IRB Coordination across Pennsylvania's State System Universities

Preface

University Institutional Review Boards (IRBS) have jurisdiction to review all research (as defined in 45 CFR Part 46) that occurs on or uses human subjects from their campus.

A University has institutional liability for poor or deficient research which may harm human subjects on or from their campus.

Therefore, all IRBs must be fully aware of qualifying research that affects their University and there is a need to coordinate multiple IRB reviews of research that uses human subjects from more than one State System universities. Procedures to do so follow. These procedures were developed in 2012 by an ad hoc committee of System University IRB chairs.

IRBs review the research methodology. System Universities also reserve approval of access to the subjects, via email, phone, advertisement etc. and have designated campus officials to exercise this authority. These procedures also provide information for contacts who can provide approval for access and scheduling of the research.

Any suggestions for revisions to these procedures should be submitted to Angela C. Smith-Aumen, asmith-aumen@passhe.edu for presentation to University IRB Chairs, as appropriate.

Angela C. Smith-Aumen
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Procedures

Revision 1, August 2014
Revision 2, June 2015

In order to: **have consistency in IRB submission requirements across Pennsylvania's State System 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).

Scope

These procedures will apply to the following types of studies:

1. Protocol originates at one of the State System schools and is seeking approval from more than one System university.
2. Protocol originates from someone, typically a faculty member, within the System but the Principal investigator (PI) is doing the work (e.g. pursuing a degree) at another, non-System school with the intent of seeking approval from more than one System university.
3. Protocol originates from a PI outside of the State System with the intent of seeking approval from more than one System university
4. Protocol originating with a consortium of State System universities supported or led by the system office.

A study that meets the criteria of 1 or 2 above, 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 State System universities. Such research projects will use the IRB of the ***"home" institution*** of the project director, as the lead IRB.

A study that meets the criteria of types 3 and 4 above will use an ***annual rotating schedule of universities*** to undertake the initial IRB review, i.e. one lead university IRB will be designated to receive all study protocols and related documents for a 12-month period. Every university will have the opportunity to be lead IRB but a university may decline if it presents a hardship for the university due to lack of support. The lead IRB will complete the initial review of the study protocol even if its university is not involved in the research.

The lead universities will be limited to those Universities that have an IRB registered with the Office of Human Subjects Protections (OHRP) and also have a Federal Wide Assurance (FWA). The FWA is an indicator of the quality of the university's IRB members and procedures. The list is maintained by the Division of Academic and Student Affairs (ASA), Office of the Chancellor, which shall solicit a lead University each year for such projects.

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. Any university contact/co-director shall be identified as a co-Principal Investigator however there are situations where there is NO campus contact or co-Principal Investigator at participating universities. The research protocol will be clear that the IRB is approving research that is occurring on multiple campuses. The lead IRB will advise the project director of the coordinated process among State System universities.

Process

The study protocol, study instruments and related documents 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 State System University IRBs.

The lead University IRB determination, the study protocol and related instruments and documents will be posted on the IRB coordination D2L website: https://passhe.desire2learn.com . 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 IRB of a university designated for inclusion in the study (by the PI) may request additional information or documents relating to the study protocol. Such requests are made directly to the Principal Investigator.

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 IRBs must release a letter accepting or rejecting the externally-approved study (including any conditions or monitoring responsibilities) and must post this also in the secure D2L website. For externally-*approved* protocols, each site's approval letter shall include a letter to the project director stating that the site IRB has reviewed all documents and the protocol meets federal standards and the site university IRB does accept/approve. Additional concerns may also be noted in this letter. If a participating IRB **rejects** a study its letter to the project director shall outline the reasons, including regulatory citations, for the rejection.

Information

In order to facilitate communication among IRBs all State System IRBs will provide their submission formats and instructions for posting on the D2L site. In lieu of providing documents, an IRB may provide a link to an individual website where those documents are available. Also, the State System (i.e. Office of the Chancellor) website will include a one-page summary of the procedures for researchers, including links to each IRB website. Likewise, each University will include a link to the State System page, clearly identified as a resource for multi-university research. The summary will indicate the lead IRB for the current year.

The IRB Coordination secure D2L website will also contain a roster of IRB chairs/contacts, the Authorization Agreement and other resources as appropriate.

Research Concerns

In regard to Type 1 or 2 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 IRBs that initially reviewed/accepted the protocol. The lead IRB will review the report and decide the appropriation action to be taken.

Table 1:
Universities with IRB OHRP registration and FWA

University	Registration	FWA	FWA #
Bloomsburg	X	X	FWA00010716
California	X	X	FWA00005308
Cheyney	X	X	FWA00018576
Clarion	X	X	FWA00015496
East Stroudsburg	X	X	FWA00008733
Edinboro	X	X	FWA00001781
Indiana	X	X	FWA00006948
Kutztown	X	X	FWA00016036
Lock Haven	X	X	FWA00008394
Mansfield	X	X	FWA00016100
Millersville	X	X	FWA00011438
Shippensburg	X	X	FWA00009792
Slippery Rock	X	X	FWA00006788
West Chester	X	X	FWA00014155

Table 2

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 3

Other 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	Office of Institutional Research and Planning
Cheyney	CAO	
Clarion	CAO	Institutional Research Director
East Stroudsburg	CAO	Chief Information Officer (Computer Services)
Edinboro	CAO	Office of Records & Registration
Indiana	CAO via Asst. Dean for Research	Asst. Dean for Research with ARL
Kutztown	CAO through the IRB director	Institutional Research Director
Lock Haven	CAO	Institutional Research Director
Mansfield	CAO	Institutional Research Director
Millersville	CAO	Asst. VP for Assessment
Shippensburg	CAO & IRB Director	Institutional Research Director
Slippery Rock	Research Permissions Committee	Research Permissions Committee
West Chester	AVP – Research & Sponsored Programs	Institutional Research Director

Table 4

Universities with unique or additional IRB requirements

University	Training	Cover sheet	Protocol additions
Bloomsburg	CITI training		Statistical analysis
California	CITI or NIH training		
Cheyney			
Clarion	----------		
East Stroudsburg	NIH or CITI		
Edinboro	CITI		
Indiana	CITI (link)		
Kutztown			
Lock Haven	NIH or equivalent		
Mansfield	----------		
Millersville			
Shippensburg			
Slippery Rock	CITI or equivalent	N/A	N/A
West Chester	CITI within 3 years		http://www.wcupa.edu/research/irb.aspx

Appendix A

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*:* _____