**Before submitting, delete all blue instructions and guidance text (including these) so they are not in the final version of your form.**

**SAINT AGNES MEDICAL CENTER**

**Informed Consent and HIPAA Authorization Form for Use and Disclosure of Health Information for Research Purposes**

|  |  |
| --- | --- |
| **IRB Number:** | *(Assigned by Research Compliance Department)* |
| **Study Title:** | *(Enter full study title exactly as listed on the Protocol)* |
| **Principal Investigator:** | *(Enter PI’s name and credentials)* |
| **Sponsor:** | *(Delete if N/A – delete row)* |
| **Funding Source:**  **National Clinical Trial Number:** | *(If none, state as such)*  *(If applicable)* |
|  |  |

**Consent Overview**

**What is the purpose of this research study?**

This study involves research. The purpose of this study is to

**Why am I being asked to participate?**

You are being asked to be in this study because

* Your participation is voluntary; you do not have to participate.
* Your decision not to take part in this research study will not affect your care here.
* If you decide to participate and then later change your mind, you have every right to do so.

**What will I need to do and how long will I be in the study?**

* Once you have consented to participate in this research study you will be asked to *(Include, if applicable, any specimen and/or data collection.)*
* You will be involved in this research study for *(state amount of time, number of visits, number of surveys, etc.).*

**What are the risks?**

We will take steps to protect your confidentiality, but there is a small risk that your information could be accidentally disclosed to people not connected to the research. To try to prevent this, we will only store information about you on our secure server.

Below is a brief list of the most common discomforts or risks: (Delete if N/A)

**What are the benefits?**

**What are the alternatives to my participation?**

**What are the costs?** (Delete if N/A)

**Introduction**

*Include the following language verbatim:*

You are being asked to participate in a research study. If you wish to participate in this study, you will be asked to sign this form.

Before making a decision to volunteer, or not to volunteer, we want you to know as much as possible about the study. The federal government requires we provide this informed consent document to you, and you or your Legally Authorized Representative will be asked to read and sign it. Please read it carefully and talk to the investigator, *(insert name)*, if you have any questions about the study. You may also want to discuss it with your family or friends.

**What are my rights and responsibilities?**

If you choose to participate in this study, you may withdraw at any time by contacting the principal investigator whose contact information is at the end of this form. *(If the participants are* ***employees****, indicate that participation will not have any effect on their employment and describe how this will be achieved. Describe the measures that will be taken to minimize the appearance of coercion or undue influence*.*)*

You will be informed of any new developments that may affect your willingness to continue participating in this study. If new information is provided to you after you have joined the study, we may ask you to sign a new consent that includes this new information.

**Return of study results** (Delete if N/A)

The general study findings will *(Include return of any study results; state timing and mechanism.)*

**Will I be paid for being in the study?** (Delete if N/A)

You will not be paid for your participation in this study.

***or***

*Address amount for each visit, completed questionnaire, etc. and total amount, method and timing of payment.* You will be asked to disclose your Social Security number so that your payments can be processed. If you decline to disclose your Social Security number, you can still participate in the study without being paid.

**HIV or AIDs testing (or) HIV or AIDS status and information** *(Select the best paragraph;* Delete if N/A*)*

Your medical records will be reviewed for your HIV, AIDS and/or AIDS-Related Complex diagnosis, status, and treatment *(delete any you are not looking at)* information. Your HIV, AIDS and/or AIDS-Related Complex status *will/will not* be shared with the study team members and the sponsor of this study. *(add or delete all groups who will see the HIV status)* Under California law all HIV and/or AIDS-Related Complex status information is confidential and cannot be released without your or your Legal Authorized Representative's consent to disclose this information, unless a statutory exception applies. If you do not wish to consent to your HIV and AIDS-related information being used and shared, you *may/may not* participate in this study.

If you do not wish to consent to your HIV, AIDS and/or AIDS-Related Complex information being used, you *may/may not* participate in this study.

*(If you selected "may", add the following; otherwise delete)*

Yes, you may use and share my HIV, AIDS and/or AIDS-Related Complex information –

Initial here: \_\_\_\_\_\_\_

No, you may not use or share my HIV, AIDS and/or AIDS-Related Complex information -

Initial here: \_\_\_\_\_\_\_

**OR**

You will be tested for HIV, AIDS and/or AIDS-Related Complex at screening. The study doctor will share the results of this test with you. You will receive counseling before and after the testing. Positive results for certain infectious diseases, such as HIV will be reported to the local health authorities in your county in California, as required by law. Your testing results *will/will not* be shared with the study team members and the sponsor of this study *(add or delete all groups who will see the HIV status)*. Under California law, all HIV, AIDS and/or AIDS-Related Complex status information is confidential and cannot be released without your *or your Legal Authorized Representative's* consent to disclose this information, unless a statutory exception applies.

If you do not wish to consent to an HIV, AIDS and/or AIDS-Related Complex test and your information being used, you *may/may not* participate in this study. *(If you selected "may", add the following; otherwise delete):*

Yes, I will take a test and you may use my HIV, AIDS and/or AIDS-Related Complex information Initial here: \_\_\_\_\_\_\_

No, I will not take a test and you may not use at my HIV, AIDS and/or AIDS-Related Complex

information

Initial here: \_\_\_\_\_\_\_

**My alcohol, drug, and substance use disorder information** (Delete if N/A)

Your medical records will be reviewed for your alcohol, drug and substance use disorder diagnosis, status, services, and/or treatment *(delete any you are not looking at)* information. *Per Substance Use Disorder law,* ***state how much and what kind*** *of information is to be disclosed, including an* ***explicit description*** *of the substance use disorder information that may be disclosed.*

(Include the following, if applicable:)

You will be tested for *(provide details of all substance use testing)*. The results of this test *will/will not* be shared with you. The test results will be reviewed by the Principal Investigator and *will/will not* be disclosed to *[the sponsor and (include any other institutions that are part of the research]*.

This information *will/will not* be shared with the study team members and the sponsor of this study *(add or delete all groups who will see the information).* Under California law, information about your alcohol and drug diagnosis, records, service, treatment, and status are confidential and cannot be released without your *or your Legal Authorized Representative's* consent to disclose this information, unless a statutory exception applies.

You may cancel your consent for use of this information at any time except to the extent that the information has already been used after consent was obtained. The date, event, or condition upon which your *or your Legally Authorized Representative's* consent will expire (if not withdrawn before) is . ***(This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided)***.

If you do not wish to consent to a drug test and your alcohol and drug information being used and shared, you *may/may not* participate in this study. *(If you selected "may", add the following; otherwise delete)*

Yes, you may use and share my alcohol and drug information - Initial here: \_\_\_\_\_\_\_

No, you may not use or share my alcohol and drug information - Initial here: \_\_\_\_\_\_\_

**My mental health *and/or* *social services* information** (Delete if N/A)

Your medical records will be reviewed for information about mental health diagnosis, status, treatment, and services information *and/or* social services that you have received, including communications made to a social worker or mental health professional *(delete any you are not looking at)*. This information *will/will not* be shared with the study team members and *(the sponsor of this study; add or delete all groups who will see information).* Under California law, mental health information and services *and/or* social services that you have received is confidential and cannot be released without your *or your Legal Authorized Representative's* consent to disclose this information, unless a statutory exception applies. If you do not wish to consent to your information about mental health information and social services that you have received being shared, you *may/may not* participate in this study.

*(If you selected "may", add the following; otherwise delete)*

Yes, you may use and share my mental health information and social services information - Initial here: \_\_\_\_\_\_\_

No, you may not use or share my mental health information and social services information - Initial here: \_\_\_\_\_\_\_

**What happens to data that are collected in the study?**

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers or their collaborators use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

The study team will do its best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups.

If data are used or shared with types of information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

**Who will see my information and how will it be kept confidential?**

All collected data related to your participation in the study will be kept in a confidential file at Saint Agnes Medical Center. Only those people who work on the study *(add others applicable)* will see any research records that could identify you. These people may copy all or part of your records related to this research. The hospital takes its responsibility to protect your research *(add* health *as well, if applicable)* information from unnecessary disclosure very seriously. You will be asked to sign a separate Authorization that describes how the primary investigator will collect and use your Protected Health Information, and who will see it. All of the information collected will be combined with data collected from other participants for a final review. Your name or any other identification will not be used in any published reports or presentations to the public. *(If the data will de-identified please explain. The HIPAA Authorization section of this form must be included if using or disclosing PHI for research purposes).*

In addition, as part of routine monitoring of research, members, the Principal Investigator and staff of the designated Institutional Review Board (IRB) for Saint Agnes Medical Center, the organization(s) that funds the study *(if applicable)*, the Office of Human Research Protections (OHRP), Office of Civil Rights (who regulates HIPAA), or other government agencies may review your records. You may be contacted by a representative of the Research Compliance Department to ask you about your experience in this research study.

***Select one of the following:***

Your private information will not be used or distributed for future research studies.

***or***

Your *(Select one: identifiable or deidentified)* private information **could be** used for future research studies or distributed to another investigator for future research studies without additional informed consent.

(Delete the following paragraph if N/A)

While it is unlikely, during your participation in this research, information may be reported to the study team that the study team is then required by law to report to appropriate authorities. Some examples of this type of information could include injury due to violence, suspected child or elder abuse (including reporting regarding newborns suspected of having drugs or alcohol in their system), or certain communicable diseases such as sexually transmitted diseases or HIV.

**Will any of my *other* health care providers have to share health information with researchers involved with this study?**(Delete if N/A)

As a part of your participation in this study, the researchers may ask to see your health care records from other care providers. You will be asked to sign a separate HIPAA Authorization form to give the study staff permission to collect the medical information needed for this study. This information will be collected from any health care provider or facility that delivers care to you during your participation in the study. In the event you have been hospitalized or treated at a facility other than Saint Agnes Medical Center, you may be asked you to sign a release form so they can retrieve your medical records for research purposes.

**What happens if I am injured as a result of this research?**

There is a possibility of risks that may occur as a result of your participation in this study. If you are injured in relation to the research, *(consider sociomedical ramifications.)*

In the case of injury resulting from this study, you do not lose any of your legal rights that you would otherwise be entitled to or to seek payment by signing this form.

**If I don’t want to be in the study anymore, what should I do?**

You are free to leave the study at any time. If you decide to leave the study early, please notify the principal investigator or study coordinator listed at the end of this form.

**Financial Conflict of Interest**

[*Where there is* ***no*** *significant financial conflict of interest, state as such]*

**(*For significant financial conflict of interest****, include:)*

* Name of office/business in which there is significant financial interest
* Developer of the *(procedure(s)/test/treatment(s)/survey)*
* If the product is marketed commercially for profit, the participant is not automatically entitled to a share of any profits.

**Who can I contact for information about this study?**

If you have any questions about this study or taking part in this study, contact:

Principal Investigator:

Mailing Address:

Telephone:

*(Omit the following if N/A; delete rows)*  
Study Coordinator:

Mailing Address:

Telephone:

**Who else can I contact if I have any concerns about the study?**

If you have questions about your rights as a research participant, general questions about what it means to be in a research study, or any concerns or complaints about the research, please contact the Director of the Research Compliance Department at (734) 712-5470.

**Where can I go for more information?** (Delete if N/A)

**Has this study been reviewed by the Hospital?**

Yes. The study has been reviewed by the Institutional Review Board (IRB) at Saint Agnes Medical Center which operates independently of the principal investigator and/or funder, if applicable. All Trinity Health Fresno IRBs have diverse representation, including community representatives, with membership considerations given to race, gender, and cultural backgrounds to ensure all federal requirements for IRB membership under the U.S. Department of Health and Human Services and Food and Drug Administration regulations are met.

**HIPAA Authorization**

**The Health Insurance Portability and Accountability Act (HIPAA Privacy Rule)** gives research participants rights when their Protected Health Information is used or released for research purposes. Protected Health Information is health information that is individually identifiable and that is created, received, or maintained by a healthcare provider in any form.

***Purpose of the use and disclosure***

Before the researchers use or share any health information about you as part of this research study, we are asking for your permission (authorization; in keeping with the HIPAA Privacy Rule) to do so. The purpose is so that the investigator may conduct the research study listed above and described in this informed consent form.

*(Add a specific and meaningful description of what will be used and disclosed in addition to the paragraph below, if this information is not covered by the paragraph below)*

***Information to be used or disclosed***

Your health information that may be used or disclosed includesany or all health care records such as: laboratory, pathology and/or radiology results; scans; x-rays; device records, hospital records, outpatient clinic letters, autopsy records; death certificate and Protected Health Information previously collected for research purposes. Some of these tests may have been done as part of your regular care. This study may use or disclose any or all of the following Protected Health Information in connection to your health information to and from the people or institutions listed above: name, address, birth date, date of service or admission to the hospital, date of death, age greater than 89, telephone number, social security number, medical record number, health beneficiary number, credit card or other account numbers, license numbers, vehicle identification numbers, serial numbers, website addresses, Internet Protocol numbers, voice or fingerprint or similar identifiers, full face images, and/or any other unique identifying characteristic or number or code. This includes information in your medical record and information created or collected during the study. The investigator will use this information about you to complete this research.

***If the following information is included in the consent portion of this document and protocol, you must also include it in this HIPAA section (edit variables as appropriate); otherwise DELETE this paragraph and instructions)***

Information about the diagnosis and testing for HIV, AIDS, and ARC(AIDS-Related Complex); alcohol and drug use diagnosis, information and/or treatment; mental health/illness diagnosis, information and/or treatment and services and social services (including communications made to a social worker or mental health professional) may be contained in these documents and will be disclosed.

***I give permission for the use and release of my Protected Health Information from the following sources of data to the following people/companies listed below for the purposes of this research:***

|  |  |
| --- | --- |
| **The following will provide data:** | **Your data will be released to and used by the following people and/or institutions:** |
| 1. **Trinity Health** *(Specify location)*   (Address)  (Phone Number)  *(Add any other sources of data below)*   1. (NAME)   (Address)  (Phone Number) | 1. **My doctor(s) who care for me** during this research, including my primary care doctor and other doctors who may take care of me during my participation.   *(List all entities or persons the PI wants to release info to below: i.e., PI and research team if receiving Trinity Health Fresno data, sponsors, companies working for sponsor, Co-I from outside institution, clinical laboratories, etc.)*   1. (NAME)   (Address)  (Phone Number) |

In addition to the above, the Saint Agnes Medical Center Research Compliance Department and designated IRB (which is also the HIPAA Privacy Board for research use), and federal agencies [such as the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), etc.] may need to review your health records that were collected as indicated in the consent portion of this form as part of their regulatory review and oversight of research activities.

***Expiration date:***Your authorization for the use and disclosure of your information has no expiration date.

***My access to my medical record: (Select ONE of these statements and DELETE the other)***

***Use this statement only if this is a clinical research trial where the participants are blinded to the treatment)***

You understand that your access to your medical record (*or specify some portion of the record, delete this note if not being used*) will be temporarily suspended until the completion of the research study and will be reinstated at the end of the study.

***All other studies use this statement:***

You understand that your access to your medical record (*or specify some portion of the record, delete this note if not being used*) will continue to be allowed during the research study.

**DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION**

***(Delete “and HIPAA Authorization” from this page title if no PHI is being accessed or collected)***

I understand that by consenting to participate in this study, I am responsible for following instructions and informing study personnel of any concerns, complications, or adverse effects. I will also express any concerns I may have about continuing to participate in this study.

I am aware I may withdraw my consent and HIPAA authorization in writing at any time without harming my future medical care or losing any benefits to which I might be otherwise entitled. I have been advised that the investigator in charge of this study may discontinue my participation in this study if it is felt to be in my best interest, if I do not follow the study requirements, or if the study is stopped.

By signing this Informed Consent and HIPAA Authorization Form, **I certify I have read this form, had the opportunity to ask questions about this study and this form, and have been given enough time to consider my participation.** I have talked to as many people as I need to help me make my decision. **I understand that my participation is voluntary.** I am voluntarily signing this consent form and HIPAA Authorization as evidence of my decision to participate in this research study. I also understand I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

Signature of Study Participant Printed Name Date

Signature of Legally Authorized Representative Printed Name Date

**Delete if diminished capacity is an exclusion criterion or is not addressed in the study.**

Signature of Person Obtaining Printed Name Date

Consent/Authorization

**You will receive a signed copy of this Research Informed Consent and HIPAA Authorization Form**.