Consent and Authorization Document

***THIS FORM TO BE USED FOR RESEARCH THAT INVOLVES HIPAA-PROTECTED INFORMATION.***

***Note to the Investigator:*** *Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.*

***DIRECTIONS FOR USE OF THIS TEMPLATE:***

* ***Do not adjust the header or footer size.***
* *Replace bracketed items in the header, such as “[Title of Study]” with the requested information.*
* *Read guidelines for each section, complete as applicable for your project and then delete the template guidelines. Example text may be used if needed but should not be italicized. Instructions in red font should be replaced or deleted.*
* *Phrases such as “I understand…” or “You understand…” are not appropriate and should not be included in the document.*
* *If your study will use deception and/or incomplete disclosure as research techniques, you should include language explaining that the information being provided in the initial consent is incomplete – see the Supplemental Consent Language Document for suggested wording.* *Please review the Research Guidance Document: Deception and Debriefing.*
* ***NOTE:*** *If your study is determined by the IRB to be more than minimal risk, there are additional elements of informed consent which will be required.*
* If your study is a clinical trial, you must include information about registration and reporting of trial results on the ClinicalTrials.gov website – see the Supplemental Consent Language Document for the necessary wording.

**Principal Investigator Name and Title:**

**Department and Institution:**

**Contact Information:**

**Sponsor (if applicable):**

**CONCISE SUMMARY/KEY INFORMATION**

In general, the beginning of an informed consent would include a concise explanation of the following:

1. The fact that consent is being sought for research, and participation is voluntary.
2. Purpose of the research, expected duration, and procedures.
3. Reasonably foreseeable risks.
4. Benefits that may be reasonably expected.
5. Appropriate alternative procedures or courses of treatment, if any.

The above five points constitute the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research. There may be additional information that should be provided in the concise summary depending on the nature of the specific research study.

Typically, studies with no more than minimal risk have a short consent process and a short consent document. For studies with limited risks or benefits, the entire informed consent may be relatively brief. Presenting the key information as described above at the beginning of the document will meet the concise summary requirement.

**If the BACKGROUND, STUDY PROCEDURE, RISKS, and BENEFITS section are fully described in less than the first page of the consent document, it is possible you do not need a separate “CONCISE SUMMARY/KEY INFORMATION” section because you are already able to provide that information to meet the concise summary requirement.**

**BACKGROUND**

State that the study involves research and explain the purpose of the research. Briefly tell the participant why this research is being done and how this study will address the problem. Please explain who is conducting the study.

*Example: You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.*

*Example: The purpose of the study is <<explain purpose of the research>>.*

**STUDY PROCEDURE**

This section should inform the participant about what they will have to do and what they will experience in the study. If any, specify which study procedures are experimental (i.e. untested or non-standard procedures) for this research. Include the length of time that the participants will be involved. Describe all procedures/interventions in lay language. Use simple terms and short sentences. When applicable, describe if audio or video recording or photography will take place as research activities. Explain whether audio-recording/video-recording/photography are required for participation or if those procedures are optional.

*Example: It will take you approximately 2 hours to complete this study. As part of this study you will be asked to take part in a focus group. Questions will be asked about <<insert topic>>.*

*Example: The following procedures are considered experimental <<list experimental, untested or non-standard procedures>>.*

[Include the following if participants are randomized to comparison groups:] Example: The group of study participants you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have an [equal/one in three/etc.] chance of being assigned to any given group.

**RISKS**

Describe any reasonably foreseeable risks or discomforts such as emotional distress/discomfort, psychological trauma from remembering past experiences, invasion of privacy, embarrassment, loss of social status, potential adverse economic or employment consequences, etc.

*Example: The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to <<insert topic>>. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and he/she will tell you about resources available to help.*

**BENEFITS**

Describe any benefits to the participant or to others that may reasonably be expected from the research. DO NOT include any compensation to be offered to participants in this section. The description of benefits to the participant should be clear and not overstated to avoid coercion. If no direct benefit is anticipated, it should be stated.

*Example: We cannot promise any direct benefit for taking part in this study. However, possible benefits include <<list benefits>>.*

*Example: There are no direct benefits for taking part in this study. However, we hope the information we get from this study may help develop a greater understanding of <<insert topic>> in the future.*

**ALTERNATIVE PROCEDURES**

List appropriate alternative procedures/interventions, if any, which might be advantageous to the participant. **This section may be omitted if there are no alternative procedures or interventions.**

*Example: If you do not want to be in the study, you may earn research participation credit by <<list alternatives>>.*

## HOW WILL THE RESEARCHERS PROTECT MY INFORMATION?

Describe procedures that will be used to keep participant information secure and confidential. For example, use of encryption, storing identifiable information separately from the rest of the research data, keeping only de-identified transcripts of interviews/focus groups, etc.

If your study has **NIH funding or plans to apply for a Certificate of Confidentiality**, you must include language about the protections and limitations of the Certificate of Confidentiality here – see the Supplemental Consent Language Document for appropriate consent language and the OPRS website for more information about Certificates of Confidentiality.

If your study will use focus groups for data collection, see additional language in the Supplemental Consent Language Document to be added here about limitations on participant privacy/data confidentiality in the focus group setting.

## WHO WILL HAVE ACCESS TO THE INFORMATION COLLECTED DURING THIS RESEARCH STUDY?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons. [include this bullet point ONLY if applicable to your study]

[Include one of the following statements in studies in which researchers are probing for or likely to elicit information about child abuse or neglect. All University of Illinois employees (including faculty, staff, and student employees) are required by Illinois law and by UIUC policy to report suspected cases of child abuse and/or neglect.]

If we learn about current or ongoing child abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

OR

We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

If your study may lead to the disclosure of information covered by Federal laws relating to **sexual harassment and sexual violence**, include language in the consent regarding Title IX reporting responsibilities – see the Supplemental Consent Language Document for appropriate consent language regarding Title IX reporting responsibilities.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]

**HOW MIGHT THE INFORMATION COLLECTED IN THIS STUDY BE SHARED IN THE FUTURE?**

We will keep the information we collect about you during this research study for study recordkeeping [and for potential use in future research projects]. If the study data contain information that directly identifies participants: Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

For longitudinal research studies, include: The researchers [plan to/may] contact you again as part of this research study.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. [If you will collect participant identifiers, include this sentence:] We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee the anonymity of your personal data.

If you plan to maintain or share identifiable data for unspecified future research, a separate IRB application should be submitted with a protocol, consent and supporting documents (e.g., research registry). If the Principal Investigator (PI) of this study would like to provide an option for a participant to be contacted for a future study conducted by this PI, this option can be provided at the end, and you should include this paragraph: The PI would like to retain your contact information to contact you for future research participation. This information will not be shared with other researchers but will only be retained for potential interest in research with this PI. We will ask for your consent to do so at the end of this form. You can be in this current research study without agreeing to future research use of your identifiable information.

[Delete if there are no plans to share identifiable data] The results of this study could be shared in articles and presentations but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

**Person to Contact**

Please include contact information for answers to any questions, complaints or concerns the participant or legal representative may have about the research or related matters. Include the name of the Principal Investigator with a telephone number where a message can be left. Co-investigator contact information may be included. Include specific information as to whom the participant should contact in case of a research-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted. If you believe that there is no chance for a research related injury, you may provide contact information in the event the participant feels they have been harmed by the research (see example).

*Example: If you have questions, complaints or concerns about this study, you can contact <<insert name>> at <<insert phone number>>. If you feel you have been harmed as a result of participation, please call <<insert name>> at <<insert phone number>> who may be reached during <<specify hours or state it is a number available 24-hours a day>>.*

Include the following statement verbatim: **Institutional Review Board:** If you have any questions about your rights as a research subject, including concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670 or e-mail OPRS at irb@illinois.edu. If you would like to complete a brief survey to provide OPRS feedback about your experiences as a research participant, please follow the link [here](https://redcap.healthinstitute.illinois.edu/surveys/?s=47X9T4NE4X) or through a link on the OPRS website: <https://oprs.research.illinois.edu/>. You will have the option to provide feedback or concerns anonymously or you may provide your name and contact information for follow-up purposes.

**VOLUNTARY PARTICIPATION**

State that participation is voluntary. Indicate that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. Also indicate that the participant may discontinue participation at any time without any penalty or loss to benefits.

*Example: Research studies include only people who choose to take part.  You can tell us that you don’t want to be in this study.  You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator.*

**COSTS AND COMPENSATION TO PARTICIPANTS**

Costs related to research procedures should be separated and explained from other regular costs participants might incur. Any additional costs to the participant that may result from the research should also be clearly indicated. If there are no costs and/or compensation, please state that.

Explain whether participants will be compensated for participation. Specify the overall amount, schedule of payment(s) and any plan for prorating payments if participant does not complete the study.

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Include the Authorization and Confidentiality information as outlined:

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records: Modify the following list as appropriate – delete or add items as necessary.

* Demographic and identifying information like *<<name, address telephone number, and email address>>*
* *<<Social Security Number – Tell participants whether they can withhold their social security number and still participate>>*
* Related medical information about you like *<<family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results>>*
* All tests and procedures that will be done in the study

**How we will protect and share your information:**

* We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
* If applicable, please provide a description of the Certificate of Confidentiality and any voluntary disclosure plans by the Investigator(s). For more information regarding Certificates of Confidentiality, please refer to the OPRS website.
* If this research represents a clinical trial that must be registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), you must include the following statement verbatim: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.
* In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
	+ Members of the research team and *<< insert appropriate institution(s) e.g. University of Illinois Urbana-Champaign, Carle Health, etc. >>*;
	+ The University of Illinois Urbana-Champaign Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;

	Modify the list below as appropriate - delete or add items as necessary. The examples below are suggestions and may be used as applicable.
	+ OOOther local hospital(s) that we are working with: *<<list any local hospitals where information could be shared>>*
	+ Other academic research centers we are working with: *<<list all other academic centers, and explain their roles in project>>*
	+ The study sponsor: *<<Name of sponsor>>*
	+ A research coordinating office: *<<Name of group or company>>*
	+ *<<Name of federal oversight agencies, i.e. the Food and Drug Administration, Centers for Disease Control, etc.>>*
	+ *<<Name any other groups that will receive data>>*
* Include this statement if you **will share PHI outside** of the University of Illinois Urbana-Champaign If we share your identifying information with groups outside of *<< University of Illinois Urbana-Champaign>>*, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
* Include this statement if you **will not share PHI outside** of the University of Illinois Urbana-Champaign: If we share your information with groups outside of *<< insert appropriate institution(s) e.g.* University of Illinois Urbana-Champaign *>>*, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.
* If testing is performed as a result of study participation for any communicable or infectious diseases reportable by Utah State law, the following must be addressed in this section (refer to <https://dph.illinois.gov/topics-services/diseases-and-conditions/infectious-diseases/infectious-disease-reporting.html> for a current list of Illinois’ reportable diseases):
	+ Tell the participant about the state reporting.
	+ Describe how results will be given to the participant to comply with state reporting requirements.
	+ Describe the methods or opportunities participants will be given for appropriate counseling and medical care.
* If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at *<< insert appropriate institution(s) e.g. Carle Health, University of Illinois Chicago, etc.>>*.

**What if I decide to Not Participate after I sign the Consent and Authorization Form?**

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

**Include the following paragraph if participants will not have access to their information during the study:**

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

**CONSENT**

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

**I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

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Printed Name of Participant

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Signature of Participant Date

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Printed Name of Person Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date