

Navigating the IRB for Education Research



Objectives

- Define research and human subjects research.
- Show the "gray area" between research and practice.
- Describe the distinction between a medical education initiative and a medical education research initiative.
- Explain the human subjects protection research regulations.
- List and explain the types of IRB submissions that would be appropriate for medical education research and how to go about the process.

I want to publish (present, etc.)....
so I have to submit to the IRB... Right?

Why does it matter?

- For research that involves human subjects, regulations require that an ethics committee (IRB) must review and approve prior to starting.
 - Risks/benefits
 - Informed consent
 - Voluntary participation
- Assures that research is conducted according to ethical principles outlined in the Belmont Report
 - Respect for persons
 - Beneficence
 - Justice



What happens if we don't get it right?

- Possible harm to the patient/subject.
- Breach of ethical obligations to the patient/subject.
- Formal evaluation by OHRP and/or FDA.
 - Determination letters /Warning letters and resulting corrective actions, enforcement actions (including debarment).
 - OHRP holds institution responsible for conduct of its agents; FDA holds sponsor, investigator and IRB responsible.
- State licensing board findings/actions.

Erosion of public trust in the research enterprise.

International Committee of Medical Journal Editors (ICMJE) and Protection of Research Participants

“When reporting research involving human data, **authors should indicate whether the procedures followed have been assessed by the responsible review committee** (institutional and national), or if no formal ethics committee is available, were in accordance with the [Helsinki Declaration as revised in 2013](#).....Approval by a responsible review committee does not preclude editors from forming their own judgment whether the conduct of the research was appropriate.”

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/protection-of-research-participants.html>

Examples of Indications of IRB Review in MedEd Journal Articles

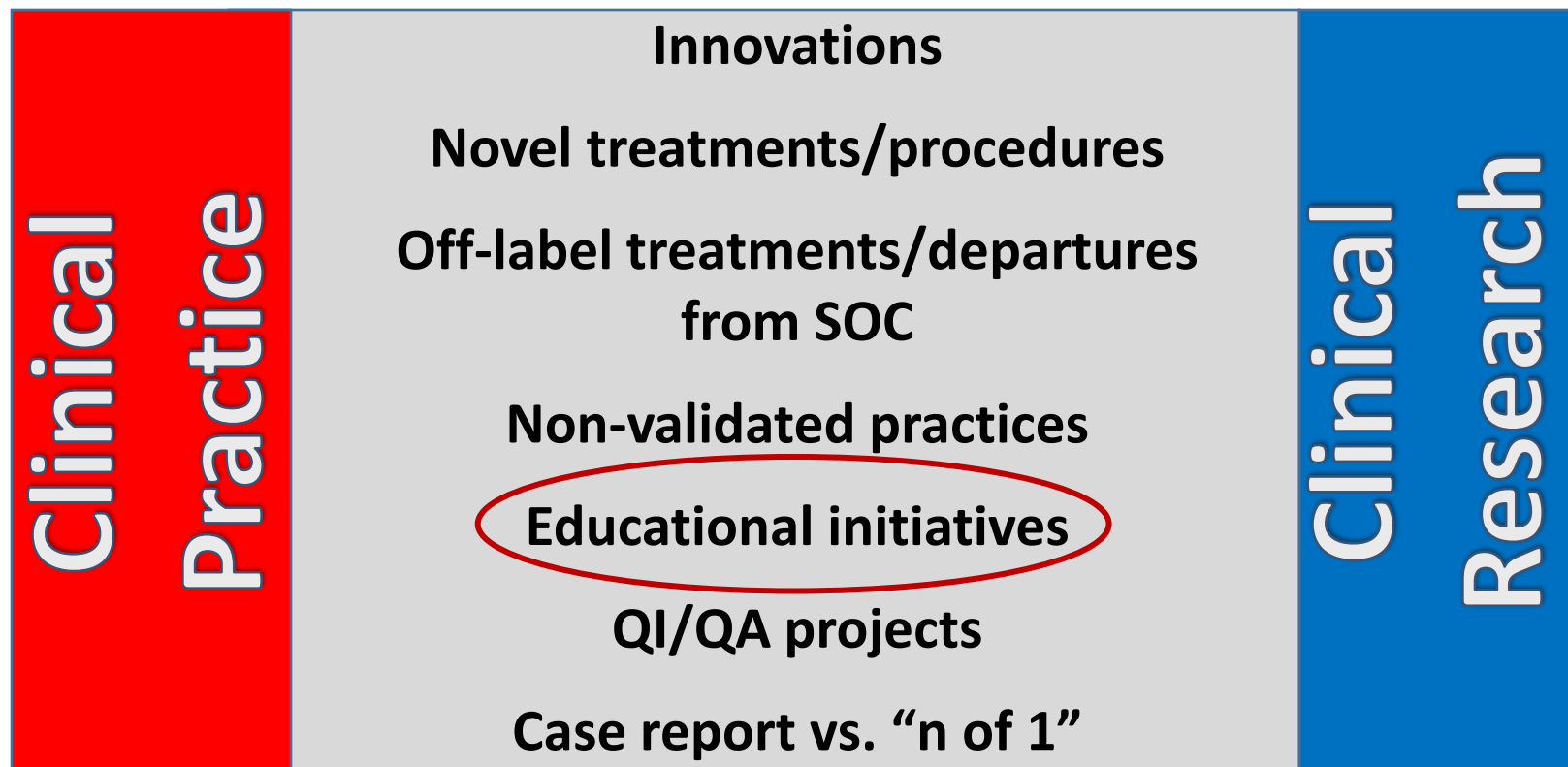
- **Enhancing motivation with the “virtual” supervisory role: a randomized trial (Wingo et al BMC Medical Education 2015, 15:76)**

The study was deemed minimal risk and exempt after Mayo Clinic IRB review. Prior to study initiation, informed consent was obtained. As part of the consent process, participants were informed that the study would “compare two module formats to see if one format promotes more effective learning than the other”.

- **The first OSCE; does students’ experience of performing in public affect their results? (Chan, et al. BMC Medical Education 2015, 15:59)**

Pre-admission statements made at the time of application (UCAS personal statements) were available in individual student files. **Following ethics committee approval** (Project SMBRER232), these statements were coded by a researcher (MC) who was not a student or graduate of this university. This was a specific requirement of the ethics committee.

Gray Area



“When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research.”

Belmont Report, 1979

Gray Area

- **Significant innovations** should be incorporated into a research project to establish safety & efficacy.

- Individual therapy
- Unit/program/dept. specific (i.e. QI/QA)
- More evidence to support goals

Intent

Extent

RESEARCH

- Generalizable

- Little/less known

PRACTICE

What is Research?

- Process of systematic inquiry or study to build knowledge in a discipline (i.e. “generalizable”).
- Results → foundation on which practice decisions and behaviors are laid.
 - “Evidence-based practice”



Overview of Research

- Activities designed to test an hypothesis, permit conclusions to be drawn, and contribute to **generalizable** knowledge.
- Usually described in a formal protocol with an objective and set of procedures. (**systematic**)
- Treatment choices made per protocol, not necess. in the best interest of the patient/subject....
 - ex: “random assignment” (**systematic**)
- Purpose is to gain knowledge, not necessarily to benefit the individual. (**generalizable**)
- Elements under study may not be of direct benefit to the subject.

Quality Improvement

- Systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings.
- Quality improvement is an intrinsic part of good clinical care, in which data from clinicians' own settings guide them in improving their practices.

Lynn, et. Al. *Ann Intern Med.* 2007;146:666-673

Is my medical education activity
QI (only) or research?

QI of Med Ed program.... Or Research?

- INTENT

- Is your activity designed to identify successful and unsuccessful initiatives and improve the local program only?
- Or, in addition to the above do you hope to provide support to change medical education beyond BMC? Are you designing this to understand what makes new educational activities better than current.... Thus intending at onset to generalize?

- EXTENT

- Is your education initiative based on existing evidence from other programs?
- Or, are you implementing something that is it particularly novel/untried?

The distinction can be difficult.....

- “.... Efforts to contribute to generalizable knowledge in order to help future populations are often driven by curiosity as well as an initial need to solve an immediate problem....”

More likely to be research.....

- Testing of new education practices that go beyond current knowledge informed by science and experience
- Randomization of learners into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection
- Deliberately delayed feedback of data to those monitoring the implementation of changes, especially if done to avoid biasing the interpretation of data.
- Involvement in key project roles of researchers who have no ongoing commitment to improvement to the local learning environment.
- Funding or substantial participation by parties outside the learning setting helps direct the implementation and/or evaluation protocols of the educational activity, and specific outcome data are required.

What requires IRB Review?

- 1) Is it research?
- 2) Are there human subjects?

Definitions

- Research (OHRP regs: 45 CFR 46.102 (d))
 - “... *a systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
- Clinical Investigation (FDA regs: 21 CFR 312.3 (b))
 - “... any experiment in which a *drug is administered or dispensed to, or used involving, one or more human subjects.* For the purposes of this part, *an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.*”

Definitions

What is "generalizable knowledge"?

- An activity may be thought to develop or contribute to *generalizable knowledge* if the information collected is intended to be applied beyond a particular patient/setting/program.

US Dept. Justice:

http://www.ojp.usdoj.gov/funding/decision_tree.htm

- Intent of the research is to add info to the field of study. Results applied beyond the subject population to other settings.
- Intent to test or develop scientific hypotheses, draw conclusions to be shared beyond the populations or situations being studied.

More on generalizable knowledge

- The knowledge *contributes to a theoretical framework of an established body of knowledge.*
- The primary beneficiaries: *other researchers, scholars and practitioners in the field of study.*
- Publication, presentation or other distribution of the results is *intended to inform the field of study.*
- The results are expected to be *generalized to a larger population beyond the site of data collection.*
- The results are intended to be replicated in other settings.

I want to publish (present, etc.).... Does *this* mean I have to submit to the IRB?

OHRP response re: publishing QI (non-research) activities:

“Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.”

Definitions

- Human Subject (OHRP regs: 45 CFR 46.102 (f))
 - “... a living individual about whom an investigator.....
conducting research obtains:
 - Data through *interventions or interactions with the individual*, or
 - *Identifiable private information.*”
- Subject (FDA regs: 21 CFR 312.3 (b))
 - “...a human who participates in an investigation, either as a recipient of the investigational new drug or as a control.
A subject may be a healthy human or a patient with a disease.”

Definitions

- **Interaction/Intervention** (45 CFR 46.102 (f))
 - physical procedures by which data are gathered...
 - manipulations of the subject or the subject's environment
 - performed for research purposes
 - interaction includes communication or interpersonal contact between investigator and subject

Definitions

- **Private information** (45 CFR 46.102 (f))
 - Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
 - ... must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.”

(See also OHRP guidance on coded data/specimens:

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>)

Determining when OHRP regs re: IRB review and informed consent apply...

1) Does activity involve Research? (46.102(c))

If yes then.....

2) Does research involve Human Subjects?
(46.102(f))

If yes, then....

3) Does the human subjects research meet
criteria for Exempt from 45 CFR 46?
(46.101(b))

Exempt determination... 45 CFR 46.101 (b)*

1. Normal educational, practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior -unless identified & sensitive**
3. Research on elected or appointed public officials or candidates for public office
4. Research using, existing data if publicly available or recorded without identifiers (existing = at time of submission to IRB)
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

*None of the categories apply to Prisoner research (Subpart C).

** does not apply to research with children except for research involving observation of public behavior when investigator(s) do not participate in the activities being observed.

Types of IRB Review

- Not Human Subjects Research (NHSR)
 - NHSR means that the project does not meet the definition of human subjects research
 - i.e. it's not research OR there are no human subjects
- Exempt
 - 6 categories of exemption under the regulations
- Expedited
 - Minimal risk research
 - 7 expedited categories
- Convened Meeting (Full Board)
 - Greater than minimal risk research

Types of IRB submissions

- NHSR: The educational activity is NOT research
 - Submit to the IRB only if you need a formal determination from the IRB that it is not research.
 - Your subsequent publication should make it clear that it is medical education practice and not research.
- NHSR: The educational activity IS research, but no human subjects are involved.
- Exempt: The medical education project IS research, but meets one of the exempt criteria under the regulations.
- Non-exempt (Expedited or full board): The QI project is research and does not meet exempt or NHSR criteria.
 - Once submitted, the IRB will determine whether this will need expedited or full-board review.

IRB Submission for MedEd projects:

NHSR (because there are no human subjects)

or

NHSR (because it's NOT research)

- Educational practice only, because it's not designed to develop or contribute to generalizable knowledge
- IRB submission and review/approval not required
- But, in this case you want to have a formal determination from the IRB that this is medical education practice-only (not research) or there no human subjects**
 - (This would be a determination, not an approval)
- **The resulting publication should not refer to this activity as human subjects research (and it's not research for med ed. practice only)!**

INSPIR and NHSR Submission

BOSTON UNIVERSITY MEDICAL CAMPUS **BOSTON MEDICAL CENTER** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Mary-Tara Roth, RN, MSN, MPH
Department: BU - MED - CLINICAL RESEARCH CENTER
Navigation: Home > my studies > study mgmt. > application list

Home X Logo

IRB Number: **H-29878** Study Nickname: 29878
PI: Roth, Mary-Tara, RN, MSN, MPH

Study Application

Printer Friendly Save and Continue to Next

Section view of Application Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 External non-BU/BMC Investigators
- 5.0 Investigator Information from INSPIR I
- 6.0 COI
- 7.0 Funding Source
- 8.0 Study Summary
- 9.0 Study Site Information
- 10.0 **Navigation Menu**
- 11.0 NHSR (Not Human Subjects Research)

10.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

10.1 Emergency Use

Is this application for an FDA approved EMERGENCY USE of an Investigational Drug or Device?

Yes No

10.2 Individual Patient IND or Humanitarian Use Device

Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?

Yes No

10.3 Review Path Determination

- This project meets the regulatory definition of **Not Human Subject Research (NHSR)**. Examples are Quality Assurance, Quality Improvement projects, or studies involving obtaining data/tissue.
- BUMC has delegated IRB review to another institution (BUMC is Institution B). (Please note: this relationship requires an Authorization Agreement.)
- According to the Engagement of Institutions in Research guidance by OHRP, neither BUMC (Boston University, Boston Medical Center) nor affiliated institutions/organizations for which the BUMC IRB has oversight responsibilities is "engaged" in human subjects research.
- This study fits into one or more of the Federal Exempt categories.
- None of the above. This study requires Expedited review or the review of the Full Board.

NHSR →

Then, make your case for WHY it is NHSR in Section 11.
- What are two examples of justification that you might use?

IRB Submission for Medical Education projects:


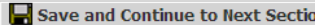
Exempt












- You want to implement an educational initiative and your intent is to generalize the knowledge learned. The initiative presents minimal risk to subjects (**exempt category 1**).
- You have implemented an evidence-based education initiative, and as part of follow-up you want to survey students and you consider this evaluation to be research (**exempt category 2**)
- You did a medical education-only project; afterwards you decide want to generalize the results as research (**exempt category 4**)
 - IMPT: This is NOT retrospective approval for something initially intended to be research! That is NOT an option!

INSPIR and Exempt Submission

  Account: Mary-Tara Roth, RN, MSN, MPH
Department: BU - MED - CLINICAL RESEARCH CENTER
Navigation: Home > my studies > study mgmt. > application list

IRB Number: **H-29878** Study Nickname: 29878 **Study Application** [Back](#)
PI: Roth, Mary-Tara, RN, MSN, MPH

Section view of Application	Entire view of the Application
1.0  General Information	<h3>10.0 Navigation Menu</h3> <p>Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.</p> <h4>10.1 Emergency Use</h4> <p>Is this application for an FDA approved EMERGENCY USE of an Investigational Drug or Device?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <h4>10.2 Individual Patient IND or Humanitarian Use Device</h4> <p>Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <h4>10.3 Review Path Determination</h4> <ul style="list-style-type: none"><input type="radio"/> This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies involving obtaining data/tissue.<input type="radio"/> BUMC has delegated IRB review to another institution (BUMC is Institution B). (Please note: this relationship requires an Authorization Agreement.)<input type="radio"/> According to the Engagement of Institutions in Research guidance by OHRP, neither BUMC (Boston University, Boston Medical Center) nor affiliated institutions/organizations for which the BUMC IRB has oversight responsibilities is "engaged" in human subjects research.<input checked="" type="radio"/> This study fits into one or more of the Federal Exempt categories.<input type="radio"/> None of the above. This study requires Expedited review or the review of the Full Board.
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3.0  Grant Key Personnel access to the study	
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6.0  COI	
7.0  Funding Source	
8.0  Study Summary	
9.0  Study Site Information	
10.0  Navigation Menu	
11.0  Categorical Exemptions	

Exempt 

In Section 11, choose Exempt category 1 if it is minimal risk education research, **Exempt category 2** if you have a survey or **Exempt category 4** if data is all existing at the time of submission, and it is anonymous (no link back to the record).

IRB Submission for Medical Education projects:

Non-Exempt (expedited or full-board review/approval)

- You want to implement a new educational practice that does not have sufficient evidence base to support its efficacy and may pose greater than minimal risk to subjects.

INSPIR and Non-exempt Submission

BOSTON UNIVERSITY MEDICAL CAMPUS **BOSTON MEDICAL CENTER** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Mary-Tara Roth, RN, MSN, MPH
Department: BU - MED - Clinical Research Resources Office
Navigation: Home > my studies > study mgmt.

Home Logout Help

IRB Number: **H-30409**
PI: Roth, Mary-Tara, RN, MSN, MPH

Study Application Back

Print Friendly Save and Continue to Next Section

Section view of Application Entire view of the Application

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10.0 **Navigation Menu**
11.0 Purpose
12.0 Subjects
13.0 Design/Procedure
14.0 Sample Size/Specimens/Data Analysis
15.0 Potential Risk/Discomforts
16.0 Data & Safety Monitoring

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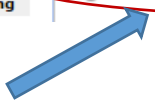
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Non-exempt



- Complete the full application, that "builds" based on your responses in Section 10.**
- Consider whether a "waiver of consent" applies; if so make that request within your application.

Flexibility in Regs re: Consent

Waiving Informed Consent for Research (45 CFR 46.116 (d))



1. Minimal Risk
2. Does not adversely affect subject rights and welfare
3. Not practicable to conduct research without the waiver
4. When appropriate, subjects provided with pertinent info after participation.

Informed Consent for Exempt (1,2)

Consent form should provide the following information:

- that this is a research study
- the purpose and what the subjects are being asked to do and approximately how long it will take
- that participation is voluntary and if they don't want to participate it will not impact their [jobs][care] in any way
- that they can choose not to answer any questions that they wish
- how their confidentiality will be protected
- payments for participation if any
- who to contact with questions about the study (must be a member of the research team)
- who to contact if they have questions about their rights as a research subject -BUMC IRB at 617-638-7207 or medirb@bu.edu

Additional considerations: Risk to Subjects

- Two types of risk under the regulations
 - Direct physiological or psychological harm
 - Loss of privacy or breach of confidentiality that could place a subject at risk for social, professional, or economic consequences, or criminal or civil liabilities
- For example: if data collected in an experimental educational initiative is used to evaluate medical residents This could pose risk to subjects and be a breach confidentiality.....

Additional considerations: Vulnerability of subjects

- Coercion
 - Consider power relationship between subjects (students) and investigators.
 - Will subjects receive extra benefits to career advancement, grades, etc. due to participation? Will subjects lose benefits they would otherwise have by not participating?
- Undue influence

IRB application sign-offs

- Department chair
- If your application involves students or employees of the hospital you must have additional sign-off:
 - Medical students – Dean Antman
 - Dental Students – Barbara Pyke (signs off on behalf of the dean)
 - Residents or fellows – Ravin Davidoff

- Examples (time permitting)
- Questions???