Alpert Medical School student guide to clinical research

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Scholarly Concentration in Medical Education

Introduction

Biomedical and clinical research is fundamental to the medical profession. This research advances basic science and practical clinical knowledge and serves as the foundation for which diagnosis, treatment, prevention, and management of illness and injury continually improve. Even those who do not elect to pursue academic medicine must be familiar with research ethics, the role of the Institutional Review Board (IRB), and study design in order to critically evaluate published literature. Approximately 40-45% of students engage in research activities during their four years at the Warren Alpert Medical School (AMS). However, a survey of 55 members of the M.D. class of 2020 revealed that while 76% of surveyed students had projects requiring IRB oversight, 53% had never worked with an IRB before, and 44% were never given any IRB-related instruction. This project intends to develop an educational reference to ensure that AMS students are equipped to evaluate published literature, design purposeful research projects, and conduct academic medical research.

Methods

The authors used the free *iBooks Author* program to create an educational text to supplement clinical research activities. The text was written using references from several bodies of literature, including modern bioethics, federal regulations, and IRB handbooks. The *iBook* was distributed to M.D. class of 2021 students as they began summer research planning and was accompanied by an 18-question survey. The survey used a combination of quantitative and qualitative measures to evaluate the organization and utility of the *iBook*. The *iBook* will be improved in future iterations for future classes using data from this survey.

Results

Preliminary survey data indicate a high demand for further clinical research instruction at AMS. Specific areas of importance are included in the *iBook*, "Clinical Research for Medical Students," written in 108 pages and 7 chapters: 1. Why Do Clinical Research?; 2. Finding Research Opportunities; 3. Ethics: Ethical Considerations in Clinical Research; 4. Institutional Review Boards; 5. Preparing for Research; 6. Research Compliance and Auditing; and 7. Publishing and Sharing Research. These chapters are ordered chronologically and will help establish the importance of clinical research, particularly tailored to medical student needs, and allow students to develop a firm foundation in modern medical research and ethics. The book builds upon principles to introduce IRBs and human subjects research. It also includes instruction for developing a research question or hypothesis, choosing a study design, executing the project, and sharing results through publication and presentation.

Conclusion

Though data regarding the *iBook's* ability to improve students' familiarity with clinical research is still being collected, preliminary survey data support further clinical research instruction at AMS. An ethics curriculum is currently being developed and implemented for the M.D. '21 class, but it does not explicitly delve into clinical research ethics at the level required for most physician-scientists. Moreover, no specific student instruction exists for how to work with an IRB, how to develop a protocol, or how to craft a publication. Traditionally, these have been skills that physicians have learned in their residency, fellowship, or as an attending physician often through a mentor-mentee relationship. By better understanding the medical research process early on, AMS students will be able to take a more active role in their scholarly pursuits while at AMS and throughout their medical careers.

INITIAL PROTOCOL REVIEW

DEFINITION

Submission of study materials, including all related forms and investigator information, to the IRB for approval to begin the study. This is usually your largest submission to the IRB. Most IRBs will have a checklist of required information and documentation on their websites. Some IRBs will allow submission via online portals (e.g. IRBNet), while others may simply use email. Most interventional research projects require **full committee review**, so turnaround time will depend on the committee's meeting schedule and may take over a month.[1] Some research projects will receive an **expedited review** and may be approved sooner. IRBs may either **approve, disapprove, or request a modification** of a protocol.

REVIEW TYPES

The study design will largely dictate the type of review a protocol will receive and therefore how long it will take to receive approval. The IRB will ultimately decide what kind of review is appropriate; this cannot be determined by the investigative team.

Exempt: Study presents little or no risk to subjects; usually relies on existing data (medical records, pathological specimens, etc.) that are de-identified. There are six categories receiving exemption:

1. Normal education practices (e.g. evaluating new instructional strategy, UNLESS students are randomized)
2. Anonymous educational tests, surveys, or interviews (UNLESS subjects can be identified)
3. Educational tests, surveys, or interviews where subjects can be identified, but they are public candidates or if confidentiality is protected by federal statute
4. Study of existing data (if publicly available or de-identified; subjects cannot be identified even indirectly or with demographic information)
5. Public benefit/service programs (e.g. Medicaid, welfare, etc.)
6. Taste and food quality evaluation (food cannot have any potential risk to consumers)[1]

Expedited: Study presents no more than **minimal risk** to subjects and a full committee review is not indicated. Review is thus performed by one or more IRB members, but not the entire committee. Retrospective or prospective evaluation of data collected under routine medical care usually fall under this category (e.g. **chart review** or specimen collection, as long as confidentiality is maintained).[1]

Per the FDA: *"'Minimal risk' means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*[2]