**STANFORD CONSENT FORM** with **HIPAA Template**

**<<INSTRUCTIONS PAGE>>**

Informed consent is required to provide potential participants or their legally authorized representatives with the information necessary for a “reasonable person” to make an informed decision about participating in research. Information in the consent form must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level.

* Consent text instructions are highlighted in blue and should be deleted.
* Required language:

**\***Denotes text that must appear verbatim

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

* Blue text represents information about the study that you must add.
* Be sure to use plain language to define all medical terms. See [Lay Language Glossary](https://stanfordmedicine.box.com/shared/static/c55fwg30hr0w92awpbfgk3jaca7o6w0x.pdf) [and other resources](https://researchcompliance.stanford.edu/panels/hs/forms/consent#templates)
* Consider using large font if you anticipate recruiting participants with visual

 impairments, e.g., older populations, or for eye studies

* Use a file name for each consent document that clearly identifies the type of consent and for which participants it is intended (e.g., adult informed consent, parental informed consent, etc.).

For questions about informed consent, please contact irbeducation@stanford.edu.

 **-------------Delete the information above this line before submitting--------------**

**STANFORD UNIVERSITY**

**CONSENT TO BE PART OF A RESEARCH STUDY**

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 include children, revise the consent form to refer to the participant as “your child...."

**\***Are you participating in any other research studies? \_\_\_\_\_ Yes \_\_\_\_\_No

**Participant identification:** Required on each page of consent forms for studies conducted at SHC and Stanford Medicine Children’s Health.

The Participant ID may be entered in the box below – this could be the participant’s name, initials, medical record number, study number – but it must ***not*** be used for the participant’s signature or social security number.  Anything entered online in this box will populate to all pages of the consent form.  Entering the name of the specific participant in the Participant ID box is ***not*** considered a modification of the approved consent form.

You may choose another way to identify the participant on each page, e.g. affixing a chart label, but if you do so, please remove the unused box unless it will be covered by a label.

**STUDY barcode:** To avoid scanning errors all photocopies must be generated directly from an original printed version – no copies of copies, please.

**# Concise Summary:** If your study is federally supported, regulations require the consent form include a concise summary of the key information a reasonable person would want to have in order to make an informed decision about whether or not to participate in the research.

Use the bulleted list below to draft your key information as a concise summary, and insert that language into the beginning of the consent, just before the “Purpose of the Research” section:

* The fact that consent is being sought for research and that participation is voluntary;
* The purpose(s) of the research, expected duration of the subject's participation, and the procedures to be followed in the research;
* Reasonably foreseeable risks or discomforts;
* Benefits to subjects or others that may be reasonably expected from the research; and
* Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject.

Other topics to consider:

* Most important reason why a participant would and would not want to participate.
* How will they feel during the study?
* What is the science?
* What's the difference between being in the study, and being treated for their condition?
* Will someone profit from the use of their samples or data?  Will they?
* What happens if they want to stop?
* Have other people taken this drug/used this device?  What happened to them?

**PURPOSE OF RESEARCH**

You are invited to participate in a research study of state what is being studied. We hope to learn state what the study is designed to discover or establish. You were selected as a possible participant in this study because state why the participant was selected.

**#**This research study is looking for state number of people with disease or condition. Clarify if enrollment will occur throughout the United States or internationally. Stanford University expects to enroll state number research study participants.

**VOLUNTARY PARTICIPATION**

\*Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take approximately x days, weeks, months, etc. (e.g., this is a 2 year study; 28 days of active participation by each participant; and 180 days collection of information for each participant).

* If there is a washout period, explain this in lay terms, including the length of time.
* If there is a follow-up period, state so and the expected length of time.

**PROCEDURES**

If you choose to participate, the Protocol Director and research study staff will describe all procedures to be followed. Consider inserting a simple chart or calendar; if using a schedule of events from a sponsor protocol, please use lay language within or define all acronyms. Images and diagrams can be very helpful to participants. Chronological descriptions are also helpful. Be sure to use lay terminology throughout and define all medical terms.

Include the following, as applicable, in this section of the consent:

* Clearly identify what is experimental in this study.
* State the purpose(s) of the procedures. Suggestion: refer to your protocol to assist you in identifying all protocol-related procedures.
* State how often each procedure will be done and how long it is expected to take.
* Identify invasive procedures, where applicable.
* If contraception is recommended, describe specifics for all participants.
* For labs and specimen collection: state what specimens will be obtained and the estimated frequency, volume, or size. The total volume should be calculated and presented to the participant in lay terms, e.g., the number of tablespoons of blood drawn.

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

You must include one of the following 2 statements regarding future research:

**\*** Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens 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 and/or specimens will not be used or distributed for future research studies even if all identifying information is removed.

If collecting specimens, state:
Your specimens will be stored insert how specimens will be stored – and if appropriate how specimens will be linked) e.g., under diagnosis and medical record or code number and unlinked.

If unlinked (if applicable): Because your specimens will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the specimens after they are taken.

If specimens will be sent out of Stanford for analysis, include a statement: **\***Your specimens will be sent outside of Stanford for analysis.

If specimens could be part of, or lead to the development of a commercially valuable product, include the following:

**\***Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Include the following language if future research on specimens will include genetic testing:

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators [may/will] do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. 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.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

A statement on whether or not whole genome sequencing will occur (include for all research involving specimens): \* The process of determining all or nearly all of your DNA sequence is called whole genome sequencing.It is different from genetic testing that does not involve whole genome sequencing because it provides a much more detailed snapshot of your genome.This research [will/might/will not] include whole genome sequencing.

INFORM PARTICIPANTS WHETHER RESULTS WILL BE RETURNED:

If investigators will not share the research results with the participant, the following language can be added:

The results of the study of your data and/or specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

OR

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

If investigators will allow participants to choose whether they want to receive test results and/or will contact participants in the future, the following language (two choices of language) can be added:

Regarding informing you of the test results, you should understand the following:

* The information may be too limited to give you particular details or consequences;
* You may be determined to carry a gene for a particular disease that can be treated;
* You may be determined to carry a gene for a particular disease for which there is no current treatment;
* You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Or

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your specimens, you should understand the following:

* The information may be too limited to give you particular details or consequences;
* You may be determined to carry a gene for a particular disease that can be treated;
* You may be determined to carry a gene for a particular disease for which there is no current treatment;
* You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Use the following subsections below if applicable to your study:

* MRI
* People of Childbearing Potential
* Reportable Communicable Diseases (e.g., COVID-19, HIV)
* Gene transfer
* Genetic Information Sharing (Genomic Data Sharing)

If your protocol uses MRI, insert the following MRI paragraphs, as applicable.

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.

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.

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.

The following language is recommended when people of childbearing potential (non-pregnant) will be enrolled in an investigational study:

People of Childbearing Potential

If you are a person who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. Please know that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk or state specific risk.

To confirm to the extent medically possible that you are not pregnant, you must have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You must notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If there are risks associated with causing a pregnancy, add appropriate language. [e.g., If you are participating in this study and you could cause your partner to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for at least insert time after last dose of study drug, e.g., 12 weeks after taking your last dose of study medication. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

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.

If you are testing for [communicable diseases](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf) (e.g., COVID-19, HIV) specifically for this research study, please include a statement that positive results will be reported to health authorities:

Reportable Communicable Diseases (e.g., COVID-19, HIV)

You will be tested for communicable diseases list which: COVID, HIV, etc. as part of this research study. If your test results are positive, the results will be reported to health authorities as required by law.

If testing for HIV, include this statement:

If you test positive for HIV, counseling will be provided.

If the protocol involves gene transfer the following must be included (please see [FDA Guidance](https://www.fda.gov/media/113768/download)):

Gene Transfer Studies

The approximate number of people who have previously received the genetic material under the study.

Explain the purpose and duration of long-term follow-up observations, the time intervals, the locations at which you plan to request the subjects to have scheduled study visits or be contacted by other means, and details as to what those contacts will involve.

If there is any possibility that an autopsy may be requested (e.g., to test vector persistence, transgene expression, or related adverse reactions), please include this or similar language:

If you participate in this study, the research doctor may ask your family for permission to perform an autopsy if you pass away while the study is still in follow-up. An autopsy may help researchers learn more about [XYZ]. Because the decision about performing an autopsy would be up to your family, we encourage you to advise them of your wishes. Your family would not be responsible for the costs of the autopsy.

If the protocol involves genetic information that will be deposited in NIH-supported repositories the following three paragraphs must be included:

Genetic Information Sharing

Information from analyses of your coded specimens and your coded information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be

violations to the security of the computer systems used to store the codes linking your genetic information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include: Choose applicable points; refer to your protocol to ensure participants know what is expected of them:

* **\***Follow the instructions of the Protocol Director and study staff.
* Take the study drug as instructed if device, explain what is required for study compliance.
* Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
* Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Tell the Protocol Director or research staff if you believe you or your partner might be pregnant.
* Keep the study drug in a safe place, away from children and for your use only.
* Keep your diaries as instructed.
* Complete your questionnaires as instructed.
* Ask questions as you think of them.
* Tell the Protocol Director or research staff if you change your mind about staying in the study.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify name of PD at telephone number.

Clearly outline the study withdrawal procedures (Suggestion: check your protocol).

If you withdraw from the study, or the study medication is stopped for any reason,

* add anticipated consequences, if any, of discontinuing the study drug or device.
* Clearly state the protocol-specific termination procedures.
* Instruct participants that they must return all study-related supplies, including unused study drug.

**#**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.

**POSSIBLE RISKS,DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

* Describe the discomforts and inconveniences reasonably expected; include the inconvenience of travel.
* If there is a washout period, describe the risks of discontinuing medications.
* *Describe any reasonably foreseeable risks - include for example*
	+ *Physical risks – from study medications and procedures (e.g., venipuncture, exposure to radiation, allergic reaction when treatment includes medication)*
	+ *If this is a placebo-controlled study, there may exist the risk that the disease/condition may go untreated and the subject’s condition may worsen*
* *Include a statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.*

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 is 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 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.**

**POTENTIAL BENEFITS**

* Describe any benefits that may be reasonably expected (key word-“reasonably”). If none can be expected, state so.

After describing any potential benefits, state**:**

**\*** We cannot and do not guarantee or promise that you will receive any benefits from this study.

**ALTERNATIVES**

**#**Describe (in lay terms) the known appropriate alternative treatments/procedures that might be advantageous to the participant, and a statement that participants discuss the potential risks and benefits of the alternatives with a physician.

* List any standard treatment that may be withheld during the study .
* If there is no alternative treatment state:

The alternative is not to participate in this research study [you may also indicate that there may be alternate palliative treatments that are not curative (e.g., some cancer research), if applicable].

**PARTICIPANT’S RIGHTS**

**\***You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

**\***You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov**

Include the following language, if this study has been *or* will be registered on clinicaltrials.gov:

 **\***A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](http://www.clinicaltrials.gov)*,* as required by U.S. Law.  This Web site will not include information that can identify you.  At most, the Web site will include a summary of the results.  You can search this Web site at any time.

**CONFIDENTIALITY**

**#**The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

**\***Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

**\***If this study falls within the jurisdiction of the Food and Drug Administration, include following:

The purpose of this research study is to obtain information on the safety and effectiveness of insert name of drug, device, etc.; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

\*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 specimens 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 specimens 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), keep the following HIPAA authorization language; otherwise, remove it.

**\*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 (formerly 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)

**FINANCIAL CONSIDERATIONS**

Payment

Clearly state if the participant will be paid for participating in the research study.

**#**Include the **amount of payment**, if any, and the schedule of payment. A statement of any anticipated prorated payments to the participant is required.

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.

**#**If the participant will not be paid, use the following statement: You will not be paid to participate in this research study.

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.

Costs

Include the following if there is no treatment involved and there will be no additional costs to the participant due to their participation in the research: **\***There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

OR

Include the following paragraphs if there might be additional costs to the participant due to their participation in the research:

**\***If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

Disclose what institution(s) -- e.g., NIH - or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. The following generic disclosure is acceptable:

**#**Name of institution/company is providing financial support and/or material for this study.

If **consultative or financial relationships exist for the Protocol Director and/or any investigators in a study,** disclose in a separate paragraph in the consent form the name and precise nature of the relationship:

**#**Consultative or Financial Relationships

Examples:

Dr. Jane Doe is a paid consultant to <insert company name>, the company sponsoring this study.

Dr. Jane Doe receives honoraria from <insert company name>, the company sponsoring this study.

Dr. Jane Doe is paid speaking fees by <insert company name>, the company sponsoring this study.

Dr. Jane Doe receives payment for lectures from <insert company name>, the company sponsoring this study.

Dr. Jane Doe is a paid advisor to <insert company name>, the company sponsoring this study.

Dr. Jane Doe is an unpaid advisor to <insert company name>, the company sponsoring this study.

Dr. Jane Doe receives royalties from <insert company name>, the company sponsoring this study.

Dr. Jane Doe has an unpaid consulting relationship with <insert company name>, the company sponsoring this study.

Dr. Jane Doe is a member of the scientific advisory board for <insert company name>, the company sponsoring this study.

**COMPENSATION FOR RESEARCH-RELATED INJURY**

The informed consent form must include language on participant compensation in the event of a research-related injury. Choose one of the two options below depending on the funding for the project. No changes are permitted to this language.

**Industry Sponsored or Funded Projects**

Option 1: Use this language if the industry sponsor or funder **is** paying for medical care costs incurred as a result of research-related injury:

Note: Before submitting the consent form to the IRB, determine if the industry sponsor or funder is paying for medical care costs incurred as a result of research-related injury. If you don’t know, contact your contract officer.

**\*** All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. You will **not** be responsible for any of these costs.

If you receive Medicare benefits, and if the sponsor of this study pays for any study-related treatment, complications or injuries, personal information about you, your treatment, and your participation in this study will be provided to the sponsor, who is required by law to provide it to Medicare.

You do not waive any liability rights for personal injury by signing this form.

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.

**Other Funding or No funding**

Option 2: Use this language for:

1. Projects with federal funding (i.e., NIH funding), Stanford Departmental funding, gift funding, medical scholars funding and projects with pilot or other internal funding.
2. Industry funded projects when the industry funder/sponsor **is not** paying for medical care costs incurred as a result of research-related injury. In these situations, the study must be reviewed and approved by the Risk Assessment Committee (RAC). For information on RAC application, please contact your contract officer.

***\**** All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

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.

**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.

**\***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:
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 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 SUBJECT’S BILL OF RIGHTS**

Add the following Bill of Rights to your consent:

***\****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

 **\*** Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

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

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

Print Name of Adult Participant

When consent is obtained from a legally authorized representative (LAR) or representatives (e.g., parent(s), guardian or conservator), include 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.*