Research Limited to the Use of Data or Specimens

This document assists researchers understand DFCI IRB review requirements when their proposed research involves the 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 as defined by the Department of Health and Human Services (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.

- 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: Data and/or specimens are considered identifiable when (a) the identity of the subject is associated with the information/ specimens or (b) the investigator conducting the research may readily ascertain the identity of individual subjects either directly or through identifiers linked to the data/specimens.

Human Subject as defined by the Food and Drug Administration (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. Request for a Not Human Subject Research (NHSR) Determination

- Investigators may request a determination from OHRS that their project does not meet the definition of research involving human subjects. This determination will satisfy funding agency and publication requirements.

- OHRS recommends that investigators submit a request for a NHSR determination if they are unsure whether their project meets the definition of research involving human subjects. The IRB is unable to issue approval for human research studies after the research begins.

- To obtain a NHSR Determination submit the New Project Application – Not Human Subjects Research Determination via OHRS Submit.

2. IRB Review

- HHS and FDA regulations require IRB review when planned projects involve the use of identifiable human specimens or identifiable private information. The FDA requires IRB review for research using de-identified biospecimens where results are held for submission to or inspection by the FDA.

- To obtain IRB review submit a New Project Application – Non-Clinical Research and all requested supplemental materials via OHRS Submit. See the OHRS website for protocol templates that the application form.

Scenarios:

1. Research involving the use of samples or data that **DOES NOT** require IRB review

Research	**Rationale**
Analysis of de-identified or coded data where investigators do not have access to the code linking identifiers	This research does not involve human subjects because there is no interaction with subjects nor is there any use of identifiable private information.
Analysis of publicly available datasets	Research does not include private information.
Analyses on biospecimens or data obtained from outside DF/HCC when the analysis is performed as a commercial service and/or fee-for-service for other investigators (or any other non-collaborative services meeting neither professional recognition nor publication privileges)	The investigator is not considered to be engaged in human subjects research. For additional information visit the OHRS Web site and review the Engagement in Research Checklist.
Laboratory research on human cells or cell lines from specified established external repositories and tissue banks. *The IRB must first review the policies and operating procedures of the bank/repository to confirm that the release of samples or data meets the definition of research involving human subjects.*	The research would not involve human subjects because repository or bank policies prohibit the identification of individual subjects. Investigators should submit a request for a Not Human Subjects Research Determination and identify the bank or repository.
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.

2. Research involving data or samples that **DOES** require IRB Review

Research	**Rationale**
Prospective collection of samples for research purposes	Research involves interaction with research subjects.
Prospective collection of identifiable data for research purposes	Research involves the collection of identifiable private information.
Research on excess clinical samples from clinical departments/services within DF/HCC that are linked to patient identifiers	Research on excess samples that are linked to identifiable private information requires IRB review.
Use of samples or data originally collected for research purposes where the investigator conducting the secondary research has access to identifiers or may readily ascertain the identity of individuals who provided the samples or data.	Research involves identifiable private information.
Research on human specimens (regardless of identifiability) where results are held for inspection by or submission to the FDA	FDA regulations consider research with deidentified human specimens to meet the definition of human subjects research.
Banking protocols that describe potential future uses of data and/or specimens.	Collection of identifiable private information or identifiable samples meets the definition of research with human subjects.
Use of data or specimens collected under a banking protocol where investigators receive identifiable data or samples.	The use of identifiable private information requires IRB review. In this case, review may occur either as an amendment to the banking protocol or as a new research protocol.
Secondary use of data or samples where the investigator was involved in the initial collection (whether or for research or clinical purposes)	The investigator has access to the code linking data or samples to identifiers or would be able to readily ascertain the identity of individual subjects.

Additional Considerations:

1. Institutional Requirements
   Investigators must comply with any institutional policies or guidance regarding secondary use. Questions: please contact Institutional Research Compliance Officer or equivalent.

2. Contracts
   There may be sponsor or contractual restrictions on the data or samples that would embargo or prohibit secondary use. Questions: Please contact Mary Melloni (DF/HCC) or Rachel Rice Ackman (DFCI).

3. 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 (OHRS Director) or Daniel P. Kronish, MD, (OHRS Associate Director for Medical Research), prior to conducting research on or with these materials.

4. Material Transfer or Data Use Agreements
   Materials (including patient samples) and patient data generated at the institution are the property of the institution. As a result, the institution typically requires a fully-executed Material Transfer Agreement (MTA) and/or Data Use Agreement (DUA), whichever is appropriate, to be in place prior to the transfer of tangible research materials/patient samples or clinical research data (or other sensitive data) from the institution to an external collaborator or entity. When a DFCI investigator is planning to conduct research with tangible materials/samples or data stored at an external site and are asked to enter into such an agreement, please contact the Institutional Compliance Office for assistance with DUAs or the Belfer Office for Dana-Farber Innovations (BODFI) for assistance with MTAs. For all other DF/HCC institutions, please work with the appropriate institutional offices managing DUAs or MTAs.

Related OHRS Guidance and Policy Documents (available on the OHRS website):

- Policy – DFCI IRB Requirements Relating to the Use of an Honest Broker and a Usage Agreement in Banking Research
- Policy – Instructions on the Collection and Sharing of Data and Tissue Specimens
- Policy – Linked and Anonymous Specimens
- Worksheet – Human Research Determination
- IRB Resource – Review of Data and/or Specimen Collection Protocols

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.