



Determination Whether Activities Represent Human Subjects Research at UIC

<http://research.uic.edu/human-subjects-irbs/>

Version: 3.4; Date: 01/21/2019

Approved by: Human Protections Administrator, Director of
OPRS

AAHRPP REF #: 114

AAHRPP Elements: I.1.A., III.1.A

POLICY:

- I. UIC faculty, staff, and students who intend to conduct activities that may not represent research with human subjects as outlined in this policy may not independently determine whether the project is subject to or requires regulatory review.
- II. 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:
 - A. 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.)
 - B. Projects limited to the use of commercial, de-identified non-embryonic human stem cell lines.
 - C. **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.
 - D. Projects limited to **death records, autopsy records, or cadaver specimens** provided that the cadaveric tissues/cells are not used for clinical investigations.
 - E. **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.)
 - F. **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.
 - G. **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,



Determination Whether Activities Represent Human Subjects Research at UIC, Version 3.3

- 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).
- H. 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.
 - I. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- III. For research activities that do not engage UIC (refer to the UIC HSPP policy [*Engagement of UIC in Human Subjects Research*](#)) please contact OPRS at UICIRB@uic.edu for further instruction regarding submission requirements.

DEFINITIONS:

- I. "Research involving human subjects" means any activity that meets the definition of "research" and involves "human subjects" as defined by DHHS.
 - A. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities are deemed not to be research are specified in the Policy section above. (45 CFR 46.102(l))
 - B. "Human Subject" means 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))
 - 1. "Intervention" includes both physical procedures by which data or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(e)(2))
 - 2. "Interaction" includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(e)(3))
 - 3. "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))
 - 4. "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))
 - 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))



Determination Whether Activities Represent Human Subjects Research at UIC, Version 3.3

- II. “Systematic investigation” is a project that is planned in advance and that uses data collection and analysis to answer a specific question, testing a specific hypothesis, or developing a theory.
- III. “Generalizable knowledge” is 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.*

PROCEDURE:

- I. UIC faculty, staff, and students must complete and submit the form, [*Determination of Whether an Activity Represents Human Subjects Research at UIC*](#), to UIC OPRS via [OPRS Live](#) for any activities that are believed to not involve human subjects research and do not fall within the categories in the Policy section above.
 - A. If a non-UIC site is to be involved in the activity, a letter of support from the site must be uploaded with this application.
- II. The individuals within the OPRS who can provide a determination as to whether an activity constitutes research involving human subjects at UIC are: a) IRB Chairs or designees; b) Director; c) Associate Directors; d) Assistant Directors; and e) coordinators designated by the Director in consultation with the IRB Chairs as being qualified to make this determination.
- III. All individuals who make the determinations use the *Determination of Whether an Activity Represents Human Subjects Research at UIC* review guide when making their determination.
- IV. A letter is generated by OPRS staff that communicates the determination which is sent via email correspondence to the investigator.

REFERENCE:

45 CFR 46.102(e), 45 CFR 46.102(l)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
2.0, 10/01/08	1.0, 4/23/07	Entire policy revised.
2.1, 03/10/09	2.0, 10/01/08	Policy revised to include <i>Determination of Whether an Activity Represents Human Subjects Research</i> form and direction for investigator to submit form.



Determination Whether Activities Represent Human Subjects Research at UIC, Version 3.3

2.2, 09/17/09	2.1, 03/10/09	Policy revised to include Department of Defense sponsored survey research requirements. Created a more detailed "procedures" section that outlined the process.
3.0, 4/17/12	2.2, 09/17/09	Order of policy revised to separate definitions and procedures. Department of Defense and VA definitions of "research" and "human subjects" included. Addition of commercial cell lines as a not human subject research determination. Name of form revised to include "at UIC" for determination of engagement of UIC.
3.1, 07/01/15	3.0, 4/17/12	Limiting the use of ICPRS datasets to secure online (publicly available) datasets. Rephrasing "research" to "projects" when possible. Restructuring "Definitions" for easier readability. Correction of website links. Removal of VA references.
3.2, 11/18/16	3.1, 07/01/15	Removal of instructions to email completed application due to implementation of OPRS Live. Clarification that submissions are logged in administratively as IRB 7, but are not associated with CHAIRb.
3.3, 09/06/18	3.2, 11/18/16	Removed requirement to submit a determination for activities determined by OPRS to not represent human subjects research.
3.4, 01/21/19	3.3, 09/06/18	Updated to incorporate 2018 Common Rule Requirements.