MCW Guidance on the Storage of Data and/or Biospecimens for Future Research

This document aims to provide guidance for clinical trial sponsors on how MCW defines "banking" as well as the institutional requirements for this research activity.

MCW Definition of a Bank

According to MCW policy, ***a bank is a collection of data and/or biospecimens to be used for future, unspecified research purposes***. An analysis of this definition is provided below to further clarify what is considered a bank under MCW policy.

MCW policy does not make any distinction between biospecimens, medical chart information, clinical data, or non-clinical data collected or taken for research. 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).

> ***Example*** – *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 biospecimens preserved in jar of formaldehyde - all in different locations.*

MCW policy does not make any distinction based on the size of a bank.

> ***Example*** – 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 and its affiliates/Versiti, Inc.

MCW policy considers unspecified research to be research beyond the purposes of a specific study or beyond the current technologies defined in the IRB-approved documents. In other words, unspecified research is anything outside of the targeted IRB-approved goals and objectives as indicated in the Protocol and corresponding study documents, even if the future research pertains to the same population enrolled in the study.

> ***Example*** – The storage of data and/or biospecimens is considered banking if a study collects blood and health information from subjects with pancreatic cancer and plans to utilize the blood and biospecimens for any future research relating to pancreatic cancer.

> ***Example*** – A study collects biospecimens from subjects and plans to store the biospecimens pending further technological advancements that may allow testing on the biospecimens that does not currently exist. *This is considered banking because the way in which the biospecimens will be handled cannot be defined at the time a subject provides consent for the study.*

Example – A study collects biospecimens from subjects and plans to use the biospecimens to reach the following exploratory objective of the project: "To identify molecular (genomic, metabolic, and/or proteomic) biomarkers that may be indicative of clinical response/resistance, safety, and/or the mechanism of action of Drug #1." This objective will be fulfilled by performing a known biomarker test, but additional biomarker tests may be used if relevant tests enter the market within the timeframe of the project. *This is NOT considered banking because the biospecimens are not being held indefinitely; rather, the biospecimens are being held solely to meet a clearly defined objective of the project. The means by which the objective is met may be expanded throughout the life of the project, but no further.*

Example – A record review that aims to investigate whether a link between obesity and subjects who have undergone a specific cardiac procedure plans to collect a few additional data points seemingly unrelated to the stated aim of the project. It is unclear how, if at all, the additional data points could help meet the stated aims. *It is unclear whether or not the collection of additional data points is considered banking. The aims of the project must be clearly defined in order to accurately categorize a project activity as "banking" or "not banking".*

In addition, regardless of the name bestowed upon the collection of data/biospecimens by another party (e.g. repository, data bank, registry, etc.), the MCW IRB considers a collection to be a bank if it meets the MCW criteria of a bank.

Consent for Banking

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.

Requirements of Industry Sponsors when Banking

When banking occurs with an industry sponsor, it is required that the study application to the MCW IRB contain a letter on the letterhead of the responsible party or organization containing the following information:

- The purpose of the bank
- The name and FederalWide Assurance number of the Institutional Review Board with jurisdiction over the bank, if applicable

The MCW IRB requests valuable and assessable information in order to properly evaluate the bank. For example, the IRB would not necessarily need to know the temperature at which the freezer storing the biospecimens is kept. Rather, the IRB would want to know information that allows the IRB to determine whether or not a project meets the criteria for approval under the federal regulations, such as where the biospecimens and/or data will be kept, the length of storage, etc.

If an industry-sponsored bank does not have IRB oversight, the IRB still requires a description of the oversight in place to protect the data and/or biospecimens of subjects.