General IRB Review Process

What activities require review by an IRB?

Federal regulations require IRB review for all research involving human subjects conducted in the U.S. According to the regulations:

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45CFR46.102(d))

A *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. (45CFR46.102(f))

When is an institution considered to be engaged in research??

In general, an institution is considered to be engaged in human subjects research when its employees or agents:

1. obtain data about living individuals for research purposes through intervention or interaction with them,
2. obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f);http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102; or
3. obtain the informed consent of human subjects.

Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

In general, an institution is considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution. In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects’ permission for investigators to contact them are not considered engagement in research. However, obtaining informed consent from a research participant is considered engagement in research.
What is a Federalwide Assurance (FWA)?

The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

FWAs also are approved by OHRP for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Institutions engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.

There is a single version of the FWA and the Terms of Assurance for domestic (U.S.) institutions and international (non-U.S.) institutions.

What is minimal risk?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 (i)).

What is expedited review?

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Federal regulations permit, but do not require, an IRB to review certain categories of research through an expedited procedure if the research involves no more than minimal risk. A list of categories was last published in the Federal Register on January 27, 1981 [46 FR 8980].

The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period covered by the original approval. Under an expedited review procedure, review of research may be carried out by the IRB chairperson or by one or more experienced members of the IRB designated by the chairperson. The reviewer(s) may exercise all the authorities of the IRB, except disapproval. Research may only be disapproved following review by the full committee. The IRB is required to adopt a method of keeping all members advised of research studies that have been approved by expedited review.

Can you give me examples of studies that cannot be expedited and would
need full board review?

- New greater-than-minimal risks
- Biopsies
- X-rays or radio-labeled agents
- MRIs with contrast agent
- Blood draws in a non-healthy adult population over 50 mls in an 8 week period or > 2 draws per week
- Blood draws in children that exceed the lesser of 50 mls in an 8 week period or 3ml/kg or > 2 draws per week
- Prisoners as potential subjects
- Potentially damaging information collected (illegal drug use, child abuse, HIV/hepatitis infection, alcoholism, mental illness)

What elements of research projects require IRB review and approval?

- Initial study submissions (new studies)
- Continuing reviews (renewals)
- Amendments
- Advertisements
- Adverse Events/Unanticipated Problems
- Protocol Deviations and Violations
- Final Progress Reports
- Any study-related correspondence between DUHS personnel/sponsors/regulatory agencies
- Noncompliance issues
- Conflict-of-interest issues

Record Retention: How long must research records be retained?

Per DUHS policy, all research records must be retained for at least six years beyond completion of all data collection, analysis, and submission of the IRB closing progress report. Research records involving minor subjects must be retained until the youngest child on the study is 21 years old or six years following completion of the study, whichever is longer. However, please always review your contracts to make sure you are retaining records for the amount of time agreed upon in the contract. The retention obligation in the contract may extend beyond the six year period required by DUHS policy.

What is a Review Preparatory to Research (RPR)?
If an investigator wishes to review protected health information (PHI) to determine the feasibility of a research project, he/she may do so by notifying the IRB of a planned "Review Preparatory to Research" (45 CFR 164.512(i)(1)(ii)). By this notification the investigator declares that he/she will use the PHI solely as needed to prepare a research protocol or for similar purposes preparatory to research, that the PHI will not be reused or re-disclosed for another purpose or leave the investigator’s institution (covered entity), and that the PHI is necessary in order to develop the protocol.

Note that a Review Preparatory to Research may be used by an investigator, prior to IRB approval, in order to review the PHI of potential research subjects; however, the investigator may not contact potential subjects to ask for their participation in the research without first obtaining IRB approval of the research. Likewise, the investigator may wish to record PHI or other identifiable private information obtained from a Review Preparatory to Research; however, the investigator may not do so without first obtaining IRB approval of the research and either consent of the research subject or IRB-approved waiver of consent, as described at: http://privacyruleandresearch.nih.gov/

When notifying the IRB of plans for a review preparatory to research, complete the interactive RPR form on the Forms page.