

Appendix 06

Collection of Human Biological Materials For Research Repositories:

Requirements for Informed Consent UTGSM Institutional Review Board

A research repository involves collection, storage and distribution of human biological materials for use in specific research studies. 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.

It is the policy of the UTGSM IRB that informed consent for the donation of human biological materials to research repositories must be secured separately from consent to the use of these materials in specific research studies.

In the following discussion of informed consent, the term “specimen” refers to items of human biological materials stored in research repositories. By contrast, the term “sample” refers to the portions of specimens that are provided to investigators for the conduct of specific studies. In addition, a distinction is drawn between the stored specimen and data that is associated with it or derived from analysis of it.

Informed consent documents for the collection of specimens for research repositories should include the following elements:

PAGE 1 OF THE CONSENT FORM:

- (a) Label “Repository Consent Form”
- (b) Full title of research study.
- (c) Principal Investigator: Name and Address
- (d) Co-investigators: Name (no addresses)

1. INTRODUCTION:

- a. Indicate that the subject is being given the opportunity to donate (whatever kind of specimens or samples) to a repository for research.
- b. Indicate the name of the repository (if applicable), its location, and the individuals and/or entity responsible for its operation.
- c. 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.

2. PROCEDURES TO BE FOLLOWED:

- a. Explain the procedures by which the specimens will be collected, including the types and amounts of specimens.
- b. 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.

- c. Explain who will have ownership of the specimens, data associated with it, data generated from analysis of it and immortalized cell lines developed from specimens.
 - d. 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.
 - e. 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.
 - f. Indicate whether or not some studies using samples from the repository might require re-contacting subjects for follow-up regarding their health status.
 - g. Indicate whether or not some studies using samples from the repository might involve concomitant review of the medical records of the subjects.
 - h. 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.
3. **BENEFITS ASSOCIATED WITH PARTICIPATION**
- a. Describe the benefits to the subject, if any, of participating in the repository. If there are no benefits to subjects, this should be stated.
 - b. Describe the general benefits accruing to society from the creation of the repository and the availability of materials in it for research purposes.
4. **RISKS ASSOCIATED WITH PARTICIPATION:**
- a. Describe any 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 risks, this should be stated.
 - b. 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.
 - c. 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.
5. **ALTERNATIVES TO PARTICIPATION:**
- a. Indicate that prospective subjects have the option of not contributing specimens to the repository.
 - b. For repositories associated with a main treatment study, explain whether subjects may participate in the main study without participating in the repository.

6. CONFIDENTIALITY:

Explain the provisions for maintaining the confidentiality of subjects who donate specimens. This explanation should include several components:

- a. One component is a description of whether specimens will be anonymized, assigned a code number with a separate key linking codes to personal identifiers, or will be stored with attached personal identifiers.
- b. Another component involves explaining who will have access to the information linking specimens to personal identifiers.
- c. A third component involves explaining whether samples provided to individual investigators may or may not include identifiers.
- d. A fourth component includes the HIPAA subject authorization language provided below. The language in this template should be precisely followed. The material in block form is the required authorization language. The *italicized* material in parenthesis provides directions for including material that may or may not be relevant for particular studies.

All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHI is health information that is, or has been, collected or maintained and can be linked back to you. Using or sharing (“disclosure”) such information must follow federal privacy guidelines. By signing the consent document for this study, you are giving permission (“authorization”) for the uses and disclosures of your personal health information. A decision to participate in this research means that you agree to let the research team use and share your PHI as described below.

As part of the study, Dr. [PI] and [HIS/HER] study team may share the results of your study and/or non-study related [*INCLUDE STUDY SPECIFIC INFORMATION: E.G. LABORATORY TESTS, X-RAYS, ETC.*], as well as portions of your medical record, with the groups named below:

- Representatives from the Federal Government Office for Human Research Protections
- the University of Tennessee Graduate School of Medicine Institutional Review Board
- [*Add others as appropriate, e.g., Food and Drug Administration, National Institutes of Health, representatives of {sponsor name}, CROs, insurance companies for billing purposes, etc.*].

Federal privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal health information private and confidential. [OPTIONAL: The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal health information, the sponsor, Dr. _____ and associated staff will keep your information in strict confidence, and shall comply with any and all applicable laws regarding the confidentiality of such information.]

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be *[INFORM PARTICIPANT WHAT WILL HAPPEN TO THE RECORD AT THAT TIME]*. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your PHI does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. [PI] in writing and let *[HIM/HER]* know that you are withdrawing your permission. *[HIS/HER]* mailing address is *[ADDRESS]*. At that time, we will stop further collection of any information about you. However, the health information collected prior to this withdrawal may continue to be used for the purposes of reporting and research quality.

[OPTIONAL: You have the right to see and copy your personal health information related to the research study for as long as the study doctor or research institution holds this information. However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.]

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to participate. You will receive a copy of this form after it is signed.

- e. Finally, it should be indicated that the identity of subjects will not be identified in any presentations or publications based on the results of the research study.

7. VOLUNTARY PARTICIPATION

- a. Indicate that subjects may choose not to participate in the repository without any loss of benefits to which they are otherwise entitled.
- b. 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.

8. QUESTIONS:

Indicate who to contact with questions regarding the nature of the research or the rights of research subjects.

9. COSTS OF PARTICIPATION:

Indicate whether there are any costs to persons of donating a specimen to the repository.

10. PAYMENT FOR PARTICIPATION:

Indicate whether subjects will be paid for donating a specimen to the repository.

11. COMPENSATION AND TREATMENT FOR INJURY:

Include the usual UT disclaimer regarding the availability of funds for compensation of injuries.

12. CONSENT OF SUBJECT:

Conclude the consent form with the following statements:

“I have read or have had read to me a description of the research repository as outlined above. The investigator collecting the specimen or his/her representative has explained the repository to me and has answered all the questions I have at this time. I knowingly and freely choose to contribute a specimen to the repository. I will be given a copy of the signed consent form for my records.”

Signature of Research Subject _____ Date _____

Signature of Person Obtaining Consent _____ Date _____

Signature of Principal Investigator _____ Date _____

ADDITIONAL FORMATTING INSTRUCTIONS

- a. Number pages 1 of 5; 2 of 5, etc.
- b. Insert “Research Subject’s Initials (and/or Legally Authorized Representative Initials, if applicable) _____” at the bottom of each page except the signature page.
- c. Include a brief title and principal investigator’s name at the top of all pages (except the title page).
- d. Add to either the top or bottom of each page of the consent form a “version date _____”. This date will change whenever a revision is made to the consent form.
- f. The consent form should be written in the 2nd persons (you), except for the section entitled “Compensation and Treatment for Injury: and “Consent of Subject” which should be written in the 1st person (I).
- g. If you are utilizing a Legally Authorized Representative, then the following two lines must be included with the signature lines above:
 - 1) Signature of Legally Authorized Representative _____ Date _____
 - 2) Relationship of Legally Authorized Representative _____

h. If the research study includes children who are between the ages of 8 – 17, then an assent signature line is required and should read:

1) Assent of Minor _____ Date _____