

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	Policy Response to an Immediate Hazard	No.: DMID Policy-009 NCRS-1.2 v 2
	Effective Date: 01-JULY-2015	Version: 2.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) policy for response to immediate hazards to clinical research volunteers.

2.0 Scope:

This policy applies to all DMID clinical research protocols.

3.0 Policy:

When there is an apparent immediate hazard to volunteers enrolled in clinical research studies, the Principal Investigator (PI) or designee is expected to react to the situation and eliminate/mitigate the potential hazard in order to protect the life or physical well-being of a volunteer. Any changes made to the implementation of the approved clinical protocol must be reported in writing to DMID within 24 hours of the change. The written report to DMID will include the exact change made, reasons for the change, potential impact of the change to the study and data interpretation, the plan to notify the Institutional Review Board (IRB), and whether a protocol amendment or informed consent form (ICF) amendment is proposed by the investigator.

4.0 Background:

No changes in approved clinical research protocols or associated documents (e.g., ICF) may be initiated without DMID and Institutional Review Board (IRB)/Independent Ethics Board (IEC) review and approval unless there is an apparent immediate hazard to study volunteers.

In the course of conducting clinical research protocols, it sometimes becomes evident that changes to a study need to be made to accommodate unforeseen conditions or occurrences. For the protection of human subjects the U.S. Code of Federal Regulations 45 part 46 (45 CFR 46.103.4) states that approval from an IRB/IEC must be obtained before implementing any modifications to previously approved clinical research, except those necessary to eliminate apparent immediate hazards to the clinical research volunteers. This is consistent with Food and Drug Administration (FDA) regulations (21 CFR 56.104, 21 CFR 312.30(b), and 812.35(a)(2)) and International Conference on Harmonization (ICH) E-6 4.5.1 Good Clinical Practice (GCP) guidelines. When DMID does not hold the Investigational New Drug Application/Investigational Device Exemption (IND/IDE), the IND/IDE sponsor may have additional requirements.

5.0 Definitions:

Independent Ethics Committee (IEC): Committee designation frequently used by non-US institutions for the body that performs the functions of an IRB.

Institutional Review Board (IRB): An independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the human subjects involved in clinical research.

Protocol: . A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial as well as provides the background and rationale for the trial.

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6.0 Responsibilities:

Role	Responsibility
DMID Scientific Branches	<ul style="list-style-type: none"> Coordinate the clinical protocol amendment review process within DMID
Office of Clinical Research Affairs	<ul style="list-style-type: none"> Acknowledge the PI's notification For multicenter studies, notify other sites as required Assess appropriateness of PI response
IND/IDE Sponsor	<ul style="list-style-type: none"> Submit to the FDA any amended protocols, amended ICFs, safety reports, and actions taken as required by regulation
Principal Investigator	<ul style="list-style-type: none"> Immediately eliminate/mitigate apparent hazard to volunteers Notify DMID immediately if there is an apparent hazard to volunteers Notify IRB/IEC and follow IRB/IEC procedures for immediate changes in a clinical protocol for the protection of participant safety

7.0 References:

7.1 U.S. Code of Federal Regulations:

[45 CFR 46: Protection of Human Subjects](#)

21 [CFR, Part 56: Institutional Review Boards](#)

21 [CFR Part 50: Protection of Human Subjects](#)

21 [CFR, Part 312: Investigational New Drug Application](#)

21 [CFR, , Part 812: Investigational Device Exemptions](#)

7.2 [International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice](#)

8.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases (DMID)
NIH / NIAID
5601 Fisher Lane, Rm. 7E60
Bethesda, MD 20892
DMIDPolicyQuery@niaid.nih.gov

9.0 Availability:

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This policy is located electronically at:

<http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Documents/hazardresponse.pdf>

10.0 Change Summary:

Version number	Date of Revision: DD/MMM/YYYY	Replaces	Effective Date: DD/MMM/YYYY	Description of Revision/Retirement
1.0	N/A	N/A	01-AUG-2013	N/A
2.0	20-JUN-2015	Version 1.0	01-JUL-2015	Administrative edits