Responsible Conduct of Research Requirement
Research Training in Hematology
(DHHS, PHS, NIH T32 HL007899)
Updated 07/01/13

All trainees supported by the hematology T32 grant are required to complete a minimum of eight contact hours of training in the responsible conduct of research (RCR). It is recognized that the grant supports trainees with a broad array of interests (basic science versus clinical research), thus, the fulfillment of this requirement is intended to be flexible. However, the **mentor and trainee must develop, institute, and document** an appropriate plan. Pre-doctoral trainees often have formalized instruction as part of their degree that will fulfill this requirement. Those courses are perfectly acceptable but still need to be documented for grant updates. During the trainee's second year they are expected to build on that foundation with more specialized seminars and interactive experiences now available through the graduate school (see below). The MSTP program offers a lecture series (5-7 seminars/year) designed to cover the RCR Topics as described by the Office of Research Integrity over a 2-3 year period. Since most pre-doctoral M.D. trainees have NOT previously had a didactic course in research ethics, we encourage that option in their first year to provide a broader view of responsible conduct issues. Ph.D. post-doctoral trainees usually have taken a didactic course during their degree work, so they may choose to either take a complementary course or utilize some of the graduate school options described below. M.D. post-doctoral trainees involved in clinical investigations will most often be taking Bioethics 545 or the three-day "Short Course in Clinical Research" offered during the summer. Tuition expenses can be supported through the grant. Finally, while many of the trainees appropriately use on-line courses or certifications towards fulfilling the RCR requirement, **they cannot solely use on-line sources**. Informal instruction in topics relevant to the responsible conduct of research is also acceptable, however, **the setting, topics covered, and contact hours should be documented.**

Graduate School Resources- One of the major changes over the past five years has been the dramatic increase in RCR options supported by the UW Graduate School. While the hematology T32 program had previously assembled a catalog of options for RCR training, the graduate school and ICTR websites have mostly supplanted our efforts due to the campus-wide need for this type of training. The main training link is: http://www.grad.wisc.edu/research/wkshop/index.html#RCR. This page contains links to online research training (animal users, Good Clinical Practice, HIPPA, Human Subjects, Safety, and Stem Cell Ethics Policy), links to downloadable descriptions of Research Ethics courses on campus (included in Appendix), and the schedule of Graduate School Seminar Series which includes intellectual property topics (consulting, data ownership, industry collaborations, legal issues in sponsored research, patents and licensing, etc) and a Video Library of previous talks (Authorship/Peer Review/Publishing, Community Research, Large Collaborative Projects, Ownership of Results, Research Misconduct). Under the RCR link is a policy page with descriptions of the RCR topics as described by the Office of Research Integrity (and NIH):

1. Animal welfare
2. Collaborative science
3. Conflict of interest and commitment
4. Data acquisition, management, sharing and ownership
5. Protection of Human subjects
6. Mentor/trainee responsibilities
7. Publication practices, responsible authorship
8. Peer review
9. Research misconduct

On this policy page is a very helpful RCR resources link that contains websites at other institutions (including the ORI) with case studies, bibliographies and other materials. Finally, the Graduate School also sponsors the "Integrating Research Ethics and Scholarship" (IRES) initiative that offers RCR educational resources and opportunities. For instance, in the Fall 2012 semester, IRES put on an interactive movie showing of "The Lab" in which characters are placed in situations of possible research misconduct and the audience is given

choices on how to respond. Thus, the UW Graduate School provides an extensive amount of on-line, seminar, and event-based RCR training opportunities.

Additionally, the ICTR website is in the process of developing extensive resources for mentors, mentees, and training mentors: https://mentoringresources.ictr.wisc.edu/. The website is nearing completion, and will be useful both to address RCR topic (6) and to provide a practical guide for new appointees and junior faculty trainers.

Didactic Courses- Available didactic courses on campus are listed in tabular form below, with the specific RCR topics (see list above) covered by each course. This table can be used as a guide for trainees in selecting the most appropriate course for their research and interests. A list of these courses with teaching faculty and descriptive syllabi are included in the appendix. Tuition expenses are supported through the training grant.

Course #	Course Title	RCR Topics Addressed								
		1	2	3	4	5	6	7	8	9
468	Introduction to Engineering Research		X		X			X	X	X
544	Introduction to Clinical Trials 2		X	X	X	X				X
545	Ethical and Regulatory Issues in Clinical Investigation					X				
559	Human Experimentation Course			X		X		X		X
565	The Ethics of Modern Biotechnology	X		X	X					
610	Regenerative Medicine: Ethical and Social Issues		X		X	X				
675	Appropriate Conduct of Science	X	X	X	X	X	X	X	X	X
728	Bioethics and Society		X		X	X		X		
802	Ethics and the Responsible Conduct of Research	X	X	X	X	X	X	X	X	X
812	Research Ethics and Career Development	X	X	X	X	X	X	X	X	X
901	Advanced Seminar: Responsible Conduct of Research	X	X	X	X	X	X	X	X	X
905	Bioethics and the Law			X		X				X
906	Law, Science, and Biotechnology		X	X	X	X		X		X
999	Research Ethics	X	X	X	X	X	X	X	X	X

The ICTR also sponsors two-day courses entitled the “Short Course in Clinical Research” offered in the early summer, and the “Advanced Short Course in Clinical Research” offered during the winter. These courses provide broad training in the fundamentals of clinical research and include RCR topics such as human subjects protections, HIPPA, consent, data management, etc. These short courses also serve as a good way to broaden the clinical exposure of a lab-based trainee in a short, focused manner.

While trainees may select any course they feel is relevant to their work, our past trainees have tended to cluster in a few didactic pathways. Trainees with limited previous research experience seeking a relatively broad exposure to RCR topics often take Oncology 675: The Appropriate Conduct of Science. Most of our post-doctoral M.D. trainees pursuing a clinical investigation pathway will take MHB 545: Ethical and Regulatory Issues in Clinical Investigation, and if pursuing the M.S. program, will also take BMI 544:

Introduction to Clinical Trials 2. Trainees in stem cell laboratories or involved in stem cell applications (basic or clinical) may take MHB 610: Regenerative Medicine: Ethical and Social Issues. Nearly all of our trainees are involved in some aspect of clinical, animal-based or patient-derived material studies, so they commonly complete on-line human subjects training/HIPPA training and/or Animal User certification. Participation in MSTP or Graduate School sponsored seminars is also recommended. Discussion of RCR reading material or case studies in the laboratory setting is also encouraged, with the **contact hours and content documented** by both trainee and his primary mentor.