**INSTRUCTIONS:**  To use this template, complete all required sections (substituting appropriate language for any italicized **red** text) and any applicable optional sections (marked in highlighted **red** ***italicized*** brackets), then **delete all instruction boxes, italicized instructions, brackets and omitted optional sections prior to submitting this form**.

|  |
| --- |
| Study Title:  |
| Researcher:  |
| Faculty Advisor: ***[if applicable]*** |
| Version Date:  ***[delete this row if version date is in footer]*** |

## Key Information

## [The “Key Information” section is intended to provide subjects with a quick snapshot of what their participation will entail. Only very brief descriptions should be included in this section.]

## The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research.]

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. Your participation is completely voluntary.
4. You can choose not to take part.
5. You can agree to take part and later change your mind.
6. Your decision will not be held against you.
7. You can ask all the questions you want before you decide.

## Why is this research being done?

[Briefly tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

## How long will the research last and what will I need to do?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

You will be asked to \_\_\_\_\_\_\_\_\_ [include a high level summary of the procedures that will be done.]

## Is there any way being in this study could be bad for me?

[This beginning section of the consent form should briefly identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project but with a particular emphasis on how those risks are changed by participating in the study]

***[OR]*** We don’t believe there are any risks from participating in this research.

More detailed information about the study procedures can be found under ***“What can I expect if I take part in this research” [Remove this statement if there are no anticipated risks associated with this study.]***

## Will being in this study help me in any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]

## ***[Include for research involving prisoners. Otherwise delete.]*** Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## Detailed Information

## The following is more detailed information about this study in addition to the information listed above.

## What is the purpose of this research?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others. This section should provide more detail than the Purpose found in the Key Information section]

How long will I take part in this research?

Include the length and duration of visits and procedures

What can I expect if I take part in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* How often procedures will be performed
* Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen
* When applicable indicate that the subject will be contacted for future research.

## What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

***[When applicable, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]***

## Is there any way being in this study could be bad for me? (Detailed Risks)

There are some risks you might experience from being in this study. They are *[*Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks]

***[OR]*** We don’t believe there are any risks from participating in this research. ***[If there are no anticipated risks and this was stated in the “Key Information Section”, delete this section, including the header.]***

***[For greater than minimal risk studies, include an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.]***

***If I take part in this research, how will my privacy be protected? What happens to the information you collect?***

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

***[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 data or specimens will be retained.]***

***[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements. Otherwise Delete.]***

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

**OR**

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

***[If a Certificate of Confidentiality has or will be obtained for this study, please include the following language. Otherwise delete.]***

***Certificate of Confidentiality***

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[***Use the following language as applicable***] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [*THE AGENCY*] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[***Language such as the following should be included if researcher intends to disclose  information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*.**] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [***List what will be reported, such as child abuse and neglect, or harm to self or others***].

[***Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants*.**] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [***Restate what will be disclosed, such as including research data in the medical record***].

***[If your study will involve genetic research, please include the following language. Otherwise delete.]***

***Genetic Research***

[Please see <https://www.genome.gov/27559024/informed-consent-special-considerations-for-genome-research/> for appropriate language to use in such studies and insert in this section. If submitting data from this study to a federal repository (dbGaP, GEO, etc.) **the consent should also include an explanation about whether participants’ individual-level data will be shared through unrestricted- or controlled-access repositories.**]

***[If your study will involve HIPAA covered data, please include the following language. Otherwise delete.]***

HIPAA-Covered Data

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

[Include if this study will be posted on ClinicalTrials.gov. Otherwise delete.]

ClinicalTrials.gov

 A description of this research study 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.

[Include this section if removal from the research without the subject’s “OK” is a possibility. Otherwise delete.]

## Can I be removed from the research without my OK?

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

[Include if subjects will be paid. Otherwise delete.] ***Compensation -*** If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.] If you are military personnel - Military personnel should check with their supervisor before accepting payment for participation in this research.

 [Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] ***If you are a prisoner -*** If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

***[Include if there is a potential for Commercial Profit. Otherwise Delete] Commercial Profit -*** Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples]*** to tell you, or to pay you, or to give any compensation to you or your family.

***[***Include for research that ***may result in additional costs to the subjects. Otherwise delete.]*** ***Potential Costs to You -*** Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

***[Include if clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. Otherwise Delete] Clinically-Relevant Results -*** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will/will not*** contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

***[Include this section if there is an identified Conflict of Interest to disclose the nature of any financial or proprietary interests. Otherwise Delete.]***

***Researcher Financial Interests in this Study***

This section should identify the researchers or research staff by name and study role.

***[Example of language to indicate the interest in an entity or the product:]*** ***[Name of person with COI]*** a researcher on the study team, has a financial interest in [name of company], ***[the company paying for this study; the company that will manufacture the study drug; the company that will sell the drug, and/or the company conducting part of this study]***.

***[Example of language if the interest is other than a financial interest in an entity, e.g., in the product being tested:]*** ***[Name of person with COI]*** a researcher on the study team, has a financial interest in the ***[product, drug, device, name of company]*** being studied.

***[Example of language to describe the interest:]***

* + ***[Name of company and relevance of company to study, e.g., sponsor]*** is paying ***[Name]*** ***[describe payment, e.g., consulting fee, salary]***.
	+ ***[Name]*** is being paid to be a scientific advisor to ***[name of company and relevance of company to study]***.
	+ ***[Name]*** is an unpaid member of the Scientific Advisory Board of ***[name of company and relevance of company to study]***.
	+ ***[Name]*** is on the board of ***[name of company and relevance of company to the study]***.
	+ ***[Name]*** is the ***[title]*** of ***[name of company and relevance of company to study]***.

***[Example of language to describe significant stock ownership in a publicly traded company, stock ownership in a non-publicly traded company, and/or holder of stock options:]***

* + - ***[Name]*** owns stock in ***[name of company and relevance of company to study]***.
		- ***[Name]*** is a ***[founder or majority or minority shareholder] of [name of company and relevance of company to study]***.
		- ***[Name]*** has a stock option from ***[name of company and relevance of company to study]*** and may receive income in the future.

***[Example language for the inventor:]***

* + - ***[Name]*** invented the ***[drug, device]*** being studied and may benefit financially if it is marketed.
		- ***[If possible, elaborate on the information provided. For example:]*** “The consulting income ***[Name]*** receives is in addition to her salary from the University.”

***[Example language:]*** This disclosure is ***[or, these disclosures are]*** made so that you may determine whether this relationship ***[or, these relationships]*** affect your willingness to participate in this study. If you have questions, please inform the study coordinator, and s/he will put you in touch with someone to talk to.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by the Harvard University Area Institutional Review Board (“IRB”). You may talk to them at (617) 496-2847 or cuhs@harvard.edu if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

 [Omit the signature page if there is no written documentation of consent.]

**Signature Block for Adult Subject**

Your signature documents your permission to take part in this research.

Signature of Subject Date

Printed Name of Subject

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

***[Add the following block if a witness will observe the consent process]***

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness to Consent Process Date

Printed Name of Witness to Consent Process

[Omit this signature page if not applicable]

**Signature Block for Adult Subject Unable to Consent**

Your signature documents your permission for the named subject to take part in this research.

Printed Name of Subject

Signature of Legally Authorized Representative Date

Printed Name of Legally Authorized Representative

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

***[Add the following block if a witness will observe the consent process]***

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness to Consent Process Date

Printed Name of Witness to Consent Process