# Ohio University
# IRB Guidance for Collaborating Individual Investigators

This document provides guidance relating to the use of Individual Investigator Agreements to extend the coverage of Ohio University's Federalwide Assurance (FWA) of Compliance to collaborating researchers.

Coverage under Ohio's FWA of Compliance of collaborating individuals who will be engaged in research involving human subjects must be formalized through execution of an Individual Investigator Agreement (IIA). The need for such coverage may arise if an individual is not affiliated with an institution with an active FWA, or is affiliated with an institution that does not require IRB review for the research. Through the terms of the IIA, the collaborator agrees to abide by the ethical principles of beneficence, respect for persons, and justice for the protection of the human subjects while engaged in the Ohio University-directed research.

The IIA must be fully executed before the collaborating individual investigators may engage in the covered research activities.

To be eligible to use IIAs for collaborating individual investigators, the following criteria must be met:

- The study involves research that presents no greater than minimal risk to subjects;
- The Ohio University PI has answered the IIA questions in Appendix A and the responses were found to be acceptable, i.e., plans for selecting, training, and monitoring are appropriate;
- If the non-Ohio University researcher will have access to subject data for research purposes, the extent of the access has been specified; the agreement to protect confidentiality may be incorporated into the IIA, or may be in a separate document that is provided with the IIA;
- The number of collaborating individual investigators is reasonable based upon the ability of the Ohio University PI and study team to oversee and manage them (e.g., it may not be reasonable to expect a study team of two to affectively oversee 50 non-affiliated staff);
- Ohio University training or equivalent requirements have been met;
- The use of an IIA is not restricted by conditions articulated in the OHRP guidance, "Extending an FWA to Cover Collaborating Investigators (2005)": http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html.

Procedures

1. During the administrative review of a submission, if the Office of Research Compliance (ORC) staff reviewer determines that the study proposes to use non-affiliated research staff, the ORC staff reviewer will assess whether the following elements are applicable and appropriately addressed:
   a. If data will be collected by an individual other than a member of the Ohio University research team, that individual must be identified.
      1) If a letter of agreement to protect confidentiality already exists, it should be provided to the IRB.
      2) If an IIA will be utilized, the agreement to protect confidentiality may be covered by the terms of the IIA.
   b. The research study includes a plan for secure data collection, protection of the confidentiality of the data, and transport of the data from the non-affiliated investigator to the Ohio University researcher.
2. The IIA and IIA questions provided in Appendix A will be forwarded to the PI via email. If the PI responses to the IIA questions are found to be acceptable by the ORC staff reviewer, the staff reviewer will present the IIA and responses to the IIA questions to the Director of the ORC for review and signature.
   a. Review of the protocol should proceed pending a decision to approve or disapprove reliance on the Ohio University IRB for non-affiliates. Approval of the protocol, however, should not be issued until the reliance decision is made, unless the Director or Associate Director of the ORC have advised that an approval may be issued but non-affiliate involvement may not begin until the IIA is fully executed.
   b. The ORC may authorize the PI to sign IIA forms instead of the IRB representative (e.g., this may be necessary in situations such as time-sensitive post-disaster research or when the study will be conducted in a remote location in which communication options are limited).
   c. If non-affiliates are non-English speaking, the IIA must be translated and an attestation of the accuracy of the translation must be provided. This requirement will be communicated in writing to the PI. The non-English speaking non-affiliate(s) must sign the translated version of the IIA unless an exception is authorized by the Director or Associate Director of the ORC.
4. The researcher will provide the signed IIAs with a list of names of non-affiliates to the IRB by email. In some cases (e.g., in protocols with many non-affiliated staff, or with studies conducted in remote locations), the researcher may not be required to send copies of every signed IIA but must keep them in his/her records for tracking and audit purposes. The IRB will provide the relevant requirements when the use of IIAs is approved.
5. ORC staff members will check the status of IIAs during review of Amendments and Periodic Reviews. If the procedures in the protocol have changed or if more non-affiliates than were originally approved need to be hired, the protocol may need to be re-evaluated to determine if it remains appropriate for the Ohio University IRB to cover non-affiliated staff.
6. For record-keeping purposes, the ORC staff reviewer will file the fully-executed IIA and responses to the IIA questions with the paper copy of the protocol.

Appendix A

IIA Questions

1. How will non-affiliated research staff (non-affiliates) be selected, i.e., by what criteria or with what qualifications?
2. Will any non-affiliate(s) conduct research activities for this study as an employee of an institution or organization? If yes, indicate whether the institution or organization has an FWA and whether it regularly conducts research. Does that institution or organization have an IRB and is the proposed research required to be submitted to that IRB? Appropriate documentation (e.g., IRB approval at affiliate's institution/organization; attestation that IRB approval at the affiliate's institution/organization is not required, etc.) should be provided.
3. Is any individual investigator affiliated in any capacity, whether paid or unpaid, with Ohio University, e.g., student, faculty, employee, volunteer?
4. Describe how non-affiliates will be trained, e.g., by whom, covering what topics, etc. The non-affiliates are expected to review the following items: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) the FWA and applicable Terms of the FWA as posted on the Office for Human Research Protections (OHRP) website; and 4) the relevant Ohio University (OU) institutional policies and procedures for the protection of human subjects as found on the Ohio University Research Compliance website at: http://www.ohio.edu/research/compliance/.
5. What procedures will non-affiliates be conducting, e.g., obtaining informed consent, administering surveys, collecting data, interacting with subjects, or analyzing identifiable data?
6. Why is the researcher proposing to engage individuals who are not associated with Ohio University or another institution in this project?
7. What is the risk level of the procedures in which the non-affiliates will be involved?
8. Describe how the Ohio University study team will be communicating with non-affiliates and the subjects (e.g., research at external sites, international research, or research with non-English speaking subjects).
9. To what degree will the Ohio University study team be supervising/monitoring the non-affiliates? Provide a plan for monitoring compliance (e.g., by assessing whether study procedures are being followed), security of data while it is in the possession of the non-affiliates, and safety of subjects (e.g., by ensuring that confidentiality, privacy, and contact procedures are being followed).
10. How many non-affiliates will be participating?
11. Are any non-affiliates non-English speaking?

# Ohio University

# Office of Research Compliance

# Principal (Primary) Investigator Status Appointments for IRB

**Qualifications**

Principal (Primary) Investigator (PI) status is granted for Institutional Review Board (IRB) proposals using the following guidelines:

PI status is automatically granted for individuals holding the following titles, provided the individual is a salaried, regular faculty member having at least a 50 percent (50%) appointment.

- professor; associate professor; assistant professor
- clinical professor; associate clinical professor; assistant clinical professor
- professor; associate professor; assistant professor of (clinical discipline or research)

PI status is automatically granted for individuals holding the following titles, provided the individual is a salaried, regular staff member having at least a 50 percent (50%) appointment.

- director; associate director; assistant director

PI status is automatically granted for active students, provided they have been enrolled at Ohio University for at least one semester in the last year. Active students must have a regular faculty member serve as advisor on the IRB proposal.

- active student with a regular faculty member serving as advisor

Persons holding the titles listed below are **not eligible for PI status, unless a formal request is made in writing and an exception granted** by the Ohio University Vice President for Research. Persons holding these titles may be granted Co-investigator status, which requires a regular faculty member to serve as PI and to assume responsibility for the project.

- emeritus professor
- lecturer; instructor
- professor (practice); associate professor (practice); assistant professor (practice)
- adjunct professor; adjunct associate professor; adjunct assistant professor; adjunct instructor
- visiting professor; visiting associate professor; visiting assistant professor; visiting lecturer
- senior research associate; research associate; research assistant
- research scientist (unless permission was granted in initial appointment letter)
- postdoctoral researchers

**Procedure to Request PI Status**

- A letter requesting PI status must be written (on department letterhead) by a candidate's dean, chair or director
- The individual's CV must accompany the request letter
- Submit the request letter and CV to the associate dean for research of the candidate's college for approval.
- The college associate dean for research will forward their approval and all documentation to the Office of Research Compliance for final approval

Contact Hayhow@ohio.edu or call 740-593-0664 with questions.

Status of Ohio University IRB review of IRB proposals from external users
Approved on September 28, 2016

The purpose of this document is to outline the Ohio University requirements for external investigators who seek IRB review at Ohio University. These requirements were determined after much consideration of the Office of Human Research Protections (OHRP) guidance and consultation with other institutions.

**First**, we should address the issue of university status to serve as a PI. In the Ohio University IRB Policies and Procedures, Section 2.4.1, it states the following:

> The primary investigator is the individual responsible for the implementation of research, and, as such, must personally conduct or supervise the research. The PI is responsible for ensuring that the research study is accurately and completely submitted for IRB review, that IRB approval is obtained prior to initiation of research and before making any changes or additions to the research; that the IRB is informed of all changes in information previously presented to the IRB; that progress reports are submitted to the IRB as required; and that all unanticipated problems or serious adverse events involving risk to human subjects are reported to the IRB promptly. The PI is also responsible for ensuring that all members of the research team comply with the findings, determinations, and requirements of the IRB, including adequate performance of the informed consent process.
>
> The role of PI implies administrative and fiscal responsibility as well as sufficient expertise for the research study. Though a trainee or another person may have primary responsibility for the intellectual content and may perform the research activities within the project, and, additionally, may garner primary credit for any publication resulting from the research, the PI has ultimate administrative and fiscal responsibility for the project, subject to University review and oversight. In cases where the primary investigator is a student, the advisor assumes the primary responsibility for ethical conduct of the study.

Based on this definition, the PI must be an Ohio University employee or student with active status. For example, employed active faculty or staff, or active student (enrolled in at least one semester within the last year). If the PI is an active student then an OU employed active faculty or member must

be listed as the advisor. Guest users, adjunct faculty, et cetera cannot submit an IRB proposal or serve as a PI but can serve as a Co-Investigator (Co-I) or research assistant. See the attached document where the definition of Principal Investigator Status Appointments is outlined.

Please note that the process to obtain Ohio University guest user access to LEO is the responsibility of the investigator. In order to obtain a guest email account from Ohio University, a current OU faculty or staff member can request a guest email account for an external investigator via Ohio Information Technology (OIT) at the following website.

https://author.oit.ohio.edu/oit/help/ohioguestform.cfm

Alternatively, an OU employed active faculty or staff member listed on an IRB protocol can choose the option to use a non-OU email account for the external user. If this option is chosen, it is important to note that the designated investigator will only be granted access to the LEO IRB program to approve a study and to upload their CITI training completion report(s). They will not have full access to the study content in the LEO IRB system.

The Corresponding Investigator (CI) cannot be a guest user. The CI must be an employed active faculty or staff, or active student and be listed on the protocol.

**Second**, each external investigator from an institution that does not have an IRB and is not under the auspices of Ohio University must sign an Individual Investigator Agreement (IIA). The IIA for Ohio University is attached. Briefly, the Office for Human Research Protections (OHRP) will permit an assured institution to extend its Federalwide Assurance (FWA) to cover a collaborating independent or institutional investigator provided the principal investigator at the assured institution directs and appropriately supervises all of the collaborative research activities to be performed by the collaborating individual investigators outside the assured institution.

**Third**, attached is guidance from Ohio University on the requirements for external collaborating investigators.

**Fourth**, Ohio University has a robust system that allows us to defer to (rely on) other universities (IRBs), as needed.

**Fifth**, Ohio University is a member of SMART IRB. This program allows Ohio University to decide how to handle review and approval of multi-site studies using a single IRB review.

**Sixth**, Ohio University has a contract with Western IRB (WIRB). This contract allows Ohio University to submit protocols for external review by an IRB with expertise that is not available here at Ohio University.

# Ohio University

# Individual Investigator Agreement

**Individual Investigator Agreement**

**Name of Institution with the Federalwide Assurance (FWA):**

Ohio University

**Applicable FWA #:** FWA00000095

**Individual Investigator's Name:** _____

**Specify Research Covered by this Agreement:** _____

_____

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
4. The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

7. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8. The Investigator, when responsible for enrolling subjects, will 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 on the FWA for the institution referenced above) and stipulated by the IRB.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
12. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
13. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

**Investigator Signature**: _____

Date: _____

Last Name: _____

First Name: _____ Middle Initial: _____

Degree(s): _____

Address: _____

City: _____ State/Province: _____ Zip/Country: _____

Phone: _____

**FWA Institutional Official (or Designee)**: _____

Date: _____

Last Name: _____

First Name: _____ Middle Initial: _____

Degree(s): _____

Address: _____

City: _____ State/Province: _____ Zip/Country: _____

Phone: _____