

Appendix 05

Use of Human Biological Materials in Research Studies Involving Genetic Analysis

Requirements for Informed Consent UTGSM Institutional Review Board

The following guidelines describe requirements for informed consent in research studies involving genetic analysis. Section A addresses informed consent in studies that are devoted exclusively to genetic analysis and involve the prospective collection of specimens. Section B considers informed consent in studies that include genetic analysis as only one component of the research and involves the prospective collection of specimens. Section C examines informed consent requirements and waivers for genetic research involving previously collected specimens.

A. Genetic Studies Involving Prospective Collection of Specimens

For studies which consist entirely in genetic research and for which specimens will be collected prospectively, informed consent is required.

The informed consent disclosure and form should include all of the following items below, presented in the following format:

PAGE 1 OF THE CONSENT FORM:

- (a) Label "Genetic 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) and to participate in a research study for genetic analysis.
- b. Describe the purpose of the research study in which the specimen will be used.

2. PROCEDURES TO BE FOLLOWED:

- a. Describe the procedures that will be performed in order to collect the specimen, as well as any other interventions involved in the study (e.g., use of questionnaires).
- b. Explain who will have ownership of the specimen, data associated with it, data derived from analysis of it, and immortalized cell lines developed from the specimen.
- c. Indicate whether any profit-making activities might result from research use of the specimen and whether subjects will share in any profits deriving from these activities.
- d. Indicate whether results of the study might be relevant to the health of the subjects and whether these results might be shared with them. If such circumstances are anticipated,

indicate that subjects will be asked whether or not they want to receive this information. Also, indicate what provisions will be made for counseling subjects about the meaning of the results for their health.

- e. If the study will involve re-contacting subjects for follow-up regarding their health status, then this should be indicated.
- f. If the study will involve concomitant review of the medical records of subjects, this should be indicated.
- g. Describe the length of time for which the specimens will be retained.

3. BENEFITS ASSOCIATED WITH PARTICIPATION:

Describe the general benefits accruing to society from the conduct of the study and any benefits accruing to subjects.

4. RISKS ASSOCIATED WITH PARTICIPATION:

Explain the following types of risks, as appropriate:

- a. Describe the risks involved in collecting the specimens which are not already associated with procedures being performed as part of the subject's treatment. 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 specimen or generated from analysis of it.
- c. Describe the possibility that, if results of the study 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 for the study.
- b. Indicate that if prospective subjects decline to participate in the study, it will not adversely affect their care in any manner.

6. CONFIDENTIALITY:

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

- a. One component is a description of whether the 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 involves explaining who will have access to the information linking specimens to personal identifiers.
- c. A third component involves explaining how access will be denied to other third parties.
- 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 APROPRIATE, E.G., FOOD AND DRUG ADMINISTRATION, NATIONAL INSTITUTES OF HEALTH, REPRESENTATIVES OF {SPONSOR NAME}, CROs, IBC, SRC, 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 published results of the study will not reveal the identity of subjects.

7. VOLUNTARY PARTICIPATION:

Indicate that subjects may discontinue their involvement by having their specimens and related data destroyed. 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 with questions regarding the rights of subjects.

9. COSTS FOR PARTICIPATION:

Indicate whether there are any costs to subjects of providing specimens for the study.

10. PAYMENT FOR PARTICIPATION:

Indicate whether subjects will be paid for participating in the study.

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 statement:

I have read or have had read to me a description of the research study as outlined above. The investigator or his/her representative has explained the study to me and has answered all the

questions I have at this time. I knowingly and freely choose to participate in the study. I will be given a copy of the consent form for my records.

Signature of Research Subject _____ Date _____

Signature of Witness _____ 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 “preparation date _____”. This date will change whenever a revision is made to the consent form.
- e. 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).
- f. 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 _____
- g. 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 _____

B. Studies Involving Genetic Analysis as One Component in Which Specimens Are Collected Prospectively

For studies in which genetic analysis comprises only one component of the investigation, the relevant items of consent information listed above should be incorporated into the consent form for the entire study. For example, under the description of study procedures, explain how the specimen will be collected for genetic analysis; or under the description of benefits, explain how the results of the genetic analysis will or will not benefit subjects.

In addition, some of the consent items listed above 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 above which are irrelevant may be deleted from the disclosure process and the consent form.

Finally, some of the items of information listed above must already be included in the consent disclosure for the overall study. For example, who to contact with questions about the rights of research subjects or the UT disclaimer regarding compensation for research injuries are otherwise necessary for consent to participation in the overall study. These items do not need to be repeated with respect to the portion of the overall study that involves genetic testing.

C. Genetic Studies Involving Previously Collected Specimens

Genetic studies involving previously collected specimens may be conducted without informed consent of subjects under three circumstances:

1. 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 in 45 CFR46.102f(2).
2. 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 45CFR46.101(b)(4).
3. The use of specimens does not satisfy the conditions in (1) or (2), but the study qualifies for waiver of informed consent under 45CFR46.116(d). According to this section, waiver of consent may be granted if (a) the research involves no more than minimal risk to subjects; (b) the waiver will not adversely affect the rights and welfare of subjects; (c) the research could not practicably be carried out without the waiver; and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Genetic studies involving the use of previously collected specimens that do not satisfy one of these three conditions require the informed consent of subjects.

Proposals to conduct genetic studies on previously collected specimens without informed consent should specify which of the three conditions described above is satisfied. Final determination that the study may be conducted without informed consent resides with UTGSM IRB.