### Instructions are in blue; bolded items must be included.

### *Before submission to the IRB*: Remove instructions and any bold emphasis.

* Consider using large font if you anticipate recruiting participants with visual impairments, e.g., older populations, or for eye studies

**DESCRIPTION:** You are invited to participate in **a research study** on (*describe project in non-technical language; include types of questions that will be asked, if applicable; explain* ***purpose*** *of the research).* You will be asked to *(describe* ***procedures****; mention video/audio taping, if applicable, and what will become of tapes after use, e.g., shown at scientific meetings; describe the final disposition of the tapes).*

**TIME INVOLVEMENT:** Your participation will take approximately *(insert* ***duration****).*

**RISKS AND BENEFITS:** The risks associated with this study are *(describe* ***foreseeable risks*** *to participants; if none, state as such).*The benefits which may reasonably be expected to result from this study are *(describe any* ***benefits****; if none, state as such).* **We cannot and do not guarantee or promise that you will receive any benefits from this study.**  *(If applicable)* Your decision whether or not to participate in this study will not affect your *(choose as appropriate): employment; medical care; grades in school.*

**PAYMENTS:** You will receive *(describe reimbursement; where there is none, state as such)* as payment for your participation.

If participants will be paid $200 or more, add the following:

\*Payments may only be made to U.S. citizens, resident non-citizens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer. You may need to provide your social security number to receive payment.

**SPONSOR:** #(Name of institution/company) is providing financial support and/or material for this study. This section may be deleted if the study is un-funded or internally funded (i.e. receiving support and/or funding only through Stanford).

**PARTICIPANT'S RIGHTS:** If you have read this form and have decided to participate in this project, please understand your **participation is voluntary** and you have the **right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled**. **The alternative is not to participate.** You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. Your individual privacy will be maintained in all published and written data resulting from the study. *(If identities will be disclosed, provide details*: With your permission, your identity will be made known in written materials resulting from the study.)

If FDA regulated, add the following:

Data collected on you to the point of withdrawal remains part of the study database and may not be removed per the Food and Drug Administration.

\*If this research study collects identifiable private information, include one of the two following statements:

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

OR

Your private information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

\*Include the following language if this study is NIH funded***:***

**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 information in the medical record].

***If the study is collecting PHI (any HIPAA identifiers along with Health Information) request an Alteration of HIPAA Authorization in the IRB application (section 15) and add the HIPAA authorization language as follows:***

\***Authorization To Use Your Health Information For Research Purposes**

State law requires that the HIPAA text be in at least 14-point type.

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you agree to this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before agreeing to it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

Provide a description of the study, such as its purpose, and describe how the individual’s health information will generally be used in the study, including any publication. If this is a clinical trial, also explain that the information in some form will be submitted to the sponsor and the FDA.

**Do I have to agree to this authorization form?**

You do not have to agree to this authorization form. But if you do not, you will not be able to participate in this research study. If the study includes any treatment, add: \*including receiving any research-related treatment.

Agreeing to the form is not a condition for receiving any medical care outside the study.

**If I agree, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: researcher's name with mailing and/or email address.

**What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, (List or describe the protected health (medical) information that will be collected in this study.  The information should be limited to the least amount of information needed to accomplish the purpose of the research (i.e., information relating to a particular medical condition, specific blood tests, specific physical examination measures, specific x-rays or MRI imaging information, including any reports such as radiology or pathology reports.) Be sure that the information in this HIPAA authorization is consistent with sections 11b and 15a in the protocol application.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Protocol Director (Insert Name of PD)
* The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
* Research Staff

(List every other class of persons or organization affiliated with Stanford who might need to use and/or disclose the participant's information in connection with this study.)

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* (Sponsor, funding agency or collaborators who may receive information)

If the study is administered by PAVIR (until recently called PAIRE), add:

* \*The Palo Alto Veterans Institute for Research (PAVIR)

List every other class of persons or organization not affiliated with Stanford -- e.g., a sponsor and affiliates, data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, etc. -- to whom the participant's information might be disclosed.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

List a specific date on which the authorization will expire, e.g., “will end on December 31, 2050”. If you are uncertain, choose a date that provides plenty of time for your work to be completed (e.g., data analysis, monitoring, etc.).

Your authorization for the use and/or disclosure of your health information will end on date or when the research project ends, whichever is earlier.

**CONTACT INFORMATION:**

*Questions:*If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director,*(name and phone number of Protocol Director).*

You should also contact them at any time if you feel you have been hurt by being a part of this study.

*Independent Contact:* If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

*(If applicable)* Appointment Contact: If you need to change your appointment, please contact *(name)* at *(phone number).*

If the research will include audio- or videorecordings, the following language should be added:

You give consent for your [video/audio] recordings to be used for (describe proposed use of the recordings and what will happen to the recordings, e.g., shown at scientific meetings; and describe the final disposition of the tapes).(Please note, this option is also applicable if the recordings are used for purposes that are not part of this research project, e.g. future analysis, professional presentations, etc)

The paragraph below must be included in all studies involving COVID-19 research.

**\***  The federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427.

**The extra copy of this consent form is for you to keep**. *(For online studies: “****Please print a copy of this page for your records****”)*

**If you agree to participate in this research, please** *(describe what the participant must do to indicate agreement to participate. For example: “complete the attached questionnaire / survey”, or “indicate this to the researcher”).*