

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases / Office of Clinical Research Resources	<b>Policy</b> <b>Enrollment of Clinical Site Study Staff in DMID-Funded Clinical Trials</b>	No.: DMID-OCRR Policy-007
	Effective Date: 9-MAR-2015	Version: 1.0

### 1.0 Purpose

To describe the policy and restrictions around the enrollment of clinical site study staff and their family members in Division of Microbiology and Infectious Diseases (DMID)-funded clinical research under Office of Clinical Research Resources (OCRR) clinical site contracts.

### 2.0 Scope

This policy applies to clinical site contractors (and their staff and family members) under OCRR contracts.

### 3.0 Policy

1. The following clinical site staff are not permitted to enroll as research subjects in DMID-funded clinical trials under OCRR contracts:
  - a. Staff who are directly or indirectly supervised by the Principal Investigator (PI) or sub-Investigators for the trial;
  - b. All staff who are paid entirely or partially by/through the OCRR contract (not just the task order for that specific trial); and
  - c. The PI and sub-Investigators listed in Form FDA 1572 or Investigator of Record Form for the trial.
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:
  - a. They meet the inclusion/exclusion criteria outlined in the study protocol; and
  - b. 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.
3. Policy deviation requests must be submitted in writing to and approved by the OCRR Director.

### 4.0 Background

Federal regulations governing research with human subjects provide little guidance on enrolling study staff in clinical research performed at the site in which the staff conduct their work. The Office for Human Research Protections (OHRP) discusses consideration around *students, employees, and normal volunteers* in Chapter VI, "Special Classes of Subjects," of its IRB Guidebook (1993). While allowing the possibility of enrolling employees as research subjects, OHRP advises addressing the issues of, "coercion or undue influence, and confidentiality," and recommends advertising generally rather than directly recruiting individuals to participate in research. The IRB Guidebook also notes that, "...employee research programs raise the possibility that the decision [to participate] will affect performance evaluations or job advancement. It may also be difficult to maintain the confidentiality of personal medical information or research data when the subjects are also employees, particularly when the employer is also a medical institution [Meyers (1979)]."

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Voluntary participation is a basic ethical principle of clinical research. Enrollment of a study site employee or family member thereof raises the issue of potential coercion or undue influence; the individual may feel pressure to participate when he/she would not have otherwise volunteered. The study site staff members may fear that their interests as employees may be adversely affected if they choose not to participate. In addition to responsibilities specifically required of the PI, the site should be familiar with and follow any IRB/IEC policies related to these issues before such research subjects are recruited and enrolled.

Both the study sponsor and the IRB/IEC have some responsibility over the recruitment of subjects and can thus allow or restrict a PI, site staff, or family members to participate in a trial. In addition to matters already noted above, sponsors and hospitals/institutions may also have concerns with respect to how the enrollment of study site staff or their family members may impact fulfilling assigned responsibilities and objectivity of the study. Regulations require that the PI identified in the Form FDA 1572 personally supervise the conduct of the study. If the PI were participating in the study as a subject, the PI would be unable to personally conduct or supervise his/her own participation, including the treatment and reporting of any unanticipated or serious adverse events. While a second PI could be selected by the sponsor to ensure that the study was properly conducted throughout the duration of the entire study, this approach may unnecessarily complicate the study. If other study site staff enrolled as research subjects in the study, there could be a need for additional staff to perform those individuals' job responsibilities if they became unavailable. The need for replacements could impact the routine activities of the study and/or increase the study-specific budget for the protocol.

This policy was developed to address concerns regarding the enrollment of clinical site staff and/or their family members as research subjects in order to ensure the ethical and objective conduct of DMID-funded clinical research and the protection of the rights of enrolled subjects.

## 5.0 References

1. Office for Human Research Protections (OHRP) IRB Guidebook:  
[http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm)
2. U.S. Code of Federal Regulations 21 CFR 312:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>

## 6.0 Inquiries

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## 7.0 Availability

This document is available electronically via the DMID Intranet:  
<http://collab.niaid.nih.gov/sites/DMID/clinical/SitePages/Home.aspx>

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## 8.0 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	09-MAR-2015	N/A