Carnegie Mellon University

Data, Research, and IRB Review

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Agenda

1. Define research and Human Subjects Research (HSR)
2. Describe the role of an Institutional Review Board (IRB)
3. Define levels of review for Human Subjects Research (HSR)
4. Outline what is needed for a protocol and Informed Consent

First Steps for Researchers

- Figure out the question. What information are you looking for and what are you going to do with it?
- Information gathered and your intent will determine review required.
- Have a very clear, defined idea and methods.

First Steps for IRB

- Answer the following questions:

  1. Is the project **RESEARCH**?
  2. Is the project research involving **HUMAN SUBJECTS**?
  3. Is the institution **ENGAGED** in the Human Subjects Research?

- If the answer to all 3 is yes, IRB review is required

Research

- A systematic investigation designed to develop or contribute to generalizable knowledge
- **Generalizable Knowledge**: designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. Information does not need to be published to be generalizable.
- Will information be published/presented, used to develop a new standard to be used nationally/globally, or otherwise shared outside of the group?

Examples of activities that typically are **not designed to develop or contribute to generalizable knowledge**:

- Biographies.
- Oral histories that are designed solely to create a record of specific historical events.
- Service or course evaluations, unless they can be generalized to other individuals.
- Services, courses, or concepts where it is not the intention to share the results beyond the specific community/group.
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices.
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the specific group/community.

Human Subjects Research

- Governed by Office of Human Research Protections (OHRP) and possibly Food & Drug Administration (FDA)
  - 45 CFR 46 and 21 CFR 50, 56, 312 & 812
- According to 45 CFR 46, a **human subject** is "a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;

    OR
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Human Subjects Research

Intervention

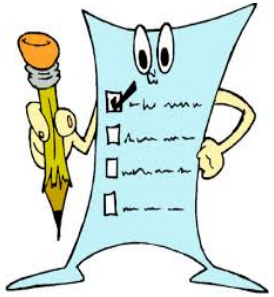
Data gathered from:

- Physical procedures
- Manipulations of the subject or their environment

Interaction

Data gathered from:

- Communication between investigator and subject
- Surveys



What is Identifiable Private Information?

•**Private information** 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 that has been provided for specific purposes by an individual and that **the individual can reasonably expect will not be made public** (e.g., a medical record).

•**Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.

•May be identifiable directly or indirectly by code or other means

- Television/movies? Social media posts? YouTube videos? Shared datasets?

Personally Identifiable Information (PII) and Protected Health Information (PHI)

Elements that are identifiable 

Anonymous – No identifiable information will be accessed or collected. No identifiable information existed in the research record.

De-identified – Identifiable information existed, but is completely and permanently removed with no possibility of re-identification of subjects

Coded – Identifiable info existed, was completely removed, and replaced with a code. A key to decipher the code exists.

Identifiable – research records contain any elements that allow for identification of a subject

Protected Health Information (PHI):	Personal Identifying Information (PII):
Protected Health Information (PHI) is an individual's health information that is created or received by a health care provider related to the provision of health care by a covered entity that identifies or could reasonably identify the individual. The 18 identifiers that are considered PHI are included in OHRPP Guidance & Procedures: Health Insurance Portability and Accountability Act (HIPAA) An individual's personal and health information that is created, received, or maintained by a health care provider or health plan and includes at least one of the 18 personal identifiers listed below in association with the health information: ○ Name ○ Street address ○ All elements of dates except year ○ Telephone number ○ Fax number ○ Email address ○ URL address ○ IP address ○ Social Security number ○ Account numbers ○ License numbers ○ Medical Record number ○ Health plan beneficiary # ○ Device identifiers and their serial numbers ○ Vehicle identifiers and serial number ○ Biometric identifiers (finger and voice prints) ○ Full face photos and other comparable images ○ Any other unique identifying number, code, or characteristic *Limited Data Set* - a limited data set can include the following identifiers: a unique number code, or characteristic that does not include any of the above listed identifiers, geographic data (without street address), and/or dates.	***Personal Identifiable Information (PII)*** is defined as data or other information which otherwise identifies, an individual or provides information about an individual in a way that is reasonably likely to enable identification of a specific person and make personal information about them known. Personal information includes, but is not limited to, information regarding a person's home or other personal address, social security number, driver's license, marital status, financial information, credit card numbers, bank accounts, parental status, sex, race, religion, political affiliation, personal assets, medical conditions, medical records or test results, home or other personal phone numbers, non-university address, employee number, personnel or student records and so on. Information about an individual which includes any of the identifiers below: ○ Name ○ Street address ○ All elements of dates except year ○ Telephone number ○ Fax number ○ Email address ○ URL address ○ IP address ○ Social Security number ○ Account number, credit or debit card number, in combination with any required security code, access code or password that would permit access to an individual's financial account ○ Driver's License numbers or Pennsylvania or other identification card number ○ Device identifiers and their serial numbers ○ Vehicle identifiers and serial number ○ Biometric identifiers (finger and voice prints) ○ Full face photos and other comparable images ○ Any other unique identifying number, code, or characteristic (e.g., student identification number).

Sensitive Data
An individual's first name (or first initial) and last name in combination with any of the following: ○ Social Security Number ○ Driver's License Number or Pennsylvania ID card number ○ Financial account information such as a credit card number ○ Medical Information

Is your institution "engaged" in research?

- An Institution is considered **engaged** in a particular human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; (3) the informed consent of human subjects for the research; or (4) the project is funded directly by HHS (i.e., Institution is the Prime awardee) which includes funding from NIH.

- An Institution's **employees or agents** refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities.

- "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

What is an Institutional Review Board (IRB)?

- Institutional Review Board is an **independent** oversight body whose primary mandate is to protect the rights and welfare of humans who participate in research.
- Composed of at least 5 members
  - Primarily scientists from institution
  - Needs at least 1 non-scientist and 1 non-affiliated member
  - Needs specific expertise when reviewing studies (i.e. psychologists for psychology studies)
  - Expertise for vulnerable populations like children and prisoners

Criteria for IRB Approval

- **Risks to Subjects are Minimized** - by using a sound research design that does not unnecessarily expose subjects to risk
- **Risks are Reasonable in Relation to Benefits** – potential benefits must outweigh the potential risks
- **Selection of Subjects is Equitable**
- **Informed Consent will be sought and documented** for each subject – (unless waiver is obtained from IRB)

Criteria for IRB Approval

- **Research Plan Adequately Provides for:**
  - Monitoring the data collected to ensure safety of the subjects
  - Protects the privacy of subjects and maintains confidentiality of the data

- 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.

  -Children

  -Decisionally Impaired

  -Prisoners

  -Students/Employees

Writing A Protocol

- Should include specific and complete information about the who, what, when, where, why, and how of the study.
- Who – population to be studied
- What – data collected
- When – time points studied and length of study
- Where – location of the study
- Why – rationale for the study
- How – procedures, methods for gathering and analyzing data, storage of data

Writing An Informed Consent

- Written in lay terminology (8th grade reading level)
- Purpose
- Involves research
- Procedures to be done
- Study duration (total participation time, number of visits)
- Responsibilities
- Compensation (class credit, monetary, parking, meals, etc.)
- Risks and benefits (always include “breach of confidentiality” as a risk)
- Alternative participation options (e.g., not to participate, another study for credit)

Considerations for IRB – Risk Level

- *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- Type of research review will depend on whether or not the study involves “Greater than Minimal Risk”.

IRB Reviews

- Three Levels of Review for Research, each with specific requirements that must be met:
  - Exempt: Minimal Risk, 6 categories (e.g. educational, surveys, etc.), approved by Chair or Designated Reviewer
  - Expedited: Minimal Risk, 9 categories (e.g. blood draws, research on group behavior, data from recordings, etc.), approved by Chair or Designated Reviewer
  - Full Board: Greater than Minimal Risk or does not meet criteria for Exempt/Expediated review, no specific categories delineated

Exempt Categories

- Exempt 1: research in established **educational settings** and normal educational practices (e.g. classroom learning study).
- Exempt 2: **tests, surveys, interviews, observation of public behavior**. Data must either be recorded anonymously or disclosure would not put subject at risk.
- Exempt 3: **benign behavioral interventions (brief, harmless – such as playing a game, organizing items).** Adult subjects ONLY. Data must either be recorded anonymously or disclosure would not put subjects at risk (physical, psychological, financial, criminal). No more than a few hours taking place on the same day.
- Exempt 4: **Secondary Use of identifiable data** if data is publicly available OR data will be recorded in your dataset in a way that subjects cannot be identified, researcher does not contact the subjects, or re-identify them.
- Exempt 5 & 6 – not commonly used so not discussed here (Federal projects and Food Tasting)

Expedited Categories (non-exempt)

- Studies that do not fit any Exempt Categories. Some examples of research that requires (or likely require) Expedited review:
  - studies involving deception/incomplete disclosure
  - most studies involving minors, all studies involving prisoners

- Categories 1-3 all deal specifically with clinical/medical research so are not covered here.
- Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes. (remains identifiable)
- Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.
- Category 7(a) Research on individual or group characteristics or behavior
- Category 7(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full Board Review

- If **any aspect** of a study does not fit into Exempt or Expedited Categories, it must be reviewed by the Full Board. Determines if study is minimal risk or not.
- If a study may be Greater than Minimal Risk, it must be reviewed by the Full Board.

Reddit research example

- “Reddit offers a level of anonymity, primarily through the ability to choose a username that doesn't reveal your real identity. However, it's important to note that Reddit is not entirely anonymous. While users don't need to disclose personal information, a motivated individual could potentially link your account to your real identity by analyzing your post and comment history.” – Google AI Overview
- Usernames may or may not be identifiable readily or posters may include information within their posts that allow for identification
- If observing PUBLIC Reddit posts to record data on a topic of discussion –
  - Not HSR because the posts are public even though they may be identifiable

Reddit research example

- If observing **PRIVATE GROUP** posts –
  - Yes, HSR because not fully public (closed groups and moderators must approve individuals to join and post) and may be identifiable
    - If NOT retaining the identifiable information in the research dataset – May be Exempt 4 (secondary use of identifiable info)
    - If retaining identifiable information in the research dataset – May be Expedited 5, 6, and/or 7 OR may require Full Board review if there may be greater than minimal risk in the information collected (e.g., criminal behavior, reputation risk)

Reddit research example

- If researcher is posting a prompting question/information to observe responses -
  - Yes HSR, because of the manipulation of the environment (intervention) and prompting interaction with people for responses – even if recording of identifiable information isn't happening (usernames or otherwise).
  - May be either Exempt 3 (Benign Behavioral Intervention), if NOT recording identifiable information OR
  - Expedited 5, 6, or 7 if identifiable info is recorded OR
  - May require Full Board review if there may be greater than minimal risk in the information collected (e.g., criminal behavior, reputation risk)

IRB Approval

- IRB will issue a notification of its determination once final approval is obtained.
- Do not begin research unless you have received the final approval!
- Keep IRB informed of study progress
  - Continuing Review (if required), problems or new information (deviations, reports, etc.), modifications, study closure

Modifications

- Any changes needed to previously approved study information (procedures, data points, study team, consent language, enrollment, etc.)
- Changes must be approved by the IRB prior to implementing changes (unless for immediate subject safety concerns).
- Submit a Modification application along with any applicable changed documents/info.
- You will receive an approval notification from the IRB when the modification is approved and you can implement changes.

Linked Administrative Processes

- Several Administrative processes are linked to the IRB process but ARE NOT under the purview of the IRB.
    - Data Use Agreements
    - Visitor Agreements
    - Foreign Data Protection Regulations (e.g., GDPR)
    - Material Transfer Agreements
    - Conflict of Interest
    - Child Protection Clearances
    - ClinicalTrials.gov registration
- The IRB may recommend the researchers contact another Administrative dept. to determine whether additional items are needed prior to the research beginning, but the IRB does not manage these processes or make related determinations.

Questions???

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