Informed Consent Guidance

OVERVIEW
Informed consent is a process that allows researchers to convey information to potential research participants and/or their legally authorized representatives, which then allows them to voluntarily decide whether or not they want to participate in a research study. Informed consent must be obtained without undue influence, fraud, deceit, duress, or other forms of constraint or coercion.

Informed consent is not a one-time event; it is an ongoing process of communication that takes place throughout a participant’s involvement in a research study. An effective informed consent process involves the following:

- Conducting the process in a manner and location that ensures privacy;
- Providing information about the research, procedures, and risks involved, in a language understandable to the participant, that a reasonable person would want to have in order to make an informed decision about whether to participate (or continue to participate);
- Providing sufficient opportunity for a participant to discuss and consider whether or not to participate, other options, etc.;
- Responding to participant questions;
- Ensuring that the participant understands the information provided;
- Obtaining the participant’s voluntary agreement for participation;
- Avoiding any coercion or undue influence on the participant’s decision;
- Continuing to provide information as the participant or research requires.

Federal regulations require that in most circumstances, informed consent is documented by use of a written consent form approved by the IRB and signed by the participant or the participant’s legally authorized representative. Consent forms must include the required (and applicable additional) elements of informed consent as outlined by SJH IRB Policy, unless the IRB approves an alteration of consent, use of a short form stating that the elements of consent have been presented, or a waiver of the requirement for consent. Signed consent must be obtained unless the IRB approves a waiver of the requirement for written documentation of consent. See the guidance Waiver of Consent or Documentation for additional information regarding waiving the requirement for consent or documentation of consent. A written copy must be given to the person signing the consent form.

DEFINITIONS

Assent: An affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Coercion: Persuasion to do or agree to something by using obvious or implied force or threats.

Elements of Consent: By regulation, the information to be provided to each prospective research participant. Basic elements are listed at 45 CFR 46.116(b), additional elements (included when appropriate) at 45 CFR 46.116(c). There are additional general informed consent requirements outlined in the “Writing the Informed Consent” section below. Consent documents used for FDA-regulated studies should refer to the elements of consent found in 21 CFR 50.25. The IRB’s review of consent forms entails a determination that all required elements are included, and when additional elements (including institutional requirements) should be included.

Exculpatory Language: As it applies to informed consent, any written or verbal communication through which a research participant (or legally authorized representative) is asked to waive or
appear to waive any of the participant’s legal rights or to release or appear to release the investigator, sponsor, or institution or its agents from liability for negligence.

Experimental Subject’s Bill of Rights: The California Health & Safety Code, section 24172, states that any person who is requested to participate as a participant in a medical experiment, or who is requested to consent on behalf of another, must be given a copy of a specified Bill of Rights written in a language in which the person is fluent.

Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant for the participant’s participation in the procedures involved in the research. See the guidance Use of a Legally Authorized Representative (LAR) for information on the circumstances in which consent by a LAR may be allowable.

Short Form: A written document stating that the elements of informed consent required by regulation have been presented orally to the participant or the participant’s legally authorized representative. The short form consent document is written in a language understandable to the participant or the participant’s legally authorized representative.

Written Summary: A written version of the information presented to a participant or the participant’s legally authorized representative during the informed consent process, used in conjunction with a short form consent document. For non-English speaking individuals, the IRB-approved English language consent form is presented as the written summary.

Undue Influence: Excessive or inappropriate reward or other incentive in which a person is influenced to act otherwise than by their own free will or without adequate consideration of the consequences.

WRITING THE INFORMED CONSENT
To assist in writing the informed consent, the Human Research Protection Program (HRPP) Office has created a template for use. Where sample language does not suit a particular study, it may be departed from, providing the content meets all federal requirements and is approved by the IRB.

Investigators may use the consent template provided by the sponsoring agency as long as the information listed in the SJH Informed Consent Boilerplate Language document is inserted into the appropriate sections of the consent form.

Informed consent forms should be written such that information is presented in sufficient detail relating to the research, and organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates participants’ understanding of the reasons why one might or might not want to participate.

Language
Consent documents must be in a language understandable to participants or the participant’s legally authorized representative. Complex, technical, or highly specialized language or medical jargon should be kept to a minimum. The consent document should be written and explained in terms that the potential participants are likely to understand. Generally, consent forms should be written at an 8th grade reading level. The NCCN Informed Consent Language Database may be used as a reference tool for defining medical terminology into plain language.
There cannot be any use of exculpatory language through which participants or representatives are made to waive or appear to waive any legal rights or release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Presentation of Key Information
Consent forms for federally-funded studies are required to begin with a concise and focused presentation of the key information that is most likely to assist participants in understanding the reasons why one might or might not want to participate in the research, organized and presented in a way that facilitates comprehension.

In general, the following key information should be concisely presented at the beginning of the consent form:

- The fact that consent is being sought for research and that participation is voluntary;
- The purpose of the research, the expected duration of participants’ participation, and the main study procedures, including any procedures that are experimental and how these differ from standard of care;
- The most likely and most significant risks or discomforts to the participants;
- The benefits to participants or to others;
- Appropriate alternative procedures or courses of treatment, if any.

However, based upon the facts of an individual protocol, the IRB may require that different (or additional) information be presented at the beginning of an informed consent to satisfy this requirement. Further guidance on developing the presentation of key information is available in the HRPP Office’s consent template.

When an informed consent form is short in length (e.g., a one to two page participation information sheet), the IRB may determine that the content of the form itself comprises a concise and focused presentation of key information about the research and not require a separate presentation of this information at the beginning of the form.

Note: The presentation of key information is not required for studies that are not federally-funded. However, the inclusion of this information is allowable, encouraged, and may be required by the IRB on a case-by-case basis if it is determined that this information is essential to ensuring participant comprehension.

State, Local and Institutional Requirements

- When an investigator has a financial conflict of interest, a disclosure statement must be included in the consent form. Be sure to provide a general statement of any other compensation such as consulting fees, speaking fees, or royalties.
- SJH is a Catholic health system; therefore, the consent form must use language that allows for abstinence as a method of birth control in order to be in conformity with the Catholic Directives. The form does not have to list abstinence as a possible method of birth control, but it cannot exclude it.
- The consent form must contain an Experimental Subject’s Bill of Rights for California sites. When the sponsor does not allow for insertion into the consent document, the following statement must be inserted: “Before you read this consent form, you should read a copy of the Experimental Subject’s Bill of Rights”. A separate document must be presented to and signed by the patient.
- HIPAA Authorization must be written in 14 point font for California sites.
- When it is required that there be a witness to the consent process, the witness must provide his/her signature to document observing the informed consent process, including the participant signing the consent form prior to returning the consent form back to the
person who obtained consent. Both the participant and the witness must sign and date the form.

Consent Form Tips
- Spell out acronyms when first used followed by the acronym in parenthesis
- Use “study drug” instead of “study medication” when the drug is investigational and also when a placebo is used. The word “medication” or “medicine” should only be used if the drug is commercially available for that particular condition.
- Use research “study” instead of research “trial”
- Use the word “participant” instead of “patient” to distinguish the participation in research from routine medical care
- When a placebo and an active drug are involved, clarify for the participant that when the consent refers to the study drug, the study drug means “placebo or active drug”
- Do not use the word “invite” (for example, “You are invited to participate in a research study.”) Preferred language: “You are being asked to voluntarily participate in a research study because…”
- Include whether or not the institution, Principal Investigator (PI) and research team are being paid to conduct the study.
- Use plain language vs. technical and medical terms: e.g., “swallow a pill” vs. “oral administration.” Describe risks using simple language in parenthesis: e.g., “hypertension (high blood pressure).”

HIPAA Authorization
Investigators must obtain authorization to use and disclose protected health information (PHI) using the Research HIPAA Authorization template provided by the HRPP. Changes to the Research HIPAA Authorization template are subject to approval by the HRPP Office prior to implementation.

Experimental Subject’s Bill of Rights (for studies conducted in California)
California law requires that any participant, participant’s conservator or guardian, or other representative in a medical experiment be provided with and sign a copy of the Experimental Subject’s Bill of Rights prior to consenting to participate.

Under California law, medical experiment means (a) the severance or penetration or damaging of tissues of a human participant or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human participant in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the participant or otherwise directly benefiting the participant; (b) the investigational use of a drug or device; and (c) withholding medical treatment from a human participant for any purpose other than maintenance or improvement of the health of the participant.

Preparing Documents for Non-English Speaking Participants
Federal regulations require that the informed consent process be conducted in language understandable to the research participant. When non-English speakers present for participation in a research study, their consent may be obtained by way of the full study consent form translated into a language understandable to the participant or a translated “short form” consent document accompanied by an oral presentation of the full study consent form.

The use of the full translated consent form is preferred whenever possible; however, the short form process is allowed when the participant population is anticipated to be primarily English speaking, a full translated consent is not yet available in the language of a non-English speaking participant population, etc. The use of the short form process and short form documents must be approved by the IRB before being used for a given study. In general, short forms should not be
used more than two (2) times per language for a study as this indicates that the participation of that particular non-English speaking population is not incidental. After the 2nd use, the site should have the consent form translated.

When full translated consent forms are used, the IRB-approved consent form should be translated by outside translator services provided by the sponsor, or this can be facilitated through the HRPP Office. This requires that the study has an existing IRB approved English consent form. Once the consent is translated, the certification of the translation, along with the consent, is required to be submitted to the HRPP Office for verification. The translated version of the consent form will be stamped with the date verified by the HRPP. Versions and version dates must be the same as the English document. When consent is obtained, an interpreter should be available to facilitate the consent discussion. The interpreter’s participation in the consent discussion should be documented in the participant’s research record. Investigators should follow the local site policy regarding those who may serve as oral translators of written consent to facilitate the consent discussion.

**OBTAINING INFORMED CONSENT**

Informed consent is mandatory unless this requirement is waived by the IRB, and must be obtained prior to initiating research-related procedures. Principal Investigators are responsible for ensuring participants’ informed consent to participate in the research is appropriately obtained, and for ensuring that no human participants will be involved in the research prior to obtaining their consent. Principal investigators are also responsible for ensuring that all study personnel involved in obtaining consent are qualified and appropriately trained to explain the research and assess participant comprehension. Accordingly, Principal Investigators should have a plan for supervision and oversight of the consent process.

It is SJH policy that the Principal Investigator or a Co-Investigator (Co-I) must be actively involved in obtaining informed consent from potential participants. The PI or Co-I must discuss the study with the research participant. Appropriately qualified and trained study personnel may further review the consent form with the participant, but the PI or Co-I is expected to take a significant role in the process, including discussing procedures, drugs or devices involved in the research, risks, benefits, and answering any questions a participant may have that fall outside the scope of practice or expertise of the other study personnel involved in the consent discussion.

The investigator or designated study personnel involved in the consent discussion may sign the consent form. Study personnel must be delegated the authority to obtain consent by the PI and the PI must ensure that the individual(s) have appropriate education, training, and experience. The individuals involved in the consent discussion should be documented in the participant’s research record (e.g., case report form) and if consent occurs in the context of a clinical encounter, the clinician should document the discussion in the participant’s medical record (e.g., in the progress notes). Informed consent must be obtained in a face to face context unless otherwise approved by the IRB, and must be obtained using the IRB approved consent documents.

**NOTE:** The California Medical Experimentation Act requires that the consent form be signed and dated by someone other than the participant, or other representative of the participant (including legally authorized representative) who can attest that the requirements for informed consent have been satisfied. This requirement is addressed via the consenting study personnel signing the consent form at the time consent is obtained.
Witness Requirements
Witness signatures are required in certain circumstances by federal and state regulations. Additionally, the IRB may require a witness signature for some studies. A witness signature is required in the following circumstances:

i. Informed Consent is obtained using the short form consent process;

ii. The participant has decision-making capacity, but cannot read, write, talk and/or is blind;

iii. The legally authorized representative (LAR) has decision-making capacity, but cannot read, write, talk and/or is blind.

It is required that the person signing as a witness observes the entire consent process and verifies that the information in the consent form was accurately explained to, and understood by, the participant, that the participant voluntarily consented to participate, and has signed and dated the consent form. For scenarios (ii) and (iii) above, the witness must be impartial (neutral), such as an adult who is not a member of the study team and who is not a friend or family member of the participant.

Child Assent and Parental Permission
When research involves children (i.e., individuals under the age of 18), the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.

Federal Regulations require permission by at least one parent or legal guardian before a child is enrolled into a research study when medical care or treatment is involved. Federal Regulations require that children assent to participate in research.

- Research involving no more than minimal risk requires permission from at least one parent/guardian.
- Research that involves more than minimal risk, but presents the prospect of direct benefit to individual participants, requires permission from at least one parent/guardian.
- Research that involves more than minimal risk and presents the prospect of no direct benefit to individual participants, but generalizable knowledge, requires permission from both parents, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
- Research that presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children, but does not provide direct benefit to the participant or societal benefit, requires permission from both parents, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

When developing consent documents for research involving children, investigators should consult with the HRPP Office for assent or permission form templates appropriate for different child age groups.

If the IRB determines that the capability of some or all of the children is so limited that the children cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

The IRB may also waive requirements for child assent and parental permission for research satisfying the conditions for waiving informed consent as described in the guidance Waiver of Consent or Documentation.
Obtaining Informed Consent by Telephone
It may not be possible in some situations to have an in-person discussion of the study with participants or their legally authorized representatives, yet the criteria for a waiver of documentation of informed consent cannot be met. When approved by the IRB, documenting written informed consent in these instances must involve a process as follows:

- The participant or their legally authorized representative receives a copy of the informed consent document in advance of a telephone discussion.
- The investigator obtains consent over the telephone after discussing the research and ensuring that the participant understands the research and the risks and benefits involved.
- If the participant or legally authorized representative agrees to participate, the consent form is then signed and dated and returned to the investigator by mail, fax, email, etc. for the remaining signatures. Participation should not be initiated until documentation of the signed consent form is received by the investigator.
- A copy of the fully executed consent would be returned to the participant by mail, fax, email, etc.

DOCUMENTING INFORMED CONSENT
Documenting informed consent occurs after explaining the research and assessing participant’s comprehension. At minimum, it involves obtaining the signature of the participant or the legally authorized representative, and the investigator obtaining consent.

Signatures and Recordkeeping Requirements
The participant or legally authorized representative must sign and date the consent form at the time of the consenting process. This must only be done after all questions are answered and the participant agrees to participate or legally authorized representative agrees that the participant can participate in the study.

The investigator, or designee, who has obtained consent from the participant must sign and date the consent form. This signature should not be pre or post-dated from the participant’s signature.

For interventional studies, copies of all the signed informed consent documents must be included in, and become a part of, participants’ medical records if the participants are patients. For participants who are not patients or for non-interventional studies, consent forms are to be stored in confidential departmental files.

USING A SHORT FORM FOR INFORMED CONSENT
In some situations, the regulations permit the informed consent process to be conducted orally, with a written “short form” consent document. This process may be used to obtain the informed consent of non-English speaking participants or their legally authorized representatives.

Though the use of the fully translated consent is preferred whenever possible, the short form which includes the Experimental Subject’s Bill of Rights (for studies conducted in California) and HIPAA Authorization, is also available. To provide non-English speaking participants with equal opportunity to take part in research studies, the IRB has approved certified translated short forms in English, Spanish, Vietnamese, Farsi, and Korean. The English version is provided for staff that do not speak a language other than English, so that they are aware of the content of the short form.

The use of the short form process and short form documents must be approved by the IRB before being used for a given study. If to be used, the existing short form(s) in the appropriate
language(s) should be submitted to the IRB, with the specific study title and investigator added and the SJH Reference number and version date entered in the header of the form. If any other changes are made to a short form document, or a version is needed in another language, the form should be submitted for translation, obtaining a new certification.

Short Form Process
When informed consent is obtained using a short form, an oral translation of the approved English language consent form (Written Summary) is presented in the language understandable to the prospective participant. An interpreter must be available to conduct the oral translation and assist with any questions from prospective participants during the consent process.

The participant or legally authorized representative must receive the signed short form consent document translated into the appropriate language, and a copy of the signed IRB-approved English language consent form to serve as the written summary of the research.

If a study has multiple consent forms for sub-studies, a separate short form must be utilized to document a participant’s consent to participate in each sub-study.

Witness Requirements for Use of Short Forms
An adult who is fluent in both English and the language understandable to the prospective participant must witness the entire consent process. A witness must be an adult who is not a member of the research team. The individual obtaining consent may not serve as a witness to the consent process. The witness will observe the entire informed consent process, including the participant signing the consent form. An individual who is certified as an SJH entity interpreter may serve as an oral translator and also serve as the witness; however, in order to serve as a witness to the consent process, the interpreter must be able to sign the consent documents. Accordingly, a consent process involving an interpreter from whom it will not be possible to obtain signatures (e.g., a remote interpreter) must also involve a witness independent of the interpreter.

Signature Requirements
The participant or the participant’s legally authorized representative and the witness must sign and date the short form consent document. The witness and the investigator obtaining the informed consent of the participant must sign and date a copy of the written summary. No one should sign the form in a language that he or she does not understand.

RE-CONSENTING
Obtaining a signature on a consent form does not complete the consent process. Assuring informed consent requires that participants be provided with any new information that becomes available during the course of the study (e.g., changes to the research plan, change in risk/benefit profile, and the results of related research) that may affect a participant’s willingness to continue participation in the study.

Consent forms should be revised when such new information is available. Investigators must submit an amendment for IRB approval of the revised consent form.

The IRB may determine that re-consenting participants is required. This process must occur within 30 days of IRB approval of the revised consent form, unless otherwise specified by the IRB. In general, the following methods are acceptable and left to the investigator’s discretion, unless otherwise specified by the IRB:

- The participant signs a new consent form after outlining all updates; or
• The investigator has a discussion with the participant informing him or her of the new information and documents this conversation in the participant’s study file
• For participants in follow up only: The participant is sent a letter, via certified mail, in a language understandable to him or her by (i) explaining the new information, and (ii) providing instructional action, if necessary.

PARTICIPANT WITHDRAWAL
The consent process for clinical trials should anticipate situations in which participants may withdraw from the interventional portion of a study and inform them of, and seek their consent for, uses of their information following withdrawal.

The consent form for FDA-regulated clinical investigations should inform participants that when they withdraw from the study, data collected on the participant to the point of withdrawal will remain a part of the study database and may not be removed, as this is necessary in order for the study to be scientifically valid. The consent form must not give the participant the option of having data removed.

A participant who is withdrawing from the interventional portion of a study may be asked whether they are willing to provide continued follow-up and further data collection subsequent to their withdrawal, such as medical course or laboratory results obtained through non-invasive chart review. Informed consent must be obtained for this limited participation in the study either via a discussion in the original study consent form or an additional IRB-approved consent document specific to continued data collection following participant withdrawal.

If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigators must not access the participant's medical record or other confidential records for study purposes. However, investigators may review study data collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

POSTING OF CLINICAL TRIAL CONSENT FORMS
Consent forms for federally-funded clinical trials must be posted to a publicly available Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant. This requirement may be satisfied by either the awardee of federal funds or the Federal department or agency supporting the clinical trial. If the Federal department or agency supporting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial or proprietary information), the department or agency may permit or require redactions to the information posted. When SJH is the prime awardee of a federal grant, investigators should consult with the central office for research regarding how to satisfy this requirement.

Note: The requirement to post clinical trial consent forms to a publicly available website does not apply to non-federally-funded research.

BROAD CONSENT
Federal regulations allow for the use of a broad consent process for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens as an alternative to the standard informed consent process outlined in this document. St. Joseph Health has decided not to implement a broad consent process; accordingly, this process is not described
in this and related guidance documents. See the guidance *Implementation of the Revised Common Rule* for more information regarding this decision.

**REFERENCES**

OHRP’s *Informed Consent Checklist*

OHRP’s *Informed Consent FAQs*

OHRP’s *Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English*

OHRP’s *Tips on Informed Consent*

FDA’s *A Guide to Informed Consent - Information Sheet*

FDA’s *Questions and Answers on Informed Consent Elements*

FDA’s *Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials*

Protection of Human Subjects in Medical Experimentation Act