MEDICAL COLLEGE OF WISCONSIN

MCW Office of Research Standard Operating Procedure

BANKING: ACCUMULATING HEALTH CARE DATA OR BIOSPECIMENS FOR FUTURE, UNSPECIFIED RESEARCH PURPOSES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

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PURPOSE:

The activity of collecting and storing data or biospecimens for **future, unspecified research purposes** is considered a "research activity" subject to IRB review and approval – independently of the IRB review/approval required for specific studies with the same data/biospecimens.

1. Most focused studies proposing to collect data or biospecimens for other future uses must be submitted as two separate IRB applications – a study application and a banking application.
2. Therefore most focused studies proposing to collect data or biospecimens for other future uses must employ two separate IRB-approved informed consent documents – one for purposes of the study and the other for purposes of banking.
3. The following types of data or biospecimens are NOT subject to this banking policy (however, they may be subject to IRB review as research studies):
    a. Truly anonymized data or biospecimens, or those which have been de-identified (only in cases where the IRB staff has verified anonymization or de-identification by providing a memo to that effect ;)
    b. Publicly available collections of data or biospecimens; and
    c. Collections of data or biospecimens created or maintained for clinical, administrative, or quality assurance (i.e., non-research) purposes.
    d. Collections of data or biospecimens created under the authority of federal, state, or local regulations.

DEFINITIONS:

1. **Bank**: A bank is a collection of data and/or biospecimens to be used for future, unspecified research purposes. The contents of a bank are defined by the scope of an approved IRB banking application, rather than by the physical characteristics or location of the data (e.g., computer hard drive or storage freezer). Thus, a single bank may encompass data on several computers, in several file drawers, in a storage freezer, on a shelf of films, and a collection of specimens preserved in jar of formaldehyde – all in different locations. Banks may be large or small. Some banks may encompass thousands of medical records or biospecimens. Other banks may be limited to twenty medical records or biospecimens. Some banks may house records and/or specimens collected from several different universities, medical centers, or sites; other banks may be limited to data collected only at MCW/Froedtert. Banks may also be described as repositories, or registries at other institutions

2. **Bank Custodian**: The investigator proposing to accumulate data and/or biospecimens for future, unspecified research is (by definition) the Bank Custodian. The Bank Custodian is responsible for the oversight of the Bank in accord with this banking policy, the IRB-approved banking protocol, and federal regulations. While the Bank Custodian may delegate other persons ("key personnel") to fulfill some of his/her duties, it is the Bank Custodian's responsibility to see that IRB requirements are consistently met. The primary responsibilities of a Bank Custodian are:
    - To maintain the security and confidentiality of the Bank;
    - To ensure that all biospecimens or records contributed to the Bank are accompanied by a signed current IRB-approved banking consent document, unless the IRB has made other provisions;
    - To document that all investigators (including the Bank Custodian) who request data from the Bank for specific studies have obtained IRB prior review and approval for their projects, and verify the nature of data access approved by the IRB (in terms of variables, numbers, and identified/de-identified status) before releasing any data;
    - To maintain a regulatory file for the lifetime of the Bank, including original copies of all banking consent documents, investigator applications for data access, copies of IRB approval notification letters with investigator applications, and a log of all data release transactions (e.g., date, name/department of investigator, reference to corresponding investigator application, reference to corresponding IRB approval letter);
    - To document that investigators authorized to access de-identified data never have recourse to any identifiers or potentially identifying codes, unless the IRB decides otherwise [*note: in most cases, a Bank Custodian will not be allowed to de-identify data for any member of the MCW/Froedtert/Children's Hospital/Zablocki VA/Blood Research Institute community*];
    - To inform the IRB in timely fashion about changes to "key personnel" throughout the lifetime of the Bank via an amendment submitted to the IRB, as well as any other amendments to the banking protocol;
    - To inform the IRB in timely fashion about protocol deviations and/or unanticipated problems via a "reportable event" submitted to the IRB; and
    - To arrange for the timely transfer of Bank Custodian responsibilities, or destroy the biospecimens and/or data populating the Bank, in anticipation of the Bank Custodian's decision to relinquish his/her responsibilities. In either case, the IRB shall be notified well in advance (via an amendment to the IRB) so the IRB has an opportunity to review and approve the disposition plan.

3. **Banking activity**: The process of collecting and/or storing data for future, unspecified research purposes requires prior IRB review and approval. There are three types of "banking" activity:
    - accessing biospecimens and/or data from subjects to create a bank with no other study agenda ("***pure banking***");
    - accessing specimens and/or data from subjects during the course of a specific study with its own IRB approval and at the same time setting aside some specimens or data for future uses or other studies ("***study plus banking***"); and
    - accessing a pre-existing collection of specimens and/or data and seeking the IRB's approval to use that collection as a bank in the future ("***rollover banking***").

All three types of banking activities require prior review and approval by the IRB.

- The investigator proposing "***pure banking***" must submit a "banking application" and a model "banking consent document" for IRB review.
- The investigator proposing "***rollover banking***" must submit a "banking application" for IRB review, and should seek guidance from the IRB Staff about how to handle related informed consent issues.
- "***Study plus banking***" proposals fall into two categories:
    - o If 100% of the banking will be done away from the Medical College of Wisconsin campus (broadly defined), the investigator does not have to submit a "banking application," and the investigator may pose an option to participate in the banking portion of the study in the study consent document (i.e., subject must given a choice to opt in or not).
    - If any of the banking will be done on the Medical College of Wisconsin campus, the investigator must submit a "banking application" in addition to the "study application," as well as a model "banking consent document" for IRB review.

4. **Recruitment bank**: Clinical research programs often want to save the names, contact information, and screening information on persons who have:
    a. already served as research subjects, or
    b. responded to advertisements by volunteering to be screened for studies, whether or not they qualify for the advertised studies.

5. **Local Study Site:** defined as MCW, Froedtert Hospital, Children's Hospital of Wisconsin, or BloodCenter of Wisconsin.

Saving the contact and screening information of subjects or callers to facilitate quick recruitment for future studies is not permitted by IRB and HIPAA policies, unless the investigator seeks the IRB's prior approval to create and maintain a **recruitment bank** for these purposes. The IRB will ordinarily require the investigator to document that each person listed in the recruitment bank – whether previous participant or screening failure – has signed an IRB-approved consent document crafted specifically for the recruitment bank, or has provided oral consent after a full discussion of the study consent script.

ASSUMPTIONS:

1. This policy does not make any distinctions between biospecimens, medical chart information, clinical data, or non-clinical data collected or taken for research. In most cases, biospecimens (for example) are collected and stored with personal identifiers, or coded, so that a person with access to the master code could trace the specimen back to a human subject.
2. The rights and welfare of subjects whose data have been "banked" are more difficult to safeguard than the rights and welfare of subjects participating in focused studies. For this reason, the IRB is generally reluctant to waive the informed consent process for "banking activities," unless the investigator can show that the subject has signed the equivalent of a banking consent document for the same material at some time in the past.

PROCEDURE:

<u>Informed consent</u>

1. In general, documented consent is required for biospecimens and/or data added to a bank. When an investigator proposes to prospectively collect biospecimens and/or data for a bank with no other study agenda ("***pure banking***"), documented consent will almost invariably be required. When an investigator

proposes to access specimens and/or data for a specific study with its own IRB approval and at the same time set aside some specimens or data for future uses or other studies ("***study plus banking***"):

a. two documented consents will be required – one for the study and the other for the related bank – if the banking will take place at MCW, Froedtert Hospital, Children's Hospital of Wisconsin, the Zablocki VA Medical Center, or the Blood Research Institute;
b. only one documented consent will be required – combining a study and banking consent – if all the banking will take place at other institutions.

Sending or receiving biospecimens and data for banking purposes

1. **Local collection / local banking**

In the simplest of cases, an investigator collects biospecimens and/or data from subjects locally for a bank housed locally on the MCW/Froedtert campus. The investigator must submit a "banking application" and a model "banking consent document" for IRB review

2. **Local collection / distant banking**

Investigators may submit a banking application to collect biospecimens and/or data from subjects locally, with a plan to transfer the biospecimens and/or data to a bank housed at a different (distant) institution – i.e., not on MCW/Froedtert campus, broadly defined. If 100% of the banking will be done away from the Medical College of Wisconsin campus, a separate "banking application" is not necessary. But the investigator should include the following information with his/her study application to the IRB:

- identification of the MCW/Froedtert Bank Custodian who will oversee the collection and shipping of biospecimens and/or data;
- (when biospecimens will be shipped), a note from the local investigator indicating that everyone who will package specimens for shipping has completed the required training on shipping of hazardous materials; and
- (when biospecimens will be shipped), a note from the MCW Grants & Contracts office, indicating whether shipments must be accompanied by a material transfer agreement.

If the distant bank…

- will be managed by a colleague at another university or academic medical center, the MCW investigator should also submit:
  - that person's name, institutional title (faculty rank and department), institution, address, and phone number, and
  - a letter from that person, indicating his/her willingness to assume responsibility for the biospecimens and/or data, with a general description of the biospecimens and/or data he/she expects to receive from the MCW investigator, and naming the institutional IRB with jurisdiction over that person's distant Bank.
- one of the National Cancer Institute Cooperative Groups, the IRB will have sufficient information about the distant bank so long as the uploaded Cooperative Group protocol explicitly identifies the biospecimens and/or data to be collected in the bank and the address of the banking site.
- a medical industry sponsor, the MCW investigator should also submit:
  - a letter from the person who will manage the bank or a senior representative of the industry sponsor, stating (in these or very similar words) that "the manager or sponsor assures the MCW/Froedtert IRB that all studies done with banked biospecimens and/or data will be

done with Institutional Review Board oversight, consistent with policies defined by the Common Rule (45 CFR 46).

The IRB should have sufficient information about the distant bank (general description, address) so long as the uploaded Sponsor's protocol explicitly identifies the biospecimens and/or data to be collected in the bank and the address of the banking site.

For all local collection / distant banking activities, the banking consent document shall identify the local Bank Custodian who oversees collection of biospecimens and/or data, the distant Bank Custodian who oversees the distant Bank, and the address of the distant Bank.

For all local collection / distant banking, the MCW/Froedtert Bank Custodian shall save the signed consent documents completed by subjects and records of all shipments to the distant Bank.

3. **Distant collection / local banking**

Investigators may submit a banking application to create an MCW/Froedtert Bank receiving biospecimens and/or data from investigators at other sites or institutions. The investigator must submit a "banking application" for IRB review.

Distant collection / local banking usually entail both "local" and "distant" collection. Thus the Bank Custodian submitting an application to the IRB in this situation must be clear about his/her intention to do both local and distant collection. The investigator must submit a "banking application" and a model consent document for IRB review. If the Bank Custodian proposes that another institution's IRB-approved consent document serves to document informed consent, the Custodian should provide the IRB with copies of all related consent documents and IRB approval letters.

Banking applications to the IRB

1. Investigators proposing to create a Bank at MCW,Froedtert Hospital, Children's Hospital of Wisconsin, or BloodCenter of Wisconsin are required to provide the following information in the form of an application to the IRB:
   - Name and faculty status of the Bank Custodian (i.e., the Principal Investigator for a banking application is considered the Bank Custodian);
   - Office address and contact information (phone, FAX, e-mail) for the Bank Custodian;
   - Names and contact information for all persons with access to the Bank database ("key personnel");
   - Documentation that the Bank Custodian and his/her key personnel have completed the "banking activity" training required by the IRB;
   - Precise physical location(s) of where all the data and/or specimens will be stored, including description of the storage medium and related security measures;
   - An estimate of the number of subjects for each group or subgroup, where groups are defined by inclusion/exclusion criteria;
   - Inventory of the kinds and quantities of human biospecimens and/or clinical information intended for the Bank (copies of study data forms are often the best way to document this for the IRB);
   - Potential sources of new "contributions" to the Bank, including a description of all subject recruitment activities and copies of all recruitment media;

- Documentation that the MCW Department of Pathology has been informed about all plans to take tissue or other biospecimen from any operating room at MCW, Froedtert Hospital, or the Children's Hospital of Wisconsin.
- A draft of the banking informed consent document (different than a study consent document) to be employed;
- Written policies and procedures covering:
    a. procedures for obtaining and documenting the informed consent of all subjects contributing data and/or biospecimens to the Bank before any new data or biospecimen is added to the bank;
    b. procedures for maintaining a central inventory of biospecimens/data by subject, with a corresponding file of executed informed consent documents;
    c. procedures for ascertaining prior IRB approval for specific studies before releasing Bank data to any investigator, and for verifying the nature of data access approved by the IRB (in terms of variables, numbers, and identified/de-identified status) before releasing any data;
    d. procedures for maintaining a central inventory of each data release transaction (by investigator, date, study-specific IRB approval);
    e. procedures to maintain the confidentiality and security of the data; and
    f. if applicable, procedures for ensuring that non-MCW investigators who access banked data at a later date never have recourse to any identifiers or potentially identifying codes.

Extra information necessary in cases of distant collection / local banking

- identification of the principal investigator contributing specimens and/or data at each distant site or institution, with address and contact information, and the institutional title of that person (usually faculty rank and department);
- a letter from the principal investigator contributing specimens and/or data at each distant site or institution, indicating his/her intention to work under the oversight of his/her institutional IRB per institutional policies; and
- (when biospeciemens will be shipped), a letter from the MCW Grants & Contracts office, indicating whether incoming shipments must be accompanied by a material transfer agreement.

<u>Continuing Progress Review for Banks</u>

1. At the time when a banking application is approved by the IRB, the IRB will define an approval period (never more than one year, and sometimes a shorter period). It is the Bank Custodian's responsibility to note and remember that approval period, because failure to maintain timely and uninterrupted approval from the IRB means that the bank may no longer function or exist. When IRB approval lapses – even by a day – the following banking activities are invalid and evidence of non-compliance:
    - Soliciting subjects for the bank;
    - Eliciting informed consent from subjects to participate in the banking activity;
    - Adding data and/or biospecimens to the bank;
    - Using banked data and/or biospecimens for any research purpose;
    - Analyzing data obtained from the bank or preparing a research report; or
    - Providing other investigators with banked data and/or biospecimens.

2. Bank Custodians should file a "Continuing Progress Review" application with the IRB two months before the scheduled banking expiration date.

3. For "Continuing Progress Review," the Bank Custodian should summarize the following information for the IRB:
    - Number of total cumulative subjects (subdivided by type of banking activity, if the bank represents different types of data collection);
    - Number of subjects added to the Bank since the last filed CPR application;
    - Inventory of all release transactions of Banked data and/or biospecimens (by investigator, date, and study-specific IRB approval) since creation of bank, and since the last filed CPR application;

Required training for the Bank Custodian and key personnel

1. Bank Custodians and all persons with access to the Bank database are required to complete a training course offered by the MCW Office of Research before a banking application can be approved by the IRB, covering the responsibilities of Bank Custodians, and the distinctions between identified and de-identified data for research purposes.

2. During the lifetime of a Bank, the Bank Custodian is responsible for informing the IRB in timely fashion of any changes in the roster of persons with access to the Bank database, and is responsible for seeing that these persons receive and verify the same training required of Bank Custodians.

Projects which utilize materials out of an IRB approved bank, and informed consent

When a project proposes to utilize material (clinical data or biospecimens) out of an IRB-approved bank:

- The Investigator must think about consent & HIPAA authorization
- The Investigator should consider how consent how consent and HIPAA authorization is documented

Informed Consent and HIPAA Authorization considerations:

1. Per this procedure, all currently approved MCW/FH banks seek and obtain consent to use the data for unspecified purposes in the future. For many banks, consent is handled when the bank is created. Informed consent for a bank is confirmed in one of three ways by the IRB:
    - A banking consent which documents the subject's consent to allow data or specimens to be used for future unspecified uses.
    - A previously completed consent form if it is interpreted as equivalent to a banking consent, or
    - The IRB grants a "waiver of consent/authorization" for future unspecified uses.

2. With this process in place, an investigator who is proposing a new project and removing data from an approved MCW local bank, informed consent and/or HIPAA authorization or the request for a waiver of these may not be required.

3. The Investigator must indicate and describe in their eBridge SmartForm application; specifically in the consent sections and HIPAA sections of the form which MCW/FH bank is being accessed for the data or biospecimens. For all MCW/FH banks, please provide the PRO# as a reference. The IRB will review these requests, and confirm the consent process from the identified MCW/FH approved bank prior to granting approval for the project.

REFERENCES:
MCW Training Course for Bank Custodians & Key Personnel

SUPPORTING DOCUMENTS:
IRB Form: De-identified Data Agreement

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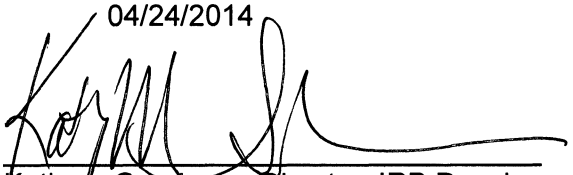

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