Subject: Research with Human Tissue, Blood, Genetic Material, and Data

Definitions:
1. **Coded Information:** For the purposes of this policy, identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
2. **Human Subject:** Any living individual about whom an Investigator (whether professional or student) conducting research obtains either data (of any kind) through intervention or interaction with the individual; or identifiable private information (of any kind) even in the absence of intervention or interaction.
3. **Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participants’ environment that are performed for research purposes.
4. **Interaction:** Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.
5. **Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human participants. This may include identifiable private information obtained from a primary participant about a third party.
6. **Non-Human Subjects Research:** Any activity determined by the HRPP to not represent “Human Subjects Research.”
7. **Prospective:** Research utilizing human participants’ specimens/data that will be collected after the research is approved by the IRB.
8. **Repository:** A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.
9. **Research:** Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
10. **Retrospective:** Research utilizing human participants’ specimens/data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.

Policy:
It is the policy of the Institutional Review Board (IRB) to review and approve the establishment and use of specimen/data repositories for research.

I. **IRB Oversight.**
   A. The IRB is responsible for overseeing the collection, use, storage, and re-use of all human tissue, blood or genetic material and all data that are generated within, transferred to, or transferred from VU or VUMC for research purposes.
   1. The IRB does not oversee the storage or management of specimens/data that are collected and stored as part of routine clinical care or hospital procedures.
2. The IRB does not oversee the use or management of specimens/data sent to a VU or VUMC Investigator/employee for specialized analysis as part of a contractual agreement.

3. IRB approval, however, is required prior to the use of these specimens/data for research purposes by a VU or VUMC Investigator.

B. The use of human participants’ specimens/data for research can be classified into the following categories:

1. Specimens/data to be collected prospectively for pre-defined research purposes only in connection with a single IRB approved proposal should submit an “Application for Human Research”. In most cases, this type of collection would not be appropriate for a “research repository.”

2. Specimens/data to be collected prospectively or retrospectively (previously stored), for undefined future research purposes that will be shared, used again, or stored for research purposes beyond the scope of the Investigator’s originally approved IRB application should be banked in a “research repository.”

3. Investigators who wish to prospectively add additional samples to an existing specimen/data collection must seek IRB approval to do so. This may be accomplished by setting up a “research repository”. The use of pre-existing specimens/data for research purposes requires IRB approval.

C. Specimens and/or data extraction from a repository requires IRB approval under a specific study protocol.

D. When specimens/data are entered into a repository then extracted as de-identified (stripped of all 18 HIPAA identifiers) for another project, the research may meet the definition of “non-human subject.”

E. Examples of Human Participant Specimens for Research:

1. Bodily human materials such as: cells, mucosal and skin; blood; urine; amniotic fluid; excreta and external secretions (including sweat); saliva; sputum; placenta tissue; organs; hair; nail clippings; teeth; dental plaque and calculus; if obtained through “intervention or interaction with an individual” or if “identifiable”; and/or

2. Residual diagnostic human specimens, including specimens obtained for clinical patient care that would have been discarded if not used for research.

HRPP policy establishes that standard surgical or medical treatment consent documents may not be used in lieu of specific research consent documents.

F. Examples of Human Participant Data for Research:

1. Private information such as clinical notes and medical information that can be identified with a specific individual, whether or not the information was specifically collected for the research study in question. This also includes private information provided for specific purposes by an individual, which the individual can reasonably expect will not be made public;

2. Data obtained from voice, video, digital or image recordings; and/or

3. Data obtained from surveys, interviews, oral histories, focus groups, program evaluations, quality assurance methodologies, etc.

G. The Investigator may receive coded private information or specimens and qualify as a “non-human subject” if the following conditions are met:

1. The code is not derived or related to the 18 HIPAA identifiers that must be stripped from the PHI (e.g., patient MR# + last 4 digits of the individual’s Social Security Number);

2. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

3. The Investigator cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain because:
   a) The key to decipher the code is destroyed before the research begins;
   b) The Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the Investigator under any circumstances until the individuals are deceased;
   c) The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the Investigator under any circumstances until the individuals are deceased; or
d) There are other legal requirements prohibiting the release of
the key to the Investigator until the individuals are deceased.

II. Establishment of Repositories.
A. A repository may be established within or outside of VU or VUMC. There is
no single "repository" site or mechanism within VU or VUMC.
B. Repositories may be proposed, built, and maintained by individuals (e.g.,
Investigators), groups, programs, departments, or institutes. A single Investigator or a
group of Investigators may wish to pool research specimens/data from multiple research
studies into a single specimen bank or database that could be accessed by the group and
others for further use.
C. Examples of outside repositories that an Investigator may wish to utilize
include the NIH, CDC, ECOG, and NSABP laboratories, as well as laboratories
managed by colleagues at other academic institutions.

III. Conditions in which an Investigator Should Consider the Establishment of a Repository.
A. When a clinical database is expressly designed for eventual research purposes,
and particularly if that database incorporates research measures, or plans for group
comparisons, the Investigator should establish a repository prior to the collection of data
for the purpose of research.
B. Databases maintained by physicians/Investigators for record-keeping of individual
patients that will be accessed for research purposes for a single project, must have IRB
approval to do so. However, if it is expected that the data contained in the database will be
accessed for multiple projects or by multiple Investigators, a repository should be
established.

IV. Informed Consent Requirements for the Establishment and Use of a Repository.
A. Informed consent is required from the participant or his/her legally authorized
representative prior to the collection of specimens/data to be deposited and stored in a
repository, unless a waiver of informed consent has been granted by the IRB (See HRPP
Policy IV.C).
B. The Investigator is required to obtain written informed consent from each
participant prior to accessing the repository for his/her proposed research activity when the
extracted data will contain personal identifiers. However, the Investigator may in some
situations be able to demonstrate that it is truly not practicable to obtain informed consent
process or authorization.
C. The Office for Human Research Protections (OHRP) recommends that a Certificate
of Confidentiality be sought for repositories, especially for the banking of genetic
samples/information (See HRPP Policy VI.D).
D. The Investigator may withdraw data from a repository without any identifiers; in
which case, the study may qualify as "non-human research" or meet criteria for exemption
from IRB approval and informed consent requirements. However, only the HRPP may
determine which activities qualify for an exempt review.

V. Medical Center and IRB Policies for Control of All Human Tissue. VUMC Medical
Staff Rules and Regulations require that all tissue or other materials removed during any operative
procedure (except hardware removal or teeth and tissue removed during routine dental extraction in
the outpatient department) be sent to the Surgical Pathology Laboratory for review and
documentation by a pathologist. Institutional policy mandates that at no time may a specimen be
removed during an operation or be removed from the Medical Center without the review and
documentation of the pathologist. All Investigators who propose to perform research with human
tissue must comply with this Medical Center policy. HRPP policy requires IRB review of all research
utilizing specimens or private data, regardless of whether the research is retrospective or prospective
and the participant is alive or deceased (See HRPP Policy I.B).

References:
OHRP: Issues to Consider in the Research Use of Stored Data or Tissues, November 1997.
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens,
45 CFR 46