

1.28 External Investigator Assurance

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for initiating an External Investigator Assurance (XIA) (also referred to as a "Collaborating Institutional Investigator Agreement").

2.0 Policy

It is the policy of the Organization that:

- 1.1. An XIA is required when the UNMC IRB is the IRB of record for non-exempt research conducted at any site by an external investigator (XI) who is not faculty, employee or student of the Organization, and who is not under the jurisdiction of another IRB which has an IRB Reliance Agreement with UNMC.
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3.0 Definitions

- 3.1. An External Investigator (XI) means an investigator who is not faculty, employee or student of the Organization who is engaged in research for which the UNMC IRB is the IRB of record.
 - 3.1.1. The Organization considers the criteria for "engagement" of an individual in the same manner as for an institution, as described in "OHRP Guidance: Engagement of Institutions in Human Subjects Research (2008)." In general, an External Investigator is "engaged in research" when he/she obtains (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.
 - 3.1.2. An investigator who is employed by or otherwise representing another institution and who is under the jurisdiction of another IRB which has an IRB Reliance Agreement with UNMC and for which the UNMC is acting as the IRB of record, is NOT considered an XI for the purpose of this policy. The reliance agreement which exists between UNMC and the relying institution obligates that institution to hold investigators at that institution to the same standards as the XIA.
- 3.2. An External Site means a facility not under the jurisdiction of the Organization where research for which the UNMC IRB is the IRB of record is performed, and which is not subject to the jurisdiction of another IRB which has an IRB Reliance Agreement with

UNMC.

- 3.2.1. In general, the Organization considers a facility “performing research” as equivalent to the criteria for “engagement” of a facility as described in “OHRP Guidance: Engagement of Institutions in Human Subjects Research (2008).”

4.0 Requirements for, and Content of, an External Investigator Agreement (XIA)

- 4.1. An XIA between the Organization and the XI is required when an XI is engaged in research under a UNMC IRB approved research protocol and is not subject to the jurisdiction of an external IRB with which the UNMC IRB has an IRB Reliance Agreement in place.
- 4.2. An XIA between the Organization and the external site is required when an external site is engaged in research under a UNMC IRB approved research protocol for which there is not an IRB reliance agreement in place between UNMC and the site.
- 4.3. The XIA must be in effect before any research activities may be performed at that site.
- 4.4. An XIA must be in effect for each XI at that site and a copy maintained on file with the UNMC PI
- 4.5. The XIA describes responsibilities of the XI including, but not limited to, assuring compliance with 45 CFR 46 including subparts as applicable, 21 CFR 50, 56, 312, 812, and HIPAA Privacy Rule, state laws, HRPP policies, and the protocol.
- 4.6. An XIA is effective for all studies that the XI conducts under the oversight of the UNMC IRB; therefore only one XIA is required.
- 4.7. The Organization, ORA, the UNMC IRB or the UNMC investigator may revoke the XIA at any time, if there is reason to believe that the XI is not satisfying responsibilities as described in the XIA.

DOCUMENT HISTORY:

? Written: 1/12/2018 (Approved: 1/12/2018) - original author not recorded (previous policy #3.14)

? Revised: 2/6/2018 - revision not documented

? Revision 12/3/2022 - Clarified that XIA is synonymous with “Collaborating Institutional Investigator Agreement”; revised definition of XI to include an investigator who is “not faculty, employee or student of the Organization, and who is not under the jurisdiction of another IRB which has an IRB Reliance Agreement with UNMC”; clarified that an XIA is required for an XI conducting research at any site (including sites operated by the Organization), not just an external site; revised definitions for clarity; provided definition of “external site”; clarified that XIA is required between the Organization and the external site when an external site is engaged in research under a UNMC IRB approved research protocol for which there is not an IRB reliance agreement in place between UNMC and the site. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board notified - 12/29/2022
