

IRB Coordination across PASSHE Universities Procedures

In order to: **have consistency in IRB submission requirements across PASSHE universities in regards to multi-university research; reduce duplicative efforts by researchers and IRB members; improve efficiency of the review process so that research is not significantly delayed**, system-level and multi-university research that is multi-campus in nature will utilize the following procedures for obtaining necessary IRB approval(s).

For the purposes of these procedures the scope of the study must be classified as Class A or Class B as explained in the following paragraphs.

A Class A research project is research originating with a system-level consortium of researchers. It has no single originating PASSHE university. Class A projects will use a rotating schedule to select a lead university IRB that will be designated to receive the study protocol and related documents. The list will be limited to those Universities that have an IRB registered with the Office of Human Subjects Protections (OHRP). The list is maintained by the Division of Academic and Student Affairs, Office of the Chancellor, which shall designate a lead University for each Class A project that is covered under these procedures.

A Class B research project is research originating with individual students, such as theses and dissertations, or research originating with individual faculty, when the scope of the research includes the researcher's (aka project director's) "home" university and one or more additional PASSHE universities. Class B research projects will use the IRB of the "home" institution of the project director, as the lead IRB.

The named project director has the responsibility to ensure any required IRB review is initiated and the proper protocol submitted in accordance with the designated lead University's IRB procedures. The study protocol will be submitted by the project director, who shall be identified as the Principal Investigator. A university contact/co-director shall be identified as a co-Principal Investigator. The research protocol will be clear that the IRB is approving research that is occurring on multiple campuses.

The study protocol will be submitted in the format required by the lead university IRB. The lead University IRB will review the protocol according to its usual procedures, including requesting additional information or clarifications.

Upon the lead University's IRB approval, the approval will be supplied by the project director to all participating PASSHE University co-project directors/ project contacts for submission to their IRB.

The lead University IRB determination, the study protocol and related documents will be posted on the IRB coordination SharePoint website: <https://secure.passhe.edu/asa/IRB/Documents/Forms/AllItems.aspx>). All users of the site can subscribe to updates via a subscription feed. Utilizing this resource, it will be unnecessary to physically forward approvals, study protocols, related documents and other study materials by email or hard copy.

Any participating university IRB may request additional information or documents relating to the study protocol.

An individual participating university IRB has the option to conduct its own review of the protocol, if for a valid reason, it disagrees with the lead IRB's review. In such case, the individual IRB will notify the project director of its individual review within 10 days of receipt of the protocol. The individual IRB will issue its decision within 45 days of such receipt.

All participating university IRB's shall release a letter accepting or rejecting the study (including any conditions or monitoring responsibilities) and post this also in the secure website. Efforts will be made to automate the work flow per software capabilities of SharePoint.

All PASSHE IRBs will provide their submission formats and instructions for posting on the SharePoint site. In lieu of providing documents, an IRB may provide a link to an individual website where those documents are available.

The IRB Coordination secure SharePoint website will also contain a roster of IRB chairs/contacts, the Authorization Agreement and other resources as appropriate.

In regard to Class A research –

In the event of an allegation of research misconduct, the allegation shall be directed to the institution(s) that employ(s) the respondent researcher(s), be it the PI, co-PI, research assistant or other personnel. The employing institution(s) shall investigate the allegation according to the institution's Research Misconduct (a.k.a. Responsible Conduct of Research) policy and notify the lead and all approving IRBs of the investigation to the extent allowed by confidentiality requirements of its policy.

In the event of a report of adverse outcomes, the report will be directed to the lead IRB, which shall notify all participating IRB that initially reviewed/accepted the protocol. The lead IRB will review the report and decide the appropriation action to be taken

Table 1

Typical/expected* timeframes for initial IRB reviews

Type of review required	Time from initial protocol submission
Exempt/expedited	2 weeks
Full IRB review	4-6 weeks

* response time is not guaranteed during academic breaks.

Table 2

Non-IRB administrators involved in multi-university research

University	Approves access to the campus, to study subjects	Provides contact information for study subjects (e.g. email addresses)
Bloomsburg	Chief Academic Officer (CAO)	Office of Planning & Assessment
California	CAO	
Cheyney		
Clarion	CAO	Institutional Research Director
East Stroudsburg	CAO	Chief Information Officer (Computer Services)
Edinboro	CAO	Office of Records & Registration
Indiana	CAO	
Kutztown	CAO	Institutional Research Director
Lock Haven	CAO	
Mansfield	CAO	Institutional Research Director
Millersville	CAO	Asst. VP for Assessment
Shippensburg	CAO & IRB Director	Institutional Research Director
Slippery Rock	CAO	Institutional Research Director
West Chester	CAO	Institutional Research Director

Sample text for an Institution with a Federal-wide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).

Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):

IRB Registration #: _____ Federal-wide Assurance (FWA) #, if any: _____

Name of Institution Relying on the Designated IRB (Institution B):

FWA #: _____

The Officials signing below agree that (name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: *(check one)*

This agreement applies to all human subjects research covered by Institution B's FWA.

This agreement is limited to the following specific protocol(s):

 Name of Research Project: _____

 Name of Principal Investigator: _____

 Sponsor or Funding Agency: _____ Award Number, if any: _____

Other (*describe*): _____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

_____ Date: _____

Print Full Name: _____ Institutional Title: _____

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official (Institution B):

_____ Date: _____

Print Full Name: _____ Institutional Title: _____