



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 701
Informed Consent

Purpose

This Standard Operating Procedure (SOP) document describes the policies and procedures for obtaining informed consent from human research subjects. It does not address the topics of consent forms, parental permission, assent from children, or obtaining consent under emergency circumstances.

Scope

This policy and procedure applies to all human participant research projects conducted by University faculty, staff, or students or by anyone conducting a research activity supported by the University of South Alabama (USA) or where USA is considered to be engaged in the research.

Policy

1.0 Requirement for consent

Researchers are required to obtain the legally effective informed consent of each subject or their legally authorized representative, for all non-exempt human subject's research, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of consent. This requirement is one of the central protections provided by the human subject's regulations. It is based on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report. The principle of respect requires that individuals be treated as autonomous agents.

The requirement for consent applies to all non-exempt human research, including situations that involve:

- Direct intervention or interaction with subjects.
- Obtaining private identifiable data, specimens, or records from subjects (including medical records).

2.0 A process, not a document

Obtaining consent is an active ongoing process, not a signature on a document. The process involves an information exchange and on-going communication that takes place between the researcher and the prospective subject.

The process begins with the initial approach to the potential subject (e.g., through a flyer, brochure, discussion, or any advertisement) and continues until the subject decides to end his/her participation or the study ends.

- 2.1 Obtaining a signature on a consent form does not complete the consent process. For example, researchers are required to provide subjects with any new information that arises during the study that may affect the subject's decision about whether to continue participation. In addition, ensuring an adequate consent may require repeating or supplementing the initial consent procedure.

3.0 Key features

The consent process involves three key features:

- 3.1 Disclosing to potential subjects the information needed to make an informed decision about whether to participate;
- 3.2 Facilitating the understanding of what has been disclosed (for example, by providing ample opportunity to ask questions and by communicating with subjects in terms and language they can understand);
- 3.3 Promoting the voluntariness of the decision about whether to participate.

4.0 Waiver of consent requirements

The IRB may waive the requirement to obtain consent, or it may approve a consent process that does not include, or that alters, some or all of the required elements of consent. Waivers of consent or of consent elements can be granted only under conditions specified in federal regulations.

4.1 IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No more Than Minimal Risk

- 4.1.1 The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3[k] and 102[(i)]) to the subjects;
- 4.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 4.1.3 The clinical investigation could not practicably be carried out without

- the waiver or alteration; and
- 4.1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5.0 Exception from Consent Requirements for FDA-Regulated Products (i.e. Emergency Use)

- 5.1 Obtaining informed consent may be waived if both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
 - 5.1.1 Participant is in a life-threatening situation necessitating use of test article
 - 5.1.2 Consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the participant
 - 5.1.3 Time is not sufficient to obtain consent from participant's legal representative
 - 5.1.4 There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.
- 5.2 If immediate use of the test article is required to save the life of the participant and time is not sufficient to obtain independent determination by another physician before using the test article, a determination by the investigator shall be made. This determination by the investigator is to be reviewed and evaluated by a physician who is not participating in the investigation within five (5) days after the use of article.
- 5.3 The documentation required for the exception under FDA regulations must be submitted by the investigator to the IRB within five (5) working days after the use of the test article.

6.0 Exempt research

Though exempt research is not required to address the consent requirements of the federal human subjects' regulations, it should still be conducted in accord with the Belmont Principles (the foundational ethical principles governing human subjects research at the University of South Alabama).

- 5.1 Per the Belmont principle of *Respect for Persons*, subjects should be given the opportunity to choose whether to participate in research. USA IRB generally expects investigators to obtain some type of consent from subjects for exempt research where the investigator will be collecting data through interaction (in-person or otherwise) with the subjects.

7.0 Who provides consent

Consent must be obtained from the subject or the subject's legally authorized representative (LAR), unless waived by the IRB.

- 7.1 A LAR may provide consent when a subject is unable to do so. When a LAR provides consent, researchers may still be expected to obtain some type of assent from the subject, if possible.
- 7.2 When it is a minor, minor provides assent. Parent provides permission. Refer to *SOP 703 Informed Consent: Research Involving Children*.

8.0 Consent requirements

8.1 Legally effective informed consent

8.1.1 Informed consent is legally effective when it is obtained and documented (unless waived) from the subject or the subject's legally authorized representative in a manner that is consistent with the applicable laws of the jurisdiction in which the research is conducted, with the U.S. Department of Health and Human Services (HHS) human subjects regulations (45 CFR 46) and with any other applicable regulations (such as the FDA regulations at 21 CFR 50 and 56).

8.1.2 The specific requirements of the HHS regulations are described below in Sections 8.3 and 8.4.

8.2 General requirements

8.2.1 The circumstances of the consent process

- Provide the prospective subject or representative sufficient opportunity to consider whether or not to participate.
- Minimize the possibility of coercion or undue influence.

8.2.2 The process and documents must be in a language understandable to the subjects or their representatives.

8.2.3 There is no exculpatory language through which the subjects are made to (1) waive or appear to waive any legal rights or (2) release or appear to release the investigator, the sponsor, the USA, or its agents from liability for negligence.

8.2.4 Information is provided throughout the study, as appropriate to the subject or the research. For example, new information about the study risks should be provided.

8.3 Basic elements of informed consent

In seeking informed consent, the following information must be provided to each prospective subject, unless the element is not applicable or an IRB approves a waiver or alteration of the element. **Starred elements can be omitted if they are not applicable. **If an element is not applicable, a waiver of the element is neither necessary nor appropriate.** For example, if there are no appropriate alternative procedures or treatments, the consent process need not say anything about alternatives to the research.*

The requirements below are from federal regulations. However, regulations do not require the use of this exact language as long as the meaning of any alternative wording is the same as the meaning of the regulatory wording. For example, the word “study” or “experiment” could be used in place of the word “research”.

- 8.3.1 A brief and concise summary of key points about the study on the first page of the consent form
- 8.3.2 A statement that the study involves research
- 8.3.3 An explanation of the purposes of the research.
- 8.3.4 An explanation of the expected duration of the subject’s participation.
- 8.3.5 A description of the procedures to be followed.
- 8.3.6 Identification of any procedures which are experimental.*
- 8.3.7 A description of any reasonably foreseeable risks or discomforts to the subject.*
- 8.3.8 A description of any benefits to the subject or to others which may reasonably be expected from the research.*
- 8.3.9 A disclosure of appropriate alternative procedures or courses of treatment, **if any**, that might be advantageous to the subject.*
- 8.3.10 A statement describing the extent, **if any**, to which confidentiality of records identifying the subject will be maintained.*
- 8.3.11 **For research involving more than minimal risk**, an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained. *[Note that the regulations do not limit “injury” to physical injury; this is a common misconception.]
- 8.3.12 **For research involving more than minimal risk**, an explanation as to whether any medical treatments are available if injury occurs and, if so what they consist of, or where further information may be obtained.*
- 8.3.13 An explanation of whom to contact in the case of a research-related injury to the subject. [Note that the regulations do not limit “injury” to

physical injury; this is a common misconception.]

- 8.3.14 An explanation of how to contact the research team for questions, concerns, or complaints about the research.
- 8.3.15 An explanation of how to contact someone independent of the research team for questions, concerns or complaints about the research, questions about the subject's right to obtain information, or to offer input.
- 8.3.16 A statement that participation is voluntary.
- 8.3.17 A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- 8.3.18 A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

8.4 Additional elements of informed consent

When appropriate, one or more of the following elements of information should also be provided to each prospective subject. *If an element is not appropriate, a waiver of the element is neither required nor appropriate.*

- 8.4.1 A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.
- 8.4.2 A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable.
- 8.4.3 Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.
- 8.4.4 Any additional costs to the subject that may result from participation in the research.
- 8.4.5 The consequences of a subject's decision to withdraw from the research.
- 8.4.6 A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, will be provided to the subject.
- 8.4.7 The approximate number of subjects involved in the study.
- 8.4.8 The amount and schedule of all payments to subjects.

8.5 Requirements of the Food and Drug Administration

There are additional requirements for research that is subject to the FDA regulations:

- 7.5.1 Study withdrawal or termination The subjects should be informed that if they decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about them up to that point will remain part of the study and may not be removed from the study database.
- 7.5.2 FDA access to study records. Subjects should be explicitly informed that the FDA may have access to the study data and records. This may be worded as “The Food and Drug Administration may inspect the records.”
- 7.5.3 Public information about the study. The FDA requires that the following statement be provided to subjects in most clinical trials as an element of the consent process, without alteration:
“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

8.6 Requirements of other agencies

There may be additional requirements associated with specific federal and state agencies and regulations. For example, there may be state reporting requirements (e.g., child abuse, elder abuse, domestic violence) that are relevant to the research and should be explained to the subjects.

8.7 Other requirements

When planning to conduct research outside of the University of South Alabama, researchers are responsible for being aware of, and complying with, any consent requirements of other states or countries.

8.8 USA IRB requirements

When applicable, the appropriate USA IRB boilerplate information should be included:

- 8.8.1 Financial conflict of interest
- 8.8.2 A federal Certificate of Confidentiality
- 8.8.3 Genetic Information Nondiscrimination Act (GINA)
- 8.8.4 Research Related Injury
- 8.8.5 Storage of Biological Materials
- 8.8.6 Drawing as Incentive
- 8.8.7 Medical Bill of Rights
- 8.8.8 HIPAA language

8.8.9 Reportable Income

8.8.10 Deception Debriefing

8.9 Deception and concealment

8.9.1 The use of deception or concealment in research is not prohibited by federal regulations or by the USA IRB.

Deception means deliberately misleading subjects about some aspect of the research. **Concealment** means deliberately withholding certain information.

Examples include:

- Withholding specific information about the true purpose of a study (concealment).
- Misinforming subjects about the purpose of a study (deception).
- Fake or rigged instruments or procedures (deception).
- Misleading play-acting by investigators, research staff, or others (deception).
- The omission of minor facts is not equivalent to deception.

8.9.2 Withholding or misinforming subjects about the true purpose of a study may be important to reduce biased responses that subjects may feel will reflect poorly on them. Research findings suggest that such deception is not harmful to subjects.

8.9.3 Use of deception or concealment usually requires a waiver of one or more of the requirement elements of consent – for example, the requirement to explain the purpose of the research.

8.9.4 The IRB will generally expect researchers to include a de-briefing procedure by which subjects are later informed about the withheld or misleading information.

Procedures

1.0 IRB Review and Approval

1.1 What is reviewed

1.1.1 The consent process, the consent form, and any other materials that are part of the consent process must be reviewed and approved by the IRB, in connection with the IRB application for the research.

1.1.2 Advertising, announcements, social media postings, and other recruiting processes and materials are generally considered to be part of the consent process.

1.1.3 Changes to approved consent and recruiting processes and materials must also be reviewed and approved by the IRB, as modifications.

1.2 Timing of the IRB review

IRB review and approval must be obtained prior to implementation of the recruiting and consent process and materials (or the changes to them). The consent process and documents are re-reviewed as part of the process of continuing review (“Status Report”) to ensure that they still meet the criteria for IRB approval and do not require revision (because, for example, significant new information is available about the study risks).

1.3 Criteria for IRB approval

The IRB approves the consent process when the IRB determines that the consent requirements described above in Section 3 have been met. The IRB pays particular attention to the following issues and context:

- 1.3.1 Risk and potential benefit information: Is it accurate, fair, and balanced?
- 1.3.2 Other information: Does the information provide the potential subject with a sufficient and accurate picture of what participation involves?
- 1.3.3 Participation incentives (monetary and non-monetary): Are they age and culture-appropriate? Are they likely to create an undue influence on a potential subject’s decision about whether to participate in the research?
- 1.3.4 Undue influence or coercion: Do the circumstances of the consent process create the likelihood of undue influence or coercion about the decision to participate?
- 1.3.5 Time: Is there ample time and opportunity to consider the information and ask questions?
- 1.3.6 Comprehension: Are potential subjects likely to comprehend the information in the proposed circumstances and format?
- 1.3.7 Local context: Is the proposed consenting process and documentation appropriate for the subject population and culture?

1.4 Waivers of consent requirements

The IRB may grant a waiver or alteration of the regulatory requirements for: (1) obtaining consent or (2) specific consent elements.

1.4.1 Criteria for waiver of consent

The IRB uses the CHECKLIST to ensure that the appropriate criteria for granting a waiver are met and to document its determination.

- 1.4.1.1 Emergency medicine research that does not qualify for a waiver of consent because it involves more than minimal risk to the subjects may nonetheless qualify for a waiver of consent.

1.4.2 Criteria for waiving or altering specific elements of consent

The **Request for Waiver of Consent**, located in IRBNet, describes the criteria for granting a waiver of specific elements of consent. The IRB uses the form to ensure that the appropriate criteria for granting a waiver or alteration are met and to document its determination.

1.4.3 The FDA allows a waiver of consent/consent elements based on the minimal risk criteria but does not allow a waiver/alteration of elements of consent for public service and demonstration projects (i.e., the criteria described at 45 CFR 46.116(c)).

2.0 Obtaining Consent

2.1 Researchers are responsible for ensuring that:

- 2.1.1 Informed consent is obtained by the IRB-approved process, prior to initiating any research activities, including screening procedures.
- 2.1.2 All individuals who will obtain consent are qualified and appropriately trained to explain the research and to answer questions.
- 2.1.3 Obtaining IRB approval for any revisions to the consent process, before implementation.

2.2 Non-English-speaking subjects

Federal regulations require that the consent process occur in a language understandable to the subjects.

2.2.1 Requiring subjects to be English speakers. Such a requirement is not in and of itself:

- Forbidden by federal regulations;
- Incompatible with the “equitable selection of subjects” criterion for IRB approval (because equitable selection has to do with fair distribution of the research benefits and burdens/risks); or
- Inconsistent with the Belmont Report ethical principle of *Justice*.

2.2.2 Researchers (and the IRB) should consider how likely it is that they will encounter subjects who do not speak English and how they will obtain consent from those individuals. They should consider the impact of excluding non-English speakers on the scientific validity and generalizability of the research.

2.2.3 The consent presentation and discussion must occur in a language that is understandable to the subjects. This may require the researcher to provide translated documents and an interpreter who is qualified to adequately obtain consent and answer questions in a consistent and reliable manner.

- 2.2.4 The IRB application should describe who will serve as interpreter, and the nature of the qualifications. See the *SOP 705: Translation and Interpretation*.
- 2.2.5 In addition to providing in-person interactions and written documents in the language of the subjects, researchers may consider additional methods of communication as well – such as showing a video of someone speaking about the research in the subject’s language.
- 2.2.6 If appropriate, researchers should have an ongoing arrangement for an interpreter, to convey the subject’s questions and concerns throughout the study. For example, a study involving an investigational drug may need to have an interpreter on call, should a subject have an urgent question or problem related to the drug.
- 2.2.7 The IRB has the authority to require revisions or additions to the consent process to ensure that non-English speaking subjects are adequately informed and are providing truly voluntary consent.
- 2.2.8 See the *SOP 702: Consent Documentation* for information about obtaining documentation of consent from non-English-speaking subjects.

2.3 Illiterate subjects

Researchers sometimes rely on the consent form to communicate specific information about the research before initiating the consent discussion. This is not possible for illiterate and functionally illiterate subjects.

- 2.3.1 The IRB expects researchers to consider the literacy level and distribution in the study population and to make appropriate accommodations to the consent process so that all consent requirements are addressed.
- 2.3.2 See the *SOP 702: Consent Documentation* for information about obtaining documentation of consent from illiterate subjects.

2.4 Re-consenting

- 2.4.1 Re-consenting is required when a child who was enrolled in the research with parental or guardian permission subsequently reaches the legal age of consent. Per federal regulatory guidance, this is required if the research still meets the definition of non-exempt human subjects research, even if there are no longer any interactions or interventions with the subjects.
 - 2.4.1.1 The IRB may waive the regulatory requirement for consent in these circumstances, applying the standard criteria for approving such waivers.
- 2.4.2 Re-consenting may be appropriate, even if not required by consent regulations, when:
 - 2.4.2.1 Significant new findings or information has been obtained during the course of the research that may relate to the subjects’ willingness to

continue participation (for example, new information about risks). Researchers are required by regulations to provide such information to subjects, and it may be appropriate to repeat or supplement the consent process at the same time.

- 2.4.2.2 There are concerns about the circumstances under which consent is being obtained.
- 2.4.2.3 A significant period of time has elapsed between the time consent was obtained and the time when the subject begins the study.
- 2.4.2.4 The subjects have been participating in a long-term longitudinal study. Periodic reiteration or affirmation of consent may be desirable, even if there have been no significant changes to the procedures, risks, or consent document.
- 2.4.2.5 Changes in the cognitive functioning, mental health, or physical health of the subjects is likely to have occurred during the course of the research.
- 2.4.2.6 Where a consent form has been modified via amendment, upon approval, investigators may be required to re-consent active participants at the discretion of the IRB. Active participants are those who still have research-related inventions or activities to complete.

Regulated Documents:

45 CFR 46, 21 CFR 50, and 21 CFR 56

University Related Documents:

[SOP 702: Consent Documentation](#)

[SOP 705: Translation and Interpretation](#)

[University of South Alabama Boilerplate Language](#)

Related Forms:

Checklist: Informed Consent (located in IRBNet forms/templates)

Waiver of Informed Consent (located in IRBNet forms/templates)

History:

Effective Date:

Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance