St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

March 2019

Greetings IRB Members!
Please read below for current updates on the
SJH Human Research Protection Program.

HRPP Updates

Annual Disclosure of Financial Interests

Members are asked to submit annual Financial Interests Disclosure forms to the HRPP Office by April 30, 2019. The disclosure form is provided with this newsletter and should be submitted to HRPP@stjoe.org. All relationships that may be perceived as or pose a conflict of interest (financial or otherwise) for the preceding 12 months should be disclosed. Questions about the requirement to disclose financial interests or completing the disclosure form can be directed to Adam Pucci, HRPP Manager, at adam.pucci@stjoe.org.

IRB Membership Changes

Two alternate IRB #1 members have recently resigned from the committee: Dr. Terry McMahon, a psychiatrist representing the Covenant Health ministry, had served since November of 2016. Patti Harrold-Runge, a nurse representing the Santa Rosa ministry, had served since May of 2017. Both resigned due to a general winding down of their clinical commitments. Dr. McMahon and Patti were assets to the IRB in their respective areas of expertise and will be missed. Please join us in wishing them well and thanking them for their time and dedication to the SJH IRBs.

Seeking IRB Member

We are still actively seeking a member living in the community of one of our ministries with a non-scientific background, and who is unaffiliated with SJH, to join the SJH IRB as a primary voting member. If you know of an individual who meets this criteria and is interested in serving on the SJH IRB, please put this individual in touch with Adam Pucci.

Reminder – Advise HRPP Office in Advance of Meeting Absences

As a reminder, please notify the HRPP Office, prior to the scheduled IRB meeting dates, if you will not be able to attend a meeting. This ensures we have adequate time to identify an alternate, if needed, to satisfy quorum. Notification can be sent to HRPP@stjoe.org or Theresa Tuckman, IRB Coordinator, at Theresa.Tuckman@stjoe.org.

HRPP Updates Continued

Updated Informed Consent Form Template

In the coming weeks, the HRPP Office will be sharing an updated Informed Consent Form template with the SJH research community. The template serves as a guide to researchers when developing their own informed consent forms for studies and provides general standards for content and language to address regulatory and institutional requirements. Revisions to the template were necessary to address requirements of the revised Common Rule and minor additional updates were made to address other regulatory changes and at the request of the IRB following a recent audit of approved consent forms. The template is provided with this newsletter and a summary of significant revisions is provided below for IRB members' reference:

- Added signature line for Experimental Subject's Bill of Rights (applicable to CA sites only)
- Included template language for new elements of consent (key information, provision of clinically relevant results, whole genome sequencing, future use of data/specimens, commercial profits from specimen testing)
- Added institutional boilerplate language regarding reporting of testing for infectious diseases
- Included template language regarding Certificates of Confidentiality for NIH-funded studies
- Explicitly identified SJH CCR and HRPP as entities that may review participant's information
- Revised language regarding reimbursement for research injury for Medicare beneficiaries to note that if reimbursement is declined, it must be done in writing
- Revised language regarding refusal to participate or withdrawal to more closely align with regulations

Questions about the Informed Consent Form template can be directed to Adam Pucci.

"Become a Research Volunteer" Brochures

As part of an ongoing quality improvement activity, the HRPP Office has been working with our partners in clinical research across the SJH ministries to identify opportunities to raise awareness and enhance understanding of research among our patient communities. An outcome of these efforts was the identification of a need for general informational materials about research that could be made available to patients. FDA has developed such resources and the HRPP Office facilitated the distribution of FDA's "Become a Research Volunteer" brochure to several of our ministries. The brochures are available in multiple languages and customized to direct patients to SJH resources regarding research participation. The HRPP Office has also made the brochure available on its website for potential research participants: https://www.stjhs.org/documents/Clinical-Research/Become-a-Research-Volunteer-Brochure-SJH.pdf

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Financial Interest Disclosure

Please disclose the combined level of financial interest that you, your spouse/domestic partner, and your dependents have had (in the previous 12 months) with companies/entities that (i) sponsor clinical research, and/or (ii) develop, manufacture, or sell medications, medical devices, and/or biologics:

Investments or ownership interest of any value including, but not limited to, stocks and options exclusive of interest in publicly-traded, diversified mutual funds: ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Description and Amount: _____
Received (or anticipate receiving) income of any amount including, but not limited to honoraria (direct or donated), consultant fees, royalties, or other income: ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Description and Amount: _____
Fees for speeches, lectures and/or presentations, or travel/meeting grants: ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Description and Amount: _____
Research grants, foundation funds and/or philanthropy: ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Amount: _____
Proprietary interest of any value including, but not limited to: patents, trademarks, copyrights, and licensing agreements: ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Amount: _____
Employment, office, directorship, partner, trustee, membership on a Board of Directors or Advisory Committee (or personal compensation): ☐ No financial interest ☐ Financial Interest: Company/Entity: _____ Amount: _____

Other Disclosures:

Do you, your spouse/domestic partner, or your dependents hold an interested position (e.g. senior administrative official, Board of Directors membership, Advisory Committee, etc.) within the St. Joseph Health organization that involves any of the following: • Licensing, technology transfer, patents • Investments of the organization • Gifts to the organization when the donor has an interest in the research • Financial interests of senior administrators, directors, or other similar positions • Other financial interests ☐ No ☐ Yes, Explain: _____
Do you, your spouse/domestic partner, or your dependents hold any collaboration agreements with non-commercial entities (i.e. professional or academic collaborations) that may have financial implications? ☐ No ☐ Yes, Explain: _____
Do you, your spouse/domestic partner, or your dependents have any personal interest or involvement with commercial or non-commercial research organizations and or research interest no indicated above that could pose or be perceived as a conflict? ☐ No ☐ Yes, Explain: _____

I have read and agree to abide by the policies which govern Financial Conflicts of Interest in Research as established by the St. Joseph Health organization and the IRB. I also agree to submit on an Ad Hoc basis disclosures that would constitute a financial interest as indicated above.

_____ _____
Signature Date

_____
Printed name

*[**When study involves a Medical Experiment:** Participants must receive the Experimental Subject's Bill of Rights as required by the California Health and Safety Code. **Recommend**: inserting Bill of Rights document before first page of the consent form. **When Sponsor does not allow for insertion into consent document add**:* "Before you read this consent form you should read a copy of the Experimental Subject's Bill of Rights." *(Provide as separate document.)]*

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form.

10. 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.

Participant *(Print name)*:	
Signature:	**Date:**

ST. JOSEPH HEALTH INFORMED CONSENT TO PARTICIPATE IN RESEARCH

[Please delete all instructional notes within each bracket throughout the consent, including these instructions. Refer to the Guidance on Informed Consent when writing this consent document.]

STUDY TITLE:

Principal Investigator:
Site Location:
Study Sponsor:

[If the study is supported by a Federal agency (e.g., NIH), the consent document is required to begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding why one might or might not want to participate in the research. Include this information in the "Key Information" section using the template below as a guide. The information presented in this section will be discussed in greater detail later in the consent document. If the study is not supported by a Federal agency, the "Key Information" section is not required and may be deleted.]

Key Information

You are being asked to voluntarily participate in a research study. The choice of whether or not to participate is up to you. The purpose of the study is to *[briefly state the primary objective of the research]*. Participants in this study will *[briefly summarize the main study procedures; if applicable, identify any procedures that are experimental, how the experimental procedures differ from standard of care, and if the research involves randomization or placebo]*. Participation in this study will involve *[number of study visits]* number of visits, each lasting about *[study visit duration]*, over *[total study duration]*.

The risks of being in this study are *[briefly summarize the most likely and most significant risks associated with the research]*. There are other risks that are described further below. We hope that this study will *[briefly state the anticipated benefits of the research to subjects and/or society]*. *[If this is a treatment study, include the following:* If you choose not to participate in this study, your alternatives include *[briefly state the other treatment options available to subjects]*.

If you are interested in learning more about this study, please continue to read below.

Introduction

We are asking you to be in this research study because you *[insert the condition or reason to be studied here]*. To make an informed decision on whether or not you want to be part of this study, you should understand the risks and benefits of participating. This process is called informed consent.

This informed consent document describes a research study. The form explains:

- Why we are doing this study.
- What you will need to do during this study.
- If there is a chance you might experience benefit from participating in this study.
- The risks and discomforts that might occur because you are in this study.
- How the personal and/or medical information about you obtained during this study will be used and shared.

Your study investigator, _____, will explain this research study to you. You do not have to participate in this research study. You should take your time making your decision about participating in this study. Before you decide, you may want to discuss the information in this document with your friends, family, or other physicians who take care of you. If you have any questions, you can ask your study investigator.

[For applicable clinical trials governed by the FDA insert the following:]
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.

If you do not have access to the internet, you can contact the study staff to provide or assist you with this information.

If you choose to be in this study, you should sign this form. If you do not want to be in this study, you should not sign this form. Choosing not to participate in this study will not affect your current or future care with your doctors or the hospital.

If you decide to participate in this study, you will receive a copy of this form.

Why is this study being done?
The purpose of this study is to *[insert a brief description in plain language of the condition being studied and the expected outcome. If using an experimental drug, device, or procedure briefly describe any previous studies in humans and a description in plain language of the mechanism of action of the item under study.]*

How many participants will take part in the study?

About *[insert number]* participants will take part in the entire study.

If I take part in the study, can I or the study investigator select what treatment I will get?
[For treatment studies only: delete section if N/A]
[*First, state "Yes" or "No." If "No," continue with the section below.]*

[For randomized studies:] We will use a computer to randomly assign you to one of the *[insert number]* study groups. Random assignment means that you are put into a group by chance *[if 2 groups]* like a flip of a coin *[OR] [if more than 2 groups]* like drawing numbers out of a hat.

Your study group assignment will determine the treatment you will receive. Neither you nor the study investigator can choose the group you will be in. You will have a(n) *[insert the numerical expression as "x out of y" or "equal"]* chance of being placed in any group.

> **If you are in group 1 (often called "Arm A") …** *[Explain what will happen for this group with clear indication of which interventions depart from routine care. If giving a drug or other treatment, indicate the dose and route of administration]*
>
> **If you are in group 2 (often called "Arm B")…** *[Explain what will happen for this group with clear indication of which interventions depart from routine care. If giving a drug or other treatment, indicate the dose and route of administration]*
>
> *[For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]*
>
> *[If a placebo is used, describe placebo as "a pill that does not have any drugs or medicines."]*

Will I know which treatment I am getting? *[For treatment studies only: delete section if N/A]* [*First, state "Yes" or "No." If "No," continue with the section below]*.

> *[For double-blind studies:]:* Neither you nor your study investigator will know which treatment you are getting. In case of an emergency, your study investigator can get this information.
>
> *[For single-blind studies:]:* You will not know which treatment you are getting, but your study investigator will know.

What will happen during this research study?

If you agree to participate in this study, you will be asked to sign this consent form. You will have the following *[tests and]* procedures done first to make sure you are eligible to participate:

[List in bullet format any <u>screening</u> procedures. Define any medical terms in plain language]

Indicate whether the test or procedure is routine care or part of the study.]

After you have completed the screening period, *[you will have the following tests and treatments/the following will happen]*:

[List in bullet format all tests, therapies, treatments, and procedures done as part of the study and their frequency. Indicate whether a test or procedure is routine care or part of the study.]

[For Non Treatment studies: Describe in detail all processes, tools, and design methods that are being done as part of the study]

[For all types of studies: If questionnaires or other forms of testing are used, describe them briefly in plain language. Submit all questionnaires, surveys, scripts etc. for review]

[For Treatment Studies only: In addition to the mandatory narrative explanation found in the preceding text, a simplified calendar (study chart) or schema (study plan) may be inserted here. The schema from the protocol should not be used as it is too complex; however a simplified version of the schema is encouraged. Instructions for reading the calendar or schema should be included. Any abbreviations used in the calendar or schema should be defined in footnotes.]

[If study procedures involve testing for infectious diseases, such as Hepatitis or HIV, include the following statement:]
Depending on state law, you may have to sign a separate consent form before the Hepatitis and HIV testing can start. The study doctor or study staff will tell you if these test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department. The tests are confidential, and the study doctor or study staff will not share your results outside this study unless state law requires it. The results of these tests must be negative in order for you to be in the study.

[If the procedures, tests, etc. conducted for research purposes only have the potential to generate clinically relevant results, include one of the following statements to inform subjects whether such results will be provided to them.
If the results of research tests will not be provided to subjects include the following statement:]

Since the tests being performed in this study for research purposes are considered experimental, the results of the testing will not be disclosed to you.

[If the results of research tests will be provided to subjects, include the following statement. Note: in general in order to report patient-specific results of tests performed for research purposes the tests must be validated and performed in a CLIA-certified laboratory.] The results of the following tests that are being performed in this study for research purposes will be provided to you and/or you treating physician: *[identify the research tests and any conditions surrounding the release of the results of the tests.]*

[If the research involves the collection of specimens and there is the potential that specimens could be used for research involving 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), include the following:]
The specimens collected from you during this study *[will be used/may be used in the future]* for research involving whole genome sequencing. A genome contains a complete set of a person's DNA. DNA is a chemical in your body that includes of all of your genetic information. Whole genome sequencing is the process of determining the complete DNA sequence of a person. We are doing whole genome sequencing in this study because *[briefly state the purpose of conducting whole genome sequencing in this study.]*

What will happen after I am finished with taking the drugs or intervention? *[For treatment studies only: delete section if N/A]*

[Explain the follow-up tests, procedures, exams, etc required, including the timing of each and whether they are part of the standard of care, but being performed more often than usual or being tested in this study. Define the length of follow-up]

How long will I be in the study?

[For short-term, uncomplicated studies]: You will be in the study for *[insert number of hours, days, weeks, months, etc.]*.

[OR] You will have *[insert number]* study visits over *[insert number]* months.

[For long-term studies with treatment and follow-up phases]:
You will be asked to take *[drugs or intervention]* for [*months, weeks or until a certain event]*. After you are finished taking *[drugs or intervention*], your study investigator will ask you to visit the office for follow-up exams for at least [*indicate time frames and requirements of follow-up. When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of long-term follow-up. Also include if telephone follow-up will continue after the office visits are completed.]*

What is my responsibility? [*Insert as applicable*]
It is important that you inform you study investigator of any changes in your health, whether or not you think that it is related to your participation in this study.

You must tell your study investigator about all medications you are currently taking, or plan to take. This includes both medications prescribed by your regular doctor or medications you are taking without a prescription, (e.g. over-the-counter medicines, herbal medication and vitamin supplements).

If you have been or are participating in another research study, you should inform your study investigator.

It is important that you follow your study investigator's instructions throughout the trial. If you have any questions or need further information, contact your study investigator or study staff.

Can I stop being in the study? *[Modify section as applicable for your study]*
Yes. You can decide to stop at any time. Your participation in this research study is completely voluntary. Please inform your study investigator if you are thinking about withdrawing or decide to withdraw. Your study investigator will tell you how to withdraw safely. This decision will not affect your current or future care with your doctors or the hospital.

It is important to tell your study investigator if you are thinking about withdrawing so any risks from the *[drugs or intervention]* can be evaluated by your study investigator. We will ask you to

come to the office for a final physical examination and to discuss what follow-up care and testing could be most helpful for you.

The study investigator or study sponsor may stop you from taking part in this study at any time if it is in your best interest. You may be removed from the study if *[Provide reasons applicable for this study protocol. Examples: if you are not taking your medicine properly, miss study visits, become pregnant, or if the study is stopped by the sponsor.]*

Are there side effects or risks related to participating in this study?

[For non- treatment studies list all possible risks related to the study and delete "side effects" from the title. Also insert as applicable:] There may be the potential for loss of confidentiality. In addition, there may be unknown risks, or risks that we did not anticipate. For more information about potential risks with participating in this study, talk to your study investigator.

[For treatment studies] You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects; however, study investigators do not know all the side effects that may happen. Side effects may be mild or very serious. Your research team may give you medicines to help reduce the expected side effects. Many side effects go away soon after you stop taking the *[insert drug(s), treatment or procedure*]. In some cases, side effects can be serious, long lasting, or may never go away. *[The next sentence should be included if appropriate.*]: There also is a risk of death. For more information about risks, talk to your study investigator.

What side effects or risks can I expect from being in this study? *[For treatment studies only: delete section if N/A]*

You should talk to your study investigator about any side effects that you have while taking part in the study.

Risks and side effects related to the *[procedures, drugs, interventions, devices]* include the following:

[For Full disclosure and greater readability for the participant: Include risk percentages (e.g. > 3%) or other numerical value (e.g. more than 3 out of 100) for likelihood of potential risks (As available from Sponsor)]

What are the risks to a fetus or embryo if I become pregnant or father a child? *[For treatment studies only: delete section if N/A]*

Whether you are male or female, your participation in this protocol includes treatment which may present certain or unknown risks to a fetus or embryo. You must avoid becoming pregnant or avoid causing a pregnancy while you are participating in this study. You should discuss the alternatives available to you for pregnancy prevention with your study investigator.

[NOTE: SJH Policy requires that our institution follow Catholic Healthcare Directives in pregnancy prevention within the consent form and protocol. This means that the consent form (and protocol) must allow for abstinence as a method of birth control in order to be in conformity with the Catholic Directives. The Reproductive Risks section of the consent does not have to list abstinence as a possible method of birth control, but it cannot exclude it.]

Are there other risks to being in this study? *[For treatment studies only: delete section if N/A]*
Yes. In addition to the risks described above, there may be unknown risks or risks that we did not anticipate that are associated with being in this study.

For more information about risks and side effects, talk to your study investigator.

What happens if I am injured because I took part in this study?
[For non-treatment studies: Modify this section accordingly by inserting language explaining that injury is not applicable as a result from this study because… (insert appropriate language). Example: Because participation in the study does not require taking any additional medicines, changing your current or future treatments or undergoing any additional procedures, no injuries are anticipated in connection with your participation in the study. Delete any language that is not applicable.]

[For treatment studies, patients should seek and receive medical treatment should any injury/illness result from the research procedures/product. The Sponsor is responsible to pay for research-related injuries. Please use the following language]:

If you are injured or become ill from taking part in this study, medical treatment is available. If you think that you may have been injured by participating in this research study, tell your study investigator or a member of the study team as soon as you can. You can either tell your study investigator in person or call your study investigator at _____. If you need to have medical treatment from another hospital, be sure and tell the doctors there that you are part of a research study.

In the event of an illness or injury that is determined to be directly related to the study drug or properly-performed study procedures, the Sponsor, _____agrees to pay all reasonable and necessary medical expenses to treat such illness or injury if:

- you have followed the directions of the Study Investigator; and
- the illness or injury is not due to the natural progression of any conditions existing before you participated in the study.

Medical expenses that fall outside of the above-outlined policy will be billed to you and your health insurance. Be aware that your health care payer/insurer might not cover the costs of injuries or illnesses that occur during your participation in the study.

The treating hospital will not routinely pay for any treatment of research-related illness or injury unless it is proven to be the direct result of negligence by an employee. Please note that the study investigator is not a hospital employee.

Financial compensation for such things as lost wages, disability, or discomfort due to any research-related injury is not available, but you do not give up any legal rights by signing this form.

[The following language is appropriate due to Medicare Secondary Payor (MSP) reporting requirements for clinical sponsors. It is CMS' position that payments made by clinical trial sponsors for study related injuries are considered payments by liability insurance and must be reported under the MSP law. The information requested in the ICF is information the clinical trial sponsor is obligated to report to CMS. This provision would only apply to Medicare beneficiaries who suffer a research-related injury.]

Medicare Beneficiaries:

If you are a Medicare beneficiary and are treated for a research injury or illness and your treatment is paid for by the Sponsor, then the Sponsor and/or its agents or representatives will request that your treating doctor, other healthcare providers, and/or their staff release certain personal and treatment related information about you (such as your name, date of birth, gender, and social security number or Medicare identification number) and information about the trial you are in to (sponsor), its representatives or agents.

If you sign this informed consent form, you are giving permission to (sponsor) and its representatives or agents to collect your personal information and report it to the Centers for Medicare & Medicaid Services (CMS), a U.S. government agency, during your participation in the study and for as long as (sponsor) is required by the government to report this information.

You have the right to refuse reimbursement by the Sponsor for any research injury or illness if you do not want your personal and treatment related information reported to CMS as required by law. However, if you refuse the reimbursement, you will be billed for the cost of any treatment for the research injury or illness. If you choose to decline reimbursement from the Sponsor, you must do so in writing to the study investigator.

Will I benefit from taking part in this study? *[Modify language in this section as appropriate for your study]*

Taking part in this study may or may not make your health better. It is possible that you may get better, stay the same, or get worse. We do know that the information from this study will help investigators learn more about *[procedures, drugs, interventions, devices]* as this information could help future patients with *[insert condition under study]*. *[If there are likely benefits from study participation, they can be listed here.]*

If I choose to not take part in this study, what other alternatives or choices do I have?
Your other choices may include: *[Use the following as applicable]*

- Receiving the usual treatment for *[insert disease or condition here]* that includes *[describe what usual treatment includes]*
- Taking part in another study
- Getting no treatment

[Add any additional bullets when appropriate, for any alternative specific procedures or treatments]

[For treatment studies:] Talk to your personal doctor or study investigator about your treatment choices before you decide if you will take part in this study.

Who will see the medical information about me that is collected during the study?
You will be asked to read and sign a separate Authorization Form for the use and disclosure of your Protected Health Information.
[When the sponsor does not allow for inclusion of HIPAA in the consent form, Provide HIPAA as separate document]

We will follow the appropriate federal laws that say we must keep your study records private and confidential. We will protect your privacy by *[insert in plain language a description of how your site will keep health information protected.]*

However, we cannot guarantee total privacy and confidentiality. Your personal information may be given out as required by law. Certain people may need to see your study records, and these people must also keep the records confidential. The people who may also see your information are:

- *[List relevant organizations like study sponsor(s) and its affiliates, pharmaceutical company collaborators, etc.]*
- The St. Joseph Health Center for Clinical Research, Human Research Protection Program, and Institutional Review Board, a committee whose purpose is to protect the safety and welfare of research subjects.
- The Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) *[If FDA-regulated drug or device, also add* "U. S. Food and Drug Administration (FDA)] that are involved in keeping research safe for people.

When the research results are published or discussed in conferences, no information will be included that reveals your identity.

[Include one of the following statements to describe the potential future use of subject's information or specimens beyond the current study:

If information or specimens may be stored for future research studies, include the following statement:]
It is possible that the data *[or specimens]* collected during this study may be used or distributed to other investigators for future research studies without additional consent from you if information that could be used to directly identify (such as your name or medical record number) you is removed from the data *[or specimens]*.

If information or specimens will not be stored for future research studies, include the following statement:]
The information *[or specimens]* collected during this study will not be used or distributed for future research studies.

[For studies funded by NIH, include the following language to describe the protections afforded by a Certificate of Confidentiality, which is automatically issued to all NIH-funded human subjects research]:
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.

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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law about incidents such as child abuse, the intent to hurt yourself or others, or to report certain communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

[When applicable for studies involving Genes (genetic studies) or taking additional blood/specimen samples for genetic research, insert the following language:] [Note: Please also complete Attachment B of the Initial Application.]
A federal law (Genetic Information Non-Discrimination Act, GINA) will help lower the risk from health insurance or employment discrimination on the basis of genetic information. The federal law does not include other types of misuse by life insurance, long-term care or disability insurance. If you want to learn more about the GINA Law, which went into effect in 2009, you can find information about it on the internet or ask the study staff. In addition to the federal law, some states have laws that also help protect against genetic discrimination.

What are the costs of taking part in this study?

[For Non Treatment Studies: If the subject is responsible for any costs please describe. If there are no costs to the participants please state that in this section]

[For Treatment Studies: If the participant or their insurance company are responsible for costs of the medical care and drug used in the study insert the following:]
You or your health insurance company (or both) will need to pay for some or all of the costs of your treatment in this study. Some health plans will not pay these costs for people taking part in research studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment.

[If the sponsor is responsible for all research costs insert]:
There will be no extra costs to you because you are participating in this study. Any routine medical care that you would have received even if you were not in this study will be billed to your insurance company or you. Some insurance plans will not pay for these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for.

The study sponsor will supply the *[study agent(s)]* at no charge while you take part in this study.

Will I be paid for participating in this study?
[Answer "Yes" or "No." If "yes" include a statement about the amount of payment and how it will be distributed. Also include the 1099 tax language below:]
The law requires that *St. Joseph Health (or entity issuing stipend)* submit an IRS 1099 for individuals to whom it provides payment or compensation exceeding $600 per calendar year. Compensation provided by this research study will count toward the annual total for this purpose. We will ask for your Social Security Number to file this form.

[Studies under SJHH oversight only] (Greenphire Language)

As a participant in this study, you will receive payments of $XX.XX per visit to help support your participation (time and travel) in the clinical trial. You will be paid for each in clinic study visits that you complete, even if you do not complete the overall study.

Greenphire is a company working together with "Institution Name" to manage the reimbursement process. You will be issued a Greenphire ClinCard, which is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available following the completed visit and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen a replacement card will be provided, at an additional charge.

Additionally, you will have the option to receive updates related to appointment reminders and payment alerts via text message (standard text messaging rates will apply) or email message. You will have the opportunity to opt-in to receive these messages. You are not required to provide your cell phone or email address to be enrolled in the study or to use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire will need to collect information about you, including:

- Your name
- Your address
- Your date of birth

This information will be collected from you by the staff at your study doctor's site.

All information is stored in a secure fashion and conforms to regulations relating to Personal Data Protection. Your information will not be shared with any third parties or the Sponsor of this trial and will be kept completely confidential. Your information will be deleted once the study has completed and the funds on your card have been exhausted.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program. Please be aware that some fees may apply for inactivity (over a period of 3 months), and specific transactions. Please be sure to read the instructions that come with the ClinCard so that you are aware of potential fees that may apply.
The law requires that St. Joseph Heritage Healthcare submit an IRS 1099 for individuals to whom it provides payment or compensation exceeding $600 per calendar year. Compensation provided by this research study will count toward the annual total for this purpose. We will ask for your Social Security Number to file this form. If you are unable or unwilling to provide a Social Security Number or Tax ID Number per federal reporting requirements, this could affect

your overall stipend amount as federal regulations require the institution to withhold 28% for tax purposes.

[If the research involves the collection of specimens, include the following:]
Any specimens collected during this study will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value. You will not receive any profits or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Does the study staff receive payment for doing this study?
[Sponsor] is paying for this study. The study investigators and hospital are being paid by the companies or other organizations sponsoring this study for their time spent and services rendered in conducting the study. No one receives a direct payment or an increase in salary from *[sponsor]*.

[Please state if an investigator receives other compensation from the sponsor such as consulting fees, speaking fees or royalties. Also include the following statement: You should discuss this matter with your study investigator if you feel that it may affect your decision to participate in this study.]

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your health care or other benefits to which you are otherwise entitled. Leaving the study will not affect your medical care.

By signing this form, you do not lose any of your legal rights to seek payment in case of injury resulting from this study.

[*Insert if applicable*] Sometimes during the course of a research study, new information becomes available about the *[drug/device]* that is being studied. If this happens, we will inform you about this new information or changes in the study that may affect your health or your decision to continue in the study.

Who can answer my questions about the study?
You should talk to your study investigator about any questions or concerns you have about your participation in this study. Your study investigator can be reached at _____. *[If there is one number for business hours and another contact number for after hours, weekends, and holidays, list both with the appropriate designation]*.

If you have any questions about your rights while participating in this study, or if you have any concerns regarding the conduct of this study, you may contact the St. Joseph Health Human

Research Protection Program (HRPP) Office at 949-381-4907, by mail at 3345 Michelson Drive, Suite 100, Irvine, CA 92612, by email at HRPP@stjoe.org, or via the Internet at www.stjoe.org/Research.

Signatures

My signature below indicates that I have been informed by the study investigator about the nature, purposes, risks and benefits of the above-named study. I have read and understand the information contained in this consent form. I have had sufficient time and have had the opportunity to consider the information, ask questions and confirm that my questions have been answered to my satisfaction. I understand that I am under no obligation to participate.

I have been provided with a copy of the Experimental Subjects Bill of Rights. [*remove this sentence when not included in the consent document or if not applicable*]

I know I will be asked to sign a separate Authorization Form. *[Only Insert when HIPAA is not included in the consent document]*

Therefore, I am willing to participate and freely giving my consent to participate in the above-named study.

After signing below, I will receive my own copy of this form.

[For appropriate documentation of informed consent for consenting adults/LAR: Includes acknowledgement of receipt of a copy of the Experimental Bill of Rights and need to sign separate Authorization form if not included in the ICF. Includes section for witness signature to be used when short form consent process is used or when subject (or LAR) cannot read, write, talk and/or is blind

Participant *(Print name)*:	
Signature:	Date:

Legal Authorized Representative (LAR) (If Applicable) *(Print name)*:	
Relationship to Participant:	
Signature:	Date:

Study Investigator or Designee who obtained consent *(Print name)*:	
Signature:	Date:

Impartial Witness (If Applicable*) *(Print name)*:	
Signature:	Date:

**Applicable when short form consent process is used and when subject (or LAR) cannot read, write, talk and/or is blind.*

AUTHORIZATION FOR USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

What is the purpose of this form?

This Authorization gives you information about how your health information may be used and disclosed to others as part of the research, and who may disclose and receive your health information.

State and federal privacy laws protect the use and release of your health information. Under these laws the hospital cannot release your health information to the research team unless you give your permission. If you decide to give your permission and to participate in the study, you must sign this form as well as the consent form.

By signing this document, you agree to the release of certain personally identifiable health information by the hospital, your study investigator, and the research team.

What Protected Health Information will be released?

If you give your permission and sign this form, you are allowing the hospital to release the Protected Health Information collected during this research study and information from your hospital records within this institution that may be reasonably related to the conduct and oversight of the research study. Your Protected Health Information includes health information in your medical records and information that could personally identify you. For example, Protected Health Information may include your name, address, phone number, medical record number or social security number.

Possible Disclosures

Researchers can only use and disclose your health information for purposes approved by the IRB or as required by law or regulations and will continue to protect your personally identifiable health information as described in the above consent form. The information may be subject to re-disclosure and the HIPAA Privacy Rule may not apply in those circumstances. SJH entities comply with the requirements of the HIPAA Privacy Rule and its privacy regulations, and with all other applicable laws that protect the confidentiality of your health information.

How will my Protected Health Information be used?

Data that is recorded about you may be sent to the sponsor and members of the research team by your study investigator.

Data recorded about you may also be released to the following agencies and companies for purposes of study oversight such as:

- Federal government regulatory agencies
- The U.S. Food and Drug Administration (FDA),
- The SJH Center for Clinical Research, Human Research Protection Program, and Institutional Review Board
- *[Continue to insert all people, organizations, labs, sponsor affiliates and other oversight agencies, as applicable]*

Data recorded about you may be used for the research purposes described in a consent form, including activities of the research sponsor, NIH, or other agencies as required by law.

If applicable, your information will be disclosed to your insurance carrier for purposes of obtaining authorization for payment and for processing payment of claims related to this research.

However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask your study investigator or a member of your research team.

If a report or article is written for publication about the study your identity will not be disclosed.

Does my authorization expire?

This permission to release your Protected Health Information expires after 50 years from the date of your signature, or when the research ends, whichever is sooner.

Can I revoke my authorization?

You can change your mind at any time and revoke your authorization to allow your Protected Health Information to be used in the research. Beginning on the date you revoke your authorization, no new protected health information will be used for research. However, researchers will continue to use your health information that was collected before you withdrew your permission.

Your authorization must be revoked in writing. You can either write to your study investigator or you can ask someone on the research team to give you a form to fill out. If you revoke your authorization, you may no longer be in the research study. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

If you agree to the use and release of your Protected Health Information, please sign below. If you do not agree to the release of your PHI, you cannot participate in the research study, but this will not affect treatment, payment, or eligibility for benefits for which you are normally entitled to. If you have questions, you may contact your study investigator. You will be given a signed copy of this form**.**

Participant *(Print name)*:	
Signature:	Date:

Legal Authorized Representative (LAR) (If Applicable) *(Print name)*:	
Relationship to Participant:	
Signature:	Date: