Considerations for Collecting Identifiable Private Information in Human Subjects Research

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NIST
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Agenda

Overview of human research protections

- Human Research Protection Program at NIST
- Common Rule

Study review

- Background definitions: identifiable, deidentified, anonymous, coded
- Use of pre-existing data with or without identifiers
- Prospective collection study data

Permissions

- Informed consent and/or data sharing agreements
- Required elements of consent
- Terms of use

Data retention and future use of data

Human Research Protection Program

- Department of Commerce is one of 20 signatories to the Common Rule for the Protection of Human Subjects, 15 CFR 27
- NIST holds a Federalwide Assurance
  - Written assurance that NIST commits to following the Common Rule and the ethical principles of protecting human subjects
- Senior NIST official with oversight of the Human Subjects Protection Program is the Institutional Official

Human Research Protection Program

- NIST policies and procedures governing the review and approval of research potentially involving human subjects
  - The RPO manages the everyday operating policies for the function of the office and management of the IRB – “Manual”
- Education and training
- Institutional Review Board (IRB)

Primary purpose of the HRPP is to protect the rights and welfare of research participants

Common Rule Overview

- The Common Rule (15 CFR 27) regulations are intended to implement the basic ethical principles governing the conduct of human subjects research – updated in 2018

- These ethical principles are set forth in the "Belmont Report"
  - **Respect for Persons** – people are autonomous agents
  - **Beneficence** – maximize benefit and minimize risk
  - **Justice** – benefits and risks are shared by the population of interest

- Additional protections for some groups
  - Subpart B – pregnant women, fetuses, neonates
  - Subpart C – prisoners
  - Subpart D – children

Common Rule Definitions

Research:

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

Human Subject:

- 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
  - Obtains, use, studies, analyzes or generates identifiable private information or identifiable biospecimens

Study Review: Research Determination

Why is a determination important?

- To determine which activities are covered by the regulations for the protection of human subjects
- To help ensure that the rights and welfare of human subjects are protected for research according to the regulations
- To abide by federal regulations and avoid applying the regulations when it is not necessary or when activities are not covered by the regulations

Data definitions in HSR

Identifiable

Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain is included in the data collected

Coded

Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code.

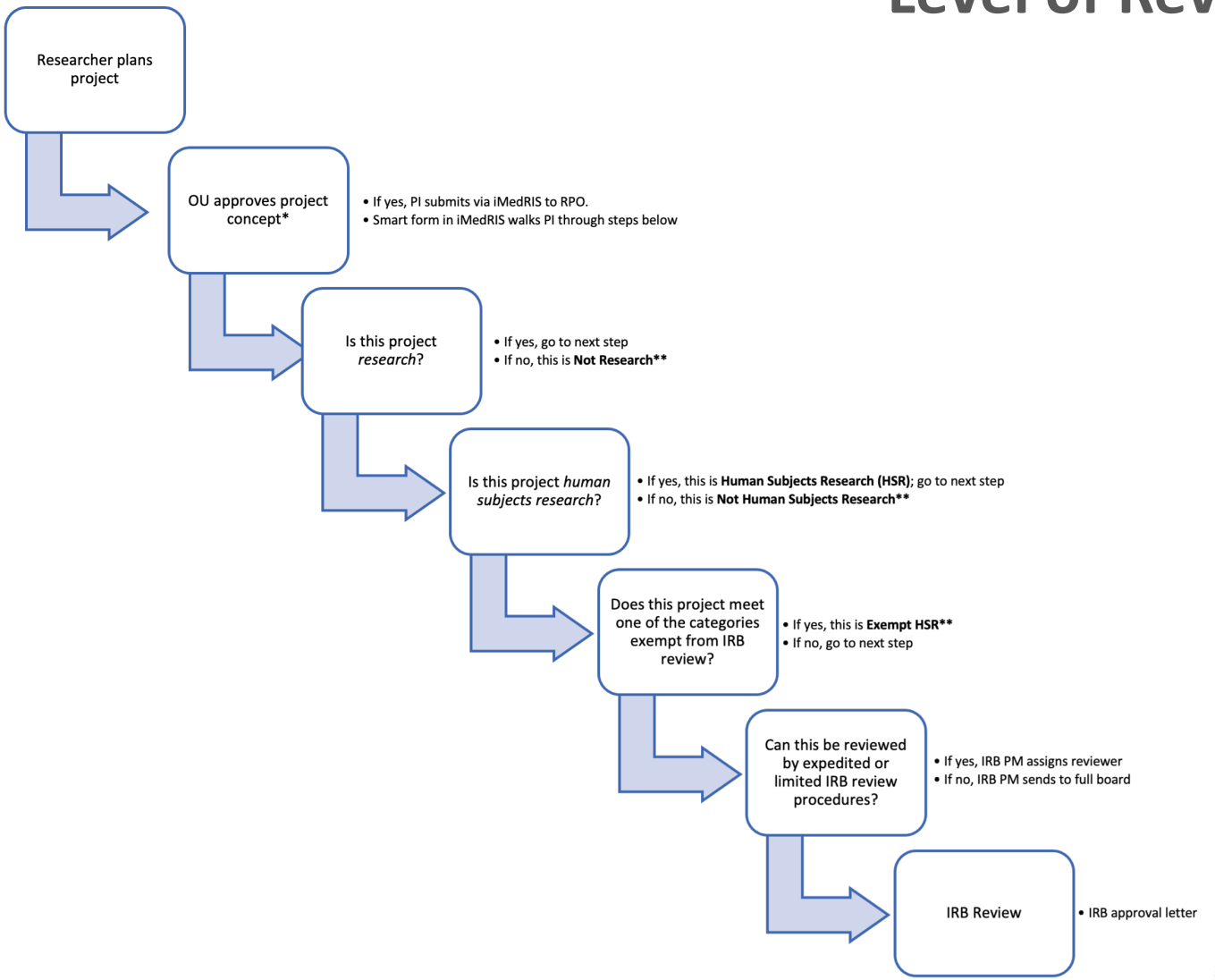
Deidentified

All direct personal identifiers are permanently removed (e.g., from data or specimens), no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s).

Anonymous

Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information or materials (e.g., data or specimens) that cannot be linked directly or indirectly by anyone to their source(s).

Level of Review



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Permissions

- Informed consent and/or data sharing agreements
  - The data we use must be permissible to use
  - Informed consent of each research participant when appropriate and possible
  - Data sharing agreement with data providing institution
  - Most agreements include a clear statement that the provider will not provide a code key to enable reidentification and the user will not make any attempts to reidentify the individuals
- Required elements of informed consent related to privacy
  - Who will collect, use, or access data
  - How will the data be stored and/or shared
  - How will data be retained for future use

Data Retention and Future Use

If the study has been approved for retention of data, any future use must also be approved

- Ensure that the future use is consistent with prior approvals and associated permissions

Thank you

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