Department: **UAMS Institutional Review Board**
Policy Number: **17.11**
Section: **Special Populations**
Effective Date: **July 31, 2002**
Revision Date: **August 25, 2004; September 1, 2015; February 15, 2016; August 18, 2021**

SUBJECT: Stored Data or Tissues in Research

Definitions:
Tissue Repository: Any collection of human tissues created with the primary intent of storage, distribution, and/or use for future human subject research.
Data Repository: Any collection of human subject data developed with the primary intent of making that data available for future research.

Policy
Human tissue or data repositories collect, store, and distribute human tissue or data materials primarily for research purposes. Repositories may be set up independently, i.e. data/tissues are initially collected specifically for the repository, or may be created secondary to other research projects, with data or specimens being retained for future use. Repositories involve three components – collection of tissue or data; storage and management of tissue/data; and investigators who receive tissue/data from the repository for research use. The UAMS IRB will review research proposals that involve repository creation in accordance with all policies and regulations governing human subject research.

The UAMS IRB will not approve so-called umbrella policies that cover both the creation and maintenance of a repository and the unspecified future use of repository material for future research. Each future research project using repository materials requires a separate IRB submission of the appropriate type.

UAMS does not, at this time, have a process in place to allow the type of broad consent process described at 45 CFR 46.104(d)(7) and (d)(8).

PROCEDURE
A. IRB Responsibilities
   1. The creation and management of a repository is subject to Institutional Review Board oversight. The UAMS IRB shall assume that role for research repositories under its purview, specifically, those ordinarily subject to UAMS IRB review, not subject to oversight by an outside IRB, and whose activities meet the regulatory definition of human subject research.
   2. The IRB will review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to

protect the privacy of subjects and maintain the confidentiality of data. The creation and use of a repository may be submitted as its own separate protocol, or as part of another clinical study giving subjects the option to, or requiring them to, allow the future storage and use of their materials.

3. The IRB may also recommend or require the investigator to obtain a certificate of confidentiality to protect confidentiality of repository specimens and data.
4. The IRB will ensure that the consent process proposed for the collection and storage of tissues/data in a repository adequately describes the repository activities and the potential future uses of tissues/data, in accordance with 45 CFR 46 and any other applicable regulations. Informed consent should include a clear description of the operation of the repository; a description of the types of research anticipated involving repository materials; conditions under which data and specimens will be released to recipient-investigators; and procedures for protecting the privacy of subjects and maintaining the confidentiality of data. All other required elements of informed consent will also be addressed or waived, in accordance with applicable regulations.

B. Responsibilities of investigators who create and/or maintain repositories.
   1. Investigators who create and/or maintain repositories shall ensure the IRB submission related to the repository addresses the following elements:
      a. Which materials or data will be stored in the repository
      b. How the materials/data will be obtained
      c. How the stored materials/data will be labeled, and who will have access to any identifiers or codes that allow relinkage
      d. How long the material will be stored, and under what conditions
      e. Who will be granted access to the material for future research
      f. How requests to use the material will be handled, including a description of how the repository manager will ensure any recipient has obtained appropriate IRB approval, or documentation that IRB review/approval are not required
   2. Investigators who create and/or maintain repositories shall follow all applicable policies and regulations related to human subject research.

C. Responsibilities of investigators who use repository materials for research.
   1. Investigators obtaining data or tissues from a repository or any other source and who are subject to UAMS IRB oversight should consult the IRB for guidance regarding whether their project meets the definition of human subject research requiring review. Investigators are strongly encouraged to submit a human subject research determination form through the IRB e-system for a formal determination.
   2. Under the definition of human subject at 45 CFR 46.102, *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research.
   3. In general, private information or specimens are considered individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.
   4. Private information or specimens are considered not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, research involving **only** coded private

information or specimens does not involve human subjects as defined under 45 CFR 46.102(e) if the following conditions are both met:

a. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
b. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    i. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
    ii. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    iii. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

D. FDA-regulated research on *in vitro* diagnostic devices.

1. Per FDA regulations, use of human specimens that are not individually identifiable in FDA-regulated *in vitro* diagnostic devices (IVD) investigations is human subject research. However, FDA does not intend to object to the use, without informed consent, of leftover human specimens – remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded – in investigations that meet the criteria for exemption from the Investigational Device Exemptions regulation at 21 CFR 812.2(c)(3), as long as subject privacy is protected by using only specimens that are not individually identifiable. FDA also extends this enforcement discretion to specimens obtained from specimen repositories and specimens that are leftover from specimens previously collected for other unrelated research, as long as these specimens are not individually identifiable. The FDA intends to exercise enforcement discretion regarding the requirements for informed consent for use of specimens in FDA-regulated IVD studies if all of the following are true:
    a. The investigation meets the IDE exemption criteria at 21 CFR 812.2(c) (3).
    b. The study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded. The study may also use specimens obtained from specimen repositories or leftover specimens that were previously collected for other research purposes.
    c. The specimens are not individually identifiable, i.e., the identity of the subject is not known to and may not readily be ascertained by the investigator or any other individuals associated with the investigation, including the sponsor. If the specimen is coded, it will be considered to be not individually identifiable if neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.

d. The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.
e. The individuals caring for the patients are different from and do not share information about the patient with those conducting the investigation.
f. The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information.
g. The study has been reviewed by an IRB in accordance with 21 CFR Part 56.

2. Studies that do not fall within the scope of the enforcement discretion described in the FDA's guidance include (but are not limited to) those where any of the following is true:
   a. The study does not meet the IDE exemption criteria at 21 CFR 812.2(c)(3);
   b. the specimens are individually identifiable, i.e., the identity of the subject is known to or may be readily ascertained by the investigator or any other individuals associated with the investigation, including the sponsor.
   c. the specimens were collected specifically for the proposed investigation. That is, the specimens are not leftover from routine clinical care or analysis or leftover from other research.
   d. the amount of specimen needed for the study is more than would be leftover from what is usually collected for routine clinical analysis or,
   e. the test results will be reported to the subject's health care provider. For example, in the course of comparative studies involving B. anthracis detection devices, it would be inappropriate not to report positive results if they occur in the course of an investigation.

REFERENCES

45 CFR 46, 21 CFR 56, and 21 CFR 812 as cited above

Coded Private Information or Specimens Use in Research (OHRP Guidance dated January 19, 2018)

In Vitro Diagnostic (IVD) Device Studies – Frequently Asked Questions (FDA Guidance dated June 25, 2010)

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable (FDA Guidance dated April 25, 2006)