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

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14F.1 PURPOSE

This Standard Operating Procedure (SOP) discusses the circumstances in which NIH staff may be enrolled as research subjects.

14F.2 POLICY

NIH staff and members of their immediate families may participate in NIH intramural research unless prohibited by their Institute or Center (IC), or excluded by the criteria of the protocol in which they want to enroll. Such research must be conducted consistent with the *Guidelines for the Inclusion of Staff 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 https://oma1.od.nih.gov/manualchapters/person/2300-630-3/* **(Appendix B)**

14F.3 DEFINITIONS

A. Staff: employees defined by 5 USC 2105, NIH contractors, Special Volunteers, Guest Researchers, and trainees.

B. Supervisor: an individual with the authority to evaluate performance, give job assignments, allocate resources, recommend pay raises or promotions or to hire or fire.

C. Subordinate: an individual in a junior position or who directly reports to another person in the same section, unit or branch who has some authority over the subordinate.

D. Work Unit: the team, laboratory, branch, department, group, or office in which staff work.

E. Co-worker: A person with whom the prospective participant works closely in their laboratory, branch, unit, group, or IC. This can be someone who currently works in this capacity with the prospective participant or has done so in the past. It can also include a supervisor or a subordinate.

14F.4 CONSIDERATIONS WHEN ENROLLMENT OF NIH STAFF IS ANTICIPATED

The following considerations apply to research where enrollment of NIH staff is anticipated regardless of whether there is a prospect of direct benefit.

14F.4.1 RESPONSIBILITIES OF THE IRB

Where enrollment of NIH staff is anticipated on an NIH protocol, the Institutional Review Board (IRB) must approve their participation with adequate protections based on the level of risk. If the enrollment of NIH staff is anticipated in research taking place within their own branch, section, or unit; or that is being conducted by any of their direct supervisors, NIH staff may participate in the study when the research outcomes are unlikely to be influenced by the inclusion of staff.

14F.4.2 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

A. When a Principal Investigator (PI) plans to enroll NIH staff, he/she must:

   1. Acknowledge this in the protocol and in the NIH Intramural Clinical Protocol Application;

   2. Incorporate safeguards for staff participants into the protocol or NIH-specific addenda for multisite studies;

   3. Have these safeguards reviewed and approved by the IRB; and

   4. Use appropriate methods to recruit staff participants: Solicitation of subordinates should not be direct, either orally or through individual mailings or email distribution. However, flyers and recruiting materials may be displayed in the workplace where public announcements are permitted to be posted, and as approved by the IRB.

B. All protocols should include the following safeguards when enrollment of NIH staff is anticipated:

   1. An acknowledgment that NIH staff may be a vulnerable class of subjects.

   2. Specific protections for staff subjects' privacy and confidentiality. This should also include an acknowledgement of the limits of those protections, for example, if sensitive information may be in the staff participant's NIH records.

   3. Information specifically on compensation to staff in accordance with NIH policy, see **Appendix B**.

   4. Provisions for the PI to provide the *NIH Information Sheet on Staff Research Participation* to staff who are considering enrolling in research prior to obtaining consent to help them understand the possible consequences of their participation (**Appendix C**). This sheet supplements the above safeguards and is not a substitute.

C. Protocols should include the following additional safeguards when enrollment of NIH staff is anticipated in research taking place within their own work unit; or in research being conducted by any of their direct supervisors:

1. A description 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 staff participant's employment or position at NIH.

2. A description of how consent will be obtained from NIH staff:

   a. If the individual obtaining consent from an NIH staff member is their supervisor, independent monitoring of the consent process should be included to minimize the risk of undue pressure on them.

      i. Independent consent monitoring in the Clinical Center (CC) is available through the CC Department of Bioethics Consultation Service or by 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.

      ii. If independent monitoring is not available, 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 work unit.

   b. If the individual obtaining consent from an NIH staff member is a non-supervisory co-worker, independent monitoring of the consent process should be included unless waived by the IRB. If independent monitoring is required refer to **section 14F.4.2.C.2.a** above for potential monitors.

3. If applicable, an outline of how study staff will be trained to obtain and manage potentially sensitive and private information about a co-worker (including a supervisor or subordinate) e.g. HIV status, sexual history, drug use, mental health history, criminal activity, specific medical diagnoses, and pregnancy status. The IRB may determine that training in addition to the prior protocol research staff training requirements is necessary.

14F.5 CONSIDERATIONS WHEN ENROLLMENT OF NIH STAFF IS NOT ANTICIPATED AND THERE IS NO PROSPECT OF DIRECT BENEFIT

A. When NIH staff enrollment was not anticipated in an approved protocol and a PI becomes aware that a staff member wants to enroll in a study that has no prospect of direct benefit, the PI is required by this policy to amend the protocol and obtain IRB approval for staff participation in accordance with this policy.

14F.6 CONSIDERATIONS WHEN ENROLLMENT OF NIH STAFF IS NOT ANTICIPATED AND THERE IS A PROSPECT OF DIRECT BENEFIT

A. When NIH staff enrollment was not anticipated in an approved protocol and a staff member wants to enroll in a study with the prospect of direct benefit, the PI is not required by this policy to amend the protocol to include the above safeguards, but should ensure that:

   1. There are adequate protections in place to protect the confidentiality of NIH staff health information,

   2. Consent procedures are in place to minimize any pressure on or discomfort of the member of NIH staff, and

   3. That the member of NIH staff is provided with a copy of the *NIH Information Sheet on Staff Research Participation* (**Appendix C**) before consent is obtained.

14F.7 CONSIDERATIONS WHEN A PI OR AI WISHES TO ENROLL IN THEIR OWN STUDY

The enrollment of a PI or AI in his or her own study is not specifically prohibited by NIH, unless by IC policy, but must be independently considered, on a case-by-case basis, by the IRB. Investigators should explain why they want to participate in the protocol as well as outline measures that will be taken to manage possible bias, obtain their informed consent, and manage privacy and confidentiality. The IRB may seek additional advice from Bioethics.

LIST OF APPENDICES

Appendix A: Guidelines for the Inclusion of NIH Staff in NIH Intramural Research Studies (December 2015)

Appendix B: Leave Policy for NIH Employees Participating in NIH Medical Research Studies (NIH Policy Manual 2300-630-3)

Appendix C: NIH Information Sheet on Staff Research Participation (December 2015)

APPENDIX A: GUIDELINES FOR THE INCLUSION OF STAFF IN NIH INTRAMURAL RESEARCH STUDIES (DECEMBER, 2015)

Introduction

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

Inclusion of NIH staff as research subjects in studies conducted within their own institution raises ethical concerns, however, especially when research is conducted by staff supervisors or others within their own laboratory or work 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 staff and requires both a protocol that specifies that staff may participate and NIH Institutional Review Board (IRB) approval.

Scope

This guidance applies to research conducted under an approved intramural clinical research protocol. NIH staff 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 staff participation in research apply to their participation in technical development activities as well.

Background

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

A. Perceived or actual pressure to participate or coercion

   NIH staff, 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.

B. Perceived or actual conflict of interest

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.

C. Privacy and confidentiality

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.

D. Scientific integrity and subject safety

The participation of those conducting or knowledgeable about the research could undermine the scientific integrity of the study. For example, a staff 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, staff 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. **Staff** - employees defined by 5 USC 2105, NIH contractors, 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: LEAVE POLICY FOR NIH EMPLOYEES PARTICIPATING IN NIH MEDICAL RESEARCH STUDIES (NIH POLICY MANUAL 2300-630-3)

A. Policy

An NIH employee may take part in an NIH funded biomedical research protocol approved by the NIH Institutional Review Board (IRB), if that protocol specifies that employees may participate. Commissioned Corps Officers should contact the Commissioned Corps Office (301) 402-9239 for authorization requirements and limitations in participating in a biomedical research protocol study.

The protocol statement should include the time period and duration that participants will be expected to spend in the study and whether or not compensation will be offered. A copy of this statement shall be provided to the employee upon request.

The employee's supervisor should request a copy of the protocol statement from the employee in order to determine the appropriate leave that may be granted. Supervisors should contact the Principal Investigator to ascertain whether or not the employee will receive financial compensation and/or will accrue medical benefits.

The employee's supervisor shall determine if the employee may be absent from duty for the necessary period(s) of time. With the approval of the supervisor, an employee may be granted appropriate leave to participate in an NIH biomedical research study as a volunteer subject during his/her normal tour of duty.

Annual Leave or Leave Without Pay shall be requested by an employee participating in an NIH biomedical research study from which compensation is offered and accepted by the employee.

Annual Leave, Sick Leave or Leave Without Pay shall be requested by an employee participating in an NIH biomedical research study from which medical benefits are gained by the employee.

Excused Absence may be granted to an employee if:

The employee earns no money, and

The employee gains no medical benefits from participating in the study.

An employee may participate in an NIH biomedical research study after the employee's tour of duty without being charged annual leave, sick leave or leave without pay. An employee participating in a biomedical research study outside of his/her tour of duty must notify their supervisor of this activity when participation may impact the employee's ability to perform work during his/her tour of duty.

An employee may be granted excused absence to donate blood or blood products through the facilities of the Clinical Center, Department of Transfusion Medicine provided there is no compensation received. The donation of blood or blood products is not considered to constitute participation in a biomedical research study and is not covered by this manual. Further information on the leave policy for blood donors is contained in the NIH Civilian Leave Guide.

B. References:

HHS Personnel Instruction 630-1 (Absence and Leave)

NIH Leave Guide for Civilian Employees

Commissioned Corps Officer's Handbook, 1998

C. Internal Controls:

The purpose of this manual issuance is to assure that all work and related activities are conducted in full accord with statutory, regulatory and policy requirements.

Office Responsible for Reviewing Internal Controls Relative to this Chapter is OD/OHR/WRD/Benefits and Payroll Liaison Branch (Issuing Office).

Through this issuance, the Office of Human Resources, Office of the Director, NIH is accountable for the method used to ensure that internal controls are implemented and working.

Frequency of Review: Every 3 years

Method of Review: Conduct surveys among ICs

Review Report is sent to the Director, Office of Human Resource, NIH

D. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, “Keeping and Destroying Records,” Appendix 1, NIH Records Control Schedule, Item 1900-D-3, Time and Attendance Report Files.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered

Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same request as the original messages.

APPENDIX C: NIH INFORMATION SHEET ON STAFF RESEARCH PARTICIPATION (APRIL 2016)

As an NIH employee, contractor, Special Volunteer, Guest Researcher, or trainee, you may participate in intramural research studies unless it is prohibited by your Institute or Center (IC), or if you are excluded by the criteria of the protocol in which you want to enroll. The inclusion of NIH staff in a particular protocol must also be approved by the IRB. 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**: 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**: Has the principal investigator (PI) spoken about what information will be collected from you as part of the study? Has the PI discussed what information will be available to those within, and outside, the study team? If applicable, 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 (e.g. pregnancy status or a new diagnosis)? Although every effort will be made to protect your information and keep it private and confidential, your information may, depending on the nature of the protocol, become available in medical records or to authorized users outside of the study team. Discuss any concerns with the PI.

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 and that your decision to participate or not should not have an effect, either beneficial or adverse, on your position at NIH.

D. **Time and Compensation**: Can you take time off from work to complete the study requirements or participate solely during non-duty hours? Can you receive compensation for your participation in this study? Will your supervisor give you permission to participate during work hours? See the NIH Policy Manual 2300-630-3 *Leave Policy for NIH Employees Participating in NIH Medical Research Studies*.

E. **Consent Process:** Is the person obtaining your consent for the study your supervisor, a subordinate, or co-worker? If so, is there an independent person monitoring the consent process? If the study PI is a supervisor and intends to obtain consent from you, an independent person (e.g., through Bioethics or the NIMH Human Subjects Protections Unit [HSPU], or others as approved by the IRB) must monitor the consent process. If the person obtaining consent from you is a co-worker then an independent person (e.g., through Bioethics or the NIMH HSPU, or others as approved by the IRB) may be required to monitor the consent process, as determined by the IRB for the specific study.

If you are thinking of enrolling as a subject at the NIH Clinical Center and you have any questions or concerns, please contact the Office of Human Subjects Research Protections (OHSRP) at 301-402-3444 and/ or the Patient Representative if you are thinking of enrolling as a subject at the NIH Clinical Center on 301-496-2626. If you are at a NIH site outside the Clinical Center then please contact local site leadership.