

<p>This document summarizes changes in <i>Policy 203 Support of IRB Operations</i> (referred to as Policy 203 in this document) that NIH investigators should be aware of, from the SOPs mentioned below.</p> <p>This policy describes the National Institutes of Health (NIH) Office of Human Subjects Research Protections (OSHRP) support of the NIH Institutional Review Board (IRB).</p> <p>OHSRP, including IRBO, staff are responsible for reviewing Policy 203 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
Policy 203 IRB Scope and Authority	SOPs Superseded by Policy 203
Policy 203 supersedes:	SOP 2 IRB Membership and Structure This SOP has been inactivated and is archived in the Policy Archive.
Policy 203 supersedes:	SOP 3 Management and Administrative Operations of the IRB When inactivated, this SOP will be archived in the Policy Archive.
Applicability of Policy 203 – This policy applies to OHSRP, which includes the OHSRP Office of IRB Operations (IRBO) and OHSRP staff.	
POLICY Requirement	SOP Requirement
<p>Section C.1. – <i>OHSRP will promote the protection of the rights and welfare of research subjects through effective management and operations of the NIH IRB in compliance with federal regulations and policy, including NIH policy.</i></p> <p>AND</p> <p>Section E.1.a. – <i>Promote the protection of the rights, safety and welfare of subjects participating in research activities at the NIH by advising and providing guidance to NIH investigators and the NIH IRB based on federal regulations and policies.</i></p>	<p>SOP 3, section 3.3.1. – <i>Each NIH IRB has an Administrative Office. The title, number, grade level and responsibilities of the administrative support staff vary depending on the IRB’s workload and research portfolio and are decided by appropriate Institute/Center (IC) leadership.</i></p> <p>Prior to the reorganization, when this SOP was published, each IRB had its own Administrative office.</p>
<p>Section C.2. – <i>OHSRP will provide administrative support to the NIH IRB and serve as the liaison between the IRB and investigators.</i></p> <p>AND</p> <p>Section E.1.b. – <i>Provide administrative support to the NIH IRB and serve as the primary liaison between the IRB and NIH</i></p>	<p>SOP 3, section 3.10. – <i>IRB-approved documents are forwarded for approval/review and signature(s) as appropriate to the: IRB Chair or designee(s), IC Clinical Director, Office of Protocol Services (OPS), CC Director or the Deputy Director for Clinical Research.</i></p>

<p><i>investigators (e.g., send reminders to investigators and notify investigators about IRB determinations.) (See, e.g., Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research.)</i></p> <p>See Policy 203 for additional details.</p>	<p>Prior to the reorganization, when this SOP was published, each IRB had its own Administrative office which fulfilled this function.</p>
<p>Section C.3. – <i>OHSRP will ensure that the NIH IRB is constituted consistent with federal regulations and policy. (See Policy 201 IRB Membership and Composition.)</i></p> <p>AND</p> <p>Section E.1.i. – <i>Maintain the IRB roster and composition, consistent with the requirements in Policy 201 IRB Membership and Composition.</i></p> <p>There is no change in Policy.</p>	<p>SOP 2, section 2.2. – <i>The NIH Human Research Protection Program (HRPP) ensures that its IRBs are constituted consistent with federal regulatory requirements. It has procedures in place for (1) appointing and reappointing members; (2) maintaining current IRB rosters; (3) communicating members’ responsibilities to them; (4) removing members for cause, and (5) clarifying their legal liability.</i></p>
<p>Section E.1.c. – <i>Promote the efficiency of the NIH IRB and its effective review of research by conducting pre-review of submissions to the IRB to verify that submissions meet regulatory and policy requirements and are complete prior to assigning them to the IRB agenda. (See Policy 205 Requirements of IRB Submissions and Policy 106 Ancillary Reviews)</i></p> <p>Pre-review has already been implemented and is already in use. Policy 203 does not change the current practice.</p>	<p>NA (Not applicable)</p> <p>SOPS 2 and 3 did not address pre-review.</p>
<p>Section E.1.d. – <i>Comply with HRPP training requirements as specified in Policy 103 Education Program.</i></p> <p>The policy makes no changes to current OHSRP staff training expectations.</p>	<p>SOP 3, section 3.5. – <i>As part of their continuing training requirements, IRB administrative staff members are expected to attend meetings of IPAC regularly in order to keep up to date on the latest developments in human subject research protections.</i></p> <p>The IPAC is no longer in operation. IRB administrative staff now take CITI training courses and refresher courses as stipulated in Policy 103.</p>

<p>Section E.1.k. – <i>Track IRB membership conflict of interests consistent with the requirements in Policy 202 Board Member Conflict of Interest.</i></p>	<p>SOP 2 described the requirements for managing IRB conflicts during meetings but did not specifically address tracking of such conflicts.</p>
<p>Section E.1.l. – <i>Support and participate in accreditation activities as directed.</i></p> <p>Accreditation was not addressed in the SOPs, though IC IRB staff participated in previous accreditation efforts.</p>	<p>NA</p>