Teaching the Responsible Conduct of Research In Humans (RCRH)

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INTRODUCTION:

Since we published, "Teaching the Responsible Conduct of Research utilizing a Case Study Approach" in 1994 (AAMC Publications), the scientific community has addressed research integrity issues with energy and, I believe, with considerable success. Trainees routinely receive instruction in responsible conduct of research (RCR) and their mentors have become much more sensitive to the issues, partly because of their prior education and surely because of heightened public interest, regulation and accountability. Institutions have developed and updated policies regarding data, patent and licensure, collaboration, sharing, conflict of interest and misconduct. Faculty committing malfeasance or misconduct are no longer sacrosanct and problems are less likely to be whitewashed. Institutional managers, in their fiduciary roles have made great efforts to prevent expensive and embarrassing misadventures from taking place, with substantial but incomplete success.

Research involving human beings remains particularly challenging to the scientific community. Studying people, their tissues and their data raises ethical complexities not seen with basic research, including responsibility for the safety and privacy of study participants. Investigators must also help participants learn before, during and after a study the rationale, procedures and results of the study. Both international and domestic research require sensitivity to the cultural background and preferences of participants. Unlike molecular, cellular or animal studies, human subjects require fairness in participation, respect for their autonomy and protection from harm.

While every scientist needs to become well versed in the ethical issues surrounding basic research, clinical investigators have the additional responsibility to fully appreciate the ethical dilemmas characteristic of clinical investigation. But clinicians who do human research rarely have the time or inclination to study and teach the responsible conduct of research with humans (RCRH). The development of national initiatives to facilitate translational medicine including the Clinical Translational Science Award (CTSA) makes it imperative for the scientific teams that assemble to be fully cognizant of the issues surrounding human research. This E-book is designed to help them.

In this book we employ problem-based learning to address ethical questions involving research in humans. Each chapter contains an introduction, a glossary of terms, problem scenarios for discussion and annotated bibliographical references to

help readers find the sources they need. Needless to say, the policies, guidelines and regulations involving research with humans continue to evolve. Our society regularly upgrades its demands for accountability as social mores steadily evolve. Therefore, the literature must be updated regularly and new scenarios developed with the evolution of important ethical issues. A section on writing scenarios is thus included.

Scenarios:

The use of scenarios is an excellent way of making instruction in RCRH interactive. A good case scenario will stimulate discussion among the students. Course participants become involved and find themselves expressing opinions as their ethical sensibilities are aroused by the case. Cases also tend to eliminate the intimidating barriers to discussion found in classrooms where faculty, staff and trainees at various levels learn together (a highly desirable situation). In courses with guest speakers, controversial cases can generate interactions between instructors that add more spice and understanding to the presentations. The scenarios can often be examined from multiple points of view and simple solutions are not required or even desirable. The teacher will often act as facilitator and allows the students to take the lead in analysis, making sure only that the appropriate topics are considered. This permits the fostering of ethical sensitivity and teaches acceptance of uncertainly in RCRH.

Students tend to keep their cases and refer to them when personally confronted with an analogous ethical dilemma. Scenarios also make good essay examination questions as the students have to wrestle with questions they raise.

The cases presented in this E-book represent major issues confronting clinical investigators. They are error-ridden by design.

Course instructors can use their imagination in creating cases on their own. Good examples reach the public domain with all-too-great frequency. Individual scenarios should not attempt to deal with all the issues in research ethics, but rather should tackle a theme. Providing a number of questions for the audience to consider generally works well. It is worth providing specific demographic information about the individuals in the scenarios including gender, title and research status because the latter two will affect judgments about behavior. It's easier and more specific for students to refer to Edith Jones rather than "the graduate student." Good scenarios avoid excessive introductions and technical detail that creates "solutions" based on technical changes rather than confronting the ethical dilemmas.

RCRH involves adherence to a myriad of Federal, State and local regulations, guidelines, and idiosyncrasies. Incorporating local conditions as features of scenarios can be very useful in the instruction process.

Many of the cases could have been placed after more than one chapter as they cover a range of issues. That's reality. I tried to have an important issue related to each chapter considered in the case. Each of these cases has been tried in my course and found to be sufficiently provocative to engender active discussion.

Bibliography:

Each chapter has an extensive bibliography focused on articles published between 2000 and February 2006. Most of the bibliographic material is annotated. The principles of the annotation process are to avoid replicating the title and giving the details in the abstract. Rather, the idea is to give an idea of the type of work, (e.g. empirical, think piece, regulatory), its significance and its quality. URLs are available for most of the articles so it is easy to go up and see the abstract for details. I have not been totally consistent in these evaluations. Those who are interested in a reference will find it relatively easy to download the abstract or the whole article for study. Materials relevant to research ethics can be found in many journals and in other written sources. Although we were reasonably thorough, significant articles can be found, especially in books that were not referred to.

I want to acknowledge the extremely valuable assistance of Andrey Finegersh, my hardworking and thoughtful student assistant. Nothing could have been achieved without his help.