**Introduction**

**This template should be used for research projects involving children aged 13-18. A separate assent document is required for children aged 7-12.**

For more information on the requirements for assent, see the [Creighton University Human Research Protection Program Policy Manual](https://my.creighton.edu/researchservices/rcocommittees/irb/policiesandprocedures/), Section 4.4, “Research Involving Children.”

**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’s Name: Dr. Research

Principal Investigator’s Department: Research and Compliance

Example Header:

PRINCIPAL INVESTIGATOR: Dr. Research
VERSION: 02

Or

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

Protocol Title:

IRB Project Number:

Assent 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 Invitation**

We would like you to join in a research study. You can ask a question at any time and you can say no anytime you want to. We will talk to your parents or legal guardian first. We will ask your parents or legal guardian if it is OK for you to be in this study.

**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

**What is this study about?**

* 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 or not the drug or device has been approved by the FDA.

**What are the possible benefits to me or others?**

* 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.

**What are the risks and discomforts you could have?**

* 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 drug or device study includes women of childbearing potential, provide a statement indicating that the study doctor will discuss medically acceptable methods of birth control with the Participant.

**What if I decide not to participate?**

* Explain alternative procedures or courses of treatment, if any might be advantageous to the Participant.
* Include important benefits and risks of the alternative treatment(s).
* Another alternative would be to choose not to participate.

**Will anyone know I am in the study?**

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 you 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, Missouri Valley Cancer Consortium, or 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, address, or 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 video 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.

**Will I be paid?**

* (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.

**Who can I talk to about the study? Do not include IRB contact information in this paragraph.**

* Provide the name and telephone number of a specific office or person 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**.

**What happens if I get hurt? (Use if there are physical risks)**

* Explain the participant’s parents/legal guardians have been given information on what to do if the participant is injured during the 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.
* By signing this consent form, you do not waive any legal rights to which you otherwise would be entitled.

**Unforeseeable Risks**

* State that the particular treatment(s) or procedure(s) may involve currently 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 contraception.
* All studies conducted under the jurisdiction of the Creighton IRB must include abstinence from intercourse as an acceptable method of contraception. Acceptable template language for birth control is:

“The effects of *[study drug]* on an unborn child are not known. We also do not know whether taking *[study drug]* now can have effects on unborn children in the future. If you are a female and you are pregnant or breast-feeding a baby, you cannot participate in this study.

If you are a female of childbearing potential, you may participate if you are not pregnant and not breast-feeding at the time of entry into the study, and you must agree to avoid pregnancy during the study.

If you are female, you must use a medically acceptable method of birth control during the whole duration of study participation.”

* Similar language can be used if the risk potential extends to a male. Please note that the protocol (or a written verification from the sponsor) must list abstinence as a medically acceptable method of birth control
* The sponsor may require specific contraceptive language (e.g., use of oral contraceptives, condom, spermicide, etc.) as per protocol. This language may be included but must be prefaced with the following statement:

Creighton University, a Catholic University, does not endorse the birth control information listed below. However, in order to maintain compliance with the study sponsor, as well as the National Institutes of Health, we are required to provide this information to participants, as a matter of public safety. Remember, however, that no method of birth control besides abstinence provides 100% protection from pregnancy.

**Participant Signature**

You do not have to be in this study. You can stop being in the study at any time and no one will be mad at you. If you decide not to be in this study, there won’t be any penalty to you, and you won’t lose any benefits that you would otherwise be entitled to. You will also continue to receive necessary medical treatment from your doctors who are taking care of you.

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

Printed Name Date of Birth

Signature Date

Name(s) of Parent(s)/Legal Guardian(s) (Print) Relationship to Child

**Investigator Signature**

I have discussed with this participant and the participant’s parent(s)/guardian(s) the procedure(s) described above, and the risks involved; I believe he/she understands the contents of the assent document and is competent to give legally effective assent.

Printed Name of Responsible Investigator

Signature of Responsible Investigator 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.

## 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:
	1. To be told about the other non-research treatment choices you have.
	2. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.