Wayne State University
Institutional Review Board (IRB)

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# Single IRB Guidance for NIH Multi-site Studies

**The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving nonexempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.**

**If all of the below circumstances apply to your research, then a single IRB Plan is needed with your NIH grant submission:**

- ☐ **Research is funded by NIH or being submitted to NIH**
- ☐ **This a multi-site study**
- ☐ **The same protocol will be used at more than one site**
- ☐ **The research meets the DHHS definition of research and does not qualify for an exempt review under the categories described in 45 CFR Part 46.104**
- ☐ **There is more than one domestic site (Foreign sites are not expected to comply)**

## Effective Date: January 25, 2018

- Grant applications - due dates on or after January 25, 2018
- Contracts - all solicitations issued on or after January 25, 2018
- Multi-site studies within ongoing, non-competing awards will not be expected to comply with the policy until a competing renewal application is submitted.

## sIRB Plan Content

The sIRB plan should include the following elements:

•Describe how you will comply with the NIH Policy on the Use of sIRB for Multi-Site Research.

•Provide the name of the IRB that will serve as the sIRB of record.

•Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.

•Briefly describe how communication between sites and the sIRB will be handled.

•Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.

•Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

•Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.

•Note: If your human subjects study meets the agency definition of "Delayed Onset," include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study in the delayed onset study justification.

### sIRB Plan Format

Attach this information as a PDF file. See NIH's Format Attachments page.

Although one sIRB attachment per application is sufficient, you must include a file for each study within your application. All file names within your application must be unique. You may either attach the same sIRB plan (with different file names) to different studies or attach a file that refers to the sIRB plan in another study within your application. For example, you may attach a file that says "See sIRB plan in the 'My Unique Study Name' study."

## Contacting the IRB ahead of grant submission

Consultation with the WSU IRB prior to grant submission is important. Please email relyirb@wayne.edu to let us know ahead of time if you would like to use the WSU IRB as the IRB of record (aka reviewing IRB) or if you need a letter stating we will rely on another IRB for the study. We do not require a full IRB submission at that time, but knowing ahead of time about your plans will help us determine whether we will be able to accommodate that request when it does come in. Please provide the grant (at least the aims section) with your request and let us know what parts of the project will be happening locally.

## Source:

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.2

## Additional Resources:

- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html
- https://osp.od.nih.gov/clinical-research/irb-review/
- https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/
- https://smartirb.org/