

National Institutes of Allergy and Infectious Diseases (NIAID) / Division of Microbiology and Infectious Diseases (DMID)	Policy DMID Clinical Research Document Translation Requirements	No.: DMID Policy-003 - NCRS 1.2 v. 5
	Effective Date: 02-MAY-2016	Version: 5.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) clinical research translation requirements and to ensure that DMID-supported clinical research documentation and site-level communication meets regulatory requirements and the International Conference on Harmonisation (ICH) E6-Good Clinical Practices (GCP) standards.

2.0 Scope:

This policy applies to translation of clinical research documentation and verbal communication at clinical site locations where English is not the primary language spoken or understood by study staff or the study volunteers.

3.0 Policy

- 3.1 All research-related documents will be provided to DMID Staff in English.
- 3.2 All documents and other communications that will be used by study volunteers and clinical site staff must be in a language they can understand.
- 3.3 Clinical site staff must include individuals on site who speak or communicate in a language and at a level the study volunteer population understands.
- 3.4 Principal Investigators (PIs) conducting DMID-supported clinical research are responsible for coordinating the translation of documents and ensuring the availability of translators or who are fluent in the language the study volunteers can understand.

4.0 Background:

Since errors in translation can change the meaning of important content in study documents, DMID requires a high degree of accuracy in the translation process. DMID supports, through both the contract and grant mechanisms, a large number of clinical studies and trials in the U.S. and abroad where non-English speaking volunteers are recruited and enrolled for clinical research studies. Adhering to requirements for equivalent documentation and verbal communication translation is important to the clinical research process because it allows:

- o **DMID** to meet regulatory requirements and GCP standards. DMID, as the study regulatory and/or fiduciary sponsor, must be able to review safety reports and essential documents such as the protocol, informed consent form (ICF), and related study documentation. Translation of these documents to English allows DMID to confirm that the documents address the scientific objectives of the project, has appropriate safety procedures, and human subject protection is appropriate.
- o **Communications to Study Volunteers** to be verbally given or written in a language understandable to them or their legally authorized representative.
- o **Site Staff** to meet requirements of the protocol and research-related documents. Study materials used by staff must be in a language understandable to the clinical site staff responsible for conducting the elements of the study described in the research-related documents and materials. Alternatively, upon approval from DMID, the relevant information may be relayed to site staff through training.

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The DMID Language and Translation Requirements Summary, Essential Document Requirements and Instructions, and the form for documentation of translation equivalence - DMID Translation Equivalence Form are available to clinical sites upon request.

5.0 Definitions:

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

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.

6.0 Responsibilities:

Role	Responsibilities
DMID Program Staff	<ul style="list-style-type: none"> • Consult with the Office of Clinical Research Affairs (OCRA) concerning translation requirements • Inform the clinical sites of documents that require translation • Confirm translation requirements are met prior to initiation of the study
Office of Clinical Research Affairs	<ul style="list-style-type: none"> • Consult with DMID Program Branches regarding essential documents that require translation
Principal Investigator and/or Clinical Research Site/Institution	<ul style="list-style-type: none"> • Initiate translation process • Provide DMID accurate and complete translation of identified/designated study documents • Provide study documents and/or training for staff in a language they understand • Verify site resources/staff are available to communicate with research volunteers throughout the course of the study in a language the volunteers understand

7.0 References:

- 7.1 [DMID Language and Translation Requirements Summary, Essential Document Requirements and Instructions](#)
- 7.2 [DMID Policies, Guidances, and Tools public web site](#)
- 7.3 [DMID Translation Equivalence Form](#)
- 7.4 [Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects](#)

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- 7.5 [21 CFR 50, Protection of Human Subjects](#)
- 7.6 [International Conference on Harmonisation \(ICH\) E6: Good Clinical Practices](#)
- 7.7 [Food and Drug Administration: A Guide to Informed Consent – Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators](#)

8.0 Inquiries

Questions or comments regarding this policy may be directed to:

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9.0 Availability:

This document is available electronically at:
<http://www.niaid.nih.gov/labsandresources/resources/dmidclinrsrch/Pages/protdev.aspx>

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	27-Nov-2007	N/A
2.0	10-Nov-2008	Version 1.0	15-Dec-2008	Annual review
3.0	19-May-2010	Version 2.0	01-Oct-2010	Annual review
4.0	21-Nov-2013	Version 3.0	20-Dec-2013	Revised to policy format
5.0	11-Mar-2016	Version 4.0	02-May-2016	Biennial review; Administrative edits