

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	<b>Policy</b> <b>DMID Requirements for IRB/IEC Review of Human Subjects Research</b>	No.: DMID Policy-006 NCRS 1.2 v 3
	Effective Date: 09-JAN-2017	Version: 4.0

**1.0 Purpose:**

To describe the Division of Microbiology and Infectious Diseases (DMID) requirements for review of human subjects research by Institutional Review Boards (IRB) or Independent Ethics Committees (IEC) in order to meet DMID’s obligations under regulation.

**2.0 Scope:**

This policy applies to DMID-funded clinical research where the participating sites meet the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) definition of engaged in human subjects research. This policy is applicable to both domestic and international studies.

**3.0 Policy:**

All sites and institutions engaged in DMID-funded clinical research that involves human subjects are required to have the protocol, consent, and other appropriate documents reviewed and approved by an IRB/IEC and must comply with all applicable national, state, and local regulatory requirements for IRB/IEC review. In addition to the initial review of the protocol and associated documents, the research must be reviewed at least once a year and whenever changes occur in the approved research. Investigators are responsible for knowing IRB/IEC procedures and reporting requirements at their site(s).

Each institution engaged in human subjects research must have a Federal Wide Assurance (FWA) from OHRP listing the registered IRB/IEC.

Studies that involve more than one domestic site should utilize a single IRB to conduct the ethical review required under 45 CFR 46 for those domestic sites, unless an exception had been granted.

**4.0 Background:**

The IRB/IEC is charged with assuring that appropriate steps are/have been taken to protect the rights and welfare of human subjects participating in clinical research. Federal regulations concerning research involving human subjects research are specified in the Code of Federal Regulations (CFR) Title 45, Part 46 (45 CFR 46), which defines the scope, constitution, documentation, and criteria for IRB/IEC approval of the research. Clinical trials involving FDA-controlled products must also comply with FDA regulations under 21 CFR Parts 50, 56, and 312 for an Investigational New Drug Application (IND) and 21 CFR Part 812 for an Investigational Device Exemption. FDA has also adopted the International Conference on Harmonisation (ICH) E6 Good Clinical Practice Guidelines, which addresses IRB/IEC review. When conducting continuing review, the IRB/IEC needs to determine whether new information has emerged from the research or from other sources that could affect continuing approval.

NIH policy creates the expectation that a single IRB of record will be used for multi-site research involving domestic sites. Foreign sites are not expected to follow this policy. For mixed domestic and foreign site, the domestic sites are expected to follow the policy.

The regulations stipulate that the IRB/IEC be sufficiently qualified through experience and expertise, as well as diversity of its members, including race, gender, cultural background, and sensitivity to issues such as community attitudes and vulnerable populations. The IRB/IEC must

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also be able to evaluate research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Generally, IRB/IEC approval for contract studies is recorded in DMID's Office of Clinical Research Affairs (OCRA) and IRB/IEC approval for human subjects research under grants is collected by Program.

## 5.0 Definitions:

**Engagement:** An institution is considered *engaged* in a particular non-exempt human subjects research project if the institution received federal funds for the research, whether the research is carried out by its employees or by agents of another institution, and the following information is obtained for the purposes of the research project: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

**Human Subjects Research:** A systematic investigation designed to develop or contribute to generalizable knowledge that involves a living individual(s) about whom an investigator obtains data through intervention or interaction with the individual; or Identifiable private information.

**Non-Exempt Human Subjects Research:** Research activities involving human subjects that are not identified as exempt from IRB review are under 45 CFR 46.101(b).

**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 a Clinical Trial.

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

## 6.0 References:

- 6.1 Code of Federal Regulations:
  - [CFR Title 45, Part 46: Protection of Human Subjects](#)
  - [CFR, Title 21, Part 50: Protection of Human Subjects](#)
  - [CFR, Title 21, Part 56: Institutional Review Boards](#)
  - [CFR, Title 21, Part 312: Investigational New Drug Application](#)
  - [CFR, Title 21, Part 812: Investigational Device Exemptions](#)
- 6.2 [International Conference on Harmonization \(ICH\) E6: Good Clinical Practices](#)
- 6.3 [Office for Human Research Protections](#)
- 6.4 [NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)

## 7.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director of Clinical Research  
Division of Microbiology and Infectious Diseases (DMID)

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**8.0 Availability:**

This policy is located electronically at:  
<http://www.niaid.nih.gov/labsandresources/resources/dmidclinrsrch/Pages/instreview.aspx>.

**9.0 Change Summary:**

Version Number	Date of Revision: DD/MM/YY	Replaces	Effective Date: DD/MM/YY	Description of Revision/Retirement
1.0	N/A	N/A	01/NOV/2011	N/A
2.0	17/NOV/2012	1.0	01/DEC/2012	Administrative edits
3.0	05/NOV/2014	2.0	01/DEC/2014	Biennial review; Administrative edits
4.0	16/DEC/2016	3.0	09/JAN/2017	Biennial review; cited policy on use of a single IRB for multi-site research