

HRPP POLICY APPROVAL & IMPLEMENTATION
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 300

SOP Title: Investigator Responsibilities

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators,
IRB Chairs, IRB Administrators, Protocol Navigators**

Revision Approval:

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POLICY

A. PURPOSE

1. 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).
2. Describes the responsibilities and requirements of non-NIH investigators when the NIH IRB is the Reviewing IRB.

B. SCOPE

1. This policy applies to:
 - a. 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.
 - I. For NIH IRP research that is overseen by an external IRB, responsibilities and requirements are outlined in [Policy 105 IRB Reliance](#).
 - b. Non-NIH investigators when the NIH IRB is the reviewing IRB.

Note: This 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.

C. POLICY

1. Investigators
 - a. 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. (See [Policy 100 NIH Intramural Research Program's Human Research Protection Program](#).)
 - b. 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.
 - c. When the NIH IRB is the Reviewing IRB, all investigators will follow the policies of the NIH IRB (NIH HRPP policies).

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- 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.

2. NIH Principal Investigators (PIs)

In addition to section [C.1.](#), the following applies:

- a. Only the following investigators may be PIs on NIH protocols:
 - I. NIH Federal Employees, including Commissioned Corp Officers, assigned to the NIH.
 - II. Non-NIH Federal Employees with the concurrence of NIH Institute/Center (IC) Leadership and the approval of the NIH Institutional Official.
- b. The following investigators may not be PIs on NIH protocols:
 - 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. 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.](#) above). While Adjunct PIs share some responsibility for leadership of the protocol, the supervisory authority remains with the NIH PI.
- c. There can be only one (1) NIH PI or Lead Site Investigator for protocols conducted by the NIH IRP.
- d. 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.
- e. The NIH PI has overall responsibility for the design, conduct, reporting and scientific integrity of the research.
- f. 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

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that OHSRP is informed of this at the time of submission, and the PI is responsible to ensure that such a review occurs.

- 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.

- g. 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.
- h. 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 Medical Advisory Investigators (MAIs), as applicable), and list them on the IRB application.
 - I. The NIH PI is responsible for ensuring that investigators designated on the IRB application are qualified to perform their delegated roles in conduct of the study, and are appropriately credentialed and licensed, as applicable, to perform their assigned tasks and are listed on the IRB application.
 - II. The NIH PI is responsible for ensuring that all 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. Trainee investigators may not sign informed consent documents. (See *Policy 301 Informed Consent.*)
 - i. Some trainees (e.g., VF’s and CRTAs) serving as Associate Investigators must be under the direct supervision and control by an NIH Employee when interacting with a subject on the research. (See [2300-320-7 - Intramural Research Training Award \(IRTA\) Program Automated Fellowship Payment System](#) and [2300-320-3 NIH Intramural Visiting Fellows Program \(VFP\) Policies.](#))

D. DEFINITIONS

Definitions demarcated with (Pre-2018 Common Rule) apply to research approved by an IRB (or deemed to be exempt, or for which no Institutional Review Board (IRB) review was

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required under the regulations) prior to the effective date of the 2018 Common Rule (January 21, 2019).

Definitions demarcated with (2018 Common Rule) apply to all research approved by an IRB (or deemed to be exempt, or for which no IRB review was required under the regulations) on or after January 21, 2019 and to research transitioned to the 2018 requirements in accordance with NIH Human Research Protection Program (HRPP) policy.

1. *Adjunct Principal Investigator (Adjunct PI)* – An individual who shares some responsibilities with the NIH PI at the NIH, or for multisite studies also conducted at the NIH Clinical Center. However, the NIH PI retains the ultimate oversight and responsibility for the research.
2. *Associate Investigators (AI)* – Individuals, other than the PI, who make substantial contributions to the conception, design, and/or execution of the study, including, but not limited to: obtaining informed consent; interacting or intervening with living human subjects to obtain, use, or analyze identifiable private information or specimens; or obtains, uses, studies, analyzes, or generates identifiable private information or specimens. Also referred to as “sub-investigator” by FDA regulation. There may be several AIs on a protocol. NIH employees, contractors, NIH trainees and non-NIH collaborators may, when appropriate, serve as AIs.
3. *Human Subject (HHS Regulations)* (2018 Common Rule definition) – (1) A living individual about whom an investigator (whether professional or student) conducting research:
 - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
 - (2) *Identifiable biospecimen* – A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
 - (3) *Identifiable private information* – Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
 - (4) *Interaction* –Communication or interpersonal contact between investigator and subject.
 - (5) *Intervention* – Physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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- (6) *Private information* – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. a medical record).
4. *Human Subject (HHS Regulations)* (Pre-2018 Common Rule definition) – A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information.
 - a. *Intervention* – includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.
 - b. *Private information* – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects ([45 CFR 46.102\(f\) pre-2018 Common Rule](#))
 5. *Human Subjects Research (HSR)* – Any activity that:
 - a. Meets the Health and Human Services (HHS) definition of research and involves human subjects as defined in the HHS regulations; and/or
 - b. Meets the Food and Drug Administration (FDA) definition of research and involves human subjects as defined in FDA regulations.
 6. *Investigator* – An individual who is involved in the conduct of human subjects research. Such involvement would include:
 - a. obtaining information about living individuals by intervening or interacting with them for research purposes;
 - b. obtaining identifiable private information or identifiable biospecimens about living individuals for research purposes;
 - c. obtaining the voluntary informed consent of individuals to be subjects in research; and
 - d. studying, interpreting, or analyzing identifiable private information, biospecimens, or data for research purposes.

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- I. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for 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.
7. *Lead Associate Investigator (LAI)* – An individual who plays a leading role in the formulation, writing, and implementation of a clinical research protocol under the mentorship and supervision of the protocol’s PI.
8. *Lead Site Investigator* – The lead investigator responsible for the conduct of research at a participating site on a multi-site protocol. If at the NIH, this investigator will be referred to as the NIH PI and will have responsibilities of a PI under NIH policy.
9. *Medical Advisory Investigator (MAI)* – The “Medical Advisory Investigator” (MAI) is the person appointed to assist the PI in the development of clinical aspects of the protocol and is responsible for ensuring that the provision of any clinical interventions mandated by the protocol are conducted appropriately and safely.
10. *NIH Federal Employee* – NIH Federal employees include those NIH staff with an appointment to the federal government pursuant to, for example, Title 5, 38 or 42, or the Commissioned Corps, and may include some fellows. Personnel appointed at NIH through an Intergovernmental Personnel Act (IPA) agreement and Special Governmental Employees (SGEs) working at NIH are considered NIH federal employees for the purposes of this policy.
11. *NIH Investigator* – An NIH federal employee (intramural or extramural), Special Volunteer, Intramural Research Training Awardee (IRTA), Cancer Research Training Awardee (CRTA) or Visiting Fellow (VF) who is conducting NIH human subjects research on behalf of the NIH. This may include a contractor in accordance with [Policy 100 NIH Intramural Research Program’s Human Research Protection Program](#).
12. *Principal Investigator (PI)* – The investigator with the overall responsibility for the design, conduct, and reporting of the research, and must assure both the protocol and the research team’s actions are compliant with law, regulation, and NIH policy, even when certain aspects of the research are delegated to other investigators.
13. *Research (2018 Common Rule Definition)* – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 45 CFR 46, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and

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service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- 1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
 - 2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
 - 3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
 - 4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. (See [45 CFR 46.102\(l\) of the 2018 Common Rule](#))
14. *Research (Pre-2018 Common Rule Definition)* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of 45 CFR 46, whether or not they are conducted or supported under a program which is considered research for other purposes. (See [45 CFR 46.102\(d\) of the pre-2018 Common Rule](#))
15. *Reviewing IRB* – The IRB responsible for reviewing human subjects research and determining that the research meets the required criteria for approval under the US Department of Health and Human Services (HHS) regulatory requirements at [45 CFR 46](#) and, as applicable, the pertinent Subparts of 21 CFR.

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E. RESPONSIBILITIES AND REQUIREMENTS

1. Responsibilities of all NIH investigators conducting non-exempt human subjects research

a. NIH investigators must:

- I. Comply with policy outlined in [C.1.](#) above;
- II. Know when an activity constitutes non-exempt human subjects research and assure IRB approval has been granted when required before performing human subjects research;
- III. Know, understand and comply with the federal laws, regulations, and policies, including NIH policy, that apply to the research;
- IV. Conduct the research compliant with the IRB approved protocol;
- V. 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;
- VI. Ensure the accuracy, completeness, legibility, and timeliness of the data;
- VII. Follow internal policies for the appropriate documentation of research related tests and procedures; and
- VIII. Be responsive to subject concerns and complaints consistent with [Policy 104 Managing Research-Related Complaints from Research Subjects](#).

2. Responsibilities of NIH Principal Investigators conducting non-exempt human subjects research

- a. The PI must comply with the requirements outlined in [C.1.](#) and [C.2.](#) above;
- b. For each protocol, the PI is responsible for designating other investigators as described below:
 - I. Medical Advisory Investigator (MAI): 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 IRB or IC CD considers it warranted, the PI will designate a MAI.
 - i. The MAI must be identified in the IRB application and approved by the IRB.
 - ii. Only one (1) MAI may be appointed to the protocol.

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- I. Associate Investigators (AIs): The PI may designate other qualified investigators as necessary to conduct safe and ethical research, consistent with [C.2.h.](#) above.
 - II. An 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 who will be responsible for the conduct of the protocol.
 - III. A Lead Associate Investigator may be designated. There can be only one (1) Lead Associate Investigator per protocol.
- c. The PI, at a minimum, is accountable to:
- I. Ensure sufficient resources are allocated to the research.
 - II. Comply with the determinations of the Reviewing IRB.
 - III. Conduct research only after the following conditions have been met:
 - i. IRB approval is obtained;
 - ii. When applicable, all other necessary institutional approvals have been obtained (See [Policy 106 Ancillary Reviews.](#));
 - 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).
 - IV. 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](#)).
 - V. 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](#).
 - VI. 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

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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. 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](#).)

- 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](#).

- 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](#).)

- 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:
 - 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.

- X. Ensure, when an investigator is leaving the NIH:
 - i. That proper arrangements are made for continued IRB oversight for any investigator who wishes to continue the research or continue to perform

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data analysis of identifiable data. (See *Policies 105 IRB Reliance* and *109*, Coverage under the NIH Federalwide Assurance.);

- ii. That data and specimens are transferred to/retained by the departing investigator only with appropriate permissions, forms, and IC oversight. (See, e.g., NIH Manual Chapter 1743, Managing Federal Records and the *HHS Technology Transfer Policies and Procedures Manual*.); and
- 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.

3. Requirements for Investigators Conducting FDA Regulated Research When the NIH IRB is the Reviewing IRB

- 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. These requirements are not described in this policy, for more information review: *Policies 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 (Test Articles)*.

4. Requirements for Investigators Conducting Exempt Human Subjects Research

- a. In addition to the requirements listed in *E.1.* above, the following apply to investigators conducting research that has been determined to be exempt from 45 CFR 46, including exempt research which was approved under limited IRB review procedures (see *Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research*). The PI will:
 - I. Submit documentation via NIH iRIS to support the request for exempt or limited IRB review determination consistent with requirements set forth in *Policy 205 Requirements for IRB Submissions*.
 - II. Upon receiving a determination for exempt research or approval by limited IRB procedures, conduct research in compliance with the approved protocol.
 - III. Submit any changes to the research to IRBO for review and approval by exempt or limited IRB procedures prior to implementation of those changes consistent with requirements set forth in *Policy 205 Requirements for IRB Submissions*.
 - IV. Maintain adequate and accurate study records and documentation. (See *NIH Manual Chapter 1743 - Keeping and Destroying Records, NIH Intramural Records Retention Schedule*, and the *NIH Privacy Act Policy*.)

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V. Report research events according to [Policy 801 Reporting Research Events](#).

F. REFERENCES

1. Federal Regulations

HHS: [45 CFR 46](#)

FDA: 21 CFR parts [50](#), [56](#), [312](#), and [812](#)

2. NIH Policy

[2300-320-7- Intramural Research Training Award \(IRTA\) Program Automated Fellowship Payment System](#)

[HHS Technology Transfer Policies and Procedures Manual](#)

[Medical Administrative Series \(MAS\) Policies](#)

[MAS Policy M80-3 \(7/3/18 version\) The Use of Investigational or New Drugs in Clinical Research](#)

[NIH Intramural Records Retention Schedule](#)

[NIH Manual Chapter 1743 - Keeping and Destroying Records](#)

[NIH Manual Chapter 2300-320-3 NIH Intramural Visiting Fellows Program \(VFP\) Policies](#)

[Policy 100 NIH Intramural Research Program's Human Research Protection Program](#)

[Policy 104 Managing Research-Related Complaints from Research Subjects](#)

[Policy 105 IRB Reliance](#)

[Policy 106 Ancillary Reviews](#)

[Policy 107 Privacy and Confidentiality](#)

[Policy 109 Coverage Under the NIH Federalwide Assurance](#)

[Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research](#)

[Policy 205 Requirements for IRB Submissions](#)

[Policy 301 Informed Consent](#)

[Policies 500 Research Involving Drugs, Biological, and Nutritional Products](#)

[Policy 501 Research Involving FDA Regulated Devices](#)

[Policy 801 Reporting Research Events](#)

3. Guidance

[FDA Guidance for Industry – Investigator Responsibilities-Protecting the Rights, Safety, and Welfare of Study Subjects](#)

[FDA Guidance for Industry - E6\(R2\) Good Clinical Practice: Integrated Addendum to ICH E6 \(R1\)](#)

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[OHRP Investigator Responsibilities FAQs](#)

[NIH Privacy Act Policy](#)

G. APPENDICES: None

H. REVISION HISTORY: NA

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