1. PURPOSE

1.1 This document describes the restrictions around the enrollment of clinical site study staff and their family members in Division of Microbiology and Infectious Diseases (DMID)-funded clinical research to ensure the ethical and objective conduct of the clinical research and the protection of the rights of enrolled participants.

2. SCOPE

2.1 This policy applies to:

- Clinical trials where DMID is the IND sponsor (regardless of funding type);
- Non-IND clinical trials funded under contract;
- Non-IND clinical trials funded under cooperative agreement and implemented through a DMID funded network;
- Clinical studies (that are not clinical trials) with a high-risk procedure funded under contract.

3. DEFINITIONS

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Principal Investigator: In addition to this policy, the site PI must also abide by local institutional and IRB policies regarding enrollment of site staff.

5. PROCEDURE

5.1 The following clinical site staff are not permitted to enroll as research subjects in DMID-funded clinical trials as noted in the scope:

5.1.1 The PI and sub-Investigators listed in Form FDA 1572 or Investigator of Record Form for the trial;

5.1.2 Staff who are directly or indirectly supervised by the Principal Investigator (PI) or sub-Investigators for the trial;

5.1.3 All staff who are paid entirely or partially by/through DMID funding for the clinical trial; and

5.1.4 The local institutional and IRB policies must also be followed. If these local policies are more restrictive than those listed above, the local policies take precedent.

5.2 Family members of the above staff or other staff who work for the associated hospital/institution may enroll in the clinical trial provided that:

5.2.1 They meet the inclusion/exclusion criteria outlined in the study protocol; and

5.2.2 The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) has no restrictions on enrolling subjects in these categories or has written associated policies for the site to follow.

5.3 Policy deviation requests must be submitted in writing to and approved by the OCRR Director.

6. REFERENCES

6.1 Office for Human Research Protections (OHRP): Informed Consent FAQ
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

6.2 U.S. Code of Federal Regulations 21 CFR 312:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312

6.3 Research Involving NIH Staff as Subjects Policy
https://policymanual.nih.gov/3014-404

6.4 Director, Office of Clinical Research Resources DMID/NIAID/NIH DMIDPolicyQuery@mail.nih.gov

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 This is the original version of this policy within the eQMS. It a revision and replacement of DMID-OCRR Policy-007.

9. ADDITIONAL INFORMATION

9.1 Document Lead: OCRR

9.2 Posting externally: Yes