



Policy	P17
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Created:	September 26, 2011
Edited	
Version	P17.1

IRB AUTHORIZATION AGREEMENTS (IAA)

POLICY

Institutional authorization agreements (IAA) are written agreements entered into between institutions to “rely” on Institutional Review Board (IRB) review. Such agreements are entered into to reduce duplicate IRB review when appropriate. Wright State University (WSU) may enter into an IAA to rely on another institution’s IRB review or to allow another institution to rely on WSU’s IRB review. WSU may enter into an IAA after a determination is made that it is appropriate under the particular circumstances. The WSU Institutional Official retains final authority to determine whether WSU may enter into an IAA.

Each IAA is situation and context-dependent. Considerations of whether to enter into an IAA may include engagement of the institutions, the location of the research interaction or intervention or subject recruitment, whether there is a prime award for a contract, grant, or cooperative agreement, whether there is a subcontract, involvement of certain types of research such as xenotransplantation, embryonic stem cell, phase I clinical trials, review and approval of other university committees such as recombinant DNA, radioisotopes, etc. For policies and procedures for reliance on a commercial IRB, see the separate procedure “Use of a Commercial Institutional Review Boards.”

When entering into an IAA where WSU will rely on another institution’s IRB, WSU will evaluate whether the non-WSU IRB has equivalent human subject protections in place. Such evaluation will include consideration of whether the non-WSU IRB is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). If the institution is not accredited, evaluation of the Human Research Protection Program (HRPP) will occur to assure equivalent human subject protections are in place. Evaluation will include review of written materials such as policies, procedures, application forms, and other relevant documents and meetings or interactions with the HRPP staff. If the institution is found to have equivalent protections, an agreement may be entered into between WSU and the institution.

TIMES WHEN AN IAA IS USEFUL

An IAA helps to reduce the burdens of multi-site research, which typically includes multiple IRB applications for the same project, multiple changes (sometimes conflicting) to secure approval, and multiple continuing review and amendment submissions.

The following are the most common situations where use of an IAA is appropriate:

- WSU acts solely as the funding recipient of an award and no research activities will be taking place at WSU.
- The involvement of the WSU investigator is limited to data analysis collected through the other institution or other minimal risk, non-exempt activities.
- The other institution’s reviewing IRB is more properly constituted to review a certain scope or topic of work, or may have knowledge of the local research context. (For

example, an international research project where the interaction with subjects is performed at an external site and that site has an FWA.)

- The WSU Investigator is involved in non-exempt research to be performed at another institution that either has or will have IRB approval.

WHEN IS AN IAA NOT NEEDED?

When WSU, its agents, or its employees are not engaged in research, IRB review (IAA) is not required. For example, if an investigator at another institution is conducting interviews on employees or students at WSU without involving an employee or student affiliated with WSU or collaborating with anyone affiliated at WSU then an IAA is not required.

In addition, an IAA is not appropriate for studies seeking exempt determinations.

PROCEDURE FOR ESTABLISHMENT OF AN IRB AUTHORIZATION AGREEMENT

A. An IAA may be requested for a specific study, or may be broader in scope to encompass any study at an approved institution meeting the description above (see “Times When an IAA is Useful”). Currently, WSU has IAA agreements with the following institutions:

1. Kettering Medical Center, Kettering
2. Miami Valley Hospital, Dayton
3. Children’s Hospital, Dayton
4. Wright Patterson AFB Medical Center

B. All studies approved under an IAA agreement will be reflected in the minutes of the WSU IRB.

C. Study-specific IAAs (non-DCOP studies)

1. A principal investigator desiring to initiate an IAA must fill out the “Form for Requesting IRB Authorization Agreement” found on the WSU RSP website and submit the form to the IRB coordinator. The following information is requested on the form:

Project Information (please number if more than one)

Identifier(s)	Title(s)

Principal Investigator Information

First Name:	Last Name:	
Academic Title :		
Department/College:		
Address:		
Phone :	Fax :	Cell Phone:

Email :

Name of Institution or Organization Providing IRB Review

Institution/Organization Name:	
Address :	
Contact Person/email and/or phone:	
IRB Registration #	Federalwide Assurance (FWA) #, if any

2. Once the information is received, the IRB coordinator will prepare the authorization agreement, and provide the information to the Institutional Officer and the IRB Chair for review.
3. After investigating the qualifications of the proposed institution, if the Institutional Officer and IRB chair agree that the authorization is appropriate (based on the elements described under "Purpose") they will sign the form and it will be forwarded to the other institution for review and signature.
4. IAAs that are specific to a particular research project will expire at the time of closure of the research project

D. Study-specific IAAs (DCOP studies)

1. For each commercial IRB to be used, DCOP will provide documentation to the IRB coordinator that the commercial IRB has received AHRPP accreditation.
2. For each study to be submitted to the commercial IRB, DCOP will either fill out the IAA request found above in section C, or the IAA agreement provided by the commercial IRB.
3. Each IAA agreement request will be signed by the Wright State Institutional Officer and the Wright State IRB Chair.

E. Broader Institutional IRB Authorization Agreements

1. Because of the community-based nature of the WSU Boonshoft School of Medicine, a number of BSOM faculty members work primarily in regional hospitals that have IRBs. These faculty members may be engaged in research that is done solely at those hospitals and requires IRB approval from the hospital. In these cases, a formal IAA agreement between the hospital and WSU is appropriate to allow the hospital IRB to serve as the IRB for these studies.
2. When an IAA is desired between the two institutions, WSU IRB officials will determine that the hospital has appropriate qualifications, and will prepare an IRB Cooperative Authorization Agreement that describes the scope and terms of the agreement. This agreement will include:
 - i. The FWA and IRB numbers of both institutions

- ii. A description of the authority granted to the institution allowing it to review research protocols that involve human subjects only at the institution (and not at WSU) where the researcher is an employee or agent of both institutions
 - iii. A statement concerning which institution will have responsibility for the actions of its agents or employees (e.g. "Wright State University shall retain responsibility for its agents, employees, and other persons under its control and supervision and shall hold _____ harmless in the regard.
_____ shall retain responsibility for the actions of its agents or employees and other persons under its control and supervision and shall hold Wright State University harmless in the regard.")
 - iv. A statement indicating that WSU shall be provided with a copy of all research protocols, consent documents and approval letters (of initial and continuing review) for its file, as well as any amendments that are approved during the course of the research.
 - v. A statement that WSU reserves the right to disapprove the protocol for cause, in which case the research shall be immediately suspended.
3. The IAA agreements will remain in effect until terminated by either signatory. Termination will be preceded by written notification to the other signatory to the intention to terminate sent by registered mail one year prior to the proposed termination date. However, if both signatories mutually agree to terminate the agreement, it may be terminated at any time.
4. The IAA agreement will be signed by the WSU Institutional Officer, the WSU IRB Chair, and the equivalent persons at the other institution.