### CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

**YALE UNIVERSITY**

*If necessary, add the name of the school or institution engaged in research.*

**Study Title:** *[Insert the title of the study.]*

**Principal Investigator (the person who is responsible for this research):** *[Insert name and mailing address.]*

*The ‘Research Study Summary’ is required for all non-exempt research studies approved after January 21, 2019 unless they are FDA or DOJ regulated and non-federally funded. It should include ‘a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension’.*

**Research Study Summary:**

* We are asking you to join a research study.
* The purpose of this research study is to *[Insert the purpose of the study.]*
* Study activities will include: *[Insert brief summary of study activities.]*
* Your involvement will require *[Insert number of hours or minutes]*  minutes/hours.
* There may be some risks from participating in this study. *[Insert summary of the study risks.]*
* The study may have no benefits to you.*[Describe benefits of the study to others. If there are expected benefits to subjects, revise the sentence and describe the benefits.]*
* There are other choices available to you outside of this research.*[For clinical trials, describe alternative procedures or treatments outside of the study. If none, you can delete the entire bullet point.]*
* Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with *[Insert NGO, University, community leaders, hospital, etc., as applicable]*
* If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

**Why is this study being offered to me?**

We are asking you to take part in a research study because *Explain briefly why the prospective subject is eligible to participate.]*. We are looking for*If appropriate, state the approximate number of participants and/or research sites involved in the study.]* of participants to be part of this research study.

**Who is paying for the study?**

*[If applicable, list all organizations/entities providing monetary support for the study, regardless of whether funds are received directly or through another organization (such as a foundation.)*

**What is the study about?**

The purpose of this study is to *[Insert the purpose of the study.]*

*Explain the purpose and goals of the research in one or two sentences.*

**What are you asking me to do and how long will it take?**

If you agree to take part, your participation in this study will involve *[describe the study procedures clearly, in roughly chronological order.]*. We think that the study will take *[Insert number of hours or minutes]*  of your time.

* *Describe the procedures using simple, lay language, short sentences and short paragraphs. The use of subheadings may help to organize this section and improve readability.*
* *For research involving interviews, surveys, questionnaires, etc., clearly describe the purpose and content of the instruments. It may also be helpful to provide examples of the types of questions subjects will be asked.*

**Are there any risks from participating in this research?**

If you decide to take part in this study, you may experience *[describe the risks such as distress over the nature of the questions, informational risks, a possible risk of loss of confidentiality, if applicable.]*

There is the possible risk of loss of confidentiality.

*[If there are no physical risks, include the following. Otherwise delete the next paragraph.]*

We do not expect any risks from taking part in this study.

* *Identify all reasonably foreseeable risks, discomforts, or inconveniences (can be psychological, social, legal, or financial risks that might result from participating in the research) associated with the study and describe how they will be managed.*
* *If the study collects anonymous data, where no code or identifiers are being recorded by the investigator, do NOT include language about the risk of confidentiality.*

**How can the study possibly benefit me or others?**

You *[Choose one: may or may not]* benefit from taking part in this study.

We hope that our results will add to the knowledge about*[describe public good]*.

* *Describe any benefits that can be reasonably expected to result from the research directly to the participant (e.g., improved health outcomes).*
* *Financial rewards for participating in research are not considered benefits and should not be included in this section.*

**Are there any costs to participation?**

You will not have to pay for taking part in this study. The only costs may include transportation and your time coming to the study visits.

**Will I be paid for participation?**

You *[Choose one: will or will not]* be paid for taking part in this study. *[Describe form of payments and the amounts, and any reimbursements.]*

* *Describe any compensation that will be made to participants (including direct monetary payment, payment in the form of a gift, or reimbursement for costs such as travel, parking, childcare, etc.), and the conditions for receiving this compensation. If using Bank of America card, use the language from the* ***Consent Glossary*** *document.*
* *If subjects are paid, add a statement ‘According to the rules of the Internal Revenue Service (IRS), payments for taking part in a study may be considered taxable income’.*
* *If participants are prisoners who will be paid, use the language from the* ***Consent Glossary*** *document.*
* *Explain if payment will be prorated for participants who do not complete the study.*
* *Explain if payment is conditional on completing the study.*

**How will you keep my data safe and private?**

All of your responses will be held *[Choose one: in confidence or anonymous]* . Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

* *Describe the methods used to safeguard the confidentiality of subjects’ data (e.g., coding data or samples with numbers, storing research materials in locked cabinets, password-protecting data stored on a computer, etc.*
* *If using* ***Amazon’s MTurk****, add MTurk language from the* ***Consent Glossary****.*
* *If using* ***focus groups****, add Focus Groups language from the* ***Consent Glossary****.*

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

**What if I want to refuse or end participation before the study is over?**

One of the following statements must be included:

(1) That identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (2) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

If you do not plan on sharing information for future research revise the last statement starting with ‘We will also share…’.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with *[Insert NGO, University, community leaders, hospital, etc., if applicable...]*

* + - * *For studies including prisoners, include* ***Prisoners as Study Participants*** *language from the* ***Consent Glossary.***
* *For studies including* ***Psychology Subject Pool****, include the Psychology Subject pool language from the* ***Consent Glossary.***

**Who should I contact if I have questions?**

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at *Insert the PI’s phone number.*

If you have questions about your rights as a research participant, or you would like to speak with someone other than the Principal Investigator or study team to discuss problems, concerns, or questions, or to obtain information or offer suggestions, you can call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

If you have questions about the Psychology Subject Pool, you may contact the coordinator at (203) 432-4518, or psychsubject.pool@yale.edu

*Include the paragraph about Psychology Subject Pool, only if you are using the pool. Otherwise, remove it.*

A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

*Remove the paragraph about Clinical Trials if the study does not meet the definition of a clinical trial and is not registered.*

**Documentation of Informed Consent**

Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will give you a copy of this consent form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant Printed Name |  | Participant Signature |  | Date |
| Person Obtaining Consent Printed Name |  | Person Obtaining Consent Signature |  | Date |