

NIH HRPP SOP 14F v1

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &  
IMPLEMENTATION**

**OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS**

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**SOP Title: RESEARCH INVOLVING NIH STAFF AS SUBJECTS**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB  
Chairs, IRB Administrators, Protocol Navigators**

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## **SOP 14F RESEARCH INVOLVING NIH STAFF AS SUBJECTS**

### **TABLE OF CONTENTS**

<b>14F.1 PURPOSE .....</b>	<b>1</b>
<b>14F.2 POLICY.....</b>	<b>1</b>
<b>14F.3. PROTECTIONS TO BE CONSIDERED WHEN EMPLOYEES WITHIN THE WORK UNIT MAY PARTICIPATE:.....</b>	<b>2</b>
<b>14F.3.1. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR.....</b>	<b>2</b>
<b>LIST OF APPENDICIES .....</b>	<b>3</b>
<b>APPENDIX A: GUIDELINES FOR THE INCLUSION OF EMPLOYEES IN NIH INTRAMURAL RESEARCH STUDIES (MARCH, 2012) .....</b>	<b>4</b>
<b>APPENDIX B: NIH INFORMATION SHEET ON STAFF RESEARCH PARTICIPATION (MARCH 2012) .....</b>	<b>7</b>

## **SOP 14F RESEARCH INVOLVING NIH STAFF AS SUBJECTS**

### **14F.1 PURPOSE**

This SOP discusses the circumstances in which NIH staff may be enrolled as research subjects.

### **14F.2 POLICY**

NIH employees and members of their immediate families may participate in NIH intramural research, unless prohibited by their Institute or Center. Such research must be conducted consistent with the *Guidelines for the Inclusion of Employees in NIH Intramural Research Studies (March, 2012)* (Appendix A) and the requirements of NIH policy Manual 2300-630-3 – Leave Policy for NIH Employees Participating in NIH Medical Research Studies (<http://oma.od.nih.gov/manualchapters/person/2300-630-3/2300-630-3.pdf>)

If the research is within their own branch, section, or unit; or in research conducted by any of their direct supervisors, they may participate when:

- A. The research outcomes are unlikely to be influenced by the inclusion of employees.
- B. The IRB approves their participation with adequate protections based on the level of risk.

Solicitation of subordinates should not be direct, either orally or through individual mailings or email distribution. Flyers and recruiting materials may be displayed in the workplace where public announcements are permitted to be posted and as approved by the IRB.

### **14F.3. PROTECTIONS TO BE CONSIDERED WHEN EMPLOYEES WITHIN THE WORK UNIT MAY PARTICIPATE:**

#### **14F.3.1. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR**

- A. When the PI plans to involve NIH employees, he/she must acknowledge this in the protocol and in the NIH Intramural Clinical Protocol Application. When employee participation in the study is anticipated, the PI should incorporate protections for employee participants into the protocol or NIH-specific addenda for multi-site studies. These protections will be reviewed by the IRB. The protections should include:
1. A statement or delineation of protections to ensure that neither participation nor refusal to participate as a subject in the research will have an effect, either beneficial or adverse, on the participant's employment or position at NIH.
  2. Specific protections for employee subjects' privacy and confidentiality and acknowledgement of the limits of those protections.
  3. A description of how consent will be obtained from employees. If the individual obtaining consent is a supervisor, independent monitoring of the consent process should be included to minimize the risk of undue pressure on the employee. If the individual obtaining consent is a co-worker, independent monitoring of the consent process should be included unless waived by the IRB. Independent consent monitoring in the Clinical Center is available through the CC Department of Bioethics Consultation Service or a Clinical Research Advocate from the NIMH Human Subjects Protection Unit. Independent consent monitoring may also be provided by others as approved by the IRB. Alternatively, the protocol can delineate, for the IRB's review and approval that consent from employees will be obtained by an individual independent of the employee's team.
  4. A description of how study staff will be trained regarding obtaining potentially sensitive and private information about a co-worker or subordinate.

5. The PI will make the NIH Information Sheet on Employee Research Participation available to employees who are considering enrolling in research to help them understand the possible consequences (Appendix B).
- B. When employee enrollment was not anticipated in an approved protocol, but an employee wants to enroll in a study with the prospect of direct benefit, the PI is not required by this policy to amend the protocol, but should take considered steps to ensure that 1) there are adequate protections in place to protect the confidentiality of employee health information, and 2) consent procedures minimize any pressure on or discomfort of the employee.

## **LIST OF APPENDICIES**

Appendix A: Guidelines for the Inclusion of NIH Employees in NIH Intramural Research Studies (March 2012)

Appendix B: NIH Information Sheet on Staff Research Participation (March 2012)

## **APPENDIX A: GUIDELINES FOR THE INCLUSION OF EMPLOYEES IN NIH INTRAMURAL RESEARCH STUDIES (MARCH, 2012)**

### **Introduction**

NIH employees can and do participate in intramural research studies. The inclusion of employees 1) is often motivated by altruism among staff who are especially committed to research in their own fields, 2) may allow employees fair access to clinical trials of potential direct therapeutic benefit, 3) enables autonomy, with employees able to make informed decisions about their own participation.

Inclusion of employees as research subjects in studies conducted within their own institution raises ethical concerns, however, especially when research is conducted by employees' supervisors or others within their own laboratory or unit. Although there is no NIH-wide intramural policy that addresses participation of subordinates in their supervisors' research, the NIH Policy Manual 2300-630-3 "Leave policy for NIH employees participating in NIH medical research studies" permits the participation of NIH employees and requires both a protocol that specifies that employees may participate and NIH Institutional Review Board (IRB) approval.

### **Scope**

This guidance applies to research conducted under an approved intramural clinical research protocol. Employees are sometimes invited to participate in activities, such as procedures for technical or assay development that do not meet the regulatory definition of "research." While such activities are beyond the scope of this guidance, many of the ethical concerns about employee participation in research apply to their participation in technical development activities as well.

### **Background**

Employees have been considered as a "special class of subjects," along with students and other healthy volunteers. Ethical concerns may arise with employee participation, especially if the employee is subordinate to or supervised by the study investigators, and especially the Principal Investigator. The concerns may extend to members of the employees' immediate families. These ethical concerns include:

- A. Perceived or actual pressure to participate or coercion
- B. Employees, especially subordinates, may feel unable to refuse participation without jeopardizing their resources, support, performance evaluation or position as part of the research team. There also may be a perception that participating will bring some benefit, such as a better rating, special treatment or additional resources. Such pressure may be especially subtle if there is a workplace expectation of participation.
- C. Perceived or actual conflict of interest
- D. Possible bias could arise due to the inherent conflict-of-interest when research team members participate in their own studies. Such individuals have a clear interest in the potential success of the studies and, by participating, may be in a position to influence the outcome either favorably or unfavorably. For example, they might consciously or unconsciously provide incorrect or misleading information, perform in a biased way on research tests or underreport adverse events.
- E. Privacy and confidentiality
- F. Many studies require a physical examination and medical history. These may include disrobing, providing blood, urine or other specimens under observation by a research staff member, giving medical history or information on sexual activity, substance use and other criminal activity, or other sensitive procedures. Unanticipated, previously unknown medical conditions may also be detected during the conduct of the study. Such procedures and information could be embarrassing or damaging if observed or known by a supervisor or other coworker.
- G. Scientific integrity and subject safety
- H. The participation of those conducting or knowledgeable about the research could undermine the scientific integrity of the study. For example, an employee subject could be reluctant to answer research-related questions truthfully when they are asked by co-workers or supervisors. If accurate answers are required to protect volunteers, employees may place themselves at increased risk. If accurate answers are required for scientific validity, validity may be diminished.

## Definitions

- A. **The terms “Research” and “minimal risk”** are as defined in 45 CFR 46.
- B. **Employee** - an individual defined by 5 USC 2105. For purposes of this guideline, employees include NIH contractors and Special Volunteers, Guest Researchers, and trainees.
- C. **Subordinate** - an individual in a junior position or who directly reports to another in the same section, unit or branch who has some authority over the subordinate.
- D. **Supervisor** - an individual with the authority to evaluate performance, give job assignments, allocate resources, recommend pay raises or promotions or to hire or fire.

## **APPENDIX B: NIH INFORMATION SHEET ON STAFF RESEARCH PARTICIPATION (MARCH 2012)**

As an NIH employee, contractor, Special Volunteer, Guest Researcher, or trainee, you may participate in intramural research studies. You may be motivated by altruism, a commitment to research in your own or related fields, or want access to clinical trials of potential direct therapeutic benefit. When deciding, you should make an informed decision about participation. This information sheet offers some points to consider for NIH staff who are considering research participation at NIH.

First, similar to any individual who is considering research participation, you should seek adequate information about the study purpose, what is required of you in terms of procedures, interventions and time, and the potential risks and benefits of participation. For more information, see the NIH Clinical Center's public website "Are Clinical Studies for You?" at <http://www.cc.nih.gov/participate/studies.shtml>.

When you are thinking about participation in a research study that is being conducted by your supervisor, or others with whom you work closely in your laboratory, branch, or unit, you should consider some additional factors:

- A. **Possible bias:** If it is important to you or your colleagues for this trial to be successful, are you confident that you can be unbiased about reporting answers, side effects, or other information that could influence the study outcome or risk to you?
- B. **Confidentiality:** Are you comfortable sharing your medical history (including, for example, mental health history or STDs) and your social history (e.g. substance use) with study investigators who may be your coworkers, or with the possibility of them discovering something about your health during the study?
- C. **Pressure:** Do you perceive any pressure or expectations from your supervisor or colleagues regarding participation? Could that pressure influence your decision or make it difficult for you to choose whether or not to participate? Remember that it is your choice whether or not to participate.
- D. **Time:** Can you take time off from work to complete the study requirements or participate solely during non-duty hours? See the NIH Policy Manual 2300-630-3 "Leave policy for NIH employees participating in NIH medical research studies."

According to NIH policy, anticipated inclusion of staff in research studies must be approved by the IRB, and when the PI is a supervisor of prospective participants, an independent person (e.g., through Bioethics or the NIMH Human Subjects Protections Unit [HSPU], or others as approved by the IRB) will monitor the consent process.

If you have any questions or concerns, please contact the Office of Human Subjects Research Protections (OHSRP) at 301-402-3444.