UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE INSTITUTIONAL REVIEW BOARD INFORMED CONSENT FOR GENETIC ANALYSIS & REPOSITORIES

I. PURPOSE

This document outlines the University of Tennessee Graduate School of Medicine Institutional Review Board procedures for informed consent and its documentation for genetic analysis and repositories.

II. SCOPE

This SOP applies to all IRB administrative staff, board members, and investigators.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

Office for Human Research Protections (OHRP) considers obtaining identifiable specimens and private information for research purposes human subjects research. Therefore, the collection, use and storage of human biological specimens and/or private information for research purposes must be reviewed and approved by the UT GSM IRB.

The term “human biological materials” encompasses a full range of specimen types, including DNA, cells, tissues, organs, gametes, embryos, fetal tissue, and human waste materials. A research “repository” involves the collection, storage, and distribution of human biological materials or private information for use in future research studies.

It is the policy of the UT GSM IRB that informed consent for the donation of human biological materials or private information to research repositories (see item #5 below) must be secured separately from consent to the use of these materials in specific research studies. For research studies that involve genetic analysis, a separate consent form following the Genetic Analysis Consent Form Template should be followed (see item #4 below). However, for research studies in which genetic analysis comprises one component of the investigation, specific elements from the genetic analysis template may be incorporated into the main consent form (see item #3 below).

In accordance with:

45 CFR 46.102(f); 45 CFR 46.109; 45 CFR 46.111; 45 CFR 46.116; 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: Issues to Consider in the Research Use of Stored Data or Tissues, Operation of Biological Repositories: OPRR Memoranda (1996, 1997)
http://www.hhs.gov/ohrp/policy/reposit.html

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=yp5GzAmXlPM

Fetal Tissue Transplantation: OHRP Guidance
http://www.hhs.gov/ohrp/policy/fetal.html

Fetal Tissue Transplantation Research, Public Law 103-43, Section 498A
http://www.hhs.gov/ohrp/policy/publiclaw103-43.htm.html

Genetic Information Nondiscrimination Act (GINA): OHRP Guidance (2009)
http://www.hhs.gov/ohrp/policy/gina.html

Human Embryonic Stem Cells, Germ Cells, and Cell-Derived Test Articles: OHRP Guidance (2002)
http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/

Informed Consent for in Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
http://www.fda.gov/RegulatoryInformation/Guidances/ucm078384.htm

Research Involving Human Biological Materials: Ethical Issues and Policy Guidance
http://www.scribd.com/doc/23891581/Research-Involving-Human-Biological-Materials-Ethical-Issues-and-Policy-Guidance

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

I. PROCEDURES

1. See SOP: UTHSC IRB 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. Requirements for **studies that consist entirely in Genetic Research** and for which specimens will be collected prospectively, informed consent is required and the consent form should be prepared according to the genetic analysis template that includes the following:
   a. A statement that the research study involves genetic analysis;
   b. An explanation of the purposes of the research;
   c. The expected duration of the subject's participation;
   d. The location(s) in which the research will be performed;
   e. Description of the procedures by which the specimens will be collected;
   f. Description of who will have ownership of the specimens;
   g. An explanation of whether profit making activities will result from research use of the specimens;
   h. An explanation of whether the results of the studies conducted will be shared with the subjects;
   i. An explanation of whether subjects will be re-contacted for follow-up regarding their health status;
   j. An explanation of whether the research will involve concomitant review of medical records;
   k. The length of time for which specimens will be retained;
   l. A description of any reasonably foreseeable risks or discomforts involved in collecting the specimens, including their probability, magnitude, duration and reversibility;
   m. A description of any benefits to the subject or to others that may reasonably be expected from the research;
   n. A description that subjects have the option of not contributing specimens;
   o. A statement describing the extent to which the confidentiality of research records/specimens identifying the subject will be maintained;
   p. Incorporation of the HIPAA subject authorization template;
   q. A statement regarding the protections for genetic information provided by the Genetic Information Nondiscrimination Act;
   r. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical

treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

s. An explanation of whom to contact for answers to pertinent questions *(include names and phone number)*:
   1. about the research (the principal investigator)
   2. about the subject's rights (the IRB Chair)
   3. whom to contact in the event of a research-related injury (the principal investigator);

t. A statement that participation is voluntary;

u. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled;

v. A statement that subjects may discontinue their involvement by having their specimens and related data destroyed without any loss of benefits to which they are otherwise entitled.

w. Any additional costs to the subject that may result from providing specimens for the research;

x. Information concerning payment to subjects, including the amount and schedule of payments;

y. A statement that subjects will be provided a copy of the consent form;

z. Dated signature lines to permit verification that consent was obtained prior to participation in any study related procedures; and

   aa. UTHSC IRB may require additional information be given subjects when such information would enhance protection for the rights and welfare of the subjects.

3. For studies in which **Genetic Analysis comprises only one component of the investigation**, the following items should be incorporated into the main consent form for the entire study [**Note**: some of the items listed below may be irrelevant given the limited role of genetic analysis in the overall study. For example, ownership of the specimens and the possibility of profit making activities may be irrelevant for studies in which specimens will be used in their entirety or disposed of after genetic testing. In these cases, items of consent information listed below which are irrelevant may be deleted from the disclosure process and the consent form]:
   a. A statement that the research study involves genetic analysis;
   b. Description of the procedures by which the specimens will be collected;
   c. Description of who will have ownership of the specimens;
   d. An explanation of whether profit making activities will result from research use of the specimens;
   e. An explanation of whether the results of the studies conducted will be shared with the subjects;
   f. An explanation of whether subjects will be re-contacted for follow-up regarding their health status;

g. An explanation of whether the research will involve concomitant review of medical records;
h. The length of time for which specimens will be retained;
i. A description of any reasonably foreseeable risks or discomforts involved in collecting the specimens;
j. A description that subjects have the option of not contributing specimens;
k. A statement describing the extent to which the confidentiality of specimens identifying the subject will be maintained;
l. A statement regarding the protections for genetic information provided by the Genetic Information Nondiscrimination Act;
m. A statement that subjects may discontinue their involvement by having their specimens and related data destroyed without any loss of benefits to which they are otherwise entitled;
n. Any additional costs to the subject that may result from providing specimens for the research.

4. For **Genetic Studies that involve previously collected specimens**, informed consent may be waived under the following circumstances:
   a. The specimens cannot be linked to "individually identifiable" persons. Previously collected specimens that have been completely anonymized prior to their use in genetic research meet this condition. The use of such anonymized specimens does not involve research with "human subjects" under the definition at 45 CFR 46.102(f)(2).
   b. The specimens can be linked to identifiable persons, but the investigator records information about the specimens "in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects." Research using specimens in this manner qualifies for exempt status under 45 CFR 46.101(b)(4).
   c. The use of specimens does not satisfy the conditions in (a) or (b) but the study qualifies for waiver of informed consent under 45 CFR 46.116(d). According to this section, wavier of consent may be granted if (i) the research involves no more than minimal risk to subject; (ii) the waiver will not adversely affect the rights and welfare of subjects; (iii) the research could not practicably be carried out without the waiver; and (iv) whenever appropriate the subjects will be provided with additional pertinent information after participation.

5. Requirements for studies that involve a **Repository**, informed consent is required and the consent form should be prepared according to the genetic analysis template that includes the following information:
   For studies that include a repository
   a. Indicate the name of the repository (if applicable), its location and the individuals and/or entity responsible for its operation;

b. Describe the kinds of medical research for which it is anticipated that samples from the repository will be used. If it is anticipated that currently undetermined, secondary uses of samples might also be permitted, this should be indicated;
c. Explain the procedures by which the specimens will be collected, including the types and amounts of specimens;
d. Explain what researchers will have access to samples from the repository: e.g., samples might be available to investigators in a particular department, all faculty at the university, colleagues at other academic institutions, personnel from commercial entities, etc.;
e. Explain who will have ownership of the specimens, data associated with it, data generated from analysis of it and immortalized cell lines developed from the specimens;
f. Indicate whether profit-making activities might result from research use of the specimens, e.g., the development of a marketable diagnostic test, and whether subjects will share in any profits deriving from these activities;
g. Indicate whether, under certain circumstances, results of studies conducted with the specimens might be relevant to the health of the subjects, and whether these results might be shared with subjects. If such circumstances are anticipated, indicate that subjects will be asked whether or not they want to receive this information;
h. Indicate whether or not some studies using samples from the repository might require re-contacting subjects for follow-up regarding their health status;
i. Indicate whether or not some studies using samples from the repository might involve concomitant review of the medical records of the subjects;
j. Indicate the length of time for which specimens will be retained in the repository. If the length of storage is indefinite, this should be stated;
k. A description of any benefits to the subject or to others that may reasonably be expected from the creation of the repository;
l. Describe any risks involved in collecting the specimens that are not already associated with procedures being performed as part of the subject's clinical care. If there are no additional risks, this should be stated;
m. Describe the risks to insurability and employability that would result from unintended disclosure of data associated with the specimens or generated from analysis of them;
n. Describe the possibility that, if results of studies using the specimens are relevant to the health of subjects, then disclosure of the information to subjects may have adverse psychological and social consequences;
o. Indicate that prospective subjects have the option of not contributing specimens to the repository;

p. For repositories associated with a main treatment study, explain whether subjects may participate in the main study without participating in the repository;
o. A statement describing the extent to which the confidentiality of specimens identifying the subject will be maintained;
p. Incorporation of the HIPAA subject authorization template;
q. Indicate that subjects may discontinue their involvement by having their specimens and related data destroyed, without any loss of benefits to which they are otherwise entitled. Explain the procedures by which this can be accomplished, including who to contact;
r. Indicate who to contact with questions regarding the nature of the repository or the rights of research subjects;
s. Indicate whether there are any costs to persons of donating a specimen to the repository;
t. Indicate whether subjects will be paid for donating a specimen to the repository;
u. A statement that subjects will be provided a copy of the consent form;
v. Dated signature lines to permit verification that consent was obtained prior to participation in any study related procedures; and
w. UTHSC IRB may require additional information be given subjects when such information would enhance protection for the rights and welfare of the subjects.