1. PURPOSE

1.1 This document describes the Division of Microbiology and Infectious Diseases (DMID) clinical research translation requirements to ensure that documentation from DMID-supported clinical research meets regulatory requirements and the International Conference on Harmonisation (ICH) E6-Good Clinical Practices (GCP) standards.

2. SCOPE

2.1 This policy applies to:

- All clinical trials performed under an IND (or international equivalent), both those where DMID is IND sponsor and other sponsors.
- All non-IND clinical trials funded by contract or cooperative agreement.
- All clinical studies (that are not clinical trials) funded by contract.

3. DEFINITIONS

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Principal Investigators (PIs) conducting DMID-supported clinical research are responsible for coordinating the translation of non-English documents into English and providing those documents to DMID according to this policy.

5. POLICY

5.1 All research-related documents provided for DMID files must be provided in English.

5.2 DMID, as the sponsor and/or funder, 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.

- If documents that are subject facing or communicate safety information or protocol procedures are not in English, an accurate certified English translation must also be provided.
- A translation equivalence form, including a summary of the information contained within a document, in lieu of a certified translation may be acceptable for documents not meeting the criteria listed above upon the approval of DMID staff.

6. REFERENCES

6.1 FDA Drug Master File Guidance

6.2 ICH GCP E6 R2

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 This is the original version of this procedure within the eQMS, and is an update to DMID Policy-003 - NCRS 1.2

9. ADDITIONAL INFORMATION

9.1 Document Lead: OCRR

9.2 Posting externally: Yes