Plan for Instruction in the Responsible Conduct of Research

The NIH has stringent guidelines for training in the Responsible Conduct of Research (RCR) and this training plan gives these the highest priority. Analysis of findings of misconduct by the Office of Research Integrity (ORI) reveals that about half of all findings are due to misconduct by trainees (McCormack, unpublished). We have taken many steps to ensure that our program will proactively provide training and supervision needed to avoid such unfortunate losses to the research enterprise, and build RCR and research ethics into the culture of clinical & translational research involving trainees and mentors throughout the training period. The NRSA Training Core (TL1) will emphasize RCR training as an integral component of trainees' professional development, and includes as an objective that trainees will "value the highest ethical standards in conducting translational research". CTSI faculty have a strong commitment to RCR education and track record for best practices in research, including the development of the Mentor Academy (Fillingim), Academy of Research Excellence (Moseley), NIH T32 and Career Development RCR guidelines (Cottler), and a novel team-based learning (TBL) curriculum for didactic RCR training (McCormack, see below for details).[5] The Mentor Academy is designed to provide training to mentors in how to optimize the mentor-mentee relationship and promote the highest integrity in research, and ARE trains promotes high-quality, innovative clinical research with the highest regard for research integrity, ethics, professionalism and regulatory requirements. TL1 mentors will be encouraged to participate in the MA and/or ARE in order to become optimal RRC role models.

Format. We are committed to providing excellent, multimodal RCR training to TL1 trainees. RCR instruction will emphasize: (i) training in the protection of the welfare of human subjects through course work, Institutional Review Board visitation and/or service, research team meeting discussions with the mentor, University initiatives, and at trainee meetings and (ii) responsible scientific conduct in the gathering and reporting of scientific data through required course work, research team meetings, discussion with the mentor, and trainee meetings. Excellence in RCR training will be accomplished for all trainees through the following mechanisms.

Didactic Instruction

Online Training: UF requires HIPAA training annually ("HIPAA & Privacy – Research"). In addition, the online courses "IRB01 Mandatory Local Training" and "Animal Awareness Seminar" will be required of all trainees. Based on relevance to individual trainees' research and roles, additional online training is available for "Human Subject Payments," "Administrators and RCR," "CTSI Informed Consent Training," "PI Responsibility for Informed Consent," "Study Coordinator Roles in Research," "Financial Conflict of Interest," "Billing for Device Studies," "FERPA Basics," and "FERPA for Faculty."

Required reading for all trainees and mentors available online includes the Belmont Report and 45 CFR 46. The Office of Human Research Protections (OHRP) considers it unethical for anyone involved in human subject research not to have read the Belmont Report, which describes the ethical principles that should be followed by investigators: respect for persons, beneficence and justice. Via Multiple Project Assurance, UF has a contract with OHRP assuring that investigators conducting human research will follow the ethical principles outlined in the Code of Federal Regulations. All trainees must read and be prepared to discuss 45 CFR 46, which describes authority and responsibility of Institutional Review Boards (IRBs) in protecting human subjects.

Novel Team-Based Learning RCR Curriculum. Typical research ethics or responsible conduct of research (RCR) training methods do not support and may harm ethical decision-making (EDM).[36] Dr. McCormack is leading an educational research project funded by the Office of Research Integrity to test the hypothesis that team-based learning (TBL) provides the necessary student engagement to have a more positive impact on EDM than traditional lecture, online, and/or small group teaching methods. TBL uses individual work, group work, and immediate feedback to motivate students to hold each other accountable for coming to class prepared, actively engaging in discussion, and focusing on the application of course concepts. Preliminary results using a biomedical science TBL RCR curriculum reveal gains in overall ethicality and in three of four dimensions of EDM, including data management, professional practices, and business practices, when compared to findings for more common RCR training methods.[5] Pre/post-test gains were observed in five of seven meta-cognitive reasoning strategies, suggesting that TBL instruction supports students' abilities to recognize circumstances, question judgment, manage emotions, anticipate consequences, and analyze personal motivations. The TBL RCR curriculum has been revised to include content characteristics that support good EDM and the "So Far No Objections" (SFNO) moral method has been incorporated to provide both a clear framework within which to assess ethical dilemmas and concrete steps to guide learners in

resolving them.[37] The revised TBL curriculum is being implemented in one engineering ethics curriculum and five biomedical RCR curricula at six universities during the 2014-15 academic year (Florida, Penn State, Yeshiva, Alabama at Birmingham, Virginia, and Mississippi). Learning outcomes are being assessed via pre/post-testing of EDM. Student perceptions about the TBL curriculum and its impact on EDM are being assessed through a mixed methods quantitative and qualitative approach, using surveys about team performance, professional moral courage, and self-efficacy, as well as student interviews. Because TBL emphasizes shared problem-solving and decision-making, development of self-protective behavior may be limited, and learners may become accustomed to making ethical decisions in a team setting, establishing a pattern of future ethical research behavior. TBL provides continual feedback about both student performance in terms of knowledge acquisition and strategies involved in ethical decision-making. Improved learner engagement and satisfaction with RCR and ethics training may help science and engineering students overcome the notion that such courses or training are simply a requirement that must be endured, and help support the development of a culture of ethics and research integrity.

The TBL curriculum is implemented in "Responsible Conduct of Biomedical Research" (GMS 7003, 1 credit, 21 contact hours), a required course in the CTS curriculum. The course is designed to introduce key issues in RCR following the research process from inception to planning, conducting, reporting, and reviewing biomedical research, and provides a practical overview of the rules, regulations, and professional practices that define RCR. Ten 2-hour sessions include ethical decision-making, defining research misconduct, human subjects, animal welfare, conflicts of interest & commitment, data management, mentor-trainee relationships, collaboration & team science, authorship & publication, and peer review. Each session entails assigned pre-readings, individual and team readiness assurance tests, and application exercises in which teams will apply the SFNO moral method of decision-making to research scenarios (many involving research trainees) that pose real-life ethical dilemmas. Learners will make decisions via intra-team and inter-team discussions.

Additional Graduate Courses. "Ethical and Policy Issues in Clinical Research (GMS 6931, 2 credits, 30 contact hours) is a required CTS core course directed by Dr. Bill Allen, and covers ethical and policy issues relating to conduct of clinical research and provides a basic understanding of regulations governing research on human subjects and an introduction to the topic of research with animals. In addition to didactic training, case-based presentations and discussions are used to facilitate active learning. A "Current Topics in Research Ethics" refresher course will be available for trainees remaining for more than four years in a single stage of training, e.g., 5th year PhD students. Discussion topics will include relevant current local and national events, recent ORI research misconduct findings, and the collaborative development of new real-life research scenarios for courses and workshops by trainee teams. Additional elective graduate courses include Ethics in Genetics (GMS 6221,1 credit) and Ethics in Population Science (PHC 7427, 1 credit).

Postdoc and Faculty RCR Workshops. As an alternative to the semester-long RCR course (GMS 7003), five workshops will be offered on a monthly basis during the Fall and Spring semesters on rotating topics (Ethical Decision-Making and Research Misconduct; Human Subjects and Animal Welfare; Conflicts of Interest and Data Management; Mentor-Trainee Relationships and Collaboration; Authorship and Peer Review). Each workshop will be approximately three hours long, and will be conducted in the TBL format. Participation in all five workshops over a two-year period of time will result in the award of a UF "RCR Training Certificate."

Journal Club Sessions. At least once each year the CTS Journal Club attended by TL1 trainees will devote a session to ethical issues in clinical and translational research. These sessions will draw on recently published cases or research articles and will include a discussion of the key ethical issues and potential solutions. They will be led by trainees, which will require that they perform some background research to familiarize themselves with specific topics and issues to be discussed.

SEMINARS AND SMALL GROUP MEETINGS

Research Seminars. CTS seminar presenters will be encouraged to incorporate research ethics issues encountered in their research, including discussion of ethical dilemmas involving IRB policies, authorship guidelines, conflicts of interest, mentoring, and/or responsible reporting of research findings. Presenters for these sessions will include KL2 and TL1 faculty, local IRB members and ethics experts.

Mentoring. Trainees are generally required to have at least weekly meetings with their primary mentors. A compilation of RCR discussion topics for lab meetings will be provided to all mentors. Trainees are also required to have regular mentoring team meetings to review progress and set goals. RCR issues are to be reviewed and documented in these meetings.

Visiting Faculty. When visiting faculty present a seminar, we will ask them to meet with trainees for lunch and informally discuss issues such as conflicts of interest, peer review, authorship, and policies for handling delicate situations. These visits occur with varying frequencies (as often as monthly) across partner graduate programs, and will be advertised to all CTSI trainees.

EXPERIENTIAL TRAINING

IRB & IACUC Protocols. In the development of their dissertation research projects, trainees will either submit their own protocols during the course of their training and/or assist with submission of a mentor's protocol if they are listed among the project key personnel, providing another opportunity to learn more about protection of human and non-human research participants. As part of this experience, trainees will attend the IRB/IACUC meeting at which these research protocols are being reviewed, in order to better understand the IRB & IACUC review processes.

Faculty Participation. Faculty members are specifically involved as instructors/leaders of the formal classes, seminars, and workshops. Most importantly, faculty members serve as mentors and mentoring team members during the more ad-hoc one-on-one mentoring components of the research training.

Duration of Instruction. Online coursework consists of approximately 2-3 hours annually. The formal coursework (GMS 6931 and GMS 7003) involves ~50 contact hours, and RCR topics will be included in at least four contact hours during journal clubs and seminars. RCR certification via postdoc and faculty workshops will entail 15 contact hours. Additional instruction will be ongoing. Mentoring meetings will entail at least 3-4 contact hours annually, plus much more, undocumented, in weekly sessions with the primary mentor and/or other mentoring team members.

Frequency of Instruction. Instruction is ongoing. Formal courses are intensive semester-long courses which will be taken early in training. Additional discussions intended to inculcate a culture of RCR and research ethics will be ongoing, including lab meeting, informal and formal mentoring meetings, journal clubs and seminars.