

Guidance on collaborative study with non BSU researchers: Individual Investigator Agreements (IIA) and Institutional Authorization Agreements (IAA)

1. Agreement types

1) Reliance Agreements/ Institutional Authorization Agreements (IAA)

A Reliance Agreement, or Institutional Authorization Agreement (IAA), is an agreement between Ball State University (BSU) and another institution that hold a Federal Wide Assurance (FWA). This agreement allows one institution's IRB to rely on another for review of human subjects research. This type of agreement may be needed when collaborating with researchers external to Ball State University (BSU).

As of January 20, 2020, the Revised Common Rule ([part 45 CFR 46.114](#)) requires that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States.

2) Individual Investigator Agreements (IIA)

An Individual Investigator Agreement (IIA) is an agreement between BSU and an individual collaborator who is not affiliated with an institution with an FWA. This agreement outlines the responsibilities of the individual investigator for the protection of human subjects.

2. IRB Guidance by cases

Case	IRB recommendation and requirements
I want to recruit participants and conduct my study at another institution. No researcher(s) at the institution will be involved in this study.	<ul style="list-style-type: none"> This is not a collaborative or multi-site study. Thus, no reliance agreement or individual investigator agreement is required. You may obtain a letter of support from the institution, if necessary. Contact the administrator or department of the institution for more information.
I am working with a researcher(s) covered by the FWA of another institution.	
Our research team wants BSU IRB to review the protocol and the other institution(s) to rely on BSU IRB.	<ul style="list-style-type: none"> You might need a reliance agreement*. Submit a Reliance Agreement Request ** with your application.
Our research team wants all institutions to review the protocol independently of each other.	<ul style="list-style-type: none"> The IRB does not recommend this option. However, if you need to choose this option, choose “All applicable IRB's will be reviewing the protocol independently of one another” in the Multi-site and Collaborative Research section. You need to explain the reason why your team wants this option. <p>NOTE: <u>if your study is federally funded, you cannot choose this option.</u></p>
Our research team wants the other institution to review this project and BSU to rely on them.	<ul style="list-style-type: none"> You might need a reliance agreement. Send a Reliance Agreement Request to Sena Lim, HRPP manager, at slim2@bsu.edu.
I am working with a researcher who works for an institution not covered by the FWA or a researcher not affiliated with any institution.	

My co-investigator works for an institution not covered by the FWA.	<p>The individual need to fill out and sign IIA (Individual Investigator Agreement) and PI must include this form in the IRB application package.</p> <p>The individual need to provide CITI training or other equivalent training certificate. PI must include this certificate in the IRB application package. See below for more information about training.</p>
My co-investigator is an independent researcher, not affiliated with any institution.	<p>The individual need to fill out and sign IIA (Individual Investigator Agreement) and PI must include this form in the IRB application package.</p> <p>The individual need to provide CITI training or other equivalent training certificate. PI must include this certificate in the IRB application package.</p>

* If your study is eligible for exempt, a reliance agreement may not be necessary.

** Reliance Agreement Request form is available in the IRBNet forms and templates.

3. Training Options for researchers not affiliated with Ball State University

1) Research team members affiliated with an institution that has the IRB

Researchers from the other institution will be required to meet the training requirements set by their own institution's IRB. If the study will be reviewed by the BSU IRB, the training certificate(s) should be submitted to BSU IRB.

2) Research team members not affiliated with any institution, or affiliated with an institution that does not have the IRB

a. **Research eligible for Exempt review** – The non BSU affiliated members have to be listed on the IRB application but are not required to complete the CITI human subjects training course. Even though the CITI training is not required, the ethical obligations in the conduct of activities that involve human subjects still apply. This individual must review the Belmont Report and available at <http://www.hhs.gov/ohrp/policy/belmont.html> and Ball State University IRB policies and procedures. It is PI's responsible for educating the non BSU researcher(s).

b. **Research requiring Expedited/Full Board review** – Non BSU affiliated members are strongly recommended to complete the CITI human subjects training course. Please contact our office for more information.