The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Planned Emergency Research

1. PURPOSE

1.1. This standard operating practice (SOP) establishes guidelines for planned emergency research where it is anticipated that a waiver of consent will be required because subjects 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 regarding planned emergency research.

1.2. This SOP affects planned emergency research reviewed and approved by the TCH IRB (both single site and multi-center) in which waiver of consent is requested and for which an TCH or TCH affiliate's physician, staff, or student serves on the research team.

2. POLICY

2.1. It is The Christ Hospital's policy to ensure the 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 and should include plans for consultation with the community from which the targeted population will be recruited. Every effort should be made on the part of the investigator to obtain informed consent from the subject, or their LAR, at the earliest possible opportunity.

2.2. 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.

3. RESPONSIBILITY

3.1. Investigator - The investigator responsibilities include the following:

3.1.1. Submission of a request to waive informed consent inclusive of the rationale for the waiver request within the IRB application.

3.1.2. Consultation with representatives of the communities from which subjects will be drawn and providing a summary of results/discussion/concerns to the IRB.

3.1.3. Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits.

3.1.4. 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.

3.1.5. Committing to, and documenting attempts to providing informed consent to subjects (or
3.1.6. the LAR if the subject is unable to consent, or a family member if the LAR is unavailable) if feasible within the therapeutic window.
3.1.7. Informing the subject (or the LAR or family member as soon as they are available) about the research and the option to discontinue at any time without penalty or loss of benefits as soon as feasible if the subject's condition improves.
3.1.7.1. 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.
3.1.7.2. Establishing an independent data monitoring committee to exercise oversight of the clinical investigation.

3.2. IRB – Institutional Review Board responsibilities include the following:
3.2.1. Review of proposed plan for emergency research involving human subjects to ensure all criteria in 21 CFR 50.24 are met when the research is FDA-regulated.
3.2.2. Review of proposed plan for emergency research involving human subjects to ensure relevant criteria in 45 CFR 46 are met when the research is not FDA-regulated.
3.2.3. Review and, if appropriate, approve the investigator's justification for waiving informed consent by assessing whether:
3.2.3.1. The clinical investigation could not practicably be carried out without the waiver of consent.
3.2.3.2. The subjects will not be able to give their informed consent as a results of their medical condition
3.2.3.3. The intervention under investigation must be administered before consent from the subjects LAR is feasible
3.2.3.4. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3.2.4. Review the consent document and procedures to be used to consent subjects (if able) and/or their LAR/family member as soon as possible along with the procedures to ensure the subject (if able) and/or LAR/family member can object to the subject's participation.
3.2.5. 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 subjects from whom informed consent cannot be obtained.
3.2.6. At its discretion, participate in the activities planned for public disclosure to the communities in which the research will be conducted, and from which subjects will be drawn, of the research and its possible benefits and risks.
3.2.7. Verifying participation in the research holds out the prospect of direct benefit to the subjects because:
3.2.7.1. subjects are facing a life-threatening situation that necessitates intervention;
3.2.7.2. 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

3.2.7.3. 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.

3.2.8. If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the applicable criteria, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation.

3.3. IRB Chair - The IRB Chair or designee is responsible for the following:

3.3.1. Review of IRB submission to determine that the planned emergency research meets the federal criteria for emergency use in accordance with DHHS and FDA regulations.

3.3.2. Ensuring compliance with this policy including verification that a licensed physician (either as an unconflicted IRB member or consultant) has concurred that a clinical investigation meets the criteria for waiving consent in planned emergency research.

3.3.3. Ensuring appropriate review by the IRB is conducted and the results of the outcome of

3.3.4. the review are communicated to the investigator.

3.4. IRB Office Staff - The IRB Office Staff are responsible for the following:

3.4.1. Consulting with investigators regarding their IRB submission information.

3.4.2. Composing written documentation of IRB committee determinations and forwarding this documentation to the research team.

3.4.3. Providing, or making available, appropriate tools/resources for review of planned emergency research based on new and evolving applicable regulations and guidelines.

3.4.4. Maintaining records of IRB determinations for at least 3 years after completion of the clinical investigation and making them accessible to federal regulatory agencies upon request.

4. DOCUMENTS

4.1. None

5. DEFINITIONS

5.1. Emergency research: is planned research with humans in a life-threatening situation for which available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions. These are situations where it is not feasible to obtain prospective informed consent from the subject, or their LAR, and participation in the research holds out the prospect of direct benefit to the subject. It is research that has received prospective IRB approval and;

5.1.1. 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;

5.1.2. subjects are not able to give informed consent due to their medical condition;

5.1.3. the window of time in which the intervention must be administered does not allow for informed consent from the subject or the subject's LAR; and

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

5.2. Waiver of informed consent: research is conducted without obtaining prospective consent from the subject or their LAR and may be requested by the investigator due to the nature of planned emergency research. xceptions: 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.

5.3. Community consultation: providing the opportunity for discussions with, and soliciting opinions from, the community in which the study will take place and the community from which the study subjects will be drawn. These communities may not always be the same; when they are not the same, both communities should be consulted. The goals of community consultation are to: 4.3.1 show respect for persons by informing the community about the study in advance; 4.3.2 inform community members about the trial in advance and provide a means for affected communities to provide meaningful input to the IRB before its decision to approve, require modifications to, or disapprove the study; 4.3.3 show respect for the community by allowing representatives of the community to identify potential community-level concerns and effects of the research; and 4.3.4 show respect for subjects' autonomy. Respect may be shown by including in community consultation activities individuals who may have, or be at risk for, the condition under study (and thereby obtain input from a group that is expected to be similar to the eventual study subjects).

5.4. Community in which the research will be conducted: the geographic area, e.g., hospital or other facility, or city or region, where the hospital or clinical investigator study site is located.

5.5. Community from which subjects will be drawn (i.e., the community at risk): the group of patients who share a particular medical or other characteristic that increases the likelihood that they (or a family member) may be enrolled in the study.

5.6. 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.

6. REFERENCES

6.1. HHS Regulation - 45 CFR 46: Protection of Human Subjects

6.2. FDA Regulation - 21 CFR 50.24: Exception from informed consent requirements for emergency research

6.3. FDA Regulation - 21 CFR 56.109: IRB Review of Research

6.4. FDA Regulation - 21 CFR 312.54: Emergency Research for Investigational New Drug Application

6.5. FDA Regulation - 21 CFR 812.47: Emergency Research for Investigational Device Exemptions

6.6. FDA Guidance - Guidance for Institutional Review Board, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (March 2011, updated April 2013)

6.7. OHRP Guidance - Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)

6.8. AAHRPP Standard II.4.C.