

RESEARCH VS. NON-RESEARCH: HOW DO I KNOW IF I NEED IRB APPROVAL?

VERSION 1.2, 03-14-2019

CHARLES HOEHNE, ASSISTANT DIRECTOR, EDUCATIONAL INITIATIVES
OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS)

ORS ADMINISTRATORS MEETING
WEDNESDAY, MARCH 20, 2019, 1:00 PM
AOB 307C

Handouts:

- PowerPoint Slides
- Policy: Determination Whether Activities Represent Human Subjects Research at UIC (v3.4, dated 01-21-2019)
- Determination application (V2.6, dated 01-21-2019)
- Screen shots: How to Submit a Determination application

Objectives:

- Examine the 2018 Common Rule definition of Human Subject Research (January 21, 2019)
- Discuss why this definition is problematic
- Discuss strategies for what to do when you aren't sure if you are conducting Human Subjects Research

Usual Disclaimer

- OVCR, OPRS and the IRB are not required to agree with me.
- To the best of our knowledge, this presentation is consistent with current OVCR, OPRS and IRB policies, procedures and requirements.

Key Concepts

- In general, oral history projects, journalism, QA/QI, course-related projects and similar activities do NOT represent human subjects research (HSR) as defined by 45 CFR 46.102(f).
- But they may.
- So, you have to understand the Common Rule definition of “human subjects research” to know whether or not you need IRB approval.
- 2018 Common Rule went into effect on January 21, 2019.

As per HHS

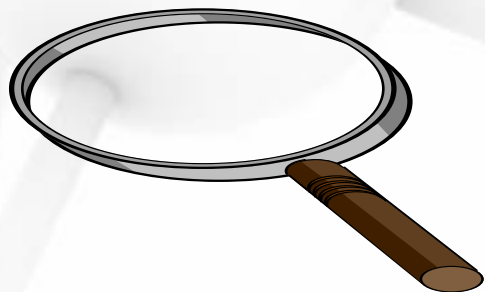
Institutions must make a Human Subjects Research (HSR) determination on a case-by-case basis by asking the following questions:

- 1) Does the activity involve *research* [45 CFR 46.102(d)]?
- 2) Does the research activity involve human subjects [45 CFR 46.102(f)]?

“Research” defined:

a systematic investigation including research development, testing and evaluation; designed to develop or contribute to generalizable knowledge.

45CFR46.102(d)



Generalizable Knowledge

The extent to which research findings and conclusions from a study conducted on a sample population can be applied to the population at large (i.e., extending the results beyond a single individual or an internal unit).

The intent to publish or present findings does not factor into the determination of whether a project satisfies the definition of research.

“Human Subject” defined:

a living individual about whom an investigator (whether professional or student) conducting research:

- (1) obtains data or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the data or biospecimens, **or**
- (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

45 CFR 46.102(e)(1)

Definitions

- **Intervention**: Includes both physical procedures and manipulation of the subject or his environment *for research purposes*.
- **Interaction**: Includes communication or interpersonal contact between investigator and subjects

45CFR46.102(e)(1-2)

Definitions

- **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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

45 CFR 46.102(e)(4)

Definitions

- **Identifiable private information**: is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. 45 CFR 46.102(e)(5)
- **Identifiable biospecimen**: is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. 45 CFR 46.102(e)(6)

So...



**WHAT'S
THE PROBLEM?**

Problems include:

- Misinterpretation of the Common Rule definitions
- Conflict between Common Rule and the ethical standards of other disciplines:
 - Project: Interview individuals with goal of exposing corruption
 - Journalist: Benefit the greater good by getting to the truth
 - Researcher: Minimize risk by safeguarding confidentiality

Problem Solving Strategies

Again- In general, oral history projects, journalism, QA/QI, course-related projects and similar scholarly activities do NOT represent human subjects research as defined by 45 CFR 46.102(f).

But, when in doubt:

1. Contact OPRS: uicirb@uic.edu or 312-996-1711
2. Submit a “Determination” application.

(Note: If you know your project is HSR, do NOT submit a “Determination” application. If you do not know what type of initial review application to submit for your HSR, contact OPRS)

Determination of Human Subjects Research Policy (1 of 4)

- Policy: UIC faculty, staff, and students who intend to conduct activities that may in part represent research with human subjects ARE NOT authorized to decide independently that the project is not subject to the Human Subjects Protection Program
- Policy updated January 21, 2019 to be consistent with the 2018 Common Rule
- Exceptions next slide

Determination of Human Subjects Research Policy (2 of 4)

OPRS has determined that the following specific activities do not represent human subjects research and, therefore, **do not require the submission of a determination application**:

- Projects limited to accessing and use of de-identified public datasets. (If you are uncertain as to whether or not the dataset meets this criteria, please consult with OPRS.)
- Projects limited to the use of commercial, de-identified non-embryonic human stem cell lines.
- Case reports pertaining to a single individual. Please note this does not include case series of more than one individual or outcomes of a clinical investigation.
- Projects limited to death records, autopsy records, or cadaver specimens provided that the cadaveric tissues/cells are not used for clinical investigations.
- Course-related activities designated specifically for educational or teaching purposes, where data is collected from and/or about individuals as part of a class exercise or assignment but are not intended for research purposes (e.g., quality improvement projects, Capstone projects). (If you are uncertain as to whether or not the activity meets this criteria, please consult with OPRS.)

Determination of Human Subjects Research Policy (3 of 4)

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Determination of Human Subjects Research Policy (4 of 4)

How does this work? If possibly HSR and NOT fully one or more of the exceptions:

1. Submit the “Determination” application via OPRS Live.
2. OPRS staff will review the application ASAP.
3. Any communications during the review can be informal.
4. Formal determination sent by OPRS to investigator via email.
5. If NOT HSR, notification will serve as formal documentation of the determination.
6. If HSR, notification will suggest appropriate required level of review based on information provided (exempt, expedited, or convened)

PIs MAY NOT:

- Initiate any activities until a written determination of not human subjects research is obtained from OPRS.

So, what's the catch?

- Projects conducted as non-research cannot be retroactively approved as research by the IRB.
- Projects conducted as non-research cannot be published or presented as being research.
- Departmental procedures may need to be developed and implemented to screen and track projects.
- Departments will be responsible for oversight of the activity. OPRS/IRB not responsible for the management of adverse events and/or unanticipated problems.



Questions or comments?

OPRS Contact Information

1737 West Polk Street, Suite 203

Phone: 312-996-1711

Email: uicirb@uic.edu

Website:

<http://research.uic.edu/compliance/irb>

Charles Hoehne, BS, CIP

Assistant Director, Educational Initiatives

Office for the Protection of Research Subjects
Office of the Vice Chancellor for Research (MC 672)

1737 West Polk Street, Room 203D
Chicago, IL 60612-7227

Ph: 312-355-2908

E-mail: choehne@uic.edu