**CONSENT TO PARTICIPATE IN RESEARCH**

 [*Insert title of the study*]

[*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 [*insert name of sponsor*].

You were selected as a possible participant in this study because [*explain succinctly and simply why the prospective subject is eligible to participate*.]

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| 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. Use lay language. 1-2 sentences.** **Study Procedures**

*Brief explanation of study procedures. 1-2 sentences.** **Risks & Potential Discomfort**

*Describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed.** **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.*  |

You should read the information below, and ask questions about anything you do not understand before deciding whether or not to participate.

** 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 health care or other services to which you are otherwise entitled.

** PURPOSE OF THE STUDY**

[*State what the study is designed to discover or establish.*]

** PROCEDURES**

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

*[Describe the procedures chronologically using lay language with short sentences and paragraphs. Use subheadings to organize this section and increase readability. Distinguish which procedures are experimental and which are standard treatments.]*

*[Define and explain medical and scientific terms in ordinary language (for example: the term placebo. If drawing blood, the amount drawn should be defined in terms of teaspoons or tablespoons).]*

*[Specify the subject's assignment to study groups, 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.]*

*[For research involving randomization of subjects into different arms of studies, specify the randomization procedures.]*

** 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.]*

*[Include the following statement:]*

The research may involve risks that are currently unforeseeable.

*[If applicable include the following statement:]*

1. Incidental 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.

*[Include a statement here regarding whether clinically relevant results will be shared with subjects and under what conditions.]*

** GENETIC INFORMATION**

***(Note: If this does not apply to your research, please omit)***

*[If human genome sequencing will or might be conducted, participants must be informed and explained the associated risks such as the risk of re-identification based on a subject’s unique genetic code.]*

*[Include the following if human genomic information might be generated:]*

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.

*[If there is a plan for returning genetic results to participants, 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]*

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

** ANTICIPATED BENEFITS TO SUBJECTS**

Based on experience with this [*drug, procedure, device, etc.*] in [*animals, patients with similar disorders*], researchers believe it may be of benefit to subjects with your condition [*or, it may be as good as standard therapy but with fewer side effects*]. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

The potential benefits may include:

[*Describe the anticipated benefits to subjects resulting from their participation in the research.*]

*If there is NO likelihood that participants will benefit directly from their participation in the research, state as much in clear terms. For example:* “You should not expect your condition to improve as a result of participating in this research” *Do not include financial rewards for participating in this section; that will be addressed later.*

** ANTICIPATED BENEFITS TO SOCIETY**

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

** 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 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**

*[State whether the subject will be paid or offered other benefits. If not, state so.]*

*[If the subject will receive payment, describe remuneration amount, when payment is scheduled, and proration schedule should the subject decide to withdraw or is withdrawn by the investigator.]*

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

*[Subjects should not lose payment if they develop side effects or illness.]*

*[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.]*

** POSSIBLE COMMERCIAL PRODUCTS**

***(Note: If this does not apply to your research, please omit)***

*[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, the subject must be informed of the fact in the consent form.]*

** FINANCIAL OBLIGATION**

***(Note: If there is no financial obligation of the subject, please say so.)***

It is possible that your insurance will not pay for all of the treatments and tests you will receive if you participate in the research. That is because many insurance companies, HMOs, and health benefits plans do not cover experimental treatments. If that happens, the charges you will have to pay will be as follows: [P*rovide an itemized list.*]

*Suggested alternative text:*

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

*[If it is likely or even possible that procedures or tests the subjects will undergo will not be covered by their insurance, health benefits plan, or other third party payers, you should make this clear.]*

*[Bills should not be submitted to third party payers without the written consent of the subject.]*

** PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are members of the research team which might include outside collaborators not affiliated with MIT and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others 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. In addition, your information may be reviewed by authorized MIT representatives to ensure compliance with MIT policies and procedures. *[Include the following sentence if your study is sponsored or supported by the Department of Defense: Department of Defense may access records to ensure subject protection (32 CFR 219.116 (b)(5)).]*

*[Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel. State if and when individual data will be destroyed following analysis, and the format in which data will be reported.]*

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.].*

[*Include the following if research includes photographs, video or audio recording; you may 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. You have the right to review the 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 photographs or recordings is limited. All such requests will be reviewed on a case-by-case basis. The research team will delete any photographs, videos or audio recordings upon your request if it is feasible and permitted by applicable regulations. [*note: if data is subject to GDPR, there must be a mechanism for subjects to withdraw their data at any time to the extent possible].*

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 applicable, include the following statements regarding the use of biospecimen:]*

Your[insert sample type here] may be used for commercial use. You [choose one: will\will not] receive any compensation*.*

*[If applicable, include the following:]*

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.

**[When the research records may be subject to inspection by FDA, a funding agency, or an industrial sponsor, you must add:]**

Authorized representatives of the Food and Drug Administration (FDA) *[and/or a funding agency(i.e. NIH), the sponsor, the manufacturer of the drug or device, etc. List all that apply to the study*] may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

[*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 research is NIH funded and is issued a* *Certificate of Confidentiality (CoC), see COUHES guideline regarding optional consent language: http://couhes.mit.edu/clinical-trials-mit/certificates-confidentiality]*

** FUTURE DATA USE**

***[If data will not be shared or will be deleted upon the completion of the research, include the following:]***

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. When the study is completed, *(specify the period of data rention and if data will be destroyed).*

***[If you plan to share data or use information upon the completion of the study, include the following:]***

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 storing, using or distributing for future research. When the study is completed, all identifiable data will be destroyed after the required data retention period.

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.] [Specify if access will be limited due to particular sensitivies related to indivudal privacy or potential for group harm.]*

When your participation is complete and data analysis has concluded, [*explain if and how participants can withdraw their data:* [*http://couhes.mit.edu/guidelines/data-handling-when-subject-withdraws-study*](http://couhes.mit.edu/guidelines/data-handling-when-subject-withdraws-study) *If data is subject to GDPR, there must be a mechanism for subjects to withdraw their data at any time to the extent possible]*

*[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 cell lines will be created, include the following passage as appropriate:]*

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.]*

***[Investigators involved in the collection and sharing of data, biospecimen and/ or cell lines must visit our website for guidance and additional required data sharing language:*** [***http://couhes.mit.edu/informed-consent***](http://couhes.mit.edu/informed-consent)***]***

***[If genetic information may be shared or stored in NIH-supported repositores, for example, if the research is NIH funded and subject to the NIH Genomic Data Sharing Policy, please visit our website for guidance on NIH Data Sharing Policy [insert link to “guidance on NIH Data Sharing Policy] and additional required data sharing language [***[***http://couhes.mit.edu/informed-consent***](http://couhes.mit.edu/informed-consent)***]***

** CONSEQUENCES OF WITHDRAWAL**

*[Note - If this does not apply to your research, please omit*:] *Explain the consequences of a subject's decision to withdraw from the research and state whether withdrawal must be gradual, for reasons of safety.*

1. **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any of the following side effects [*list and describe*] or if you become ill during 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. 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 you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will be paid [*insert amount of payment or other remuneration*].

** 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 will 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, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services.  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. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study. *(If the study is sponsored by a private drug or device manufacturer, delete the previous sentence.)*

** 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.*]

** RIGHTS OF RESEARCH SUBJECTS**

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 research subject, 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.

*[GDPR and/or UK Data Protection Act Only: If you plan to collect “personal data” from participants residing in the EEA (EU), UK, please include the following language. For more guidance, please see the COUHES website - General Data Protection Regulation (GDPR)* [*http://couhes.mit.edu/guidelines/general-data-protection-regulation-gdpr-and-research-activities*](http://couhes.mit.edu/guidelines/general-data-protection-regulation-gdpr-and-research-activities) *]*

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].*

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| **SIGNATURE OF RESEARCH SUBJECT 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 Subject

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

Name of Legal Representative (if applicable)

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

Signature of Subject or Legal Representative Date

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

I have explained the research to the subject 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 subject’s)

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

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

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

Name of Witness

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Signature of Witness Date (must be the same as subject’s)