Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title:

Principal Investigator:

Site Principal Investigator:

Description of Subject Population:

INSTRUCTIONS: Many sections of this document include brief instructions to provide the user with a general overview of information required in the section. The instructions are shaded so that you can tell the difference between the instructions and required information. Some sections are password protected and cannot be edited. Detailed instructions for preparing consent forms are available at: **https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/Research-Consent-Form-Templates.aspx.**

Please delete all shaded instruction boxes prior to submitting this form to the Partners Human Research Committee (PHRC) for review. To delete, select a shaded box and click the cut button on the Word toolbar.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

INSTRUCTIONS: Include the following paragraph **only** if some or all of the adult subjects are incapable of providing consent and permission for their participation will be obtained from their authorized representative. Delete the following paragraph when all subjects are adults capable of providing consent.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

INSTRUCTIONS: Include the following paragraph **only** when some of the subjects are minors (less than 18 years of age) and permission for their participation will be obtained from their parent(s)/guardian. Delete the following paragraph when all subjects are adults.
Note: For studies that are limited to minors, use the Parent Consent Form, and if minors are less than 14, also prepare a Youth Assent Form.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part study.

KEY INFORMATION

This section is only required for studies approved by Partners IRB on or after 1/21/19.

This section is designed to meet the regulatory requirement that consent documents begin with a concise and focused presentation of key study information. The Key Information section should be no longer than 1-2 pages. Consent forms 5 pages or less do not require a key information section.

The goal of this section is to assist potential subjects with understanding the reasons why one might or might not want to participate in the research. This section should address:

- The information you hope to learn from the study.
- How long the subject will be in the study.
- What type of procedures/activities subjects will be asked to complete.
- Potential benefits to subjects or others that may be important in deciding whether to join the study.
- Important risks or reasons why a potential subject would not want to join the research study. For treatment studies, this might include side effects that are different from those associated with standard treatment. It could be those risks a clinician would consider essential to discuss with a patient.
- Appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
- Contact information for the research team and IRB.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about _____.

How long will you take part in this research study?

If you decide to join this research study, it will take you about **[X days/weeks/months/years]** to complete the study. During this time, we will ask you to make **[X]** study visits to **[HOSPITAL/ STUDY LOCATION].**

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen **[include brief description of procedures, for example include: blood sample collection, physical exams, biopsies, etc.]**.

Why might you choose to take part in this study?

[Include the following if there are potential direct benefits to subjects. Otherwise delete.] We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include _____. Others with **[medical condition]** may benefit in the future from what we learn in this study.

[Include the following for a study with no direct benefits to participation. Otherwise delete.] You will not benefit from taking part in this research study. Others with **[medical condition]** may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include _____.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are **[include description of time commitment and any travel requirements**].

What other treatments or procedures are available for your condition?

Other treatments or procedures that are available to treat **[medical condition being studied]** include _____.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[Insert name and academic degrees] is the person in charge of this research study. You can call him/her at **[Insert phone number] [insert when person is available M-F 9-5 or 24/7]**. You can also call **[Insert name(s)] at [Insert phone number(s)] [insert when each person is available M-F 9-5 or 24/7]** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **[Insert name(s)]** at **[Insert phone number(s)]**.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

INSTRUCTIONS: At the end of the Key Information leave the remainder of the page blank and add a page break if needed. The next section of the consent form should start on a new page.

Detailed Information

INSTRUCTIONS: Include the following paragraph if the study will be registered on clinicaltrials.gov to meet FDAAA clinical trials registration requirements. This paragraph must be included even if the sponsor is the responsible party for clinical trials registration. This paragraph is not required when registering only to meet journal requirements.

A description of this clinical trial will be available on *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.

Why is this research study being done?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information, when applicable, in this section:

- Purpose of the research, e.g., "We are doing this research to…"
- Information about the drug/device, including FDA status, e.g., "The drug/device is/is not approved by the U.S. Food and Drug Administration (FDA) to treat..."

Who will take part in this research?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information, when applicable, in this section:

- Study population: We are asking you to take part in this research study because you…
- Number of Participants: About 100 people will take part in this research study. About 20 subjects will take part at **[Name of Hospital/Partners Entity]**.
- Sponsor/funding information: **[Sponsor/Funding Agency/Foundation]** is paying for this research to be done.

What will happen in this research study?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information, when applicable, in this section:

- Description of the study visits and procedures the research participants will undergo (whenever possible, organize the information chronologically by study visit, and use headings for visits and bullets to list procedures; indicate how long visits will take)
- Information about the study design, e.g., randomization, placebo, blinding
- Special requirements, e.g., stopping current medications, fasting before tests
- Off-site testing, e.g., MRI center in Charlestown
- Partners Alert System, include statement, **"**Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study."
- Reasons for and procedures for early withdrawal from the study, e.g., tapering medications, final study visit.
- Sending data/specimens to research collaborators outside Partners,
- Study information that will be included in the electronic medical record: In most studies, some information from the research will become part of the subject's electronic medical record. Include one of the statements below. The IRB will review your selection of statement, and if it agrees, will approve the use of the statement for the study.

  Study Information Included in Your Electronic Medical Record

  [Statement 1: Use this statement for most studies.]

  A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

  [Statement 2: Use this statement if you consider the study topic to be highly sensitive (for example, studies of sexual practice; sexual victimization; illegal behaviors; alcohol, drugs or other addictive products; or stigmatizing illnesses) such that the study title should <u>not</u> appear in the subject's medical record.]

  A notation that you are taking part in this research study may be made in your electronic medical record. **For this study, only a study number, and NOT the title of the study, will be in your record: for example Study #123.** Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs).

  Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

INSTRUCTIONS: For research involving biospecimens, include the statement below if the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome analyses, all or most of your genes are looked at and used by researchers to study links to **[Generally this should be limited to the disease under study and/or related disorders. Note if your research is subject to the NIH Genomic Data Sharing policy and submitted to dbGaP you may state "many diseases and conditions" if required].**

INSTRUCTIONS: If the tissue/data will be sent to NIH or other tissue/data repositories, include the paragraph below:

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

INSTRUCTIONS: Delete the paragraph below if the tissue/data will only be used for the condition under study and research related to that condition.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.

How may we use and share your samples and health information for other research?

INSTRUCTIONS: The following paragraph is designed to explain to subjects how we may remove identifiers from any samples and health information collected for the study and use or share the de-identified samples and information for other research, now or in the future, without additional consent.

If you know definitively that you will not keep de-identified samples/information to use or share for other research (rare – this might occur, for example, if a researcher is collecting blood samples with no health information and all samples will be used up during the study), you may replace the paragraph below with the following language, but note that PHRC will hold you to the statement in the consent form.

"Your samples or health information collected for this study will NOT be used or shared for other research, even if we remove identifiable information like your name, medical record number, or date of birth."

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

INSTRUCTIONS: The following language is designed to seek permission from subjects to store, use and share identifiable samples and health information for other related research, now or in the future. Include this language if you plan to store, use, and/or share identifiable samples and/or health information for this purpose.

At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Partners for other research related to [**specify disease area – note this should be related to initial focus of research**]. If we share your samples and/or health information with other researchers outside of Partners, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code in a **[password protected computer/locked file].**

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share them for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research related to **[specific disease/condition]**?

☐ YES ☐ NO Initial _____

Will you get the results of this research study?

INSTRUCTIONS: There are three options listed below to choose from when considering whether to return results (aggregate study results and individual results) to subjects: Option 1) You will not return any results to subjects; Option 2) While there are no plans to return any results, you do not want to exclude that possibility; or Option 3) You will return aggregate and/or individual results and have a plan to do so. Choose one option that makes the most sense for your study and delete the others. The issues to consider when returning research results are addressed in the "Return of Research Results" guidance document at this link: https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Points-to-consider-RORR-Final-Guidance.pdf
Note that the issue of returning the results of the research is distinct from the issue of reporting incidental findings. The language options below pertain only to the issue of returning the results of the research. Please see the noted guidance document for assistance with how to address the issue of reporting incidental findings if relevant to your study.

Option 1: If you have determined that you will not return any research results to participants you may use the language in the following section. (Note: This option may continue to be appropriate for some studies, but we recommend that you consider Option 2 because Option 2 allows for some flexibility if return of research results becomes a more standard procedure in the future.)

No. The research study we are doing is only a stepping stone in understanding **[condition].** Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

Option 2: If you do not anticipate or have a plan for returning any results, but do not want to exclude the possibility, you may include the following neutral language.

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We **[modify as needed:** and the researchers involved in this study**]** will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we **[modify as needed:** or the researchers**]** could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

Option 3: If you anticipate returning results (particularly individual results) to subjects (genetic or otherwise), your plan must be extensively discussed in the protocol and consent form. Language that may be used for return of results is included below.

- If the study sponsor gives us general information about the results of the research study to share with you, we will do so.
- Generally, we will not give you or your doctor information about the results of your individual participation in the research study. The research we are doing is only a stepping stone in understanding **[condition]**. Most of the findings that come from studying your samples or information will not be relevant to your personal health. However, in the future, this may change.
- It is important to remember that research results are not always meaningful and are not the same as clinical tests. While you should not expect to get any information about the results of your participation in this research, if experts from the study decide that research results from your samples are of high medical importance, we will attempt to contact you. In some situations, follow-up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these follow-up tests and any follow-up care, including deductibles and co-payments.
- It is possible that you will never be contacted with individual research results. This does not mean that you don't have or won't develop an important health problem.

If your group has a newsletter or other way of *generally* notifying subjects of research results, the following sentence can be added to any of the above statements.

You can choose to get a newsletter that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about **[condition]**. We will also publish what we learn in medical journals. In the future, when research results are published, they may show that certain groups (for example, racial or ethnic groups, or men/women) have genes that are associated with increased risk of a disease. If this happens, you may learn that you are at increased risk of developing a disease or condition.

What are the risks and possible discomforts from being in this research study?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. The information in this section should be limited to the risks and discomforts related to the procedures done for research purposes, and should not include those related to a research participant's routine medical care. Be careful not to minimize risks or discomforts. Include the following information in this section:

- Reasonably foreseeable physical, psychological, economic, legal, or social risks, or discomforts that may result from study procedures (drugs, devices, tests), or from a breach in confidentiality
- Unforeseeable risks that may result from study drugs, devices, procedures, e.g., "There may be other risks that are currently unknown."

What are the possible benefits from being in this research study?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Do not include compensation as a benefit. Include the following information in this section:

- Reasonably expected benefits to the participant (if any)
- Reasonably expected benefits to future patients with the disease/condition being studied.

What other treatments or procedures are available for your condition?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information in this section:

- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Be specific; when mentioning alternative drugs used to treat the medical condition being studied, provide the name of 3-5 alternative drugs. For example: "You do not have to take part in this study to be treated for [medical condition being studied]. Other treatments or procedures that are available to treat [medical condition being studied] include:
    - [list alternatives]"
- Palliative care or no treatment, when appropriate

Note: This section may not be relevant for all studies. You may delete this section heading if the study involves healthy volunteers and/or is designed to study human physiology. This section should be included when the research is designed to test the safety and/or effectiveness of a procedure or course of treatment, or if the tests or evaluations are available outside the study.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information in this section:

- Money or other forms of compensation or reimbursement, e.g., gift certificate, meal voucher, parking voucher, and travel expenses
- Include how the amount of compensation is calculated if the participant does not complete the entire study for any reason, e.g., "If you do not complete the study, we will pay you $25 for each visit you complete."
- You will not be paid for taking part in this research study.

- If you are collecting biospecimens, include the possibility that the biospecimens collected for this research will be used for commercial profit and, if so, whether subjects will or will not share in this commercial profit.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

INSTRUCTIONS: The following information is provided to help you prepare this section of your consent form. Include the following information in this section:

- Costs that are paid for by study funds, e.g., "Study funds will pay for the study drug and the MRI that is done only for research."
- Any additional costs to the participant that may result from participation in the research, including costs associated with routine care billed to health insurers

  A common misconception amongst patients is that if they participate in a research study all of the costs of their care will be covered by the research sponsor. Although this is true in a few cases, the hospital is entitled to and generally will bill a subject's health insurer for, among other things, routine care that the subject would have received had they not participated in the study. Although the amounts vary by insurer, a research subject is likely to be responsible for co-pays and deductibles associated with this routine care. It is important to make sure that patients who volunteer to participate in your research study understand their potential financial responsibility. If these or other costs billable to insurance or billable to the subject directly can be identified in advance (such as through a Medicare Coverage Analysis billing grid), it is a good idea to give the subject notice of specific items or services that may result in significant financial responsibility for the subject. If specific amounts cannot be identified in advance, you should make sure that the subject understands that they might incur some financial responsibility as a result of their participation.

  At a minimum, you must include the following language in the consent form:

  "Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for

payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs."

Note: You may add further language to describe specific items/services/amounts that will be the subject's responsibility, but you may not delete any portion of the standard language.

What happens if you are injured as a result of taking part in this research study?

INSTRUCTIONS: Include the following paragraph if this study is being conducted at BWFH, MGH or NSMC.

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

INSTRUCTIONS: Include the following paragraphs if this study is being conducted at McLean Hospital.

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

INSTRUCTIONS: The sponsor may request to include a statement about the injury coverage the sponsor will offer. When the sponsor requests to include such a statement, the statement may be entered below, after the institution's commitment to provide care for the injury. For example: "In this study, [Sponsor] will pay for medical treatment for any injury that is not paid for by your health insurer if the injury is a direct result of your taking part in the study. [Sponsor] has no plans to offer you any other payments or other type of compensation."

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

GENERAL INSTRUCTIONS: Include signature line(s) as appropriate to the subject population and consent process described in the protocol documents. Delete those signature lines that are not applicable. Note: Time is highly recommended when study procedures will be performed on the same day as informed consent is documented. Otherwise time is optional.

INSTRUCTIONS: Include the following signature line when informed consent and authorization for participation of some or all subjects will be obtained directly from the subjects.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject | Date | Time (optional)

INSTRUCTIONS: Include the following signature line when informed consent and authorization for participation of some or all child subjects will be obtained from parents/guardian.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child | Date | Time (optional)

INSTRUCTIONS: Include the following signature line when informed consent and authorization for participation of some or all adult subjects will be obtained from a guardian, health care proxy, durable power of attorney, or family member/next-of-kin.

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy

☐ Durable Power of Attorney
☐ Family Member/Next-of-Kin

Signature _____ Date _____ Time (optional) _____

INSTRUCTIONS: Include a line for relationship to adult subject when informed consent and authorization for participation of some or all adult subjects will be obtained from a family member/next-of-kin.

Relationship to Subject:_____

INSTRUCTIONS: Include this section when assent of children ages 14-17 or of decisionally-impaired adult subjects will be obtained. Do not include this section for assent of children ages 7-13. For assent of children ages 7-13, use the separate Youth Assent Form.

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

INSTRUCTIONS: Include signature line(s) for children ages 14-17 or decisionally-impaired adult subjects as appropriate to the subject population and assent process described in the protocol documents. Delete those signature lines that are not applicable. When assent of subjects will be obtained, always include at least one of the following signature lines.

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Child, Ages 14-17	Date	Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

INSTRUCTIONS: The PHRC does not routinely require a subject advocate be involved in the consent process; therefore, delete this section unless the sponsor requires a subject advocate, or you plan to use a subject advocate. Should the PHRC require a subject advocate, they will instruct you to add the following signature line to the consent form.

Subject Advocate

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks

out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing and dating below, the subject advocate represents (or "says") that the subject has given meaningful consent to take part in the research study.

Statement of Subject Advocate

I represent that the subject or authorized individual signing above has given meaningful consent.

Subject Advocate (when required)	Date	Time (optional)

INSTRUCTIONS: Include the following signature line when you anticipate using the "short form" consent process to obtain and document informed consent of subjects who do not speak English. For more information, refer to **https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.pdf.**

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name _____ Date _____ Time (optional) _____

INSTRUCTIONS: Include the following signature line when you anticipate enrolling subjects who cannot read or write in any language or subjects who are physically unable to talk or write.

Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

The consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

Consent Form Version:

INSTRUCTIONS: The unlocked area below is provided to help the study site manage consent documents and versions. You may use this unlocked area to type in the file name and location (path name) of the consent document. Alternatively, you may choose to use one of several tools available in Word that automatically adds file name and location and/or date created to the document, as specified by the user. **NOTE: THE USE OF THIS UNLOCKED AREA IS OPTIONAL.**
For example:
Consent Form Created on: 10/18/14 12:57 PM
Consent Form Path/File Name: sfa\RAHRC\PHSResearchConsentForm