

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-026.0
Policy Title: Planned Emergency Research

Purpose

The purpose of this policy is to describe the mechanisms for obtaining approval from the IRB for planned emergency research, including how consent from subjects will be addressed.

Definitions

See policy 2011-007.0 for definitions of Legally Authorized Representative

Policy

A protocol for planned emergency research must be approved in advance by the IRB, and when applicable the FDA, and be publicly disclosed to the community in which the research will be conducted.

For planned emergency research subject to FDA regulations the IRB must review and approve the study and the request for waiver of consent and must document the following:

- that the research activity is subject to regulation codified by the FDA and will be carried out under an FDA investigational new drug application or an FDA investigational device exemption, the application for which clearly identified the protocols that would include subjects who are unable to consent, and
- how the requirements on the form to request a waiver of consent for planned emergency research have been met.
 - this provision for waiver does not extend to research involving fetuses, pregnant women, and human in vitro fertilization, or research involving prisoners.

For planned emergency research not subject to FDA regulations the IRB must review and approve the study and the request for waiver of consent for planned emergency research and must document:

- that the research activity *is not* subject to regulation codified by the FDA, and
- how the requirements on the form to request a waiver of consent for planned emergency research have been met,
 - this provision for waiver does not extend to research involving fetuses, pregnant women, and human in vitro fertilization, or research involving prisoners.
- that OHRP has been notified of the IRB's findings to support approval of the research and the waiver of consent.

When making determinations required on the request for waiver form, the IRB must do so 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/research.

The IRB determinations and the associated documentation are to be retained by the IRB for at least 3 years after completion of the research, and, if subject to FDA regulations, the records shall be accessible for inspection and copying by the FDA.

Procedure

In addition to the standard documents required for an IRB submission, the PI will be required to complete and submit the form to request a waiver of consent for planned emergency research. The form addresses all regulatory criteria for granting such a waiver.

Through assignments in the electronic submission system, IRB staff will provide the IRB members with 1) the standard reviewer sheet used to determine if a protocol meets the regulatory criteria for approval and 2) the request for waiver form that has been completed by the PI.

The reviewer will use the forms as a guide in the review process and discussion at the meeting.

The IRB Regulatory Specialist (RS) will document in the minutes the findings of the convened board for each required criteria for approval and for the waiver. Determinations made at the convened board supersede the opinion of the individual reviewers.

In all cases the IRB RS will prepare communication back to the investigator regarding the decision of the IRB.

- If the IRB cannot approve the research because the research does not meet the criteria for approval, the criteria outlined in the form to request a waiver, or because of other ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the investigator and to the sponsor (via the investigator) of the research.
- When the research is subject to DHHS regulations, the IRB will find, document and report to DHHS that the conditions required for approval (as outlined on the request for waiver form) have been met.

Related Policies

2011-007.0 – Definitions Applied to Policies

2011-009.5 – Institutional Review Board - Review by Convened Board

2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

21 CFR 50.24

Document Attributes

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Reviewed and Approved By:

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Date