

DFCI IRB Requirements Relating to the Use of an Honest Broker and a Usage Agreement in Banking Research

Repositories for the collection and storage of human biological specimens and data for use in research require IRB approval and ongoing review.

This document outlines requirements relating to the role of the honest broker in bio-banking activities approved by the DFCI IRB, and the requirement for the use of a usage agreement.

Definitions:

Coded Data or Samples: identifying information has been replaced with a number, letter, symbol or combination (i.e., a code). An investigator who receives coded information is not able to readily ascertain the identity of the individual to whom the private information or specimen pertains.

Anonymous Data or Samples: identifying information has been forever stripped from the data or specimen (i.e., anonymized) and there is no way for anyone to go back and find out the identity of the individual from whom the specimen or data was obtained. No re-identification is possible.

Honest Broker: the individual who ensures that information is provided to investigators in such a manner that it would not be reasonably possible for the investigator or others to identify the corresponding patients-subjects directly or indirectly. The Honest Broker is the person who holds the key to the code. The Honest Broker is the designated person to link the information and the specimen to the individual from whom it was originally obtained.

General Requirements:

A. Bio-banking Activities that Involve the Use of Coded Specimens or Data Research

1. Protocols that include use of coded specimens must describe who will serve as the Honest Broker. The DFCI IRB does not permit an individual to wear two hats and serve as both the honest broker and a researcher. In effect, this would permit the same individual to sign a document as the researcher and as the honest broker.
 - a. Individuals, including bank directors, pathologists and others who link identifiable information and specimens are considered to be "holders of the key." These individuals are known as the "Honest Broker".
 - b. The Honest Broker who does the linkage may not participate in the research.
 - c. If a person who has served as an Honest Broker wishes to participate in the research, then the research is considered to involve identifiable information and is no longer research with coded information.

2. Protocols that include the use of coded specimens must describe procedures surrounding release of the coded information.
 - a. Release of coded specimens must be done pursuant to a usage agreement that is entered into between the honest broker and the individual receiving the coded specimens.
 - b. A template usage agreement is provided in this Guidance Document.
3. Study teams are encouraged to consult with the Information Services Department that supports their institution to determine the most secure and appropriate methods of overseeing the disbursement of the coded data.

B. Anonymized Specimen or Data Research

1. A biobanking protocol is considered to have anonymized specimens where some one 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.

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

- 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
- IRB Resource – Review of Data and/or Specimen Collection Protocols

Resources:

1. Guidance on Research Involving Coded Private Information or Biological Specimens (October 16, 2008), <http://www.hhs.gov/ohrp/policy/biodata/index.html>
2. [NCI Best Practices for Biospecimen Resources \(2011\)](#)
3. [ISBER Best Practices for Repositories \(2008\)](#)