

Policy 300 Investigator Responsibilities – Policy Overview

<p>This document summarizes changes in <i>Policy 300 Investigator Responsibilities</i> (referred to as Policy 300 in this document) that NIH investigators should be aware of, from the SOPs mentioned below.</p> <p>The policy describes the responsibilities and requirements of all NIH investigators, which includes NIH Principal Investigators (PIs), when conducting human subjects research (both exempt and non-exempt human subject research). The policy also describes the responsibilities and requirements of non-NIH investigators when the NIH IRB is the Reviewing IRB.</p> <p>Investigators are responsible for reviewing Policy 300 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
<p><i>Policy 300 Investigator Responsibilities</i></p>	<p>SOP Superseded by Policy:</p>
<p>Policy 300 supersedes</p>	<p>SOP 19 Investigator Responsibilities When inactivated, this SOP will be archived in the Policy Archive.</p>
<p>Applicability of Policy 300 - This policy applies to:</p> <ul style="list-style-type: none"> • NIH investigators, including NIH PIs, conducting human subjects research on an NIH protocol, whether the reviewing IRB is the NIH IRB or an external IRB. (For NIH IRP research that is overseen by an external IRB, responsibilities and requirements are outlined in <i>Policy 105 IRB Reliance</i>.) • Non-NIH investigators when the NIH IRB is the reviewing IRB. <p>The policy focuses on key responsibilities of NIH investigators. However, additional responsibilities are established in the other NIH Human Research Protection Program (HRPP) policies. NIH investigators are expected to be familiar and comply with those additional requirements, as applicable.</p>	
<p>Policy Requirement</p>	<p>SOP Requirement</p>
<p>Section D.6. Definitions</p> <p>Investigator – <i>An individual who is involved in the conduct of human subjects research. Such involvement would include:</i></p> <p><i>a. obtaining information about living individuals by intervening or interacting with them for research purposes;</i></p> <p><i>b. obtaining identifiable private information or identifiable biospecimens about living individuals for research purposes;</i></p> <p><i>c. obtaining the voluntary informed consent of individuals to be subjects in research; and</i></p> <p><i>d. studying, interpreting, or analyzing identifiable private information, biospecimens, or data for research purposes.</i></p> <p><i>1. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for</i></p>	<p>SOP 19, section 19.3.1 – <i>An “investigator” is any individual who is involved in conducting human subjects research (HSR) studies. Such involvement includes: (1) obtaining information about living individuals by intervening or interacting with them for research purposes; (2) obtaining identifiable private information about living individuals for research purposes; (3) obtaining voluntary informed consent of individuals to be subjects in research, or (4) studying, interpreting, or analyzing identifiable private information or data for research purposes.</i></p> <p>There is no change in the definition of investigator, nor of investigator responsibilities.</p>

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<p><i>the study. For more information see the OHRP Investigator Responsibilities FAQs. At the NIH, this term also includes study coordinators and may also include other individuals as determined by the NIH PI.</i></p> <p>Policy 300 adds additional detail and specificity for clarity.</p>	
<p>Section C.1.a. – <i>All investigators are expected to conduct themselves according to the highest standards of professional conduct and integrity and to adhere to the ethical principles that address the protection of human subjects in research.</i></p> <p>AND</p> <p>Section C.1.b. – <i>All NIH investigators will comply with federal law, regulation and policy, including NIH policy, and will conduct the research in compliance with the IRB approved protocol.</i></p> <p>There is no change in the obligation to comply with relevant law, regulation and policy.</p>	<p>SOP 19.3.2. – <i>The following responsibilities are applicable to any investigator:</i></p> <p>A. <i>The ethical treatment of the participants</i></p> <p>AND</p> <p>SOP 19.4.B. – <i>Relevant federal regulations (e.g. Common Rule (45 CFR 46) and Food and Drug Administration (FDA) regulations (e.g., 21 CFR parts 50, 56, 312, and 812), as applicable)</i></p> <p>Policy 300 is reorganized for clarity.</p>
<p>Section E.1.a.II. – <i>All NIH investigators must: Know when an activity constitutes non-exempt human subjects research and assure IRB approval has been granted when required before performing human subjects research.</i></p> <p>There is no change in the obligation to obtain IRB approval, or an exempt determination, prior to conducting human subjects research.</p> <p>This paragraph addresses non-exempt human subjects research. Section E.3. of this policy addresses exempt research separately. These distinctions were not present in SOP 19.</p>	<p>SOP 19.5.A. – <i>Research involving human subjects begins only after NIH IRB review and ... or, when appropriate, after the OHSRP grants a written determination that IRB review is not required.</i></p> <p>AND</p> <p>SOP 19.3.2.D – <i>Not engaging in human subjects research until proof of IRB-approval has been provided by the PI.</i></p> <p>AND</p> <p>SOP 19.3.2.E. – <i>Complying with the terms of the IRB-approved protocol and PI instruction.</i></p> <p>Policy 300 adds specificity for clarity.</p>
<p>Section C.1.c. – <i>When the NIH IRB is the Reviewing IRB, all investigators will follow the policies of the NIH IRB (NIH HRPP policies).</i></p> <p>I. <i>When an external IRB is the Reviewing IRB, in addition to NIH policies, NIH investigators will also comply with the applicable policies and procedures of the external IRB.</i></p>	<p>SOP 19.5.O. – <i>The NIH PI must comply with the requirements set forth in SOPs SOP 20 - NIH HRPP Requirements for Collaborative Research and SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH.</i></p>

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<p>Policy 300 adds specificity for clarity.</p>	
<p>Section C.2. applies to Principle Investigators (PIs), and notes that PI responsibilities are <u>in addition to</u> investigator responsibilities. Described in section C.1.</p> <p>AND</p> <p>Section C.2.a. – <i>Only the following investigators may be PIs on NIH protocols:</i></p> <p><i>I. NIH Federal Employees, including Commissioned Corp Officers, assigned to the NIH.</i></p> <p><i>II. Non-NIH Federal Employees with the concurrence of NIH Institute/Center (IC) Leadership and the approval of the NIH Institutional Official.</i></p> <p>AND</p> <p>Section C.2.b. – <i>The following investigators may not be PIs on NIH protocols:</i></p> <p><i>I. Non-NIH investigators who are not federal employees (e.g., those employed by academia, practicing at a community hospital, etc.), such as contractors, Special Volunteers, guest researchers, research collaborators, and trainees (e.g., IRTAs, CRTAs and Visiting Fellows).</i></p> <p><i>i. However, contractors and Special Volunteers investigators may be Adjunct Principal Investigators (Adjunct PI). In such cases, the NIH PI must be a federal employee and must meet the requirements for an NIH PI (see C.2.a.). While Adjunct PIs share some responsibility for leadership of the protocol, the supervisory authority remains with the NIH PI.</i></p> <p>Policy 300 specifies that even when an Adjunct Principle Investigator is in place, the overall responsibility for the research remains with the NIH PI and that only the PI as a federal employee has formal supervisory authority.</p>	<p>SOP 19.3.3. – <i>The following requirements determine who may be a PI:</i></p> <p><i>A. NIH employees including Public Health Service (PHS) commissioned officers assigned to the NIH:</i></p> <p><i>B. Non-NIH Federal employees may serve as PIs on an NIH protocol on a case-by-case basis with the following conditions: 1. The Deputy Director for Intramural Research (DDIR) must approve in writing a request for a non-NIH Federal employee to serve as a PI.</i></p> <p><i>C. Non-NIH, non-Federal employees: Extramural researchers (e.g., in academia, practicing at a community hospital) may serve as Adjunct Principal Investigators on a protocol where the PI is an NIH employee.</i></p> <p>AND</p> <p>SOP 19 stated the DDIR could make exceptions, while Policy 300 states the IO must approve the request. At this time, the DDIR serves as the IO, but Policy 300 introduces flexibility by citing the IO role.</p>
<p>Section C.2.c. – <i>There can be only one (1) NIH PI or Lead Site Investigator for protocols conducted by the NIH IRP.</i></p>	<p>SOP 19.3.3. – <i>There can be only one PI for each protocol.</i></p>

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<p>Policy 300 adds specificity for clarity.</p>	
<p>Section C.2.d. – <i>NIH Principal Investigators must be approved by IC leadership, based on the IC leadership’s determination that the PI is qualified on the basis of education, training and experience to conduct the proposed research.</i></p> <p>AND</p> <p>Section C.2.e. – <i>The NIH PI has overall responsibility for the design, conduct, reporting and scientific integrity of the research.</i></p> <p>AND</p> <p>Section C.2.g. – <i>The NIH PI may assign responsibility for specific aspects of the conduct of the research to appropriately qualified individuals consistent with the IRB-approved protocol and the requirements, as described in this policy. However, at all times the PI retains overall responsibility for the conduct of the research, and must assure both the protocol and the research team’s actions are compliant with law, regulation, and policy.</i></p> <p>Under Policy 300, IC leadership determines whether a PI is qualified based on education, training and experience.</p> <p>SOP 19 also indicated the PI was responsible for assuring all investigators were qualified to perform duties assigned to them. Policy 300 clarifies that the PI retains overall responsibility for the conduct of the entire study even, when study tasks are assigned to others.</p>	<p>SOP 19.3.3.A. – <i>To be a PI, an NIH employee will have appropriate credentialing. At the NIH Clinical Center (CC), a PI will be a member of the senior or junior medical, research; adjunct or affiliate staff (see References below for the link to the Medical Staff Bylaws). Non-CC NIH employees must comply with the credentialing requirements, as applicable, of their Institute/Center (IC). Consult the IC Clinical Director (CD) for direction.</i></p> <p>AND</p> <p>SOP 19.3.3 – <i>The Principal Investigator is responsible for assuring that all investigators are qualified by education, training, and experience needed to perform their delegated roles in conduct of the study.</i></p> <p>Policy 300 does not call out the specific CC requirements.</p>
<p>Section C.2.f. – <i>When the NIH is initiating the research, the NIH PI is responsible for knowing whether additional IRB oversight is required by regulation (e.g., when dual review is needed, by either a tribal IRB or a foreign IRB). The PI is responsible for ensuring that OHSRP is informed of this at the time of submission, and the PI is responsible to ensure that such a review occurs.</i></p>	<p>Not applicable (NA)</p>

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<p><i>I. If dual IRB review is required, research may not commence at the site subject to the non-NIH IRB oversight, until approval is granted by all required reviewing IRBs.</i></p> <p>PIs have always been responsible for ensuring all relevant approvals are in place prior to commencing research. Policy 300 adds specificity for clarity.</p>	
<p>Section C.2.h. – <i>NIH PIs must designate those individuals who are conducting human subjects research as investigators on the protocol (e.g., Associate Investigators (AIs), Adjunct PIs, Lead Associate Investigators (LAIs), or Medically Advisory Investigators (MAIs), as applicable), and list them on the IRB application.</i></p> <p><i>I. The NIH PI is responsible for ensuring that investigators are qualified to perform their delegated roles, are appropriately credentialed/licensed, and are listed on the IRB application.</i></p> <p><i>II. The NIH PI is responsible for ensuring that all Associate Investigators (AIs) that interact with human subjects, are permitted to do so in accordance with all NIH policies. For example, there are significant restrictions on activities permitted for trainees.</i></p> <p>Although not a new NIH Intramural program requirement, Policy 300 explicitly states that trainee investigators may not sign informed consent documents and some trainees must be under the direct supervision and control by an NIH Employee when interacting with a subject on the research. See Policy 300 for more information.</p>	<p>NA</p>
<p>Section E.I.a.V. – <i>All NIH investigators must: Ensure that informed consent is obtained from each human subject and documented before conducting human subjects research, consistent with the IRB-approved protocol and according to Policy 301 Informed Consent, unless the requirements for consent or documentation of consent have been waived or altered by the IRB.</i></p>	<p>SOP 19.5.C. – <i>The PI ensures that: the research is conducted in accordance with the NIH IRB-approved protocol, including the approved recruitment and consent procedures.</i></p>

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<p>This regulatory and policy requirement has not changed.</p>	
<p>Section E.I.a.VI. – All investigators must: <i>Ensure the accuracy, completeness, legibility, and timeliness of the data</i></p> <p>AND</p> <p>Section E.I.a.VII. – <i>Follow internal policies for the appropriate documentation of research related tests and procedures.</i></p> <p>These requirements are unchanged.</p>	<p>SOP 19.5.3.B. – <i>PI responsibilities include but are not limited to: 1. Ensuring the accuracy, completeness, legibility, and timeliness of the data. 2. Following internal procedures for the appropriate documentation of research related tests and procedures.</i></p>
<p>Section E.I.a.VIII. – All investigators must: <i>Be responsive to subject concerns and complaints consistent with Policy 104 Managing Research-Related Complaints from Research Subjects.</i></p> <p>This obligation has been added to Policy 300.</p>	<p>This obligation was previously addressed in SOP 22.</p>
<p>Section E2 specifies responsibilities of NIH Principal Investigators conducting non-exempt human subjects research.</p> <p>Section E.2.a. – <i>The PI must comply with all requirements of Sections C.1. and C.2. of the policy.</i></p> <p>AND</p> <p>Section E.2.b. – <i>For each protocol, the PI is responsible for designating other investigators as described below:</i></p> <p>I. Medical Advisory Investigator (MAI): <i>When the research involves medical care or clinical interventions and the PI is not a member of the senior or junior medical staff, research, adjunct staff or affiliate staff, or is not licensed to provide the appropriate level of medical care, or when an IC CD considers it warranted, the PI will designate an MAI.</i></p> <p><i>i. The MAI must be identified in the IRB application and approved by the IRB.</i></p> <p><i>ii. Only 1 MAI may be appointed to the protocol.</i></p> <p>III. Adjunct PI may be designated: There can be only one (1) Adjunct PI per protocol and there must be a named NIH PI who is a federal employee, consistent with C.2.a. above, and</p>	<p>SOP 19.3.6 Medical Advisory Investigator (MAI) – <i>When the PI is not a member of the senior or junior medical staff, or when an IRB, IC CD, or the Director, CC considers it warranted, a MAI must be identified in the protocol and approved by the IRB. There is only one MAI per protocol.</i></p> <p>The requirement to designate a MAI when the PI is not a member of the senior or junior medical staff, or when the IRB, IC CD, or the CC Director considers it appropriate, has not changed.</p> <p>AND</p> <p>SOP 19.3.5 Adjunct Principal Investigator (API) – <i>An API is an individual who is not an NIH employee and who shares some responsibilities with the NIH PI at the NIH or for multisite studies also conducted at the NIH Clinical Center.</i></p> <p>AND</p> <p>19.3.7 Lead Associate Investigator (LAI) – <i>An individual who plays a leading role in the formulation, writing, and implementation of a clinical research protocol under the mentorship of the protocol’s PI is a LAI. There is only one LAI per protocol.</i></p> <p>Policy 300 adds specificity for clarity.</p>

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<p>who will be responsible for the conduct of the protocol.</p> <p>III. Lead Associate Investigator may be designated. There can be only one (1) Lead Associate Investigator per protocol.</p> <p>Policy 300 specifies that the NIH PI is responsible for the conduct of the protocol even when an Adjunct PI has been designated and approved by the IRB.</p>	
<p>Section E.2.c – <i>The PI, at a minimum, is accountable to:</i></p> <p>Section E.2.c.i. – <i>Ensure sufficient resources are allocated to the research.</i></p> <p>AND</p> <p>Section E.2.c.ii. – <i>Comply with the determinations of the Reviewing IRB.</i></p> <p>Policy 300 is reorganized for clarity.</p>	<p>SOP 19.5 – The PI ensures that:</p> <p>SOP 19.5.2 – The PI will conduct the research only when adequate resources to protect research subjects exist.</p> <p>AND</p> <p>SOP 19.5.A – Research involving human subjects begins only after NIH IRB review and approval.</p> <p>These obligations have not changed</p>
<p>Section E.2.c.iii. – <i>Conduct research only after the following conditions have been met:</i></p> <p><i>i. IRB approval is obtained;</i></p> <p><i>ii. When applicable, all other necessary institutional approvals have been obtained (See Policy 106 Ancillary Reviews.);</i></p> <p><i>iii. As applicable, appropriate agreements have been executed with outside entities (e.g., FDA sponsors, collaborators). This agreement may be a MOU, Clinical Trial Agreement (CTA), or Cooperative Research and Development Agreement (CRADA).</i></p> <p>There are no changes in obligations, though Policy 300 adds specificity for clarity.</p>	<p>SOP 19.5.A – Research involving human subjects begins only after NIH IRB review and approval</p> <p>AND</p> <p>SOP 19.5.G. – <i>Other NIH requirements, as appropriate such as those of the: Radiation Safety Committee, the Recombinant DNA Advisory Committee (RAC), and the NIH Biosafety Committee</i></p> <p>Collaborative and other agreements were previously discussed in SOPs 20, 20A, and 20C.</p>
<p>Section E.2.c.iv. – <i>For research involving the use or disclosure of identifiable private information or biospecimens, subjects’ privacy and confidentiality is protected in compliance with relevant laws, regulations, policies, and the terms of the informed consent or other documents. (See Policy 107 Privacy and Confidentiality.)</i></p>	<p>NA</p>

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<p>This obligation has not changed, but is added to Policy 300 for clarity.</p>	
<p>Section E.2.c.V. – <i>Ensure proper arrangements for IRB oversight when conducting non-exempt human subjects research at a non-NIH site, or with a non-NIH institution, including when seeking single IRB review for multi-site research (whether by the NIH IRB or an external IRB). This arrangement occurs via a reliance agreement or other appropriate mechanism, consistent with the requirements set forth in Policy 105 IRB Reliance.</i></p> <p>The requirement to obtain a reliance agreement or other mechanism has not changed. See Policy 105 for additional information about multi-site or cooperative research, and IRB reliance.</p>	<p>SOP 19.5.O. – <i>When conducting collaborative research at a non-NIH institution, or when a non-NIH investigator, engaged in HSR wishes to rely on an NIH IRB, or when conducting multi-site research using a single IRB review, the need for a Reliance (also referred to as an Authorization) Agreement is considered. The NIH PI must comply with the requirements set forth in SOPs SOP 20 - NIH HRPP Requirements for Collaborative Research and SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH.</i></p>
<p>Section E.2.c.VI. – <i>Ensure that, when Continuing Review is required by either regulation or by the IRB, submission of the required documents for IRB review occurs with sufficient time to allow for IRB review and approval prior to the expiration of the current IRB approval and with sufficient time for response by the PI to any stipulations of the IRB. (See Policy 205 Requirements for IRB Submissions.)</i></p> <p>There is no change in this obligation.</p> <p><i>i. Alternatively, for those studies that do not require continuing review, ensure timely submission to the IRB of amendments, progress reports, reportable events and any documentation required by other NIH policies, and also that the study is closed with the IRB upon completion of the research. (See Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research.)</i></p> <p>For studies initially reviewed under the 2018 Common Rule, or transitioned to it, some minimal risk protocols do not require continuing review. However, all other requirements still apply.</p>	<p>SOP 19.5.J. – <i>The CR submission to the IRB is submitted with sufficient time to allow for IRB review and approval prior to the expiration of the current IRB approval, and with sufficient opportunity for response by the PI to any stipulations of the IRB (see SOP 9 - Continuing Review by the Convened IRB).</i></p> <p>The PI’s obligation to submit appropriate documents for continuing review in a timely fashion has not changed for studies that require continuing review. The revised 2018 Common Rule (45 CFR 46) was not in effect at the time of publication.</p>

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<p>FDA-regulated studies continue to require CR at least once per year.</p>	
<p>Section E.2.c.VII. – Report Unanticipated problems (UPs), non-compliance or other research events to the IRB and, as necessary, to sponsors or other regulatory agencies in accordance with requirements set forth in Policy 801 Reporting Research Events.</p> <p>Policy 300 references reporting obligations to sponsors and regulatory agencies. These obligations have not changed, but are now specified in this policy.</p>	<p>SOP 19.5.H. – Unanticipated problems (UPs) involving risks to subjects or others (including adverse events and protocol deviations) are reported to the IRB in accordance with requirements set forth in SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations and SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP).</p>
<p>Section E.2.c.VIII. – Maintain a regulatory file with current and accurate records of all study documentation as required by applicable regulatory requirements. (See NIH Manual Chapter 1743 - Keeping and Destroying Records, the NIH Intramural Records Retention Schedule, and the NIH Privacy Act Policy.)</p> <p>There is no change in this obligation.</p>	<p>SOP 19.5.3.D. – Records retention will be consistent with NIH Manual Chapter 1743, Keeping and Destroying Records, and other applicable policies (see References below).</p>
<p>Section E.2.c.IX. – Cooperate with NIH oversight (e.g., IRB, OHSRP, ORSC, or IC), authorized federal regulatory agencies, and sponsors, including for: investigations, monitoring, audits, and actions. Provision of certain documents to auditors or monitors may be privileged and not appropriate for disclosure, consult with appropriate NIH offices (e.g., OHSRP, OGC, ORSC or IC Privacy Officer) as needed. Regarding FDA inspections:</p> <ul style="list-style-type: none"> i. NIH researchers who are informed of an FDA inspection must immediately notify their Clinical Director, Clinical Center (CC) CEO, ORSC, and OHSRP. ii. Any written responses to the FDA submitted by NIH researchers must first be approved by the Clinical Director, CC CEO, ORSC, and OHSRP. The appropriate party must provide a draft response to the Clinical Director, CC CEO, ORSC, and OHSRP at least four business days before it must be submitted to the FDA. <p>Policy 300 adds the expectation that researchers notify their CD, CC CEO, ORSC and</p>	<p>SOP 19.5.M. – Upon request for monitoring and/or oversight of the research, research records are made available to the IRB, OHSRP, the IC Quality Improvement Program, and when applicable, the DSMB, the sponsor, the DHHS Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA).</p> <p>Policy 300 specifically references the expectation that investigators cooperate with the Office of General Council (OGC) and Privacy, as well as the Office of Research Support and Compliance (ORSC) which was formed after SOP 19 was published.</p>

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<p>OHSRP when notified of an FDA inspection. The policy also requires a draft of all written responses to the FDA to be first submitted to the CD, CC CEO, ORSC and OHSRP before they must be submitted to the FDA.</p>	
<p>Section E.2.c.X. – Ensure, when an investigator is leaving the NIH:</p> <p><i>i. That proper arrangements are made for continued IRB oversight for any investigator who wishes to continue the research or continue to perform data analysis of identifiable data.</i></p> <p><i>ii. That data and specimens are transferred to/retained by the departing investigator only with appropriate permissions and IC oversight. (See, e.g., the HHS Technology Transfer Policies and Procedures Manual.); and</i></p> <p><i>iii. That if it is the PI who is leaving, to revise the protocol and obtain IRB approval of a new PI who is suitably qualified to be responsible for the conduct of the research.</i></p> <p>These existing obligations are now specified in Policy 300.</p>	<p>NA</p>
<p>Section E.3 – Requirements for Investigators Conducting FDA Regulated Research When the NIH IRB is the Reviewing IRB</p> <p><i>a. In addition to the applicable requirements listed above, investigators conducting research regulated by the Food and Drug Administration (FDA) must comply with FDA requirements and NIH policy.</i></p> <p>See Policy 500 Research Involving Drugs, Biological and Nutritional Products; Policy 501 Research Involving FDA Regulated Devices; and Policy 502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices for more information.</p>	<p>SOP 19.1 – Additional requirements for PIs conducting research regulated by the Food and Drug Administration (FDA) are provided in SOP 15 “Research Regulated by the FDA: General Procedures for Both IND and IDE Applications”.</p>
<p>Section E.4 – Requirements for Investigators Conducting Exempt Human Subjects Research</p> <p><i>a. In addition to the requirements listed in E.1., the following apply to investigators conducting research that has been determined to be</i></p>	<p>NA</p>

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<p><i>exempt from 45 CFR 46, including exempt research which was approved under limited IRB review procedures:</i></p> <ul style="list-style-type: none">I. Submit a request for exempt or limited IRB review determination.II. Upon receiving a determination or approval, conduct research in compliance with the approved protocol.III. Submit any changes to the research for approval prior to implementation.IV. Maintain adequate and accurate study records and documentation.V. Report research events according to Policy 801 Reporting Research Events. <p>These existing obligations have been added to Policy 300 for clarity.</p>	
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