

**1. PURPOSE**

1.1 This document describes the circumstances in which Division of Microbiology and Infectious Diseases (DMID) staff may enroll as research subjects in protocols funded by the Division.

**2. SCOPE**

2.1 This policy applies to DMID staff who wish to participate in research funded by the division.

**3. DEFINITIONS**

For other definitions, see [DMID glossary](#).

**4. RESPONSIBILITIES**

4.1 DMID Staff have the responsibility to follow the policy prior to study participation.

**5. PROCEDURE**

5.1 DMID policies do not apply to family members of DMID staff. Family members of DMID staff can participate in clinical research funded by the division.

5.2 DMID staff should not participate in IND clinical trials where DMID is the IND sponsor.

5.2.1 An exception for extenuating circumstances (e.g. for the health of a staff member) is permissible but requires approval by the Director of DMID.

5.3 For all other clinical trials and clinical studies, if DMID staff are part of the work unit supporting the research, including the program officers (PO), project scientist (PS), or contracting officer representatives (COR), supervisor approval is required.

5.3.1 If a conflict is identified, a risk mitigation plan must be put in place prior to participation.

5.4 DMID staff who participate in NIH-funded clinical research must comply with NIH leave requirements. (See NIH Manual Chapter: 2300-630-3 - Leave Policy for NIH Employees Participating in NIH Medical Research Studies)

5.5 DMID staff participation in intramural research may have additional restrictions (See <https://policymanual.nih.gov/3014-404>)

**6. REFERENCES**

6.1 [ICH GCP E6 R2](#)

**7. APPENDICES**

Not applicable

**8. REVISION HISTORY**

8.1 DMID-TM-POL-00003 is the original version of this procedure within the eQMS.

Division of Microbiology and Infectious Diseases

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**04 May 2024**Page:  
**2 of 2**Document Title: ***Enrollment of DMID Staff in Research Protocols Funded by DMID*****9. ADDITIONAL INFORMATION**

9.1 Document Lead: DMID Associate Director for Clinical Research

9.2 Posting externally: Yes