IRB Review Requirements for Secondary Use Research

This document assists researchers understand IRB review requirements when their proposed research involves the collection and/or use of:

- identifiable private information and/or
- identifiable biospecimens and/or
- de-identified biospecimens used in the testing or development of a device (where results are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit)

Definitions:

Human Subject (HHS): A living individual about whom an investigator conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- Intervention: 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.
- Interaction: Communication or interpersonal contact between investigator and subject.
- Private Information: 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).
- Identifiable Information: 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).

Human Subject (FDA): 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. A human subject includes an individual on whose specimen a medical device is used.

Review Paths

1. **Verification that Project is Not Human Subject Research**
   All planned projects involving the use of human specimens or data should be reviewed by OHRS for a determination that the activity does not constitute research involving human subjects.

- Submit to OHRS the New Project Application – Not Human Subjects Research Determination
    - This determination satisfies funding agency and publication requirements

2. **IRB Review**
   The IRB is charged with the review of planned projects that involve the use of identifiable human specimens or identifiable private information. IRB review may also be required when de-identified biospecimens are used.
   - Submit to OHRS a New Project Application – Non-Clinical Research along with the completed protocol template for Data Collection and/or Specimen Use and supplemental materials.

Scenarios

1. Research involving the use of biospecimens or data that **DOES** require IRB review

   A. Research on samples obtained prospectively, explicitly, and solely for research purposes
      - Examples include blood samples drawn or extra blood taken at the time of a clinical blood draw specifically for a research project, or additional tissue biopsies performed solely for research purposes during a clinically indicated biopsy procedure. Written consent/authorization is required of each recent participant in these scenarios.

   B. Research involving the prospective collection of data including information from patient medical records.
      - The DF/HCC IRB Chair or their designee is responsible for determining the level of IRB oversight required depending on the nature of the research.

   C. Research on excess clinical samples from clinical departments/services within DF/HCC
      - Any proposed research use of excess clinical samples obtained from clinical/department services within DF/HCC, including clinical laboratories and pathology, or clinical care areas.
      - The DF/HCC IRB Chair or their designee is responsible for determining the level of IRB review required based on the nature of the research proposed. **IRB determinations do not guarantee the provision of samples by clinical laboratories or pathology departments. Typically, release is at the discretion of the User Committees.**

D. Secondary use of previously collected research samples or data
   - DF/HCC IRB review is required for any proposed secondary use of existing samples collected previously for research.
   - The DF/HCC IRB Chair or their designee will determine the level of IRB oversight required. Considerations include:
     - the nature of the research,
     - the source of the tissue,
     - the use and/or disclosure of identifiable health information,
     - privacy and confidentiality protections, and
     - whether informed consent/authorization of subjects should be required

     The determination also depends on the scope/intent of the original research project, as well as a copy of the consent form subjects signed when the sample(s)/data were originally provided for the initial research use.

   - Banking protocols that describe potential future uses of data and/or specimens may not provide sufficient IRB oversight for studies proposing to use the data or specimens collected under that protocol. **Contact OHRS to determine whether a new protocol or an amendment to the originally approved study is required.**

2. Research involving the use of data and/or biospecimens that **DOES NOT** require IRB review

   A. Analysis of de-identified or coded data where investigators do not have access to the code linking identifiers or where investigators cannot readily ascertain the identity of individuals included in the data set.

   B. Analysis of publicly available datasets.

   C. Laboratory research on human cells or cell lines from specified established external repositories and tissue banks where the DF/HCC IRB has reviewed the operating policies and procedures of these commercial entities and determined that the release of samples or data does not meet the regulatory definition of research involving human subjects.
   NOTE: To date, there are no external banks or repositories approved by the DF/HCC IRB. Sites will be added to this guidance as policies and procedures are reviewed and approved.

D. Research on (1) non-identifiable tissue or (2) coded tissue that provided without linked identifiable information, when the tissue is obtained from DF/HCC IRB-approved Research Tissue Banks at DFCI or within DF/HCC. In these cases the DF/HCC IRB has approved the Bank's policies and procedures for distribution of non-identifiable tissue or coded tissue without linked identifiable information to investigators. The Research Tissue Bank is responsible for complying with the IRB-approved Research Tissue Bank operating policies and procedures.
NOTE: To date, there are no internal banks or repositories that have received DF/HCC IRB approve. Please contact OHRS if you would like to have your bank's policies and procedures considered for approval.

E. Analyses on biospecimens or data obtained from outside DF/HCC when the analysis is performed as a commercial service for other investigators (or any other non-collaborative services meeting neither professional recognition nor publication privileges).
   - For additional information visit the OHRS Web site and review the Engagement in Research Checklist. Additional Information is provided by HHS in the OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008).

Additional Considerations

1. Special Samples
   There are special ethical, legal, financial and institutional issues related to the research use of certain samples, for instance, human embryonic stem cells (hESC) and fetal tissue. Please contact Emily Eldh, Director of OHRS or Daniel P. Kronish, MD, Associate Director for Medical Research prior to conducting research on or with these materials.

Resources

Partners Human Research Committee. "Human Tissues: Brief Primer on Research Use and Requirements for Partners IRB Review". November 9, 2005

Secretary's Advisory Committee on Human Research Protections. "FAQ's Terms and Recommendations on Informed Consent and Research Use of Biospecimens". July 20, 2011

United States Food and Drug Administration. *Code of Federal Regulations Title 21 Part 50 Protection of Human Subjects*.

United States Department of Health and Human Services Office of Human Research Protections. *Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects*.

United States Department of Health and Human Services Office of Human Research Protections. "Engagement of Institutions in Human Subjects Research." 2008.