MCW IRB Committee Procedure

PLANNED EMERGENCY RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
This procedure outlines the steps taken when an Investigator wishes to conduct a clinical investigation involving planned emergency research.

Emergency Research is a planned investigation and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory. For emergency research the IRB must also evaluate materials to determine if the investigation satisfies the criteria outlined here and determine whether it is appropriate to proceed under this section.

DEFINITIONS:
Community Consultation: Community consultation means providing the opportunity for discussions with, and soliciting opinions from, the communities in which the project will take place and from which the subjects will be drawn.

Emergency Research: is a planned clinical investigation that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory.

Life-threatening: Diseases or conditions where the likelihood of death is high unless the course of the disease or condition is interrupted. The FDA regulations which allow an exception from informed consent for emergency research (21 CFR 50.24) apply only to life-threatening emergency situations.

Public disclosure: Public disclosure means dissemination of information about the emergency research sufficient to allow a reasonable assumption that the communities are aware of the plans for the investigation, its risks and expected benefits, and the fact that the project will be conducted. Public disclosure also includes dissemination of information after the investigation is completed so that the communities and scientific researchers are aware of the project's results.

Therapeutic window: (1) The therapeutic window is the time period, based on available scientific evidence, during which administration of the test article might reasonably produce a demonstrable clinical effect. (2) For investigations of in vitro diagnostic devices (IVDs) that meet the criteria for emergency research, the therapeutic window is the time period, based on available scientific evidence, during which diagnosis must occur to allow administration of appropriate therapy.

PROCEDURE:

1. The IRB Committee conducts initial review of a project at intervals appropriate to the identified degree of risk, but not less than once per year. The review will be carried out in accordance with *IRB Member SOP: Initial Review and Primary Reviewer Responsibilities* and assigned to IRB Reviewers in accordance with *Staff: Assigning Primary Reviewers and Use of Consultants*
2. For projects which involve planned emergency research, the IRB Committee considers the project and reviews it in conjunction with the federal regulations regarding the conduct, design and consenting process of these projects.
3. The standards for the review of an initial submission and/or consent form are outlined in the *IRB Member Form: New Protocol Review Checklist* which includes the federal regulations criteria for approval (45 CFR 46.111 & 21 CFR 56.111). These forms are available to members via the HRPP website, and during the meeting. See *IRB Member SOP: Initial Review and Primary Reviewer Responsibilities*.
4. Additional criteria for the review of planned emergency research will be applied. The IRB Committee will review the additional information provided by the Investigator and complete the *IRB Member Form: Planned Emergency Research Reviewer Checklist.*

The specific criteria are made available to all members via the HRPP website and during the meeting.

IRB Review

1. The IRB Committee will review the initial submission and the details of the community consultation plan.
2. The IRB Committee must determine if the project meets the criteria for approval and the additional requirements as defined in the federal regulations and issue an approval for the project to allow the Investigator to conduct the community consultation.
3. Using the amendment pathway, the Investigator should submit to the IRB results of the community consultation, along with the feedback received. The Investigator should indicate if additional changes have been made to the original protocol in light of community feedback. The amendment should also include plans to conduct public notification.
4. The IRB Committee will review the results of the community consultation and any changes made to the original protocol. Information that will be publicly disclosed will be reviewed to assure that the information will reach the broader communities involved and will adequately inform affected communities of plans to conduct this research. The IRB will issue an approval to conduct public notification. Using the amendment pathway, the investigator should submit the results of public notification to the IRB. The IRB Committee will review the report and determine if final approval can be granted or if additional changes are required. An IRB decision letter granting approval to begin the investigation and enroll human subjects will be issued to the Investigator in accordance with *Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters.*
5. If the IRB determines that the project cannot be approved because it does not meet the criteria for exception from informed consent regulations or because of relevant ethical concerns, the IRB will promptly (within 30 days) provide this information to the investigator and sponsor.

REFERENCES:

21 CFR 50.24
21 CFR 56.111
21 CFR 312.54
45 CFR 46.101 (i)
45 CFR 46.111

61 FR 51531
OHRP Guidance: Informed Consent Requirements in Emergency Research
FDA Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research

SUPPORTING DOCUMENTS:
IRB Member SOP: Initial Review and Primary Reviewer Responsibilities.
Staff: Assigning Primary Reviewers and Use of Consultants
Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters.
IRB Member Form: New Protocol Review Checklist
IRB Member Form: Planned Emergency Research Reviewer Checklist

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Approved By
HRPP Authorized Official: David Clark, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin