

**Institutional Authorization for
Determining whether Research or
Other Activities Represent Human
Subjects Research**

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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. UIC faculty, staff, and students must complete and submit the form, [*Determination of Whether an Activity Represents Human Subjects Research*](#), to UIC OPRS for all activities that involve human subjects and might represent human subjects research. The completed form can be e-mailed to: uicirb@uic.edu, with the subject line "Determination of Human Subject Research," or delivered in person to the OPRS Office. An Assistant Director will communicate the decision promptly via email and/or letter communication. Refer to III below for the four activities excluded from this policy.
 - A. Please refer to the [*Decision Tree: Are You Conducting Human Subjects Research as Defined by DHHS or FDA?*](#), available on the UIC OPRS web site.
 - B. If applicable, please also refer to the [*Decision Tree for Submitting Medical Record Review Research*](#), available on the UIC OPRS web site.
- III. Four specific activities that OPRS/IRB has determined do not represent human subjects research and do not require submission for a human subjects research determination are:
 - A. Access to specified public use datasets (refer to Procedure Section VI for a list of applicable data sets);
 - B. 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);
 - 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; and

- D. Research which is limited to death records, autopsy records, or cadaver specimens provided that the cadaveric tissues/cells are not used for clinical investigations.
- IV. Department of Defense Sponsored.
- A. Surveys involving Department of Defense or US military personnel typically require Department of Defense Survey Review and approval.
 - B. When appropriate, the research project is reviewed and approved by the IRB prior to Department of Defense approval.
- V. See the glossary for the definition of research involving human subjects that applies to the type of research involved:
- A. Research - Social Sciences and Biomedical Sciences (non-FDA; non-VA);
 - B. Research - FDA Regulated - Drugs;
 - C. Research - FDA Regulated - Devices;
 - D. Research - VA Research.
- VI. "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.
- VII. "Research" as defined by DHHS regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d))
- VIII. "Human Subject" as defined by DHHS regulations 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))
- A. "Intervention" as defined by DHHS regulations means 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))
 - B. "Interaction" as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))
 - C. "Private information" as defined by DHHS regulations means 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))
 - D. "Identifiable information" as defined by DHHS means 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).

- IX. "Research " as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the 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, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic 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))
- A. "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))
 - B. "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))
 - C. "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))"
- X. "Human Subject" as defined by FDA regulations means an 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.
- XI. Department of Defense (Navy). Research Involving a Human Being as an Experimental Subject. An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include: activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Armed Force Health Protection programs of the Department of Defense.
- A. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.
 - B. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.
 - C. Activities exempt under 32 CFR Part 219 (reference (c)).

- D. Support. Unless otherwise clarified in a specific paragraph of the referenced Directive, this term generally means the provision of funding, personnel, facilities, and all other resources.

XII. 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.
- C. The project is limited to accessing one or more of the following public use datasets: Inter-University Consortium for Political and Social Research (ICPSR), 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), and PRAMS.

PROCEDURE:

- I. As a reminder, UIC faculty, staff, and students must complete and submit the form, [Determination of Whether an Activity Represents Human Subjects Research](#), to UIC OPRS for all activities that involve human subjects that might represent human subjects research.
- II. The individuals within the OPRS who can provide a determination about whether an activity constitutes research involving human subjects is the IRB Chair or designee, the UIC OPRS Assistant Directors or coordinators designated by the OPRS Director in consult with the IRB Chairs as being qualified to make this determination , and the UIC OPRS Associate Director and Director.

III. All individuals who make the determinations use the Determination of Whether an Activity Represents Human Subjects Research pre-review and review guide when making their determination.

IV. A letter is generated by the appropriate OPRS staff that communicates the determination and is sent via US post and email correspondence to the investigator.

REFERENCES:

[21 CFR 50, 21 CFR 56](#)
[45 CFR 46.102](#)

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.