8.1 Staff Support of IRB Membership

The IRB has a qualified staff, dedicated to supporting the IRB in its mission to protecting human participants in research. The IRB staff are reviewed at least annually by the HSPPO Director and HSPPO Assistant Director and the AVPRI to ensure they continue to provide sufficient resources to the IRB. The IRB staff has knowledge, skills and abilities appropriate to their respective roles. The HSPPO Director oversees the Assistant Director (IRB Administrator), the IRB Compliance Audit Team, the Research Administrative Systems Analyst (IRB Module Administrator) and an administrative assistant, and is responsible for the overall management of the HSPPO. See the HSPPO Organization Chart. For policies on qualifications, education and periodic evaluation of HSPPO staff, see Chapter 4.

The IRBs maintain documentation of their activities. IRB records include IRB study files, minutes for convened IRB meetings, and other documentation.

8.1.1 IRB Roster Requirements

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<tr>
<th>AAHRPP Std./Element</th>
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<tbody>
<tr>
<td>II.1.A</td>
<td>The IRB membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB roster. The IRB has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.</td>
</tr>
<tr>
<td>II.1.E</td>
<td>The IRB has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan.</td>
</tr>
</tbody>
</table>

IRB Rosters are constituted to meet the requirements of 45 CFR 46.107 and 108; 21 CFR 56.107 and 108.
An IRB Member database is maintained by the HSPPO and used as the data source for all IRB membership roster needs. The IRB Member database includes all information required under FDA and DHHS regulations and OHRP guidance (45 CFR 46.107 and 108; 21 CFR 56.107 and 108) including:

- Names of members
- Names of alternate members (and regular members for whom they substitute)
- Gender
- Earned degrees
- Scientific status
- Representative capacity
- Affiliation

Representative capacity is presented in enough detail to indicate which appropriate participants can be represented by each member (e.g., children, pregnant women, prisoners). When research protocols include vulnerable participants, a member who is knowledgeable about that population, or who has experience working with similar participants, should be assigned to the protocol review.

Scientific status, (including the designation of “nonscientist” – see Chapter 6.3), is determined during recruitment and annually upon evaluation of IRB members. Scientific status and area of scientific expertise (e.g., pediatrician, radiologist, psychologist, anthropologist, pharmacist) are presented in sufficient detail to allow appropriate protocol assignment and in-depth protocol review.

Affiliation is determined during recruitment and annually upon evaluation of IRB members. An IRB member is considered affiliated if he or she, or any member of his or her immediate family, has any employment or other relationship (e.g., current employee, consultant, Board of Directors, current volunteer, trainee or student) with any of the affiliated entities:

- University of Louisville and the University of Louisville Research Foundation
- University Medical Center, Inc. (University of Louisville Hospital – Operated by KentuckyOne Health)
- Jewish Hospital-St Mary’s Healthcare (Jewish Hospital-Operated by KentuckyOne Health)
- Norton Healthcare, Inc. (Norton Hospital, Norton Children’s Hospital and other clinical sites as named in the Norton’s FWA).

The role of unaffiliated members is to represent the general perspective of participants. Changes in IRB membership require reporting to OHRP. The HRPP Assistant Director (or delegate) submits a revised IRB membership list to OHRP whenever membership changes occur, but at a minimum once a year and whenever a new IRB is formed.

### 8.2 Quorum Requirements and Voting at IRB Meetings

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</tbody>
</table>
II.2.C The IRB has and follows written policies and procedures for conducting meetings by the convened IRB.

The IRB Chair is a voting member of the IRB. The Chair determines that quorum is established and maintained, chairs the meeting discussions, and calls for votes as appropriate.

Maintenance of quorum and voting at convened meetings is based on the following:

1. A majority of the (voting) members of the IRB (or their designated alternates), including at least one member whose primary concerns are in nonscientific areas, must be present to conduct a convened meeting. In order for research to be approved, it must receive the approval of a majority of such members present at the meeting.

2. **Members may be present in person or through audio (telephone) or audio-visual teleconference.** Members present via teleconference shall be noted as such in the meeting minutes, which shall also indicate that the members received all pertinent information prior to the meeting and were able to participate actively and equally in all discussions.

   The standard for members participating by audio or video conferencing is the same for those attending in person, giving all members the opportunity to participate fully in IRB deliberations.

3. IRB minutes shall include documentation of quorum and votes for each IRB action and determination by recording votes as follows:
   - Total number voting;
   - Number for;
   - Number opposed; and
   - Number abstaining

   **Members leaving the meeting room** due to a conflicting interest, or for any other reason, will not be recorded as part of the quorum for a particular protocol.

4. An **individual who is not listed on the official IRB membership roster** may not vote with the IRB.

5. A **non-voting ex-officio member** of, or representative to, a University of Louisville IRB may not vote with the IRB.

6. **Ad hoc consultants** may not vote with the IRB.

7. A **nonscientist** must always be present for any vote to be taken.

8. Regular attendance of **unaffiliated** members is strongly encouraged. Individual members of the IRB may satisfy more than one required type of member (i.e. a nonscientific member may also be the unaffiliated member).

9. **When a member and their alternate both attend a meeting,** either person (but not both) may vote on each protocol. Generally if one of these individuals was the primary reviewer of a given protocol for that review cycle, that person votes on the protocol at the convened meeting.
10. **Voting by proxy** is not permitted.

11. **If the quorum fails during a meeting**, such as due to lack of a majority of IRB members being present or an absence of a nonscientist member, the IRB cannot take any further actions or vote until the quorum is restored.

12. The **IRB Administrator is responsible for monitoring** the members present at a convened IRB meeting to ensure that at the beginning of the meeting and for each subsequent vote the meeting is appropriately convened.

13. When the IRB reviews research that **involves participants vulnerable to coercion or undue influence**, at least one member must be present who is knowledgeable about or experienced in working with these participants.

14. When the IRB reviews **research that involves prisoners**, a majority must have no association with the prison involved, apart from their membership on the IRB.

15. When the IRB reviews **research that involves prisoners**, at least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

See Chapter 8.6 for information about convened meeting minutes.

### 8.3 Meeting Times, Materials, and Preparation for IRB Meetings

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<td>II.2.C</td>
<td>The IRB has and follows written policies and procedures for conducting meetings by the convened IRB.</td>
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</table>

Each IRB meets each month according to a regular schedule. Some IRB members, who review protocols according to the expedited review procedure and confirm exemptions meet on an ad hoc basis as needed.

Individual meetings may be rescheduled, or additional meetings may be held, as needed by agreement of the IRB Chair and the HSPP Director.

The deadline for receipt of research proposals to the IRBs is the Wednesday before the Thursday of the following week.

Protocol materials are available online, via the IRB electronic submission system. All IRB Members in attendance have access to individual laptop computers to access the IRB ESS, and pertinent material is also projected. A hardcopy set of the most commonly referenced guidance documents are maintained in the IRB Conference Room.

**Protocol Materials**

The IRB staff assigns protocols in sufficient time for them to be reviewed before the meeting, generally one week prior, but not later than 72 hours before an upcoming meeting. Assignment is done via the IRB electronic submission system. All submitted study materials are available to the primary reviewers through the IRB ESS. All IRB members are granted view access to the presented protocol materials, generally one week but not later than 3 days prior to the convened meeting.

Materials necessary for review may be presented to IRB members less than 72 hours prior to a meeting only where determined necessary by the IRB Chair or HSPP Director.
Meeting Documents
Approximately five days prior to the IRB convened meeting, all members have access to the following electronically:

Agenda List for the coming meeting, typically containing:
- a statement on confidentiality of meetings,
- conflict of interest statement(s),
- vote on previous meeting minutes,
- education and information items (including reports to be discussed)
- Minutes from the previous meeting.

The Agenda details:
- Protocols (Initial Submissions, Continuation Reviews, Amendments) which will be presented at the meeting.
- Local Serious Adverse Event Reports that the Chair/Vice Chair has determined should be circulated to all IRB members.
- UPIRTSOs submitted by any investigator detailing the incident and the rationale for the determination that the incident meets the UPIRTSO criteria.
- A list of actions taken since the previous convened meeting for the IRB is circulated with the meeting agenda.
- Other items, such as Compliance Auditor reports that are presented at the convened meeting or miscellaneous information shared by the HSPPO Director or IRB Chair(s).

8.4 IRB Study Files

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<tr>
<td>II.5.A</td>
<td>The IRB maintains a complete set of materials relevant to the review of the research protocol or plan for a period to time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures.</td>
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The HSPPO employs an electronic submission system, “iRIS”, called ESS within this Policy Manual. Copies of some documents are also maintained in hard copy files.

Electronic Submission System (ESS)
The ESS maintains electronic records of all documents submitted through the system for every protocol event. The ESS contains a search function for locating and retrieving studies by protocol number, protocol title, name of Principal Investigator (PI), names of co-investigators, review type, meeting date, internal funding number, sponsor, IRB number, reviewer or any combination of the above categories. Electronic copies of all materials submitted to the IRB can be accessed through the ESS on an event by event basis through the ESS Submissions History function, thus all documents supporting each protocol event are accessible to reconstruct the entire history of a study.

A study file contains, as applicable to the research:

Application(s). The study file includes one or more of the following application types:
Biomedical IRB or SBE IRB research application (Regular, Expedited and Exempt review) submitted for all new research projects;
Amendment/Modification Form, submitted for modifications to approved research;
Continuing Review Form, submitted for continuing review of research;
Reports submitted for reportable events;
Final Report Form, submitted for closing Regular review protocols, if applicable.

IRB comments and investigator responses that occurred during IRB review are included with each application. Comments and responses exchanged via fax or email are also included as attachments.

- The IRB-approved informed consent document(s). The study file includes all approved consent forms, including the currently approved consent form. When a sample DHHS consent form is provided, it is included in the study file.
- The IRB-approved Assent form(s). If a study involves children from whom the investigators will obtain assent, copies of approved assent forms will be included in the protocol file.
- Scientific evaluations of the proposed research. Documentation of scientific review is included in the protocol file and is required in the ESS before the study can be submitted. See Chapter 7 for information on the SSMR/Department Chair Review.
- Sponsor Materials. For investigational drug studies, the Investigator’s Brochure and Sponsor’s Protocol, including current amended editions of these documents and all previous versions are included in the protocol file.
- For investigational devices, a report of prior investigations and the Sponsor’s Protocol are filed.
- Application for federal grant support. For research supported by federal funds, a copy of the grant proposal is included in the protocol file. If the federal funding is subcontracted through another institution, the sub-contract with that institution is noted in the protocol file.
- Advertisements, phone screening scripts and non-medical oral scripts, flyers, website or other subject recruitment materials.
- Questionnaires, surveys, interview scripts, diaries or other documents used in the course of the study.
- Participant informational sheets, brochures and sponsor newsletters.
- Reports submitted for reportable events.
- Final reports submitted for regular protocols.
- Data and Safety Monitoring Board (DSMB) reports.
- Continuation Review reports.
- Conflict of Interest (COI) documents, when COI or ICOI is applicable.
- Correspondence and communication between IRB members, IRB staff and investigators.
- Other IRB correspondence related to the research.
- Documentation of all actions including approvals, disapprovals, waivers or alterations of consents and HIPAA authorizations (as documented in the protocol application forms).
- Approval letter (or Determination of Exempt Review for research subject to exempt review.)
- Documentation of protocol closeout if any, including Final Report forms for regular protocols.
- Expiration notice sent-date.
- Various IRB Checklists.
IRB approvals from collaborating institutions are requested and included in the research file. IRB approval notices are requested from collaborating institutions when the University of Louisville is the coordinating center for a multi-site study. If the study is a multi-site study, with the University of Louisville as one of several participants, no other IRB approval is gathered or included from other participating sites.

In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records include copies of:

- Protocols or research plans.
- Investigator brochure, if any.
- Scientific evaluations, when provided by an entity other than the IRB.
- Recruitment materials.
- Consent documents.
- Progress reports submitted by researchers.
- Reports of injuries to participants.
- Records of continuing review activities.
- Data and safety monitoring reports, if any.
- Modifications to previously approved research.
- Unanticipated problems involving risks to participants or others.
- Documentation of non-compliance.
- Significant new findings.
- All correspondence between the IRB and researchers.

Other IRB-related Information
Other information is maintained by the Human Subjects Protection Program Office, such as correspondence between the IRB and outside agencies and institutions, IRB convened meeting documentation - minutes, minutes lists, agenda, and agenda lists, information about each IRB Member including; contact information, background and experience, curriculum vitae, etc.

8.5 Record Retention

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<tbody>
<tr>
<td>II.5.A</td>
<td>The IRB maintains a complete set of materials relevant to the review of the research protocol or plan for a period to time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures.</td>
</tr>
</tbody>
</table>

In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), IRB records are retained for at least three years after the completion of the research, either electronically or as hard copy. In accordance with federal HIPAA privacy regulations, IRB records containing protected health information (PHI) are retained for at least six years after the completion of the research. It is University of Louisville policy to retain records for the greatest amount of mandated time. Thus, HSPPO retains all research records for at least six years. This policy applies to all research studies, whether or not participants were enrolled. Sponsored grants and contracts may require additional periods for record retention.

Other documents, such as meeting agendas and agenda lists and meeting minutes and minutes lists for the current IRB year are maintained in the office of the IRB Manager. Periodically, these documents are sent to an external vendor for long-term storage.
General correspondence from investigators and other documents not specific to a particular research protocol are maintained for a period of three years in the HSPPPO. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records include copies of:

- Protocols or research plans.
- Investigator brochure, if any.
- Scientific evaluations, when provided by an entity other than the IRB.
- Recruitment materials.
- Consent documents.
- Progress reports submitted by researchers.
- Reports of injuries to participants.
- Records of continuing review activities.
- Data and safety monitoring reports, if any.
- Modifications to previously approved research.
- Unanticipated problems involving risks to participants or others.
- Documentation of non-compliance.
- Significant new findings.
- All correspondence between the IRB and researchers.

### Maintenance of and Access to IRB Records

The ESS resides on a secured server, with password-protected access. Access to IRB records is routinely provided to the Executive Vice President for Research and Innovation, IRB Chairs, IRB members, and IRB staff to carry out HSPP operations. Research investigators are provided reasonable access to files related to their own research.

## 8.6 IRB Minutes

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<th>Domain/Element</th>
<th>Description</th>
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<tr>
<td>II.5.B</td>
<td>The IRB documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, sponsor requirements (if any), and organizational policies and procedures.</td>
</tr>
<tr>
<td>II.2.D</td>
<td>The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB.</td>
</tr>
<tr>
<td>II.2.D.1</td>
<td>Initial review</td>
</tr>
<tr>
<td>II.2.D.2</td>
<td>Continuing review</td>
</tr>
<tr>
<td>II.2.D.3</td>
<td>Review of proposed modifications to previously approved research</td>
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</table>

The IRB documents discussions, decisions, and findings either through the IRB minutes or for studies subject to expedited review, through documentation in the study file or other records.

The IRB minutes document:

- Meeting attendees and invitees
- Discussions and actions taken by the IRB and the separate deliberations for each action
- Determinations made by the IRB and the protocol-specific findings that justify those determinations
- Votes for each action recorded as numbers for, against, or abstaining
• Other issues requiring convened IRB review.

Attendance at an IRB Convened Meeting
Attendance at an IRB convened meeting is recorded in the minutes by documenting:

• The IRB members (voting, non-voting, and ex-officios) who are in attendance. Non-voting members include ex-officio members or alternate members attending for informational purposes
• The IRB members who are not in attendance
• When an alternate member replaces a primary member in attendance and voting at the convened meeting
• The continued presence of quorum for all votes, including a member whose primary concern is in a nonscientific area
• Attendance of members and alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and had the opportunity to actively and equally participate in all discussions
• The IRB members who leave the meeting because of a conflicting interest
• The IRB members who leave the meeting briefly, are not present during a vote, and are not counted as part of the quorum
• The IRB members who arrive late or depart early from the meeting and their arrival or departure times
• The Human Subjects Protections Program Office staff present
• Any others present (e.g., invited guests, investigators invited to address the IRB, and consultants)

Discussions and Actions Taken By the IRB
Discussions and actions taken by the IRB, and the separate deliberations and basis for each action are documented in the minutes, such as:

• Discussion of protocol events – new, continuing review, modifications, reports of unanticipated problems and events and information requiring prompt review
• Approval of research – including the approval period for research, at initial and continuing review, (and if appropriate to the degree of risk determination of an approval period of less than one year)
• Suspensions and terminations of previously approved research
• Disapproval of research
• Discussion of controverted issues and their resolution or disposition
• Requests for consultant review or input from an expert in the field (e.g. requests made during a convened meeting)
• Actions resulting from review of reports of unanticipated problems involving risks to participants or others, or other reportable events and information
• Actions resulting from determinations of serious or continuing non-compliance
• If a protocol is using a DHHS-approved sample consent:
  The justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample consent document

Determinations made by the IRB
Determinations made by the IRB are recorded in the minutes with documentation of the protocol-specific findings justifying those determinations as appropriate, such as:

• Significant risk and non-significant risk device determinations, pursuant to: 21 CFR 812.2(b), 21 CFR 812.150(b)(9) and considering FDA Information Sheet Significant and Non-significant Risk Medical Device Studies
• Approval of waiver or alteration of informed consent, pursuant to: 45 CFR 46.116(c) and 45 CFR 46.116(d)
• Waiver of informed consent documentation, pursuant to: 45 CFR 46.117(c) and 21 CFR 56.109(c)(1)
• Research involving adults with impaired decision-making
• Waiver of HIPAA Authorization, pursuant to 45 CFR 164.512(i)(2)(ii)
• Waiver of HIPAA Authorization for recruitment or screening, pursuant to 45 CFR 164.512(i)(2)(ii)
• Alteration of HIPAA Authorization, pursuant to 45 CFR 164.512(i)(2)(ii)
• Use of short form process for consent 45 CFR 46.117(b)(2) or 21 CFR 50.27(b)(2)

When research involves children, the following IRB decisions are documented:
Appropriate children finding applicable to research:

Whether the permission of one parent/guardian is sufficient or if permission from both parents/guardians is required. How assent is to be solicited or obtained, unless waived.

The participation of children who are wards of the state is approved under:
45 CFR 46.406, 45 CFR 46.407 only if 45 CFR 46.409(a) is satisfied, or
21 CFR 50.53, 21 CFR 50.54 only if 21 CFR 50.56(a) is satisfied

Appropriate involvement of pregnant women, fetuses, and neonates pursuant to:
- 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, and 45 CFR 46.207

Approval of research involving transplantation of fetal tissue:
- 42 USC 498A(b)(1) and (2)

Approval of research involving prisoners as participants under the following regulations:
45 CFR 46.305 and 45 CFR 46.306

• Determination of the level of risk
• Determinations of serious or continuing non-compliance
• Unanticipated Problems and Unanticipated Adverse Device Effect

For research funded by the National Institute on Disability and Rehabilitation Research, when the IRB reviews research that purposefully requires inclusion of children with disabilities or individual with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of those research participants.

Other Issues
Other issues are documented in the minutes, including but not limited to:
• Other events and information that require prompt reporting to the IRB
• DSMB reports
• Approval of minutes of prior convened IRB meetings
• The approval of research contingent on specific minor conditions by the chair or designee, in the minutes of the first IRB meeting that takes place after the date of the approval
• Presentation of information from an outside consultant or expert as previously requested by the IRB
• Special situations such as use of a test article and humanitarian use devices
• The names of IRB members who abstain for reasons other than conflict of interest
• Other items as applicable.

Disposition of the IRB Minutes
The IRB staff writes minutes and makes them available for IRB review usually within three weeks of the meeting date. Minutes may not be altered by anyone including a higher authority once approved by the members at a subsequent IRB meeting.

The minutes of convened IRB meetings are considered confidential, and access to them is restricted and secured.

8.7 IRB Review of Planned Emergency Research

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<tr>
<td>II.4.C</td>
<td>The IRB has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.</td>
</tr>
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</table>

Prior to scheduling a study which qualifies as Emergency Research for initial IRB review, the IRB Analyst will discuss the study with the Director/Assistant Director, HSPPO. The IRB Chair/Vice Chair and the assigned primary reviewer will be notified by the Director/Assistant Director that such a study has been received and will be scheduled for review after the IRB staff and members have participated in an Emergency Research educational presentation. The planned emergency research presentation will include: a review of the FDA regulations; review of the responsibilities of the principal investigator; review of the responsibilities of the sponsor; review of the responsibilities of the IRB; review of the process of community consultation; a review of the documentation requirements that must be part of the minutes of the IRB meeting record; and review of the responsibility of public disclosure (both before the study begins and disclosure of the results of the research).

When following FDA regulations for Planned Emergency Research:

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:

The research activity is subject to regulations codified by the Food and Drug Administration (FDA) 21 CFR 50 and will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE).

• The application clearly identifies the protocols that will include participants who are unable to consent.
• The research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which might include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
• Obtaining consent is not feasible because:
  o The participants will not be able to give their consent as a result of their medical condition.
  o The intervention under investigation must be administered before consent from the participants’ legally authorized representatives is feasible.
There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

- Participation in the research holds out the prospect of direct benefit to the participants because:
  - Participants are facing a life-threatening situation that necessitates intervention.
  - Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual participants.
  - 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.

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

- 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 participant 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.

- The IRB has reviewed and approved consent procedures and a consent document consistent with 50.25. These procedures and the consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documented 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 participant’s participation in the clinical investigation consistent with the paragraph below.

- Additional protections of the rights and welfare of the participants will be provided, including, at least:
  - 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.
  - Public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.
  - 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.
  - Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
  - If obtaining 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 participant’s family member who is not a legally authorized representative, and asking whether he or 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.

- Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant’s inclusion in the clinical investigation, the details of the investigation and other information contained in the consent document.

- There is a procedure to inform the participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, that he or she might discontinue the participant’s participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

- If a legally authorized representative or family member is told about the clinical investigation and the participant’s condition improves, the participant is also to be informed as soon as feasible.

- If a participant is entered into a clinical investigation with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the participant’s legally authorized representative or family member, if feasible.

- The protocol is performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identified such protocols as protocols that might include participants who are unable to consent.

- The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.

- If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly (no longer than within 30 days) in writing to the clinical investigator and to the sponsor of the clinical investigation.

**For Planned Emergency Research NOT subject to FDA regulations:**

When research is not subject to FDA regulations, but follows DHHS regulations, the IRB finds, documents, and reports to DHHS that the following conditions have been met relative to the research add to policies and procedures:

- The IRB found and documented that the research is not subject to regulations codified by the FDA at 21 CFR 50.

- The research participants 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.

- Obtaining consent is not feasible because:
  - The participants are not able to give their consent as a result of their medical condition.
o The intervention involves in the research is administered before consent from the participants’ legally authorized representatives is feasible.

o There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

- Participation in the research held out the prospect of direct benefit to the participants because:
  
o Participants are facing a life-threatening situation that necessitated intervention.
  
o Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual participants.
  
o The risks associated with the research 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.

- The research could not practically be carried out without the waiver.

- 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 participant within that window of time and, if feasible, 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.

- The IRB has reviewed and approved consent procedures and a consent document in accord with 45 CFR 46.116 and 46.117.
  
o These procedures and the consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documented is feasible.
  
o The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a participant’s participation in the research consistent with the paragraph of this waiver.

- Additional protections of the rights and welfare of the participants are provided, including, at least:
  
o Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research is conducted and from which the participants are drawn.
  
o Public disclosure to the communities in which the research is conducted and from which the participants are drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits.
  
o Public disclosure of sufficient information following completion of the research to appraise the community and researchers of the study, including the demographic characteristics of the research population, and its results.
  
o Establishment of an independent data monitoring committee to exercise oversight of the research.
  
o If obtaining 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
participant’s family member who is not a legally authorized representative, and asking whether he or she objects to the participant’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.

- Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remained incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant’s inclusion in the research, the details of the research and other information contained in the consent document.

- There is a procedure to inform the participant, or if the participant remained incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, that he or she may discontinue the participant’s participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

- If a legally authorized representative or family member is told about the research and the participant’s condition improves, the participant is also informed as soon as feasible.

- If a participant is entered into research with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the research is provided to the participant’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 participant is the equivalent of a family relationship.

See also: HRPP Chapter 12.6

8.8 The Role of the Chair(s) and Vice Chair(s) and Their Voting Responsibilities

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<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
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<td>II.2.C</td>
<td>The IRB has and follows written policies and procedures for conducting meetings by the convened IRB.</td>
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The IRB Chair and the IRB Vice Chairs are voting members of the IRB. The Chair determines that quorum is established and maintained, chairs the meeting discussions, and calls for votes as appropriate.

The IRB Chair, in this instance used as the individual who chairs the scheduled IRB meeting, reviews all protocols presented to the full IRB. The IRB Chair notes and communicates with other reviewers any important IRB issues that may be resolved or identified prior to the scheduled IRB meeting.

The IRB Chair directs the proceedings and discussion of the full IRB meeting. This includes keeping the discussion focused on important IRB issues.

The Chair and Vice Chairs have an in-depth understanding of ethical issues, state laws, institutional policy, and federal regulations.
The Chair may assist in drafting letters from the IRB to researchers regarding IRB decisions. The Chair also represents the IRB in defending or discussing IRB decisions with researchers.

The Chair or Vice Chairs serve as the reviewer for research that is reviewed by the Expedited Review procedure. They may also serve as the final reviewer of revisions made by the researcher to determine that researchers have made the appropriate requested changes. Proscriptive changes made by the IRB at a full committee meeting may be reviewed by the IRB Chair, Vice Chairs, experienced IRB members and/or an appropriate IRB designee (HSPPO Director or Assistant Director).