TITLE: Individual or Institutional Investigator Agreement		POLICY/PROCEDURE NUMBER: IRB 10.1	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	6/2021	DATE EFFECTIVE:	7/2021
Page 1 of 4			

x	CFNI Munster, Indiana	x	Community Hospital Munster, Indiana	x	St. Catherine Hospital East Chicago, Indiana	x	St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:
To describe a permissible mechanism under which an institution holding an Office for Human Research Protections (OHRP) approved Federalwide Assurance (FWA) may extend, for one or more research protocols, the applicability of its FWA to cover two types of collaborating individual investigators: collaborating **independent** investigators and collaborating **institutional** investigators. This mechanism provides an alternative to establishing additional FWA's for numerous institutions that do not hold FWA's and do not routinely conduct human subjects research.

The CHS CIRB office will determine the need for an Individual or Institutional Investigator Agreement when reviewing a Protocol Submission Form or a Facilitated Protocol Submission Form. The CHS CIRB Office will contact the investigator(s) and Key Personnel directly in the event an Agreement is necessary.

DEFINITIONS:

Assured Institution: one that holds an OHRP approved FWA

Non-assured Institution: one that does not hold an OHRP approved FWA

Individual Investigator Agreement: may be used by an assured institution to extend – for one or more research protocols – the applicability of its FWA to cover either collaborating independent investigators or collaborating institutional investigators. The Individual Investigator Agreement will be renewed every two (2) years. Failure to renew the Agreement will result in the investigator's termination to conduct research until such time as the investigator renews the Agreement.

A collaborating **independent** investigator is:
1. Not otherwise an employee or agent of the assured institution;
2. Conducting collaborative research activities outside the facilities of the assured institution; and
3. Not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

A collaborating **institutional** investigator is:
1. Not otherwise an employee or agent of the assured institution;
2. Conducting collaborative research activities outside the facilities of the assured institution;
3. Acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and
4. Employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

GENERAL INFORMATION

OHRP will permit an assured institution to extend its FWA to cover a collaborating independent or institutional investigator provided all of the following conditions are met:

1. The principal investigator at the assured institution directs and appropriately supervises all of the collaborative research activities to be performed by the collaborating individual investigator outside the assured institution.

2. The extension of the coverage of the FWA is put in place by use of an appropriate written agreement, such as the individual Investigator Agreement, for each collaborating individual investigator who will be engaged in the research being conducted by the assured institution. The assured institution must maintain the individual Investigator Agreement, or other written agreement used by the assured institution, on file and provide copies to OHRP upon request.

3. For collaborating institutional investigators, the appropriate authorities at the non-assured institution state in writing that the conduct of the research is permitted at their institution.

4. The assured institution and the responsible IRB designated under the FWA approve the extension of the assurance through either the Individual Investigator Agreement or other written agreement used by the assured intuition.

5. The following documents are made available to the collaborating individual investigator:
(a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (see http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) or other internationally recognized equivalent (see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html);
(b) the HHS regulations for the protection of human subjects at 45 CFR part 46 (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) or other procedural standards designed by the non-U.S. Institution under its FWA (see section B.3. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html);
(c) the FWA and applicable Terms of the FWA for the assured institution; and
(d) the relevant institutional policies and procedures for the protection of human subjects of the assured institution.

6. The collaborating individual investigator understands and accepts the responsibility to comply with the standards and requirements stipulated in the documents referenced in the preceding paragraph and to protect the rights and welfare of human subjects involved in research conducted under the individual Investigator Agreement used by the assured institution.

7. The collaborating individual investigator agrees to comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects participating in research conducted under the Individual Investigator Agreement or other written agreement used by the assured institution.

8. The collaborating individual investigator agrees to abide by all determinations of the Institutional Review Board (IRB) Independent Ethics Committee (IEC) designed under the FWA of the assured institution and agrees to accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities conducted under the Individual Investigator Agreement or other written agreement used by the assured institution.

9. The collaborating individual investigator agrees to complete any education training required by the assured institution and/or the IRB/IEC prior to initiating research covered under the Individual Investigator Agreement or other written agreement used by the assured institution.

10. The collaborating Individual Investigator agrees not to enroll subjects in research under the Individual Investigator Agreement or other agreement used by the assured institution, prior to the research being reviewed and approved by the IRB/IEC.

11. The collaborating individual investigator agrees to report promptly to the IRB/IEC any proposed changes in the research conducted under the Individual Investigator Agreement or other agreement used by the assured institution. The collaborating institutional investigator agrees not to initiate changes in the research without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

12. The collaborating individual investigator agrees to report immediately to the IRB/IEC any unanticipated problems, involving risks to subjects or others in research covered under the Individual Investigator Agreement or other agreement used by the assured institution.

13. The collaborating individual investigator, when responsible for enrolling subjects, agrees to obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected in the FWA for the institution referenced above) and stipulated by the IRB/ICE.

14. The collaborating individual investigator acknowledges and agrees to cooperate with the IRB/IEC's in its initial and continuing review, record keeping, reporting, and certification for research covered by the Individual Investigator Agreement, or other agreement used by the assured institution. The collaborating institutional investigator agrees to provide all information requested by the IRB/IEC in a timely fashion.

CROSS REFERENCE(S):
IRB 10: External Institutional Review Boards and Reliance Agreements for Multi-Site Research
Reliance Agreement (Form)
Institutional Review Board (IRB) Reliance Agreement (Form)
Reliance Agreement and Delineation of Responsibilities Addendum I
Individual Investigator Agreement Form

REFERENCE(S):
HHS: 45 CFR §46.103, §46.114
HHS: Extending an FWA to Cover Collaborating Investigators (January 31, 2005) (Content last reviewed March 19, 2016)
FDA: 21 CFR § 56.109, §56.114
FDA Information Sheets – Cooperative Research
FDA Information Sheets – Non-Local IRB Review
NIH: Policy on the Use of a Single Institutional Review Board for Multisite Research (January 25, 2018)

ACCEPTED BY:

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DATE(S) REVISED:

REVIEWED BY: CHS CIRB 7/2021

Date	Initials