**NIH Requirements to use a single IRB for Multicenter Clinical Research**

For applications with due dates on or after January 25, 2018 NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. The NIH single IRB policy allows exceptions for domestic sites when review by a single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

**Human Subjects and Clinical Trial Information Section 3.2: Multi-site study, use of single IRB:**

* Describe the single IRB plan. The 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.
	+ If your study meets the agency definition of "[Delayed Onset](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy)," 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.
* For Studies with Legal, Regulatory, or Policy-based Claims for Exception as described by the sIRB Policy: Indicate that review by an sIRB will not be possible for all or some sites (specify which sites) because local IRB review is required by an existing federal/state/tribal law or policy. Include a specific citation to the relevant law, policy, or regulation.
* For sites requesting an exception based on compelling justification: Indicate which site(s) is requesting an exception to the use of the sIRB and provide compelling justification based on ethical or human subjects protection issues or other well-justified reasons. NIH will determine whether to grant an exception following an assessment of the need.
* Links to more information:
	+ NIH single IRB policy webpage: <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>
	+ NIH Frequently Asked questions single IRB policy (costs, responsibilities, exceptions): <https://grants.nih.gov/faqs#/hs-single-IRB-policy-for-multi-site-research.htm>
	+ NIH IRB Review, single IRB Resources: <https://osp.od.nih.gov/clinical-research/irb-review/>
	+ Scenarios illustrating direct and indirect costs for single IRB: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html>