Instruction Manual for the Consent Form for a Research Study

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General

How to Read the Instruction Manual and Prepare the Consent Form Template:

- Instructions are not italicized. *Language that should be modified and inserted into the consent template is italicized in this Instruction Manual.*
- Template of sample language that could be copied directly into the consent form is denoted in this Instruction Manual with the color brown.
- Sections where an option needs to be selected are highlighted in yellow.
- Instructions are ordered in parallel with the consent form template so that you can move through both documents simultaneously if you are working with both.
- For the consent form, modify the [bracketed, blue text] as appropriate for your study, or remove it if it is a note for you, the author. As you work, please remove all prompts to the author.
- Please use simple words and short sentences when adding study specific information to this consent form. See Appendix B for resources regarding lay language in consent forms.
- You are responsible for version control of consent documents. For auditing purposes, you should maintain in your files the consent documents with file version names/numbers for tracking of drafts and current versions.

Second Person Point of View

- The consent form should be written using the pronoun 'you' to address the reader
- If this form will be used only as a parental permission form, change all appropriate wording such as changing "you" and "your" to "your child" and "your child's".
- If this form will be used both for adults and for children and their parents or guardians, please include the following statement after the Bolded line on the first page and before the 'What Is the Key Information You Need to Know About This Study?' section
    - Please note: this form is being used both for adults and for children and their parents or guardians. If you are reading this form as a parent or guardian, please note that this form is about the child who may take part in this study.

Use Gender-Inclusive Language

- Consent language should not assume the reader's gender or imply there are only two genders. (Use they/them where applicable.)
- Regarding pregnancy, please use:
    - 'Participants able to become pregnant' instead of 'women'
    - 'Participants able to cause a pregnancy' instead of 'men'

Consent Form Templates

OHR-8F: Subject Recruitment Letter

OHR-8H: Verbal Consent with Optional Use of Disclosure of PHI

OHR-8K: Consent Form Template for NCI CIRB Studies Only

OHR-8S: Short Form Consent

HIPAA Authorization: Authorization to use and/or disclose PHI

Definition of Terms for Heading

Principal Investigator: at Jefferson

- The individual at Jefferson designated in this role

Lead Investigator: (if multi-site study)

- Overall lead investigator for a multi-site study, may be a Jefferson investigator
- Responsible for all sites of the study

Site Investigator: (if multi-site study)

- If Jefferson is the lead investigator, the site investigator is the non-Jefferson investigator overseeing the participating site
- If Jefferson is not the lead investigator, the site investigator will be the Jefferson-based PI

Thomas Jefferson University
Consent Form for a Research Study
[And HIPAA Authorization Form]
[Remove for studies not collecting personal health information]

What Is the Key Information You Need to Know About This Study?

- Include the italicized text at the top of this section on the consent template
- Complete the bullet points in the consent template as applicable
- Remove non-applicable statements

How Is This Study Different From Standard Medical Care?

- Briefly describe the main experimental aspects of this study including how the study differs from standard of care and any drugs/devices that are not yet approved or not approved for this particular indication.
- Consider including a table to differentiate study-specific verses standard of care activities, such as the table below. This information is also entered on the Master Application in Section 7.8.

Procedure	Study Specific	Standard of Care
EXAMPLE 1: CT Abdomen visits 1 and 6		X
EXAMPLE 2: CT Abdomen visit 8	X	
EXAMPLE 3: Pregnancy test each visit	X	

Will You Receive Payment for Participating in This Study?

- Describe the payment schedule and/or reimbursement OR include the statement provided in the template
- This section MUST be consistent with the budget and terms of any applicable study agreement.

What Happens if You Leave the Study Early?

- In addition to the statement at the top of this section on the consent template, please describe any other actions/procedures that will occur if the participant has to leave the study early.

What Happens if New Information Becomes Available?

- Include this section if the study is biomedical research
- If appropriate, include the following: Information arising from the study that may affect your health may be provided to you.
- Modify this as necessary and include under what conditions the participant would/would not be given the results. An example of this would be a separate condition that may be detected while doing the test for this study

What Can You Expect if You Decide to Take Part in This Study?

Include the statement at the beginning of this section in the consent template.

This section should provide a clear and detailed explanation of what the participant will agree to and/or be expected to do if they decide to take part in the study. The information included must reflect what is detailed in the protocol in lay language (see Appendix B for sources for glossaries of lay language terms) and must make clear what is study specific and what is part of standard medical care. The information can be formatted in any manner that makes it easy to understand. Define and explain all medical and scientific terms in ordinary language. Use headings, timelines, or visual aids that may be helpful in explaining procedures and schedule of events. Confirm permission with sponsors to include any visual aids or pictures.

Include all as applicable:

- *Name and describe the drug(s)/device(s) used in this study. Explain if any of the products are experimental or experimental in the way they are being used. Include information about dose, route, frequency, and device implantation/use.*

- *Describe all procedures, tests, and evaluations that will be done during this study. Include when, where, and how often they will be done. Identify if any procedures are experimental. Distinguish which procedures/tests are being performed as part of the study and which are being performed as part of standard medical care.*
- *Include length and duration of visits and procedures.*
- *Identify when and where the study will be done and with whom the participant will interact.*
- *Explain all hospitalizations, outpatient visits, and telephone calls or written follow-up required as part of the study.*
- *Consider including a schedule of events, flow chart, or other diagram to help explain the study timeline.*
- *Blood draw measurements should be provided in teaspoons/tablespoons, cups, etc. For reference, during blood donation, about 2 cups (450-500 mL) of blood are collected.*
    - ***Note to Author:*** *In general, the amount of blood drawn from healthy non-pregnant adults should not exceed 550 mL (about 2 ⅓ cups) in an 8-week period with collection occurring not more than twice a week. The amount drawn from other adults and children, considering age, weight, and health of subjects, should not exceed the lesser of 50 mL (slightly more than 3 tablespoons) or 3 mL/Kg and should not occur more than twice a week.*
    - ***Example language:*** *You will have about 270 mL (a little more than 1 cup) of blood drawn over the 5-week duration of the study. For comparison, about 500 mL is the amount taken when people donate blood. Your blood will be drawn approximately 6 times for laboratory safety testing, each time requiring about 10 to 15 mL of blood (about 1 tablespoon) and about 36 times for determination of drug levels (about 3 mL of blood or a little less than a teaspoon per sample) throughout the study.*
- *Specify the assignment to study groups. Describe the different groups a participant may be assigned to and the probability of assignment to each. Explain if the study is blinded.*
    - *If the study is double-blinded, include:* Neither you nor the study doctor will know which treatment you are getting.
    - *If the study is single-blinded include:* You will not be told which treatment you are getting, however, your study doctor will know.
- *For studies involving the use of placebo, clearly define the term placebo.*
- *Describe the information you will be collecting and using, where it will come from, and how it will be collected.*
- *Describe what information will be collected from the medical record, when and for how long, and how it will be used.*
- *If the study will collect information that may be sensitive or require additional protections (i.e. related to genetic testing, treatment for AIDS/HIV, psychiatric care/treatment, or treatment for drug and alcohol abuse) the extent of the information, use, and access must be detailed.*

- *If applicable, include the following IRB statement using IRB wording:* This study includes or might include whole genome or exome sequencing. This is like taking an inventory of your DNA, which contains your genetic information.
- *Identify if any parts of the study, such as certain tests or evaluations, are optional.*

What Are the Risks or Discomforts for the Study?

Include the statement at the beginning of this section in the consent template.

Describe the risks of all drugs, devices, procedures, tests, and evaluations that are required by the protocol. Even those that are standard of care must be included.

Include all as applicable:

- *Include relative probability of risks (e.g., "likely," "less likely" or "unlikely," and "rare but serious"). It is recommended to format risks as a bulleted list or table. Always include risk of death where this risk exists. As a guideline, "likely" can be viewed as occurring in greater than 20% of patients and "less likely" in less than or equal to 20% of patients. However, this categorization should be adapted to specific study agents. Whenever possible, use lay language to describe side effects (see Appendix B for sources for lay terminology).*
- *For clinical trials, the lists itemized in the consent should be consistent with the Expected Adverse Event Table from the Investigator Brochure.*
- *Include potential drug or food interactions and a list of contraindicated medications.*
- *In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information.*

Are There Risks Related to Pregnancy or Breastfeeding?

- Only include this section if applicable
- Please use gender-inclusive language:
  - 'Participants able to become pregnant' instead of 'women'
  - 'Participants able to cause a pregnancy' instead of 'men'

Only include the sections below that apply.

Option 1: For studies involving a treatment/intervention with known or unknown reproductive risks.

Include the language below if the study has known reproductive risks or if it is unknown whether such harm could occur: Taking part in this study may involve certain risks to a pregnant person, embryo, fetus, or nursing child. In addition to the risks described below, there may also be risks that are not known at this time.

Include any known reproductive risks including risks for any participant with reproductive potential, partner of a participant with reproductive potential, pregnant participant, embryo, fetus, and/or nursing child.

If applicable to protocol: If you are pregnant, plan to become pregnant, or are breastfeeding, you **cannot** be in this study.

If you are able to have children, you will be required to use birth control during the study and for *[timeframe]* after your last dose of the study drug *(OR modify according to the protocol).* Appropriate methods of birth control will be discussed with you. Describe any required contraceptive measures. Describe any required pregnancy testing and actions that may be taken if the participant or a participant's partner becomes pregnant according to the protocol.

If you or your partner become pregnant during the study or for *[timeframe]* following the study, you must tell the study personnel immediately. Include if applicable: We will ask to follow up with you for the outcome of the pregnancy.

Option 2: For studies involving minors.

What if Your Child Becomes Pregnant During This Study?

This section is only included WHEN APPLICABLE.

Include the language below if the study has known reproductive risks or if it is unknown whether such harm could occur: Taking part in this study may involve certain risks to a pregnant person, embryo, fetus, or nursing child. In addition to the risks described below, there may also be risks that are not known at this time.

Include any known reproductive risks including risks for any participant with reproductive potential, partner of a participant with reproductive potential, pregnant participant, embryo, fetus, and/or nursing child.

If applicable to the protocol: If your child is pregnant, plans to become pregnant, or is breastfeeding, they **cannot** be in this study.

Describe any required pregnancy testing and actions that may be taken if the participant or a participant's partner becomes pregnant according to the protocol.

Your child should not become pregnant while in this study. If sexually active, your child will be required to use birth control during the study and for *[timeframe]* after the last dose of the study drug *(OR modify according to the protocol).* Appropriate methods of birth control will be discussed with your child. By law in Pennsylvania, all minors age 12 or over (Note: For other

states, contact OHR) have a right to talk about birth control and pregnancy privately with their doctor.

Will There Be Any Costs to You for Taking Part in This Study?

This section is a required section of the consent document.

This section MUST be coordinated with JCRI Business Operations in order to be consistent with the budget and terms of any applicable study agreement. JCRI Business Operations Contact:

Jenny A. Campbell
Senior Associate Director, Business Operations
Jefferson Clinical Research Institute (JCRI)
Phone: 215-503-4282

In addition to the statements included in the consent template, please select the applicable option below.

Option 1: For studies with no billable activity, or where the sponsor pays for all study procedures.

There will be no study related procedures billed to you or your insurance company. If applicable: Some of the procedures and services performed in the study are part of the regular treatment for your condition. These would be performed even if you were not enrolled in the study. The costs for these procedures and services will be billed to your insurance.

OR

Option 2: For studies with billable activity and where the sponsor is not paying for all study procedures.

There may be items or services performed during your participation in this study that will be paid for by the sponsor. If applicable: The study drug(s)/device [identify drug or device] will be provided to you free of charge. Some of the procedures and services performed in the study are part of the regular treatment for your condition. These would be performed even if you were not enrolled in the study. The costs for these procedures and services will be billed to your insurance. Additional items may also be billed to your insurance while you are taking part in the study. These items may include administration of the study drug, as well as procedures and services to prevent, diagnose or treat potential complications arising from your participation in the study. You will be responsible for any costs your insurance does not cover. You will be responsible for insurance co-pays and deductibles. You should talk to your insurance carrier to find out what costs you will need to pay before taking part in this study.

If you are a Medicare beneficiary and have opted for a Medicare Advantage plan to manage your health care needs, your out-of-pocket expenses may increase while you are on this

study. Depending on your insurance carrier, some of the costs not covered by your insurance may be sizeable. You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should talk to the study team who will help you contact and discuss the study with your insurance company. If you do not have health insurance, you will have to pay all the costs for your medical care just as you would if you did not take part in this study.

For NCI Supported Trials. For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's website at https://www.cancer.gov and type "paying for clinical trials" into the website's search bar. Another way to get this information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What Happens if You Become Ill or Are Injured While Taking Part in This Study?

This additional information section is a required section of the consent document except for those minimal risk studies involving only surveys, focus groups, interviews, educational studies, or benign educational intervention. Please contact the OHR if you have questions about whether this applies.

This section MUST be coordinated with the JCRI Business Operations in order to be consistent with the terms of any applicable study agreement. See the previous section for the contact information for JCRI Business Operations.

Include the section below that applies.

Option 1: For all Commercially Sponsored Studies.

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study *[drug(s)/device]* or a study procedure. If you have a research-related injury, reasonable and necessary medical care will be available to you. The cost of care for the research-related injury will be paid by the sponsor of the study. If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, social security number, or Medicare ID.

OR

Option 2: For all Government, Philanthropic, or Jefferson Sponsored Studies.

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study *[drug(s)/device]* or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this study. Neither Jefferson nor the study will pay for costs associated with

treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan.

Is There Any Additional Financial Information You Should Know About This Study?

- Complete the statement in the template if applicable
- Add any other financial disclosures for Jefferson or the investigators/study personnel

What Happens to the Information Collected About You During the Study?

This additional information section is a required section of the consent document: Insert the section below in the Informed Consent that applies. Contact your contract specialist with any questions.

Option 1: Studies collecting or using personal health information

Information will be collected about you for this study. The information will be seen by the people involved with this study. Steps will be taken to protect your identity. However, we cannot promise complete confidentiality.

To do this study, we need to collect, use, and share your personal health information. We are committed to respecting your privacy and keeping your personal health information confidential. The federal law known as "HIPAA" (Health Insurance Portability and Accountability Act) that protects your personal health information requires us to get your permission to use the personal health information about you that we create, collect, or use as part of the study. This form will explain why your personal health information is being collected, what information will be collected, and who will have access to it. By signing this form, you are giving us permission to use your information including your personal health information as described in this form.

Your personal health information includes the information in your health care records and information that can identify you. For example, information in your health care record may include your name, address, phone number, and medical information. The personal health information that may be collected, used, and shared for this study includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research-related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- *List any additional information that will be collected that is not included above. Examples: demographics including race and ethnicity (required if the study is federally funded), labs,*

imaging results (e.g., x-rays), questionnaires, photos, video, audio and any other information/results collected for this study.

Your personal information will be used by and shared with the following:
Modify the list below as necessary.

- Study Personnel at Thomas Jefferson University and its affiliates for the purpose of this study
- Institutional Review Boards (ethics committees that review studies) including *[insert reviewing IRB(s)]*
- Health insurance providers
- *Insert Sponsor* (sponsor), which is providing money to the researcher to carry out this research
- Study monitors hired by the sponsor to oversee the study and review health care records to ensure study-related information is correct
- Government Agencies like the Food and Drug Administration (FDA)
- An organization such as a contract research organization (CRO) that has been hired to coordinate the study *[Specify if known]*
- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- *[Add other specific names as appropriate]*
- Others as required by law

When your personal health information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect your personal health information and biospecimens samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The results from this study may be published in scientific or academic journals or presented at scientific or academic meetings, but you will not be personally identified unless you give us your separate written permission.

[One of the following statements must be included if the study involves the collection of identifiable personal health information or identifiable biospecimens.]

Your personal health information and specimens, with the identifiers removed, could be used for future studies or distributed to other researchers for future studies without your additional permission.

OR

Your personal health information and specimens will not be used or distributed for future studies, even if the identifiers are removed.

OR

Option 2: studies not collecting personal health information.

This may include collecting potentially sensitive personal information from surveys, interviews with the participant, or other participant derived materials. (e.g. views on controversial topics, criminal behavior, or educational performance) If information is being collected from the participant's health record, Option 1 should be selected.

Information will be collected about you for this study. The information will be seen by the people involved with this study. Steps will be taken to protect your identity. However, we cannot promise complete confidentiality.

To conduct this study we may need to collect personal information. We are committed to respecting your privacy and keeping your personal information confidential.

The personal information that may be collected, used, and shared for this study includes:
Modify the list below as necessary.

- Demographic information including *[name, gender, birth date, ethnicity, etc.]*
- *List any additional information that will be collected that is not included above. This includes questionnaires, video, audio, etc.*

Your personal information will be used and shared by the following:
Modify the list below as necessary.

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this study
- Institutional Review Boards (ethics committees that review studies) including *insert reviewing IRB(s)*
- Sponsor
- *[Add other specific names as appropriate]*
- Others as required by law

The results from this study may be published in scientific or academic journals or presented at scientific or academic meetings, but you will not be personally identified unless you give us your separate permission.

Where Can You Find Additional Information About This Study?

- Additional guidance regarding when to include the following statement can be found on the clinicaltrials.gov website: https://www.clinicaltrials.gov/about-site/about-ctg
- Include the following statement only if applicable.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who Should You Contact About This Study?

- Add contact information/phone numbers as needed to the table in the template

Signatures

Make sure the finished signature page fits on one page.

Please be reminded that:

- The name of the participant needs to be included.
- The name of the person obtaining/assisting with consent must be included.
- The name of the investigator or qualified practitioner must be included as further described below.
- For clarity, the consent form must be signed by the person obtaining/assisting with consent and by the investigator or qualified practitioner. The person obtaining/assisting with consent may be the same as the investigator or qualified practitioner. As such, that person would be signing the consent form twice on the person obtaining/assisting with consent line and the investigator or qualified practitioner line.

MCARE requirements apply to specific medical procedures occurring in Jefferson studies regardless of location. If this study involves MCARE procedures (see list in OHR Policy IC 701), a physician investigator or “qualified practitioner” must review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant.

The other elements of consent may be provided by properly trained and qualified key personnel. For this purpose, the term "qualified practitioner" means a co-investigator or key personnel who is one of the following: Physician Assistant, Certified Registered Nurse Practitioner, Midwife, Certified Registered Nurse Anesthetist, another physician or a physician participating in a medical residency or fellowship training program who has knowledge of the patient's condition and the

procedure to be conducted on the patient and shall be acting under the supervision of, at the direction of, or in collaboration or cooperation with, the physician.

There is a signature line to be completed by an investigator. The person obtaining consent is certifying that the appropriate individual(s) reviewed the consent information with the study participant. Please choose the appropriate option below:

- Include for studies involving MCARE procedures. The other elements of consent may be provided by properly trained and qualified key personnel.

  By signing below, you the **physician investigator**, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant.

- Include for all other studies.

  By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

Copy of Consent offered to participant/parent/legally authorized representative (LAR)

If you will be consistently using a different method of documenting that the Participant/Parent/LAR was given a copy of the signed and dated consent form (e.g., progress note, EPIC), the checkbox may be deleted, but include the statement below:

Copy of the signed and dated consent form offered to the Participant/Parent/Legally Authorized Representative (LAR).

Surrogate Consent Form

- If the study does NOT involve surrogate consent, delete this entire form.
- Make sure the finished signature page fits on one page.
- See the Signatures section above to select the proper Investigator Statement.

Copy of Consent to Surrogate/Participant

If you will be consistently using a different method of documenting that the Surrogate/Participant was given a copy of the signed and dated consent form (e.g., progress note, EPIC), the above checkbox may be deleted, but include the statement below.

Copy of the Signed and Dated Consent Form Offered to the Surrogate/Participant.

Assent Section

- If the study does NOT involve assent, delete this entire section.
- This section should be used for studies that will involve assent (e.g., studies enrolling infants, minors and/or individuals with impaired decision-making capacity at Jefferson). A separate assent form (i.e., sponsor provided assent form) is also acceptable.

Additional Consent Documents Available on the OHR Website

Optional Teach-Back Questions Form – This form contains questions that may be asked to help ensure that the participant understands the study.

Subject Recruitment Letter – OHR-8F

Verbal Consent with Optional Use of Disclosure of PHI – OHR-8H

Consent Form Template for NCI CIRB Studies Only – OHR-8K

Short Form Consent – OHR-8S

Appendices

Appendix A: Explanations of Common Procedures and their Associated Risks
Appendix B: Glossary of Lay Terms for Use in Informed Consent Forms

Appendix A: Explanations of Common Procedures and their Associated Risks

Children's Hospital of Philadelphia Research Institute's Compendium: Explanations of Common Procedures and their Associated Risks: https://www.research.chop.edu/services/standard-language

Appendix B: Glossary of Lay Terms for Use in Informed Consent Forms

University of Florida IRB's Glossary of Lay Terms for Use in Informed Consent Forms: https://irb.ufl.edu/irb01/forms/glossary.html#B

National Comprehensive Cancer Network Oncology Research Program's Informed Consent Language Database: https://www.nccn.org/icl/default.aspx