RESPONSIBLE CONDUCT OF RESEARCH (RCR) RESOURCES SUMMARY

2.28.2014

1.0 Graduate Students

1.1 Molecular Biology Program: MBIOL 7570 Research Ethics – Required (year 1)

1.2 Biological Chemistry Program: MBIOL 7570 Research Ethics – Required (year 1)

1.3 Neurosciences Graduate Program (also applies to MD/PhD students entering the NS Graduate Program): MBIOL 7570 Research Ethics – Required

1.4 MD/PhD Program – MBIOL 7570 Research Ethics – Required during year 1 of PhD training

Course Description: **PHIL/MBIOL 7570 Case Studies and Research Ethics (1.0 credit hours)**
An examination of research integrity and other ethical issues involved in scientific research. Topics may include scientific fraud, conflicts of interest, plagiarism and authorship designation, and the role of science in formulating social policy. This course is designed for graduate students, post-docs and faculty.

2.0 Medical Students

Ethics education is integrated into the curriculum; no separate RCR training is required unless students participate in the summer research programs (see below).

3.0 Federally Mandated Responsible Conduct of Research (RCR) Training

Many federal agencies, including the NIH and NSF, require grantees to certify that they provide appropriate training and oversight in the responsible and ethical conduct of research (RCR).

3.1 **NIH/NSF RCR Requirements.** For more on the RCR requirements of the National Institutes of Health, see the "Update on the Requirement for Instruction in the Responsible Conduct of Research (NOT-OD-10-019) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html. For all grants submitted after January 24, 2010, the NIH "requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research."

For more on the RCR requirements of the National Science Foundation, see http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp#IVB. The NSF stipulates that institutions can "provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research."

3.2 To meet these requirements, the University offers a 9-week **Research Ethics course** (**PHIL/MBIOL 7570**/1.0 credit hours) each academic semester.

3.3 As an alternative, the Office of Research Education (sponsored by the Office of the VP for Research) provides two **RCR Certificate of Achievement programs** through the Research Administration Training Series (RATS) that also meet the instructional requirements (see (www.education.research.utah.edu). The RATS RCR Certification is awarded for the completion of a minimum of 10 hours of RCR training comprised of select RATS online and live lecture classes. Anyone involved in a federal grant in which there is an RCR requirement must complete one of these three RCR training options.

Both RATS RCR Certificates of Achievement programs include a 2-hour online training class consisting of 9 instructional modules, review quizzes, and a proficiency test requiring a minimum 85% passing grade. Trainees may attend four 2-hour live lecture classes on select RCR instructional topics to complete the 10 hours of training. As an alternative, trainees may attend live lecture classes on select RCR instructional topics and attend pre-approved RCR classes developed by faculty at the department level (up to 6 hours) to complete the 10 hours of training. The RCR RATS Certificate of Achievement is awarded upon successful completion of either program.

3.4 **NIH Short-Term Training Programs (T35).** NIH recognizes that RCR training for participants in short-term institutional programs, such as the T35 award, should be tailored to a shorter timeframe. Thus, because Medical Student Research Program participants are only funded for 10 weeks in the summer between the 1st and 2nd years of medical school, the RATS RCR Certificate will be awarded for completion of the following curriculum:

- RATS Online / Introduction to the Responsible Conduct of Research (RCR) – 1.5 to 2 hours
- Two pre-approved, faculty-led and discipline-specific RCR classes conducted onsite at SOM - 1.5 to 2 hours each

4.0 Other Courses for Completing RCR Education (Center for Clinical and Translational Science)

4.1 **MDCRC 6430 - Bioethical Issues in Clinical Research.** This course fulfills the responsible conduct of research (RCR) training requirements made by the NIH and the NSF. It does this with a specific focus on ethical issues involved in clinical and translational research. Topics include: the nature of clinical research, the assessment of harms and benefits, the investigator-participant relationship and the investigator-community relationship, research on non-human animals, mentoring and collaboration, research misconduct, authorship and peer review, data management, conflicts of interest, and the scientist as a responsible member of society. Prerequisite: MD, DO, PhD degree

Instructors:
Howard Mann, M.B.B.Ch., Professor of Radiology

James Tabery, Ph.D., Assistant Professor of Philosophy

5.0 Other Relevant Office of Research Education RATS Courses

5.1 **Investigator Training Workshop: Responsible Conduct of Research (RCR).** The proper conduct and reporting of research is of paramount importance at the University of Utah as noncompliance can result in severe penalties to the institution, the individual(s), and their reputations. Continued education and heightened awareness of ethical issues contributes to fostering a "culture of compliance" throughout the University research community. Participants will become familiar with federal regulations, professional standards and University policies regarding research integrity and responsibilities, ethics and compliance obligations, personal conflicts of interest, and issues related to authorship and peer review. An overview of case history, procedures for suspected abuse, potential sanctions for noncompliance, and the requirements for completing a conflict of interest disclosure form will be discussed.

Instructors:
Jeffrey Botkin, M.D., M.P.H., Associate Vice President for Research & Professor of Pediatrics
Michael Kay, M.D., Ph.D., Associate Professor of Biochemistry

5.2 **Case Studies in the Responsible Conduct of Research (RCR).** The responsible conduct of research (RCR) is a relatively new discipline. It is focused on the multifaceted social and ethical issues that arise in the practice of scientific research. But scientific research itself is hundreds, perhaps even thousands, of years old. Reflecting on this history of biology, chemistry, physics and medicine provides insightful examples of both responsibly conducted research, and irresponsibly conducted research, by some of the most famous scientists in history. Participants will examine a number of notable cases from the history of science and will consider how prominent scientists and their research would fare in the modern age of RCR.

Instructors:
James Tabery, Ph.D., Assistant Professor, Department of Philosophy and Adjunct Assistant Professor, Division of Medical Ethics and Humanities
Jeffrey Botkin, M.D., M.P.H., Associate Vice President for Research & Professor of Pediatrics

5.3 **Institutional Review Board (IRB) and Human Subject Research.** Participants will develop a basis for understanding the background and regulations for the protection of human research subjects. The Human Research Protection Program will be discussed including the informed consent process, vulnerable populations, Serious Adverse Event (SAE) reporting, inclusion and exclusion criteria, HIPAA authorization, and protocol applications. The Electronic Research Integrity Compliance Administration (ERICA) program will be presented and IRB documentation standards will be explained.

Instructor:
John Stillman, Director, Institutional Review Board

5.4 **Introduction to Research Integrity.** Participants will become familiar with federal regulations, professional standards and University policies regarding research integrity and responsibilities, ethics and compliance obligations, and conflict of interest issues. A case history review, procedures for suspected abuse, potential sanctions for noncompliance, and instructions on completing a Disclosure Form will be discussed. The proper conduct and reporting of research is of paramount importance at the University of Utah as noncompliance can result in severe penalties to the institution, the individual(s), and their reputations. Continued education and heightened awareness of ethical issues contributes to fostering a "culture of compliance" throughout the University research community.

Instructors:
Jeffrey Botkin, MD, MPH, Associate Vice President for Research and Professor of Pediatrics
Jahn Barlow, MPA, Conflict of Interest Office and Director, RGE

5.5 **Introduction to the IRB, the IACUC, and the IBC.** Participants will learn about the comprehensive policies and procedures regarding the IRB for the protection of human subjects in research, the IACUC for the protection of animal subjects in research, and the IBC for protection of laboratory personnel, building occupants, and the environment. Instructional presentations will be conducted regarding when and why researchers must apply for approval from each Committee, what constitutes an approved application, and what to expect during the application process. An overview of how to use the Electronic Research Integrity Compliance Administration (ERICA) program for IRB submissions will be described.

Instructors:
John Stillman, Director, Institutional Review Board
Steven Dickman, Director, Institutional Animal Care and Use Committee
Michele Johnson, MPH, RBP, Director & Biosafety Specialist, Environmental Health and Safety

6.0 RCR-related Presentations

6.1 **Linda J. Miller, PhD, Associate Dean for Basic Science, New York University School of Medicine**

March 3, 2014 - HSC Chairs/Leadership Research Lunch: Research Integrity and Reducing Lapses in Responsible Conduct.

March 3, 2014 – 10am Seminar/town hall (campus audience): Research Integrity

Related reading materials to be posted centrally.

6.2 **Diana Lim, Technical Reviewer/Advisor, Molecular Medicine Program**

August 13, 2013 - Hands-on teaching sessions to University of Utah Molecular Medicine Program: Principles of Manuscript Preparation - PhotoShop and Illustration Software.

August 14, 2013 - Presentation to University of Utah Molecular Medicine Program: Image Control: Responsible Digital Data Processing.

Related supplemental reading materials are posted on the U2M2 website.