

<p>This document summarizes changes in <i>Policy 404 Research Involving NIH Staff as Subjects</i> (referred to as Policy 404 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.</p> <p>The policy describes the circumstances under Human Research Protection Program (HRPP) policy in which NIH staff or immediate family members of the study team, may be enrolled as research subjects on NIH Intramural Research Program (IRP) protocols.</p> <p>NIH investigators are responsible for reviewing Policy 404 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
<p>Policy 404 Research Involving NIH Staff as Subjects</p>	<p>SOP Superseded by Policy 404</p>
<p>Policy 404 partially supersedes:</p>	<p>SOP 14A Research Involving Vulnerable Subjects (General Considerations) This SOP will not be replaced by an HRPP policy and will be inactivated. When inactivated, this SOP will be archived in the Policy archive.</p>
<p>Policy 404 supersedes:</p>	<p>SOP 14F Research Involving NIH Staff as Subjects When inactivated, this SOP will be archived in the Policy archive.</p>
<p>Applicability of Policy 404 – This policy applies to:</p> <ul style="list-style-type: none"> • This policy applies to NIH staff who wish to participate in NIH IRP research at an NIH site. • This policy applies to NIH Principal Investigators (PIs) who recruit and/or enroll subjects who are NIH staff or immediate family members of the study team. • This policy applies to the NIH IRB, when reviewing research that anticipates, or is modified to allow, the recruitment and/or enrollment of NIH staff or immediate family members of the study team. • An external Reviewing IRB, when the research occurs at an NIH site. • NIH Institutes and Centers (ICs) may have additional requirements, policies, or restrictions, not addressed in this policy. 	
<p>Policy Requirement</p>	<p>SOP Requirement</p>
<p>Section C.1. – <i>NIH staff and immediate family members of the study team are generally permitted to participate in human subjects research conducted by the NIH. This is true whether or not the research offers the prospect of direct benefit.</i></p> <p>Policy 404 now specifically addresses requirements pertaining to “immediate family members of the study team” in addition to NIH staff.</p>	<p>SOP 14F, Appendix A, Background – <i>The concerns may extend to members of their immediate families.</i></p> <p>Policy 404 adds specificity for clarity.</p>

<p>Section C.2. – <i>NIH staff who participate in NIH intramural research must comply with NIH policy including, but not limited to:</i></p> <ul style="list-style-type: none"> a. <i>Any prohibitions or restrictions on participation in NIH research by the NIH staff member’s Institute or Center;</i> b. <i>NIH compensation requirements; and</i> c. <i>NIH leave requirements. (See NIH Manual Chapter: 2300-630-3 - Leave Policy for NIH Employees Participating in NIH Medical Research Studies)</i> <p>Policy 404 reorganizes the SOP for clarity.</p>	<p>SOP 14F addressed NIH staff requirements in various sections.</p>
<p>Section C.3. – <i>NIH staff interested in participating in NIH Research should review the “NIH Frequently Asked Questions (FAQs) for Staff Who are Considering Participation in NIH Research.”</i></p> <p>The robust new FAQ document is designed to help NIH staff make informed decisions about research participation, and fully replaces the NIH Information Sheet on Staff Research Participation.</p>	<p>SOP 14F, Appendix C – NIH Information Sheet on Staff Research Participation.</p> <p>The information sheet has been replaced by the “NIH Frequently Asked Questions (FAQs) for Staff Who are Considering Participation in NIH Research.”</p>
<p>Section C.5 – <i>When an external IRB is the reviewing IRB, and when the research occurs at an NIH site, the requirements of this policy will be provided by the NIH PI as local context information, as appropriate.</i></p> <p>Policy 404 now requires that the requirements of this policy be provided to external reviewing IRBs.</p>	<p>N/A</p>
<p>Section E.1.a.i. – <i>General Requirements when NIH Staff or Immediate Family Members of the Study Team Participate in NIH Research that Offers No Prospect of Direct Benefit (e.g., studies on healthy volunteers or natural history protocols):</i></p> <ul style="list-style-type: none"> I. <i>When recruitment or enrollment of NIH staff or immediate family members of the study team is anticipated, the NIH PI must describe in the protocol the safeguards that will be put in place for the recruitment and/or enrollment of this population.</i> <ul style="list-style-type: none"> i. <i>When the protocol does <u>not</u> (emphasis added) anticipate the</i> 	<p>SOP 14F was organized by whether enrollment of NIH staff was anticipated on the protocol. Policy 404 reorganizes requirements based on whether the research offers the prospect of direct benefit.</p>

<p><i>enrollment of this population and the PI wants to enroll NIH staff or immediate family members of the study team, an amendment, indicating such safeguards, must be approved by the IRB prior to enrollment.</i></p> <p>When the study does not offer the prospect of direct benefit, <u>IRB approval is required prior to recruiting or enrolling</u> NIH staff or immediate family members of the study team.</p> <p>When there is no prospect of direct benefit, and enrollment was not anticipated in the initial protocol, an amendment must be approved by the IRB prior to enrolling or recruiting staff or immediate family members of the study team.</p> <p>As in SOP14F, no amendment is required when the study offers the prospect of direct benefit to NIH staff or immediate family members of the study team.</p>	
<p>Section E.1.a.ii. – <i>The NIH PI must indicate in the protocol whether NIH staff or immediate family members of the study team will be recruited and/or will be allowed/permitted to enroll in the research protocol, and:</i></p> <ol style="list-style-type: none"> i. The NIH PI must incorporate safeguards for recruitment and/or enrollment into the protocol, and ii. The NIH PI must describe the plan for recruiting this population. <p><i>In addition, the PI must <u>always</u> (emphasis added) follow the requirements listed below:</i></p> <ul style="list-style-type: none"> • <i>Solicitation of subordinates should not be direct, either orally or through individual mailings or email distribution.</i> • <i>Flyers and recruiting materials may be displayed in the workplace only where public announcements are permitted to be posted.</i> <p>Policy 404 reorganizes the SOP for clarity.</p>	<p>SOP 14F.4.2. – RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR</p> <p>A. <i>When a Principal Investigator (PI) plans to enroll NIH staff, he/she must:</i></p> <ol style="list-style-type: none"> 1. <i>Acknowledge this in the protocol and in the NIH Intramural Clinical Protocol Application;</i> 2. <i>Incorporate safeguards for staff participants into the protocol or NIH-specific addenda for multisite studies;</i> 3. <i>Have these safeguards reviewed and approved by the IRB; and</i> 4. <i>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.</i> <p>These requirements are retained in Policy 404.</p>

<p>Section E.1.a.III. – <i>Prior to enrollment the NIH investigator must request NIH staff member to review the Leave Policy for NIH Employees Participating in NIH Medical Research Studies (NIH Policy Manual 2300-630-3)</i></p> <p>Policy 404 requires that the investigator ask the NIH staff member to review the leave policy.</p>	<p>N/A</p> <p>The leave policy was addressed in SOP 14F, but there was no requirement that investigators ask the NIH staff member to review it.</p>
<p>Section E.1.a.IV. – <i>Prior to enrollment the NIH investigator must provide and request the NIH staff member to review the NIH Frequently Asked Questions (FAQs) for Staff Who are Considering Participation in NIH Research.</i></p> <p>Policy 404 now requires the investigator to provide this document to staff who are considering participating in the research.</p>	<p>The NIH Information Sheet on Staff Research Participation has been replaced by the “NIH Frequently Asked Questions (FAQs) for Staff Who are Considering Participation in NIH Research.”</p>
<p>Section E.1.b. – <i>Additional Requirements for NIH Staff Participating in Research Taking Place Within Their Own Work Units or Conducted by Any of Their Supervisors</i></p> <p>The PI must assure the following:</p> <ol style="list-style-type: none"> i. <i>The subject is informed that neither participation nor refusal to participate as a research subject will have an effect, either beneficial or adverse, on the subject’s employment, training, or position at the NIH,</i> ii. <i>When possible, consent should be obtained by an individual in a non-supervisory relationship with the subject, and</i> iii. <i>When consent is conducted, a third party (e.g., a consent monitor) must be present to observe the consent process. This process is used to minimize the risk of undue pressure on the NIH staff member when an investigator on the research team is also the staff member’s supervisor. This can be achieved by one of the following methods:</i> <ul style="list-style-type: none"> • <i>At the NIH CC, a consent monitor is available through the CC Department of Bioethics</i> 	<p>SOP 14F.4.2, Appendix A, and Appendix C all address various requirements for NIH staff participating in research occurring within their own units or conducted by their supervisors.</p> <p>Policy 404 reorganizes and adds specificity for clarity.</p> <p>SOP 14F.4.2.C.1 – <i>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.</i></p>

<p><i>Consultation Service or by a Clinical Research Advocate from the NIMH Human Subjects Protection Unit (HSPU); or</i></p> <ul style="list-style-type: none"><i>• A consent monitor may also be another party independent of the research team (e.g., an IC monitor); or</i><i>• Lastly, if a consent monitor is not available, the consent process will be observed by another qualified investigator on the study who is independent of the NIH staff member's work unit and not a supervisor to the NIH staff member. If no such person exists, consent observation may be performed by any qualified investigator on the study.</i> <p>Policy 404 now specifically requires that staff subjects be informed their participation, or refusal to participate, will not affect their employment.</p>	<p>SOP 14F did not specifically require that staff subject be informed their participation or refusal to participate would not affect their employment.</p>
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