**Banks – Tissue, Data, Registries**

Modified: January 2017

**Background:**

Tissue and Data banks and Research Contact Registries are used to store data and/or tissues for future research use. Federal regulations and University of Florida policies that protect the privacy of patients and research subjects apply to both the creation and the use of research banks.

Banks involve the collection, storage and later distribution of information and/or biological tissues for some future research purpose. Research bank activities involve three components: 1) the collection of materials, 2) the tissue/data storage and data management and 3) the release by the bank, and subsequent use by recipient investigators. Each component of the bank is governed by Federal research and privacy regulations. Some banks are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes, but may be accessed for research uses. The purpose of establishing a formal research bank is to give the investigator the authority and responsibility for distributing data and/or tissues from the bank, to minimize the regulatory paperwork burden and to define future uses in a fashion that protects participants’ rights yet supports scientific inquiry.

**Q: If all or part of the Tissue, Date, or Contact Bank is kept internal to the University or Shands, must a separate local protocol be submitted?**

Yes. Banks that are partially or completely kept internal to the local institutions must be submitted to the UF IRB as a separate protocol. The myIRB software will provide guidance on these submissions. If an informed consent form is required, a specifically designed “Banking Consent Template” is provided on the UF IRB website.

**Q: If the Tissue, Date, or Contact Bank is only kept external to the University or Shands, must a separate local protocol be submitted?**

No. Banks that are only kept external to the local institutions can be referred to as part of the protocol. As it relates to the consent form, a description of the banking can be provided in the “Banking Consent Addendum” provided on the IRB website, or within the description of the study. When banking is an optional part of the primary study, a section in the consent where the subject signs or initials their agreement to the banking option, should be provided. Other ways to present an external banking may be approved on a case-by-case basis.

**Q: When offering a potential subject participation in a primary study, is it required that the subject sign both the consent form for the primary study and the bank if they are also interested in participating in the internal bank?**

Yes. Subjects are offered both the primary study consent form and the optional banking consent form. Signed consent forms are kept with the appropriate study. This allows the primary study to be closed once completed, but the record of the subject consenting for the bank is maintained with that bank.

**Q: If tissue or data is being kept in order to analyze at the end of the current research project, is that considered “banking?”**
No. Keeping tissue or data for use or batch analysis as part of your research is not banking. Banking refers to tissue, data, or contact information that is being kept to answer future, currently unknown research projects.

**Q: If you have tissue, data, or contact information that was collected under an old research study, what is the best option?**

It is best to open a tissue\data\contact registry joint bank. If the plan is to add additional tissue\data or contact information, then an informed consent should be submitted with the banking request. Once the bank is approved, you can request to close the old studies and move the tissue\data\contact information to the new bank.

**Q: If the PI of the bank wishes to use some of the banked tissue\data\contact information for a new study, can they just take it?**

No. If the PI develops a new research question, that study must be submitted and approved by the IRB prior to extracting tissue\data\contact information for that new study. The source (approved IRB bank protocol number) of the tissue\data\contact information must be included in the submission of the new study.

**Q: Who should be listed as the “gatekeeper” of a bank?**

A bank can have multiple gatekeepers or just one. The gatekeeper is the person or people that have electronic and/or physical access to the bank, and has the authority to dispense tissue\data\contact information to others based on IRB approval. Gatekeepers are typically study coordinators, departmental IT folks, and can also include the PI and other study staff listed on the banking protocol.

**Q: When tissue\data\contact information is dispensed from a bank, what should the gatekeeper be responsible for?**

When dispensing tissue\data\contact information to the PI or any other investigator or to another institution, the gatekeeper must ensure that the person who is receiving the tissue/data/contact information has proper IRB approval. The gatekeeper must also ensure that what they are dispensing is what the requestor has been given IRB approval to obtain. This may require reviewing the IRB approval letter, the IRB approved protocol or consent. When dispensing tissue\data\contact information, the gatekeeper should log what was dispensed, when, and to whom. The IRB website has template forms that can be used for this purpose. The PI of a study can be a gatekeeper, but if that is the case, that PI cannot conduct non-human research from that bank. To summarize, the gatekeeper is responsible for:

- Ensuring that data/tissues are received and released according to UF IRB banking guidelines.
- Ensuring that data/tissue are released for research purposes, and to an IRB approved protocol
- Ensuring the security and confidentiality of stored data and tissues.
- Tracking acquisitions and release of data and tissues, for reporting to the IRB at continuing review.

**Q: Are there any security and confidentiality issues with research banks?**

Yes. The security and confidentiality of the materials must be protected. The following minimum measures must be described in the bank protocol:

- Control of access to the data/tissues - access to the un-coded data/tissues must be restricted to the gatekeeper(s). Accountability for controlling and monitoring access must be provided.
- Security procedures - a method to limit access to the coded data/tissues (including computer security and tissue storage security measures) must be provided.
• Data transfer security - methods to ensure confidentiality during the collection and release of data and tissues.
• Location and appropriate housing of data/tissues must be included in your submission.

Q: Are all tissue/data/contact information banks minimal risk?

No. If you are collecting sensitive data that will be stored with subject identifiers, the IRB may consider the risk of disclosure greater-than-minimal risk. If you are collecting tissue that involves an invasive procedure (e.g. spinal tap) that is only being conducted for the bank, the IRB will consider the bank greater-than-minimal risk. In both such cases, the Full Board must review and approve these types of banks.