

## **PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH**

UAB has a strong and ongoing commitment to the responsible conduct of research (RCR). UAB offers many opportunities for such initial and annual training including formal courses through graduate school programs and postdoctoral and junior investigator specific curricula, online tools to support research customized preparation and periodic workshops to enhance the investigative experience.

UAB is one of eight institutions recently awarded funding by the Council of Graduate Schools and the Office of Research Integrity to develop strategies to integrate RCR educational materials into the graduate curriculum, for use by faculty and graduate students in discussion of scholarly integrity. UAB's national and international leadership in the area of ethics training was reflected by presentations at the 2010 Project for Scholarly Integrity Capstone Conference and the 2012 ORI conference "Quest for Research Excellence" and were highlighted in the book, "Research and Scholarly Integrity in Graduate Education: A Comprehensive Approach," published in 2012 by the Council of Graduate Schools.

Trainees will work with T32 Program Directors and their mentoring team to identify the curricula and tools that will be most beneficial and appropriate for the trainee's career development. The training program and mentors, along with relevant UAB offices (i.e. IRB, Compliance Office), will also ensure that trainees complete a minimum of 8 hours of instruction in responsible conduct of research every 4 years.

All T32 trainees will be required to complete human subjects training through the Collaborative IRB Training Initiative (CITI) program or UAB's internal training. They will complete an approved training course on human subjects protection and will update their training annually. There are a number of avenues for fulfilling this training requirement, including on-line opportunities and seminars. Completion of requisite training is documented by the Institutional Review Board.

All T32 trainees at **UAB also will engage in education in Responsible Conduct of Research and in scholarly integrity through one or more of the following activities:**

### Coursework

1) *Principles of Scientific Integrity (GRD 717: Jeffrey A. Engler, PhD)*: A semester-long course (10 2.5 hour session), provides a survey of ethical issues and principles in the practice of science. It uses research faculty in the biomedical sciences to lead discussions with graduate students and postdoctoral fellows on topics included in the responsible conduct of research. Among the areas discussed are: Ethical Decision Making, UAB Policies on Research Misconduct, Protection of Human Subjects in Research, Welfare of Laboratory Animals, Best Practices for Data Management, Identifying and Managing Conflicts of Interest, Ethical Authorship and Avoiding Plagiarism, Best Practices in Collaborative Research, Mentor and Trainee Responsibilities, and Expectations of the Peer Review Process.

All entering biomedical sciences students are educated during orientation about requirements to complete human subjects and animal use and care training programs; completion of requisite training is arranged and documented by their specific graduate programs. All requisite training and annual updates must be completed in order for final Graduate School acceptance of the PhD thesis.

2) *Research Writing and Style (GRD 712: Susan Olmstead-Wang, Ph.D.)*

This course is designed for pre and postdoctoral trainees managing personal writing efforts (e.g., journal article for publication or dissertation), in which goals for effective strategies of successful writers are conveyed, with emphasis on ethical standards in publishing scientific literature, peer review, and techniques for efficient editing. Topics include the different types of writing that students and professionals do (such as abstracts, proposals, journal articles, progress reports, and correspondence), publishing, and ethical issues related to writing and publication.

### Institutional Resources

1) *The Center for Ethics and Values in the Sciences (EVIS)*

Established in 1998 by the University of Alabama Trustees, the *UAB Center for Ethics and Values in Science* offers seminars and symposia that discuss issues related to scientific integrity and research ethics training.

Center for Ethics and Values in the Sciences video presentations, "*In the Lab: Mentors and Students Behind the Scenes*" and "*Teaching Research Integrity in Analysis and Reporting: A Web-site with Case-Based Vignettes*", are focused on best practices for presenting image data in research publications and are utilized both locally and nationally. Other videos about plagiarism and whistle blowing are available at <http://www.uab.edu/images/gradsil/rcr/index.html>. Trainees and their mentors will be encouraged to attend and/or participate in the training opportunities offered through the Center.

#### 2) *Ethics for Authors Integrity Workshop*

New scholarly integrity workshop "*Ethics for Authors*" is organized around interactive and facilitator-led discussions and exercises. It is organized by the Professional Development Program of the Graduate School. These workshops have been hosted by departments, lab groups and journal club groups. There is also a website with these materials available: [www.uab.edu/ethicsforauthors/](http://www.uab.edu/ethicsforauthors/).

#### 3) *Ethical issues in Underpowered Clinical Trials*

By **George Howard**, DrPH, Professor and Chair, UAB Department of Biostatistics and HSOER Primary Mentor, this presentation reviews the organizational needs of clinical trials from a statistical perspective and the possible implications as they may impact human subject research.

#### 4) *Center for Clinical and Translational Sciences (CCTS)*

The Research Ethics, Education and Training Component of the UAB CCTS (UAB's CTSA) is helping to produce intellectually innovative and methodologically rigorous clinical and translational researchers. As part of this effort, this component has an ongoing commitment to the development of training tools in the Responsible Conduct of Research. In collaboration with the Center for Ethics and Values in the Sciences, the CCTS aids in promoting the research ethics training and development of research integrity educational materials at UAB.

Additionally, the CCTS provides a 20-hour survey course, the *Vocabulary of Clinical and Translational Science*, includes fundamental information on hypothesis generation and testing; informatics; biostatistics; epidemiology and population research; clinical trials; ethics; overviews of translational and outcomes research; accessing information; the IRB and oversight of research; and critical review of clinical and translational literature. The Vocabulary course is required for all School of Medicine fellows who are in fellowship programs longer than one year and serves as the introductory coursework for the Clinical and Translational Science Training Program.

#### 5) *Written Materials*

All trainees will receive copies of the following ethics resources: 1) "*On Being a Scientist*" published by the National Academy of Sciences; and 2) the UAB misconduct policy.

#### 6) *UAB Compliance Office (previously the Office of Research Compliance; Teresa Bragg, CPA, CHC, Director)*

With its mission to promote practices based in core values so that UAB is known for a strong ethical culture worthy of the public trust, the UAB Compliance Office is responsible for implementing UAB's enterprise compliance strategy and administering a comprehensive compliance program. The UAB Enterprise Compliance Program is championed at the highest levels of the organization, with direction provided by senior leaders who comprise the UAB Enterprise Compliance and High Risk Council. Together with the UAB Enterprise Joint Compliance Committee, the UAB Compliance Office: develops and executes compliance program initiatives; reviews or recommends compliance policies; explores emerging laws and regulations that impact the enterprise; establishes a compliance workplan that assesses risk, identifies and satisfies training needs, and monitors outcomes; and ensures that when non-compliance is identified the organization responds appropriately.

#### 7) *UAB Institutional Review Board for Human Use (IRB; Jonathan E. Miller, MPPA, CIP, Director)*

The IRB is a committee of UAB faculty and staff designed to oversee all research conducted in affiliation with UAB that involves human subjects with the aim to protect the rights and welfare of research participants, to minimize risk and to ensure ethical practices in scientific investigation.

8) *Collaborative IRB Training Initiative (CITI)*

The CITI Courses in the Protection of Human Research Subjects generally provides the initial training opportunity for researchers seeking to engage in human subjects research. Online training modules include information for biomedical and social-behavioral researchers in a myriad of areas, including defining research with human subjects, basic IRB regulations and review process, informed consent, social and behavioral research, regulations, assessing risk, records-based research, genetic Research, vulnerable subjects, FDA-regulated research., international research, internet research, HIPAA, and conflicts of interest.

9) *Continuing IRB Training*

Bi-annual renewal of IRB training, established in the 2009-2010 calendar years, is required of anyone affiliated with an active human subject research. This module is available online and reviews informed consent procedures and associated IRB regulations.

10) *Institutional Animal Care and Use Committee (David Cannon, CPIA, Director)*

The Institutional Animal Care and Use Committee office oversees the proper use of vertebrate animals (and some invertebrate animals) in research, ensuring that the laws governed by the Public Health Service/Office of Laboratory Animal Welfare, United States Department of Agriculture (USDA), and the American Association for Accreditation of Laboratory Animal Care (AAALAC) are followed. To help researchers maintain compliance, the Institutional Animal Care and Use Committee reviews protocols on an annual basis in affiliation with any project proposing animal use.

11) *Institutional Animal Care and Use Committee Training*

Before a researcher or trainee may work with animals, he/she must complete Institutional Animal Care and Use Committee training, which encompasses a set of online modules including an introduction to the Institutional Animal Care and Use Committee regulations, policies, and procedures, personnel health and safety, and chemical safety training. Additional species specific training courses are available, which may be customized to the research program.

12) *Occupational Health and Safety (Max Richard, Asst. Vice President)*

The department strives to provide a safe workplace and to equip researchers with the tools to conduct research in a safe and compliant manner. The Occupational Health and Safety has several key functions, including: issuance and control of radioactive materials licenses, development of control programs for biological and chemical agents; safe disposal of biohazardous, radioactive, and chemical wastes, health and safety education and training, and establishment of procedures and standards of safe work practices, among other responsibilities.

13) *Occupational Health and Safety Training*

The Occupational Health and Safety provides a myriad of training courses tailored to the research program needs. Some of these courses, based on their broad applicability to fundamental laboratory research, have become standard requirements of pre and postdoctoral training at UAB, including: Hazardous Waste Handling and Packing (CS055), Online Initial Radiation Safety Training (RS1001), Basic Biosafety Training (BIO303), Laboratory Safety Workshop (LSW2001) and Chemical Safety Training (CS101). Other specialized courses are also available, which may be customized to the research program.

14) *Office of the Health Insurance Portability and Accountability Act Coordinator (Joan Hicks, CIO)*

UAB has implemented policies and procedures necessary to comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) with a priority to maintain the highest respect for the privacy of our patients and research participants and for the protection of their personal health information. All trainees engaged in projects that may involve human subjects use are required to participate in HIPAA training.