# Indiana University Informed Consent Statement for Research

**[Insert Protocol Title]**

**[Insert IRB Protocol Number]**

**[Insert Sponsor Name and Sponsor Protocol Number, if applicable]**

**Note regarding use of template: This template has been customized to include only the sections most commonly required for minimal risk social behavioral research. If your research involves any of the following factors, additional language may be needed:**

* **greater than minimal risk,**
* **will generate clinically relevant research results,**
* **has subject payment of $600 or more in a calendar year,**
* **collects biospecimens,**
* **has a research-related financial conflict of interest,**
* **is NIH-funded or an NIH-funded clinical trial, or**
* **is subject to HIPAA.**

**The Biomedical Informed Consent template posted on the** [**HRPP website**](https://research.iu.edu/forms/human-subjects-irb.html) **includes language that can be used in these situations.**

**You are being asked to participate in a research study.** This consent form will give you information about the 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 the study.

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

[For research involving deception or incomplete disclosure, insert the following (or similar), as appropriate:]We are not able to provide you with the full purpose of the study at this time, but willprovide additional information after you finish your study participation.

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 or funding agency name, if any].

**If you agree to be in the study, you will do the following things.** [Insert explanation of all activities/tests that are included in the study (e.g., assignment to study groups, study visits, surveys and questionnaires, focus groups, audio or video recordings, etc.) using language understandable to the subject (i.e., eighth grade level). Include the following:

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

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

**Before agreeing to participate, please consider the risks and potential benefits of taking part in this study.** [Insert explanation of the risks and/or discomforts of each of the activities listed above using language understandable to the subject (i.e., eighth grade level). Include an explanation of measures that will be employed to minimize the risks. **It is never appropriate to state that there are no risks.**

Examples of risk statements with protection procedures:

You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.

There is a risk someone outside the study team could get access to your research information from this 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. [If the study may directly benefit participants, an explanation of the benefit may be substituted.]

**You [will/will not] be paid for participating in this study.** [If there is payment, insert a description of the details and any conditions of payment, including if partial payment is applicable].

**We will protect your information** and make every effort to keep your personal information private, but we cannot promise complete 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 and when the recordings will be destroyed. If audio or video recordings may be shared during publication or for educational purposes, this must be explained, as this data is considered identifiable.]

Your personal information may be shared outside the research study if required by law. We also may need to share your research records with other groups for quality assurance or data analysis. These groups include the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law). [Add any other organizations that may receive or review identifiable research records. For example: Additionally, your research information may be shared with our collaborators on this research study at [institution name(s)], [sponsor name], etc.]

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

**If you have questions about the study or encounter a problem with the research**, contact the researcher, [Insert name of investigator], at [Insert telephone number]. [You may also include an email address.]

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.

**If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future.** If you decide to withdraw, [explain the procedure for withdraw from the study. You should not require subjects to withdraw in writing]. [If withdrawal from the study prior to completion could pose risk to the subject, insert a description of what those risks might be and how orderly termination will occur.]

[Optional section: remove if you do not want to use text or email communications] **We would like to communicate with you about this study by text message and/or email.** We might use text or email to [insert brief description of purposes: for example, send you reminders about upcoming study visits, check on how you are doing, or tell you about the progress of the research.]

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

\_\_\_\_\_\_ I authorize the researchers to send me emails related to this research study

Email address for this communication: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_ I authorize the researchers to send me text messages related to this research study

Phone number for this communication: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

You can still participate in this study even if you do not want us to contact you by text or email.

**[This section is only required for research documenting informed consent with a signature of the participant. Otherwise, this section should be deleted.]**

## Participant’s Consent

I agree to participate in this research study.

**Participant’s Printed Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant’s Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**: \_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Person Obtaining Consent:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_

[If the study involves children whose parents will provide consent for their child’s participation, include the following:]

**Printed Name of Parent:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Parent**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_\_\_\_

[If the study involves children who will be providing their assent on this consent document rather than on an assent document, include the following:]

**Printed Name of Child Participant:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Child Participant**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_\_\_