glass, MD, Executive Director, Muscle Diseases, Novartis Institutes for Biomedical Research and Lecturer, Department of Cell Biology, HMS

Description: Before generating publication quality data, researchers must focus on proper experimental design. In this half-day course, postdocs will be reintroduced to the concepts of asking when, how, and whether hypotheses or questions should be used to frame experiments, and how these frameworks may perturb experimental design and interpretation.

This half-day course will cover the following topics:

- I. Experimental Frameworks
- II. System Validation
- III. Experimental Controls
- IV. Data Gathering, Interpretation & Model Building

Based on elements from Glass' book and Cell Biology Course entitled "Experimental Design for Biologists".

Research Irreproducibility: The Seven Deadly Selection Biases (2h)

Workshop Speaker: Xiao-Li Meng, PhD, Dean, Graduate School of Arts and Sciences, and the Whipple V.N. Jones Professor of Statistics, Harvard University

Description: This talk provides a statistical perspective on the roles the seven S's (sins?) play in increasing the amount of irreproducible research, in medical and life sciences and beyond:

- Selections in hypotheses (e.g., subgroup analysis);
- Selections in data (e.g., deleting "outliers" or only using "complete cases");
- Selections in methodologies (e.g., for goodness of fit);
- Selections in due diligence and debugging (e.g., triple checking only when the outcome seems undesirable);
- Selections in publication (e.g., only when p -value < 0.05);
- Selections in reporting/summary (e.g., suppressing caveats);
- Selections in understanding and interpretation (e.g., our preference for deterministic, "common sense" interpretation).

The Big Data Paradox and Simpson's Paradox will be used to demonstrate that the problem of irreproducible research is getting BIGGER with Big Data. A cocktail treatment approach together with a selfish/blowfish test is suggested to combat this problem.

Relevant Courses for HMS Graduate Students

***Cell Biology 302qc. Advanced Experimental Design for Biologists**

Catalog Number: 91286 Enrollment: Limited to 24.

Instructors: Randy King (Medical School) and David Jonathan Glass (Medical School)

Quarter course (spring term).

Description: Theory and practice of experimental design. Build on principles from experimental design boot camp. Conducted in workshop setting to apply those principles to current student projects. Emphasis placed on interpretation and strategic project planning.

***Genetics 391qc. Advanced Experimental Design in Genetics**

Catalog Number: 70918 Enrollment: Limited to 8.

Instructors: Fred Winston (Medical School) and members of the Department
Quarter course (spring term).

Description: To be run concurrently with Genetics 390qc. Students will have the opportunity to design experimental approaches that aim to answer specific questions in the field of genetics. Combined with the hands-on laboratory experience of Genetics 390qc, students will use their knowledge of experimental methods and data analysis with a variety of model organisms and techniques. Over the two-week course period, students will be asked to reflect daily on their experiences and design two unique experiments that will broaden their experience in the areas of hypothesis testing and data interpretation.