

KUMC CONSENT FORM CHECKLIST

for Consent Template #1 - FDA-Regulated Research

INTRODUCTION

This section should include, as applicable:

- An invitation to the research study
- A general statement about the condition or the study drug/device
- 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 the difference between research and standard care.

BACKGROUND

This section should include, as applicable:

- Description of the condition under study
- Description of typical problems or symptoms of the condition that are relevant to the study
- Current standard therapy
- Description of the test article or intervention under investigation.
- Discussion about how the proposed test article or intervention differs from other treatments
- Explanation on why researchers think the test article or intervention might be more effective than current treatments
- FDA status of the test article
 - If the product is FDA-regulated, include a statement about whether or not it has approval by the U.S. Food and Drug Administration for this condition. If not,
 - State that the use of the product does not have FDA approval and is considered investigational.
 - Explain that investigational products are still being studied to find out what a safe dose is, what the side effects are, and whether or not the product is effective in the disease or condition being studied.

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, days in the hospital, etc.*]
- A description of all study procedures, where and when they will occur

- Identification of any procedures that are experimental
- If there is standard care for the condition under study, an explanation of the difference between standard care and the study procedures.
- Discussion of commonly taken medications, herbs, etc. that are not allowed during the study.
- If applicable, a description of the 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.
- Dosages, device types for each group.
- Time involved for each study visit.
- 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, discussion of 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, a reference to the optional test and a statement that subjects who are interested in participating will sign a separate consent form.
- When appropriate, a description of what will happen to the subject when the study is over, such as opportunity to continue getting the drug in an open-label study, being transferred to standard medical care, etc.
- 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 drug, device or procedure. Use a bulleted list format for better readability.
- Risks of previous animal studies, only if very few human studies have been done and the results from the animal studies have direct implication for human participants.
- Risks categorized by their predicted frequency, using categories such as Common, Less Common, Rare but Serious. Add percentages of frequency, if this information is available.
- If subjects will be withdrawn from standard care, risk that the study

drug/device would not be as effective as standard care. Discuss the ramifications of this risk.

- When risks include changes in lab results, the ramifications of a particular risk, e.g., what it would mean to the subject if a particular lab value was elevated.
- Notation of any risks that are permanent, life-threatening or fatal
- If the study involves a placebo, the risks of being assigned to the placebo group (i.e., worsening of symptoms or disease progression). Discuss any rescue measures that would be used if the subject's condition worsens.
- If there is a washout period, the risks of stopping the current therapy.
- 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.

Pregnancy Related Risk:

- When applicable, statement about known teratogenicity; otherwise, a general statement that it is not known whether the test article will affect an unborn or nursing child.
- If applicable, a statement that male subjects should not father a child.
- The number of forms of birth control required.
- Examples of allowable birth control methods
- If applicable, information about how long after the study subjects must prevent pregnancy.
- A statement that there may be other pregnancy risks that are not yet known

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 correct, a statement the test article or intervention is FDA-approved or otherwise available outside the study. *This statement should be included even if the availability outside the study would be considered off-label.*

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 sponsor. Provide specific examples of these costs, such as the study drug/device, lab tests, hospitalizations, scans, etc.

FINANCIAL DISCLOSURE

- A general statement about payments from the sponsor to the institution
- When 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**
- **A statement that the FDA may inspect study records**
- **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**
- **Conditions under which the subject's participation could be ended without their consent. As applicable, discuss the arrangement for transition to other therapies**
- **Notification that subjects may not have access to the test article if the study is cancelled**

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.