Types of studies expected to use a sIRB:

* Domestic sites of NIH funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.
* Does not apply to career development, research training or fellowship awards
* Multi-site = two or more sites
* Foreign sites not expected to follow the policy
* Policy provides for exceptions by recognizing that may not always be possible to use a sIRB.

Exceptions:

* When review by the proposed sIRB would be prohibited by federal, tribal, or state laws, regulations or policies.
* Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification
* NIH will determine whether to grant an exception following an assessment of the need
* COGR develop a list of scenarios where use of sIRB would not be efficient or cost effective (e.g., community based research; SBIR)

Why is NIH promoting the use of sIRB for multi-site studies?

* Help streamline IRB review process
* Remove redundant hurdles to the initiation of multi-site studies
* Should allow research to proceed as effectively and quickly as possible
* Expected to reduce unnecessary administrative burdens and system inefficiencies while maintaining human subjects protections
* Reduce IRB workload by removing redundant reviews

Who is responsible for selecting the sIRB and when must this be done?

* The applicant is expected to submit a plan describing the use of a sIRB that would be selected to serve as the IRB of record for all study sites.
* The plan should include the registration number issued to the IRB by OHRP
* If the IRB cannot be identified, applications/proposals should include a statement that awardees will follow the sIRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site protocol.

What if the sites are in disagreement about the selection of a sIRB?

* If the sIRB cannot be identified prior to award, terms and conditions restricting human subjects research will be placed on the award.
* The Insitute/Center funding the research will assist in resolving the matter
* sIRB will need to be identified before the release of funds under the award.

How will the sIRB policy be enforced?

* Will be a term and condition of the award.
* Failure to comply with terms and conditions may result in enforcement actions, including termination of funding.

What is the role of the IRB at a site that is not the IRB of record?

* IRB at participating sites will be responsible for meeting all of their current responsibilities
* Responsible for other regulatory obligations such as obtaining informed consent, overseeing the implementation of the approved protocol and reporting unanticipated problems and study progress to the sIRB.
* Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and stat/local regulatory requirements during its deliberations.

What is the difference between a central IRB and a sIRB?

* Both designed to help streamline IRB review and terms are sometime used interchangeably.
* Central IRB is generally used to refer to an IRB that reviews many different research protocols and sometimes referred as independent IRBs. (Western IRB comes to mind)
* sIRB refers to the IRB, which may be a central IRB or an institution-based IRB, that is selected to serve as the one IRB of record for the review of one protocol that will be carried out at many sites.

When does the policy take effect?

May 25, 2017