



# Division of Clinical Research



## ANNOUNCEMENTS

### [Responsible Conduct of Research Program at MGH](#)

Responsible conduct of research (RCR) training is required of students, trainees, and investigators with career development awards who are supported by NIH funds. In addition, the National Science Foundation (NSF) requires RCR training of undergraduates, graduate students and postdoctoral fellows with any NSF support.

In order to fulfill the RCR training requirement Partners developed a curriculum that must be completed by all awardees. Once the Partners Program is complete awardees must obtain an additional 4 credits. MGH offers sessions that are RCR-credit eligible to complete the remaining 4credits (1 credit = 1 hour).

<a href="#">QI Bootcamp</a>	February 3   10:00-12:30pm Garrod/Mendel
<a href="#">Academic Medicine, Industry and Collaborative Research in the Era of Emerging Technologies and Precision</a>	February 25   1:00-2:00pm   CNY 149
<a href="#">Academic Medicine, Industry and Collaborative Research in the Era of Emerging Technologies and Precision</a>	February 27   10:00-11:00am   Simches 3.120
<a href="#">QI Bootcamp</a>	March 2   10:00-12:30   Garrod/Mendel
<a href="#">The Lab: Avoiding Research Misconduct</a>	March 12   2:00-3:00pm   Simches 3.120
<a href="#">The Lab: Avoiding Research Misconduct</a>	March 13   12:00-1:00pm   CNY 149
<a href="#">Responsible Authorship and Publication</a>	March 10   1:00-2:00pm Simches 3.120
<a href="#">QI Bootcamp</a>	April 6   10:00-12:30   Garrod/Mendel
<a href="#">Mentor and Mentee Relationships and Responsibilities</a>	April 14   2:00-3:00pm   Simches 3.120
<a href="#">Mentor and Mentee Relationships and Responsibilities</a>	April 17   12:00-1:00pm   CNY 149
<a href="#">QI Bootcamp</a>	May 4   10:00-12:30   Garrod/Mendel
<a href="#">QI Bootcamp</a>	June 1   10:00-12:30   Garrod/Mendel
<a href="#">Research Integrity and Data Management</a>	June 22   1:00-2:00pm   CNY 149
<a href="#">Research Integrity and Data Management</a>	June 23   12:00-1:00pm   Simches 3.120
<a href="#">QI Bootcamp</a>	July 13   10:00-12:30   Garrod/Mendel
<a href="#">QI Bootcamp</a>	August 3   10:00-12:30   Garrod/Mendel

## ONLINE COURSES

**New online modules!**

[Clinical Trial Billing: Study Start to Finish](#)

[Epic Research Charge Review and Insight Patient Care Corrections](#)  
[IND and IDE Responsibilities for Sponsor-Investigators and Study Staff](#)  
[Basics of Drafting a Manuscript for Publication in a Scientific Journal](#)  
[Constructing a Hypothesis](#)  
[What makes a Good Article? Techniques for Critical Appraisal of Scientific Literature](#)

**Other courses:**

[Applied Methods in Designing and Conducting Health Survey](#)  
[Clinical Research Study Staff Orientation Manual](#)  
[Guide to the Research Patient Data Registry \(RPDR\)](#)  
[Is a K Grant Right for You?](#)  
[Mentoring Corner](#)  
[MGH Research Out of Hospital Research Visits](#)  
[Peer to Peer Review](#)  
[Series on Global Health](#)  
[The Art of Scientific Presentations \(Fundamentals in One Easy Lesson\)](#)  
[Tips and Tools for Drafting a Poster](#)  
[What are the changes to the Common Rule? How do they impact researchers?](#)

Browse the complete list of the [online courses](#) offered by the Division of Clinical Research on HealthStream.

## JANUARY

### **MGH Research Compliance Quarterly Discussion Group**

Thursday, January 30 | 10:00-11:00 | Simches 3.120 | [Register here](#)

Speaker: Kele Piper, Director of MGH Research Compliance

The discussion will focus on DEA Registration and Massachusetts Controlled Substance Registration for clinical research.

- When is registration required? Are both registrations needed
- How to apply and renew registration?
- What is required to be compliant with the regulations?
- What is Partners policy on controlled substance registrations?

### **MGH Research Compliance Quarterly Discussion Group**

Thursday, January 30 | 11:30-12:30 | Simches 3.120 | [Register here](#)

Speaker: Kele Piper, Director of MGH Research Compliance

Join us for the 2nd quarterly meeting for controlled substances in NON-human use of controlled substances in research. We will discuss common mistakes that are made with controlled substances in relation to ordering, receipt, storage, and documentation of controlled substances. Bring your questions as we will save time for some Q&A; chances are someone else has the same concerns or questions that you do. If there is a particular question or issue that you would like to have addressed send it to me in advance to [kkpiper@mgh.harvard.edu](mailto:kkpiper@mgh.harvard.edu).

## FEBRUARY

### **QI Bootcamp for Clinical Researchers and Study Staff**

Monday, February 3 | 10:00am-12:30pm | Garrod-Mendel Conference room

Speaker: Pamela Richtmyer, Director, Partners Human Research Quality Improvement Program

The QI Program and the MGH Division of Clinical Research are excited to offer QI Bootcamp. QI Bootcamp is a "clinical research 101" for study staff and investigators. The goal of the course is to review

GCP guidelines and institutional policies, and instruct study staff and investigators on how to implement those guidelines and policies into the day to day conduct of clinical research. Topics include:

- Informed Consent documentation
- Study Documentation (source documents and data collection forms)
- Unanticipated Problems, Deviations and Violations
- Investigational Product Accountability
- Regulatory binder
- ClinicalTrials.gov, inspections and common rule revisions

### **Conquering the K: Applying for an NIH Career Development Award: Clinical Investigator Track**

*This course is sponsored by the MGH Division of Clinical Research*

**Weekly starting February 5- March 4 | Simches 3.120**

\*Please note that there is an additional Conquering the K course with a Fundamental Research Track starting on February 11- please click this [link](#) to be directed to that offering

*Are you planning on submitting a grant application for an NIH Career Development Award (K Award)? Then plan on attending Conquering the K!*

Conquering the K is a comprehensive, five-session course, which focuses on the preparation of an NIH career development proposal. MGH faculty will discuss research design and the career development plan, focusing on how all the sections of the application must fit together to demonstrate the applicant's commitment to and potential for becoming an independent investigator. Hands-on workshops and a mock study section are included to help participants prepare each section.

Application deadline is tomorrow. Due to the interactive design of this course, there will be a limited number of spots. **\*\* Incomplete applications will not be considered \*\***

**Who should attend?** Fellows and instructors interested in submitting an application for an **NIH K23 Award, K08 focused on behavior research, or any K grant in the area of epidemiology or other patient-oriented research** in June/October 2020 or February 2021.

**Course Requirements:** All attendees will be required to submit a rough draft of Specific Aims and name of mentor.

### **Brief Introduction to NVivo Software for Coding Qualitative Research Data**

**Thursday, February 6 | 10:00 – 11:00am | Simches 3.120**

*Sponsored by the MGH Division of Clinical Research and the Mongan Institute of Health Policy*

Speaker: Lara Traeger, PhD

This course offers an overview of NVivo capabilities for qualitative research projects. We will cover setting up a coding scheme, formatting and storing source documents to be coded, utilizing coding functions, and checking coding consistency across coders. We also will briefly provide a basic introduction to reporting and query functions. \*This course is only offered to MGH faculty and staff.

### **Conquering the K: Applying for an NIH Career Development Award: Fundamental Research Track**

*This course is sponsored by the MGH Division of Clinical Research*

**Weekly starting February 11- March 10 | Simches 3.130**

*Are you planning on submitting for an NIH Career Development Award (K Award)? Then plan on attending Conquering the K!*

Conquering the K is a comprehensive, four-session course, which focuses on the preparation of a NIH career development proposal. MGH faculty will discuss research design and the career development plan focusing on how all the sections of the application must fit together to demonstrate the applicant's commitment to and potential for becoming an independent investigator. Hands-on workshops are included to help participants prepare each section.

Application deadline is tomorrow. Due to the interactive design of this course, there will be a limited

number of spots. **\*\* Incomplete applications will not be considered \*\***

**Who should attend?** Post-docs and instructors interested in submitting an application for an NIH K08 or other K Award application focused on a fundamental research topic in 2020 or 2021.

**Course Requirements:** All attendees will be required to submit a rough draft of Specific Aims and name of mentor.

### **Applied Biostatistics for Clinical Trials**

**Fridays February 28- March 20 | 10:00am – 11:30am | Simches 3.110**

*Sponsored by the MGH Division of Clinical Research and the MGH Biostatistics Center*

**Brian Healy, PhD, MGH Biostatistics Center**

This four-session seminar series will be offered on Thursdays in March. In this series, participants will review the statistical approach to problems commonly encountered in research. Each of the four sessions will focus on a different theme using concrete and realistic examples. In particular, you will learn how to perform specific types of analyses in the class using the statistical package called R, which is a free software package. This course is intended for investigators who are interested in clinical research.

Course Outline:

Session 1 – Introduction to statistics and computing

Session 2 – Linear regression

Session 3 – Survival Analysis

Session 4 – Repeated Measures

You can download R from this website <http://lib.stat.cmu.edu/R/CRAN/>. R is a very powerful statistical package. The dataset that we will analyze each week will be posted course site. The datasets will be saved in comma delimited format, which can be imported into all statistical packages.

#### **OTHER**

### **Save the Date: Are You Writing a K? Workshop**

**Wednesday, February 26, 2020 | 12:15 – 4:00pm | Joseph B. Martin Conference Center, Rotunda Room, 77 Avenue Louis Pasteur, Boston, MA 02155**

Are you writing a K? Get practical advice. This workshop is appropriate for clinical and basic science researchers from all fields. K99 applications will not be discussed in detail.

### **The 21st Annual Nutrition Obesity Research Center at Harvard (NORCH) Symposium on “Non-Alcoholic Fatty Liver Disease (NAFLD): Mechanisms and Novel Therapeutics”**

**Tuesday, June 30, 2020 | 7:15am - 5:30pm | Joseph B. Martin Conference Center, 77 Avenue Louis Pasteur, Boston, MA, 02114**

An educational, all-day event. This event will feature internationally recognized speakers addressing interesting topics such as the genetics behind the disease, the global and clinical burden, and mechanisms and novel therapeutics for NAFLD. Registration will be free of charge, but space is limited. Join thought leaders in the field for this signature event! Fill out [this form](#) of interest if you would like us to contact you when registration opens!

Please contact Pamela Yurrita with questions or concerns at [HarvardNORC@mgh.harvard.edu](mailto:HarvardNORC@mgh.harvard.edu)

**Speaker Line-up:** Steven Grinspoon, MD, Sudha Biddinger, MD, PhD, Laura Dichtel, MD, MHS, Zobair Younossi, MD, Elizabeth Speliotes, MD, PhD, MPH, Jeffrey Schwimmer, MD, Bernd Schnabl, MD, Jagpreet Chhatwal, PhD, Rohit Loomba, MD, MHSc, Raymond Chung, MD, Kathleen Corey, MD, MPH, MMSc, Arun Sanyal, MD, Mary Rinella, MD, Miriam Vos, MD, and Manal Abdelmalek, MD, MPH

**Direct Link to Form of Interest:**

<https://app.smartsheet.com/b/form/f648035d77b74ee5bfae35ebccafc4cd>

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**RESOURCES**

[DCR Website](#)

[Mass General Research Institute](#)

[Executive Committee on Research](#)



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