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

**For MINIMAL RISK Medical Human Subject Research**

## e.g., for blood draws, information collection, leftover specimens, interviews, surveys, behavioral interventions.

* 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 recordings, if applicable, and what will become of the recordings after use, e.g., shown at scientific meetings; describe the final disposition of the recordings).

This research study is looking for (state number of people) to be enrolled. Clarify if enrollment will occur throughout the United States or internationally. Stanford University expects to enroll (state number) research study participants.

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;* anddescribe 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)

Please initial your choice: \_\_\_Yes \_\_\_No

If specimens will be obtained for this research, include this statement as applicable: **\***This research will/might/will not include whole genome sequencing.

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.

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.

**\***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 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.

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.

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.

**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.

**REIMBURSEMENTS:**

# 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**.**

For studies involving surveys: You have the right to refuse to answer particular questions.

*\*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), 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 (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.

If this consent is to be used for *medical experimentation\* (e.g., blood draws)*, include the following Experimental Subjects Bill of Rights: *[\*Severance, penetration, or damaging the specimen of a human subject, or using a drug, device, electromagnetic radiation, heat cold, or a biological substance or organism, in or upon a human subject, or withholding medical treatment, in a manner not reasonably related to maintaining or improving their health or otherwise directly benefiting them.]*

**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.*