Completing Your Education Research IRB

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Disclosure

• I have no commercial interests or financial relationships to disclose.
Learning Objectives

By the end of this presentation, participants will:

• Explain why an IRB is needed for Educational research projects

• Explain when an educational project does and doesn’t need a consent form

• Use the iRIS website to complete and submit an IRB application
• Who has submitted a new project application in iRIS?
All project participants must do IRB training to submit a project for IRB approval

• Education and training requirements- http://compliance.ouhsc.edu/hrpp/OUHSC/Education.aspx
  • There are 3 possible CITI online training courses to choose from
    • Biomedical— Group 1
    • Social/ Behavioral— Group 2
    • Both— Group 3

• Only faculty can be the PI on the project for the IRB application
You must **always** submit an IRB application, even if you think your study is exempt.
When do you need a consent form?

• If trainees are REQUIRED to complete the work/ course evaluation etc.
• If your research involves sensitive subjects like political affiliation, mental health problems, sex behavior, self-incriminating admissions...
• If your work potentially involves more than minimal risk
When can you skip the written consent form?

• If your assessments are anonymous (so that the consent would be the only thing connecting trainees and their study records)
• If participation involves no more than minimal risk
Why do educational projects need IRB approval?

• Research
  • Systematic investigation to develop or contribute to generalizable knowledge
  • Includes testing and evaluation

• Interventions or interactions with human subjects, or identifiable private information from these subjects

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3186257/#
OUHSC IRB

• iRIS -
https://iris.ouhsc.edu/Login.jsp?s=1520888311721
Forms and templates

- Login to iRIS
- On the left, Under “My Assistant”, go to “Operating Procedures”.

### 01_Form/Document Templates - ALL Investigators
- Initial Application Template
- Medical Assessment Form - SAMPLE
- Determination of Human Research Worksheet Template
- How to Obtain Informed Consent
- Modification Summary Report
- Protocol Deviation Summary Report
- Summary of Participant Harms Report

### 02_Form/Document Templates - Health Sciences Center (HSC)
- Protocol Template Outline
- HSC Consent Template - UPDATED 9/21/16!
- Child Assent Template
- Consent/Assent for Tissue Repository
- Consent Statement (Cover Sheet) for Surveys - SAMPLE
- Patient Information Sheet - Tissue Banking
- Addendum Consent Template
- VA Consent Template (Form 10-1086) - updated 9/2017!
- Sample Consent for Emergency Use
- Short Form Consent Template - English
- Short Form Consent Template - Spanish
Which box to check?

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<td>○ Determination of Human Subjects Research Worksheet</td>
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<td>○ Investigator Representation for Research on PHI of Decedents, Privacy Form 7 (Privacy Board Review)</td>
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<td>○ Investigator Representation for Review of PHI - Preparatory to Research, Privacy Form 6 (Privacy Board Review)</td>
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<td>○ One-Time Emergency Use of a Test Article (5-Day Notice of Use)</td>
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<td>○ CIRB Independent Model (Privacy Board Review)</td>
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I checked this box for a study of grand rounds presentations that were publically available. On the worksheet, the study met all requirements of human subjects research, but because the videos were publically available it was deemed exempt.
RESEARCH PROTOCOL OUTLINE

Instructions: Protocols should be formatted according to the following outline and include all of the elements indicated.

Title of Project:

Principal Investigator: Name; Degree; Department
(Example: John Smith, M.D., Dept of Medicine)

Co-Investigators: Name; Degree; Department
(Example: Sally Thompson, Ph.D., Dept of Biostatistics)

Abstract

Include all the essential elements of the protocol - no more than 250 words.

Note: The Research Plan, A through E, should not exceed 1,500 (approx 5 pages) word limit.
Protocols should be single-spaced, have 1” margins, and contain characters of no less than size 12 font.

A. Specific Aims

State the hypothesis and specific aims. List the long-term objectives and what the proposed research will accomplish. (Suggested length: a paragraph or two)

B. Background and Significance

Sketch the background leading to this study, evaluate existing knowledge, and identify gaps, which this study will fill. State the importance of the research by relating the specific aims to the long-term objectives. (suggested length: ½ page)

C. Preliminary Studies/Progress Report

Provide an account of previous studies and/or information that establishes the experience and competence of the investigator to pursue the protocol. (suggested length less than ½ page)

D. Research Design and Methods

Describe the research design and procedures to be used (what, when, how). Include the duration of participation and early termination criteria. Provide a flow diagram or timetable. Procedures, situations, or materials that may be hazardous to personnel and the precautions, should be outlined here. (suggested length at least 2 pages).

If this site is the “lead” center of a national study, describe how information management related to risk, interim reporting and implementation of amendments will be carried out.

E. Statistical Methods

Provide biostatistical design, power calculations determining the number of participants, and the proposed analysis.

Statisticians should be consulted early on in the study design process. A statistician should be involved in study design, sample size planning, and statistical methods.

F. Gender/Minority/Pediatric Inclusion for Research

All protocols must include documentation of the inclusion of women and
minorities in the research protocol.

G. Human Participants
1. Provide number, age range, and health status of the participant population. Identify criteria for inclusion or exclusion. IF ONE GENDER AND/OR MINORITIES ARE NOT INCLUDED, INCLUDING CHILDREN (Age up to 21 yrs.), PROVIDE A CLEAR RATIONALE FOR THEIR EXCLUSION.
2. Identify sources of research material in the form of specimens, records or data.
3. Describe plans for recruitment and consent procedures to be followed.
   a. Describe the location where consent is most likely to take place (will consent be obtained while an inpatient, in the ER/ICU, will consents be mailed with follow-up meeting to discuss the consent, etc.).
   b. Describe provisions for recruiting non-English speaking participants.
   c. Describe measures to decrease coercion of participants (allowing adequate time to review the consent, avoid recruitment of your own private patients – or have a qualified assistant assist with the consent of these individuals, avoid recruiting employees or staff to serve as controls, etc.).
4. Describe risks and assess likelihood and seriousness.
5. Describe procedures for protecting against or minimizing potential risks.
   a. Address measures instituted to protect the privacy and/or confidentiality of participant PHI (locking cabinets for participant records containing PHI, use of password protected programs, limited access to PHI, etc.).
6. Describe potential benefits and importance to the participants and others.
7. Discuss why risks are reasonable in relation to benefits.

H. Data and Safety Monitoring Plan
All protocols must have a Data and Safety Monitoring Plan
1. Describe the Data and Safety Monitoring Plan (DSMP)
   a. reporting mechanisms for adverse events to the IRB, FDA, and NIH.
   b. adverse event (AE) grading
   c. plan for unanticipated AE reporting
   d. plan for annual reporting of AEs
   e. interim efficacy analysis where appropriate
2. Describe the Data and Safety Monitoring Board (DSMB) that will be responsible for monitoring the study.
   • Institutional studies provide:
     a. Chair, members
     b. Frequency of safety reviews
   • Phase III, NIH Studies, or Co-Operative Studies (e.g. ECOG; ACTG), or Drug Sponsored (D) Studies provide:
     a. Contact name
     b. Brief description of Sponsor’s plan

I. Literature Cited
List only literature cited within the text. Use NIH format: names of all authors, title, book or journal, vol, page, year. (suggested length: no more than 12 references)
Request for Waiver or Alteration of Authorization to Use or Disclose Protected Health Information in Research

1. Principal Investigator:

2. Protocol Title:

3. Type of Waiver Requested: □ Complete Waiver
   □ Alteration (Partial Waiver)
   Describe Alteration:

4. Regulatory Criteria for Waiver or Alteration of Authorization:

   The Privacy Rule permits the Privacy Board to waive or alter the requirement to obtain authorization from research participants in order to use their PHI, provided that the investigator justifies, and the Privacy Board agrees, that specific criteria have been met.

   4.1 Describe the PHI to be used/disclosed without authorization.

   4.2 Describe how this information will be used/disclosed.

   4.3 Will the use/disclosure involve more than a minimal risk to privacy? □ No. □ Yes.

      A. What is the plan to protect the identifiers from improper use and disclosure?

      B. What is the plan, if any, to destroy the identifiers?

      C. Will the information be reused or disclosed to any other person or entity?

         □ No.

1 Protected Health Information includes all identifiable information relating to any aspect of an individual’s health whether past, present or future, created or maintained by a Covered Entity.
□ Yes. If yes, describe
(i) when and under what circumstances; and
(ii) how others will be required to protect the privacy and confidentiality of the information:

4.4 Is it practicable to conduct the research without the waiver/alteration?

□ Yes.
□ No. If no, why not:

4.5 Is it practicable to conduct the research without access to and use of the PHI?

□ Yes.
□ No. If no, why not:

Principal Investigator Certification

I certify that:

a. The requested information constitutes the minimum necessary data to accomplish the goals of the research.

b. The research cannot be practicably conducted without the use of the PHI or without the requested waiver or alteration.

c. The risk to the participant’s privacy is minimal.

d. I agree that the PHI will not be re-used or disclosed, except as required by law, for the authorized oversight of the study, or for other research as permitted by the Privacy Rule (45 CFR 164.512).

By providing electronic sign-off for this submission, the Principal Investigator agrees to the certifications listed above.
It used to be…fairly easy to get a proposal through IRB. Now it is easier to write the grant proposal than the IRB proposal. Anonymous researcher

**Background**

Stamina and mental fortitude are necessary attributes for the present-day researcher seeking approval from his institution’s human subjects protection review board (IRB). Both popular media and respected journals continue to report extremely rare but serious harms to research subjects as well as overly bureaucratic IRB responses. This leads to a pervasive perception of IRB overregulation yet underprotection of human subjects. Although the Office for Human Research Protections (OHRP) reports that 70% of allegations of research misconduct are ultimately not substantiated, the risk of suspension or disruption of research during an investigation, in addition to the possibility of damaging reputations and future funding, creates a national climate of anxiety among researchers and ensures continuation of excessive scrutiny of research processes. In fact, deficiencies detected by OHRP are primarily failures of documentation or failure to follow required procedures, not claims of harm to persons or unethical conduct.

However, a recent article by members of the National Institutes of Health and OHRP emphasizes that current regulations do permit significant streamlining of ethical review. Options including exemption or expedited review are underutilized: in the past, 25%–77% of United States IRBs were found to review more rigorously than regulations required. These streamlined processes are particularly relevant to medical education research.

**Does Medical Education Research Require IRB Approval?**

Yes, these studies usually meet requirements for IRB review, as they entail both (1) research (see box 1) and (2) interventions or interactions with human subjects, or identifiable private information from these subjects. The Code of Federal Regulations Governing the Protection of Human Subjects in Research is based on the 1979 Belmont Report and earlier work. The report proposed guidelines for ethical treatment of research subjects guided by 3 ethical principles, beneficence, respect for persons, and justice, which are to be accomplished through attention to informed consent, risk-benefit assessment, and equitability of subject selection. The primary responsibility of an IRB is to protect the rights and welfare of human research subjects and to ensure that risks undertaken by subjects are reasonable in relation to the potential benefits. If your institution accepts federal funding, you must adhere, even if your research is not federally funded: although not required by the Code of Federal Regulations Governing the Protection of Human Subjects in Research, currently IRBs extend federal regulations to all nonfederal research. Private IRBs and review boards are not subject to this law and are increasingly used in clinical research.

Ethical issues in medical education research often arise in subject recruitment, informed consent, confidentiality, and use of de-identified existing medical education data. Students in particular are considered “at risk” subjects due to the underlying power differential between teachers and students, who may receive grades, recommendations, and promotion ratings from their teacher-researcher. As a result, students may feel coerced to participate. Although a power differential may not always exist, residents, faculty, other physicians, and members of the health care team are human subjects, and thus IRB review is required when these groups are studied. In contrast, research involving meta-analyses, systematic reviews, consensus reports, or curriculum proposals does not require IRB review.

**Coercion and Informed Consent**

Medical education research subjects must not be coerced or unduly influenced to participate but rather allowed to “opt out.” Subjects must be provided informed consent for their participation, unless waived by the IRB (see box 2). Even data previously collected, such as routine course evaluations, are subject to IRB review if the course director will be using the data for research. Ideally, one should anticipate the potential future use of data, although this is not always possible. An IRB may refuse to grant approval

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**Box 1** Definition of Research

- Systematic investigation to develop or contribute to generalizable knowledge
- Includes testing and evaluation

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retrospectively, although this should be unlikely if data are de-identified and no harm to subjects can be perceived.

Are anonymous evaluations or questionnaires, distributed by organizations disconnected to the subjects surveyed, subject to IRB review? An example is the Association of American Medical Colleges (AAMC) medical student graduation questionnaire. In 2004 allegations against AAMC’s use of information from the questionnaire were brought. Allegedly, use of this data represented human subjects research that had not received IRB approval or exemption status. Upon review many allegations were not upheld. However, the AAMC agreed to submit future administrations of the questionnaire for IRB review.

At a university where an IRB decided an educational research project evaluating a new medical school curriculum did not require review, allegations of ethical violations were brought against the research faculty, who had carefully complied with all IRB policies. Despite refutation of the allegations, research data were destroyed and valuable study results lost.

Course evaluations, if used for a publication, require IRB review and often informed consent. One strategy includes use of a cover sheet, attached to the evaluation, containing a recruitment script. The script will inform students that their answers may be used as part of a research project, that their participation is entirely voluntary, and that if they choose not to participate their grades will not be prejudiced. This process ensures that all medical students complete evaluations, often required by schools as well as essential for course improvement; data from students who opt out will not be used for research or outside presentations. Anonymity must be preserved as well. If demographic data are needed (e.g., age), use of ranges rather than actual numbers will ensure no individual can be identified.

Education Research Potentially Exempt From IRB Review

The granting of exempt status is always determined by the IRB, not the researcher. The essential elements of exempt research are that risks are minimal and subjects’ identities are unknown (see Box 3). The Code of Federal Regulations Governing the Protection of Human Subjects in Research states that research activities are exempt from regulations if the “research is conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”

This definition of exempt research holds unless the data are both identifiable and potentially harmful if disclosed.

If data are obtained from individuals whose identities cannot be ascertained, the study is not considered human subjects research and thus is not subject to regulation. It is therefore exempt from review. In this category processes must be created that ensure the researcher cannot determine the identity of the participants. Assurances must be provided that the code linking the data to specific individuals will never be disclosed. Researchers can specify future processes to receive data and remove identifiers to allow future data to be exempt from IRB review as well.

Decision trees for exemption categories are available at the OHRP website, which has a wealth of relevant information (http://research.fiu.edu/compliance/humanResearch/guidelineDocuments/humanSubjectsDecisionCharts.pdf).

Variability in IRBs

Each IRB is independent and uses individual criteria to judge issues of human safety. Studies have documented variability in review decisions. Changes requested by an IRB may be minute yet must be done in order to proceed, and substantial delays are common. Education researchers report frustration with the required paperwork, multiple copies, prolonged delays, and other “hurdles” of the IRB oversight process. Also, education researchers may have less assistance than biomedical researchers for creating
and tracking IRB submission paperwork. Those IRBs lacking members with medical education expertise may not be familiar with education protocols, which also may not fit easily into biomedical-focused IRB templates and language. The language of medical risk permeates the language of IRB templates and remains the default language of most forms, including consent forms, which often have weak relevance to trainees.³

**Multisite Research**

Multisite studies typically entail IRB approval from each site involved in the study, although this is not actually required by the Code of Federal Regulations Governing the Protection of Human Subjects in Research.⁵ Each IRB may request minor changes in the protocol or consent document, which results in researchers making multiple applications before approval by all panels. A 2005 study examined the results of the same education proposal, which included an anonymous survey and focus groups of medical students, submitted to 6 medical school IRBs.¹² Four of the IRBs judged the study appropriate for expedited review, whereas 2 performed a full review. For the reviews by a single member, the time to decision ranged from 1–101 days. By 164 days after proposal submission, 1 IRB had not responded; as a result, the study was reduced from 6 to 5 schools participating. The 5 IRBs made 22 unique requests for additional information and 25 unique changes to the protocol. In addition to reducing the number of schools and students participating, the study had to be truncated due to the greatly delayed start and time-sensitive nature of the survey. Most striking is that no IRB designated the anonymous survey portion of the project as exempt research.

Many discussions with education researchers demonstrate that delays of this type are not uncommon. Experts from the National Institutes of Health and OHRP advise that only 1 IRB be used for multisite studies and that IRBs from other participating institutions agree in writing to abide by a single IRB review.⁵ Diverting finite resources of time and money to the effort of multiple reviews, particularly of education research, which usually poses at most minimal risk, is “ethically troubling.”³

**IRBs’ Effects on Research**

A significant problem for both clinical research and education research has been what experts term “mission creep” or “ethics drift,”¹¹,² in which IRBs are unable to clearly delineate and employ the exempt or expedited categories for work that is extremely low risk to human subjects. Even more concerning are reports that university IRBs have required proposal review and approval for routine academic activities, such as interviews performed by students for a class on investigative journalism,⁷ and a national organization requiring IRB review for kindergarten science fair participants.¹ Experts question whether the driving force behind the noticeable expansion of IRB review since the late 1990s is due more to fears of losing federal funding than to true concerns regarding human abuses.¹ Given limited resources of researchers and universities, a rebalancing of resources is in order to “increase the likelihood that the cases most likely to have serious consequences will be most likely to receive the most thorough level of review.”²

Rather than hypothesizing every conceivable harm, IRBs could direct more resources toward research that represents higher risk. IRBs should look for “identifiable harm,” not every “imaginable harm.”² Since the 1990s, IRBs have grown enormously: at 1 university, from 2 full-time staff to 26, a single review panel to 6, and a 2-page protocol template to 15 pages.¹ Yet administrative inefficiency has also continued to expand with major increases in time to approval, even for low-risk protocols. In addition, faculty are more reluctant to serve as members of IRB panels due to heavy workload, numerous complex and ill-defined rules, and the mixture of “gratitude and vilification” that IRB members face from faculty communities.¹

Negative effects of “mission creep” include research dropped altogether, major portions removed, diversion of research topic or population to one more likely to pass easily through IRB review, choosing new research themes according to the likelihood of swift IRB approval above inherent importance of the research itself, and choosing methods, such as meta-analysis, rather than new data collection to avoid IRB review.¹ These are examples in which researchers shied from topics not due to fear of harm to subjects but rather to avoid delays and excessive interference from IRB panels. Time-limited research, such as student summer projects or time-restricted funding, is at particular risk from IRB delays and may discourage trainees from working outside of previously approved projects or existing data sets.

Anecdotal and other reports demonstrate that IRB members can identify risks to subjects that researchers have missed. However, to date there are no valid evaluations of the United States’ IRB system that demonstrate whether IRB review has successfully protected subjects and, if so, which aspects of the IRB process proved most valuable. Because no other research regulatory system is similar in scope or process to that of the US system, valid comparisons are not feasible.¹

**National Consensus on Education Research**

Most researchers agree that the US IRB system is in crisis, due to an imbalance between measures to avoid OHRP attention and litigation and the goals of identifying new ethical questions and risks to subjects.¹⁴ Many groups have called for change, particularly for education research, as well as a national consensus statement on the IRB’s role.
in medical education research.\textsuperscript{8,15} The Editorial Board of the Journal concurs with the need for a consensus statement from relevant stakeholders. Box 5 lists recommendations commonly made regarding IRB oversight of medical education research.

\textbf{JGME Policy}

The Journal of Graduate Medical Education requires all submitted research manuscripts to include a statement regarding IRB exemption or approval, unless human subjects are not studied (ie, reviews, meta-analyses, and descriptions of educational materials without evaluation). This policy applies to the United States and countries with similar regulations; papers from countries with different ethical oversight approaches will be reviewed according to the accepted approaches of those countries. For concerns or questions, authors are encouraged to contact JGME or the Editorial Board for assistance (jgme@acgme.org).

\textbf{References}