

## Research Informed Consent Template

### Instructions

Guidance on what should be included is in red. **All red text should be removed** in the form submitted to the IRB for review.

You must use the black text exactly as written; you may not edit or change it.

- Font must be at least 12 point. If enrolling older adults, consider using larger print.
- Page numbers are required and must be on the bottom of the page.
- PI name and the version of the document (this can be a date or a number) must be on the first page and in the header of all following pages.
- If applicable, participant ID should be in the header.
- Bottom margin must be at least 1 inch.
- Use language that the average person is likely to understand.
  - Written no higher than sixth grade- reading level.
  - Define any technical terms and/or acronyms.
- Write using second person (i.e., participant addressed as “you” and investigators as “I/we”).

Do not include this page in your page numbers. **This page can be deleted.**

### Example First Page:

**Protocol Title:** Research on Research

**IRB Project Number:** 2000000-02

**Protocol Version:** 12/15/2024 or 02

**Principal Investigator Name:** Dr. Research

**Principal Investigator Department:** Research and Compliance

### Example Header:

PRINCIPAL INVESTIGATOR: Dr. Research  
VERSION: 02

Or

PRINCIPAL INVESTIGATOR: Dr. Research  
VERSION: 12/15/2024



## Research Informed Consent

Protocol Title:

IRB Project Number:

Consent Version:

**Sponsor:**

Principal Investigator's Name:

Principal Investigator's Department:

Principal Investigator's Telephone Number:

**Research Investigators' Names and Departments:**

**Research Coordinators' Names and Departments:**

***Only personnel listed above may be involved in the consent process.***

24-Hour Telephone Number:

***Must have a 24-hour number listed if the research has more than minimal risks.***

### Study Summary

**Provide a 1 to 2 sentence summary describing the study.**

Important things to know:

- Taking part in research is voluntary. You can choose not to be in this study or stop at any time.
- If you decide not to be in this study, your choice will not affect your (healthcare, any services you receive, or your relationship with the investigator of this study). There will be no penalty to you.
- [For potentially therapeutic trials, add: You don't have to be in this study to get care for your health condition.]

If you agree to participate in this study;

- (Approximate number of males/females) between the ages of (age range) will be involved in this study.
- Brief summary of all procedures.
- (X) number of visits are required (enter number of visits).
- You may be compensated between (X and X) for each completed visit for a total of (X) for your participation in the study.
- These visits will take (X) hours (amount of hours total).
- The potential benefits of participating in this study are (list no more than 3).
- The potential risks to be in this study are (list no more than 3 main risks). (**Note:** All research has some risk. If the risks are minimal, must state that there is no more risk expected than is encountered in everyday life.)

### Introduction

**Provide a brief introduction to the study and invite participants to participate in the study. Explain why they were selected for participation. Explain that you are available to answer any questions they may have about the project**

**Study Purpose and Procedures**

- State that the study involves research.
- Explain the purposes of the research.
- Describe the expected duration of the participant's participation.
- Describe the procedures to be followed and their purpose.
- Identify any experimental procedures, therapies, or treatments.
- Explain any procedures relating solely to research (e.g., randomization, placebo control, additional tests).

For drug and device studies, include the following information:

- Identify generic name(s), trade name(s), and manufacturer(s).
- Provide information on dosage and frequency of use.
- Provide information about the randomization schedule.
- When appropriate, provide information about use of placebo.
- Do not include statements that the drug or device is safe or that its safety has been established.
- In studies to evaluate the effectiveness of the drug or device, state that purpose, but do not make claims regarding effectiveness.
- State whether the drug or device has been approved by the FDA.

**Benefits of Participating in the Study**

- Describe any benefits to the participant, society, or both that can reasonably be expected from the research. The description of benefits to the participant should be clear and not overstated.
- If there are no benefits to the participant, state that no direct benefits to the participant can be expected.
- Do not include information about compensation for study participation in this section.

**Risks of Participating in the Study**

- If risks and/or discomforts are minimal, state that no more risk than is encountered in everyday life is expected.
- Describe any risks and/or discomforts to the participant that can reasonably be expected as a result of participating in this study. The explanation of risks should be reasonable and should not minimize reported adverse effects. The explanation of risks of drugs or devices should be based on information presented in documents such as the protocol and/or investigator's brochure, package labeling, and previous research study reports.
- If the study includes women of childbearing potential and there are risks specific to them, provide a statement indicating that the study doctor will discuss medically acceptable methods of birth control with the participant.
- A possible risk involved in this study is the potential social and psychological risks associated with accidental disclosure of confidential information from the

data collected throughout the study. Methods of storing and securing data are designed to minimize this risk.

### Disclosure of Appropriate Alternatives

- For studies that are giving class credit to participate, list the alternative option.
- Explain alternative procedures or courses of treatment if any might be advantageous to the participant.
- Appropriate alternative treatment(s).
- Another alternative would be to choose not to participate.

### Confidentiality

We will do everything we can to keep your records confidential. However, it cannot be guaranteed. We may need to report certain information to agencies as required by law. The records we collect identifying you as a participant will be maintained and stored (explain how you will do this).

Records that identify you and this consent form signed by you may be looked at by others. The list of people who may look at your research records are:

- The investigator and his or her research staff and students.
- Federal offices, such as the Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA), that protect research participants like you.
- The Creighton University Institutional Review Board (IRB) and other internal departments that provide support and oversight at Creighton University (add if research done at any of these facilities: Creighton University, CHI Health, or other as per your protocol).

We may present the research findings at professional meetings or publish the results of this research study in relevant journals. However, we will always keep your name and other identifying information private.

[Projects using Protected Health Information] We will also ask you to sign a separate form called the HIPAA Authorization, which will give you more specific information concerning the use of your health information.

If the study involves videos, pictures, or audio recording, explain what will happen to the recordings after the study is completed or if a participant withdraws before completion. Note where the recordings will be stored to ensure confidentiality of the data.

### Disclosure of Potential Future Use of Private Information

You must choose one of these statements if private information (name, dates, medical record numbers, etc.) is being collected. **If no private information is being collected, then you may delete this section.**

- This study will involve the collection of private information (name, dates, medical record numbers, etc.) that could be used and or distributed to another investigator for future research studies without an additional assent from your

child and parent permission from you. Identifiers (name, dates, medical record numbers, etc.) will be removed prior to being distributed.

or

- This study involves the collection of private information (name, dates, medical record numbers, etc.). Even if identifiers (name, dates, medical record numbers, etc.) are removed, information collected as part of research will not be used or distributed for future research studies.

### Biospecimen Research

You must choose one of these statements if biospecimens (tissue, blood, etc.) are being collected. **If no biospecimens are being collected, then you may delete this section.**

- This study will involve the collection of biospecimens (tissue, blood, etc.). Even if identifiers (name, dates, medical record numbers, etc.) are removed, the biospecimens could be used for commercial profit and or genome sequencing (genetic testing). As a participant you **(will or will not)** share in this commercial profit.

or

- This study will involve the collection of biospecimens (tissue, blood, etc.). Even if identifiers (name, dates, medical record numbers, etc.) are removed, the biospecimens collected for research will not be used for commercial profit or genetic sequencing (genetic testing).

### Compensation for Participation

- (If applicable) Describe the amount and nature of any compensation (e.g., money, gifts, class credit, or other) to the participant.
- (If applicable) Describe the compensation per encounter and give the total for completion of the study.
- (If applicable) Inform the participant that he/she will not be required to complete the entire study in order to receive compensation.
- If the participant will be paid more than \$600 in a calendar year, please add the following statement: Creighton University is required by law to report to the IRS payments greater than \$600 in a calendar year.
- If there is no compensation, state that there is none.

### Contact Information **Do not include IRB contact information in this paragraph.**

- Provide the name and telephone number of a specific office or person(s) to contact for answers to general questions concerning this research or in case of a research-related injury to the participant.

### ADDITIONAL ELEMENTS

Everything below this header until the signature page may be removed if it is not needed. **IF NOT APPLICABLE PLEASE REMOVE BLACK BOLD HEADINGS.**

**Research-Related Injury** (use if there are physical or psychological risks)

**Sponsor Statement** (include if applicable)

**Creighton Statement** (include this subhead only if there is also a sponsor statement)

[The following statement must be included unaltered (except for items in red) in all research in which the risks are judged to be more than minimal and in all investigational clinical studies.]

**What should you do if you are injured or have a medical problem during this research study?**

The investigator(s) will make every effort to prevent study-related injuries and illnesses. If you are injured while you are in the study and the injury is due to your participation in this study, you will receive necessary medical care at the usual charge. The costs of this care (that are not covered by the sponsor) will be charged to you or to your health insurer. Creighton University and CHI Health (if applicable) has no plans to repay you or compensate you for a study-related injury, or to provide you with payment for your lost wages or other losses.

By signing this consent form, you do not waive any legal rights to which you otherwise would be entitled.

**Unforeseeable Risks**

- State that the treatment(s) or procedure(s) may involve unforeseeable risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant).
- If relevant animal data are insufficient, the consent document should explain that studies of mutagenicity (the capability to induce genetic mutations) and teratogenicity (the capability to induce fetal malformations) have not yet been conducted or completed in animals.
- If relevant animal data are available, however, the significance of the data should be explained to potential participants.
- Monitoring for pregnancy and taking measures to prevent pregnancy during exposure to investigational agents is required; however, the FDA does not specify acceptable or unacceptable methods of birth control.
- All studies conducted under the jurisdiction of the Creighton IRB must include abstinence from intercourse as an acceptable method of birth control. Acceptable template language for birth control is:

**Pregnancy Prevention Language**

The effects of the (select as appropriate: drug(s)/procedure(s)) used in this study on a fetus or unborn child are unknown. If you (include if applicable: or your partner) are a pre-menopausal participant who is capable of becoming pregnant, you must agree to avoid pregnancy during your participation in this study (if applicable include: and for \_\_\_\_\_ months after the completion of this study). Your study doctor will talk with you about acceptable methods of preventing pregnancy and other safety concerns.

As a Catholic institution, Creighton University (if applicable include: and CHI Health), endorses abstinence as the preferred method of pregnancy prevention. (If a listing of

specific contraceptive methods is required by the sponsor, include:) However, in order to meet the requirements of the study sponsor we are required to provide the following information: (Insert acceptable methods only if required by sponsor). It should be noted that no method of preventing pregnancy besides abstinence provides 100% protection from becoming pregnant.

If a pregnancy occurs while you are in this study (if applicable include: or for \_\_\_\_\_ months after you complete this study), you should immediately notify your study doctor.

If you (if applicable include: or your partner) are already pregnant or planning to become pregnant, (if applicable include: or are breast feeding) you will not be able to participate in this study.

### **Sperm and Ova Retrieval Concerns**

Because the effects of the study drug on sperm or eggs are known to be harmful or are unknown, participants should talk to the study doctor about options for retrieving and banking eggs or sperm for future use. However, as a Catholic institution, Creighton University (if applicable include: and CHI Health), does not endorse certain methods of egg and sperm retrieval and certain methods of assisted conception that are not aligned with Catholic Church teaching.

### **Clinical Trial Registry Data Bank**

If this trial is supported or funded by a federal department or agency, it is mandatory to be posted on the [clinicaltrials.gov](http://www.clinicaltrials.gov) site and is recommended to be posted for all others. (This statement shall be added to the consent):

A description of this clinical trial 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.

### **Termination of Participant's Participation by Investigator**

- Explain anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.

### **Additional Costs to the Participant**

- Explain any additional expenses that participants (or their third-party payers) may incur from any source (including health care providers who are not researchers) as a result of participating in the study.
- When necessary, indicate that some care might not be covered by insurance.

### **Consequences of Participant's Decision to Withdraw**

- Explain the consequences of a participant's decision to withdraw from the research and procedures for termination of participation by the participant.
- When withdrawal from the study may have harmful effects on the participant's health or welfare, explain any withdrawal procedures that are necessary for the

participant's safety and specifically state why they are important to the participant's welfare.

**For Clinical Trials with FDA Oversight, When Participants Withdraw**

- Explain that if a participant withdraws from a study, the data collected on the participant to the point of withdrawal will remain a part of the study database and will not be removed.
- When necessary, give the participant who is withdrawing the option for continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. In this case, distinguish between study-related interventions and continued follow-up of associated clinical outcome information. The following language must be used in the original consent form if the sponsor/investigator believes follow-up is necessary. If it is not included in the original consent form, a separate consent form must be provided to and signed by the participant:

If you decide to withdraw from the study, you will be given three options: (if none of the below apply, please describe the participants options)

- First, you may withdraw and agree to provide continued follow-up and further data collection after your withdrawal from the study drug or device (if applicable).
- Second, you may withdraw and allow the investigator(s) to look at your medical records to check for any issues related to the study drug or device.
- Third, you may withdraw and request that the investigator(s) do not have access to your medical records. However, all data collected before you withdraw will be included in the study data and may not be removed.

**Significant New Findings**

- When it is anticipated that significant new findings are likely to develop during the research that would be pertinent to the participant's continued participation, describe how participants will be informed of such significant new findings.

**Research Results**

- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what circumstances.

**Disclosure Statement**

- The template language below is to be used only when an investigator has a financial relationship with sponsored projects. The language listed below is for the different types of potential conflicts.
- All projects in which any investigator has a potential financial conflict of interest must have an institutional management plan prior to final Institutional Review Board (IRB) approval.

*[For Stock Ownership]* **ONLY IF APPLICABLE**

The investigator, (insert name), owns stock in (insert name of sponsor). This ownership has been deemed a potential conflict of interest regarding the conduct of this clinical trial sponsored by (insert name of sponsor). Creighton University's Conflict of Interest Review Committee (CIRC) and Institutional Review Board (IRB) have reviewed (insert name)'s stock ownership and the possible financial benefit to (insert name) resulting from the clinical trial. The CIRC and the IRB believe that (insert name)'s stock ownership is not likely to affect your safety and/or the scientific quality of this clinical trial. Additional information is available upon request from the investigator.

*[For Speaker Fees]* **ONLY IF APPLICABLE**

The investigator, (insert name), associated with this research has received speaker fees of greater than \$5,000 from (insert name of sponsor). These fees have been deemed a potential conflict of interest in regard to the conduct of this clinical trial sponsored by (insert name of company). Creighton University's Conflict of Interest Review Committee (CIRC) and Institutional Review Board (IRB) have reviewed (insert name)'s payment relationship with (insert name of company). The CIRC and the IRB believe that (insert name)'s payment relationship with (insert name of sponsor) is not likely to affect your safety and/or the scientific quality of this clinical trial. Additional information is available upon request from the investigator.

*[For Advisory Board]* **ONLY IF APPLICABLE**

The investigator, (insert name), associated with this research is paid fees by (name of company) to serve on the advisory board for (name of company). These fees have been deemed a potential conflict of interest regarding the conduct of this clinical trial sponsored by (insert name of sponsor). Creighton University's Conflict of Interest Review Committee (CIRC) and Institutional Review Board (IRB) have reviewed (insert name)'s payment relationship with (insert name of company). The CIRC and the IRB believe that (insert name)'s payment relationship with (insert name of company) is not likely to affect your safety and/or the scientific quality of this clinical trial. Additional information is available upon request from the investigator.

*[For Institutional Conflict of Interest]* **ONLY IF APPLICABLE**

Creighton University has a licensing agreement with the company sponsoring this study. This means the Creighton University may make money if the study shows the (insert medicine/device/vaccine) works well. This may be a potential conflict of interest. Creighton University's Conflict of Interest Review Committee (CIRC) and Institutional Review Board (IRB) have reviewed the possible financial benefit to Creighton University resulting from the clinical trial. The CIRC and the IRB believe that the possible financial benefit to Creighton University is not likely to affect your safety and/or the scientific quality of this clinical trial. Creighton University employs the investigators of this study; however, none of the investigators have a financial relationship with the company sponsoring this study. Additional information is available upon request from the investigator.

**Participant Signature**

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled, **or any effect on your medical care.**

*My signature below indicates that all my questions have been answered. I will be given a copy of this informed consent document to keep for my records. I agree to participate in the project as described above.*

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Printed Name

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Signature

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Date Signed**Witness *Delete if not applicable.***

Most studies initiated by a Creighton University faculty, staff, or student do not require a witness. A witness is defined as an adult person not associated with the study, or a family member. If the investigator wishes to have a witness and retains this option, all consents used in the study must have a witness.

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Signature of Witness

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Date Signed**Legally Authorized Representative *Delete if not applicable.***

If your project will require legally authorized representative (LAR) to consent for a participant not able to consent for himself/herself, this must be approved on a study-by-study basis and will require review at a convened meeting.

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Name of Participant

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Printed Name of LAR

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Signature of LAR

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Date Signed

If you are signing this Consent on behalf of someone else, all references to “you” or “your” mean the Study Participant named above.

**Investigator Signature**

I have discussed with this participant (and, if required, the participant's LAR) the procedure(s) described above, and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

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Printed Name of Responsible Investigator

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Signature of Responsible Investigator

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Date Signed

The Creighton University Institutional Review Board (IRB) offers you an opportunity (anonymously if you so choose) to discuss problems, concerns, and questions; obtain information; or offer input about this project with an IRB administrator who is not associated with this particular research project. You may call or write to the Institutional Review Board at (402) 280-2126; address the letter to the Institutional Review Board, Creighton University, 2500 California Plaza, Omaha, NE 68178 or by email at [irb@creighton.edu](mailto:irb@creighton.edu).

***Bill of Rights for Research Participants***

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.
3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
4. To be told about the reasonably foreseeable risks of being in the study.
5. To be told about the possible benefits of being in the study.
6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
7. To be told who will have access to information collected about you and how your confidentiality will be protected.
8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research participant.
9. If the study involves treatment or therapy:
  - a. To be told about the other non-research treatment choices you have.
  - b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.