

Individual Investigator Agreement (IIA)

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Overview

There are instances when an external individual is *engaged* in human subjects research, in collaboration with a Pitt or UPMC researcher. In most cases, that individual does not have access to an IRB to provide approval and/or oversight for the research activities being performed. For these situations, an Individual Investigator Agreement (IIA) may be appropriate. All inquiries related to an IIA should be directed to irb.reliance@pitt.edu.

Definitions

External individual: An individual who is not acting as an employee/agent of either Pitt or UPMC.

Engaged: The Pitt HRP utilizes the guidance document issued by the Office of Human Research Protections to determine engagement: [Engagement of Institutions in Human Subjects Research \(2008\)](#). Examples of when an institution/individual is engaged in human subjects research include:

1. Receiving direct federal funding for research (i.e. Primary Awardee of the grant)
2. Obtaining data about research subjects through intervention/interaction
3. Obtaining identifiable private information about research subjects
4. Obtaining informed consent
5. Implementing/administering research intervention

Individual Investigator Agreement: A formal agreement, executed between Pitt and the external individual, describing the expectations and responsibilities of the individual in relation to the research project.

Training

The external individual must complete one of the following training programs prior to executing an IIA ([Training for Researchers](#)):

1. **COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**

The CITI training program is a leading global provider of online research ethics education. Many of the CITI courses qualify for continuing education credits (CMEs/CEUs) which can be purchased directly from CITI.

To access the CITI training, individuals must log into the Pitt CITI access portal using a [Pitt HSConnect](#) username/password as it provides a database for University Departments and other systems to verify CITI training. Detailed instructions are found here: [CITI Access Portal](#). Questions should be directed to citi@pitt.edu.

2. **COMMUNITY PARTNER RESEARCH ETHICS TRAINING (CPRET)**

The Community Partner Research Ethics Training (CPRET) and Certification is intended for community partners that are non-university employees who actively participate in research with human subjects (but will not be listed as a member of the research team in the IRB application). This course provides them with the opportunity to learn about conducting research that is ethical and safe.

For more detailed information regarding what CPRET training entails, see [Community Partners Research Ethics Training](#). For questions about how to use this training, contact the CTSI Community PARTners (Community Engagement Core) at ctsi7@pitt.edu.

Requesting an Individual Investigator Agreement

The *first step* in requesting an IIA for an external individual who does not have access to an IRB to provide approval and/or oversight for research activities being performed, is completing and submitting a request using the [Reliance Request System](#).

Note, you cannot save work in the Reliance Request System and return to it later. A request must be made in one sitting. Therefore, the Pitt HRP created the *Overview of Reliance Request System Content* guidance document, which can be found at www.hrpo.pitt.edu > Guidance & Forms > "R" for Reliance Guidance. This document outlines all information and materials you will need to have available to submit a reliance request.

Upon receipt of this paperwork, the Pitt HRP will review all reliance requests to determine if reliance is appropriate based on the details of the project.