

UMKC AHS IRB Guidance for writing a consent form for collection and storage of human biomaterials for genetic or future research

In writing your consent form, please refer to three documents.

1. Refer to the template for the general informed consent document, which will include the general requirements for all consent forms.
2. The template for re: human biomaterials further outlines requirements, tailored to consent to obtain human biomaterials for research, storage, or banking for future research.
3. This guidance.

Generally, when research involving human biomaterial is conducted in the context of a therapeutic or other research protocol, informed consent for the former should be obtained separately from consent for the clinical trial.

The consent template was designed to assist investigators in developing a consent document that contains all of the required elements of informed consent, including those critical to research with human biomaterials. Use the following guidance to tailor the consent template to your study. Statements in the template that are italicized are statements that need to be modified for your study (and may be omitted if not applicable to your study).

1. Header with UMKC AHS IRB #

You can complete the IRB number after it has been assigned. If the consent form has many revisions it is also necessary to put a version number in the header.

2. Template title

Nothing to add or change here.

3. STUDY TITLE

Insert your study title here.

4. Introduction

Use the template text and fill in your study location/site, investigator and co-investigator names, and study sponsor if applicable.

5. Background

Use this text to provide the overview of the planned genetic research. Fill in the blanks as applicable to your study. If your project absolutely will not involve genetic research, but other research on biomaterials instead, then provide a brief overview in language understandable at a 6th grade reading level.

6. Purpose of This Research Study

In as simple language as possible, state the purpose of the study. State how approximately how many subjects will be enrolled at your study site (and nationwide if it is a multicenter study).

7. Study Treatments and Procedures

Describe what will happen to the subject if they agree to participate in the study. Study events should be detailed and in chronological order.

If the specimen will be collected during a clinical procedure which is indicated for the clinical diagnosis or care of the patient, state this. However, limit this description to the additional procedures, beyond those of the indicated procedure, that will occur to collect the research specimen. Keep descriptions of clinical care separate from the details regarding the research specimen.

Include the italicized content as described in the template.

8. Possible Risks or Side Effects of Taking Part in this Study

Include the risks involved with the specimen collection. It is critical to evaluate all additional potential risks and accurately describe these to the subject. Risks to privacy and confidentiality are often the greatest risk in these studies. The investigator must also consider risks such as psychological or emotional burden, impact on family relationships, potential for discrimination in employment and insurability, and risks associated with false positive and false negative results.

9. Possible Benefits of Taking Part in this Study

Select the template text that is applicable to your study; more than one may apply.

10. Costs for Taking Part in this Study

Select the template text that is applicable to your study; more than one may apply

11. Payment for Taking Part in this Study

Detail financial compensation for participation. State whether subjects should expect to receive an IRS form 1099. Tell subjects when they will be paid, i.e., at the end of each visit, at the end of their study participation. State the type of payment, i.e., cash, gift certificate, merchandise, or check.

12. Alternatives to Study Participation

Usually for these studies, the alternative is to not participate.

13. Confidentiality and Access to your Records

Include the template text verbatim, with the exception of including only the agencies listed in the second sentence that are applicable to your study. For example if you do not have a sponsor, delete sponsor, or if you are not studying an experimental drug, do not include the FDA.

14. In Case of Injury

Include the text verbatim from the template, filling in blanks where appropriate.

If there is a study sponsor, insert the sponsor name and the sponsor's written policy regarding injury resulting from research.

If the investigator and/or subjects are affiliated with Truman Medical Center you are required to include the paragraph which describes the Truman Medical Center Injury policy; be sure to insert

the investigator name and correct contact number. If this paragraph is not applicable to your study you may omit it.

Include the required text which describes UMKC's policy regarding injury resulting from research, and be sure to include the investigator name and correct contact number.

15. Contacts for Questions about the Study

Do not edit, but use verbatim, filling in the investigator name and contact number.

16. Emergency Contact

A contact number must be provided. Using this number a research subject must be able to reach someone knowledgeable about the study, 24 hours a day 7 days a week. Acceptable means to accomplish this include having the investigator paged through hospital operator or having the specialty doctor on call paged. If you wish to provide your beeper number or home telephone number, you may, although this is not required. It is not acceptable to simply refer study subjects to the Emergency Department, unless the study is performed by an ED investigator, and all ED staff are sufficiently knowledgeable about the study.

17. Voluntary Participation:

Use the template text verbatim; except to fill in the study contact name and phone number for subjects' questions. Note the investigator and witness signatures are not required.

18. Date consent form written/revised

Insert the date the consent form was written or revised; this is important for record keeping.