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WSU IRB Serving as the Reviewing IRB (Single IRB)

Introduction:

For non-exempt federally funded Common Rule agency multi-site research, in most cases, a single IRB (sIRB) is required due to NIH Policy and/or Federal Regulations. When the WSU IRB is named in the proposal as the Reviewing IRB, the WSU IRB must have agreed to take on this responsibility in advance.

Requests for Wayne State University to be the Reviewing IRB or sIRB should be submitted as early in the process as possible by emailing relyirb@wayne.edu. The steps for requesting WSU to be the Reviewing IRB are as follows:

1. Request WSU to be the Reviewing IRB
2. WSU IRB Administrative Pre-Review of Studies for Reliance on WSU IRB
3. Submission to WSU IRB via eProtocol
4. WSU IRB Expedited Amendment Process to Add Relying Sites' Site-specific Forms
5. Communication Responsibilities

1. Request WSU to Be the Reviewing IRB:

The following two forms should be emailed to relyirb@wayne.edu ***prior to*** submitting the grant proposal to the funding agency:

- Engagement Determination Checklist (pdf)
- WSU Preliminary Intake Form (WSU as Reviewing IRB) (pdf)

An administrative assessment will be made based on the information provided in these two forms about whether Single IRB is required for the study, and if WSU IRB is willing and able to be the Reviewing IRB. If WSU IRB agrees to be the Reviewing IRB for an NIH study, that information should be included in the NIH SIRB Plan for NIH proposals (see NIH SIRB in References).

There are several items that factor into the determination of whether WSU IRB is willing and able to serve as the Reviewing or Single IRB for a given project. Generally, WSU is willing to be the Reviewing IRB if:

- WSU is the main grantee for a multi-site project requiring use of a single IRB (e.g., NIH or other Common Rule Agency funding);
- The overall study PI is a WSU (or local affiliate) investigator;
- WSU is also engaged in the research;
- The project is not deemed "exempt" (if it is, each site does its own review);
- The number of study sites is manageable (if a large number of sites, a commercial IRB would likely be recommended);
- All of the participating sites are willing to rely on WSU (Note: Exception – WSU is willing to be the Reviewing IRB for domestic sites when there are international sites involved that would do their own review).

After review of the two forms listed above, you will receive a confirmation that the WSU IRB is willing to be the Reviewing IRB, or an explanation of alternative processes. Please save these two forms and the confirmation for your records. You will need them in Step 2.

2. WSU IRB Administrative Pre-Review of Studies for Reliance on WSU IRB

An administrative pre-review process will take place ***prior to*** expedited or full board IRB review of the initial protocol submission when WSU is the Reviewing IRB for a multi-site study.

Submission Requirements:

The application should be prepared in eProtocol and should remain "In preparation" for this step. Do not click "submit" until you receive notification of pre-review completion. The application should include the following:

Completed eProtocol Application Form (see IRB Forms and Submission Requirements web page)

For the eProtocol Application, include the following in your attachments:

- Engagement Checklist and WSU Preliminary Intake Form that were submitted in Step 1;
- Confirmation from Step 1 from relyirb@wayne.edu that WSU agreed to be the Reviewing IRB;
- Informed consent form(s) for use at WSU site (master consent template);
- Coordinating Center Application/Single IRB Form
- Research Protocol
    - Submission of the protocol is required. If the protocol will ***not*** be implemented in the same way at each relying site, the protocol should clearly state what study activities the various relying sites are performing.

After completion of the above steps, please notify relyirb@wayne.edu to initiate the pre-review process. In your email, include the eProtocol WSU IRB number.

3. Submission to WSU IRB via eProtocol:

After pre-review is complete and any necessary changes have been implemented, the study application may be submitted in eProtocol for expedited or full board WSU IRB review.

- Select “check for completeness” to confirm all application requirements are complete.
- Submit eProtocol application for Department Chair/Dean/Authorized signatory sign off.
- Following the Department Chair/Dean/Authorized signatory signoff, submit the eProtocol application to WSU IRB for review.

After you have received your initial WSU IRB approval of the study, you may work with the relying sites to get the relying site-specific documents in place.

4. WSU IRB Expedited Amendment Process to Add Relying Sites’ Site-specific Forms

WSU IRB approval of the overall study protocol and the local/master consent documents should be obtained first (See Sections 2 & 3), and site-specific documents are added by expedited amendment.

After initial WSU IRB approval, in order to add the site-specific consent and advertising documents for use at each site, the following will need to be submitted as an expedited amendment (or individual amendments, depending on timing of site readiness) to the WSU IRB:

- Relying Institution (Non-WSU) Local Context Information Sheet - Local Context Form with each site’s administrative reliance authorization for all participating sites that are not affiliated with WSU;
- Reliance Agreement or acknowledgement of existing agreement being used for each site;
- All site-specific advertising materials, data collection tools to be used at each site;
- Coordinating Center Application/Single IRB Form
- Site-specific Local Context consent addendum:
    - This version will be an addendum to the WSU IRB-approved consent form.
    - The relying institution may perform their own Local Context review and include site-specific language (e.g., the availability of treatment and compensation for research-related injury, payment/reimbursement of costs incurred by subjects for participation, confidentiality, and Relying Site Investigator contact information).

Please email relyirb@wayne.edu to notify that the site addition amendment has been submitted. Be sure to include your WSU IRB#, PI name, and study title in your email.

PLEASE NOTE: Each relying site may begin research only after they have provided local documentation of their institution's authorization to rely on WSU IRB, a reliance agreement is in place, and the site documents have been officially approved by WSU IRB.

5. Communication Responsibilities:

WSU IRB NOTIFICATION TO PI

WSU IRB approval documents will be issued to the WSU PI per the usual IRB notification process. See Policy 4-12: Notification of the IRB Decisions to Principal Investigator and PI Response.

PI COMMUNICATION RESPONSIBILITY

The WSU PI is responsible for ensuring that the relying site(s) PI(s) have received the most current versions of all the protocol documents and IRB approval memos.

POST-APPROVAL REQUIREMENTS

Modifications and Continuations

As the Reviewing IRB, the WSU IRB is responsible for continuing oversight and review of amendments and continuations for each of the relying sites that have ceded review for a multi-site project. It is the WSU PI's responsibility to submit all modifications and continuing reviews to the WSU IRB per the following policies:

- 4-6 Amendments to Research Protocols and Consent Forms
- 4-7 Continuation/Renewal of a Protocol

Continuations should be submitted at least 8-10 weeks before expiration to allow time for administrative review.

Each relying site maintains responsibility for approving key personnel changes and any changes related to local context (e.g., local context consent language, HIPAA changes). The relying site's documentation should be submitted to WSU IRB as an expedited amendment. Continuation submissions must include an update for progress at each relying site as part of the overall progress update for the study.

Event Reporting

As the reviewing IRB, the WSU IRB is responsible for the review of all unanticipated problems for each of the relying sites that have ceded review for a multi-site project. It is the WSU PI's responsibility to submit all unanticipated problems to the WSU IRB per the following policy:

- 13-1 Unanticipated Problems and Event Reporting

Resources

NIH Single IRB policy: https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm

Common Rule Cooperative Research Provision: Cooperative Research Provision Guidance Tool (pdf)

Common Rule agencies this provision is applicable to can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Relevant WSU IRB Policy: https://research.wayne.edu/irb/docs/04-17-_external_institutional_review_boards_reliance_agreements_for_multi-site_research.doc