

<p>This document summarizes changes in Policy 106 Ancillary Reviews (referred to as Policy 106 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.</p> <p>The policy describes the NIH institutional ancillary reviews required for human subjects research activities, in addition to Institutional Review Board (IRB) review.</p> <p>NIH investigators are responsible for reviewing Policy 106 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
Policy 106 Ancillary Reviews	SOP Superseded by Policy 106
Policy 106 Ancillary Reviews partially supersedes	SOP 8 Procedures and Required Documentation for Submission and Initial Review of Protocols
<p>Applicability of Policy 106 - This policy applies to:</p> <p>NIH investigators conducting human subjects research within the NIH Intramural Research Program (IRP), regardless of whether the NIH IRB or a non-NIH IRB is the Reviewing IRB.</p>	
Policy Requirement	SOP Requirement
<p>Section C.1. - <i>In addition to the requirement for IRB review for non-exempt human subjects research conducted by NIH investigators, ancillary reviews may also be required. Ancillary reviews include but are not limited to: Ethics Review, Office of Technology Transfer Review, Scientific Review, Radiation Safety Committee (RSC), Radioactive Drug Research Committee (RDRC), Institutional Biosafety Committee (IBC), and the Select Agent Program (SAP).</i></p> <p>AND</p> <p>Section E.1.a. - <i>NIH Principal Investigators (PIs) are required to ensure that necessary ancillary reviews are completed and approved prior to initiation of non-exempt human subjects research.</i></p> <p>This requirement remains unchanged from SOP 8, newly initiated non-exempt human subjects research may not commence until both IRB approval and any applicable ancillary review approvals are received by the NIH PI.</p>	<p>Section 8.3.1.F.- <i>Other required approvals, such as those of the Radiation Safety Committee, Recombinant DNA Advisory Committee (RAC), as applicable. If the PI has not submitted these other required approvals (as applicable) at the time of the initial application, approval must be contingent upon receipt of these approvals to the IRB Office or deferred if additional IRB review is required.</i></p> <p>Policy 106 contains a more complete description of the NIH-required ancillary reviews than SOP 8 previously addressed.</p>
<p>Section C.3. – <i>When an NIH IRB is the Reviewing IRB, documentation of approval by the required NIH ancillary review entities must be provided to the NIH IRB.</i></p>	<p>As stated above, in SOP 8, IRB approval was held until all applicable ancillary review approvals were received by the Reviewing IRB.</p>

<p>AND</p> <p>Section C.4. – <i>When the NIH relies upon a non-NIH Reviewing IRB, approvals by NIH ancillary review entities are still required, and documentation of such approval must be provided to the Office of IRB Operations (IRBO) prior to submission to the Reviewing IRB.</i></p> <p>AND</p> <p>Section E.1.b – <i>The IRB Office (IRBO), during its pre-review of a submission, may inform a Principal Investigator that any missing ancillary approval is necessary before the NIH IRB will review or approve the research, or before the protocol can be submitted to a non-NIH IRB for review.</i></p> <p>When an external IRB is the reviewing IRB, IRBO <u>conducts an institutional pre-review and local context review</u> to ensure that all NIH policy requirements are met, such as ancillary reviews, prior to issuing an “Institutional Review Memo” to the PI. This memo must be submitted to the reviewing IRB and is needed before the external IRB will initiate review the research.</p>	<p>The change in Policy 106 is that some ancillary reviews are required before IRB review (e.g., RSC review), and IRB review may be delayed until such ancillary review approvals are received.</p> <p>This is true whether the reviewing IRB is the NIH IRB or an external IRB.</p>
<p>Section E.1.C. – <i>The Reviewing IRB is responsible for incorporating into the informed consent any language required to be disclosed to a research subject by an ancillary review committee (e.g., disclosure that an investigator on the protocol is listed on the government-owned patent or employee invention report).</i></p> <p>Although written as an IRB responsibility, NIH PIs must ensure that any disclosures to subjects, as required by an ancillary review committee, are included in the informed consent document when submitting to the reviewing IRB. When developing consents, NIH PIs are reminded to review the Informed Consent templates and the consent library found on the Templates and Forms page of the OHSRP website.</p>	<p>N/A</p>

<p>Section C.2. – <i>All non-exempt human subjects research conducted by NIH investigators must undergo scientific review consistent with the Policy for Scientific Review of Clinical Protocols Utilizing the NIH Intramural Program, unless waived by the Institute/Center (IC) leadership. All waivers of Scientific Review must be approved by the Chief Scientific Officer, Clinical Center (CC).</i></p> <p>AND</p> <p>Section E.2.a. – <i>The scientific review process applies to clinical protocols and generally occurs at the time of initial protocol review, annual and quadrennial review of the ongoing protocol, and review of substantive amendments to a protocol that pose new scientific questions or substantially alter the scientific approach.</i></p> <p>See also E.2.b. which specifies that NIH PIs are responsible for obtaining Scientific Review or seeking a waiver.</p> <p>Note that previously the IC Clinical Director could waive scientific review. Now these waivers must be approved by the Chief Scientific Officer, (Dr. John Gallin). For questions, contact the Office of Protocol Services.</p>	<p>Section 8.3.1.C. – <i>A copy of the Institute or Center (IC) scientific review (SR) and approval, or correspondence from the IC Clinical Director (CD) providing a justification for waiver of SR (when applicable).</i></p> <p>The requirement for scientific review prior to IRB review is unchanged from SOP 8. However, since the publication of SOP 8 the new IRP-wide scientific review policy has gone into effect and Dr. John Gallin became the Chief Scientific Officer, Clinical Center (CC).</p>
<p>Section E.3. – <i>NIH PIs are responsible for ensuring DEC review of covered research protocols occurs prior to IRB review, as described in Policy 102 Investigator Conflict of Interest and Government Royalties.</i></p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the Deputy Ethics Counselor (DEC) clearance, if required, must occur prior to NIH IRB review of the applicable submission.</p> <p>When an external IRB is the reviewing IRB, the DEC clearance, if required, must be submitted to IRBO before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	<p>Section 8.3.1.G. – <i>The completed Clearance of NIH Investigator Personal Financial Holdings (PFH) form(s) (see SOP 21 – Conflict of Interest Requirements for Researchers and Research Staff). If a protocol is “covered” and the PI has not submitted the IC Deputy Ethics Counselor (DEC)-approved PFH at the time of the initial application, the IRB, if it were to otherwise approve the study, must delay approval until the final DEC Clearance has been submitted to the IRB Office (see SOP 21 – Conflict of Interest Requirements for Researchers and Research Staff)</i></p>

<p>Section E.4.b. – <i>When there is research radiation use in the protocol that is subject to RSC review, the Principal Investigator must apply to the Radiation Safety Committee for review, consistent with RSC policy. (See information about submissions to the RSC: https://drs.ors.od.nih.gov/rsc/Pages/forms_index.aspx.) If the investigator is unsure whether Radiation Safety Committee review is required s/he should consult with either the RSC or the IRB for guidance.</i></p> <p>Note: What is reviewed by RSC and the NIH IRB regarding research radiation has changed, investigators should review the following notification: IRB and RSC Review of Research Protocols Using Radiation and Radiation Dosimetry Calculations for NIH protocols (May 15, 2020)</p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the RSC review, if required, must be submitted to the NIH IRB before the NIH IRB will review the applicable submission.</p> <p>When an external IRB is the reviewing IRB, the RSC review, if required, must be submitted to IRBO before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	<p>Section 8.3.1.F. – <i>Other required approvals, such as those of the Radiation Safety Committee, Recombinant DNA Advisory Committee (RAC), as applicable. If the PI has not submitted these other required approvals (as applicable) at the time of the initial application, approval must be contingent upon receipt of these approvals to the IRB Office or deferred if additional IRB review is required.</i></p>
<p>Section E.5.a. – <i>The RDRC is responsible for reviewing and approving the use of certain “non-approved” radioactive drugs for research purposes in humans that would otherwise require review by the FDA in the form of an Investigational New Drug (IND). Use of radioactive drugs in such studies is generally intended to obtain basic research information and is “not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).”</i></p> <p>AND</p> <p>Section E.5.b. – <i>Principal Investigators must follow instructions for submission for RDRC review that can be found at</i></p>	<p>See above.</p>

<p>https://drs.ors.od.nih.gov/rsc/RDRC/Pages/rdrc_index.aspx</p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the RDRC review, if required, must be completed before the NIH IRB will review the applicable submission, or issue final approval.</p> <p>When an external IRB is the reviewing IRB, the RDRC review, if required, must be completed before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	
<p>Section E.6 – <i>In cooperation with the technology-transfer offices of the Institutes and Centers (ICs) of the NIH, OTT is responsible for managing the docketing process for securing patents, enforcing terms in the licenses negotiated by the ICs, and managing the royalties collected under those licenses to encourage the development of new products and services to benefit public health.</i></p> <p><i>Principal Investigators should contact their IC Technology Transfer Office, Technology Development Coordinator, and Licensing & Patenting Managers for assistance in the various phases of the intramural technology transfer processes: review of Employee Invention Reports (EIRs); managing patent prosecution for inventions; licensing available technologies; establishing various agreements, such as Confidential Disclosure Agreements (CDAs), Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs); and Clinical Trial Agreements (CTAs). HHS OTT policies can be accessed at HHS Technology Transfer Policies.</i></p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the OTT review, if required, must be completed before the NIH IRB will review the applicable submission, or issue final approval.</p> <p>When an external IRB is the reviewing IRB, the OTT review, if required, must be completed before IRBO will issue the NIH Institutional</p>	<p>N/A</p>

<p>Review Memo that is needed before the external IRB will review the applicable submission.</p>	
<p>Section E.7.a. – <i>When a company seeks the right to license inventions made by NIH staff during a clinical trial, the IC Technology Development Coordinator will work with the company and the CRADA Principal Investigator to arrange a CRADA. When the CRADA is ready for execution, the IC Technology Development Coordinator will refer the CRADA to the CRADA Subcommittee for advisory review, and then route the final agreement for signatures.</i></p> <p>AND</p> <p>Section E.7.b. – <i>When a clinical trial involves a CRADA, the CRADA PI is responsible for notifying the IRB. Specifically, the CRADA PI must inform the IRB when the CRADA partner will receive identifiable human data or identifiable materials.</i></p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the CRADA Subcommittee review, if required, must be completed before the NIH IRB will review the applicable submission, or issue final approval.</p> <p>When an external IRB is the reviewing IRB, the CRADA Subcommittee review, if required, must be completed before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	<p>N/A</p>
<p>Section E.8.a. – <i>The (Institutional Biosafety Committee) IBC oversees a review and registration process and addresses concerns regarding the Dual Use Research of Concern (DURC) nature of proposed research. The Committee provides recommendations for safety policy to the Director of the NIH or his designee and the DDIR and reviews all infectious disease research performed at BSL-2 and above and any research that falls under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).</i></p>	<p>N/A</p>

<p>AND</p> <p>Section E.8.b. – <i>All Principal Investigators (PIs) working with human, plant, or animal pathogens must register their work with the Institutional Biosafety Committee (IBC). This is done through the DOHS electronic biological registration interface ('PI Dashboard'), which can be accessed through the DOHS Principle Investigators resource page. PIs may consult with IBC contacts, Institute assigned safety specialists, or a Biological Safety Officer, BSO through DOHS at 301-496-2960 if they will be conducting basic and/or clinical research involving recombinant DNA, including human gene transfer, or potentially infectious/toxic materials to ensure that proper containment and biosafety practices are employed.</i></p> <p>AND</p> <p>Section E.8.c. – <i>Principal Investigators considering whether their research constitutes DURC should refer to the NIH Dual-Use Research webpage for information and requirements. All IBC registrations include a series of questions that evaluate the work for DURC. (NIH Office of Intramural Research oversight on Dual Use Research)</i></p> <p>See Policy 106 for more helpful details about submissions to the IBC.</p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the IBC review, if required, must be completed before the NIH IRB will review the applicable submission, or issue final approval.</p> <p>When an external IRB is the reviewing IRB, the IBC review, if required, must be completed before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	
<p>Section E.9.a. – <i>The SAP manages the oversight of the possession, use, or transfer of select agents at the NIH. This oversight is performed by</i></p>	<p>N/A</p>

<p><i>the entity assigned Responsible Official (RO) for the SAP. The NIH must comply with the regulations and requirements of 42 CFR 73, 7 CFR 331 and 9 CFR 121.</i></p> <p>AND</p> <p>Section E.9.b. – <i>Principal Investigators planning to work with select agents/toxins must enroll in the SAP and receive approval prior to the possession, use and transfer of select agents/toxins. It is critical that enrollment in the NIH Select Agent Program occur well in advance of IRB submission. For additional information, training and requirements, see the NIH Select Agent Program webpage.</i></p> <p>When the NIH IRB is the reviewing IRB, under new IRB procedures, the SAP review, if required, must be completed before the NIH IRB will review the applicable submission, or issue final approval.</p> <p>When an external IRB is the reviewing IRB, the SAP review, if required, must be completed before IRBO will issue the NIH Institutional Review Memo that is needed before the external IRB will review the applicable submission.</p>	
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