# INDIANA UNIVERSITY INFORMED CONSENT STATEMENT [AND AUTHORIZATION] FOR RESEARCH

**[Insert Protocol Title]**

**[Insert Sponsor Name and Sponsor Protocol Number]**

## ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent [and Authorization] form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

## WHY IS THIS STUDY BEING DONE?

[Insert explanation for why the research is being done. Use language understandable to the subject (i.e., eighth grade level).]

We are asking you if you want to be in this study because [Insert explanation regarding how and/or why the subject was identified]*.*

The study is being conducted by [Insert investigator(s) name(s) and University/Departmental affiliation]. It is funded by [Insert Sponsor name or funding agency name, if any].

## HOW MANY PEOPLE WILL TAKE PART?

[**This section is only required for greater than minimal risk research. Otherwise, this section can be deleted.]**

You will be one of [Insert number] participants taking part in this study. [For multi-center studies, include both the local and multi-site number of subjects.]

## WHAT WILL HAPPEN DURING THE STUDY?

This study involves collection of information about you. [Insert explanation of all procedures that are included in the study using language understandable to the subject (i.e., eighth grade level). For example, completing surveys and questionnaires, audio or video recordings, collection of information from your medical record, etc.

For each procedure, explain:

* Where the procedures are performed and how frequently they are performed
* The expected amount of time each procedure and/or visit will last

Include the total duration of subject participation, e.g., You will be in this study for about two years.]

## WHAT ARE THE RISKS OF TAKING PART AND HOW WILL MY INFORMATION BE PROTECTED?

Since this study only includes collection of information about you, the only risk to you is a possible loss of confidentiality. Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. [If audio or video recordings will be made, insert an explanation regarding who will have access to the recordings, if the recordings will be used for other non-research purposes (such as educational), and when the recordings will be destroyed.] Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies [if study is subject to HIPAA and this document will serve as the consent and Authorization, insert:] and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

[If the study is subject to HIPAA and this document will serve as the consent and Authorization, include the following. In general, this language should not be edited.] The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include [insert description of the purpose of each use or disclosure of identifiable health information (e.g., making sure you meet the criteria to be in this study, gathering information about your medical history to include in the research data, reviewing results of your medical tests for safety purposes, checking on your health in the future to help answer our research question, etc.], or to inspect and/or copy your research records for quality assurance and data analysis.

[If the study is subject to HIPAA and this document will serve as the consent and Authorization, include one of the following options. In general, this language should not be edited.]

The information released and used for this research will include all of your medical records. Those records may contain information related to mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

**OR**

The information released and used for this research will include: [insert description or bulleted list of record that will be accessed or used]

[If the study is subject to HIPAA and this document will serve as the consent and Authorization, include the following. In general, this language should not be edited.] If you agree to participate, you authorize the following to disclose your medical record information:

* [list of entities from whom medical records will be obtained]

[Include the following language for **all** studies, even those not subject to HIPAA.]

The following individuals and organizations may receive or use your identifiable [health] information:

* The researchers and research staff conducting the study
* The Institutional Review Boards (IRB) or its designees that review this study
* Indiana University
	+ [If the study will be conducted at the ICRC:] The Indiana Clinical Research Center (ICRC)
* US or foreign governments or agencies as required by law

[Include the following as applicable. Delete all lines that do not apply.]

* Research teams at other institutions or research site(s): [list]
* Data safety monitoring boards and others authorized to monitor the conduct of the study
* The following research sponsors: [list]
* Contract research organization(s): [list]
* State or Federal agencies with research oversight responsibilities, including but not limited to:
	+ [For federally-funded research:] Office for Human Research Protections (OHRP)
	+ [For NIH sponsored research:] National Institutes of Health (NIH)
	+ [For research funded or supported by NCI:] National Cancer Institute (NCI)
	+ [For FDA regulated research and research involving positron-emission scanning:] The United States Food and Drug Administration (FDA)

[If the study is an FDA-regulated or NIH-funded clinical trial, insert the following:] A description of this clinical trial will be available on [ClinicalTrials.gov](http://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.

[If the study is NIH funded, you automatically receive a Certificate of Confidentiality, and must include this section. If the study is not NIH funded, but the study has obtained or intends to obtain a Certificate, insert the following, as appropriate:] This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations. [If FDA-regulated, insert:] The Certificate also does not stop sharing of information required by the Food and Drug Administration (FDA).

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

## WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

[If the research involves the collection of identifiable private information, insert the following:] Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

## WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

We don’t think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

## WILL I BE PAID FOR PARTICIPATION?

[Insert one of the following:]

You will not be paid for participating in this study.

**OR**

[Insert a description of the details and any conditions of payment, including if partial payment is applicable.]

[For research involving payment of more than $600 in one calendar year, insert the following:] If you receive $600 or more in one calendar year from Indiana University, you will need to complete a form giving us your Social Security number (SSN) or tax identification number (TIN). You will receive a 1099 tax form the following January from Indiana University and will need to report this payment as income on your federal and state tax returns. You are responsible for paying any local, state, or federal taxes. If you have questions about how this impacts your tax return, please contact a tax professional. If you do not have an SSN or TIN, the Internal Revenue Service (IRS) requires Indiana University to deduct 30% from your research payment to pay required taxes on your behalf.

## WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

## WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

**[Required only when an investigator has a financial interest deemed related to the research by the Conflict of Interest or IRB office. Otherwise, this section should be deleted.]**

[Insert description of individual and nature of interest, e.g., Dr. XXX provides consulting services for the sponsor of this study.] The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit due to this relationship. The Board determined that the possible financial benefit to the [study doctor or other appropriate description] is not likely to affect your safety or rights as a research participant. If you would like more information, please ask the researchers or study staff.

## WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study [or a research-related injury], contact the researcher, [Insert name of investigator], at [Insert telephone number]. After business hours, please call [Insert alternate number and person/title the subject should request].

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

## WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your [usual care/treatment/relationship] with [Insert appropriate entity (e.g., hospital, university)].

If you change your mind and want to stop participating in the study in the future, [explain the procedure for withdraw from the study].

[If the study is subject to HIPAA and this document will serve as the consent and Authorization, include the following. In general, this language should not be edited.] If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying [name and mailing address]. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed [OR insert date or description of a specific event or circumstance].

[If appropriate, insert the following:] The researchers may stop your participation in the study even if you do not want to stop if [Insert a description of when and why study participation may be terminated and how orderly termination will occur]. [If appropriate:] Also, this study could be stopped by [Insert Sponsor/investigator, as appropriate] if [Insert a reason for possible premature termination of the entire study].

[If appropriate, insert the following:] You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

## PARTICIPANT’S CONSENT [AND AUTHORIZATION]

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

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

**Participant’s Printed Name Date**

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

**Participant’s Signature**

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

**Participant’s Address [required only when document is being used as HIPAA Authorization]**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Person Obtaining Consent Date**

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

**Signature of Person Obtaining Consent**

**[For research involving CHILDREN, use the following signature blocks, as applicable]**

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

**Printed Name of Parent Date**

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

**Signature of Parent**

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

**Research Participant’s Address [required only when document is being used as HIPAA Authorization]**

**[If a 2nd parent signature is NOT required, REMOVE the 2nd parent signature block below]**

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

**Printed Name of 2nd Parent Date**

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

**Signature of 2nd Parent**

**[If the child participant will NOT sign this document, REMOVE the signature block below]**

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

**Printed Name of Child Date**

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

**Signature of Child**

[**For research involving INDIVIDUALS LACKING CONSENT CAPACITY, use the following signature block**]

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

**Research Participant’s Printed Name**

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

**Research Participant’s Address [required only when document is being used as HIPAA Authorization]**

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

**Printed Name of Legally Authorized
Representative (LAR) Date**

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

**Signature of LAR**