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

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

You are invited to participate in **a research study** about (*describe project in non-technical language; explain* ***purpose*** *of the research).* You will be asked to *(describe* ***procedure,*** *such as “participate in a short interview”;* (*Include types of questions that will be asked; describe* ***alternative procedures****, if any).*

*(If applicable)* With your permission, the *(describe activity/procedure, e.g. “interview”)* will be audio taped. *(Explain video/audio taping and what will become of tapes after use, e.g.“These tapes will be transcribed for data analysis purposes and then destroyed after completion of the study”.)*

Your participation will take approximately *(insert* ***duration****).*

The **risks** associated with the study are *(describe foreseeable risks or discomfort to subjects; 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)*. You will receive *(describe reimbursement; where there is none, state as such)* as **payment** for your participation.

Please understand **your participation is voluntary** and you have the right to withdraw your consent or **discontinue participation at any time without penalty**. You have the right to refuse toanswer particular questions. Your individual privacy and **confidentiality** of the information you provide will be maintained in all published and written data resulting from the study. *(If identities will be disclosed, provide details*, e.g. “With your permission, your identity will be made known in written materials resulting from the study.)

*\*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.

*If you are consenting participants on the phone, please include the following:*

If you have any questions about this study, or about anything else, you can contact me at *(provide your phone number)* or the Stanford IRB at 650-723-2480 or toll free at 1-866-680-2906. *(Remove toll free number if research is conducted overseas.)*

*If you are consenting participants face to face, please include the following:*

I will provide you with my **contact information** if you have any questions for me about this study, or anything else. The card I am giving you also has the contact information for the Stanford Institutional Review Board (IRB) if you have any questions about your rights as a participant. *(If research is conducted overseas, please also add the following:*Locally, you can

also contact *(provide local name and contact information)* who can contact the Stanford IRB on your behalf and answer any questions you may have regarding this study.

*Hand out a separate business card or contact sheet to subjects which includes the following contact information:*

**FOR QUESTIONS ABOUT THE STUDY**

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

*(If research is conducted overseas, please also add the following)*Locally, you can also contact*(provide name and contact information)* who can answer any questions you may have regarding this study and assist you in contacting the Stanford IRB.

*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 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 650-723-2480 or toll free at 1-866-680-2906 *(Remove toll free number if research is conducted overseas.)* You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

*If participants do not speak English, identify a local contact person to act as a liaison and translator for subjects who may want to contact the Human Subjects Office with questions or complaints. Include the following statement:*

If you have questions about your rights as a study participant or are dissatisfied at any time with any aspect of this study, you may contact - anonymously, if you wish, *(insert name and contact information for the designated liaison/translator)*, who will assist you in contacting the Stanford IRB.

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](https://www.hrsa.gov/cicp/about/index.html%20) or call 1-855-266-2427.