



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Informed Consent – Types and Elements

Informed Consent – Types and Elements

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the necessary elements of the informed consent process for the IRB.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

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3.0 Policy/Procedure

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek such consent only under circumstances that provide:

- the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- That minimize the possibility of coercion or undue influence
- The information that is given to the subject or the representative shall be in a language understandable to the subject or the representative.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative 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.

The Informed consent is required to contain (§46.116):

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if

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injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent: when appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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; and

(6) The approximate number of subjects involved in the study.

The consent form should:

- Use the IRB template with University header and IRB approval box
- be targeted for comprehension at a 6th grade reading level
- use brief paragraphs
- use section headers to introduce topics
- use simple sentence structure
- use second person tense
- use a type size readable to a person who may have poor vision
- limit use of complex terms or provide a parenthetical definition/description of the term

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Consent Types

There are three types of consent processes that can be requested and/or granted by the IRB.

(The regulations allow for an additional type of consent process called the “short” form. see SOP- Non English Speaking Participants)

The IRB will determine if the research is subject to FDA regulations when considering if the research meets the regulatory requirements for all types of consents.

Written Consent

- Contains all of the elements (delineated previously) of the informed consent
- A template incorporating all of the elements and providing suggested language has been developed by the IRB. The template can be accessed at <http://research.missouri.edu/irb/templates>
- The signatory requirements for this document are Principal Investigator/study personnel obtaining the consent and the potential subject or LAR. A witness signature is not required on this document unless the potential subject or LAR is able to understand but is not able to read or sign their name to the document. The IRB does have the authority to require a witness if they feel the project warrants one.
- FDA requires signature and date.
- A copy of the consent document must be provided to the participant or the participant’s legal representative.

Waiver of documentation of informed consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds *either*:

1. the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context*;
or
2. the informed consent is the only record linking the subject to the research, the harm from the possible breach of confidentiality is the principal risk to the subject and each participant will be asked whether the participant wanted documentation linking the participant with the research, and the participant’s wishes would govern.

*If the study is regulated by the FDA this is the only option for allowing a waiver of documentation of consent.

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The investigator or study representative has to present the project and the elements of consent to the subject or LAR and obtain a verbal consent to participate. The IRB may require the investigator to provide subjects with a written statement regarding the research.

If applicable, the investigator must document the consent and the consent process with a note in either the research records or the subject's medical record.

The Principal Investigator has to provide the IRB the written version of what will be presented to the subject or LAR. In cases in which the IRB requires the investigator to provide the subjects with a written statement regarding research, such statement has to be submitted, reviewed and approved by the IRB as well.

The IRB has developed a template incorporating the necessary information and elements to be provided to the potential participant when using waiver of documentation of consent. The template can be accessed at <http://research.missouri.edu/irb/templates>

Waiver of informed consent or request for alteration of the required elements

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- 1) the research involves no more than minimal risk to the subjects;
- 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3) the research could not practicably be carried out without the waiver or alteration; and
- 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation

The research is not regulated by the FDA.*

*Waiver of consent cannot be utilized in FDA regulated research except in accordance with Emergency Use of a test article FDA 21 CFR 50.23 (see Emergency Use of a Test Article SOP) or planned emergency research FDA 21 CFR 50.24.

Informed Consent Requirements in Emergency Medical Research

Under Section 46.101(i), a waiver of the applicability of the 45 CFR Part 46 requirement for obtaining and documenting informed consent for a strictly limited class of research, involving research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of

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legally authorized representatives of the subjects, no legally effective informed consent can be obtained

This waiver applies to the Basic HHS Policy for Protection of Human Research Subjects (Subpart A of 45 CFR Part 46) and to research involving children (Subpart D of 45 CFR Part 46). However, because of special regulatory limitations relating to research involving fetuses, pregnant women, and human in vitro fertilization (Subpart B of 45 CFR 46), and research involving prisoners (Subpart C of 45 CFR Part 46), this waiver is inapplicable to these categories of research.

Emergency Research Consent Waiver

Pursuant to Section 46.101(i), the Secretary, HHS, has waived the general requirements for informed consent at 45 CFR 46.116(a) and (b) and 46.408, to be referred to as the "Emergency Research Consent Waiver" for a class of research consisting of activities, each of which have met the following strictly limited conditions detailed under either (a) or (b) below:

(a) Waiver of consent for emergency research not subject to FDA regulations

The IRB is responsible for the review, approval, and continuing review of the research has approved both the research and a waiver of informed consent and has (i) found and documented that the research *is not subject* to regulations codified by the FDA at 21 CFR Part 50, and (ii) found and documented and reported to the OHRP that the following conditions have been met relative to the research:

- (1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- (2) Obtaining informed consent is not feasible because:
 - (i) the subjects will not be able to give their informed consent as a result of their medical condition;
 - (ii) the intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible; and
 - (iii) there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.
- (3) Participation in the research holds out the prospect of direct benefit to the subjects because:
 - (i) subjects are facing a life-threatening situation that necessitates intervention;
 - (ii) appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
 - (iii) risks associated with the research 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.

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- (4) The research could not practicably be carried out without the waiver.
- (5) The proposed research protocol defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
- (6) The IRB has reviewed and approved informed consent procedures and an informed consent document in accord with Sections 46.116 and 46.117 of 45 CFR Part 46. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with paragraph (b)(7)(v) of this waiver.
- (7) Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - (i) consultation* (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn;
 - (ii) public disclosure** to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits;
 - (iii) public disclosure** of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
 - (iv) establishment of an independent data monitoring committee to exercise oversight of the research; and
 - (v) if obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

In addition, the IRB is responsible for ensuring that procedures are in place to inform, 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 research, the details of the research and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the 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, 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. If a legally authorized representative or family member is told about the research and the subject's condition improves, the subject is also

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to be informed as soon as feasible. If a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research is to be provided to the subject's legally authorized representative or family member, if feasible.

For the purposes of this waiver "family member" means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

OR

(b) Research Subject to FDA Regulation (Planned Emergency Research)

****NOTE: Do NOT confuse with Emergency Use of a Test Article – See SOP.**

The IRB responsible for the review, approval, and continuing review of the research activity has approved both the activity and a waiver of informed consent and found and documented:

- (1) that the research activity *is subject* to regulations codified by the Food and Drug Administration (FDA) (see **Federal Register**, Vol. 61, pp. 51498-51531) at Title 21 CFR Part 50 and will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE), the application for which has clearly identified the protocols that would include subjects who are unable to consent, and
- (2) that the requirements for exception from informed consent for emergency research detailed in **21 CFR Section 50.24** have been met relative to those protocols

21 CFR 50.24 The IRB may review and approve a clinical investigation without requiring that informed consent of all research participants be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

- A. The target population for the research is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- B. Obtaining informed consent is not feasible because of all of the following:
 1. The participants will not be able to give their informed consent as a result of their medical condition;
 2. The intervention under investigation must be administered before consent from the participants' legally authorized representatives is feasible; and
 3. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- C. Participation in the research holds out the prospect of direct benefit to the participants, and:
 1. The participants are facing a life-threatening situation that necessitates

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- intervention.
2. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual participants; and
 3. The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
- D. The clinical investigation could not practicably be carried out without the waiver.
- E. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the Investigator has committed to attempt to contact a legally authorized representative for each participant within that window of time and, if feasible, to ask the legally authorized representative for consent within that window rather than proceeding without consent. The Investigator must agree to summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
- F. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Federal regulations and Human Research Protections Program and/or UMB IRB policies and procedures. The informed consent procedures and the informed consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documents is feasible.
1. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a legally authorized representative to object to a participant's participation in the clinical investigation.
 2. Additional protections of the rights and welfare of the participants will be provided, including, at least:
 - a. Consultation * (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn;
 - b. Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn of plans for the investigation and its risks and expected benefits;
 - c. At the completion of the clinical investigation there are plans for public disclosure **of sufficient information to apprise the community and researchers of the study. The information must include the demographic characteristics of the research population and results of the clinical investigation.
 - d. Establishment of an independent data and safety monitoring committee to exercise oversight of the clinical investigation; and

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- e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the Investigator must commit to attempt to contact within the therapeutic window an adult relative of the patient who is not a legally authorized representative, and ask whether he/she objects to the participant's participation in the clinical investigation. The Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

- G. Procedures must be in place to inform each participant, at the earliest feasible opportunity, or if the participant remains incapacitated, a legally authorized representative of the participant, of the participant's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, including that he/she may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- H. If a legally authorized representative is told about the clinical investigation and the participant's condition improves, the participant is also to be informed as soon as feasible.
- I. If a participant is entered into a clinical investigation with waived consent and the participant dies before a legally authorized representative can be contacted, information about the clinical investigation is to be provided to the participant's legally authorized representative, if feasible.
- J. The IRB determinations and all clinical investigation records, including regulatory files, must be maintained for at least three years after the completion of the clinical investigation and will be accessible for inspection and copying by the regulatory authorities, as applicable.
- K. Clinical investigations that are granted an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies that the clinical investigation may include participants who are unable to consent. The submission of these clinical investigations to the FDA for a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for this IND/IDE may not be submitted as an amendment to the existing IND/IDE.
- L. If the IRB determines it cannot approve a request for exception from informed consent requirements in emergency research because the clinical investigation does not meet the criteria according to Federal regulations, or other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator, who will forward the findings to the sponsor of the clinical investigation.
 - 1. The sponsor of the clinical investigation must promptly disclose this information to the FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent

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clinical investigation of the sponsor, and to other IRBs that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

*Acceptable mechanisms of **consultation** with the communities in which the study will be conducted and from which the subjects will be drawn include, but are not limited to, the following:

1. Consultation with associations, support groups, and other agencies representing people who have survived the conditions and treatments by presentation, question and answer sessions, focus groups, and surveys;
2. Consultation with associations, groups, and agencies representing the communities in which the studies will be conducted by presentation, question and answer sessions, focus groups, and surveys. The groups may include, for example, neighborhood associations and councils, city councils, parent- teacher groups, community advisory boards, church and civic groups specific to the institution and community;
3. Community representation on the Human Subjects Review Committee specifically from survivor groups or from communities in which the studies will be conducted.
4. Development of a community advisory board specific to the proposed study.

Acceptable mechanisms of **notification (pre- and post- study) of the communities in which the study will be conducted and from which the subjects will be drawn include, but are not limited to, the following:

1. Public meetings;
2. Press releases;
3. Presentations before interested and affected agencies, groups, or organizations

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4.0 Related SOP

SOP Informed Consent – Process and Issues

SOP- VA Requirements

SOP- Non-English Speaking Participants

FDA Guide to Informed Consent- Consent Process