West Virginia University • Institutional Review Board

APPLICATION to Develop an On-Site WVU Tissue Bank or Database

FOR RESEARCH OR DATABASE DEVELOPMENT

INVOLVING SPECIMENS OR RECORDS STORED WITH OR WITHOUT CLINICAL HEALTH INFORMATION

v. 03.07.13

**\*\*\*\*\*\*\* TO CONTACT IRB: IRB@mail.wvu.edu or (304) 293-7073 \*\*\*\*\*\*\***

**Instructions:**

This form is intended to register a database or tissue bank to be used for database research with the Office of Research Integrity and Compliance. Once this Application is approved, the form needs to be attached to the appropriate IRB application.

Conceptually, specimens are considered a medium for data and a database is the equivalent of a tissue or blood bank.

**Please send 1 copy of this application electronically to register the tissue bank with the IRB office IRB@mail.wvu.edu.**

**LOCAL PRINCIPAL INVESTIGATOR:**       **DEPT:**

**LOCAL CO - INVESTIGATOR(S):**       **DEPT:**

**CONTACT PERSON:**       **EMAIL:**

**STUDY TITLE:**

**FUNDING SOURCE (SPONSOR):**

**SPONSOR PROTOCOL # AND VERSION DATE, OR FEDERAL AWARD #:**

**SIGNATURES**:

*Principal Investigator* DATE

*\*Department Chairperson* DATE

\* Department Chairperson signature indicates : a) the scientific questions addressed for which this database will be used have adequate merit to justify experimentation involving human tissue b) the PI understands that collection and future study will necessitate the submission of an IRB application.

PI check here to confirm all investigators and key personnel have completed IRB education. See “Education Requirements” on our website for more information: <http://oric.research.wvu.edu>

**Instructions:**

**Respond to each of the following sections** **that request information, even if to indicate “not applicable”,** leaving the template language of this form intact. Some guidance is provided under each category of requested information. For questions please call the IRB office.

**1. This application is to establish a database for future research.**

YES or  NOIf no, please explain**:**      

**2. Describe the research purpose or the purpose of the database:**

**3. Describe the data fields necessary for research or to be retained in the database:**

**4. Describe the source of the data to be used in this research or to be retained in the database.** Specifically explain the process for *collecting and storing* database specimens:

**5. Describe the methods of data abstraction:**

**6. For database creation:**

a. List individual(s) with direct access to database and confirm individuals are aware of confidentiality procedures. If access is provided via 'database managers' please describe process.

b. Please explain the plan for internal review of future use of the database.

**7. Provide the inclusive dates of the information collected for the research or to be retained in the database:**

What is the status of the specimens?

Currently existing YES or NO

To be collected Yes or NO

**8. Will identifiable protected health information (PHI) be disclosed (released) outside of the WVU HSC ?** (Note: This release does not refer to publication (which should be released with no patient identifiable information); rather, is the PHI being collected for release to an entity outside of WVU HSC (e.g. data analysis, archiving).  YES or  NO

If yes, explain to whom:

**9. Please indicate which type of data you will collect, A, B, or C. These terms are defined at the end of this form:**

**A. “De-identified Health Information"**

(Note: If using Statistical Waiver fill out justification section at end of this form)

**Check one:**

There is or will be a link established with de-identified data in order to trace back to PHI.

There is no and will be **no** link established with de-identified data. No data can be possibly traced to PHI.

**B. "Limited Data Set"** Review the list of excluded data elements on the last page. The project involves only the collection of data elements listed in the Limited Data Set.

**Check one:**

There is or will be a link established with the Limited Data Set in order to trace back to PHI.

There is no and will be **no** link established with the Limited Data Set. No traceability to PHI is possible.

**C. "Individually Identifiable Health Information"**

**10. Conflict of Interest Review for Researchers:**

West Virginia University and West Virginia University Hospitals have adopted a policy on Conflict of Interest in Research. Copies of the policy are available on the West Virginia University, Office of Research Integrity and Compliance web site at <http://oric.research.wvu.edu/conint>.

Each individual on the above list should complete a Disclosure of Interest in Research Form. The Disclosure of Interest in Research Form is available on the ORIC website at: <http://oric.research.wvu.edu/conint/disclosure-of-interest-in-research> or <http://oric.research.wvu.edu/conint/disclosure-of-interest-in-research-doir-form-for-non-wvu-affiliated-investigators>.

Approval: IRB Chair/VChair ID & Date:\_\_\_\_\_\_\_ ORIC Dir ID & Date:\_\_\_\_\_\_\_

Approval by the IRB office: [ ] Approved Registration # ­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB MANAGER'S SIGNATURE: DATE:

**DEFINITION OF TERMS USED IN THIS FORM**

**De-Identified Data:** HIPAA Safe Harbor 45 CFR 164.514(b)(2)(i)

In order to be considered "De-identified data" the data collected may not contain any of the following items **or** a qualified statistician must verify methods as outlined below to qualify for a Statistical Review Waiver:

* Names
* Geographic subdivisions smaller than a state
* Zip codes\*
* All elements of dates (except year)
* Age, if over 89
* Telephone numbers
* Fax numbers
* E-mail addresses
* Social security numbers
* Medical record numbers
* Health plan beneficiary numbers
* Account numbers
* Certificate and license numbers
* Vehicle identification and serial numbers
* License plate numbers
* Device identifiers and serial numbers
* URLs
* Internet Protocol address numbers
* Biometric identifiers (finger and voice prints)
* Full face photos and comparable images
* Any other unique identifiers

\*The first 3 digits of a zip code can be retained if publicly available data from the Bureau of the Census indicates that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and the initial 3 digits of a zip code of all such geographic units containing 20,000 or fewer people is changed to 000.

**Statistical Review Waiver 45 CRF 164.514(b)(1)**

* A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
* Determines that the risk of re-identification of the data, alone or in combination with other reasonably available data, is very small; and
* Documents the methods and results of the analysis to justify the determination.

Signature of Statistical Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name:

Justification of analysis:

## Re-identification

A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

1. Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
2. Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose and does not disclose mechanism for reidentification.

**Limited Data Set**:The limited data set permits retention of some identifying items not found in the "de-identified" list.

**Not Allowed** **Allowed**

* Names \* Admission Dates
* Street Addresses \* Discharge Dates
* Telephone and Fax Numbers \* Service Dates
* e-Mail Addresses \* Death Date
* Certificate or License Numbers \* Age (including 90 or over)
* Vehicle ID and Serial Numbers \* Five Digit Zip Codes
* URLs and IP Addresses
* Full Face Photos and Comparable Images
* Social Security Number
* Medical record number

**Identifiable Protected Health Information (PHI)**

Any information created or received by the DHPG in any form that identifies an individual and is related to the past, present, or future:

* Physical or mental health of the individual,
* Provision of health care to the individual or
* Payment for health care provided to the individual.