Policy and Procedures for Conducting Educational Research
UNC Eshelman School of Pharmacy

Overview

The UNC Eshelman School of Pharmacy's Strategic Plan outlines the School's aspirations to transform pharmacy education. This is evident in Strategic Initiative 1: Educational Renaissance. An important strategic objective of this initiative is the School's commitment to creating an environment that fosters educational research and the scholarship of education. While the School will seek to advance its commitment to excellence in educational research in many ways, one of the initial steps is to provide guidance and support to faculty pursuing educational research and the scholarship of education. To this end, it is important to establish clear policies and procedures for the conduct of educational research. This is important not only to elevate the rigor and systematic approach to research in the educational environment, but to protect the participants who are core to the mission of this School: our students and our faculty who teach them.

Educational research has undergone significant growth in recent years amid increasing demands for accountability, data-driven decision making, and evidence-based quality improvement. Curricular changes and pedagogical innovations are not only permeating pharmacy schools, but are at the forefront of higher education today. As such, careful consideration should be given to the ability of educational research to inform, transform, and empower faculty as they strive to understand and improve educational outcomes.

These policies and procedures are not intended to infringe upon academic freedom by unduly limiting the scope or subject of a University researcher's academic projects. Rather, they are provided to protect faculty, students, and the organization while promoting educational research that upholds the highest standards of academic integrity. We expect our researchers to adhere to these standards, as failing to do so can put the institution, participants, and researcher at risk.

Educational Research Defined

Educational research generally refers to the systematic and critical investigation of any aspect of education that advances knowledge and benefits society. Although assessment, evaluation, and research are closely related and often complimentary, educational research requires a systematic and rigorous approach that results in new knowledge that can guide theory, contribute to conceptual frameworks, and advance education.

Responsibilities Related to Oversight and Ethical Conduct of Educational Research

The UNC Office of Human Research Ethics (OHRE) includes both the Biomedical and Non-Biomedical Institutional Review Boards (IRB). OHRE is responsible for the ethical and regulatory oversight of research that involves human subjects at the University of North Carolina at Chapel Hill, including the conduct of educational research.

The School is responsible for the oversight of educational research that involves UNC Eshelman School of Pharmacy students and our faculty who teach them. This is important to ensure that efforts are well designed; coordinated, where possible; aligned with the Schools educational efforts; and are seamlessly implemented to minimize disruption in teaching and learning.

An Educational Research Review Committee has been formed to review all School-based educational research proposals involving faculty, students, and/or trainees as participants prior to IRB submission. Currently, the School's Educational Research Review Committee includes:

- Director of the Office of Strategic Planning and Assessment and tenure track faculty member in Educational Innovation and Research
- Co-Chair of the UNC Biomedical IRB
- Two faculty engaged in educational research and the scholarship of education
- Staff member

We have a legitimate educational interest in determining the impact of our educational programs and further aspire to conduct educational research inspired by faculty research interests. At the same time, we acknowledge the importance of FERPA and protecting student records. The following criteria reflect our commitment to rigorous and ethical educational research:

- All proposals reviewed by the School's Educational Research Review Committee will be critically evaluated on each of the eight sections (study purpose and significance; primary research question; sample population and number of participants; anticipated timeline; recruitment and enrollment; data collection methods and identified measures; data analysis plan; relationship between the proposed research question and the primary investigator's job responsibilities; intended use of findings and audience);
- All proposals will be returned to the primary investigator with a list of feedback documented in writing for consideration and a recommendation for moving forward;
- Division chairs will be notified of faculty name, date proposal was reviewed, and the Committee's recommendation;
- All educational research reviews conducted by the committee will be maintained on file in The Academy at the UNC Eshelman School of Pharmacy;
- Studies using identifiable student records:
    - Faculty and staff members who have had access to identifiable student data as a part of their normal job requirements, including course directors, instructors, and admissions personnel will access this data for research purposes only with approval from the committee and in accordance with University policy. Upon approval, the faculty/staff members who seek to use this data will work with the School of Pharmacy's data stewards who will strip the records of any identifying information and provide the data to the researcher. Faculty and staff members who have used this data to inform programmatic and curricular change (e.g., assessment of teaching and learning, admissions review, program evaluation), but are now interested in disseminating findings will be instructed to include clear language in the IRB application to that effect and reminded that all data and results should be de-identified prior to IRB submission.
    - Studies requiring access to FERPA-protected student records maintained in our local registrar's office will be handled by the School's data stewards. The data stewards will strip the records of any identifying information and provide the data to the researcher.
    - **Studies requiring access to FERPA-protected student records from the university's registrar office will be required to obtain documented approval from the Provost office prior to IRB submission.**

Faculty, students, and trainees interested in conducting educational research that involves professional or graduate students, trainees, or faculty must adhere to the following processes and procedures to ensure the ethical conduct of research and to ensure that research being conducted meets acceptable standards of scientific rigor.

While the UNC IRBs are designed to protect the rights and welfare of individuals involved in research, and the School maintains oversight of the process, it remains the researcher's responsibility to ensure that risks are minimal, participant identities are protected, and informed consent is obtained appropriately.

The Process

Step 1: Submit Your Proposal to the Educational Research Review Committee

- To begin the process, you must complete and submit a brief form, the Educational Research Review Form. Once completed, the form will be automatically routed to the Educational Research Review Committee upon submission. The form asks that you outline: 1) study purpose and significance; 2) primary research question; 3) sample population and number of participants; 4) anticipated timeline; 5) recruitment and enrollment; 6) data collection methods and identified measures; 7) data analysis plan; and 8) intended use of findings and audience. *The form is located on the School's website under Faculty Resources and The Academy.*
- The Review Committee will reply within 1-2 weeks to provide information regarding next steps.
- The review is important to ensure that the study is well designed; coordinated, where possible with ongoing studies in the School; aligned with the School's educational and curricular initiatives; and is planned and seamlessly implemented to minimize disruption in teaching and learning.
- If you are not sure whether what you are doing is outside of normal practice or you would like to develop your ideas further, please consult the Committee.
- The Educational Research Review Committee will reach a decision regarding the proposed study, which may include that the investigator:
    - Move forward with IRB submission (i.e., no revisions necessary)
    - Move forward with IRB submission, with suggestions for improving the proposal
    - Revise the proposal, based on specific feedback, and resubmit to the review committee
    - Modify its timeline to prevent conflicts with other ongoing studies

  Note: In all cases, the Educational Research Review Committee will provide justification to support its decision and will discuss this with the investigator and/or study team.
- The Educational Research Review Committee will report to the Dean.
- In the event that the investigator is not satisfied with the decision made by the Educational Research Review Committee, the investigator can appeal the recommendation in writing to the Dean of the School who will evaluate the merits of the process and respond accordingly.

Step 2: Complete and Submit an IRB Application

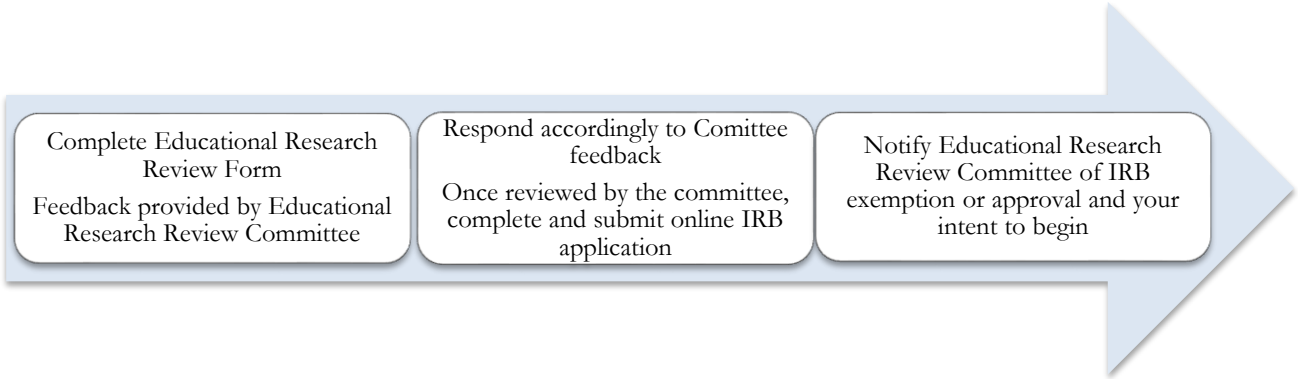
- The UNC IRB does not allow researchers to decide for themselves whether or not their research meets the standards for exemption. Faculty are required to submit an IRB application seeking exemption or approval of a proposed educational study if **any** one of these is true:
    - The faculty member is engaging in the evaluation of any aspect of teaching and learning within the School of Pharmacy, whether in the classroom or experiential setting, beyond the normal practice of course evaluations.
    - The faculty member is interested in collecting identifiable data, such as student PID.
    - The faculty member is interested in accessing student records outside normal practices.
    - The faculty member has an intent to analyze new or existing data for purposes of answering a question or disseminating findings.
    - The faculty member has an intent to disseminate results or findings whether presenting at a meeting, publishing an abstract, or publishing a manuscript.

- All faculty, staff, and students (i.e., all study personnel) engaging in educational research will need to complete Human Ethics Research Training before submitting the IRB application.
    - Completion of either the Biomedical training or Social and Behavioral Sciences is acceptable.
    - Link to online Ethics training: https://research.unc.edu/offices/human-research-ethics/researchers/training/index.htm
- An IRB application should be completed and submitted for each unique project being conducted. The UNC Eshelman School of Pharmacy no longer has an umbrella policy for the conduct of educational research. *Note: Please indicate in the notes section of the IRB application that the proposal was reviewed with feedback provided by the UNC Eshelman School of Pharmacy Educational Research committee.*
- Any surveys, instruments, or questionnaires administered as part of an educational research study must be submitted to the IRB along with the application.
    - Anyone engaging in educational research who has contact with identifiable student records to extract data must have completed Family Educational Rights and Privacy Act (FERPA) training. In many cases, the registrar can access and generate reports of student data for the research team and de-identify this data; however, any investigator coming into contact with identifiable data must have completed FERPA training. http://registrar.unc.edu/training/ferpa/ferpa-online-training/
    - Exemption or approval must be granted by the IRB before any data can be collected, any survey administered, and prior to the start of any research project.
- If a trainee investigator is listed as a principal investigator (PI), the faculty supervisor remains responsible for appropriate supervision of study compliance with all research, ethical, and regulatory requirements.
- If a student is involved in the educational research study as study personnel, their role must be clearly described and assurance provided that the student has no contact with or access to student data.
- An IRB modification must be completed and submitted if there are any changes to:
    - the study personnel;
    - surveys, instruments, or questionnaires (this includes any modification to the survey); or,
    - the design of the study in any way.

Step 3: Once Approved or Deemed Exempt by the IRB

Once a study has received IRB approval or has been exempt from further review by the IRB, the PI must notify the School's Educational Research Review Committee. The Review Committee, on behalf of the School, will ensure that implementation of all studies are coordinated, where possible, to minimize disruption in teaching and learning.

Overview of Process



Resources/Links

- All applications regarding educational research must be submitted to UNC's IRB. A link to the IRB Online Application can be found here: https://research.unc.edu/offices/human-research-ethics/index.htm
- The following serves as an excellent resource and overview on Educational Research and the IRB: Miser WF. Educational Research - To IRB, or Not to IRB? Fam Med 2005;37(3):168-73: http://www.stfm.org/fmhub/fm2005/march/william168.pdf
- IRB Examples from Peers: https://pharmacy.unc.edu/faculty/the-academy/educational-research/irb-templates
- FERPA Training: http://registrar.unc.edu/training/ferpa/ferpa-online-training/
- CITI online Ethics Training: https://research.unc.edu/offices/human-research-ethics/researchers/training/index.htm