



## **Institutional Authorization for Determining Whether Research or Other Activities Represent Human Subjects Research at UIC**

Version: 3.2; Date: 11/18/2016

Approved by: Human Protections Administrator, Director of OPRS, and  
Executive IRB Chair

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 in part represent research with human subjects as outlined in this policy and procedure are not authorized to determine independently whether the project is subject to the HSP, except in limited circumstances.
- II. Five specific activities that OPRS/IRB has determined do not represent human subjects research are:
  - A. Projects limited to accessing one or more of the following public use datasets: U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), Inter-university Consortium for Political and Social Research [ICPRS- Secure online analysis (publicly available) datasets only], and PRAMS;
  - B. Projects limited to the use of commercial, de-identified non-embryonic human stem cell lines;
  - C. Case reports involving the observation of a single patient whose novel condition or response to treatment was guided by the care provider's judgment regarding the best interest of the individual;
  - D. Projects limited to death records, autopsy records, or cadaver specimens provided that the cadaveric tissues/cells are not used for clinical investigations; and
  - E. Course-related activities designated specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom (not intended to develop or contribute to generalizable knowledge). *(OPRS does not require the submission of a determination application for activities that fall under this description.)*



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- III. Research or other activities that do not engage UIC do not require UIC IRB approval. For more information, refer to the UIC HSPP policy [Engagement of UIC in Human Subjects Research](#).

## DEFINITIONS:

- I. "Research involving human subjects" means any activity that either:
- A. Meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS; or
  - B. Meets the FDA definition of "research" and involves "human subjects" as defined by FDA.
- II. DHHS Definitions:
- A. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d))
  - B. "Human Subject" means 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. (45 CFR 46.102(f))
    1. "Intervention" includes both physical procedures by which data 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(f))
    2. "Interaction" includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))
    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(f))
    4. "Identifiable information" is information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
- III. FDA Definitions:
- A. "Research" means any experiment that involves a test article and one or more human subjects, and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (Act), or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c), 21 CFR 56.102(c))



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1. “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. (21 CFR 312.3(b))
  2. “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a device. (21 CFR 812.2(a))
  3. “Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. (21 CFR 50.3(c), 21 CFR 56.102(c))”
- B. “Human Subject” means a living individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. (21 CFR 50.3(g), 21 CFR 56.102(e)) A human subject includes an individual on whose specimen a medical device is used.
- IV. Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research. (28 CFR 512.10)
- V. Department of Defense Definitions:
- A. “Research” means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. (32 CFR 219.102(d))
  - B. “Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or through identifiable private information. (32 CFR 219.102(f))
  - C. For additional information regarding Department of Defense research, please refer to UIC HSPP policy [Research Involving Department of Defense Components](#).
- VI. “Systematic investigation” is a project that is planned in advance and that uses data collection and analysis to answer a question.
- VII. “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.

**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



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[OPRS Live \(beta\)](#) for all activities that involve human subjects and might represent human subjects research at UIC.

- A. OPRS does not require the submission of a determination application for course-related activities, as described in item II.E. in the Policy section. OPRS will return applications meeting this description to the investigator
  - B. OPRS does require the submission of a determination application for activities described in items II.A. - II.D. in the Policy section. .
  - C. The submissions are logged into the RiSC database under “IRB 7”. This is for administrative purposes only. Please note that the submissions are not associated with University of Illinois at Chicago IRB #7 - Chicago Area Institutional Review Board (CHAIRb) (IRB00009693).
- II. The individuals within the OPRS who can provide a determination about whether an activity constitutes research involving human subjects at UIC: a) IRB Chairs or designees; b) Director; c) Associate Directors; d) Assistant Directors; and e) coordinators designated by the Director in consult 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 promptly and is sent via email correspondence to the investigator.

#### EXAMPLES:

- A. Examples of activities typically representing human subjects research by federal or UIC policies include:
  1. Pilot studies involving individuals that are performed to refine study methodology;
  2. Human genetic research;
  3. Retrospective medical record review;
  4. Masters thesis or doctoral dissertation;
  5. Surveys, interviews or observations of individuals (including use of the Internet);
  6. Data or tissue banking; and
  7. Two or more case reports.
- B. Examples of activities that may or may not represent human subjects research by federal or UIC policies include:
  1. Quality improvement or quality assurance activities;
  2. Service surveys;
  3. Obtaining coded or de-identified data from a data or tissue bank or repository;
  4. Study or use of coded data;
  5. Biographical or oral history research (See UIC HSPP [Tip Sheet: IRB Review of Oral History and Other Social Science Projects](#)); and
  6. Health services or outcomes research.



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- The project is limited to accessing one or more of the following public use datasets: U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), Inter-university Consortium for Political and Social Research [ICPRS- Secure online analysis (publicly available) datasets only], and PRAMS.

**REFERENCES:**

- 21 CFR 50.3
- 21 CFR 56.102
- 45 CFR 46.102
- 32 CFR 219.102
- 28 CFR 512.10
- Department of Defense Instructions 3216.02

**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.
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.



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		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.