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 onetime event; it is a 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;
- Giving adequate information about the research, procedures, and risks involved in a language understandable to the participant;
- Providing adequate opportunity for a participant to consider other options;
- Responding to participant questions;
- Ensuring that the participant understands the information provided;
- Obtaining the participant’s voluntary agreement for participation;
- 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 written documentation of consent.

DEFINITIONS
Assent: A minor’s 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(a), additional elements (included when appropriate) at 45 CFR 46.116(b). Consent documents used for FDA-regulated studies should refer to the elements of consent found in 21 CFR 50.25.

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 subject 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 subject for the subject’s participation in the procedures involved in the research.
**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 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 approved Boilerplate Checklist is inserted into the appropriate sections of the consent form.

**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 a 6th to 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.

**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.
- A witness must provide his/her signature for observing the signature and date of the subject, prior to returning the consent back to the person who obtained consent.
Consent Form Tips

- Spell out acronyms when first used following with 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” since this is research
- 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 participate in a research study because (insert condition here).”
- Include whether or not the institution, PI and research team are being paid to conduct the study.
- Use plain language vs. technical and medical terms: i.e. swallow a pill vs. oral administration.

HIPAA Authorization
Investigators must obtain authorization to use and disclose protected health information (PHI) using the HIPAA Authorization template provided by the HRPP.

Experimental Subjects Bill of Rights
California law requires that any subject, subject’s conservator or guardian, or other representative in a medical experiment be provided with 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 subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; (b) the investigational use of a drug or device; and (c) withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

Preparing Documents for Non-English Speaking Subjects
Federal regulations require that the informed consent process is conducted in language understandable to research subject.

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 IRB approved English consent. Once the consent is translated the certification of the translation along with the consent is required to be submitted to the HRPP staff for verification. The translated version of the consent form will be stamped with the date verified by SJH HRPP. Versions and versions dates must be the same as the English document.

OBTAINING INFORMED CONSENT
Informed consent is mandatory unless this requirement is waived by the IRB, and must be obtained prior to initiating any research activities, including screening procedures. Investigators are
responsible for obtaining the participants’ informed consent to participate in the research, and for ensuring that no human subjects will be involved in the research prior to obtaining their consent. Principal Investigators are also responsible for assuring that all Investigators obtaining consent are qualified and appropriately trained to explain the research and assess participant comprehension.

It is SJH policy that only Principal Investigators or Co-Investigators may obtain informed consent from potential participants for research. 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.

**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 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 subject has signed and dated the consent. 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.

**NOTE:** The California Medical Experimentation Act requires attestation that the consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject (including legally authorized representative) who can attest that the requirements for informed consent have been satisfied.

**Consenting Minors**
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 Regulation and California law require permission by at least one parent or legal guardian before a minor is enrolled into a research study when medical care or treatment is involved. Federal Regulation and California law require that minors 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 subjects, 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 subjects, but generalizable knowledge, requires permission from both parents, unless one parent is deceased, unknown, incompetent, not reasonable 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 subject or societal benefit, requires permission from both parents unless one parent is deceased, unknown, incompetent, not reasonable available, or does not have legal responsibility for the custody of the child.
Please consult with the HRPP for consent, assent, or permission form templates used for each age group.

If the IRB determines that the capability of some or all of the children is so limited that they 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.

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.
- A copy of the fully executed consent would be returned to the subject by mail, fax, email, etc.

DOCUMENTING INFORMED CONSENT
Documenting informed consent occurs after explaining the research and assessing participant comprehension. At a 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.

Copies of all the signed informed consent documents must be included in, and become a part of, participants’ medical records if the subjects are patients. For subjects who are not patients, 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 subjects or their legally authorized representatives.

Though the use of the fully translated consent is preferred whenever possible, the short form which includes Bill of Rights and HIPAA is also available. To provide non-English speaking subjects 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 does not speak a language other than English, so that they are aware of the content of the short form.

The SJH Reference number and version date should be entered in the header of the form. The English version can be used as a guide to determine if any other sections should be taken out because they may not apply to the study. If any changes are made the document should be submitted for translation, obtaining a new certification.

Short Form Process
When informed consent is obtained using the short form, an oral translation of the approved English language consent form (Written Summary) is presented. An interpreter should be available to assist with any questions from prospective subjects 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.

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 neutral, such as an adult who is not a member of the research team and who is not a family member of the participant. The witness will observe the entire informed consent process, including the subject signing the consent form. An individual who is certified as an SJH entity interpreter may serve as oral translator and also serve as the witness. The individual obtaining consent may not serve as a witness to the process.

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 subjects 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 subject’s willingness to continue participation in the study.

Consent forms should be revised when such new information is available. Investigators must submit an amendment to revise the consent.

The IRB may determine that re-consenting subjects is required. This process must occur within 30 days, 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 subject signs a new consent form after outlining all updates; or
- The investigator has a discussion with the subject informing him or her of the new information and documents this conversation in the subject’s study file
• *For subjects in follow up only*: The subject 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.

**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*

Protection of Human Subjects in Medical Experimentation Act