

STUDENT PROJECTS AND THE IRB

CRAIG KANDELL, RESEARCH RESOURCES, MSPH
AUGUST 11, 2014



Learning Objective

- ✓ - The goal of this session is to familiarize you with the rationale, structure, requirements and process of IRBs. The goals are:
- ✓ - A brief history on why IRBs were established
- ✓ - Purpose and structure of IRBs
- ✓ - What types of research need IRB approval
- ✓ - Requirements for IRB approval
- ✓ - Protocol development, timeline, and process, including common pitfalls
- ✓ - Working with multiple IRBs at once for specific contexts (for example, an in-country IRB and a CU IRB)
- ✓ Discussion and reflection about summer experiences



Ethics: Historical Highlights

- Hippocrates
 - Rights and safety of patients of paramount importance
- Nuremberg Code (1947)
 - Responds to WWII era Nazi atrocities
- Declaration of Helsinki (1964)
 - 12 basic principles for the conduct of human biomedical research
- Belmont Report (1979)
 - Responds to syphilis patients in Tuskegee, AL (1972)
[**1997** On May 16th President Clinton apologizes on behalf of the Nation.]
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993)
 - Council for International Organization of Medical Sciences (CIOMS) and WHO – currently undergoing revisions



Ethical Principles of Research:

Belmont Report

- ✓ Researchers fully informed of purpose and competent to conduct w/scientific integrity
- ✓ **Respect for Persons:** Full disclosure and free choice (informed consent) for participants, including the right to withdraw, and consideration of special needs of vulnerable populations
- ✓ **Beneficence: No Harm. Do Good.** What are the benefits? Who benefits? Consider potential for risk to subject (physical, psychological, social or economic, or legal harm) and balance risks and benefits
 - Confidentiality and anonymity of participants
- ✓ **Justice:** Research participants are chosen so that specific communities or specific groups share both the risks and benefits of the research. No one should be overburdened or excluded, and there needs to be some direct or indirect benefit to the community

Crosby et al. [Research Methods in Health Promotion](#). 2006



What does this have to do with me?

- Real issues in student projects:
 - Remuneration for participation in a project?
 - Photographs?
 - Facebook?
 - Blogs?
 - Opening old wounds?*
 - Expectations?*
 - Confidentiality?*
 - Security risks?*
- Is IRB approval needed?



*Goodhand, J. 2000. [Research in Conflict Zones: Ethics and Accountability](#). Forced Migration Review 8

Ethics Committees/IRBs

- ✓ Purpose: All health care research is intrusive, thus, ethical approval needed
- ✓ Membership: lay and religious persons, lawyers, researchers, clinicians, social work
- ✓ Convened to Ensure Ethical Research:
 - Protect rights and welfare of subjects (Respect for Persons)
 - Ensure informed consent is obtained
 - Assess if potential benefits warrant risks ([Beneficence](#))
 - Attention to vulnerable populations (Justice)



IRB Approval

- ✔ Risks minimized/reasonable
- ✔ Selection of subjects is equitable
- ✔ Informed consent documented
- ✔ Subjects' safety monitored
- ✔ Privacy/Confidentiality of data



Institutional Review Boards

“Columbia policy is that **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



Students should consider the following two questions:

- Will my practicum be a **research project**? In other words:
- Is the work being done for the sole purposes of developing, improving, adapting or evaluating a program or educational curriculum, with your deliverables to be used internally by your host organization (*not research*)?
- OR
- Is it a systematic investigation intended to extend knowledge in the field through publication or other dissemination of your results (*research*)?



Defining “research”

“Any systematic investigation...
designed to develop or contribute
to **generalizable knowledge**”

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



If Yes, Will my research involve **human subjects**?

- ☞ Will you be interacting with living individuals, including collecting data from them and/or implementing an intervention/educational curriculum OR will you be working with data that contains personal identifiers?
- ☞ If your answer here is "NO", you do not need IRB approval.

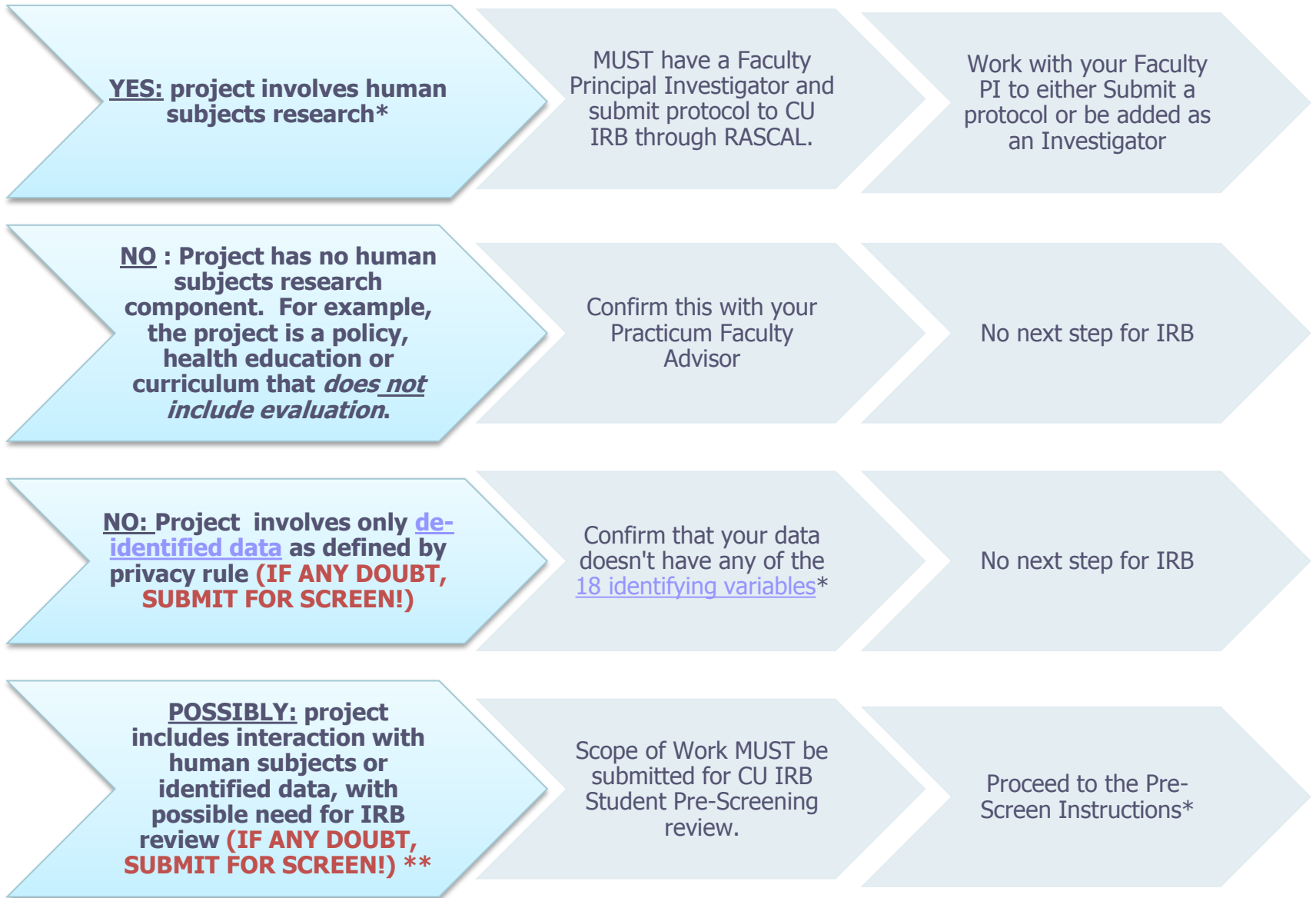


Defining “human subject”

“...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 ?



(*) For more information please refer to <http://cphs.berkeley.edu/hipaa/hipaa18.html>; (**) Caveat: if the procedures could be considered greater than minimal risk (e.g. either physical risk OR the data is particularly sensitive) then a pre-screen must be submitted

(**) Caveat: if the procedures could be considered greater than minimal risk (e.g. either physical risk OR the data is particularly sensitive) then a pre-screen must be submitted



HIPAA PHI: List of 18 Identifiers and Definition of PHI

List of 18 Identifiers

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)



Types of IRB Review

- Exemption
- Expedited (Administrative) Review
- Full Board Review

Exempted Research

- The IRB, not the investigator, decides which studies are exempt
- Exempt research is not exempt from ethical principles or institutional rules
- Remember, at Columbia, all research involving human subjects must be registered with/reviewed by the IRB



Expedited Review

An IRB may conduct an "Expedited Review" for studies that entail only minimal risk, and for minor changes in existing, approved protocols.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Full Board Review

- What it sounds like – the protocol is reviewed by the full IRB
- Additional experts may be consulted, depending on study specifics
- Each IRB meets twice a month – once your protocol is assigned to a Board it will stay with that Board for the life of the project



IRB and Student Research: projects with faculty

- Participation in research conducted by Columbia faculty member (including data collection or analysis)
 - *Faculty member should add student to their IRB protocol*
- Participation in research conducted by faculty member at another university
 - *Must submit an IRB protocol for Columbia University*



IRB and Student Research: projects with existing data sets

- Analysis of de-identified publically available data does not require IRB registration/approval
 - Demographic and Health Surveys ([DHS](#))
 - [NHANES](#) (National Health and Nutrition Examination Survey)
 - De-identified data from a nongovernmental organization probably would be acceptable to IRB for student thesis



IRB and Student Research: service-based projects

- Work conducted towards improvement of health care services such as operations research MAY NOT be human subjects research
 - Monitoring and evaluation
 - Disease surveillance
 - Focus groups and exit interviews to improve patient satisfaction

Depends on how the information will be used

Must submit a “pre-screening” request to IRB for determination



IRB and Student Research: data collection for eventual publication

- Collection of project (or student's own) data in field setting
 - Must be IRB reviewed and approved*
 - Columbia faculty member must stand in as PI whether this is done with CU faculty or other investigators*
 - Language of survey instrument must be translated and certified*



How to “prescreen”

- Write an email to: irboffice@columbia.edu, following the directions below **exactly**.
- Subject Line: “Mailman MPH Practicum Student Pre-Screening”
- Copy your Practicum Faculty Advisor on the email submission to IRB
- In the text of the email: Student Information:
- Full Name:
- CU Email address:
- School and Degree: “I am a Mailman MPH student”
- Mailman Department:
- Create a PDF of your faculty reviewed Scope of Work form and attach it to the email. You must name the file:
UNI LastName FirstName MPH Practicum SoW

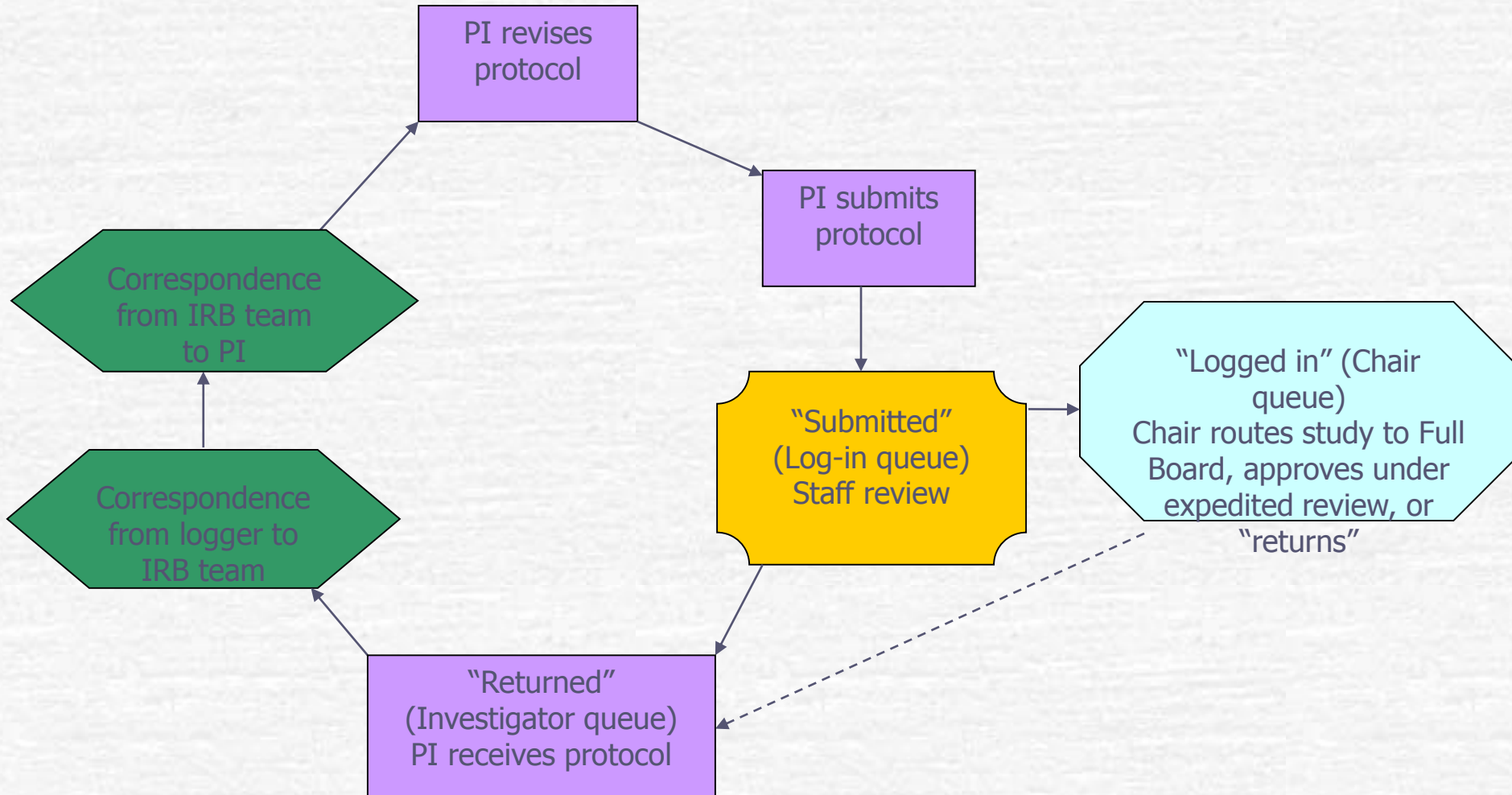


Helpful wording!

- A statement of the risks and benefits to the participant in the study.
 - *e.g. "The risk to participants is extremely minimal. Although some questions may be perceived as 'personal,' respondents can decide to skip any question that they do not wish to answer."*
 - *e.g. "Benefits are usually minimal, although some respondents may feel it is a benefit to provide their opinions and experiences in order to improve programs."*
- A statement regarding how the data/information/report will be utilized.
 - Is publication in a journal or presentation at a professional conference planned? Or will the information be used for program development, enhancement, improvement. **(Please note: final presentations of practicum work to supervisors is NOT professional presentation/publication.)**



Overview of the IRB Process



1. [How long will it take for the IRB to review my application?](#)

Depending on the nature of the study, IRB review may take one day or as long as one month. The IRB may request additional information from the investigator which could lengthen the process.

2. How long is my approval valid?

Your approval is valid for one year from the date of approval



Helpful Links:

Columbia University IRB:

<http://www.columbia.edu/cu/irb/>

Columbia University RASCAL, FAQs:

<https://www.rascal.columbia.edu/help/irbfaq.html#qe1>

