UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

INSTITUTIONAL REVIEW
BOARD WRITTEN PROCEDURES
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**Authority of the IRB**

The President of the University confers the institutional authority under which the UT Southwestern Medical Center Institutional Review Board (IRB) is established and empowered.

**Purpose of the IRB**

The over-riding purpose of the UT Southwestern Medical Center IRB is the protection of human participants in biomedical and behavioral research.

**Principles Which Govern the IRB**

The ethical principles, which govern the UT Southwestern Medical Center IRB in assuring that the rights and welfare of human research participants are protected, are those embodied in *The Belmont Report*. 
Review of New Research

Review by Convened Institutional Review Board (IRB)

Initial review of research is conducted by the convened IRB, except in instances where 1) the research is determined to be exempt under DHHS regulations at 45 CFR 46.101(b)(1-6) or in instances where the research is determined to qualify for expedited approval under regulations at 45 CFR 46.110(b)(1), 21 CFR 56.110(b)(1), and 63 FR 60364-60367, November 9, 1998.

Initial Review Materials

In conducting full Board, initial review of proposed research, the IRB obtains information in sufficient detail to make the determinations required under DHHS regulations at 45 CFR 46.111 and, when applicable, Food and Drug (FDA) regulations at 21 CFR 56.111. Materials include (1) the full protocol, (2) an electronic protocol application form (eIRB Smartform), (3) any proposed informed consent document(s), (4) the investigator’s brochure (when applicable), (5) any recruitment materials intended to be seen or heard by potential research participants, and (6) any grant application.

A primary reviewer, all other members of the IRB, and any consultant(s) deemed by the IRB in its discretion to possess competence in special areas, per 45 CFR 46.107(f), receive materials sufficiently in advance of the meeting date to allow review of the material. Materials are distributed electronically the week prior to the next scheduled meeting of the full Board.

Primary Reviewer System

The primary reviewer performs an in-depth review of all documentation and evaluates the protocol for all required findings with the aid of a checklist (“Institutional Review Board Evaluation of New Research”). All IRB members have access to all study materials in eIRB and are expected to review protocol submissions and other documents prior to the convened meetings and to participate in committee discussion.

Review Procedure

At a regularly scheduled meeting of the board, the primary reviewer presents an assessment of the study from the standpoint of human research participant protections, including scientific merit, and concludes with a recommendation regarding approval of the project. In those instances when a person with special expertise has been invited to attend, he or she is available for questions and elaboration at any point in the presentation of the primary reviewer and subsequent discussion, but does not participate in any vote. As part of the recommendation regarding approval of the project, the primary reviewer proposes a continuing review interval based upon the degree of risk, and recommends special findings such as those required for research involving children. The
recommendations are then discussed by the full board and affirmed or modified, with a vote of the majority of IRB members present determining the outcome.

During the discussion of all research proposals, controverted issues are resolved, and an account of such issues and their resolution is prepared for inclusion in the minutes of the meeting.

There are three possible outcomes of the IRB vote regarding a research proposal: (1) Approval; (2) Deferral; or (3) Disapproval.

Approval may either be as submitted, or conditional upon stipulations imposed by the Board.

1. Conditional Approval with Simple Changes: If a majority of the IRB members vote to approve a research proposal contingent upon stipulations being met, the members will determine, at the time of such vote, whether review and approval of responsive material may be performed by the IRB Chairman or other member(s) of the IRB, and this determination will be documented in the minutes. Only stipulations requiring simple concurrence on the part of the investigator are eligible for approval by this expedited means.

2. Deferral: When the IRB requires substantive changes—i.e., changes requiring more than simple concurrence by the investigator—responsive material must be re-submitted for full Board review at a subsequent meeting.

3. Disapproval of a research proposal is a determination that may not be overturned by any University authority or procedure other than by written appeal of the investigator to the IRB and subsequent deliberations of the Board that previously reviewed and disapproved it.
Continuing Review of Approved Research

Review by Convened Institutional Review Board (IRB)

Continuing review of research is conducted by the convened IRB, except in instances where 1) the research is determined to be exempt under DHHS regulations at 45 CFR 46.101(b)(1-6) or in instances where the research is determined to qualify for expedited approval under regulations at 45 CFR 46.110(b)(1), 21 CFR 56.110(b)(1), and 63 FR 60364-60367, November 9, 1998.

Continuing review of approved research eligible for expedited review

The application is screened by the IRB Coordinator and reviewed by the Chairman of the appropriate IRB. If the research meets criteria under 45 CFR 46.110(b)(1), 21 CFR 56.110(b)(1), and 63 FR 60364-60367, November 9, 1998, the approval of the research will be reported in writing to the investigator and to the IRB. The IRB Chairman may also approve the research conditionally; in which case, the conditions for final approval will be conveyed in writing to the principal investigator.

Continuing review of approved research not eligible for expedited review

The investigator submits electronically the continuing review smart form to the IRB office. Each member of the Board receives and reviews the continuing review forms. The continuing review submission provides: (a) a status report on the progress of the research, (b) the number of subjects accrued, (c) a description of any adverse events or unanticipated problems involving risks to subjects or others, (c) any withdrawal of subjects from the research, (e) any complaints about the research, (f) a summary of any literature produced or findings obtained thus far, (g) amendments or modifications to the research since the Board’s last review, (h) centralized reports from multi-center trials and any other relevant information, especially information about risks associated with the research.

Primary reviewer system

The primary reviewer, assigned by the IRB coordinator in consultation with the IRB Chairperson, when necessary, performs an in-depth review of all documentation and evaluates the protocol for all required findings with the aid of a modified form of the checklist used at initial review (“Institutional Review Board Evaluation of Continuing Research”).

Review Procedure

At a regularly scheduled meeting of the board, the primary reviewer presents an assessment of the study from the standpoint of human research participant protections

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and concludes with a recommendation regarding approval of the project. In those instances when a person with special expertise has been invited to attend, he or she is available for questions and elaboration at any point in the presentation of the primary reviewer and subsequent discussion, but does not participate in any vote. As part of the recommendation regarding approval of the project, the primary reviewer proposes a continuing review interval based upon the degree of risk, and recommends special findings such as those required for research involving children and other vulnerable populations. The recommendations are then discussed by the full board and affirmed or modified, with a vote of the majority of IRB members present determining the outcome.

During the discussion of all research proposals, controverted issues are resolved, and an account of such issues and their resolution is prepared for inclusion in the minutes of the meeting.

There are three possible outcomes of the IRB vote regarding a research proposal that has been submitted for continuing review: (1) Approval; (2) Deferral; or (3) Disapproval.

Approval may either be as submitted, or conditional upon stipulations imposed by the Board.

1. **Conditional Approval with Simple Changes:** If a majority of the IRB members vote to approve new or continuing research contingent upon stipulations being met, the members will determine, at the time of such vote, whether review and approval of responsive material may be performed by the IRB Chairman or other member(s) of the IRB, and this determination will be documented in the minutes. Only stipulations requiring simple concurrence on the part of the investigator are eligible for approval by this expedited means.

2. **Deferral:** When the IRB requires substantive changes—i.e., changes requiring more than simple concurrence by the investigator—responsive material must be re-submitted for full Board review at a subsequent meeting. If the time required for this process to be completed and reapproval granted causes the previous IRB authorization to expire, subject enrollment in the study must be suspended until the issue(s) are resolved.

3. **Disapproval of an application for continuation of a research protocol** is a determination that may not be overturned by any University authority or procedure other than by written appeal of the investigator to the IRB and subsequent deliberations of the Board that previously reviewed and approved it.


Reports of the Actions of the Board to Investigators and Institutions

For new and continuing research, the actions of the IRB, including the decision regarding approval, deferral or disapproval, stipulations required to be met for approval (when applicable), and requests for additional information are reported in writing to the principal investigator in a timely manner. The institutional administration is likewise informed of these mailers by making the minutes of the meetings available to the Institutional Official electronically.

Right of Appeal

Any decision(s) of the board, including disapproval and stipulations for approval, may be appealed by means of a written submission by the investigator to the applicable Board, in which case such appeal shall be considered at the next convened meeting of that Board that is feasible.

The IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to subjects. The reasons for the Board’s consideration of suspension or termination are detailed in written correspondence with the investigator and reported in writing to members of the Board at their next convened meeting.

Suspension or termination of research requires the vote to approve such action by a majority of the members of the IRB at a convened meeting of the Board, except in cases of apparent immediate hazard to subjects, in which case it may be ordered by the IRB Chairperson. In the latter case the action(s) of the Chair must subsequently be submitted for discussion and ratification of the convened Board.

Suspension or termination may be appealed by an investigator, in writing, and at the discretion of the Board, in person. Suspended or terminated research may receive re-approval by the IRB upon approval of the majority of Board members present at a convened meeting.

The Board’s decisions regarding suspension and termination are reported in writing to the investigator and are recorded in the minutes of the Board.

The Board’s final decision regarding suspended or terminated research is promptly reported to the Office for Human Research Protections, the Food and Drug Administration (when applicable), and the appropriate funding agency (when applicable).

Noncompliance

Any serious or continuing noncompliance with applicable federal regulations governing human subject research or with the requirements or determinations of the IRB is reported
at a convened meeting of the Board. The Board may consider appropriate action, including suspension or termination of IRB approval.
**Information the Investigator Provides to the IRB**

Information that the investigator is required to submit to the IRB for initial and continuing review is obtained through required electronic submission.
Determining Which Projects Require Review more Often Than Annually

In accordance with 45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2), and 56.109(f), the IRB shall have written procedures which the IRB will follow for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

The minutes of the IRB meeting and the letter of approval of research by the IRB shall state the duration of the IRB’s approval (not to exceed twelve months).

For research involving minimal risk to subjects, the duration of IRB approval will last twelve months.

For research involving more than minimal risk to subjects, the duration of IRB approval will last twelve months unless one or more voting members present at a regularly scheduled IRB meeting reports concern for the safety of subjects. Special consideration for a shorter period of IRB approval will be given to studies involving a high-risk population of subjects that undergoes a high-risk study procedure. In such a case, a majority of the Board must agree upon the amount of time for which a research activity may receive IRB approval.

The minutes of the IRB meeting and a letter to the investigator shall clearly document the Board’s decision about any approval by the IRB which imposes a more restrictive period for duration of approval than twelve months.

Documentation of Risk and Approval Period

The IRB will determine which protocols require continuing review more often than annually, as appropriate to the degree of risk. One or more members may determine that continuing review should be conducted at an interval less than twelve months. The minutes of the IRB meeting will clearly reflect these determinations regarding risk and approval period (review interval).
Verification of Material Changes in Research

As part of continuing IRB review of all ongoing research, the Coordinators of IRB Education and Compliance will regularly conduct post-approval monitoring of research operations and report their findings to the Board.

At a regularly scheduled IRB meeting, one or more members of the IRB may request that the IRB receive verification from sources other than the investigators that no material changes have occurred since previous IRB review.

The minutes of the IRB meeting shall document the Board’s discussion about the need for such verification and shall specify what shall constitute such verification. The letter of approval of the research by the IRB shall also notify an investigator that the Board requires verification from an independent source.

The IRB requires investigators to provide progress reports, including information about the safety of study procedures, at the time of continuing review, for all research deemed by the Board to entail more than minimal risk. The vote of the majority of the IRB members present will determine whether a research activity which does not already have a data and safety monitoring board must have such a committee, or a similar locus of responsibility for continuous monitoring of the safety of research participants.

Upon the recommendation of a majority of the Board members, a study may be required to have verification from sources other than the investigators that no material changes have occurred since previous IRB review. The Board will determine the specific requirements for a given study.
Insuring Prompt Reporting of Revisions

Investigator’s Reporting Requirements
An investigator’s assurance statement and electronic signature on IRB applications represents a statement of assurance to report promptly any proposed changes in a research activity and to ensure that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazard to a subject. An investigator’s signature also represents assurance to report promptly to the IRB any serious and unexpected adverse events and to comply with any requirements to report serious, unexpected adverse events to others (institutional offices and Department or Agency heads).

In addition, the requirement for prospective IRB review and approval of changes to approved research is disseminated in various other ways, as opportunities present themselves. Among these are: research publications, the campus researchers’ listserv, and, occasionally, by means of letters to principal investigators/research coordinators written in response to reports of “protocol deviations.”

Application for approval of changes to ongoing research is made by means of submission of Modification Form in eIRB along with associated materials (if any), such as revised informed consent documents. This material is then reviewed by an IRB Chair and either given expedited approval, or, at the discretion of the Chair, the request is sent for consideration of approval by the next available convened Board, if the proposed changes are deemed by the Chair to be sufficiently substantive, complex or of a nature that could change the risk benefit ratio of participation in the research.

Expedited Review of Minor Changes
The IRB Chair, Vice-Chair, or an experienced IRB Member designated by IRB Chairman will approve minor changes in previously approved research which can be approved by expedited review in accordance with the applicable regulations and guidance in sections I and II (initial and continuing review of research). “Minor” changes are those that do not appear to increase the potential risks to subjects nor lessen possible benefits from participating in the research.
Prompt Reporting of Problems, Non-Compliance, or Suspension of Approval

Unanticipated Problems Involving Risks to Subjects or Others
In accordance with 45 CFR 46.103(b)(5), the IRB shall have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.

The IRB policy for reporting of adverse events is located in the Study Management section of the IRB website.

For an unexpected or a serious adverse event that occurs at UT Southwestern (or at an affiliated performance site), an investigator shall report to the IRB in accordance with the Adverse Events and Other Reportable Events Policy at: http://www.utsouthwestern.net/intranet/research/research-administration/irb/study-management/adverse-events.html using the Reportable Event Form in eIRB. For adverse events that occur after gene transfer, an investigator shall submit one copy of the NIH OBA Form to the IRB, Environmental Health & Safety Committee, Professional Liability, and any DSMS at UT Southwestern, the Investigational Drug Service at the local performance site, OHRP, NIH OBA, and the FDA.

In accordance with 45 CFR 46.103(b)(5), 21 CFR 56.103(b)(5), and 21 CFR 312.66, an investigator shall report unanticipated problems involving risk to the subject or others to OHRP and FDA and send a copy of such reports to the IRB.

The IRB Administrator in consultation with the IRB Chairman will determine which reports of serious adverse events require distribution for review by the full Board. A summary of all reports of serious adverse events received in the IRB office are distributed to each Board member in advance of regularly-scheduled’ meetings of the Board.

Noncompliance, Suspension, Termination
An investigator must comply with the ethical principles in the Belmont Report, the regulations in 45 CFR 46, and the Federalwide Assurance of UT Southwestern on file with the OHRP. An investigator’s failure to follow the IRB’s requirements shall be investigated.

Evidence of any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB shall be reported to the Chairman of the IRB and the Associate Dean for Research. The two coordinators of IRB Education and
Compliance shall investigate evidence or allegations of serious or continuing noncompliance and provide a written report to the Board.

At the next regularly scheduled meeting of the IRB, a vote of a majority of the Board present will determine whether or not a research activity requires suspension or other sanctions on the investigator. All suspensions and sanctions shall be reported to the President of the University, the investigator’s department chairman, the director of OHRP, the Secretary of DHHS, and the director of FDA (if applicable).

The IRB may suspend or terminate IRB approval of specific research protocols or of all research involving human subjects in which an investigator participates. The IRB also has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to subjects.

The IRB shall report any suspension or termination of IRB approval to the investigator, appropriate university representatives, and the OHRP and FDA as appropriate. This report will include a statement of the reasons for the IRB’s actions.
IRB Review in Emergency Situations

DHHS regulations do not permit research activities to be started, even in an emergency, without prior IRB review and approval (45 CFR 46.103[b], 46.115[f] and OPRR Report 91-01). When emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements shall be satisfied.

Both DHHS and FDA regulations make provision for emergency use of a test article without prospective IRB review and approval, provided the conditions outlined in the regulations are met. Emergency use requires notification of that action to be given to the IRB by the investigator/treating physician within five workdays after such use.

Inform the IRB:
Within five workdays after the use of the test article,
- inform the IRB Manager by telephone (214-648-3060) or electronic mail (irb@UTSouthwestern.edu)
- Submit the Emergency Use Request/Notification Form
- Submit a copy of the informed consent, if applicable.
Conflict of Interest

IRB members will be recused during all discussion and voting on research in which they have a conflicting interest (45 CFR 46.107(e)). Such members will only be allowed to be present as may be requested by the Board to answer questions, whereafter they shall leave the meeting until further deliberations and voting have been completed. Such action(s) shall be noted in the minutes of the meetings.

Conflict of Interest Office

The Conflict of Interest (COI) Office assists the IRB in identifying members with a qualifying conflict of financial interest in advance of each meeting by providing an IRB preparation worksheet with that information. Such members are recused from the discussion and vote of applicable protocols as described above.
Expedited Review

*Initial and Continuing Expedited Review*

Research reviewed by means of an expedited procedure will strictly follow the categories specified in the list published on 9 November 1998 (63 FR 60364 and 63 FR 60353). This list is available to the research community on the IRB website. Research projects approved by the expedited review mechanism will be reported at a convened meeting of the full Board.
**Documentation of Findings**

Where DHHS regulations require specific findings on the part of the IRB, such as (1) approving a procedure which alters or waives the requirements for informed consent (45 CFR 46.116[d]), (2) approving a procedure which waives the requirement for obtaining a signed consent form (45 CFR 46.117(c), (3) approving research involving prisoners (45 CFR 46.305-306), or (4) approving research involving children (45 CFR 46.404-407), these findings will be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.
Procedures for Determining Exemptions

The IRB reviews all research involving human subjects and determines whether (1) research involves minimal or more than minimal risks to subjects and (2) whether research involving minimal risk to subjects will be classified as “exempt” or will be deemed eligible for expedited review. Information in 45 CFR 46.101(b) is available to the research community on the IRB website.

Application for approval as exempt research is made by means of an electronic form that lists the criteria for exemption as published in the regulations (45 CFR 46.101(b)) and requires identification by the investigator (subject to concurrence or rejection by the reviewing Chair) of the category into which his or her proposal fits, as well assurances and electronic signature of the principal investigator. This form is received in the IRB office covering a description of the project describing the study and providing an explanation of how the project meets the regulatory requirements for exempt research. Upon receipt in the IRB, an initial review Coordinator examines the proposal, and, if not perceived to be obviously incorrect or inappropriate for exempt research, presents the proposal to a Chair for consideration at the earliest opportunity.

Studies acknowledged by the IRB Chair as meeting the exempt criteria are not subject to the continuing review requirements.
Applicability of State and Local Laws

Texas state and local laws do not conflict with any of the regulations of the DHHS or the Food and Drug Administration. These federal regulations do not affect any applicable state or local laws which provide additional protections for human subjects.
**Procedures for Appointing Chair and Members**

The President of the University appoints Chair and members to the UT Southwestern IRB, on the recommendation of the Vice President for Research Administration. A letter from the President of the University to the individual Chair or member confirming his or her appointment to the Board signifies such appointment.

There is no specified term of service for Chair or members.

**Compensation of Members**

UT Southwestern faculty will receive a financial stipend from the University for each meeting they attend for their time and service.

No financial compensation is given to non-faculty and/or community members.
Procedures for Training and Education of the IRB Members, Staff and Investigators

Orientation of new members and Chairs of the UT Southwestern IRB is given in the form of a packet of information, including The Belmont Report, applicable Code of Federal Regulations, and Chapter III of the Institutional Review Board Guidebook (‘Basic IRB Review”). Additionally, members are given a copy of UT Southwestern’s Institutional Review Board Member Reference Book and receive initially, and periodically, as needed, specific information in personal sessions with the Associate Dean for Research and/or the IRB Manager. Continuing Education of IRB Chairs and members is accomplished by various methods, including lists of reference materials, regular distribution of articles/monographs and the periodical, IRB: Ethics and Human Research these materials are included in the IRB packets and discussed at meetings of the Boards. University-subsidized attendance at human participant protections conferences is offered according to availability of funding.

Education of IRB staff is given in general by the same means described above for new IRB members, and each new staff member is given a copy of the UT Southwestern’s Institutional Review Board Member Reference Book. Additional training is provided as time permits, and consists of dedicated educational meetings, interaction with more experienced members, including the IRB Manager, and job training provided on the specifics of their particular position. Education of investigators and other key personnel involved in research is accomplished by means of successful completion of an on-line tutorial, documentation of which must be provided to the IRB office as a precondition for IRB consideration of any research proposal involving human subjects.
Procedures for Ensuring that the IRB Possesses Sufficient Knowledge of the Local Research Context

Procedures for ensuring that the IRB possesses sufficient knowledge of the local research context include:

1. Recruitment of Board membership that is as diverse as possible with regard to ethnicity, race, cultural, and professional background.

2. Recruitment of Board membership from affiliated hospitals and other research centers.
Conduct of Full Board Meetings

Quorum Requirements
A quorum for IRB meetings is a majority of the IRB’s voting members (45 CFR 46.108). Approval of research is by majority vote of those present (i.e., a valid quorum). A majority is one member more than half of those present in a validly constituted quorum. Should the quorum fail during a meeting (e.g. those with conflicts being excused, early departures, toss of a non-scientist), the meeting is terminated from further votes unless the quorum can be restored. A quorum requires the attendance of at least one member with expertise in a nonscientific area and the attendance of a member who is knowledgeable about or experience in working with vulnerable subjects, when the research involves such subjects who are likely to be vulnerable to undue influence are reviewed.

IRB Records
IRB records include all of the information stipulated at 45 CFR 46.115

Recording of Votes
DHHS regulations at 45 CFR 46.115(a)(2) require that the minutes of IRB meetings document the vote on all IRB actions including the number of members voting for, against, and abstaining. Votes will be recorded in the minutes of the IRB meetings using the following format: Total = 15; For-14, Opposed-0, Abstained-1 (NAME). Controverted issues will be discussed in the form of a written summary that includes their resolution.
Waivers and Alterations of Informed Consent

Informed consent is an important component of human subject protection. Unless the IRB approves a waiver of informed consent or approves a waiver of documentation of informed consent (i.e. verbal consent), investigators are responsible for obtaining and documenting informed consent from research subjects or from their legally authorized representatives.

Waiver of Informed Consent

In accordance with 45 CFR 46.116, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or may waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration;

or

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.

Investigators who wish to request a waiver of informed consent for research must address the criteria set forth above in the Recruitment section of the protocol summary document and indicate a waiver of informed consent is requested in the Consent of Subjects section of the eIRB form.

In such cases, the minutes of the IRB meetings shall document in detail how each of the four criteria apply to a particular research activity. This same information shall be included in the letter documenting the IRB’s initial approval of the research.
Waiver of Documentation of Informed Consent (Verbal Consent)

In accordance with 45 CFR 46.117, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Investigators who wish to request a waiver of informed consent for research must address the criteria set forth above in the Recruitment section of the protocol summary document and indicate a waiver of informed consent is requested in the Consent of Subjects section of eIRB form. In these cases the IRB Chair will review and determine if the waiver of documentation of informed consent criteria have been met.
Exception from Informed Consent for Emergency Research

Federal regulations allow for an exception to the informed consent requirements for a limited class of research activities involving emergency medicine. These regulations permit enrollment of human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. Protocols involving an exception to the informed consent requirement for emergency medicine research must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies the protocol as including subjects who are unable to consent. The submission of a separate IND or IDE is required even if an IND for the same drug product or an IDE for the same device already exists. According to 21 CFR 50.24, in order for the IRB to approve the consent waiver under these circumstances, the IRB must find and document each of the following:

1. The human subjects are in a life-threatening situation; available treatments are unproven or unsatisfactory; and 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 informed consent as a result of their medical condition; (ii) the intervention under investigation 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 clinical investigation.

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 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.

4. The clinical investigation could not practicably be carried out without the waiver.

5. The proposed investigational plan 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 legally authorized representatives and make this information available to the IRB at the time of continuing review.

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6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Sec. 50.25. 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 clinical investigation consistent with paragraph (a)(7)(v) of this section.

7. Additional protections of the rights and welfare of 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 clinical investigation will be conducted and from which the subjects will be drawn (ii) public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits; (iii) public disclosure of sufficient information following completion of the clinical investigation 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 clinical investigation; 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 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.

8. 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 clinical investigation, the details of the investigation 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 clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. 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.
In such cases, the minutes of the IRB meetings shall document in detail how each of the eight criteria apply to a particular research activity. This same information shall be included in the letter documenting the IRB’s initial approval of the research.

**Documentation of Informed Consent for Non-English Speakers**

Informed consent information will be presented in “language understandable to the subject” and, in most situations, that informed consent will be documented in writing (45 CFR 46.116 arid 46.117). Where informed consent is documented in accordance with 46.117(b)(1), the written consent document will embody, in language understandable to the subject, all of the elements necessary for legally effective informed consent. Subjects who do not read English will be presented with a consent document written in a language understandable to them. Alternatively, 46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject will be given copies of the short form document and the summary.