

Policy 100 NIH Intramural Research Program’s Human Research Protection Program – Policy Changes Overview

<p>This document summarizes changes in Policy 100 from the Standard Operating Procedures (SOPs) listed below that NIH investigators should be aware of.</p> <p>NIH investigators are responsible for reviewing Policy 100 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
<p>Policy 100 NIH Intramural Research Program’s Human Research Protection Program</p>	<p>SOPs Superseded by Policy 100</p>
<p>Policy 100 supersedes:</p>	<p>Introduction to the NIH Human Research Protection Program (HRPP) When inactivated, this policy will be available on the Policy Archive.</p>
<p>Policy 100 supersedes:</p>	<p>NIH Manual Chapter 3014. This policy will become the new NIH Manual Chapter under a new number (TBD). NIH Manual Chapter 3014 will be archived in the OMA Policy Archive.</p>
<p>Policy 100 partially supersedes:</p>	<p>20 NIH HRPP Requirements for Collaborative Research 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 100 partially supersedes:</p>	<p>SOP 20D NIH FWA Coverage for Non-NIH Employees Working on NIH Protocols When inactivated, this SOP will be archived in the Policy Archive.</p>
<p>Policy Requirement</p>	<p>SOP Requirement</p>
<p>Section C.1. – Describes the foundational principles for human subjects protection requirements that NIH Investigators are expected to adhere to. – This section is expanded to include the Nuremberg Code of 1947 and the HHS Common Rule (45 CFR 46).</p> <p><i>The policies of the NIH HRPP are grounded in the foundational ethical principles embodied in the Nuremberg Code of 1947 and in particular, the Belmont Report: Ethical Principles and Guidelines for the</i></p>	<p>Introduction Section 1.A – <i>NIH performs clinical research according to the highest scientific and ethical standards and in a manner that promotes and respects the rights and welfare of all human subjects, consistent with applicable laws, regulations and policies including but not limited to The Belmont Report and, when applicable, the Food and Drug Administration’s (FDA) Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance (1996)</i></p>

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<p><u>Protection of Human Subjects of Research</u> (<i>Belmont Report</i>) issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The <u>Belmont Report</u> principles of respect for persons, beneficence and justice are the basis for the ethical conduct of human subjects research, and are the foundation for the federal regulations for the Protection of Human Subjects (<u>45 CFR 46</u>, HHS Common Rule)</p> <p>Note that although Good Clinical Practice (GCP) is not mentioned in this policy it is still expected that NIH Investigators will follow GCP guidelines as a best practice. See <u>Policy 103 Education Program</u> or contact the CC Office of Research Support and Compliance (ORSC) for more information.</p>	<p>Introduction Section D.6. – Describes the responsibility for education and training of investigators, including GCP training. See <i>Policy 201 (will be renumbered to Policy 103) Education Program</i> for current GCP requirements.</p>
<p>NIH Investigators should be aware that there are now two (2) active versions of the HHS Common Rule, based on the initial approval date of the research. NIH Investigators should know which version of the Common Rule applies to their research.</p> <p>Section E.1.a.i and ii – Describes the applicability of the pre-2018 Common Rule and the 2018 Common Rule. (45 CFR 46).</p> <p>i. Research subject to the <u>pre-2018 Common Rule</u> requirements: Research that was, prior to January 21, 2019, initially approved by an IRB, or for which IRB review was waived, or was determined to be exempt, will follow the requirements of the pre-2018 Common Rule, unless the IRB has documented that the research will be</p>	<p>NA – This was not addressed in the Introduction because at the time there was only one version of the Common Rule.</p>

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<p>transitioned to the 2018 Common Rule requirements.</p> <p>ii. Research subject to the 2018 Common Rule requirements: Research approved by an IRB, or for which IRB review was waived, or determined to be exempt on or after January 21, 2019, will comply with the 2018 Common Rule requirements.</p>	
<p>Section E.1. Compliance with Law, Regulation and Policy – Addition of the new privacy regulation commonly referred to as the 21st Century Cures Act- Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). (Certificates of Confidentiality.)</p> <p><i>To further protect the privacy of research participants enrolled in research conducted by NIH investigators, or in collaboration with NIH investigators, the NIH IRP has been issued a Certificate of Confidentiality for applicable research pursuant to Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). (See the NIH Policy for Issuing Certificates of Confidentiality, and also Policy 107 Privacy and Confidentiality.</i></p> <p>This section was also expanded to describe the applicability of FOIA.</p> <ul style="list-style-type: none"> <i>In addition, under Section 301(f) of the Public Health Service Act (42 U.S.C. 241(f)), the Secretary may exempt from disclosure under the Freedom of Information Act (FOIA) biomedical information about a research participant that is gathered or used during the course of biomedical research if, A) the participant is</i> 	<p>Introduction Section 1.B. – Describes compliance with federal laws, regulations and policies, including NIH policies. However, it did not mention the 21st Cures Act which was not enacted at the time of publication and it did not mention FOIA, which has been added for completeness to Policy 100.</p>

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<p><i>identified; or B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of a participant. (See Policy 107 Privacy and Confidentiality).</i></p>	
<p>The requirement for NIH investigator to know and understand the regulatory definitions of “Human Subject” and “Research”, will be listed in <i>Policy 300 Investigator Responsibilities</i>.</p>	<p>Introduction Section 1.D. – <i>NIH requires its investigators to understand the regulatory definition of research with human subjects, to know when they are conducting research with human subjects.</i></p>
<p>The requirements for Human Subject Protection Training and is now described in Policy 103 Education Program.</p>	<p>Introduction Section 1.D. – Requires NIH investigators to take human subjects protection training.</p>
<p>There are no longer IC-based IRBs. The NIH IRB is constituted within the Office of the Director (OD) and is managed by the Office of IRB Operations (IRBO) in the Office of Human Subjects Research Protections (OHSRP). IRB operations are no longer located within the ICs. IRB operations are now centrally located within the Office of IRB Operations (IRBO), an office within the OHSRP.</p>	<p>Introduction Section 1.E. – Describes that the NIH ICs establish the NIH IRBs.</p>
<p>The IC IRBs are no longer listed. All IC IRBs have been unregistered with the HHS Office of Human Research Protections (OHRP).</p> <p>There are only 2 intramural IRBs, located within the NIH Office of the Director (OD):</p> <ol style="list-style-type: none"> 1. The NIH Intramural IRB is the IRP central IRB, and 2. The Research Compliance Review Committee (RCRC), which is a specialty committee that reviews potential serious and/or continuing non-compliance. 	<p>Introduction Section 4.C.3. – Describes the role of NIH IRBs, the relationship of the IC-based IRBs to OHSRP and levels of IRB review. This section also lists the IC-based IRBs.</p>

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<p>Throughout the NIH HRPP Policies they are referred to collectively as the “NIH IRB.”</p>	
<p>Although NIH FWA information is not provided in the policy, the NIH files an FWA with OHRP, (FWA# 00005897 which expires: 7/16/2023) and the NIH FWA and its expiration date can be found on the OHSRP website.</p> <p>Policy 100 is expanded to explain which investigators are covered under the NIH FWA with or without a written agreement (e.g. automatically), when conducting NIH human subjects research. This policy is far more nuanced than SOPs 20 and 20D with regard to who is covered without an agreement and who requires an agreement to be covered under the NIH FWA.</p> <p>Section D – Changes definition of NIH Investigator. This definition changes to clarify who is covered under the NIH FWA without an agreement:</p> <p><i>“NIH Investigator – An NIH federal employee (intramural or extramural), Special Volunteer, Intramural Research Training Awardee (IRTA) or Cancer Research Training Awardee (CRTA) who is conducting human subjects research on behalf of the NIH. This may include a contractor in accordance with policy.”</i></p> <p>Section E.2. Federalwide Assurance –</p> <ul style="list-style-type: none"> • E.2.C.I. – This section specifies which NIH staff are covered under the NIH FWA automatically (i.e., without a written agreement). <p><i>“NIH investigators are covered with no additional agreement. This includes NIH federal employees</i></p>	<p>Introduction Section 2. Federalwide Assurance (FWA) – <i>The NIH has a (sic) FWA (#00005897) on file with the DHHS Office for Human Research Protections (OHRP). Through this document NIH commits to DHHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR 46.</i></p> <p>SOP 20 Section 20.5.6 – <i>When an individual, not an NIH employee, is engaged in NIH human subjects research, working on an NIH protocol, at an NIH site, that individual is usually covered by the FWA of the NIH and is viewed the same as an NIH employee with respect to IRB approval at the NIH.</i></p> <p>SOPs 20 and 20D – Describes which non-NIH employees may be covered under the NIH FWA:</p> <ul style="list-style-type: none"> • <i>Researchers who are engaged in NIH human subjects research, working on an NIH protocol, at an NIH site with NIH employees.</i> • <i>Former employees or researchers at a non-NIH site and who want to remain on an NIH protocol performing only data analysis with identifiable data.</i> • <i>Non-employee collaborating investigator(s) (usually physicians) who provide NIH protocol interventions at non-NIH sites that do not hold a Federalwide Assurance (FWA) and will be engaged in human subjects research.</i>

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<p><i>(intramural or extramural), SV, Visiting Fellows, IRTAs and CRTAs.”</i></p> <ul style="list-style-type: none">• E.2.C. II. – This section specifies which NIH contractors are covered under the NIH FWA automatically, all other contractors not mentioned below. must be covered under a written agreement.<p><i>“Unless otherwise specified by the terms of the contract, NIH contractors are only covered by the NIH FWA without an additional written agreement, if:</i></p><ul style="list-style-type: none">○ <i>The contractor is working at an NIH site with an NIH employee; or</i>○ <i>It has been determined by the OHSRP Director or designee, in writing, that the contractor’s activities are covered by the NIH FWA.”</i>• E.2.C.III. – This section describes who must have a written agreement in order to seek coverage under the NIH FWA:<p><i>“All other investigators (e.g., external collaborators, guest researchers, rotating fellows and rotating students) conducting human subjects research, who are not described in E.2.C.I. above, are not covered under the NIH FWA unless through a written agreement. (For more information see Policies 105 IRB Reliance and 109 Coverage Under the NIH</i></p>	
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<p><i>Federalwide Assurance, 2300-308-1 - Guest Researcher/Special Volunteer Programs, and 2300-320-3 NIH Intramural Visiting Fellows Program (VFP) Policies.)”</i></p> <p>See <i>Policy 109 Coverage under the NIH Federalwide Assurance</i> for more information.</p>	
<p>Section E.5.e. – See the addition of the role of the CC Office of Research Support and Compliance (ORSC) which provides important regulatory support and guidance for NIH investigators:</p> <p><i>“The ORSC is located within the NIH Clinical Center (CC) and reports to the CEO of the NIH CC. ORSC ensures the quality and integrity of clinical research and product manufacturing/compounding conducted at the NIH, by providing regulatory and compliance support and guidance for all NIH investigators in the areas of protocol navigation and coordination, quality assurance, auditing and monitoring, support for FDA regulated studies, and centralized facility oversight.”</i></p>	<p>NA</p>