

Policy 401 Research Involving Prisoners – Policy Overview

<p>This document summarizes changes in <i>Policy 401 Research Involving Prisoners</i> (referred to as Policy 401 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below. The policy defines the ethical and regulatory requirements that apply to human subjects research involving prisoners.</p> <p>NIH investigators are responsible for reviewing Policy 401 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
<p>Applicability:</p> <ul style="list-style-type: none"> • This policy applies to all research involving prisoners as subjects, whether prisoners are an intended population, or if a subject becomes a prisoner at any time during the course of the research; and • all NIH investigators conducting NIH research involving prisoners, whether the reviewing IRB is the NIH IRB or an external IRB; and • non-NIH investigators, including Lead Site Investigators, when the NIH IRB is the reviewing IRB. 	
Policy 401 Research Involving Prisoners	SOP(s) Superseded by Policy 401
Policy 401 partially supersedes:	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.
Policy 401 supersedes:	SOP 14C Research Involving Prisoners When inactivated, this SOP will be archived in the Policy Archive.
POLICY Requirement	SOP Requirement
<p>Section C.1. – <i>The NIH Principal Investigator (PI)/Lead Site Investigator will ensure that all non-exempt human subjects research that involves prisoners as subjects, is conducted in compliance with 45 CFR 46 Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (“Subpart C”) and has been approved by the IRB to permit the enrollment of prisoners.</i></p> <p>This policy now specifies responsibilities of both PIs and Lead Site Investigators to ensure that all requirements are met prior to enrolling prisoners, or allowing prisoners to continue participating, in non-exempt human subjects research.</p>	<p>Lead Site Investigators and PIs are now equally responsible when conducting research involving prisoners.</p> <p>SOP 14C was published prior to the NIH Single IRB Policy, and prior to the 2018 Common Rule, and therefore did not specifically address Lead Site Investigators.</p>

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<p>Section C.2. – <i>Non-exempt human subjects research involving prisoners will not be initiated or continued until there is both IRB approval and HHS Office for Human Research Protections (OHRP) written approval except as noted in E.1.c.II.</i></p>	<p>SOP 14C.2. states, in part – <i>Research involving prisoners may not be initiated or continued until there is both Institutional Review Board (IRB) approval and Office for Human Research Protections (OHRP) approval.</i></p>
<p>Section C.3. – <i>For research subject to the pre-2018 Common Rule, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners (45 CFR 46.101(i), Footnote 1).</i></p> <p>Exempt research involving prisoners is not allowed in research approved under the pre-2018 Common Rule.</p> <p>Section C.3.a. – <i>For research subject to the 2018 Common Rule, research involving prisoners cannot be deemed exempt under 45 CFR 46.104(d), except for research aimed at involving a broader subject population that only incidentally includes prisoners. (46.104(b)(2))</i></p> <p>Under the 2018 Common Rule, research aimed at involving a broader subject population that only incidentally includes prisoners may be approvable under exempt categories of research when all criteria for exemption are met.</p>	<p>SOP 14.C.2.D. – <i>The exemptions at 45 CFR 46.101(b) cannot be applied to research involving prisoners.</i></p> <p>The 2018 Common Rule was not in effect at the time of publication.</p>
<p>Section C.4. – <i>Informed consent can be waived or altered in research involving prisoners only in accordance with applicable regulations. However, even if informed consent is waived or altered, subjects will be clearly informed in advance that participation in the research will have no effect on their parole, if such notification is relevant. (45 CFR 46.305(a)(6))</i></p>	<p>This requirement is addressed in SOP 14C.2.A.</p>
<p>Section C.5. – <i>Prisoners cannot be involved in emergency research where the requirement for informed consent has been waived by the Secretary under the authority of 45 CFR 46.101(i). (See 61 Fed. Reg. 51531 (Oct. 2, 1996).)</i></p>	<p>This requirement is addressed in SOP 14C.2.B.</p>

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<p>Section E.1. – Principal Investigator (PI)/Lead Site Investigator Responsibilities.</p> <p>This policy expands these requirements to the Lead Site Investigator in addition to the PI. There are no changes in responsibilities, only to whom those responsibilities apply.</p> <p>Responsibilities are summarized below:</p> <ul style="list-style-type: none">• Do not initiate research that enrolls prisoners, or anticipates subjects will become prisoners, unless IRB and OHRP approval have been obtained.• Provide sufficient information in the protocol.• Promptly notify the Office of IRB Operations (IRBO) if a subject becomes a prisoner while on-study.• Halt all research interventions or collection of identifiable private information relating to the now-incarcerated prisoner-subject except as noted in section E.1.c.II. of the policy.• Even under the circumstances noted in section E.1.c.II., no research activities involving the prisoner-subject may take place prior to IRB approval and OHRP authorization except for those necessary for the welfare or safety of the subject. <p>Refer to Policy 401 for a complete description of PI/Lead Site Investigator responsibilities.</p>	<p>SOP 14.C.9.2. – ACTIONS REQUIRED IF AN ONGOING PROTOCOL WAS NOT REVIEWED UNDER THE REQUIREMENTS OF THIS SOP (SUBPART C, 45 CFR 46) AND AN ALREADY-ENROLLED RESEARCH SUBJECT BECOMES A PRISONER DURING THE COURSE OF THE STUDY</p> <p>This language has been replaced in the policy by Section E.1. which describes PI/Lead Site Investigator responsibilities for conducting all research involving prisoners.</p>
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