**STANFORD CONSENT FORM** **TEMPLATE**

**For MRI Human Subject Research**

**(e.g., for fMRI use in behavioral research)**

* Instructional text is in blue ***and should be removed prior to submission to the IRB***
* Blue text in parentheses ( ) should be replaced by information for your study, e.g., (*your name here*)
* Consider using large font if you anticipate recruiting participants with visual impairments, e.g., older populations, or for eye studies

****Denotes text that must appear verbatim

**#** Denotes text that must appear - use verbatim or in variation

OPTIONAL FORMAT to use when there are BOTH adults and children in the same study; otherwise remove this box.

If you choose to use this format, please insert the information below into your consent form.

Please check all that are applicable:

[ ]  I am an adult participant in this study.

Print your name here:

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

[ ]  I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or “your ward.”)

Print child’s name here:

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

For studies that ONLY involve children, revise the consent form to refer to the participant as “your child...."

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**FOR QUESTIONS ABOUT THE STUDY, CONTACT:** (Protocol Director Name, address and phone number). Only protocol directors or academic sponsors whose names appear on application cover page may be listed here.

**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; answer questions, take a survey, 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).

MRI (magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. During the scan you will be asked to lie on a long narrow couch for a certain amount of time (state how long) while the machine gathers information. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken steps to relieve the "claustrophobic" feeling.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed, so it very important that you notify the operator. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. There is also a possibility of tinnitus (ringing in the ears) after the MRI.

If the study will use contrast media, insert the following:

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator.

It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects.  You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs.

If you might use any radio frequency coil, device, or software that has not been approved by the Food and Drug Administration - please check with your Magnetic Resonance facility - add the following:

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately.

If you are operating at 3.0T or above, include the following statement:

Dizziness or nausea may occur if you move your head rapidly within the magnet.

**if you feel discomfort at any time, notify the operator and you can discontinue the exam at any time**

The following language is recommended for studies performed at the Lucas Center or other locations if the scan is not a diagnostic study:

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

If your study involves pregnancy testing and children, please note that there are California minor consent laws that impact how pregnancy results can be communicated. Please add this language to your consent form:

As part of this study, pregnancy testing will be performed. If you are a parent whose minor child is participating in this study, under most circumstances, California law does not permit us to disclose the result of your child’s pregnancy test to you without a signed authorization from your child. If your child’s pregnancy test comes back positive, results will be given to your child by one of the study nurses or doctors in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Circumstances, in which we might be compelled to reveal this information without authorization from you or your child include when your child's life or someone else's life is at risk or if abuse is suspected. If we believe it is legally necessary to tell a parent or guardian of a positive pregnancy test without your child's permission, we will meet with your child first in private to discuss our concerns before divulging any information regarding pregnancy. During research, if your child has a positive pregnancy test, we may withdraw your child from the study, but unless it is legally necessary or your child provides authorization, we will not be able to confirm that pregnancy is the reason for withdrawal. If your child becomes pregnant or if there is any chance that your child is pregnant (late menstrual period), please contact the study personnel immediately so that we may provide medical assistance and counseling.

**RISKS AND BENEFITS:** **#**The risks associated with this 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). ****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 employment/medical care.

**TIME INVOLVEMENT:** Your participation in this experiment will take approximately (amount of time).

**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.

Reimbursement:

# If participants will be reimbursed:

Include a statement on reimbursement (i.e., funds paid to participants to repay them for out-of-pocket expenses incurred as a result of participating in a study such as study-related travel, gas, non-business mileage (medical/move rate), lodging, and meals). Reimbursement payments must be based on actual incurred expenses and is not considered taxable income.

**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 results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

If applicable: You have the right to refuse to answer particular questions.

****If this study collects identifiable private information, you must 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 information will not be used or distributed for future research studies even if all identifying information is removed.

\*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].

** 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 written authorization. If you sign 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 signing 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 sign this authorization form?**

You do not have to sign 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.

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

**If I sign, 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 a clinical investigation involving a test article (drug, device, biologic) that is subject to FDA regulations, add:

* \* The Food and Drug Administration

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.

If the research involves treatment include:

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Print Name of Adult Participant

If authorization is to be obtained from a legally authorized representative -- e.g., parent(s), legal guardian or conservator - signature line(s) for representative(s) must be included on the authorization, as well as a description of his/her authority to act for the participant:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

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

Print Name of LAR

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
LAR’s Authority to Act for Participant

(e.g., parent, guardian or conservator)

If applicable:

**WITHDRAWAL FROM STUDY**

**#**The Protocol Director may also withdraw you from the study and the study medication may be stopped [if applicable], without your consent for one or more of the following reasons: (Note to investigator: check your protocol; you may use these reasons and/or add some of your own).

* + Failure to follow the instructions of the Protocol Director and study staff.
	+ The Protocol Director decides that continuing your participation could be harmful to you.
	+ Pregnancy
	+ You need treatment not allowed in the study.
	+ The study is cancelled.
	+ Other administrative reasons.
	+ Unanticipated circumstances.

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.

**Contact Information:**

Contact information should include the following as appropriate.
****Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, (name of Protocol Director). You may contact them now or later at (Protocol Director’s phone number).

****Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, (name of Protocol Director) at (Protocol Director’s phone number).

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.

****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 applicable:

Alternate Contact: If you cannot reach the Protocol Director, please contact (name) at (phone number and/or pager number).

If the contact person for both the first two paragraphs will be the Protocol Director, you may combine the two as follows:
If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask 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.

**EXPERIMENTAL SUBJECTS BILL OF RIGHTS:** As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

* be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* be given a description of any attendant discomforts and risks reasonably to be expected;
* be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* be given an opportunity to ask questions concerning the experiment or the procedures involved;
* be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
* be given a copy of the signed and dated consent form; and
* be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

If you would like to contact participants about future studies, include the following statement:

May we contact you about future studies that may be of interest to you?

\_\_\_\_ Yes  \_\_\_\_ No

****The extra copy of this signed and dated consent form is for you to keep.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Adult Participant  Date

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

Print Name of Adult Participant

When consent is obtained from legally authorized representative(s) (e.g., parent(s), guardian or conservator), include these signature lines for representatives and a description of their authority to act for the participant:

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

Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

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

Print Name of LAR

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

LAR’s Authority to Act for Participant

(e.g., parent, guardian or conservator)

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

(If available) Signature of Other Parent or Guardian Date

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

Print Name of Other Parent or Guardian

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

Authority to Act for Participant

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

Signature of Person Obtaining Consent Date

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

Print Name of Person Obtaining Consent

Add the following if you are using the Short Form Consent Process:

****The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

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

Signature of Witness                                                        Date

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

Print Name of Witness

*(e.g., staff, translator/interpreter, family member)*

* *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
* *The English consent form (referred to as the "Summary Form" in the regulations):*
	+ *Must be signed by the witness AND the Person Obtaining Consent (POC).*
	+ *The non-English speaking participant/LAR does not sign the English consent.*
	+ *The non-English speaking participant/LAR should not sign the HIPAA participant line*
	+ *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*