

Rush University Medical Center

Policies and Procedures

Policy Number:	RA-IRB-118
Category Name:	Research
Title:	Determining Whether an Activity is Research Involving Human Subjects
Type:	Policy and Procedure
Revised:	8/2014 (replaces 12/2011 version)

Applies To: Rush Investigators/Study Staff, Rush IRB Chairs, and IRB Administrative Staff

Policy: **Any Investigator who intends to conduct a project or projects that may or may not represent research with human subjects is not authorized to determine independently whether the project is subject to IRB or IRB Administrative review. Investigators must contact the IRB Administrative staff in the Research and Clinical Trials Administration Office (RCTA) to determine whether the project must be entered into the Rush Research Portal (RRP) for review.**

Definitions **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.

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))

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).

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))”

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. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Procedure:

Individuals who make the determinations as to whether the activities constitute human subjects research may use the Office for Human Research Protections Human Subject Regulations Decision Chart (Chart 1) as a review guide when making their determination.

Activities that the Rush IRB may determine do not represent human subjects research and would not require submission in the Rush Research Portal (RRP) include:

- 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);
- Case reports involving the observation of a patient or patients whose novel condition or response to treatment was guided by the care provider's judgment regarding the best interest of the individual and no comparison of data is taking place ;
- Research involving only the use/analysis of deceased individuals information or specimens(cadaveric studies); and
- Collection of data with the sole purpose to conduct a quality improvement/quality assurance project for internal use only. This also applies to students of Rush University who are employed at another medical center, when the work is part of their class requirements and the employer institution has certified the activities do not constitute human subjects research.

Investigators who will be conducting any of the above activities must complete the Determination of Whether an Activity Constitutes Human Subjects Research Form. The completed form should be emailed to the Director of Human Subjects Protection, IRB Manager, Senior IRB Consultant, and/or IRB Chair. The subject line should be entitled "Determination of Human Subject Research". The email must include the completed form, a description of project goals and an abstract of the project including project methods.

If the project involves use/analysis of deceased individuals' identifiable tissue or data, a completed "HIPAA Use/Disclosure without Authorization" form must also be included. Additionally, a copy of the data/material transfer agreement or contract specifying the origin of the deceased individuals' information and/or specimens must be attached.

If the project will be conducted at an outside institution, a letter or other documentation of review must be included from the institution where the activities will occur that indicates the institution does not consider the activities to be human subjects' research and/or require IRB review.

Upon confirmation that the project does not constitute human subjects research, the form is signed by the appropriate IRB Administrative staff member. The completed form is then returned to the investigator for their files. A paper copy of the submission is then stored by IRB Administrative staff in files labeled by Fiscal Year. These files are stored per methods outlined in "Maintenance of IRB Regulatory Files" RA-IRB-301.

If the proposed activities appear to constitute human subjects research, IRB Administrative staff will inform the Investigator that the project must be submitted in the RRP for review and approval.

Of note, studies that meet the regulatory criteria for exempt review still require review in the RRP. "Exempt" does not mean the study does not require regulatory review by the IRB.

For studies that are determined to not constitute human subjects research, all other activities (such as grants and contracts) must be submitted through the RRP for review. Any project submitted to the IRB in the RRP that is determined to not constitute human subjects research will be forwarded by the IRB Administrative staff to one of the following individuals within the Research and Clinical Trials Administration Office who can confirm whether an activity constitutes research involving human subjects: Director of Human Subjects Protection, IRB Manager, Senior IRB Consultant, IRB Chair, and/or a designee of one of these individuals.

Reference	21 CFR 50, 21 CFR 56, 45 CFR 46.102, Office of Human Research Protections (OHRP) Human Subject Regulations Decision Charts (Chart 1, September 2004)
Related Forms:	Determination of Whether an Activity Constitutes Human Subjects Research

Last Reviewed: 8/13/2014