

KUMC CONSENT FORM CHECKLIST

Consent Template #2 – Studies that do not involve FDA-Regulated products

INTRODUCTION

This section should include, as applicable:

- An invitation to the research study
- A general statement about the study topic or the condition being studied
- The name of the KUMC PI
- A statement identifying that the study will be conducted through KUMC.
- The number of subjects to be enrolled, both at KUMC and at other locations.
- Statements explaining that the main purpose of research is to create new knowledge rather than providing benefit to the individual participant

BACKGROUND

- Description of the topic or condition under study
- Discussion of what is already known and why researchers need to understand more

PURPOSE

- A succinct purpose statement, such as “By doing this study, we hope to learn _____.”

PROCEDURES

This section should include, as applicable:

- A general statement that study participation will last [*total time period*] and involve [*number of study visits, phone calls, follow-up, etc.*]
- A description of all study activities, when and where they will occur.
- If applicable, a description of any randomization strategy:
 - The number of groups and the randomization ratio.
 - How the group assignments will be made.
 - The double-blind or single-blind nature of the design.
- The time involved for each study visit.
- Identification of any procedures that are experimental.
- If the study involves multiple study visits with many study procedures, a lay-language table of study visits at the end of the consent form.
- When applicable, the total amount of blood drawn during the study:
 - If applicable, describe testing for communicable diseases. State that the results may be reported to health officials of the State of Kansas, as required by law.
 - If the study involves an optional genetic test, make reference to the

optional test and state that subjects who are interested in participating will sign a separate consent form.

- If the study involves the review of medical records, the nature of the information that will be collected from their records.

RISKS

- The general template paragraph stating that:
 - the study will have risks
 - study personnel will monitor safety throughout the trial
 - there may be risks that are not known at this time
- Risks for each intervention or study activity. Use a bulleted list format for better readability.
- When applicable, radiation risk language approved by the Radiation Safety Committee.
- Genetic risks, when the study involves DNA analysis where parentage, predisposition to disease or other sensitive information could become known.
- When the primary risk of the study is breach of confidentiality, discussion of this risk and the steps being taken to prevent a breach.
- If the study involves a blood draw, risks such as bruising, soreness, pain, and, rarely, infection, fainting or bleeding.
- If the study involves questionnaires or surveys about sensitive topics, the risk of being embarrassed by some of the questions and assurance to subjects that they are free to not answer questions that make them uncomfortable

NEW FINDINGS STATEMENT

- Template statement

BENEFITS

- Any potential benefits to the individual.
- A statement about societal benefits/benefits to future patients.

ALTERNATIVES

- List of other treatment options, as applicable. If there are none, state that participation is voluntary and subjects have the choice not to participate.

COSTS

- Any study-related costs that will be charged to the subject or the subject's insurance.
- Any costs that will be covered by the investigator or sponsor.

FINANCIAL DISCLOSURE

- If applicable, a general statement about payments from the sponsor to the institution
- If applicable, a disclosure of financial conflicts of interest, as approved by the KUMC Conflict of Interest Committee

PAYMENT TO SUBJECTS

- A statement that subjects will not be paid
---- OR ----

If payments will occur, include:

- The amount of payment, generally listed by visit
- The total amount being paid for subjects who complete the entire study.
- The type of payment (check, gift card, etc.)
- The timing of payments
- A statement that if subjects withdraw before the end of the study, they will be paid for the visits they have completed
- Template paragraph about IRS requirements

For studies involving retention of biologic specimens, include a statement about whether the study might involve the development of a commercial product.

IN THE EVENT OF INJURY

- The individual and phone number to contact in the event of an injury or problem with the study.
- *For studies that are greater than minimal risk:*
 - a statement about provision for treatment of research-related injuries and who will pay for the treatment.
 - a 24-hour contact for emergencies or after hours

INSTITUTIONAL DISCLAIMER STATEMENT

- Template statement

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

- General statement about confidentiality
- An assurance that any publication will not contain individual identifiers

IF THE STUDY INVOLVES PROTECTED HEALTH INFORMATION:

- Statement introducing the HIPAA law
- Statement that if subjects do not sign the consent/authorization, they cannot be in the study.
- Description of the information to be used or disclosed
- Persons or groups who the health information
- Persons or groups with whom the health information will be shared
- The purpose of disclosing the health information
- A disclaimer that some recipients of the health information may not be covered entities under HIPAA and there is the potential for re-disclosure.
- An expiration date or event for the authorization
- A statement, if applicable, about the subject's access to their research-related health information during the study.

If applicable, include information in this section about any of the following:

- State-mandated reporting requirements for positive HIV, hepatitis and tuberculosis
- Mandatory reporting of child abuse or neglect
- Protections offered by a Certificate of Confidentiality and the limits of those protections.

QUESTIONS

- Name and phone of the investigator, if subjects have questions, complaints, concerns or input
- Opportunity to contact someone who is not associated with the research for questions about subject rights (contact information for the HSC office)

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

- A statement that research is voluntary and that subjects can decline or withdraw early without penalty
- A statement that the subject's participation could be ended without their consent.

IF THE STUDY INVOLVES PROTECTED HEALTH INFORMATION:

- Subject's right to withdraw permission to revoke their HIPAA authorization and the mechanism for doing so
- Exceptions to the right to revoke

CONSENT

The “consent” section should be formatted so the text and the signatures are all on the same page. Include in this section:

- **Statements of consent**
- **Notation that subjects will receive a signed copy of the consent form.**
- **Signature lines for:**
 - **Name and signature of the subject**
 - **Name and signature of the person obtaining informed consent**
 - **Signature of the principal investigator is optional**
 - **For pediatric studies, name and signature of parent/guardian**
 - **For studies involving adults without decisional capacity, use a separate surrogate form that meets state of Kansas requirements.**

Optional aspects of the study should be presented after the consent section for the main study.