

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

### **5A. Overview**

UAB has a strong and ongoing commitment to the responsible conduct of research. The campus offers many opportunities for such initial and annual training including formal courses through graduate school programs and T32-specific curricula, online tools to support research customized preparation and periodic workshops to enhance the investigative experience.

#### **5A1. Coursework**

##### *Principles of Scientific Integrity (GRD 717)*

This course, which is taught by Graduate School faculty, surveys ethical issues and principles in the practice of science. Among the topics discussed are the nature, extent, and causes of fraud in the sciences; UAB policies on fraud; ideals of good science; the responsibilities of authorship and peer review; potential problems raised by the commercialization of research; scientists as public policy advisors; and ethical issues involved in animal experimentation and in clinical trials. This course is required of all trainees appointed to the Training Program in Rheumatic Diseases Research. A syllabus is listed in the Appendix.

##### *Research Writing and Style (GRD 712)*

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.

#### **5A2. Institutional Resources**

##### *Center for Ethics and Values in the Sciences*

Directed by Harold Kincaid and Sara Vollmer, the Center is committed to providing academic enrichment in the responsible conduct of research by overseeing a didactic curriculum, seminar series and workshops. The Center also hosts a national conference annually on topics related to ethics and values in the sciences and assists in the development of research integrity educational materials at UAB.

##### *Online Learning Tool for Research Integrity and Image Processing*

UAB has a web-based learning tool featuring video illustrations of responsible conduct and best practices for presenting image data in research publications and grants. This site demonstrates issues in image processing for research publications and image-related issues regarding the detection of manipulated data. Users can learn about the boundary between questionable practices and practices that demonstrate research integrity and can improve their decision-making skills in analysis and reporting.

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

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

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

The Research Ethics, Education and Training Component of the UAB CCTS 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.

*Office of Postdoctoral Education (OPE; Lisa Schwiebert, PhD, Director)*

The OPE, established in 1999 as one of the first Postdoctoral offices in the country, is instrumental in establishing and maintaining competitive terms, benefits and training programs for all postdoctoral fellows at UAB. It works closely with the University's academic administration, the UAB Council on Postdoctoral Education and the UAB Postdoctoral Association to address the needs and concerns of postdoctoral fellows in a timely and professional manner.

*UAB Compliance Office (UCO, 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 UCO 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 UCO: 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.

*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.

*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.

*Continuing IRB Training*

Bi-annual renewal of IRB training, established for 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.

*Institutional Animal Care and Use Committee (IACUC; David G. Cannon, CPIA, Director)*

The IACUC office oversees the proper use of vertebrate animals (and some invertebrate animals) in research, ensuring that the laws governed by the Public Health Service (PHS)/Office of Laboratory Animal Welfare (OLAW), 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 IACUC reviews protocols on an annual basis in affiliation with any project proposing animal use.

*IACUC Training*

Before a researcher or trainee may work with animals, he/she must complete IACUC training, which encompasses a set of online modules including an introduction to the IACUC, 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.

*Occupational Health and Safety (OHS; 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 OHS 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.

## *OHS Training*

The OHS 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.

### *Office of the HIPAA 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.

### **5A3. Other Resources**

#### *RCR Resources - General RCR Training*

Funded by a grant from the Office of Research Integrity (ORI) for the Department of Health and Human Services, this resource collates a myriad of html, pdf, and video files focusing on issues of mentoring, student conduct, and scientific integrity. The material is provided in complement to the didactic curriculum made available to our trainees.