1.0 **Purpose:** This standard operating practice (SOP) establishes guidelines for planned emergency research where it is anticipated that a waiver of consent will be required because participants will not be able to provide consent or where a Legally Authorized Representative (LAR) will be unavailable. This SOP will address the responsibilities of both the investigator and the IRB in regards to emergency research.

2.0 **Research Protocols Affected:**

2.1 Human emergency research reviewed and approved by the Biomedical IRB (both single site and multi-center) in which waiver of consent is requested.

2.2 Human emergency research in which waiver of consent is requested and in which an ECU or ECU affiliate’s faculty, staff, or student serves on the research team.

3.0 **SOP:** This SOP is to ensure the Biomedical IRB meets its responsibilities for the review, approval and oversight of clinical investigations that require an exception from informed consent requirements for planned emergency research. These actions must be decided at a convened meeting, after consultation with the community from which the targeted population will be recruited and with every effort made on the part of the investigator to obtain informed consent from legally authorized representatives, at the earliest possible opportunity.

Protocols involving an exception to the informed consent requirement must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as those that may include individuals who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND or an IDE already exists.

4.0 **Definitions:**

4.1 **Emergency research:** planned research on life-threatening conditions for which available treatments are unproven or unsatisfactory in situations where it is not possible to obtain informed consent from the participant. It is research that has received prospective IRB approval and;

4.1.1 may include drugs, devices, and biologics that are not approved for marketing or are not approved for emergency situations in which the investigator proposes to use them;

4.1.2 participants are not able to give informed consent due to their medical condition;

4.1.3 the window of time in which the intervention must be administered does not allow for informed consent from the participant or the participant’s’s LAR; and

4.1.4 there is no reasonable way to prospectively identify individuals likely to become eligible for participation.

4.2 **Waiver of informed consent:** research is conducted without obtaining consent from the participant or their LAR and may be requested by the investigator due to the nature of emergency research.

4.3. **Legally Authorized Representative (LAR):** is defined as an individual or judicial or other body authorized under applicable law to consent on behalf of a potential study participant to
his or her participation in the procedure(s) involved in the research.

4.4 Exceptions: Because of special regulatory limitations relating to research involving prisoners (subpart C of 45 CFR part 46), and research involving fetuses, pregnant women, and human in vitro fertilization (subpart B of 45 CFR part 46), this waiver is inapplicable to these categories of research.

5.0 Responsibilities:
5.1 Investigator responsibilities include:
5.1.1 submission of a request to waive informed consent inclusive of the rationale for the waiver request;
5.1.2 consultation with representatives of the communities from which participants will be drawn;
5.1.3 public disclosure to the communities in which the research will be conducted and from which the participants will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits;
5.1.4 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;
5.1.5 committing to providing informed consent to participants, if feasible; the LAR if the participant is unable to consent and a family member if the LAR is unavailable;
5.1.6 informing the participant as soon as feasible if his/her conditions improves or the LAR or family member as soon as they are available;
5.1.6.1 If an individual is entered into a clinical investigation with waived consent and then dies before a LAR or family member can be contacted, information about the clinical investigation is to be provided to the subject's LAR or family member, if feasible;
5.1.7 establishing an independent data monitoring committee to exercise oversight of the clinical investigation.

5.2 Institutional Review Board responsibilities include:
5.2.1 review of proposed plan for emergency research involving human participants to ensure all criteria in 21 CFR 50.24 are met when the research is FDA-regulated;
5.2.2 review of proposed plan for emergency research involving human participants to ensure all criteria in 45 CFR 46 are met when the research is not FDA-regulated;
5.2.3 review and, if appropriate, approve the investigator’s justification for waiving informed consent;
5.2.4 review and approve, if appropriate, procedures for ensuring all reasonable efforts are made to obtain proxy or surrogate informed consent to protect the rights of participants from whom informed consent cannot be obtained; and
5.2.5 at its discretion, participate in the activities planned for public disclosure to the communities in which the research will be conducted and from which participants will be drawn of the research and its possible benefits and risks;
5.2.6 verifying participation in the research holds out the prospect of direct benefit to the participants because:
5.2.6.1 participants are facing a life-threatening situation that necessitates intervention;
5.2.6.2 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 subjects; and
5.2.6.3 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.

5.3 ORIC Administrative Director or designee responsibilities include:
5.3.1 ensuring compliance with this policy;
5.3.2 ensuring appropriate tools/resources are available for review of planned emergency research based on new and evolving applicable regulations and guidelines;
5.3.3 assisting the committee/chair in the review of submission as needed.

5.4 The IRB Chairperson or designee responsibilities include:
5.4.1 review of submission to determine that the planned emergency research meets the federal criteria for emergency use in accordance with DHHS and FDA regulations; and,
5.4.2 ensuring appropriate review by the committee is conducted and the results of the outcome of the review are communicated to the investigator.

5.5 ORIC Staff responsibilities include:
5.5.1 consulting with investigators regarding their IRB submission information;
5.5.2 composing written documentation of IRB committee determinations and forwarding this documentation to the research team; and
5.5.3 assist investigators in explaining the proposed research at community or town hall meetings.

6.0 Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<tbody>
<tr>
<td>11.13.14</td>
<td>1.0</td>
<td>Revised format to standalone SOP.</td>
<td>All Sections</td>
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References
45 CFR 46
21 CFR 50.24
21 CFR 56.109
21 CFR 312.54
21 CFR 812.47