***NOTES TO RESEARCHERS WHEN USING THIS TEMPLATE***

1. Instructional text is *in italics*
	1. **Instructions and (\*) must be removed prior to submission to COUHES**
2. Standard text (non-italicized) is language that can be directly used or directly inserted.
3. Text in brackets [] should be replaced by information specific to your study
4. (\*) Denotes sections and text that must appear verbatim. DO NOT REMOVE OR EDIT THESE SECTIONS
5. **\\ Conditional language //** are statements that appear in \\ **orange //** that must be included when the described conditions are met. Delete this text if not applicable. Text may be verbatim or similar variation
6. **{{ FDA language }}** are statements that appear in **{{** **green }}** that must be included when the study is FDA Regulated and when conditions are met. To determine if your study is FDA see <https://couhes.mit.edu/>
7. Please make all text black and Times New Roman font prior to submission.
8. Appendix of [Additional Standard Language for Informed Consent](#_Participation_and_Withdrawal) includes COUHES suggested phrasing for use when appropriate

***NOTES TO RESEARCHERS WHEN DRAFTING A CONSENT FORM***

1. **The consent template is 10 pages.** The size of a consent form may vary from one page to many pages depending on study complexity.
2. Consent forms must be written in 2nd person (e.g. “You are being asked to take part…”).
3. Language must be written at an 8th grade level and appropriate to the participant demographic.
	1. Complex terms must be described or defined in lay language. If jargon is used give a short explanation or real-life comparison to improve understanding.
4. Do not use the word “subject” or “patient” when referring to an individual taking part in the study. Alternative terms should be used such as study participant or research participant.
5. Use inclusive and gender-neutral language.
6. Define all abbreviations and acronyms the first time used.

**Delete this cover page prior to submission to COUHES**

**CONSENT TO PARTICIPATE IN RESEARCH**

 [*Insert title of the study. Title should match COUHES application title*]

[*If the study involves using different consent forms for different populations,*

*identify the population group as the subtitle of the study.*]

You have been asked to participate in a research study conducted by [*insert names and degrees of all investigators*], from the [*insert department affiliation*] at the Massachusetts Institute of Technology (M.I.T.) [\\ *if applicable, insert the name of any collaborating institution //*]*.* [*If student, indicate that results will be contributed to senior project, thesis or dissertation.*] This study is sponsored by [{{ *If the study is FDA regulated, insert name of study sponsor (i.e. IND or IDE holder) }}*] [*\\ If the study is funded, include funding source //]*.

You were selected as a possible participant in this study because [*explain succinctly and simply why the prospective participant is eligible to participate*. *This must be consistent with inclusion criteria described in the COUHES protocol*]. We expect [*maximum number of enrolled participants*] people will be in this research study.

|  |
| --- |
| \*The information below provides a summary of the research. Your participation in this research is voluntary and you can withdraw at any time. * **Purpose**

*Short sentence describing purpose of research. 1-2 sentences.** **Study Procedures**

*Brief explanation of study procedures. 1-2 sentences.* We expect you that you will be in this research study for [*number of hours/days/months/weeks/years, until a certain event*]. * **Risks & Potential Discomfort**

*Describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. 1-2 sentences.** **\\ Alternatives to Participation** (*Remove this section if no alternatives exist //*)

*\\ Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subject decide whether or not to participate in the study. //*  |

Your participation in this research is completely VOLUNTARY. You should read the information below, and ask questions about anything you do not understand before deciding whether or not to participate.

**• PURPOSE OF THE STUDY**

The purpose of this research study is to [*State what the study is designed to discover or establish.*]

{{ This study involves the use of an investigational [drug/device/biologic]. The purpose of the study is to evaluate whether the investigational [drug/device/biologic] [state the purpose of the investigational drug/device/biologic] (Describe and *include information about the investigational product, such as whether it is approved/cleared for marketing and if so, for what purpose). }}*

**• PROCEDURES**

If you volunteer to participate in this study, we would ask you to do the following experimental procedures:

[*Describe the procedures chronologically using lay language with short sentences and paragraphs. Use subheadings for each intervention to organize this section and increase readability.*]

[*Outline what the individual’s participation will entail in addition to experimental procedures, such as travel or dietary restrictions or normal classroom activities. Procedures related solely to research must be clarified in relation to non-research activities. If there are procedures occurring as part of a person’s standard treatment, such as during a regularly scheduled medical appointment, identify this as a standard treatment versus the experimental procedures.*]

[*Specify any assignment to study group and/or study design features: for example, if* [*randomized assignment*](#_Randomization_1)[*, blinding of study participant and investigator*](#_Blinding)*, and* [*placebo-controlled*](#_Placebo) *studies, will occur.*]

[*Include the length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.*]

\\ [*Indicate if the participant will be contacted about future research.] (Note: Participants should be able to* ***opt-OUT*** *of being contacted for future research.*) //

**• POTENTIAL RISKS AND DISCOMFORTS**

[*Identify each intervention with a subheading and then describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed.*]

[*In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research.*]

[*If there are significant risks to participation that might cause the researcher to terminate the study, please describe them.*]

This research may involve risks to you \\ (or to your embryo or fetus, if you are or may become pregnant // {{ *[if this is applicable and the research is FDA-regulated, this language must be included]) }}* that are currently unforeseeable.

**\\ Incidental Findings //**

\\ (*If there are any procedures and/or results gathered that may have clinical relevance, include this sub-header. Otherwise delete.) //*

**\\** [*Indicate whether clinically relevant research results, including individual research results, will be disclosed, and if so, under what conditions. The plan for offering research results to participants should be carefully articulated. An explanation of who will be interpreting results must be described. If clinicians will not be interpreting results, it may not be appropriate to return individual results. Include information on the result reliability and validity; whether the result is urgent, actionable, or does not have established medical utility; any interpretation limitations; and if any follow-up care or counseling will be provided. See* [*Incidental Finding*](#_Incidental_Findings_Section) *for suggested language*]*//*

**\\ Genetic information** *//*

**\\** *(If the study procedures involve the generation or use of human genetic information, include this subheader. Otherwise delete. See* [*Genetic Information*](#_Genetic_Information_Section) *for required language.) //*

**\\** *[If there is a plan for returning genetic results to participants, describe here. It should be made clear to the participants whether individual or summary level results will be returned, and if participants can opt-out of receiving genetic results. See* [*Return of Individual-Level Genetic Results*](#_Return_of_Individual-Level) *for suggested language] //*

**• ANTICIPATED BENEFITS**

***One of the following TWO statements MUST be included:***

***(If the participants may benefit directly from their participation in the research, use*)** The direct potential benefits to you may include: [*Describe the anticipated benefits to subjects resulting from their participation in the research.*]

*Or*

***(If there is NO likelihood that participants will benefit directly from their participation in the research, use)***There are no direct benefits to you from taking part in this research study*. \\(If the study enrolls non-healthy participants include the following)* You should not expect your condition to improve as a result of participating in this research*. //*

[*State the anticipated benefits, if any, to science or society expected from the research.*]

*(Do not include financial rewards for participating in this section.)*

**• PARTICIPATION AND WITHDRAWAL**

Your participation in this research is completely VOLUNTARY. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with M.I.T. [\\ *if applicable, insert the name of any collaborating institution //*]or your right to [\\ healthcare or *//*] other services to which you are otherwise entitled.

**Consequences of Withdrawal**

You can stop taking part in this research study at any time; it will not be held against you. If you decide to withdraw, contact the study investigator. \\ [*When appropriate, include the consequences of an individual’s decision to withdraw from the research and procedures for orderly termination of participation by the study participant, such as tapering off a medication*]. *//*

\\ (*If participants CANNOT withdraw their data, use the following. // {{ Required for FDA-regulated studies*) If you choose to withdraw, your data up until the point of withdraw will be retained as part of the study records. No additional data will be collected from you for this study.}}

{{ If you stop being in the research, already collected data may not be removed from the study database. (*When applicable, include)* You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.}}

{{ We may also consult with public records for safety reporting. }}

\\ (*If participants can withdraw their data, use*) // You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to [*PI name and address*]. {{ (*Do NOT use for FDA-regulated studies)* }}

**Withdrawal of participation by the investigator**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

\\ [*If applicable, describe foreseeable conditions that would result in withdrawal*] //If you experience any of the following during your participation: *\\* [*list and describe any side effects, screening results, conditions etc*.] // or if you are unable to follow procedures required by the research, you may have to drop out, even if you would like to continue. The investigator, [*insert name*], will make the decision and let you know if it is not possible for you to continue.

**• ALTERNATIVES TO PARTICIPATION**

[Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If applicable, explain why these procedures are being withheld.  If there are no efficacious alternatives, state that an alternative is not to participate in the study.

If the purpose of the research is not intended to affect treatment of a subject’s current medical condition, or the investigator intends to recruit only healthy subjects, you should state that the alternative is, when appropriate, to continue with the standard of care determined by the subject’s physician.

If the prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, you should say so; but avoid suggesting that participation in the research is the only way to obtain medical care and attention.]

**• PAYMENT FOR PARTICIPATION**

\\ (If participants will NOT receive compensation, use) // You will not be paid for participating in this research study.

\\ (If participants will be paid, use) // 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 or if the participant decides to withdraw or is withdrawn by the investigator.] //

*(Participants should not lose payment if they develop side effects or illness.)*

*\\ [If the participant will be reimbursed for expenses such as parking, bus/taxi, baby-sitter, travel companion/assistant, etc., list payment rates.] //*

*\\ (If participants are enrolled internationally include) //* Legally, you can be paid only if you are a US citizen, a legal resident noncitizen (e.g., possess a “green” card), or have a work eligible visa sponsored by the paying institution. You will also be reimbursed for transportation costs to and from the experiment site.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will be compensated in accordance with the payment for participation described above

**• POSSIBLE COMMERCIAL PRODUCTS**

*\\ [If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, include a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.* *If the study does not involve the collection of human materials that may in the future be of commercial value, delete this section and header.]//*

\\ Your[*insert sample type here*] may be used for commercial use. They may be used create products or to deliver services, including some that may be sold and/or make money for others. You [*choose one: will\will not*] receive any compensation. //

**• FINANCIAL OBLIGATION**

\\ (If there are no anticipated costs to the participants, use) // Taking part in this study will not lead to any added costs for you. \\ [If time or travel costs are to be assumed by participants, add] However, researchers will not pay you for your travel or the time it will take for you to be in the study. //

\\ (If the research may result in additional costs to the participants, use) // There may be costs to you for taking part in this study. [Describe what these costs are if known, such as copays, transportation to and from study visits, missing a day of employment, and childcare during study visits]

{{ Neither you nor your insurance company will be billed for your participation in this research.}}

{{ (*If participants may be billed as part of the research, consult with COUHES for appropriate language.*) }}

**• PRIVACY AND CONFIDENTIALITY**

The following will know that you are a research participant and may inspect your study records:

* Members of the research team which might include outside collaborators not affiliated with MIT.
* Authorized MIT representatives to ensure compliance with MIT policies and procedures.
* {{ Authorized representatives of the Food and Drug Administration [*and the study sponsor (e.g. the IDE or IND holder), the manufacturer of the drug or device, etc. List all that apply to the study*]. }}
* \\ Authorized representatives of a federal funding agencies[*e.g. NIH, NSF, DOE*] //
* \\ [*If there is a sponsor associated with the study, list the sponsor*] //
* {{ [*If information will be released to any other party not included above such as independent study monitors, Data Safety Monitoring Boards, CROs, etc., state the agency to whom the information will be disclosed, the nature of the information, and the purpose of the disclosure.]* }}
* \\ [*If your study is sponsored or supported by the Department of Defense, include*]Department of Defense may access records to ensure subject protection (32 CFR 219.116 (b)(5)). //
* \\ Your physicians and nurses for the purposes of [*Describe if investigators may provide study data to the participant’s medical professional, such as to provide new information about the participant’s condition*]. //

No information about you, or provided by you during the research will be disclosed to others not listed above without your written permission unless otherwise specified in this consent form, except: if necessary to protect your rights or welfare, or if required by law.

[*Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel. Include data retention period. State if and when individual data will be destroyed following the data retention period and the format in which data will be reported.]* When the study is completed and the required data retention has passed, all identifiable data will be [*Describe plans for data deletion. For example,* all identifiable data will be destroyed]

When results of the research are published or discussed in conferences, data may include [*Describe how data will be reported, such as aggregate, de-identified, individual-level data, summary information, etc.].*

You have the right to review your data, including photographs or recordings, at any time before your completion of this study. When your participation is complete and data analysis has concluded, the research team’s ability to honor your request to review your data is limited. All such requests will be reviewed on a case-by-case basis. [\\ *If data is subject to GDPR, include a mechanism for subjects to withdraw their data at any time to the extent possible. //*]{{ (*If the data are from FDA-regulated research, include)* The research team will not be able to delete your data already collected as part of your participation before the required data retention period. This includes photographs, video or audio recordings. After the required data retention period has passed, the research team will delete any data upon your request if it is feasible.}}

*\\ (Include the following if research data includes photographs, video or audio recordings. Revise the language according to your research plan*) // If photographs, videos, or audio-tape recordings of you will be published, discussed in conferences or used for educational purposes, your identity will be protected or disguised. Any identifying features (such as your face or voice) will be shielded or disguised from photographs, videos or audio recordings before such use.

Please add your initial and date if you give permission for your photograph, audio or video to be recorded for this study. Initial \_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_

*\\ (If the study is an* [*Applicable Clinical Trial*](https://cdn.clinicaltrials.gov/documents/ACT_Checklist.pdf)*, add // {{ [if this is applicable and the research is FDA-regulated, this language must be included]) }}) \\* A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include any information that can identify you. At most, the website will include a summary of the results. You can search the website at any time. //

*\\ (If your research is NIH funded and is issued a* *Certificate of Confidentiality (CoC), see* [*Certificate of Confidentiality*](#_Certificate_of_Confidentiality) *for required language.) //*

**• FUTURE DATA USE**

***One of the following TWO statements MUST be included:***

***(If data will not be shared or will be deleted upon the completion of the research, use)*** Your data (such as your information, biospecimens, cell lines, photographs, videos, audios) collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

***OR***

***(If you plan to share data or use information upon the completion of the study, use)*** Your non-identifiable data [*describe the type of information that will be shared:* such as your information, \\demographics data, biospecimens, genetic information, phenotypic information, health information, photographs, videos, audios, etc.] // collected as part of the research (*select one*: will/might) be stored, used for future research studies, and/or shared with other researchers for future research studies without additional informed consent from you or your legally authorized representative. Your data [*will\might*] be shared with [*include all that applies:* \\ academic research institutions, non-profit entities, and/or for-profit entities //].

Traditionally used identifying information about you such as your name, address, phone number, medical record, social security number, your identifiable features or your voices, etc. will be removed before using or distributing for future research. Your samples and information will be available for any research question, such as research aimed at understanding the development and causes of many diseases and conditions or the development of new scientific methods. \\ [*Specify the terms of release of future sharing, such as IRB approval or approval by a governance committee. Include if access will be limited due to particular sensitivities related to individual privacy or potential for group harm.*] //

\\ [*If your research involves storing data, biospecimen and/or cell lines in a biorepository and/or data repository for research purposes, include information on the repository including the type, whether data or biospecimen will be stored in an identifiable or de-identified format, who will have access, for how long, and any other important info such as restrictions on usage.*] //

*\\ [If the study involves depositing samples into a biobank, consider the derivatives (such as cell lines or other products that could be propagated and used for many years) and data (including genomic data, epigenetic data, and other unanticipated types of data) that may be generated from those samples, and to include this information in the informed consent.*] //

*\\ (If genetic information may be shared or stored in NIH-supported repositories, for example, if the research is NIH funded and subject to the NIH Genomic Data Sharing,* [*see Deposition of Genetic Information*](#_Deposition_of_Genetic) *for required language.) //*

**• (\*)NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

**• (\*)EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury from the direct result of your participation in this study, M.I.T. will provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, and reimbursement for such medical services not covered by your insurance. M.I.T. does not provide any other form of compensation for injury, however, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

{{ [(*If the study is sponsored by a private drug or device manufacturer, delete the forgoing and replace with)* In the event you suffer such an injury from the direct result of your participation in this study, M.I.T. will provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed. The sponsor has made plans to pay for medical costs related to research-related injuries. *(Describe how the subject can contact the sponsor for more information.)*]. You are not precluded however, from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. }}

You will be financially responsible for any services received for any injuries determined not to be directly related to your participation in the study.

**• (\*)IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact [i*dentify all personnel involved in the research as listed in the COUHES Application under the following subheadings: Principal Investigator, Faculty Advisor (if student is the P.I.), Co-Investigator(s). Include the daytime telephone numbers and addresses for all listed individuals. For greater than minimal risk studies, include night/emergency telephone numbers. {{For FDA-regulated studies, include email address of contact person }}*]

**• (\*)RIGHTS OF STUDY PARTICIPANTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a study participant you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

*\\ (If your research is subject to GDPR, see* [*GDPR*](#_GDPR) *for required language.) //*

|  |
| --- |
| **SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE** |

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form. \\ [*GDPR and/or UK Data Protection Act Only: include the following statement*] By signing this consent form, I acknowledge my understanding and consent to the collection, storage and transfer (if applicable) of my personal information to the United States. //

**BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.**

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

Name of Participant

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

Name of Legal Representative (if applicable)

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

Signature of Participant or Legal Representative Date

|  |
| --- |
| **SIGNATURE OF PERSON OBTAINING INFORMED CONSENT** |

I have explained the research to the participant or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

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

Name of Person Obtaining Informed Consent

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

Signature of Person Obtaining Informed Consent Date (must be the same as above)

|  |
| --- |
| **SIGNATURE OF WITNESS (If required by COUHES)** |

[ ]  This section is required

My signature as witness certified that the participant or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

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

Name of Witness

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

Signature of Witness Date (must be the same as above)

END OF CONSENT TEMPLATE

DELETE THIS PAGE AND APPENDIX PRIOR TO SUBMITTING TO COUHES

Appendix: Additional Standard Language for Informed Consent

*Below is standard or canned language investigators can add when appropriate to their research. Each section includes a brief description of when the language would be appropriate. Please complete the italicized or empty sections with the necessary information.*

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# Key Information (Summary Box)

## Compensation for Injury

*Include for FDA Regulated research determined to be greater than minimal risk.*

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.

# Participation and Withdrawal Section

## Recruiting from MIT Community

*Include the following when participants will be* ***recruited from MIT****:*

If you are a member of the MIT community, your decision to participate or not to participate will not in anyway influence your grade, funding, or other relationship with \_\_\_\_\_\_(PI name) or MIT.

# Procedures Section

## Blinding

*Include if research procedures involve* ***double******blinding****:*

This is a double-blinded study, which means that neither you or the study doctor or the study staff will know which treatment you are receiving.  However, in an emergency, study doctor can get this information.

*Include if research procedures involve* ***single blinding****:*

You will not be told which treatment you are getting, however your study doctor will know.

## Focus Groups

*Include if* ***focus groups*** *will occur:*

Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.

## Placebo

*Include if research procedures are* ***placebo-controlled****:*

This study compares an active drug to a placebo. A placebo is an inactive substance made to look/taste like an active medicine. You will either get the study drug/product, \_\_\_\_\_\_\_\_(name of drug/device) or a placebo. Researchers use a placebo to see if the study drug works better or is safer than not taking anything.

## Randomization

*Include if research procedures involve* ***randomization****:*

Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. (OR If the randomization is not equal; then state the odds).

## Self-Experimentation

*Include the following when your research is* ***self-experimentation****:*

I am an investigator or key personnel on the above-referenced research study and intend to conduct the procedures as described in the approved protocol and consent form on myself: I am aware that the procedures are considered to constitute research on human subjects. I am performing these procedures on myself voluntarily.

## Ultrasound

*Include if* ***ultrasound*** *tests will occur:*

Ultrasound (or sonography) is a test that uses high-frequency sound waves to show what is in your body. Gel will be applied to your skin/ the gel acts as a conductor. A transducer, which is a hand-held device that sends and receives ultrasound signals, will be moved over the area of your body being imaged. Images instantly are seen on a television-like monitor.

# Potential Risks and Discomforts Section

## Mental Health Topics

*Include the following when* ***data are anonymous*** *and include* ***topics relating to mental health****:*

There are no anticipated risks from your participation in this study. However, some people become anxious or upset when answering questions about (behaviors, well-being, mood, views).Your responses will not be individually identified, so we cannot provide you with personal feedback or intervention based on any of your answers. If you are worried about your mood, please refer to the attached resource referral information sheet.

*Include the following when* ***data are identifiable*** *and include* ***topics relating to mental health****:*

In the event that you tell the research team you are thinking about harming yourself or others, the research team will provide you resources and may ask you more questions about these thoughts. Based on your responses, the research team may provide you will additional resources or assistance to identify appropriate follow-up. This may include working with you to contact your doctor, contacting a trusted family member or therapist to discuss your thoughts, or working with you on a plan that may include getting you to a hospital for safety.

## MRI Procedures

*Include the following when your research involves* ***MRI procedures:***

The known risks or side effects associated with conventional MRI procedures are minimal, except for those people who have electrically, magnetically or mechanically activated implants (such as cardiac pacemakers) or those who have intracerebral vascular clips. The greatest risk is of a metallic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all ferrous metal from their clothing and pockets before entering the magnet room. No metal objects are allowed to be brought into the magnet room at any time, unless they are permanently installed. There are no other known risks associated with high-speed MRI. Both the conventional and the high-speed MRI systems have been approved by the FDA and will be operated within the operating parameters reviewed and accepted by the FDA.

A magnetic resonance scan is not uncomfortable but if you are prone to claustrophobia (fear of enclosed spaces) you should notify the researcher in charge of the scan. You can expect to hear a knocking sound during the imaging. For loud scanning sequences, ear plugs or headphones will be provided so the sound should not be bothersome. In some cases, it may be necessary to use earphones that provide less sound attenuation, in which case, a quieter scanning sequence will be used.

It is important in these studies that you remain motionless. The head holder is reasonably comfortable, and is designed to keep your head immobilized and in a relaxed position. If the head holder is uncomfortable, you should notify the researcher in charge of the scan. You are free to stop the study at any point if for any reason you do not wish to continue.

## Simulators

*Include the following when* ***simulators*** *will be used:*

There is a small risk that people who take part will develop what is ordinarily referred to as simulator sickness. It occurs once in a while to people who are exposed to prolonged continuous testing in simulated environments. Symptoms consist of nausea and a feeling of being light- headed. The risk is minimized as a result of the short duration of each session in the simulator. If you experience any of the symptoms mentioned, please tell the researcher and remain seated until the symptoms disappear. You are free to stop the study at any point if for any reason you do not wish to continue.

## Virtual Reality

*Include the following when* ***virtual reality*** *will be used:*

Side effects of VE (virtual environment) use may include stomach discomfort, headaches, sleepiness, dizziness and decreased balance. However, these risks are no greater than the sickness risks participants may be exposed to if they were to visit an amusement parks and ride attractions such as roller coasters. You will be given [n]-minute breaks during the exercise to lessen the chance that you will feel sick. If you experience any of the symptoms mentioned, please tell the researcher and remain seated until the symptoms disappear. You are free to stop the study at any point if for any reason you do not wish to continue.

# Anticipated Benefits Section

## FDA-Regulated Products

*Include the following if the study uses an {{* ***FDA-regulated product****: }}*

{{ This product is intended to [*describe purpose of the product*]; however, we cannot guarantee that you will receive any benefit from it or from being in the study. Your participation in this research may not benefit you, but information learned from this study may benefit patients with your disease or condition in the future. }}

# Incidental Findings Section

## Clinical Review of Findings

*Include the following if research team members include* ***non-clinician researchers*** *only:*

The experimental procedure(s) performed in this study are for specific research purposes and are not designed to diagnose or treat any medical conditions. The investigators for this project are not clinicians, may not be trained to perform medical diagnoses, and are not responsible for any medical evaluation or treatment.

*Include the following if* ***clinicians*** *will be involved with risk assessment and/or review research findings:*

The experimental procedure(s) performed in this study are for specific research purposes and are not designed to diagnose or treat any medical conditions. Although some of the investigators for this project are trained clinicians, they are not acting as your doctor, but as research staff with relevant clinical knowledge to administer risk assessments and to act on them in urgent/emergent instances. The research staff are not responsible for any medical evaluation or treatment.

## MRI Procedures

*Include the following when your research includes* ***MRI procedures****:*

The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project are not clinicians trained to perform medical diagnoses, and are not responsible for failure to find existing abnormalities.

This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have found a medical problem in your MRI scan, we will ask a doctor who is trained in their reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care doctor, we can contact your doctor, with your permission, and help him or her get the right follow-up for you. No information generated in this study will become part of a hospital record routinely. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

*If your study does not have access to a radiologist, include the following:*

The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project are not clinicians trained to perform medical diagnoses, and are not responsible for failure to find existing abnormalities. If we find results that could potentially be clinically relevant, we will share with you and advise you to follow up with your primary care doctor. It is your responsibility to follow up with your doctor for further discussion. We {will OR not will} provide you with a copy of the scan.

## Return of Individual-Level Genetic Results

*Include the following if* ***individual, actionable genetic results*** *will be returned:*

It is possible that we will discover that you have a gene variant/medical issue that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

* Any results we return to you will first be verified in a clinical lab.
* \\ The results will be explained to you by a genetic counselor, a health professional who has training in genetics and counseling //
* Sometimes the meaning of the results will be uncertain. It is important to know that our understanding of genetics is changing quickly, and in many cases, we will not know for sure what the results mean for your future health.
* Sometimes, even if you learn of a clear diagnosis, there will be no clear treatment.
* You should not assume that if you are not contacted, that you do not have any gene variants that might be related to a disease.

*Include the following if results of* ***unclear clinical significance*** *will be generated:*

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.

# Genetic Information Section

## Required language for research involving use or generation of genetic information

As part of the analysis on your specimens, the investigators may complete genetic testing. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Since every person’s genome is unique there is a small risk of identifying an individual based on their genetic code. Although pre-cautions are taken to protect your identity, there is a small risk of loss of confidentiality. There is a small risk of someone finding out private information about you or your family from the biospecimen or cell lines. There may be other risks we do not know about.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for US health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law **does not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

I have read the information above and understand my genetic information may be generated for this research. If my genetic information may be shared for future research, it will be described in the “Future Data Use” section in this consent form.

Initial \_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_

## WGS Studies

*If* ***whole exome or whole genome sequencing studies*** *(i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) will be done, include the following:*

We (may/will) perform a whole genome or whole exome analysis on your sample. Some research involves just studying a few genes that are linked to a disease or condition. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of [signify here whether the sequencing data will be limited to the disease under study and related disorders or "many diseases or conditions"]. [Explain the associated risks such as the risk of re-identification based on a subject’s unique genetic code.]

***Note if your research is subject to the NIH Genomic Data Sharing policy and submission to dbGaP, please see “Future Data Use” section below for additional language specific to dbGaP.***

*If participants can* ***opt-in/opt-out of genome sequencing*** *in the research include the following:*

My blood/tissue sample may be used for genetic research in this study.

 \_\_\_\_Yes \_\_\_\_ No

My blood/tissue sample may be stored/shared for future genetic research in \_\_\_\_\_\_[specify health problems (such as cancer, heart disease, etc.)].

 \_\_\_\_ Yes \_\_\_\_ No

My blood/tissue sample may be stored/shared for future genetic research without limitations. This means my samples and genetic information will be available for any research question, such as research aimed at understanding the development and causes of many diseases and conditions or the development of new scientific methods.

 \_\_\_\_ Yes \_\_\_\_ No

Please add your initial and date. Initial \_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_

## Microbial Sequencing

*Include the following when human DNA is sequenced but not analyzed, such as during* ***microbial sequencing*** *of human biospecimens:*

When your samples are sequenced, both microbial sequences and human genetic sequences will be generated. Please be informed that we will not analyze or release any human genetic information. Any human sequences generated as a result of the sequencing technique will be removed before analysis.

There is some possibility that someone might be able to use bacterial sequence information to identify close contacts with other people. This is a minor risk, as it is only possible if they have also whole-genome sequenced information about the bacteria from the other individuals that are close contacts. Additionally, certain health and lifestyle information might be theoretically predictable from bacterial composition at various body sites.

# Future Data Use Section

## Creation of Cell Lines

*Include the following if* ***cell lines will be created****:*

As part of this project, your de-identified tissue samples will be used to create cell lines that will keep reproducing and can be used for many purposes, including those uses related to genomic information. We will store the cell lines [*include if appropriate: and samples*] and your de-identified data in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. [*Specify the terms of release established by the repositories, such as IRB approval or approval by a governance committee*.]

## Deposition of Genetic Information – NIH Repositories

*Include the following when* ***genetic information*** *may be shared or stored in* ***NIH-supported repositories****:*

In order to allow researchers to share results, the National Institutes of Health (NIH) and other repositories have developed special data databases. Information, including your demographic, phenotypic and genetic information, may be placed into these databases to be used for future research [include if applicable: and to be shared broadly]. No traditionally used identifying information about you, such as your name, address, telephone number, or social security number, will be placed into the database. However, we cannot predict how genetic information will be used in the future. It may be possibly to identify you based on the information in these databases and/or other public information. The risk of this happening is currently very low. In addition, there are many safeguards in place to protect your privacy. Your de-identified, individual-level data may be shared through [unrestricted or controlled] access repositories. [There should be data use limitations considering risks to individual participants, their families, groups or populations associated with data submitted to the databases and subsequent sharing. Access should be limited if data are considered to have particular sensitivities related to individual privacy or potential for group harm. Examples include but are not limited to: study populations from isolated geographical regions, small and easily identifiable populations, tribal populations, Native Americans/Alaska Natives, indigenous populations, rare disease communities, or potentially stigmatizing traits.]

*If the research is* ***NIH funded and subject to the NIH Genomic Data Sharing Policy****, please include the following information:*

Portions of your de-identified, individual level data and health information will be stored for an unlimited period of time in a database [include database name: such as in the database of Genotypes and Phenotypes (dbGaP )]to be used for future research and to be shared broadly. The data may include:

1. Your genomic data: Genomic data is information about a person’s complete DNA. DNA stores messages or codes, which are passed on to future generations.
2. Your phenotypic data: Phenotypic data are the observable characteristics about DNA, such as hair color or height.
3. Your demographic data such as your age, gender, [include other demographic variables if applicable: ethnicity]
4. Your health information such as [your disease diagnosis.]

*When appropriate, include the following passage:*

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, geographic region, age range, and sex [specify demographic variables]. This information may help researchers study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

*Investigator must include one of the following paragraphs regarding data access when the research is NIH funded and subject to the NIH Genomic Data Sharing Policy, either for Unrestricted Access or Restricted Access.*

**Unrestricted access**

[For data sharing to unrestricted access databases:]Your de-identified, individual level demographic, genomic and phenotypic data and health information will be shared in a database [database name: such as in dbGaP] with unrestricted access. This means that anyone from the public can access and use the data. [For example], the public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you. We believe it is unlikely that this will happen, but we cannot make guarantees.

**Controlled-Access**

[For data sharing to controlled-access databases:]Your de-identified, individual level demographic, genomic and phenotypic data and health information will be shared in a database [ database name: such as in dbGaP] with controlled-access. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to directly identify you. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information. We believe the chance that this will happen is very small, but we cannot make guarantees. Researchers approved to access information in the database will agree not to attempt to identify you.

*In addition, include one of the two following paragraphs regarding access to Genomic Summary Results (GSR):*

**Genomic Summary Results (GSR) under Unrestricted access**

The genomic summary results from this study will be made available through unrestricted-access. It will be possible for outside researchers to access some summary-level information about all the participants included in a dataset (including you), or across multiple datasets, without applying for permission. This information may be shared through the scientific literature or through other public scientific resources, such as data repositories that provide unrestricted access to the information. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants from many studies. The risk of anyone identifying you with this information is very low.

**Genomic Summary Results (GSR) under Controlled-Access**

The genomic summary results from this study will be made available through controlled-access. Although researchers will not be able to access information specific to you without permission, some summary-level information about all the participants included in a dataset (including you) may be shared through the scientific literature. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants. The risk of anyone identifying you with this information is very low.

## Certificate of Confidentiality

*Research funded by the NIH that include a* ***Certificate of Confidentiality,*** *must include the following passage:*

The privacy protections, and limitations of those protections, afforded by a Certificate of Confidentiality to individual-level data do not apply to summary results.

# Rights of Research Participants Section

## GDPR

*Research data that is subject to* ***GDPR*** *must include the following:*

As part of your participation, we will collect certain personal information about you, including: *[list all types of personal information collected].* In addition, we will collect special category data, your personal information that is especially sensitive: *[INCLUDE ALL THAT APPLY: racial or ethnic origin; political opinions; religious or philosophical beliefs; trade union membership; processing of genetic data; biometric data; health data; and/or sex life or sexual orientation information;]*

The purpose of the data collection is [purpose of research]. The information you provide will only be available to *[list organization who has access].* Your data will be secured through the following methods*: [information regarding data security, including storage and transfer of data].*

This information will be retained for *[duration, this may be indefinite].* You have the right to withdraw your data from the study at any time. To do so, contact *[investigator contact information]*. If you withdraw from the study, no new information will be collected about you or from you by the study team*. [Include whether and under what conditions data may be used for future research, either related or unrelated to the purpose of the current study]*

Your personal information *[“will” or “may”]* be transferred to the United States. You understand that the data protection and privacy laws of the United States may not offer you the same level of protection as those in the *[country or countries of data’s origin/EEA/UK].*