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 submit research involving planned emergency research for IRB review.

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

PROCEDURE:

1. 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.
2. 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

   and assigned to IRB Reviewers in accordance with

3. The standards for the review of an initial submission and/or consent form are outlined in the which includes the federal regulations criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111). These forms are available to members via the HRPP website, and during the meeting. See

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   Additional criteria for the review of planned emergency research will be applied. The IRB Committee will review the additional information provided by