Secondary Research Involving Data and Biospecimens

**Definitions**

**Secondary Research**: Research use of information or biospecimens originally collected for non-research purposes or research studies other than the proposed project

**Research (HHS)**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

**Clinical Investigation (FDA)**: Any experiment that involves a test article and one or more human subjects that either

1. Meets the requirements for prior submission to FDA under sections 505(i) or 520(g) of the Food, Drug, and Cosmetic Act; or
2. Need not meet the requirements for prior submission to FDA under the sections noted above, but the results of which are intended to be later submitted to or held for inspection by FDA as part of an application for a research or marketing permit

**Systematic Investigation**: A planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question

**Generalizable knowledge**: Information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances

**Human subject (DHHS)**: 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

**Human subject (DHHS) Effective 1/21/19**: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**Human subject (FDA)**: An individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. For research that involves medical devices, a human subject also includes an individual on whose specimen an investigational device is used.

**Private information**: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.
**Individually identifiable:** Materials are considered individually identifiable when the identity of the participant is or may readily be ascertained by the investigator or the investigator’s staff, or associated with the information

**Human Subjects Research Questions**

1. **Is the project** research **according to the applicable regulations (DHHS, FDA, etc.)?**
   - Is it systematic?
   - What is the purpose of the project? Are there multiple purposes (quality improvement, teaching, clinical, research, etc.)?
   - Are drugs or devices involved in a way that triggers FDA requirements?
   - Is the project designed to develop or contribute to generalizable knowledge?
   - How will the data and/or specimens be used?

2. **Does the project involve** human subjects **according to the applicable regulations (DHHS, FDA, etc.)?**
   - Is information about individuals collected?
   - Is information about living individuals collected?
   - Exactly what data points are being collected? From where/who? How?
   - Are the sources public or private?
   - Do the sources contain individually identifiable information?
   - Is the development or testing of a device involved?

3. **Is our institution** engaged **in the research involving human subjects?**
   - What activities will Ohio State personnel perform?
   - What materials will Ohio State access or receive?
   - What are the roles of any external institutions/investigators?
   - What agreements are in place?
   - Is Ohio State the direct awardee on a federal grant?
Case Examples

Case 1
A faculty member from Nursing wants to collect and analyze student demographics, student grades, and student assignments, as well as instructor demographics and instructor feedback for the past 5 years in all sections of two introductory level courses generally taught by new faculty.

Case 2
A doctoral student in the College of Public Health wants to access an existing, federal dataset. The data will be analyzed for her dissertation. It has already been established that the project meets the definition of research under the federal regulations.

Case 3
A faculty member contacts ORRP about a federal award received for a collaborative research project. Ohio State investigators will only be analyzing de-identified specimens, but there is some work being done with identifiable data at other institutions. Our investigator states that the external investigators are obtaining their own IRB approvals and asks if Ohio State IRB approval is also required.
Resources

HRPP Policies:  http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/

HRPP Glossary:  http://orrp.osu.edu/irb/osuirbpolicies/hrppglossary/


Ohio State Research Involving Data and/or Biological Specimens Policy:  
http://orrp.osu.edu/files/2012/02/Research-Involving-Data-andor-Specimens.pdf

ORRP Determinations Mailbox:  ORRPDeterminations@osu.edu

FERPA Policy:  https://registrar.osu.edu/policies/privacy_release_student_records.pdf

Ohio State Student Data:  http://oesar.osu.edu/

HIPAA Guidance:  http://orrp.osu.edu/irb/investigator-guidance/hipaa/

Ohio State University Privacy Officers:  http://orrp.osu.edu/files/2016/04/privacyofficers-041416.doc

OHRP Video:  Regulatory Options for Secondary Research with Private Information and Biospecimens (Note: exempt categories 7 and 8 will not be implemented at Ohio State)

Part 1:  https://youtu.be/tQPEqnawZ04

Part 2:  https://youtu.be/475N2Zn-VZs

OHRP Guidance:  Engagement of Institutions in Human Subjects Research