

1.26 PI Qualifications and Responsibilities

1.0 Purpose

The purpose of this policy and procedure is to describe the qualifications and responsibilities of the PI during the conduct of research within the Organization and at external sites under the PI's protocol.

2.0 Policy

It is the policy of the Organization that the PI and all other personnel involved in the conduct of research must possess the required experience, skill, and appropriate medical licensure to safely conduct the research in full compliance with all applicable regulatory and Organizational requirements specified in [HRPP policy 1.1](#) (Human Research Protection Program).

3.0 Definitions

- **3.1. *Investigator*** is defined broadly by the Organization as an individual who actually conducts human subject research as either a Principal Investigator (PI) or a Secondary Investigator (SI).
Investigator is not specifically defined by HHS regulations. However, HHS guidance defines “investigator” as the individual performing various tasks related to the conduct of human subject research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an “investigator” to be any individual who is involved in conducting human subject research. Such involvement would include:
 - **3.1.1.** Obtaining information about living individuals by intervening or interacting with them for research purposes.
 - **3.1.2.** Obtaining identifiable private information about living individuals for research purposes.
 - **3.1.3.** Obtaining the voluntary informed consent of individuals to be subjects in research.
 - **3.1.4.** Studying, interpreting, or analyzing identifiable private information or data for research purposes.
- **3.2. *Principal Investigator (PI)*** is the individual under whose direction the research is conducted and who assumes overall responsibility for the safe and proper conduct of the

research (single or multi-site) in full compliance with all applicable regulations and UNMC HRPP policies.

- **3.3. Secondary Investigator (SI)** is an individual who shares responsibility with the PI for the safe and proper conduct of the research in full compliance with all applicable regulations and UNMC HRPP policies.

- **3.4. External Investigator (XI)** is an investigator who is not employed by or otherwise representing the Organization who is engaged in research for which the UNMC IRB is the IRB of record.

A researcher employed or otherwise representing another institution who is under the jurisdiction of another IRB which has a reliance agreement with UNMC and for which the UNMC is acting as a central or single IRB is NOT considered an XI (per HRPP policy 1.28 ; External Investigator Assurance).

- **3.5. Investigational New Drug** is a new drug or biologic that is used in a clinical investigation (21 CFR 312.3(b))
 - **3.6. Investigation New Drug Application (IND)** is an application submitted to FDA to conduct a clinical investigation with an investigational new drug.
 - **3.7. Investigational Device** is a device, including a transitional device, which is the object of the investigation.
 - **3.8. Investigational Device Exemption (IDE)** is an application submitted to FDA to conduct a clinical investigation with an investigational device that is classified as a significant risk device (SRD).
 - **3.9. Sponsor-Investigator** is the individual, who initiates the research, assumes overall responsibility for the research as indicated in section 3.2 above and also fulfills the FDA-required responsibilities of a sponsor.
 - **3.10. External Investigator Assurance (XIA)** is an assurance of compliance which must be completed by all XIs when the UNMC IRB is the IRB of record.
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4.0 Qualification Requirements for the PI

- **4.1.** The PI must be an employee, faculty, or student of the Organization. Faculty shall include full- or part-time persons or emeritus faculty. Faculty include those with special faculty appointments, such as volunteer, adjunct, courtesy (without a UNMC faculty appointment) research or visiting faculty (collectively referred to as “volunteer faculty”).
 - **4.1.1.** Volunteer faculty may serve as PI only with the written permission of the appropriate UNMC Dean or his/her designee. The UNMC Dean may, at his or her discretion, place additional requirements (such as the concurrent approval of a department chairperson). The UNMC Dean or designee must accept ultimate responsibility to assuring the PI fulfills his/her responsibilities under this policy.
 - **4.1.2.** If the research involves any direct contact with human subjects on the facilities of the Organization, then volunteer faculty serving as PI must be present physically on the facilities of the Organization, or have a secondary investigator who is UNMC faculty present physically on the facilities, to allow them conduct and oversee research activities.
 - **4.1.3.** Volunteer faculty may not serve as PI on a protocol which requires review and approval of the Institutional Biosafety Committee.
 - **4.1.4.** Medical or dental practitioners or other allied health practitioners who have admitting privileges but do not have a faculty appointment as above may not serve as PI.

- **4.2.** Individuals other than employee, faculty, or student of the Organization may serve as PI only if a special memorandum of understanding exists between the Organization and another entity which sponsors that individual and that research (for example, faculty of University of Nebraska Lincoln for FDA regulated research, or faculty of National Strategic Research Institute).
 - **4.2.1.** When a student or trainee is the PI, a researcher sufficiently experienced in the area of the trainee's research interest and satisfying the requirements of Section 4.1 above must serve as a co-investigator for research and be jointly responsible for oversight of the research.
 - **4.2.2.** A student may not serve as the PI of a study which involves the administration or use of an FDA regulated drug, device or biologic.
- **4.3.** The PI must be qualified by education, training, experience and licensure (as applicable) to assume overall responsibility for the safe and proper conduct of the research in full compliance with all applicable regulations and UNMC HRPP policies.
 - **4.3.1.** When a student or trainee is the PI, a researcher sufficiently experienced in the area of the trainee's research interest and satisfying the requirements of Section 4.1 above must serve as a co-investigator for research and be jointly responsible for oversight of the research.
 - **4.3.2.** A student may not serve as the PI of a study which involves the administration or use of an FDA regulated drug, device or biologic.

5.0 Responsibilities of the PI During the Conduct of Research

- **5.1.** The PI will conduct protocols with sound research design consistent with current methods and ethical standards. The PI will seek independent review and consultation by other experts prior to submission to the IRB when appropriate.

Note: Research designed and conducted by students and trainees must be thoroughly reviewed by the faculty advisor and exhibit sound research design.

- **5.2.** The PI is responsible for obtaining IRB approval (or exempt determination) prior to initiating the research. Documentation of this approval must be written and dated.
- **5.3.** The PI is responsible for conducting research in compliance with the detailed protocol, the IRB application, and any other documents approved by the IRB.
- **5.4.** The PI will ensure compliance with applicable regulatory and HRPP requirements specified in HRPP policy 1.1 (Human Research Protection Program).
- **5.5.** The PI must oversee and be responsible for ensuring all research personnel comply with all applicable requirements, including, but not limited to, implementing the research in accordance with the IRB-approved protocol and completing all educational requirements as specified in HRPP policy 1.23 (HRPP Training Requirements and Opportunities for Research Personnel).

- **5.6.** The PI is responsible for ensuring that research is conducted in accordance with the terms of any grant, contract, and/or signed agreement.
- **5.7.** The PI will ensure all secondary investigators (sub-investigators) and other study personnel conducting the research are qualified by education, training, experience, and medical licensure (as applicable) to safely conduct the research in full compliance with the applicable federal regulations, HRPP policies and the protocol.
- **5.8.** The PI will provide all secondary investigator(s) conducting the research and other study personnel (as appropriate) with a copy of the: a) UNMC IRB-approved application and ICF(s)/information sheet(s), b) detailed protocol, c) Investigator's Brochure, and d) other necessary documents.
- **5.9.** The PI will ensure that all secondary investigator(s) and other study personnel fully understand the study and their obligations consistent with assigned responsibilities.
- **5.10.** The PI will disclose, and assure that responsible personnel and other covered persons disclose potential financial COI, in accordance with HRPP policy 1.25 (Financial Conflicts of Interest) and Organizational policies.
- **5.11.** The PI will ensure risks to subjects and others have been minimized to the greatest extent possible, as per HRPP policy 3.2 (Data and Safety Monitoring).
- **5.12.** The PI will ensure the protocol contains a plan for just, fair, and equitable recruitment and selection of subjects.
- **5.13.** The PI will ensure the protocol contains adequate provisions for monitoring the data collected to ensure the safety of subjects.
- **5.14.** The PI will ensure there are adequate provisions to protect the privacy of subjects and the confidentiality of data, as per HRPP policy 3.3 (Privacy Interests and Confidentiality of Research Data).
- **5.15.** The PI will ensure there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment and space.
- **5.16.** The PI may not make any changes in the research without IRB approval, except in accordance with 45 CFR 46.108(a)(3)(iii) and 21 CFR 56.108(b) where necessary to eliminate apparent immediate hazards to human subjects or provide the subject/LAR with critical information that is vital to the subject's continued participation in the research in accordance with HRPP policy 2.4 (IRB Review of Changes in Previously Approved Research).
- **5.17.** Any change to the research, which is made to eliminate immediate hazards to subjects without prior IRB approval, shall be reported promptly to the IRB in accordance with HRPP policy 2.4 (IRB Review of Changes in Previously Approved Research).
- **5.18.** The PI is responsible for informing all study personnel and participating sites (as applicable) of IRB approved modifications in the protocol, IRB application, and/or consent form.
- **5.19.** The PI will ensure that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects in accordance with HRPP policy 4.1 (Additional Protections for Vulnerable Populations).
- **5.20.** The PI is ultimately responsible for ensuring that legally effective informed consent is developed, obtained and documented in accordance with, and to the extent required by 45 CFR 46.116, 45 CFR 46.117, 21 CFR 50 (as applicable) and HRPP policy 5.1 (Obtaining Informed Consent From Research Subjects).

- **5.21.** When consent is obtained by other authorized study personnel, the PI will ensure the individual is appropriately trained to obtain valid informed consent. In addition, the PI will exert ongoing supervision of all authorized study personnel.
- **5.22.** The PI will ensure that all secondary investigator(s) and other study personnel promptly report to the PI the following as applicable:
 - **5.22.1.** Internal Adverse Events which are unexpected and related, or possibly related, to the study interventions, and Unanticipated Adverse Device Effects, per HRPP policy 8.1 (IRB Review of Adverse Events and Adverse Device Effects).
 - **5.22.2.** Unanticipated problems involving risk to the subject or others, per HRPP policy 8.3 (IRB Review of Unanticipated Problems Involving Risk).
 - **5.22.3.** Noncompliance, per HRPP policy 8.4 (Review of Noncompliance)
 - **5.22.4.** Complaints, per HRPP policy 8.2 (IRB Review of Study Related Complaints)
- **5.23.** The PI will ensure that all of the incidents listed under Section 5.20 above are reported to the IRB in accordance with the applicable HRPP policies.
- **5.24.** The PI will permit and facilitate monitoring and auditing of research, at reasonable times, by the IRB, funding agencies, and other authorized federal and state regulatory agencies.
- **5.25.** The PI, or a qualified person(s) designated by the PI, shall conduct periodic audits of research records.
- **5.26.** The PI is responsible for the accuracy, completeness, legibility, and timeliness of the data recorded and reported in presentations and publications about the research.
- **5.27.** The PI will fulfill registration and reporting requirements of ClinicalTrials.gov in compliance with HHS regulations at 42 CFR 11 (Final Rule for Clinical Trials Registration and Results Information Submission), and the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.
- **5.28.** The PI will maintain records after the study ends for at least seven years or longer as required by applicable FDA, HIPAA, state, or sponsor requirements and should take measures to prevent accidental or premature destruction of these documents.
- **5.29.** The PI is responsible for submitting continuing review reports to the IRB in accordance with the approval period specified by the IRB. The PI should fulfill the requirements for continuing review in time for the IRB to carry out the review prior to the expiration date of the current IRB approval.
- **5.30.** Upon completion of the research (or premature closure of the study), the PI will provide the IRB with the Study Completion Report and will provide the funding and regulatory agencies with any required reports.
- **5.31.** Once a study has been completed or closed, the PI must continue to honor any confidentiality protections of the data as well as other commitments agreed to as part of the approved research.

6.0 Responsibilities of the PI for the Conduct of PI-Initiated Multicenter Research

- **6.1.** The PI will fulfill all the applicable responsibilities described in Section 5.0 above.
- **6.2.** The PI assumes overall responsibility for the safe and proper conduct of the research at all sites (within the Organization and external sites) in full compliance with all applicable regulations and UNMC HRPP policies.

- **6.3.** The PI must have a process in place to coordinate and communicate issues related to the protection of human subjects to all performance sites including:
 - **6.3.1.** IRB initial review
 - **6.3.2.** IRB continuing review
 - **6.3.3.** IRB review of amendments
 - **6.3.4.** Consent requirements
 - **6.3.5.** HIPAA requirements
 - **6.3.6.** Information security including the confidential collection and transmission of data
 - **6.3.7.** Reporting requirements for:
 - **6.3.7.1.** Unanticipated problems involving risks to the subject or others
 - **6.3.7.2.** Adverse events
 - **6.3.7.3.** Noncompliance
 - **6.3.7.4.** Complaints
- **6.4.** The PI will ensure that all external investigators promptly report to the PI the following (as applicable):
 - **6.4.1.** Adverse Events which are unexpected, related or possibly related to the research.
 - **6.4.2.** Unanticipated Adverse Device Effects
 - **6.4.3.** Unanticipated problems involving risk to the subject or others
 - **6.4.4.** Noncompliance
 - **6.4.5.** Complaints
 - **6.4.6.** Audits by sponsors, CRO's, FDA, OHRP, or other federal authorities,
 - **6.4.7.** Study reports as required by the protocol,
 - **6.4.8.** Continuing review reports
 - **6.4.9.** Interim results
 - **6.4.10.** DSMB results
- **6.5.** The PI, or a qualified person(s) designated by the PI, shall conduct periodic audits of research records maintained by external investigator(s) at all sites.
- **6.6.** If the PI determines the research presents an unreasonable risk to subjects, the PI will discontinue the study immediately and notifications shall be sent immediately to all investigators, the IRBs of record for all sites, the sponsor and FDA (as required).
- **6.7.** When the external performance site(s) utilize(s) their own local IRB for oversight of the research, the PI must assure:
 - **6.7.1.** The IRB application identifies the external sites.
 - **6.7.2.** A copy of all of the following documents from the external sites are maintained in the research records:
 - **6.7.2.1.** A copy of the external IRB approval letter(s) and approved ICF(s)/information sheet(s).
 - **6.7.2.2.** The external site's FWA number (required for HHS funded research)
 - **6.7.2.3.** The external site's IRB Registration number (required for FDA registered research)
 - **6.7.2.4.** The external site's HRPP accreditation status
- **6.8.** When the external performance site(s) utilize(s) the UNMC IRB for oversight of research. The PI must assure:
 - **6.8.1.** Compliance with HRPP policy 1.3 (UNMC IRB Serving as Central IRB).
 - **6.8.2.** The IRB application identifies the external site(s).
 - **6.8.3.** An ICF is developed for each site deferring to UNMC IRB review.
 - **6.8.4.** The research records contains:
 - **6.8.4.1.** Signed copies of each signed External Investigator Assurance (XIA).

- **6.8.4.2.** A copy of each external investigator's Curriculum Vitae (CV).
- **6.8.4.3.** Copies of all signed ICFs obtained from subjects enrolled in the research by the external investigator(s) when the UNMC IRB is the IRB of record.

7.0 Additional Responsibilities of the PI during the Conduct of Research under the Oversight of an External IRB

- **7.1.** The PI will fulfill all applicable requirements of the external IRB.
- **7.2.** The PI will fulfil all applicable requirements specified in HRPP policy 1.4 (UNMC IRB Ceding Review to an External IRB), and as described in the Reliance Agreement.

8.0 Additional Responsibilities of the PI During Conduct of FDA Regulated Research

Note: FDA guidance regarding investigator responsibilities can be found in "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (October 2009)

- **8.1.** For clinical investigations involving an investigational drug, the PI is responsible for ensuring that the conditions of 21 CFR 312.60, 61, 62, 64, 66, 68, and 69, are met:
 - **8.1.1.** Ensure that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation (21 CFR 312.60).
 - **8.1.2.** Ensure that informed consent is obtained in accordance with the provisions of 21 CFR 50. (21 CFR 312.60)
 - **8.1.3.** Ensure control of the investigational drug in accordance with 21 CFR 312.61.
 - **8.1.4.** Prepare, maintain and retain records in accordance with 21 CFR 312.62 and Nebraska State Law per HRPP policy 1.17 (Retention of Research Records).
 - **8.1.5.** Report to sponsor in accordance with 21 CFR 312.64.
 - **8.1.6.** Assure that the IRB complies with 21 CFR 56 (21 CFR 312.66)
 - **8.1.7.** Report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others; and not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects (21 CFR 312.66)
 - **8.1.8.** Allow inspection of investigator's records and reports by FDA, in accordance with 21 CFR 312.68.
 - **8.1.9.** Handle controlled substances in accordance with 21 CFR 312.69.

- **8.2.** For clinical investigations involving an investigational device the PI is responsible for ensuring that the conditions of CFR 812.100 and 110 are met:
 - **8.2.1.** Ensure that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation (21 CFR 812.100)
 - **8.2.2.** Ensure that informed consent is obtained in accordance with the provisions of 21 CFR 50 (21 CFR 812.100).
 - **8.2.3.** Not request the written informed consent of any subject to participate, and not allow any subject to participate before obtaining IRB and FDA approval (21 CFR 812.110(a)).
 - **8.2.4.** Conduct the investigation in accordance with the signed agreement with the sponsor, the investigational plan, applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA (21 CFR 812.110(b))
 - **8.2.5.** Permit use of the investigational device only with subjects under the investigator's supervision (21 CFR 812.110(c)).
 - **8.2.6.** Disclose financial information to sponsor, as required per 21 CFR 54 (21 CFR 812.110(d)).
 - **8.2.7.** Dispose of remaining devices per 21 CFR 812.110(e).
- **8.3.** For clinical investigations subject to ICH GCP the investigator is responsible for requirements of ICH E6 (Guideline for Good Clinical Practice) section 4.
- **8.4.** The PI is responsible for ensuring all study personnel:
 - **8.4.1.** Read and understand the information in the Investigator's Brochure, including the potential risks and side effects of the drug or device.
 - **8.4.2.** Ensure that a clinical investigation is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products, or agreement for clinical investigations of medical devices, the investigational plan and other applicable FDA regulations and any conditions of approval imposed by the IRB or FDA.
 - **8.4.3.** Control drugs, biological products, and devices according to FDA regulations.
- **8.5.** The PI must maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., CV, certifications), and identify the dates of involvement in the study. The PI should maintain separate lists for each study conducted by the investigator.

Note: PIs who conduct clinical investigations of drugs and devices under the FDA regulations commit themselves to personally conduct or supervise the investigation. When certain study-related tasks are delegated by a PI, the PI is responsible for providing adequate supervision of those to whom the tasks are delegated.

9.0 Additional Responsibilities of a Sponsor-Investigator under an Investigator-Initiated IND

- **9.1.** When the investigator also acts as a sponsor for a clinical investigation involving an investigational drug he/she must submit a signed assurance that he/she understands and accepts his/her obligations per FDA regulations (21 CFR 312) (see Addendum O).
- **9.2.** When the investigator also acts as a sponsor for a clinical investigation involving an investigational device, in addition to all responsibilities as investigator as above, he/she is also responsible for ensuring that the following regulatory obligations are met:
 - **9.2.1.** General responsibilities, including select qualified investigators, provide them with the information they need to conduct an investigation properly, ensure proper monitoring of the investigation(s), ensure that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintain an effective IND with respect to the investigations, and ensure that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug (21 CFR 312.50).
 - **9.2.2.** Select qualified investigators and monitors, who make the required assurances and commitments as per 21 CFR 312.53.
 - **9.2.3.** Keep each participating investigator informed of new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use, as per 21 CFR 312.55.
 - **9.2.4.** Monitor the progress of the clinical investigation (21 CFR 312.56)
 - **9.2.5.** Monitor the compliance of investigators and respond accordingly, including ending the investigator's participation in the clinical investigation, in accordance with 21 CFR 312.56.
 - **9.2.6.** Review and evaluate the evidence relating to the safety and effectiveness of the drug, and make reports to the FDA regarding the safety of the drug and the progress of the investigation (21 CFR 312.56)
 - **9.2.7.** Discontinue the investigation if he/she determines that the investigational drug presents an unreasonable and significant risk to subjects, and notify FDA, all institutional review boards, and all investigators, and assure the disposition of all stocks of the drug outstanding (21 CFR 312.56)
 - **9.2.8.** Maintain and retain adequate records as described in 21 CFR 312.57, and allow FDA access to such records, as per 21 CFR 312.58.
 - **9.2.9.** Handle controlled substances in accordance with 21 CFR 312.59.
- **9.3.** The PI shall ensure there is on-going review and evaluation of evidence relating to the safety and effectiveness of the drug, and report such evaluation to (a) FDA in accordance with 21 CFR 312.33, and (b) the UNMC IRB when there is a safety concern.
- **9.4.** If the PI determines the investigational drug presents an unreasonable risk to subjects, the PI will discontinue the study immediately and notifications shall be sent immediately to all external investigators, the IRBs of record for all sites and FDA.

10.0 Additional Responsibilities of a Sponsor-Investigator under an Investigator-Initiated IDE

- **10.1.** When the investigator also acts as a sponsor for a clinical investigator involving an investigational device he/she must submit a signed assurance that he/she understands and accepts his/her obligations per FDA regulations (21 CFR 812) (see Addendum P).
- **10.2.** When the investigator also acts as a sponsor for a clinical investigator involving an investigational device, in addition to all responsibilities as investigator as above, he/she is also responsible for ensuring that the following regulatory obligations are met:
 - **10.2.1.** General Duties (21 CFR 812.40), including submitting an IDE to the FDA in accordance with the requirements of 21 CFR 812.20.
 - **10.2.2.** Selection of Investigators (21 CFR 812.43)
 - **10.2.3.** Monitoring (21 CFR 812.46)
 - **10.2.4.** Controlling Distribution and Disposition of Devices. The sponsor-investigator must take proper measures to ensure that devices are not diverted outside of legally authorized channels, may ship investigational devices only to qualified investigators participating in the clinical investigation (21 CFR 812.43(b)), must maintain complete, current, and accurate records pertaining to the shipment and disposition of the investigational device (21 CFR 812.140(b)), take appropriate measures to instruct investigators regarding their responsibilities with respect to recordkeeping and device disposition per 21 CFR 812.140(a).
 - **10.2.5.** Prohibition of Promotion and Other Practices (21 CFR 812.7)
 - **10.2.6.** Supplemental Applications [21 CFR 812.35(a) and (b)]
 - **10.2.7.** Maintaining Records [21 CFR 812.140(b)]
 - **10.2.8.** Submitting Reports [21 CFR 812.150(b)]
 - **10.2.9.** Inspections [21 CFR 812.145]
- **10.3.** The PI shall ensure there is on-going review and evaluation of evidence relating to the safety and effectiveness of the device and report such evaluation to (a) FDA, and (b) the UNMC IRB when there is a safety concern.
- **10.4.** If the PI determines the investigational device presents an unreasonable risk to subjects, the PI will discontinue the study immediately and notifications shall be sent immediately to all investigators participating in the research, the IRBs of record and FDA, in accordance with 21 CFR 812.45.

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Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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