

SOP Obtaining Informed Consent

Version number: _____

Effective date: _____

Approved by: _____
Investigator's Name Signature Date

Site name:
The University of Texas Health Science Center at San Antonio

Department/Division name:

I. Purpose

This SOP describes the procedures for obtaining and documenting informed consent from a study subject or the subject's legal representative. A verbal explanation is given and an informed consent document is provided to a subject to ensure that he or she understands what he or she is signing. The consent process continues throughout the subject's participation in the study.

I. Background

In the research context, informed consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a research study. Informed consent of all subjects is required unless it has been waived by the IRB as allowed by the federal regulations; refer to the IRB's [Informed Consent Policy and Procedure](#) for details about circumstances when waiver of consent may be permitted. Informed consent is obtained only after the prospective subject is provided sufficient opportunity to consider whether or not to participate. The prospective subject must be informed of all the aspects of a research study that are relevant to the subject's decision to participate and must have been given the opportunity to ask questions relevant to the research. Informed consent is documented in a written, signed and dated consent form (ICF), unless documentation of consent has been waived by an Institutional Review Board (IRB). The consent process should continue beyond the initial discussion and documentation of consent in the form of an ongoing conversation between the subject and the study team that includes any new information that

could impact the subject's decision to participate and confirmation of the continuing willingness of the subject to participate.

II. Procedures

1. General

- a) Check that the contents of the informed consent contain the essential elements required by the [Informed Consent Policy and Procedure](#). The consent template available from the UT Health San Antonio Office of the IRB (OIRB) includes all of the essential elements.
- b) A statement about the subject's receipt of a copy of the informed consent document should be included in the ICF.
- c) Ensure that the information stated on the ICF is written in a language that the subject can comprehend.
- d) Ensure that the ICF and any other written information provided to the subject or the subject's legal representative has been approved by an IRB. If the study was approved by the UT Health San Antonio IRB the IRB-approved ICF will have an approval stamp on the first page. Ensure that the ICF is the most current approved version. Ensure that the ICF copy that will be provided to the subject is of adequate quality to be clearly legible and is not missing any pages.
- e) The principal investigator may delegate conduct of obtaining informed consent to specific study personnel. Obtaining informed consent should only be delegated to study staff who have been trained in the consent process, and competency must be verified prior to consenting subjects. Personnel who obtain informed consent must also be approved by the Office of Clinical Research (OCR) to perform this duty (i.e. listed on the OCR-approved study personnel list in a role that includes consenting subjects). The person who conducts the informed consent process must sign and date the consent form. It is the principal investigator's responsibility to ensure that the consent is obtained according to this SOP, even if the task of obtaining informed consent has been delegated to another individual.
- f) Before the start of the study or whenever new study staff join the research team the informed consent process should be rehearsed with the help of other study site staff, so that comments can be provided for improvement.
- g) The informed consent process must be conducted and the signed ICF obtained before study site staff carry out any study-specific procedures for the trial subject.

- h) During the study, the subject should be made aware of any new information that arises which may be relevant to his or her willingness to continue participating in the trial. New information that significantly affects the risk/benefit balance of the study should be updated on a revised ICF that needs to be reviewed and approved by an IRB in advance of its use. However, information should not be withheld from study participants while awaiting approval of the revised ICF and the new information should be shared with the participants verbally in a timely manner.
- i) For subjects that require a legal representative, ensure that the representative fits the definition of a “legally authorized representative” as defined in the IRB’s guidance document “[Legally Authorized Representatives Under Federal and Texas Law](#)” for studies at UT Health, or in the Veterans Health Administration (VHA) Handbook for Veterans Affairs (VA) research.

2. **Explanation and discussion of the study**

- a) Prior to requesting consent from the subject, a description of the study should be given to each subject or subject’s legal representative, using non-technical language that is easily understandable. The discussion should begin with a concise summary of the study that includes the information that is most likely to assist the prospective subject or representative in understanding the reasons why he or she might or might not want to participate in the research. The consent discussion should be tailored to each individual subject as much as is feasible, both in terms of the language used and in considering the subject’s individual values and needs in relationship to the study; for example, if a subject being considered for a randomized study is not comfortable with being randomized to one or more of the arms, then the subject should not be enrolled in the study. It may be useful to employ tables, diagrams, or other graphics to enhance the subject’s understanding of the study.
- b) When explaining the study information to a subject or subject’s legal representative, discuss all the contents of the consent form, including the critical elements required by the [Informed Consent Policy and Procedure](#) guidelines.
- c) The study team member should ask the subject/representative to explain the study back to the study team member to ensure that the description provided was understood by the subject. If the subject cannot explain the study after the description, then the study should be described to the subject again using different language. This process should be repeated until the subject can adequately explain the study to the team member or the subject is not enrolled.

- d) The subject or subject's legal representative should be provided sufficient time and opportunity to inquire about details of the trial before he or she decides whether to participate.
- e) Trial-related questions posed by the subject should be answered to the satisfaction of the subject or the subject's legal representative.
- f) Never unduly influence (offer excessive or inappropriate rewards or capitalize on a position of authority over the subject) or coerce (threaten with harm or punishment) a subject to agree to participate or to continue to participate in a trial.
- g) Do not include exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence in the consent form or discussion.
- h) If a subject or subject's legal representative is unable to read, an impartial witness is required to be present during the entire informed consent process and discussion. Subjects might not freely volunteer that they are unable to read—subjects who “forgot their glasses,” “will read the consent later,” or cannot tell you about their medications and what they were prescribed for could be concealing limited literacy. The impartial witness attests that the information in the consent form is accurately explained to and fully understood by the subject or the subject's legal representative, and that informed consent was freely given by the subject or subject's legal representative. An impartial witness should not be a member of the study site staff who has been designated a role in the study by the principal investigator.
- i) Same procedures would apply for any revised or updated ICF.

3. Documentation of informed consent

- a) When the subject is willing to participate under his or her own free will or the subject's legal representative agrees to the subject's participation, informed consent should be documented in the following ways:
 - The names of the subject or subject's legal representative, and the person obtaining consent should be printed on the consent form;
 - The subject or the subject's legal representative signs and personally dates the consent form;
 - 1. If the subject or representative cannot sign, they may “make their mark” instead.

2. If the subject cannot write or “make their mark,” then an impartial witness will be required for the entire consent process to confirm the subject’s agreement to participate.
 3. Effective February 23, 2023, the University no longer requires that a witness signature be obtained unless required by the IRB.
- The person who conducts the informed consent process signs and personally dates the consent form; and
 - A witness to the subject’s signature or the legally authorized representative’s signature also signs and personally dates the consent form, when required by the IRB.
1. The witness should be someone not affiliated with the research: neither investigator nor study personnel. “Study personnel” means persons involved in carrying out the particular research protocol for which the subject is signing the consent.
 2. It is preferred that the witness not be associated with the subject. However, a family member or friend may serve as a witness if an impartial witness is not available.
 3. In settings where securing the signature of any witness may not be feasible, such as when subjects are enrolled in their homes, the study personnel should write “none available” on the line for the witness’ signature and make a notation in the study record describing the situation.
 4. If the sponsor or the IRB requires a witness to the consenting process in addition to the witness to the participant’s signature (such as when the subject does not read or if the subject is unable to write or “make their mark”) the informed consent contains a note to that effect below the witness’s signature line. If the subject is unable to write or “make their mark” then the consent must also state that the subject was unable to sign the consent form, the subject willingly agreed to participate in the study, and the method used to communicate their decision (e.g. nodding head, verbal agreement, etc.). A checkbox is available on the UT Health consent form template for this purpose; for high risk studies consider further documenting the consent process by making a video recording of it.
- b) A signed copy of the ICF must be provided to the subject/representative when the IC and HIPAA Authorization is combined.
 - c) One original copy of the signed and dated ICF should be kept in the investigator site file.
 - d) If all or part of the research takes place in a medical facility, a copy of the signed and dated ICF and/or a research enrollment note should be added to the subject’s medical record if required by the facility’s policies. A research enrollment note should

document the study name and IRB number, the name of the PI, the date of subject enrollment, a description of the consent process (including whether the patient met all of the inclusion criteria and none of the exclusion criteria, who was present for the consenting process, whether a translator was required, that all of the subject's questions were answered, and that the subject freely consented to participating in the study), and study team contact information.

- e) If the study is regulated by the FDA or is being conducted according to Good Clinical Practice standards, document that informed consent was obtained and the date it was obtained in the subject's case report form and/or source documentation, unless this information has already been documented in the medical record.
- f) Consent may be documented electronically provided that the system used for the documentation meets the requirements for electronic consent specified in the [Informed Consent Policy and Procedure](#).
- g) If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative has to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing (or an appropriate alternative mechanism for documenting that informed consent was obtained if the subject or legally authorized representative is a member of a distinct cultural group or community in which signing forms is not the norm).
 - If the subject/representative declines, take no further action.
 - If the subject/representative accepts, follow the process to document consent according to this SOP.
- h) The same procedures apply to any revised or updated ICF.

4. **Special procedures for obtaining and documenting consent via telephone, mail, or fax**

In some situations, such as when contacting subjects who have been identified for screening from medical record data under a waiver or consent and authorization or who have responded to IRB approved advertisements, the IRB may approve an alteration of consent that allows the consent process and/or documentation to take place via telephone, mail, fax, or email.

a) **Consent via telephone**

- If protected health information is recorded during a telephone screening process, the potential subjects must be informed about the research study and their verbal consent must be obtained before any questions are asked. The interviewer must

use an IRB-approved telephone script that includes the identity and affiliation of the interviewer, the names of the study and of the PI, how the interviewer obtained the subject's contact information, a short description of the study population, purpose, research procedures, duration, and any compensation that is available. The script should also make clear that study participation is voluntary. If the subject verbally consents, verbal screening questionnaires or special instructions (such as arriving for the initial study visit in a fasting state) may be given. If the subject indicates that they are not interested, then the interviewer should immediately thank them for their time and terminate the call.

b) Consent via mail or fax

- Consent via mail or fax may be useful if a written documentation of consent is needed in the absence of face-to-face contact between the subject and the study team. Subjects may initially be contacted by phone to explain the study and consent process; an IRB-approved script should be used to explain the study and inform potential subjects that a consent will be mailed to them, after which they will be called in about two weeks to answer their questions. Alternatively, the initial contact may be made by mailing the consent form with an IRB-approved cover letter that explains the study and gives instructions. The cover letter should instruct the subject to read the form carefully, but to wait to sign the consent form until after the subject has spoken to a research team member by phone about any questions. Once the subject's questions have been answered, the subject should sign the form if willing to participate in the study, then send the signed form back to the researcher by mail or fax. The signature of a witness should be obtained when required by the IRB. The research personnel who conducted the consent call should sign the consent form once it is received. The study team should not start using the subject's PHI for research prior to receiving the signed consent form from the subject.

c) Consent via email

- Unencrypted email should not be used to return a signed consent to the study team due to increased risk of unintentional disclosure of identifiable protected health information protected by the Health Insurance Portability and Accountability Act (HIPAA). Use of encrypted electronic submission methods, such as end-to-end encrypted email or a secure portal, may be permitted if approved by an IRB.

5. Special procedures in a trial involving vulnerable subjects

The procedures of obtaining informed consent from vulnerable subjects may vary according to the types of clinical studies, local ethical considerations and applicable

regulations. Enrollment of the subject should require measures described in the protocol and with documented approval by the IRB for such measures. The following procedures are usually applied and should be considered together with the points outlined in Sections 1, 2 and 3:

a) Infants and children

- The investigator is required to obtain a signed ICF from the parent, legal guardian, or legally authorized representative.
- For a clinical study that involves greater than minimal risk and provides no foreseeable direct benefit to its subjects, but mainly contributes vital knowledge about the subject's disorder or condition, or about another serious problem affecting the health or welfare of children, informed consent should be obtained from both parents.
- Assent should be obtained from a child who is able to understand unless assent is waived by the IRB. The child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. In addition to providing the informed consent document to the parent or legal guardian, an information sheet should be developed for the appropriate age range of the child for his or her easier comprehension.
- Informed consent should be documented on the consent form, using the Surrogate Signature Section. The parent, guardian, or representative signs and personally dates the consent form as the Person Giving Consent, and the assent of the child, when appropriate, is documented by having the child sign as the Subject.
- Children reaching the age of majority during study participation should be re-consented as adults prior to any further interactions or interventions, as the regulations regarding parental permission and child assent no longer apply to the now-adult subject. Consent of the adult subject should also be obtained if the research continues without any ongoing interactions or interventions with the subject (such as continued analysis of identifiable data or specimens) unless a waiver has been granted by an IRB.
- Minors may, in some circumstances, have statutory authority to provide consent for their own medical care without a surrogate. Refer to the IRB's guidance document "[Legally Authorized Representatives Under Federal and Texas Law](#)" for details, and consult the OIRB if there are questions.
- If the protocol requires consenting children outside the state of Texas, the requirements of the state/country in which the research will be conducted must be followed. Consult the OIRB for guidance.

b) Individuals with Impaired Decision-Making Ability (IDMA)

- Subjects who have not been documented to have [impaired decision-making ability](#) (medical documentation of the inability to understand and process information and to make choices based on that information), [incapacity](#) (medical or legal documentation of the inability to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to any proposed treatment decisions) or [incompetence](#) (a legal term referring to the inability to manage one's own affairs), are considered to be capable of giving informed consent for research.
 - Subjects with impaired decision-making ability or who are incapacitated or incompetent are not capable of giving informed consent and may only be enrolled in the trial on the condition that an ICF has been signed and provided by the subject's legal representative.
 1. The subject should also be informed about the trial to the extent compatible to the subject's understanding, and the subject's assent should be obtained if possible.
 2. If capable, the subject should sign and personally date the consent form.
 - If the protocol requires consenting persons with IDMA outside the state of Texas, the requirements of the state/country in which the research will be conducted must be followed. Consult the OIRB for guidance.
- c) **Individuals with diminished autonomy** – IRB-approved safeguards should be used when enrolling subjects with diminished [autonomy](#) or who are likely to develop diminished autonomy after enrollment (such as prisoners, military personnel, or the employees, students, or patients of the investigator) to ensure the decision to participate is made voluntarily.
- d) **Economically-disadvantaged persons** – It may be necessary to implement additional safeguards to ensure that a potential subject who is also economically-disadvantaged is not participating in a study solely for the compensation. Under these circumstances, the investigator should seek additional guidance on the appropriate safeguards from the OIRB and/or the sponsor.

6. Non-English Speaking Subjects

- a) All information regarding the consent/assent must be delivered to potential subjects or their representatives in the subject's native language(s) or one that the subject understands. An IRB-approved translation of the consent form should be provided to the subject/representative.

- b) If an IRB-approved translation of the consent form in the subject's language is not available and obtaining an IRB-approved translated consent form is not practicable, the IRB may approve the use of a short-form written consent. A witness who is conversant in both English and the language of the subject must be present for the entire consent discussion, and an IRB-approved written summary (usually the long-form English consent) must be provided. Informed consent should be documented as follows:
 - The subject or the subject's legal representative signs and personally dates the short consent form only;
 - The person who conducts the informed consent process signs and personally dates the summary only; and
 - A witness to the subject's signature or the legally authorized representative's signature also signs and personally dates both the short consent form and the summary.
- c) Copies of both the short form and the summary should be provided to the subject or representative.

7. Emergency situations

The procedures for obtaining informed consent in emergency situations may vary according to the type of clinical study, local ethical considerations and applicable regulations. Enrollment of the subject should require measures described in the protocol and with documented approval by the IRB for such measures. The following procedures are usually applied and considered with the points outlined in Sections 1, 2 and 3:

- a) When prior consent of the subject is not possible, the consent of the subject's legal representative, if present, should be obtained.
- b) The IRB may approve [delayed informed consent and/or waive documentation](#) of informed consent for a study involving an investigational treatment when all of the following conditions are met:
 - informed consent by the subject is not possible, the subject's legal representative is not available at the time the investigational treatment needs to be started, and there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation;
 - the clinical condition is potentially life-threatening or permanently disabling;
 - there is no accepted therapy that is clearly superior to the trial therapy, and the investigational therapy has potential for direct benefit based on appropriate preclinical studies;
 - risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and

benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity; and
the clinical investigation could not practicably be carried out without the waiver.

Further guidance regarding the requirements for planned emergency research may be found in the [Planned Emergency Research Exception from Informed Consent Requirements Policy and Procedure](#).

- c) The IRB may also approve delayed informed consent and/or waiver of consent for research in emergency settings in which participation in the study does not direct the standard of care and represents no more than a minimal increase in risk for the subject.
- d) At the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, should be informed about the details of the investigation and other information contained in the informed consent document, and informed that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- e) If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
- f) If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

8. Non-therapeutic trial

A non-therapeutic trial is one without foreseeable benefits to the subject. Only subjects who personally give consent and who sign and date the written informed consent document should be included in such a trial. However, it may be conducted in subjects with consent of the subject's legal representative when:

- a) The objective of the trial cannot be met by means of a trial in subjects who can give informed consent personally.
- b) The foreseeable risks to the subjects are low.
- c) The negative impact on the subject's well-being is minimized and low.

- d) The trial is not prohibited by law.
- e) The IRB approval covers the inclusion of such subjects.

III. References

1. Informed Consent Policy and Procedure
2. IRB Consent policy attachment 1 (Guidance related to LARs)
3. Veterans Health Administration (VHA) Directive
4. Planned Emergency Research Exception from Informed Consent Requirements Policy and Procedure