### COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION

### IN A RESEARCH STUDY

**YALE UNIVERSITY**

*Template Dated 7/24/2023, Social, Behavioral Research*

*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.

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…’.

***NOTE:*** *The next 4 sections starting with ‘What Information Will You Collect About Me in this Study?’ through ‘What if I change my mind?’ refer to HIPAA Authorization.* ***Do not remove any of the sections and only tailor the suggested areas for the study.***

**What Information Will You Collect About Me in this Study?**

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

*Describe in detail the information to be used and where it comes from, e.g., your entire medical record from YNHH, information from your record including how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth, etc. Examples are provided below.* ***Delete and add as needed.***

* Research study records
* Medical and laboratory records of only those services provided in connection with this Study.
* The entire research record and any medical records held by[the name of institution or hospital created from: [start date] to: [end date] \_\_\_\_\_\_\_\_
* Records about phone calls made as part of this research
* Records about your study visits
* Information obtained during this research regarding
	+ - HIV / AIDS test results
		- Hepatitis infection
		- Sexually transmitted diseases
		- Other reportable infectious diseases
		- Physical exams
		- Laboratory, x-ray, and other test results
		- Diaries and questionnaires
		- The diagnosis and treatment of a mental health condition
		- Use of illegal drugs or the study of illegal behavior
		- Records about any study drug you received
		- Records about the study device

In next section, ‘*How will you use and share my information?’,* you must include the entries for **DHHS, Yale HRPP, PI, co-investigators and research staff**. Other examples are provided below. **Delete and add as needed.**

**How will you use and share my information?**

We will use your information to conduct the study described in this consent form.

We may share your information with:

* The U.S. Department of Health and Human Services (DHHS) agencies
* Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
* Governmental agencies to whom certain diseases (reportable diseases) must be reported
* Health care providers who provide services to you in connection with this study.
* Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
* Principal Investigator of the study
* Co-Investigators and other investigators
* Study Coordinator and Members of the Research Team
* Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

**Why must I sign this document?**

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

**What if I change my mind?**

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to [Name and the address of the PI:] at the Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

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

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, 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.*

**Authorization and Documentation of 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 form.

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