Student Research

Brenda Ruotolo
Executive Director
Human Research Protection Office
Institutional Review Boards
IRB = Institutional Review Board

An Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

**IRB Membership**
- Columbia University has 5 IRBs on the Medical Center Campus and 1 IRB on the Morningside Campus.
- Membership: faculty, staff, and representatives from the community.

**Authority**
- IRBs have the authority to review, approve, disapprove, suspend and monitor all research proposing or approved to include human subjects.

**Operational Goal**
- The Human Research Protection Office provides services that facilitate and strengthen human subjects research conducted by investigators at Columbia University.
IRB Mission and Scope

Mission: Protection of human subjects in research that is supported or conducted by Columbia personnel

Scope: Review of research that involves human subjects, and other activities as specified by institutional policy, state law or other applicable statute

- Genetic testing of deidentified biospecimens
- Student projects that are not “research” but involve greater than minimal risk to participants

Columbia applies the requirements of Title 45 of the Code of Federal Regulations Part 46 (45 CFR 46) to all research with human subjects
Definition of *Research*

A *systematic* investigation designed to develop or contribute to *generalizable* knowledge

(45 CFR 46.102(d))

*Accepted research methods are employed to gather data that will be analyzed to explore a research question or test a hypothesis.*

**Knowledge that could be applied to populations or situations outside of the population or situation being studied.**
Definition of *Human Subject*

A *living* individual

*about whom*

an investigator (whether professional or student)

conducting *research* obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

(45 CFR 46.102(f))
Research

Theses, dissertations and honors research projects are considered to meet the regulatory definition of research per 45 CFR 46.

Students conducting these activities have reached a level of sophistication with respect to research design and conduct that may lead to generalizable results, e.g., those that may inform policy, apply to individuals or groups beyond the subject population, and/or contribute to the professional or scholarly literature on the topic.

If human subjects are involved, IRB review is required, regardless of risk level.
Drawing the Lines with Key Definitions

1-Research?

2-Human Subject?

3-Exempt (admin)?

Non-exempt activities covered by the Regulations=IRB review

Adapted from M. Carome, OHRP
Ethical Principles

Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research)

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Respect for Persons (autonomy and protection for those with diminished autonomy)

Beneficence (obligation to minimize risk)

Justice (fairness in distribution of benefits and burdens)
Regulations: Ethical Principles

**Respect for Persons**
- Informed Consent will be sought for each prospective subject
- Informed Consent will be documented
- Research plan adequately protects the privacy of subjects and maintains confidentiality

**Beneficence**
- Risks are minimized (consistent with a sound research design and does not unnecessarily expose subjects to risk)
- Risks are reasonable in relation to benefits
- Research plan adequately provides for monitoring the data collected to ensure safety of subjects
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects

**Justice**
- Selection of subjects is fair and equitable
IRB Determinations and Levels of Review

- **NHSR**
  - Determination of Non-Human Subjects Research
  - Does not meet the definition of “research” and/or “human subject” per regulations

- **EXEMPT**
  - Exempt Determination
  - Generally Low Risk
  - 6 Exemption Categories

- **EXPEDITED**
  - Expedited Review
  - Minimal Risk
  - 9 Expedited Review categories

- **FULL BOARD**
  - Convened Review
  - Greater than minimal risk research
  - Not eligible for exempt/expedited
Basis for Student Research Policy

Ensure that *non*-research student activities that may incur >minimal risk of harm have adequate protections (equivalent to that required for non-student research)
Drawing the Lines with Key Definitions

1-Research?
2-Human Subject?
3-Exempt (admin) ?

Non-exempt activities covered by the Regulations = IRB review
> min risk student projects

Adapted from M. Carome, OHRP
Current Students as Researchers Policy

Except for:

Low Risk Introductory Research Methodology Exercises

• Campus/public setting
• Learning research methodology
• Minimal risk
• Anonymous data collection

All research activities involving human subjects and conducted by Columbia students must be approved by the IRB prior to the initiation of the research activity.
Responsibility for determining level of risk and whether a project requires IRB review rests with the student’s faculty advisor and/or department.

Student projects, e.g., introductory research exercises or practicum assignments, must be reviewed and approved by … IRB when they involve greater than minimal risk of harm to participants, to provide increased protection to the participants.

MSPH has permission to implement the draft policy.
Submission Process

• Rascal: electronic submission, review and tracking system
• PI must meet Columbia criteria; student will be an investigator
• Ensure training requirements are met
• Complete all required screens/questions
• Attach all study instruments
• Allow time for review
• Respond promptly to IRB requests
• IRB website: http://www.cumc.columbia.edu/dept/irb/
Rascal IRB 2.0

Enhanced Module is now live!

IRB 2.0 Site Map

Updated Schedule of Informational and Support Sessions

Current list of CUMC IT certified systems:

https://rsam.cumc.columbia.edu/RSAM_DEFAULT.aspx

8/7/2015

Combined Consent and HIPAA Authorization Form - new process

- Updated Rascal Consent Builder Sample Text
- Minimal Risk Consent Template
- Information Sheet Template

Policy & Guidance Refresher

July/August 2015

Research with Minors Training

If the study population includes children, completion of the CITI Biomedical Research with Minors module is required. This module is accessible within the CITI Human Subjects Protection Training Program, and should be accessed through the RASCAL Training Center.
Have questions, suggestions, or concerns about research that involves human subjects? Use the IRB Staff Directory, Phone Tree, Office email address ("Ask the IRB" link), or suggestion box to contact us!
Key points

Students do not meet eligibility criteria to serve as PI

Whether IRB review is required or not, faculty advisors must ensure that projects are conducted in an ethical manner and provide active oversight throughout the life of the project.

*Research* that qualifies for exemption is HSR but is not subject to the requirements of 45 CFR 46

Projects that are not *research* and/or do not involve *human subjects* are termed “Not Human Subjects Research” or NHSR
Contacts

Brenda Ruotolo, Executive Director, HRPO/IRBs
blr2102@columbia.edu

HRPO Office: 154 Haven Avenue, First Floor

Walk-in Consultations: Tuesdays, 10-11 am

CUMC IRB website:
http://www.cumc.columbia.edu/dept/irb/
IRB and Students As Researchers

Anne Paxton
Cassie Landers
March 28, 2017
OFP
Frequently Asked Questions

If a Columbia student will be working on a Columbia IRB-approved study for which a Columbia faculty member is the PI, in a manner that constitutes engagement in that study, is a submission to the IRB required?
If a Columbia student researcher will be analyzing a de-identified data set under the mentorship of either a Columbia or non-Columbia advisor, is a submission to the Columbia IRB required?
Frequently Asked Questions

- If a Columbia student will be working, in a manner that constitutes engagement, on a research project approved by a non-Columbia IRB for which a non-Columbia researcher is the Principal Investigator, is a submission to the Columbia IRB required?
What if, a practicum project is completed, the results are such that they can contribute to the professional or scholarly literature and the student would like to publish them?
IRB Pre-screening Review through OFP

1. After consulting with academic advisor, IRB pre-screen is needed
2. Send email to mshp-ofp@Columbia.edu
   1. Subject line: MPH Practicum Student Pre-Screening
   2. Copy Faculty Advisor
   3. Include name, Uni, Degree and Department
   4. Attach PDF of faculty reviewed SOW
3. In addition, submit a one page document with the following information:
   1. A statement of the risks and benefits to the study participants
   2. A statement regarding how the data/information/report will be utilized
IRB Prescreening Review through OFP

- Student will receive feedback within one week:
  - NO further action, or
  - Submit IRB protocol

- Utilize the pre-screening process only when you are unsure and required further guidance
Additional Information:

- **Rascal Website:**
  - [Https://www.rascal.columbia.edu](Https://www.rascal.columbia.edu)

- **IRB Open Office Hours**
  - Every Tuesday 10:00-11:00 154 Haven, First Floor
Contact Information

Office of Field Practice (OFP)

- General E-mail: msph-ofp@cumc.columbia.edu
- Linda Cushman, PhD – Associate Dean for Field Practice (lfc2)
- Cassie Landers, EdD – Faculty Lead (cl689)
- Ana Jimenez-Bautista, MSW – Director (aj2168)
- Tabaitha Rodriguez, BS – Administrative Officer – (tr2217)
- Koma Ogaye, BS – Student Administrative Support
Columbia University
Human Research Protection Office
Students as Researchers Policy

Scope

This Policy applies to all human subjects research and other scholarly activities involving human participants conducted by students at Columbia University (“Columbia”) and clarifies which research projects or activities require review by the Columbia Institutional Review Board (IRB) for the protection of human subjects in research.

Effective date: February, 2017; this Policy replaces the Students as Researchers Policy that was effective on March 16, 2012.

Definitions

Research: as defined in 45 CFR 46.102(d) i.e., a systematic investigation designed to develop or contribute to generalizable knowledge. [45 CFR 46(d)]

Exempt Research: Research involving Human Subjects that includes only procedures that fall into one or more of the categories of research that have been designated by the U.S. Department of Health and Human Services as exempt from the requirements of the regulations for the protection of human subjects in research. [45 CFR 46.101(b)]

Greater Than Minimal Risk: a risk of harm that is greater than that which the individual would normally experience in the course of his/her daily life or in routine medical or psychological examinations.

Human Subject: as defined in 45 CFR 46.102(f), i.e., a living individual about whom an investigator (whether professional or student) conducting research obtains

- Data through intervention or interaction with the individual; or
- Identifiable private information. [45 CFR 46(f)]

Student Researcher: an individual who is pursuing a degree or course credit at Columbia and, as part of a Columbia course or degree requirement, is either:

- conducting Research that involves Human Subjects, or
- in order to learn or practice research methodology, is collecting private identifiable data about living individuals, or interacting with them to collect data about them.

Students cannot be Principal Investigators: all students submitting an IRB protocol require a faculty member, usually their advisor, to submit as the PI.

Background

All Research with Human Subjects that is conducted by Columbia faculty, staff or students, or is otherwise conducted under the aegis of Columbia, requires submission of a protocol to a Columbia IRB and prospective IRB approval prior to commencement of research procedures.
Dissertations, theses and honors research projects are considered to be Research. Students conducting these activities may have reached a level of sophistication with respect to research design and conduct that may lead to generalizable results, e.g., those that may inform policy, apply to individuals or groups beyond the subject population, and/or contribute to the professional or scholarly literature on the topic. Publication may be an outcome of such Research, but is not a requirement for a project and its results to be considered generalizable. IRB review for dissertations, theses, and honors research projects is required if they involve Human subjects.

Many student projects are not dissertations, theses or honor research activities, but are designed to provide students with an opportunity for service-based learning, e.g. to practice public health skills to improve a program or project of a service organization. In general, these service-based learning opportunities, including but not limited to needs assessments, program design activities, program monitoring and evaluation, quality improvement assessments, and reports of lessons learned, do not constitute Research because the results would not likely be generalizable. Presenting results of these projects in a program report, within the student’s department or school, and even possibly in a peer review journal would not ordinarily be considered ‘generalizing from the project’; thus this level of discussion or sharing about the student practice experience does not mandate IRB review prior to inception.

Some of the “non-Research” projects have characteristics that may place the individuals about whom data are gathered for the purpose of the project, at Greater Than Minimal Risk. In addition, student investigators as a group have minimal experience in conducting research. Accordingly, these projects require additional scrutiny in order to protect the individuals who are involved as subjects. At Columbia, the IRB has been designated as the appropriate body to review these projects.

Policy

Dissertations, theses and honors research projects constitute Research and when they involve Human Subjects must be reviewed and approved by a Columbia IRB, or an IRB upon which Columbia has chosen to rely through the terms of an IRB Authorization Agreement (Reviewing IRB), prior to commencement of research procedures. Exempt Research at Columbia University Medical Center may also be reviewed by the Administrative Review Committee in the Columbia Human Research Protection Office (HRPO). Other student projects, e.g., introductory research exercises or practicum assignments, must be reviewed and approved by a Columbia IRB or a Reviewing IRB only when they involve Greater Than Minimal Risk.

For projects other than dissertations, theses and honors research projects, the responsibility for determining the level of risk and whether a project requires IRB review rests with the student’s faculty advisor and/or department. The HRPO will provide training with respect to making these determinations and will conduct quality assurance audits to evaluate whether determinations that have been made are consistent with this Policy.
Types of risk to which individuals may be exposed that must be considered when evaluating the level of risk for a project include, but are not limited to, physical, psychological, financial and social harm. When project participants are members of vulnerable populations, or are in a subordinate position to, or in a fiduciary relationship with, those conducting the project, the risk level may be increased as a result and additional protective measures may be necessary to avoid elements of coercion or undue influence. Consultation with the HRPO is recommended for these cases.

To facilitate ethical conduct of a student project, whether IRB review is required or not, faculty advisors must ensure that students are appropriately trained and procedures are in place for communication between advisor and student throughout the life of the project. Being familiar with details of the project and incorporating human subject protection requirements into research methodology courses will facilitate this objective.

See Appendix A for the question flow for determining whether a student project must be submitted to the IRB for review and Appendix B for Frequently Asked Questions relating to student projects.
Appendix A

Decision flow

Does the activity that the Student Researcher will conduct meet the regulatory definition of Research, i.e., the design of the project is such that it may develop or contribute to generalizable knowledge?

- If yes and
  - Private, identifiable data will be collected about living individuals, submission of a protocol to the IRB is required
  - Data about living individuals will be collected through interaction with them, submission of a protocol to the IRB is required
  - Data will NOT be collected about living individuals, submission of a protocol to the IRB is generally* NOT required

- If no and
  - Data will be collected about living individuals (i.e., private identifiable data, or any data collected through interaction with them) and
    - The activity presents Greater than Minimal Risk to the individuals, submission of a protocol to the IRB is required
    - The activity presents no more than minimal risk to the individuals, submission of a protocol to the IRB is NOT required
  - Data will NOT be collected about living individuals, submission of a protocol to the IRB is not required

*Exceptions:

1. Genetic testing to which New York State Civil Rights Law Section 79-l, when deidentified human biological samples will be used; the definition of human subject is not met but IRB certification that the samples are deidentified must be obtained.

2. Testing of a medical device, when deidentified biological samples will be used, and study data may be submitted to or held for inspection by FDA as part of an application for a research or marketing permit; the definition of human subject in the FDA medical device (technically, Investigational Device Exemption) regulations includes individuals whose biological samples are being used for research.
Appendix B

Frequently Asked Questions

1. What if, after a practicum project is completed, results are such that they can contribute to the professional or scholarly literature and the student would like to publish them?

A pre-screen should be submitted via the Office of Field Practice, requesting approval to further analyze the existing data and disseminate results. The faculty advisor should be listed as the Principal Investigator and the Student Researcher as a co-investigator. The document sent to OFP for pre-screening purposes should describe the procedures that were used, noting that the project was designed to make a programmatic public health contribution, not to produce generalizable results. Approval of additional analyses that are proposed and dissemination of results is not guaranteed. Analysis to confirm preliminary findings and release results of the analysis may not occur prior to hearing whether or not the student needs to formally submit to the IRB and not prior to IRB approval if required.

2. If a Columbia student will be working on a Columbia IRB-approved study for which a Columbia faculty member is the PI, in a manner that constitutes engagement in that study, is a submission to the IRB required?

Engagement reflects participation beyond administrative activities, e.g., involvement as an investigator, coordinator or research assistant. Activities that indicate engagement include obtaining informed consent, interacting with study participants to collect research data, and having access to identifiable research data about participants. A modification must be submitted to add the student to the approved protocol.

Review of the student’s activities will be conducted by the Columbia IRB using the appropriate level of review, which is dependent upon the type and risk level of study procedures.

3. If a Columbia student will be working, in a manner that constitutes engagement, on a research project approved by a non-Columbia IRB for which a non-Columbia researcher is the Principal Investigator, is a submission to the Columbia IRB required?

Yes. In some circumstances, a non-Columbia IRB will be the Reviewing IRB for the student’s involvement. An IRB Authorization Agreement (IAA) to formalize the reliance must be executed. Certain information is required to be submitted to the Columbia IRB to track the research activity, regardless of which IRB is the Reviewing IRB. A Columbia faculty member must be listed as the Principal Investigator and the student should be listed as a co-investigator. Both the student and the Columbia PI must have satisfied the Columbia research training requirements.
The IRB review conducted at Columbia will be an administrative review, acknowledging the Reviewing IRB’s approval and confirming satisfaction of Columbia-specific research requirements, e.g., training. The role of the Columbia Principal Investigator in this situation is to ensure that Columbia requirements (e.g., training, conflict of interest) are met, to confirm that IRB approval from the non-Columbia institution has been obtained and ensure that it remains current during the student’s involvement, to serve as a resource when the student has questions or concerns about the research, and to appropriately route concerns or reports of unanticipated problems to the non-Columbia researcher and/or the IRB, should these situations arise. A brief summary of the project in which the student will be involved, and a description of the role of the student, are required in the Rascal IRB submission, and documentation of approval from the non-Columbia IRB must be provided.

4. If a Columbia Student Researcher will be analyzing a de-identified dataset under the mentorship of either a Columbia or non-Columbia advisor, is a submission to the Columbia IRB required?

Analysis of de-identified data does not generally require IRB review because the definition of Human Subject is not usually met, i.e., there is no interaction with the subjects and no private, identifiable information is collected.

A submission to the Columbia IRB is not required provided that all of the following criteria are met:

- The activities in which the student will be involved are limited to analysis of a de-identified dataset;
- The mentor ensures that the student will not have access to identifiers or other information that would enable the student to identify the individuals about whom the data were collected; and
- The Columbia faculty advisor and/or department maintain records of the student’s involvement in the project, including documentation that the student’s role was limited to analysis of de-identified data.

The same requirements apply when the data are coded, provided that the student is not provided with the key to the code.

In these situations the student is considered a mentee with a limited and defined role. The student is not considered a member of the “research team” that is conducting, has conducted or will conduct the procedures through which the data will be or have been collected. This distinction is important because members of the research team are all considered to have access to identifiable subject data, if at least one member of the team has such access. Research personnel, including students, with access to identifiable subject data must be covered under an appropriate IRB approval.
5. Do federal regulations require IRB review of projects that do not meet the definition of research?

No, the requirement for submission of Greater Than Minimal Risk projects conducted by students, when the project does not meet the regulatory definition of Research, is an institutional policy. It was implemented to safeguard individuals in investigative projects conducted by students, who are in the process of learning and practicing research methodology, and therefore are less experienced.

6. Why is it important to differentiate projects that are or are not subject to federal regulation?

For projects that are not subject to federal regulation, the HRPO has more flexibility. An assessment of regulatory requirements is needed to determine how much flexibility the HRPO has with respect to consent and approval requirements and to consider whether reliance agreements are needed, among other issues.

7. Can IRB Authorization Agreements (IAAs) apply to student research?

Yes, but only when federal regulations, other applicable statutes, or Columbia policies require an IRB submission. The IAA can be for a single project or groups of projects, e.g., all student projects overseen by Department of Health mentors. Note that IAAs generally only improve efficiency when used for projects that do not qualify for exemption or expedited review, or for multiple projects.

1/23/17 Version.