

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT FOR THE STORAGE AND USE OF REPOSITORY
MATERIALS**

I. PURPOSE

This document outlines the procedures for University of Tennessee Health Science Center Institutional Review Board concerning informed consent and its documentation for the storage and use of repository materials.

II. SCOPE

This SOP applies to all UTHSC investigators.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

Office for Human Research Protections (OHRP) considers the research use of identifiable biospecimens and identifiable private information to constitute research with human subjects. Therefore, the collection and storage of identifiable private information and/or biospecimens for research purposes must be reviewed and approved by the UTHSC IRB.

Creation of a **repository** involves the storage and maintenance of private information and/or identifiable biospecimens for future research studies (in addition to, or separate from, any current study in which they might be collected). Private information and/or biospecimens may be initially collected for a repository, or the private information and/or biospecimens may be originally collected for some other primary purpose, such as the clinical care of patients, and then placed in a repository.

Under federal regulations and UTHSC IRB policy, there is a presumption that informed consent must be secured from prospective subjects for the donation of identifiable private information and/or biospecimens to a repository. The federal regulations under the revised Common Rule at 45 CFR 46.104(d)(7) permit exempt status for the storage and maintenance of identifiable private information and/or identifiable biospecimens for future research studies, if these materials have been or will be collected for other primary purposes, such as the clinical care

of patients. Utilization of this exemption requires limited IRB review to determine that appropriate protections for the privacy and confidentiality of subjects are implemented. The IRB must also determine that the consent of prospective subjects will be secured, utilizing the broad consent provisions of the revised Common Rule at 45 CFR 46.116(d). The UTHSC IRB repository consent template incorporates these broad consent elements and should be used to draft the consent form for exempt category 7 research repositories. When a repository is established under exempt category 7, investigators who wish to utilize materials from the repository in future research studies may also apply for exempt status under 45 CFR 46.104(d)(8) for each of these studies.

Research repositories cannot meet the requirements for exempt status if they involve the initial collection of identifiable private information or biospecimens specifically for the repository. However, the creation of a repository involving the initial collection of information/biospecimens may be eligible for expedited or full board review. Expedited review is permitted if all procedures used in the collection of materials fall within the range of procedures eligible for expedited review and involve no more than minimal risk. Review of a repository application under the expedited or full board rules involves a presumption that informed consent of prospective subjects will be secured. The UTHSC IRB repository consent form template incorporates the general consent elements required under the federal regulations and must be used for these repositories as well. However, unlike repositories approved under the exempt provisions of the federal regulations, an alteration or waiver of consent can be granted for repositories approved on an expedited or full board basis if the conditions for alteration or waiver of consent outlined below are satisfied.

It should also be noted that, when repositories are approved under the exempt or expedited provisions of the federal regulations, continuing review of such studies is not required for studies reviewed and approved (or approved pending a satisfactory response to administrative provisos) on or after January 21, 2019, unless the IRB determines otherwise. However, FDA-regulated expedited repositories are required to undergo continuing review under 21 CFR 56.109.

In accord with:

For studies approved under the revised Common Rule:

45 CFR 46.102(e); 45 CFR 46.109; 45 CFR 46.111; 45 CFR 46.116;

For studies approved under the pre-2018 Common Rule:

[45 CFR 46.102\(f\)](#)

For FDA-regulated studies:

21 CFR 50.20, 50.25 and 50.27; 21 CFR 56.109, 56.111, and 312.62; and applicable state and local laws.

Coded Private Information or Biological Specimens: OHRP Guidance on Research

<http://www.hhs.gov/ohrp/policy/cdebiol.html>

Coded Private Information or Biological Specimens, Research Use (Video)

<http://www.youtube.com/watch?v=yp5GzAmXPM>

Genetic Information Nondiscrimination Act (GINA): OHRP Guidance (2009)

<http://www.hhs.gov/ohrp/policy/gina.html>

Compliance with this policy also requires compliance with state or local laws and regulations that provide additional protections for human subjects.

IV. DEFINITIONS:

Biospecimen encompasses a full range of specimen types, including DNA, cells, tissues, organs, gametes, embryos, fetal tissue, and human waste materials.

Identifiable means that the identity of the individual from whom the private information or biospecimen has been obtained is or may be readily ascertained by the investigator or associated with the private information or biospecimen.

Private information includes information about behaviors that occur in a context in which individuals can reasonably expect that no observation and recording is occurring, and information that has been provided for a specific purpose (like health care) that individuals can reasonably expect will not be made public.

Repository means the storage and maintenance of private information and/or biospecimens for future research studies. Identifiable private information and/or biospecimens may be initially collected for a repository, or the private information and/or biospecimens may be originally collected for some other primary purpose, such as the clinical care of patients, and then placed in a repository.

V. PROCEDURES

1. See IRB SOP: Informed Consent for the general requirements for adequate informed consent, documentation of consent, and formatting instructions. UTHSC IRB consent form templates are available on the UTHSC IRB website at <http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php>.
2. When a repository is being established that involves the storage of identifiable private information and/or biospecimens, a separate repository consent form should be developed using the UTHSC IRB repository consent form template, unless the study qualifies for a waiver of consent. This template should be used for all repositories, including repositories established under exempt category 7 of the revised Common Rule involving storage and maintenance for research use of identifiable private information or identifiable biospecimens that will be, or have already been, collected for another purpose. This template includes the following informational elements:
 - a. A summary of key information:
 - i. Explains whether identifiable private information and/or biospecimens will be collected for the repository.
 - ii. Describes the kinds of medical research for which it is anticipated that information/specimens from the repository will be used. This description must include sufficient detail such that reasonable persons would expect that their consent would permit the kinds of research that will actually be conducted.
 - iii. Explains the procedures by which the specimens will be collected, including the types and amounts of specimens;
 - iv. Indicates what researchers will have access to private information and/or specimens from the repository (e.g., specimens might be available to investigators in a particular department, all faculty at the university, colleagues at other academic institutions, personnel from commercial entities, etc.). In addition, if the materials will be shared with investigators outside the repository, explain whether these materials will be individually identifiable, coded, or de-identified.
 - v. Formulates in lay terms the most common (highest in frequency) physical risks involved in collecting the specimens, which are not already associated with procedures being performed as part of the subject's clinical care. If there are no additional physical risks, this should be stated.
 - vi. Indicates the possible benefit for both the subject and the ways in which the repository has the potential to develop medical knowledge important to society. If there are no direct benefits to

- subjects associated with participation in the repository, then this should be clearly stated.
- vii. Explains that participation in the repository is voluntary. For repositories associated with a main research study, it should be explained whether subjects may participate in the main study without participating in the repository. The procedures for withdrawing biospecimens and related information from the repository should also be described, including whom to contact and in what manner this can be accomplished.
- viii. Underscores the fact that participation is voluntary.
- b. A detailed description of procedures involved in the operation of the repository that:
- i. Explains how the specimens will be collected, including the types and amounts of specimens, as well as any other interventions involved in the repository.
- ii. Describes the period of time that the identifiable (or de-identified) private information or identifiable (or de-identified) biospecimens may be stored and maintained (including indefinitely), as well as the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes.
- iii. Indicates for repositories involving biospecimens, when it is possible that genetic analysis may be performed, whether the research will (if known) or might include analyses of the genetic makeup of subjects. This might include sequencing to determine the differences between subjects in terms of disease severity, likelihood of disease progression, and so forth; sequencing of genes that may indicate a disease susceptibility heretofore unknown to the subjects; sequencing to determine pharmacogenomic phenotypes; and whole genome sequencing, i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.
- iv. Includes a statement that results will not be disclosed to subjects, if clinically relevant research results (e.g., general or aggregate information regarding the outcome of the research that could affect/change clinical care for a disease), OR individual research results (i.e., results specific to the subject and his/her health), **will not be** disclosed to subjects in **ANY** circumstances. Alternatively, if at least some clinically relevant research results, including individual research results, may be disclosed to subjects, this must be indicated and a choice provided to the subject regarding receiving results.
- v. Includes a statement indicating that details of any specific research studies that might be conducted using the subject's identifiable

private information and/or specimens, including the purposes of the research, will not be provided, and that the subject may have chosen not to consent to some of those specific research studies.

- vi. Indicates that subjects may discontinue their involvement by having their specimens and related information destroyed, without any loss of benefits to which they are otherwise entitled, and explains the procedures by which this can be accomplished, including whom to contact.
- c. A description of the risks associated with participation in the repository, including any risks involved in collecting the specimens that are not already associated with procedures being performed as part of the subject's clinical care, risks that would result from unintended disclosure of data associated with the specimens or generated from analysis of them, and the risks of adverse psychological and social consequences if results of studies using the specimens are relevant to the health of subjects and disclosed to them.
- d. A description of the provisions for the protection of the confidentiality of the information and biospecimens should be provided. This should include a description of the protections provided by a Certificate of Confidentiality, if applicable. For repositories involving genetic analysis that may reveal the genetic susceptibility of subjects or others to health problems of which they are currently unaware or from which they do not presently suffer, the description should also include an explanation of the protections afforded by the Genetic Information Non-Discrimination Act.
- e. A statement regarding the availability of compensation and/or treatment for injury.
- f. An explanation regarding whom to contact with questions regarding the nature of the repository or the rights of research subjects, and whom to contact in the event of a research-related harm.
- g. An explanation of whether subjects will be paid for donating a specimen to the repository.
- h. An explanation of whether profit-making activities might result from commercialization of the information and/or specimens collected during the research study (e.g., the development of a marketable diagnostic test), and whether subjects will share in any profits deriving from these activities.
- i. An explanation of whether there are any costs to persons for donating a specimen to the repository.
- j. A description of any conflicts of interest of those investigators responsible for the repository.
- k. If applicable, a request to re-contact subjects in the future, with a description of how this might be done and the provision of an option for prospective subjects to decline being re-contacted.

- i. A statement that subjects will be provided a copy of the consent form.
 - m. Dated signature lines to permit verification that consent was obtained prior to participation in any study related procedures.
 - n. Documentation of informed consent for participation in the repository in accord with the requirements of 45 CFR 46.117 and the UTHSC IRB SOP on informed consent.
 - o. UTHSC IRB may require additional information be given to subjects when such information would enhance protection for the rights and welfare of the subjects.
3. There is a presumption that consent must be secured from subjects whose identifiable private information or identifiable biospecimens are submitted for storage and maintenance in a repository. A request for a waiver of consent for the submission of identifiable materials to a repository is approvable only if all of the following conditions obtain:
 - a. Creation of the repository does not require interaction or intervention with subjects for the initial collection of identifiable private information or identifiable biospecimens for placement in the repository, i.e., the information/biospecimens have been or will be initially collected for some other purpose.
 - b. Approval for the creation of the repository is not being sought under the provisions of the exemption at 45 CFR 46.104(d)(7) in the revised Common Rule. The latter exemption is approvable only if the consent will be secured in accord with the informed consent requirements at 45 CFR 46.116(d) of the revised Common Rule and only if the consent form utilizes the UTHSC IRB template for repository consent.
 - c. The proposed storage and maintenance of identifiable private information and/or biospecimens satisfies the conditions for waiver of consent at 45 CFR 46.116(f) (45 CFR 46.116(d) of the previous Common Rule):
 - i. the research involves no more than minimal risk to subjects;
 - ii. the research could not practicably be carried out without the requested waiver;
 - iii. the research could not practicably be carried out without using the information or biospecimens in an identifiable format;
 - iv. the waiver will not adversely affect the rights and welfare of subjects; and
 - v. whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
 - d. No subjects whose identifiable private information or identifiable biospecimens are submitted to the repository have previously refused consent for the use of those materials by the repository.

4. There is a presumption that consent must be secured from subjects whose identifiable private information or identifiable biospecimens are submitted for storage and maintenance in a repository. A request for an alteration of some or all of the elements of informed consent, or for alteration of the consent process, for the submission of identifiable materials to a repository is approvable only if each of the following conditions obtain:
 - a. Approval for the creation of the repository is not being sought under the provisions of the exemption at 45 CFR 46.104(d)(7) under the revised Common Rule. The latter exemption is approvable only if the consent will be secured in accord with the informed consent requirements at 45 CFR 46.116(d) under the revised Common Rule and only if the consent process utilizes the UTHSC IRB template for repository consent.
 - b. The proposed storage and maintenance of identifiable private information and or biospecimens satisfies the conditions for alteration of consent at 45 CFR 46.116(f) (45 CFR 46.116(d) of the previous Common Rule):
 - i. the research involves no more than minimal risk to subjects;
 - ii. the research could not practicably be carried out without the requested alteration;
 - iii. the research could not practicably be carried out without using the information or biospecimens in an identifiable format;
 - iv. the alteration will not adversely affect the rights and welfare of subjects; and
 - v. whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
5. Creation of a repository that includes only private information and/or biospecimens that have previously been anonymized and are no longer individually identifiable does not constitute the use of “human subjects” under the definition at 45 CFR 46.102(e)(1) (45 CFR 46.102(f) of the previous Common Rule). Therefore, the human subjects regulations do not apply to the creation of a repository that includes only such materials and informed consent is not required. However, note that under IRB policy on Determination of NCSR or Exempt Status, you must submit a project application to the IRB in order for the IRB to determine that the repository does not include “human subjects” and that obtaining informed consent is not required.
6. Investigators who utilize identifiable private information and/or identifiable biospecimens from a previously IRB-approved repository are not required to obtain additional informed consent from subjects, provided that all of the following conditions are satisfied:

- a. The research will be conducted within the scope of the consent originally used to secure the approval of subjects for the storage of their materials in the repository, unless informed consent was waived under the above provisions;
 - b. Informed consent for the storage of materials in the repository was secured using the UTHSC IRB informed consent template for repositories and was secured according the procedures outlined in the UTHSC IRB SOP on informed consent.
 - c. Informed consent for participation in the repository was documented in accord with the requirements of 45 CFR 46.117 and the UTHSC IRB SOP on informed consent.
 - d. The investigator does not include returning individual research results to subjects as part of the plan of study.
7. However, investigators must submit a project application to the IRB for each project in which they wish to use information/specimens from the repository so that the IRB can determine whether the proposed use of the information/specimens is within the scope of the consent originally used to secure the approval of subjects for the storage of their materials in the repository (if consent was obtained) and that the proposed use is within the scope of the protocol and/or application for the repository.