MARQUETTE UNIVERSITY

Office of Research and Sponsored Programs
1324 W. Wisconsin Ave.
Holthusen Hall, 341
414-288-7200
www.marquette.edu/orsp

NIH Single IRB Plan Guidance

December 2017

A “Single IRB Plan” is required if this is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site.

Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?
Select "Yes" or "No" to indicate whether this is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site.

If yes, describe the single IRB 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."

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.