DFCI IRB Review of Data and/or Specimen Collection Protocols

I. Overview

This guidance will assist OHRS staff and DFCI IRB reviewers to assess data and/or specimen collection protocols.

II. Considerations

A. Regulatory Determinations:

Research involving the collection of data and/or specimens may qualify for either exempt or expedited review provided it presents no greater than minimal risk to study participants and is not classified.

B. Study Design:

Data/Specimen Sources: Data collection may include information from the medical record (e.g., results of lab tests, physician notes, imaging tests, etc.) or data originally collected for research purposes. Human biological specimens (e.g., organ tissue, blood, plasma, urine, feces, cells) may be collected as part of routine care and may include medical waste. Alternatively, specimens may have been collected initially for research purposes. Although human cells and tissues may be broadly available through biospecimen banks or brokers, these materials are not usually available to the public at large and are therefore subject to IRB review.

Retrospective vs. Prospective: Research which is entirely retrospective (all data or specimens are in existence prior to the initial IRB submission date), may qualify for exempt review. This does not include research that involves the ongoing collection of data and/or specimens regardless of identifiability or reason for collection. Expedited review procedures may be applicable to retrospective, prospective, or a combination of both, including when data and/or specimens are banked for future research.

Amendments: If the study design of an initially exempt study is revised after approval to include prospectively collected data or the inclusion of additional identifiers, the IRB can change the review classification from Exempt to Expedited. However, additional regulatory considerations need to be addressed when a study moves from Exempt to Expedited review.

The investigator is responsible for submitting an amendment prior the implementation of any changes; the amendment must address the additional regulatory criteria for approval that the Exempt submission may not have included. HIPAA requirements remain applicable to studies initially determined to be Exempt.

C. Consent and Authorization:

Waiver of Informed Consent

Studies limited to the use of data and/or specimens may be eligible for a waiver of informed consent. The submission should request a waiver of informed consent and provide justification for the waiver that satisfies the regulatory criteria listed below.

- Study poses no greater than minimal risk
- Waiving consent does not impact subjects rights or welfare
- There is a mechanism for returning pertinent information to subjects when applicable
- The study cannot be practicably* conducted without the waiver

*Note: Impracticability does not equate to inconvenience. Examples of when it may be impracticable to obtain consent include:

- research requiring a sample size so large that limiting to only records/data for which consent can be obtained would skew study results
- research where the investigator is not involved in the clinical care of the participant and the research is being conducted only after clinical care takes place
- research involving data and/or specimens from participants who are no longer under clinical care and may be lost to follow-up
- instances where the link between the participant and data may pose an unnecessary increase in risk

Waiver of HIPAA Authorization:
If a study is requesting a waiver of informed consent, it is likely that a waiver of Authorization is also needed to achieve study aims. The submission should include a request for a waiver of HIPAA Authorization and satisfy the requirements for a waiver, which are listed below:

- There is an adequate plan to protect PHI for improper use and disclosure
- There is an adequate plan to destroy PHI at the earliest opportunity
- There is an assurance that PHI will not be reused or disclosed without IRB permission
- The minimum necessary PHI will be collected to conduct the research

D. Confidentiality:

Release of Data and/or Specimens: If data and/or specimens are collected with the intention of conducting future research or for distribution to other investigators, the conditions for future use should be described and incorporated into a "Usage Agreement". The submission should also indicate a plan for secure distribution of data and/or specimens to outside sites.

Honest Broker: Use of honest broker system ensures compliance with both the Federal Policy and HIPAA Privacy Rule regulations since no identifiable medical record information is being obtained or used directly by the investigators. Providing an investigator with coded data and restricting access to the code, allows the investigator to request additional data on individual participants via the honest broker in a way that does not identify a subject. Data and/or specimens obtained in this manner would not meet the criteria for human subjects research.

Anonymization: Research data and/or specimens are considered to be anonymized when someone not on the research team anonymizes the specimens. If an individual on the research team is the person who is anonymizing specimens, the entire team is considered to have access to private identifiable information.

Data Security: Study teams should work with the Information Security Office to determine the most secure and appropriate methods of overseeing the distribution of data and/or specimens.

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
- Guidance – Research Limited to the Use of Data or Specimens
- Worksheet – Human Research Determination