

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	<b>Policy</b> <b>Medical Officer Assignments and Responsibilities for DMID Clinical Protocols</b>	No.: DMID Policy-001 NCRS 1.1 v2.0
	Effective Date: 12-FEB-2016	Version: 2.0

**1.0 Purpose:**

To describe the Division of Microbiology and Infectious Diseases (DMID) procedure to assign Medical Officers (MO) for DMID-supported clinical research.

To describe the role of a DMID MO in clinical protocol development and execution.

**2.0 Scope:**

This policy applies to DMID-supported clinical protocols and DMID staff involved in clinical protocol development and execution.

**3.0 Policy:**

An MO must minimally have a Doctor of Medicine or Doctor of Osteopathy degree from a U.S.-accredited medical or osteopathic school or have graduated from from a medical or osteopathic school during a year that the school was certified by the Educational Commission for Foreign Medical Graduates to sit for a qualifying exam in the United States. This list is available at the International Medical Education Directory(<https://imed.faimer.org>).

MOs may reside in the DMID scientific branches or in the DMID Office of the Director (OD). These individuals can function as MOs for specific protocols or provide support for the scientific branches, as necessary.

- (1) If the branch/office has an MO, the branch/office chief is responsible for deciding whether to assign a scientific branch MO or for requesting that an MO from the OD be assigned to a branch protocol.
- (2) If a branch/office does not have an MO, the branch/office chief can request that an MO from the OD be assigned to a protocol. The OD MO will be assigned by the OD after consultation with the branch/office chief.

An MO will be assigned to review and approve the following:

- (1) Protocols where DMID is the responsible party.
- (2) Protocols under Investigational New Drug Application (IND) or Investigational Device Exemption (IDE).
- (3) Protocols under a DMID clinical contract.

MOs are not required to review any other protocols. Each branch/office has discretion to assign or request an MO for review. Oversight of low risk contract studies will be the purview and responsibility of each branch/office and the Contract Officer's Representative (COR).

MOs, through the DMID consensus review process, will review amendments that included changes to eligibility criteria, endpoints, clinical study procedures, or safety information/oversight sections of the protocol.

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#### 4.0 Background:

The process of protocol review and implementation within DMID is a process incorporating staff with different areas of expertise. The MO is a key member of the team to assure that the assigned protocols are appropriately designed for the target population and if using an investigational product, the level of product development.

It is the branch chief's responsibility to assure that an MO is assigned to all protocols meeting the DMID resource assessment criteria and that the assigned MO has appropriate medical credentials and expertise to evaluate assigned protocols.

#### 5.0 Definitions:

**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.

#### 6.0 Responsibilities:

Role	Responsibility
Branch Chief	<ul style="list-style-type: none"> <li>• Assign branch protocols to branch MOs or request MO services from the Associate Director of Clinical Research</li> </ul>
Medical Officer	<ul style="list-style-type: none"> <li>• Participate in the development of protocols that are assigned to ensure that: <ul style="list-style-type: none"> <li>○ The studies are based on a sound progression from pre-clinical studies and/or current experience in humans</li> <li>○ The appropriate safety requirements and procedures are well defined in the protocol</li> </ul> </li> <li>• Review protocols as part of the DMID approval process</li> <li>• Consult on implementation questions</li> <li>• Familiar with Good Clinical Practice (GCP) guidelines and U.S. Code of Federal Regulations 21 CFR 50 and 45 CFR 46 and DMID policies and guidances</li> </ul>
DMID Scientific Branches	<ul style="list-style-type: none"> <li>• Request services of an MO from the branch chief, if needed for review or consultation for low resource protocols</li> </ul>
Associate Director of Clinical Research	<ul style="list-style-type: none"> <li>• Assign MOs from the OD as requested by branch chiefs</li> </ul>

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## 7.0 References:

[DMID Protocol Review Process](#)

[DMID Clinical Research and Operations Management](#)

[International Conference on Harmonisation E6, Section 6: "Good Clinical Practice: Clinical Trial Protocol and Protocol Amendments":](#)

U.S. Code of Federal Regulations:

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

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

[21 CFR 812.25\(b\): "Investigational Device Exemptions"](#)

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

## 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@mail.nih.gov](mailto:DMIDPolicyQuery@mail.nih.gov)

## 9.0 Availability:

This policy is located electronically at:

<http://www.niaid.nih.gov/labsandresources/resources/dmidclinrsrch/Pages/clinicalsitegmt.aspx>.

## 10.0 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-2012	N/A
2.0	27-JUN-2015	1.0	12-FEB-2016	Changes in the categories of protocols assigned to MOs; Administrative edits