

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/Office of Clinical Research Affairs	Policy DMID Initial and Ongoing Clinical Research Site Evaluation	No.: DMID Policy-011 – NCRS 2.1 v 4
	Effective Date: 01-APR-2015	Version: 4.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) policy for evaluation/assessment of clinical sites conducting DMID-supported human subjects research, prior to and throughout the life cycle of approved DMID clinical protocols.

2.0 Scope:

This policy applies to DMID staff involved in the oversight of DMID-supported clinical studies.

3.0 Policy:

All clinical studies will have appropriate initial and on-going evaluations/assessments of clinical sites to ensure that the requirements of the protocol(s) can be/are being implemented; applicable regulatory requirements are met; Good Clinical Practices (GCP) standards are followed; and that human subjects' rights are being protected and data are accurate and complete.

4.0 Background:

The National Institutes of Health (NIH) peer review award process is the primary mechanism for selecting qualified investigators and sites for clinical studies. Although the peer review is an independent process outside of DMID's control, all DMID proposed clinical studies are evaluated/assessed post award using DMID-established mechanisms to ensure the site(s) meet standards of operation appropriate to the requirements of the planned protocol(s) and applicable regulatory requirements.

DMID's evaluation of clinical study sites occurs along a continuum from reviewing a funded award proposal throughout the life cycle of a clinical research protocol. These evaluations cover a broad spectrum of activities that are matched to the study.

Pre-study site evaluations are made prior to initiating a clinical study. In addition to evaluating the site and investigator qualifications, the pre-study assessments, as appropriate, examine logistics, feasibility, need for training, and any relevant regulatory issues.

Ongoing evaluation of site performance is reviewed by DMID. The ongoing evaluation and follow-up are performed by the Scientific Branches and, if under contract, the Contract Officer's Representative (COR), through periodic interactions and annual reports. When deemed necessary, site visits by DMID staff or independent monitors provide additional information on site performance.

The type of clinical site evaluations is based upon several factors, the most common being 1) risks to participants; 2) use of investigational agents; and 3) DMID's experience with the site/investigator.

Studies that do not meet the criteria for independent clinical monitoring require greater oversight by the Scientific Branch. In addition to surveys, periodic reports, and/or teleconferences, increased interaction may be appropriate, which might include on-site visits from the Scientific Branch staff or the COR. Alternatively, Scientific Branch staff may request services of a contract monitor through OCRA or, if the study is international, from the international support contractor.

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DMID has developed criteria for site evaluation that require oversight support from independent contract clinical site monitors. For studies, such as those in which DMID is the regulatory sponsor for Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE) or other trials that have been assigned a DMID medical monitor, the Scientific Branch staff and OCRA will develop a Clinical Site Monitoring Plan that describes who will conduct on-site monitoring, and at what frequency and level of detail. Site visits by Scientific Branch staff are not usually needed when the independent monitors are being used, but the Scientific Branch staff is responsible for reviewing monitoring reports and providing direction on corrective actions.

5.0 Responsibilities:

Role	Responsibility
Scientific Branches	<ul style="list-style-type: none"> • Primary DMID responsibility for oversight of the conduct and quality of clinical studies • Request site visit when deemed necessary • Review site monitoring reports and follow up to ensure corrective action is completed
Office of Clinical Research Affairs (OCRA)	<ul style="list-style-type: none"> • Provide operational and clinical monitoring review and support, as applicable
Office of Regulatory Affairs (ORA)	<ul style="list-style-type: none"> • Provide regulatory review and support to clinical sites for protocols with interventional products and studies with special human subjects as required/requested • Perform consultative reviews of clinical site monitoring reports and provide comments when requested
Contract Officer's Representative (COR)	<ul style="list-style-type: none"> • Primary responsibility for ensuring that the contractor has resources necessary to conduct the study and meets the requirements of the contract

6.0 References:

[International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice](#)
[U.S. Code of Federal Regulations 21 CFR 312 Subpart D](#)

7.0 Inquiries:

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8.0 Availability:

This policy is located electronically:

<https://www.niaid.nih.gov/sites/default/files/clinresearchevaluation.pdf>

9.0 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/OCT/2010	N/A
2.0	11/JAN/2012	1.0	15/JAN/2012	Annual review, administrative changes
3.0	20/MAR/2013	2.0	30/MAR/2013	Annual review, administrative edits
4.0	05/MAR/2015	3.0	01/APR/2015	Biennial review, administrative edits
4.0	10/MAR/2017	N/A	01/APR/2015	Biennial review; no changes