STUDENT PRACTICUM PROJECTS AND THE IRB

Columbia Policy

"all research… involving human subjects must be registered with or reviewed by the IRB without regard to the sources of funding"

- even if considered exempt from Federal law

Defining "research"

"Any systematic investigation… designed to develop or contribute to generalizable knowledge"

(If you're planning to publish, it is "research")

Defining "human subject"

"...a living individual about whom an investigator conducting research obtains...data through intervention or interaction with the individual or identifiable private information."

Does your practicum require IRB approval ?

YES: project involves human subjects research*	MUST have a Faculty Principal Investigator and submit protocol to CU IRB through RASCAL.	Work with your Faculty PI to either Submit a protocol or be added as an Investigator
NO : Project has no human subjects research component. For example, the project is a policy, health education or curriculum that *does not include evaluation and does not pose more than "minimal risk"*	Confirm this with your Practicum Faculty Advisor	No next step for IRB
NO: Project involves only de-identified data as defined by privacy rule (IF ANY DOUBT, SUBMIT FOR SCREEN!)	Confirm that your data doesn't have any of the 18 identifying variables*	No next step for IRB
POSSIBLY: project includes interaction with human subjects or identified data, with possible need for IRB review (IF ANY DOUBT, SUBMIT FOR SCREEN!)	Scope of Work MUST be submitted for MSPH Student Pre-Screening review.	Proceed to the Pre-Screen Instructions*

** For more information please refer to IRB instructions posted in OFP courseworks*

MAILMAN'S NEW "*prescreen*" process

- Review by Mailman faculty and administrators
- Need to submit SOW *after consulting with academic advisor*
- Submit to: msph-ofp@columbia.edu with "IRB Pre-Screen +UNI" on subject line
- Decision will be either:
  - NO further action, or
  - Submit IRB protocol

- ***PRE-SCREEN ONLY WHEN UNSURE ABOUT IRB NECESSITY!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!***

RASCAL Website

- Https://www.rascal.columbia.edu/

IRB Open Office Hours

- Tuesdays from 10 AM to 11 AM at 154 Haven Avenue, first floor (CUMC IRB Office)

Contact Information

Office of Field Practice (OFP)

- Linda F. Cushman, PhD – Associate Dean for Field Practice (lfc2)
- Cassie Landers, EdD, MPH – Faculty Liaison (cl689)
- Ana Jimenez-Bautista, MSW – Program Manager (aj2168)
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THANK YOU FROM THE OFFICE OF FIELD PRACTICE AND OFFICE OF CAREER SERVICES

Columbia University Medical Center

Student Research

Brenda Ruotolo

Executive Director

Human Research Protection Office

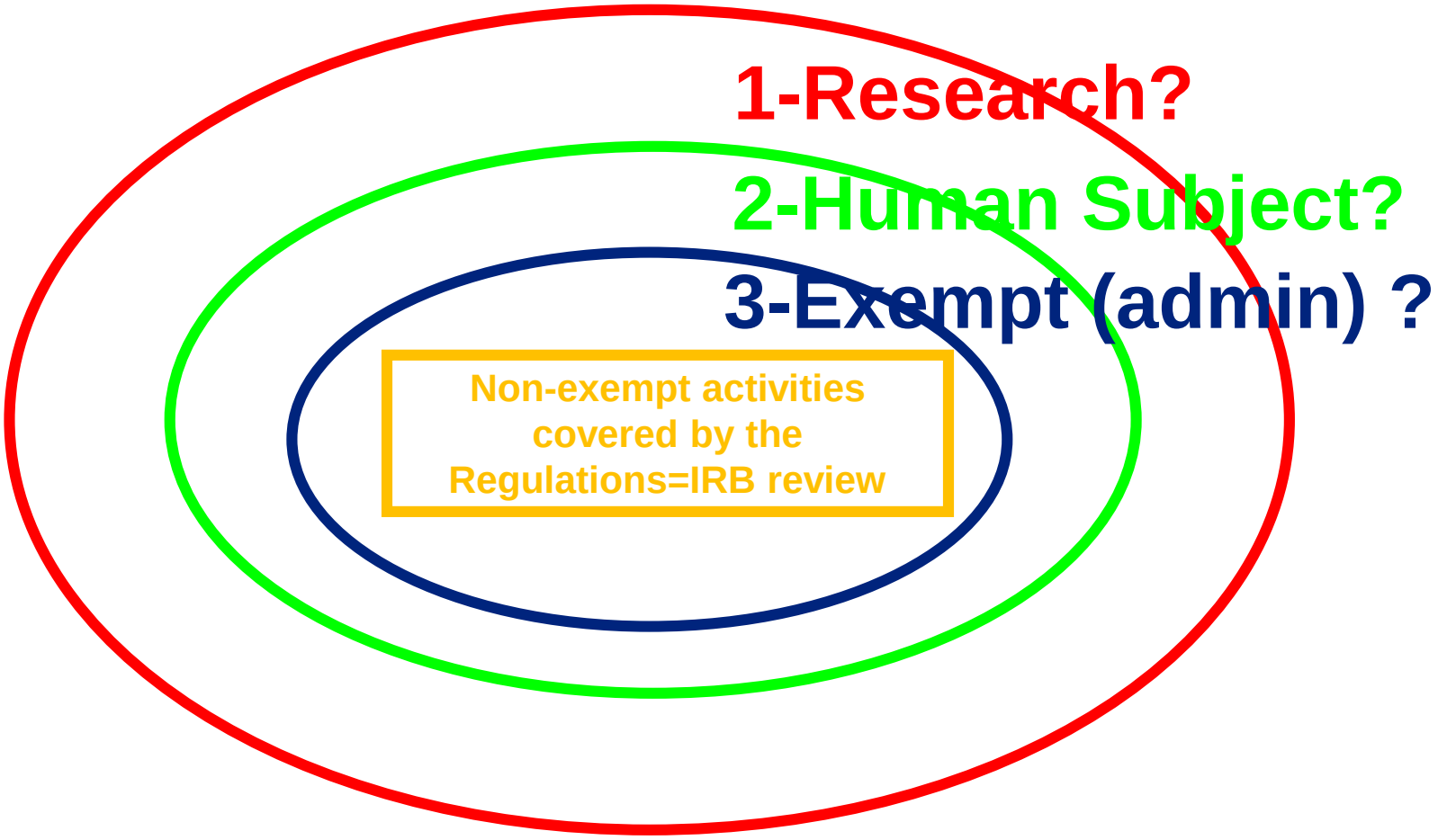
Institutional Review Boards

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

Drawing the Lines with Key Definitions



Adapted from M. Carome, OHRP

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.

In both current and *revised (draft)* policy.

Basis for Student Research Policy

Ensure that non-*research* student activities

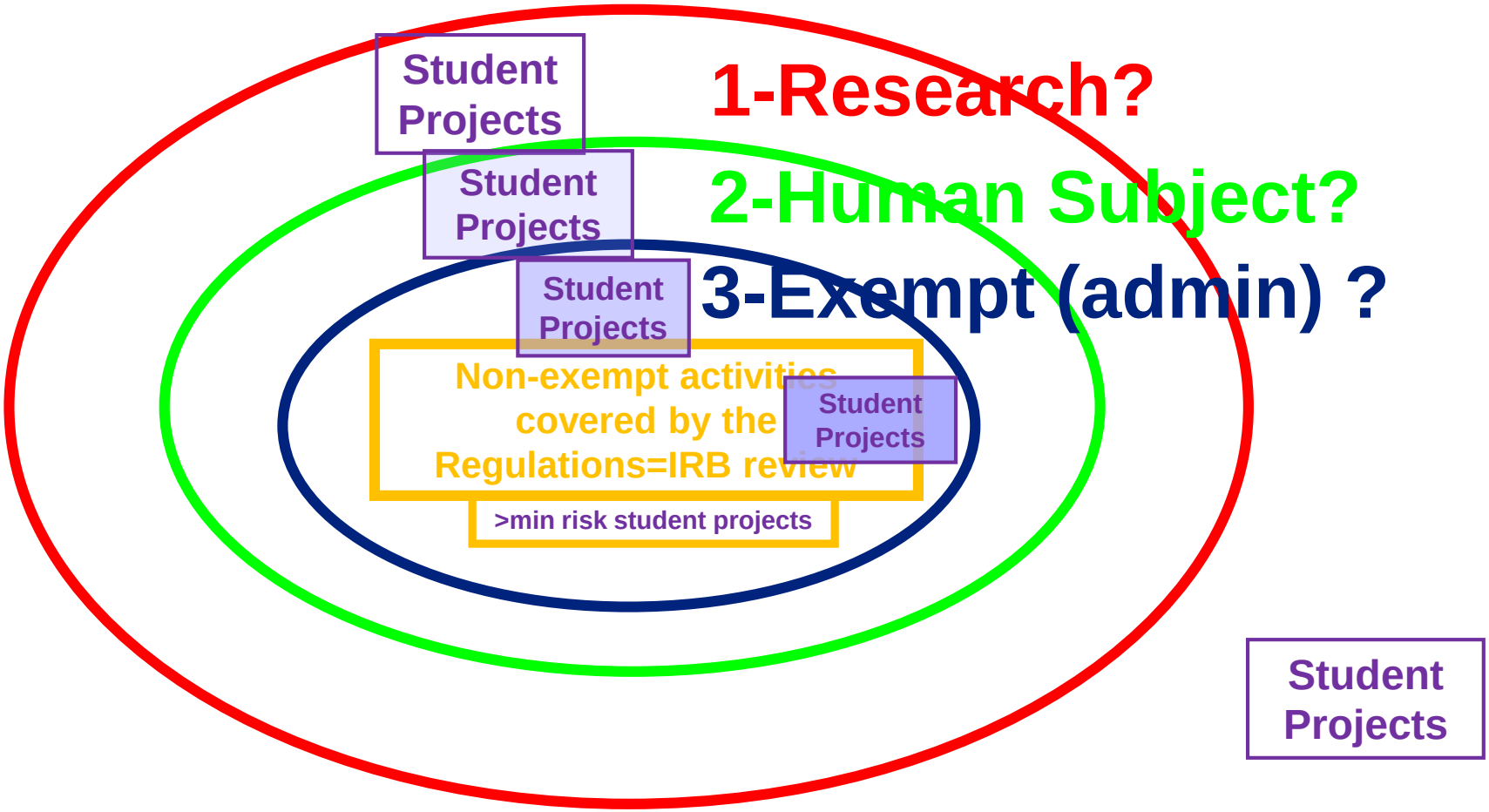
that may incur

>minimal risk of harm

have adequate protections

(equivalent to that required for non-student research)

Drawing the Lines with Key Definitions



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.

Draft revised Policy

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.

Reminders

Research that qualifies for exemption is HSR

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

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.

Contacts

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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: *[date]*; this policy replaces the Students as Researchers Policy that was effective on March 16, 2012.

Definitions
Research is defined in 45 CFR 46.102(d), which applies to all research conducted by Columbia personnel or under the aegis of Columbia University, as a systematic investigation designed to develop or contribute to generalizable knowledge.

Human subject is defined in 45 CFR 46.102(f) as 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.

Student Researcher is defined as an individual conducting research, or interacting with individuals in a way that exposes the individuals to greater than minimal risk as defined in this policy, as part of a course or degree requirement.

Background
All *research* with *human subjects* that is conducted by Columbia faculty, staff or students, or is otherwise conducted under the aegis of Columbia University, requires submission to a Columbia IRB and prospective IRB approval prior to commencement of research procedures.

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. Publication may be an outcome but is not a requirement for a project and its results to be considered generalizable. IRB submission is required if the *research* involves *human subjects.*

Many student projects are not theses, dissertations or honors research activities, but are designed to provide students with experience in practicing research methodology, e.g., introductory research exercises or practicum assignments. In general, these activities do not meet the regulatory definition of *research* because the results would not likely be generalizable. However, some of these projects have characteristics that may place the individuals about whom data are gathered, for the purpose of the project, at risk of harm that is greater than that which the individual would normally experience in the course of their daily life or in routine medical or psychological examinations, i.e., the activity may present greater than minimal risk of harm to them. 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. At Columbia, the IRB has been designated as the appropriate body to review these projects.

Policy

Dissertations, Masters' theses and honors research projects that 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 ("Designated IRB"), prior to commencement of research procedures. Other student projects, e.g., introductory research exercises or practicum assignments, must be reviewed and approved by a Columbia or Designated IRB when they involve greater than minimal risk of harm to participants, to provide increased protection to the participants.

The responsibility for determining level of risk and whether a project requires IRB review rests with the student's faculty advisor and/or department. The Human Research Protection Office will provide training with respect to making these determinations and will conduct quality assurance audits to evaluate whether determinations that are being made are consistent with the policy.

Types of risk to which individuals may be exposed, and must be considered when evaluating 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 fiduciary relationship with those conducting the project, risk level may be increased as a result, and additional protective measures may be necessary to avoid elements of coercion or undue influence.

Whether IRB review is required or not, faculty advisors must also ensure that projects are conducted in an ethical manner and provide active oversight 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 these objectives.

See Appendix A for the question flow for determining whether a student project must be submitted to the IRB for review.

Frequently Asked Questions that may arise for student projects are addressed in Appendix B.

Appendix A

Decision flow

Does the activity that the student will conduct meet the regulatory definition of *research*?

- If yes and
    - Identifiable data will be collected about living individuals, submission to the IRB is required
    - Data will be collected through interaction with individuals, submission to the IRB is required
    - Data will NOT be collected about living individuals, submission to the IRB is NOT required
- If no and
    - Data will be collected about living individuals and
        - The activity presents more than minimal risk to the individuals, submission to the IRB is required
        - The activity presents no more than minimal risk to the individuals, submission to the IRB is NOT required
    - Data will NOT be collected about living individuals, submission to the IRB is not required

Appendix B

Frequently Asked Questions

1. What if, after a project that was designed to practice research methodology is completed, results are such that they can expand the professional or scholarly literature?
    a. A proposal should be submitted to the IRB, requesting approval to analyze the existing data and disseminate results. The faculty advisor should be listed as the Principal Investigator and the student as a co-investigator. The IRB submission should describe the procedures that were used, noting that the project was conducted to learn research methodology, i.e., there was no intent to disseminate results. Approval of the proposed analysis and dissemination of results is not guaranteed. Data and results of analysis of the data may not be disseminated prior to IRB approval.

2. If a Columbia student will be working on a Columbia faculty member's IRB-approved protocol, in a manner that constitutes engagement, what approval is required?
    a. Engagement reflects participation beyond administrative activities, e.g., as an investigator, coordinator, or research assistant, and includes 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 protocol.

3. If a Columbia student will be working, in a manner that constitutes engagement, on a 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?
    a. Engagement reflects participation beyond administrative activities, e.g., as an investigator, coordinator, or research assistant, and includes obtaining informed consent, interacting with study participants to collect research data, and having access to identifiable research data about participants. A submission in Rascal is required in order to track the research activity. A Columbia faculty member must be listed as the Principal Investigator and the student should be listed as a co-investigator. The role of the 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, and documentation of approval from the non-Columbia IRB must be provided. Both the student and the Columbia PI must have satisfied the Columbia research training requirements.

4. If a Columbia student 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?
    a. A submission to the Columbia IRB is not required provided that all of the following criteria are met:
        1. The activities in which the student will be involved are limited to analysis of a de-identified dataset;

2. 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;
3. 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.

b. The same requirements apply when the data are coded, provided that the student is not provided with the key to the code.
c. 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 or has conducted 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?

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

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.

8. When IRB review is provided by a Designated IRB, is submission to the Columbia IRB also required?

   A submission to the Columbia IRB is required for tracking purposes and to confirm that local requirements are met, e.g., training requirements, conflict of interest disclosures, and data security protections. Documentation of approval by the Designated IRB should be attached to the submission. At Columbia, the submission will receive an administrative review.