**Human Review is Required**

This document represents a computational draft generated using artificial intelligence. It is provided as an initial draft and the contents require comprehensive human review, validation, and refinement by qualified research personnel.

All stakeholders are advised to conduct thorough verification of scientific accuracy, regulatory compliance, and institutional requirements before proceeding with formal Institutional Review Board (IRB) submission or other regulatory processes.

**PRINCIPAL INVESTIGATOR:** {{PI}}

**STUDY TITLE:** {{Title}}

**STUDY SITE:** NIH Clinical Center

Cohort: {{Cohort}}

Consent Version:

# WHO DO YOU CONTACT ABOUT THIS STUDY?

{{Contact\_Name}} by email at {{Contact\_Email}} or by phone at {{Contact\_Phone}}

# KEY INFORMATION ABOUT THIS RESEARCH

|  |
| --- |
| This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.  You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.  {{Why\_Asked}}  {{Study\_Purpose}} {{FDA\_Approval\_Status }}  {{Phase\_Trial}}  {{Time\_Commitment}}  {{Brief\_Happenings}}  {{Responsibilities}}  {{Brief\_Benefits }}  {{Abbreviated\_Risks}}  {{Brief\_Alternatives}}  {{Voluntariness}} |

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

{{Parent\_Permission}}

{{Impaired\_Adults}}

# IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

# WHY IS THIS STUDY BEING DONE?

This is a research study. {{Study\_Purpose}}

{{FDA\_Approval\_Status}}

# WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to:  
  
**Before you begin:**

{{FOR item IN Before\_You\_Begin}}

* {{$item}}

{{END-FOR item}}  
{{ Randomization\_Process}}

{{ Blinding\_Process}}

**During the study:**

{{FOR item IN During\_The\_Study}}

* {{$item}}

{{END-FOR item}}  
  
**After the study:**

{{FOR item IN Follow\_Up}}

* {{$item}}

{{END-FOR item}}

# HOW LONG WILL THE STUDY TAKE?

{{How\_Long}}

# HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

{{How\_Many}}

# WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

**{{Risks\_Study\_Drug\_Title}}**

{{Risks\_Study\_Drug\_General}}

{{FOR item IN Points\_Side\_Effects}}

* {{$item}}

{{END-FOR item}}

{{FOR item IN Risks\_Discomforts}}

* {{$item}}

{{END-FOR item}}

{{FOR item IN Privacy\_Confidentiality\_Risks}}

* {{$item}}

{{END-FOR item}}

**{{Risks\_Pregnancy\_Title}}**

{{Risks\_Pregnancy\_Rationale\_Women}}

{{Risks\_Pregnancy\_Rationale\_Men}}

*{{Pregnancy\_Women\_Title}}*

{{Pregnancy\_Testing\_Requirements}}

{{Pregnancy\_Testing\_Women\_Over\_Forty}}

{{FOR item IN Required\_Contraception\_Women}}

• {{$item}}

{{END-FOR item}}

{{Pregnancy\_Event\_Women}}

{{Fertility\_Risk\_Women}}

*{{Pregnancy\_Men\_Title}}*

{{FOR item IN Required\_Contraception\_Men}}

• {{$item}}

{{END-FOR item}}

{{Seminal\_Transmission\_Text}}

{{Pregnancy\_Event\_Men}}

{{Fertility\_Risk\_Men}}

**{{Risks\_Radiation\_Title}}**

{{Rad\_Risk\_LT3}}{{Rad\_Risk\_GE3\_LT5}}{{Rad\_Risk\_GT5}}{{RDRC\_Reviewed\_Rad}}

*{{Thera\_Rad\_Title}}*

{{Thera\_Rad}}

{{Overall\_Rad\_Risk}}

# WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

{{Potential\_Benefits\_You}}

## Are there any potential benefits to others that might result from the study?

{{Potential\_Benefits\_Others}}

# WHAT OTHER OPTIONS ARE THERE FOR YOU?

{{Other\_Options}}

# DISCUSSION OF FINDINGS

## New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

## Return of research results

{{Return\_Results}}

# EARLY WITHDRAWAL FROM THE STUDY

{{Early\_Withdrawal}}

# STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

## Will your specimens or data be saved by the study team for use in other studies?

As part of this study, we are obtaining specimens and data from you. We plan to store and use these specimens and data for studies other than the one described in this consent form that are going on right now, as well as studies that may be conducted in the future. The specimens and data will be kept in a way that we will still know that they came from you (i.e., they will be identifiable to us). If we use your identifiable specimens or data for future research, our study will be reviewed and approved by an Institutional Review Board who will make sure that we are protecting your confidentiality. These future studies might help us better understand {{ Disease\_Condition}} or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my identifiable specimens and data to be stored and used by the study team for future studies as described above.

\_\_\_\_\_ Yes \_\_\_\_\_ No

Initial Initial

## Will your specimens or data be shared with other researchers for use in other studies?

We may share your specimens and data with other researchers. The other researchers may be doing studies in similar areas to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or at commercial entities.

One way that we may share your data is by putting it into a large database called a repository, which is a way to make it widely available to the research community. If we do place your data in a repository, it will be labeled with a code, (not with your name or other information that could be used to easily identify you). Even though it will only be labeled with a code, some types of data, in particular data about your genes (called genetic or genomic data), can be used to figure out who you are, although this is difficult to do, and we think it is unlikely to happen.

{{Data\_Save\_Type}}

If we do share your specimens or data, we will know that the specimens and data came from you. However, the other researchers will not know that they came from you (i.e., they will be de-identified).

I give permission for my **de-identified** specimens and data to be shared with and used by other researchers for future studies.

\_\_\_\_\_ Yes \_\_\_\_\_ No

Initial Initial

In some cases, it may help other researchers to know that the specimens or data were collected from you (i.e., they will have your identifiers). If we share your identity with other researchers, their study will be reviewed and approved by an Institutional Review Board who will make sure that the study team is protecting your confidentiality.

I give permission for my **identifiable** specimens and data to be shared with and used by other researchers for future studies.

\_\_\_\_\_ Yes \_\_\_\_\_ No

Initial Initial

{{Genomic\_Sensitivity}}

{{Anonymized\_Specimen\_Sharing}}

## Risks of storage and sharing of specimens and data

When we store your specimens and data*,* we take precautions to protect your information from others who should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known, or that no one will gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

## Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your specimens and data for future studies, you should contact the study team. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data is already complete, the information from that research may still be used. Also, if the specimens and data have been shared already, it might not be possible to withdraw them.

## How long will your specimens and data be stored by the NIH?

{{Specimen\_Storage}}

# PAYMENT

## Will you receive any type of payment for taking part in this study?

# {{Payment\_Information}}

# REIMBURSEMENT

## Will you receive reimbursement or direct payment by NIH as part of your participation?

{{Reimbursement\_Information}}

# **COSTS**

## Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

{{Costs}}

# CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

{{Conflict\_Of\_Interest\_Information}}

{{Clinical\_Trial\_Agreement\_Information}}

# CLINICAL TRIAL REGISTRATION and RESULTS REPORTING

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

# CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

{{Confidentiality}}

## Will your medical information be kept private?

We do our best to keep your medical information private. However, we cannot promise this. Certain groups may look at and copy your medical records. This may be for research, quality and data review including:

* The NIH and other government groups. (For example, the Food and Drug Administration (FDA) to help keep research safe.)
* NIH Institutional Review Board
* {{Confidentiality\_Study\_Sponsor}}
* {{Confidentiality\_Manufacturer}} {{Confidentiality\_Drug\_Device}}

NIH and researchers doing this study follow special laws and policies to keep your information as private as possible. However, your identity and information about being in this study may accidentally be seen by others.

In most cases, NIH will not share any identifiable information about you unless you say it is okay in writing. More information about sharing your information is below.

Information gathered for this study is protected under a Certificate of Confidentiality and the Privacy Act.

## Certificate of Confidentiality

To help us protect your privacy, NIH has a Certificate of Confidentiality (Certificate). With this Certificate, researchers may not release or use information about you except in certain cases.

NIH researchers must not share information that may identify you in any legal proceedings, such as if a court requests it with a subpoena.

The Certificate does not protect your information when it:

1. is shared with people connected with the research. For example, information may be used for internal reviews by NIH; or
2. is required by law to be disclosed. For example, information may be shared with the FDA or with public health agencies.
3. is for other research if allowed by other regulations;
4. is shared with your consent.

Researchers may provide your information when you say it is okay. The Certificate does not keep you from sharing your own information.

The Certificate will not prevent telling authorities about harm to yourself or others. Examples are child abuse and neglect.

## Privacy Act

The Privacy Act helps keep your NIH medical information confidential.  In some cases, it is different from the Certificate.  Sometimes the Privacy Act allows sharing your information without your permission. An example is if Congress requests it.

Information may also be shared for some research. It can be given to some federal and state agencies. It can be used for HIV partner notification, or for infectious disease, abuse, or neglect reports. It may be shared with tumor registries, for quality and medical reviews. It may also be shared if NIH is involved in a lawsuit. However, NIH will only release medical record information if allowed by both the Certificate and the Privacy Act.

# RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

{{COVID\_PREP\_Act\_Language}}

# PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, {{Contact\_Name}}: By email at {{Contact\_Email}} or by phone at {{Contact\_Phone}}

{{Other\_Contact\_Name}} {{Other\_Contact\_Email}} {{ Other\_Contact\_Phone}}

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713 if you have a research-related complaint or concern.

# CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adult Research Participant:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study. | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Research Participant | | | | |  | Print Name of Research Participant | |  | | Date | |
|  | | | | | | | | | | | |
| **Legally Authorized Representative (LAR) for an Adult Unable to Consent:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study. | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of LAR | | | | |  | Print Name of LAR | |  | | Date | |
|  | | | | | | | | | | | |
| **Parent/Guardian of a Minor Participant:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study. | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Parent/Guardian | | | | |  | Print Name of Parent/Guardian | |  | | Date | |
|  | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Parent/Guardian | | | | |  | Print Name of Parent/Guardian | |  | | Date | |
|  | | | | | | | | | | | |
| **Assent:** I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study. | | | | | | | | | | | |
| **Assent of Minor:** | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Minor | | | | |  | Print Name of Minor | |  | | Date | |
| **Investigator:** | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Investigator | | | | |  | Print Name of Investigator | |  | | Date | |
| **Witness should sign below if either:**   1. **A short form consent process has been used to enroll a non-English speaking subject or** 2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject** | | | | | | | | | | | |
|  | | | | |  |  | |  | |  | |
| Signature of Witness | | | | |  | Print Name of Witness | |  | | Date | |
|  | |  | |  | | |  | |  | | |
|  | | | | | | | | | | | |
| **NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:** | | | | | | | | | | | |
|  | | | | | | | | | | | |
|  | An interpreter, or other individual, who speaks English and the participant’s preferred language facilitated | | | | | | | | | | |
| the administration of informed consent and served as a witness.The investigator obtaining consent may not also serve as the witness. | | | | | | | | | | | |
|  | |  | |  | | |  | |  | | |
|  | An interpreter, or other individual, who speaks English and the participant’s preferred language facilitated | | | | | | | | | | |
| the administration of informed consent but did not serve as a witness. The name or ID code of the person | | | | | | | | | | | |
| providing interpretive support is: | | |  | | | | | | | | . |
|  | |  | |  | | |  | |  | | |