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MEDICAL EDUCATION

NIH Ethics Education Programs and Initiatives: Training the Next Generation of Clinical and Translational Researchers

Emily Abdoler

The National Institute of Health's (NIH) longstanding commitment to ensuring that its research is undertaken ethically serves both as a safeguard against abuse and an investment in the public's trust in research [1, 2]. This commitment is manifest in a variety of programs and initiatives—a number of which focus on training future clinical and translational researchers. In some cases, these programs are required or highly encouraged; in others, they are available for students with a special interest.

The NIH invests heavily in the education of future researchers, particularly with regard to their ability to design and carry out robust and valuable research projects. Some intramural training programs and initiatives geared to medical students and residents may be found on the web site for the NIH Office of Intramural Training & Education and the NIH Clinical Center Office of Clinical Research Training & Medical Education (OCRTME). Medical students and residents can also benefit from various extramural initiatives, which are NIH-funded but organized by other institutions; examples include individual and institutional NIH training grants, as well as the National Center for Research Resources Clinical and Translational Science Awards.

While instruction on such topics as statistical design and hypothesis generation may seem only tangentially related to training ethical clinical and translational researchers, it is actually an essential component. The first two of seven requirements for ethical clinical research are social value and scientific validity [3]. Clinical research that exposes subjects to risks is ethical only when it is designed to generate valuable knowledge through the use of valid methods. The NIH provides training in other aspects of ethical clinical research through specific initiatives, described below (see [Table 1](#)).

Intramural Courses and Programs

Intramurally, the NIH offers a variety of opportunities for medical students and residents to learn about the ethical conduct of research.

Introduction to the Principles and Practice of Clinical Research. This free course, offered at the NIH by the OCRTME, covers topics related to ethical human-subjects research within the context of general clinical-research training [4]. It is open to any interested party and may be viewed from approved videoconference sites or online. At least 22 of last year's 952 participants were medical students or residents,

although the number participating is probably much higher since enrollees are not required to designate their status.

Clinical Research Training On-Line. The OCRTME also offers Clinical Research Training On-Line, which includes instruction in the ethical conduct of human-subjects research [5]. The course is free to all interested parties and required for all NIH intramural principal investigators.

Ethical and Regulatory Aspects of Clinical Research. This free course, offered each fall by the Clinical Center's Bioethics Department, was developed to help investigators fulfill the NIH's requirement for education in the protection of human-research participants [6]. The course is open to all and frequently includes remote groups (including some in Peru, Sri Lanka, Maryland, and Washington) who attend via satellite. It is also available online and through podcasts. Since 2005, approximately 250 to 350 individuals have enrolled annually. This enrollment includes medical students, residents, and fellows, but the exact numbers are unknown.

Clinical Research Training Program (CRTP). Specifically for medical and dental students who have completed at least one year of clinical rotations, the NIH CRTP provides a year of intensive training and experience in clinical and translational research, including ethical conduct, through the program's required clinical research group seminar [7]. CRTP enrollment is limited to 30 students each year.

Summer Internship Program (SIP) in Biomedical Research. SIP, coordinated by the Office of Intramural Training & Education, offers clinical and basic research experiences for high school, college, graduate, and professional students [8]. Students can undertake research projects in the Clinical Center's Bioethics Department or attend the optional summer lecture series, which includes the session, "What Makes Clinical Research Ethical?"

Additional intramural NIH initiatives for medical students and residents interested in clinical research include:

- Inter-Institute Bioethics Interest Group—monthly discussion forum of specific ethical issues open to all; cosponsors "Bioethics Resource on the Web" with the Office of Science Policy.
- Ethics Grand Rounds—regular discussions of ethical issues in clinical research for all interested participants.
- Clinical Investigator Student Trainee Forum—annual forum for medical and dental students in certain "year out" research enrichment programs that sometimes includes a session on clinical-research ethics [9].
- NIH GME programs—some require training in the ethics of clinical research [10].
- NIH-Duke Training Program in Clinical Research—open to physicians who have already completed residency training, dentists, and advanced-degree

nurses, has coursework in research ethics, and requires training in responsible conduct of research [11].

Extramural Training Grants and Awards

Extramurally, the NIH's efforts to train the next generation of ethical clinical researchers are generally tied to training grants and other awards meant to support education in biomedical research.

Training Grants. All individual and institutional NIH training grants and K awards (career development), some of which can be applicable to medical students and residents, require participants to receive training in the responsible conduct of research (RCR). The NIH encourages institutions to involve *all* graduate students and postdoctoral fellows in their RCR initiatives [12].

While the NIH RCR requirement is deliberately flexible, allowing institutions to determine much of the form and content of the training, issues related to the use of human and animal subjects must be included [12, 13]. RCR training is designed for all types of investigators, including clinical and translational researchers.

Clinical & Translational Science Awards (CTSA). CTSA fund the development of centers for clinical and translational research at academic institutions across the country and, more broadly, bring the centers together in the form of a national consortium for shared resources and endeavors [14]. The CTSA centers are designed to be the sites where the next generation of clinical and translation researchers will be trained. Most CTSA sites have graduate and postgraduate programs in clinical and translational research, sharing curriculum through an online repository. As with similar NIH training initiatives, CTSA-sponsored clinical-research training programs should include research ethics; each CTSA center has a faculty member trained in research ethics to coordinate this training and lead research studies in bioethics or research ethics.

K30 Clinical Research Curriculum Award (CRCA.) CRCA focus exclusively on formal, multidisciplinary clinical-research training programs and curricula and seek a diverse pool of trainees, including those with backgrounds in medicine; they are especially designed for early career professionals and academics [15, 16]. The core curriculum funded by a CRCA must include coursework in bioethics.

Development of a Short-Term Course in Research Ethics (T15). Earlier this decade, the NIH awarded 29 T15 grants for institutions to design and undertake short-term courses in research ethics [17, 18]. While these courses were intended for researchers rather than students or trainees, and although only one course retains an active award, many may still be offered at their original institutions. In such instances, medical students and residents can take advantage of the curricula developed by the T15 grants.

Fogarty International Center—International Research Ethics Education and Curriculum Development Award (R25). As the NIH's largest bioethics training program, this development award supports courses and training related to the education and professional development of ethical clinical researchers and bioethicists from developing countries [19, 20].

Required Education in the Protection of Human-Research Participants

A final component of the NIH's effort to train ethical clinical researchers includes its requirement, beginning in 2000, that all key personnel for NIH-funded research studies involving human subjects complete training on the protection of human-research participants [21, 22]. Insofar as medical students and residents are involved in research with human participants, they are subject to the requirement. While institutions may design their own educational program (much like the RCR mandate), both the free online tutorial provided by the NIH Office of Extramural Research and the OCRTME's Clinical Research Training On-Line course may be used to meet this requirement [23].

Conclusion

A recent survey found that the average number of hours of required coursework for medical students in bioethics may be as low as 35.6 across all four years of medical school and distributed disproportionately to the preclinical years (where it may be less relevant) [24]. It is likely that only a small percentage of this training extends to clinical and translational research ethics.

While the NIH provides opportunities for instruction in this area, medical students are in a unique position to contribute positively to their own training in the ethical conduct of clinical and translational research. Through the organization of interest groups, forums, and other student-led programs and activities, they can enhance their own educational experience and that of their peers. They can also lobby their institutions to provide more in-depth training through the bioethics curriculum. Interested students and trainees can take the initiative to pursue training themselves, taking advantage of the myriad free courses and programs offered by the NIH. Finally, students and trainees at institutions with CTSA's or CRCAs may have an opportunity to involve themselves actively in research projects focused on the ethics of clinical and translational research, increasing their own familiarity with the subject while furthering the work of the field in general.

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Emily Abdoler is a predoctoral fellow in the Department of Bioethics, Clinical Center of the National Institutes of Health in Bethesda, Maryland. She received a bachelor of arts degree in molecular biology and bioethics from William Jewell College and will begin medical school in fall 2009.

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