



F32 BOOT CAMP

From start to submission (grants due Aug 8, 2019)

Class 5: Responsible Conduct of Research



Training in the Responsible Conduct of Research

- 1 page
- Not part of score.
 - Either 'Acceptable' or 'Not Acceptable'
- Brief instructions are in the SF424.
- Supplemental instructions are at:
(<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf>)



Training in the Responsible Conduct of Research

What counts?

- Instruction in responsible conduct of research occurs formally and informally in educational settings
- Informal instruction occurs throughout the research training experience
- Must address
 1. Format
 2. Subject Matter
 3. Faculty Participation
 4. Duration
 5. Frequency

Should also include past training – document recurring ‘Reflection’ on responsible conduct of research at each stage of your career.



Training in the Responsible Conduct of Research

What counts? Formal Instruction

- Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants;
- A combination of didactic and small-group discussions (e.g. case studies);
- Participation of research training faculty members in instruction in responsible conduct of research are highly encouraged.
- While on-line courses can be a valuable supplement to instruction - online instruction is not considered adequate as the sole means of instruction (with specific exceptions).



Training in the Responsible Conduct of Research What counts? Subject Matter

Highly suggested topics

- a. conflict of interest – personal, professional, and financial
- b. policies regarding human subjects, research involving live vertebrate animals, and safe laboratory practices
- c. mentor/mentee responsibilities and relationships
- d. collaborative research including collaborations with industry
- e. peer review
- f. data acquisition and laboratory tools; management, sharing and ownership
- g. research misconduct and policies for handling misconduct
- h. responsible authorship and publication
- i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research



Training in the Responsible Conduct of Research What counts? Subject Matter

While **courses** related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they **generally are not sufficient** to cover all of the above topics.



Training in the Responsible Conduct of Research What counts? Subject Matter

At a minimum:

To continue this training as a new postdoctoral fellow at Emory University, I completed The Responsible Conduct of Research Ethics course (GAH:601A) in the spring of 2016. This course is designed specifically for postdoctoral research fellows, and was designed with advice from expert faculty and Emory's Ethics center. Topics in this course are in line with the national guidelines of ethics training, and more importantly, this course evolves each year based on feedback from postdoctoral fellows to assure its relevance trainees now and in their future careers. This course consisted of 8 one-hour small group sessions that were based on case studies submitted by the postdocs, and was complimented by on-line sessions that were to be completed prior to each meeting. The course objectives are listed as follows:

- To inform Postdoctoral and Research Fellows of the national and university principles, laws and policies that guide the ethical conduct of research and facilitate their understanding of these policies
- To increase the awareness of Postdoctoral Fellows of these ethical principles and policies and how they would be applied in decisions in everyday research
- To have Postdocs use these guiding principles in planning their future research and careers.
- To foster Postdoc discussions of these principles with expert and experienced faculty to expand their understanding of the broad complexity of ethical issues and the resolution.

Topics covered included *Mentor and Postdoc Relationship, Responsible Authorship & Review, Data Acquisition and Management, Research Misconduct, Conflict of Interest, Collaborative and Team Science, Use of Human Subjects in Research, Use of Animals in Research.*



Training in the Responsible Conduct of Research What counts? Faculty Participation

- Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research.
- Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year.
- Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors.

So describe if your sponsor is involved in teaching responsible conduct of research



Training in the Responsible Conduct of Research What counts? Duration of Instruction

- A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

Make sure some aspect of training occurs over time



Training in the Responsible Conduct of Research What counts? Frequency of Instruction

- Reflection on responsible conduct of research should recur throughout a scientist's career
- Individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved.

Options:

Center for Ethics (<http://ethics.emory.edu/>)

Office of Postdoctoral Education (<https://med.emory.edu/postdoc/index.html>)

Office of Research Compliance

- Education programs and training courses on regulatory requirements, compliance obligations, best practices and ethical decision-making

GaCTSA (<http://www.actsi.org/index.html>)

CITI (humans)

ALAS (animals)

Your Sponsor (one on one, lab meetings, in lab, etc)

Workshops

Online

Other

Prior to beginning my research, I attended the Emory University Division of Animal Resources orientation, animal surgery training, and completed online training (CITI modules). I will continue to renew every two years the required credentials using the Collaborative Institutional Training Initiative (CITI) program and completing the course on “Working with mice and rats in research settings”, a course offered by Emory University’s Training Program for the Care and Use of Laboratory Animals and required by the Institutional Animal Care and Use Committee (IACUC). Finally, I also have completed the yearly online courses in Biosafety, Laboratory Safety, and Laser Safety from EHSO, the Environmental Health and Safety Office at Emory University. Beyond formal ethics training, my sponsor, Dr. W. Robert Taylor, provides guidance on ethical issues and oversees my participation in the training activities described above.

Responsible Conduct of Research

The culture at Emory University and the sponsor's lab uphold high values in the ethical and responsible conduct of research and provide several training opportunities. My first year as a postdoctoral fellow at Emory, I completed the Responsible Conduct in Research Course for Postdoctoral Fellows offered by the Office of Postdoctoral Education (Spring 2013, no credit, organized by Dr. Mary DeLong). The course satisfies the ethics training requirements of the NIH and the eight topics covered in the course were recommended by the NIH Office of Research Integrity as key elements in training for responsible conduct of research for young researchers. Emory School of Medicine faculty with expertise in the area led each class session. Course topics included (1) mentor and postdoc relationship (discussion led by Dr. John Banja), (2) responsible authorship and reviewing of publication (Dr. Judith Fridovich-Keil), (3) data acquisition and management (Dr. Mabelle Pardue), (4) research misconduct (Dr. Michael Kuhar), (5) collaborative and team science (Dr. Arri Eisen), (6) conflict of interest (Dr. Ned Waller), (7) human subject research (Dr. Sarah Putney), and (8) ethical issues in animal research (Drs. Stuart Zola & Denyse Levesque). The course met four times over the course of the semester for 2.25 hours each session, with 2 topics covered each session. Before each class, a required reading and assignment was distributed online using Emory's "Blackboard" website. Online information included (1) an introduction to the topic, (2) background information, (3) National and Emory guidelines and policies relevant to the topic, and (4) two example case studies with guide questions on the topic. The assignment for each topic was to write a case study and discussion questions to be discussed in class. In class, the faculty led large group discussions as well as dividing the class of 20-25 students into small groups to discuss a number of case studies written by the students and then debriefed as an entire class. Course evaluations were conducted for each topic. I have also attended a seminar on "Managing Emotionally Painful Conversation" offered by the Emory Center for Ethics (ECE).

My mentor, Dr. David Katz, takes ethical research conduct seriously and strongly encourages all his graduate and postdoc trainees to attend the Jones Program in Ethics (JPE) sessions that are offered through the Emory's Laney Graduate School. As a postdoctoral fellow, I also have access to these sessions and will attend two sessions (2 hours) each year of my postdoctoral fellowship. JPE sessions are designed to introduce students to a range of ethics topics that they will encounter throughout their graduate careers and upon completion of JPE sessions attendees will be able to describe and give examples of ethical reasoning in daily life; differentiate ethical issues from issues of law, regulation, or policy; identify, assess, and address ethical issues as they arise in the context of research, scholarship, and teaching; locate resources (local, institutional, regional, and national) for enhancing and preserving scholarly integrity through research, scholarship, and teaching.

Along with ensuring that trainees take advantage Emory's ethics and responsible research training resources, Dr. Katz is also committed to maintaining a lab environment that supports open dialogue about ethical issues, such as discussing authorship when collaborating with others and maintaining the highest standard of data production. Dr. Katz's commitment to responsible and ethical research is exemplified by his consistent involvement in monthly ethics training sessions hosted by the Biochemistry, Cell, and Developmental Biology Graduate Program at Emory University. Laboratory safety is also important to me and is taken very serious in Dr. Katz laboratory. As a postdoctoral fellow, I have completed all the required lab safety training required for animal research, and will continue to keep my training up to date by following the requirements mandated by Emory's Environmental Health and Safety Office.

My commitment to my ethics training and responsible research fits with both Emory University's and Dr. David Katz's philosophies, and through my postdoctoral research, I will continue to develop methods to build an ethical and responsible research culture as I start my own lab as an independent research scientist.



Reviewer Comments

Unacceptable

Comments on Format (Required):

- Sufficiently described.

Comments on Subject Matter (Required):

- Detailed subject areas are adequately described.

Comments on Faculty Participation (Required):

- Not clear the extent of faculty or mentor participation in this area.

Comments on Duration (Required):

- Not stated.

Comments on Frequency (Required):

- Not stated.



Reviewer Comments

Training in the Responsible Conduct of Research:

- Acceptable

Comments on Format (Required):

- Responsible Conduct in Research course and workshops on various topics.

Comments on Subject Matter (Required):

- Mentoring and postdoc relationship, responsible authorship and review, data acquisition and management, research misconduct, conflict of interest, collaborative and team science.

Comments on Faculty Participation (Required):

- Not clear who runs this course; informal meetings with faculty mentor.

Comments on Duration (Required):

- Course lasts one semester; informal training throughout application period.

Comments on Frequency (Required):