NIH Policy on the Use of a Single IRB for Multi-site Research

Effective Date: January 25, 2018

Summary: Policy requires all domestic sites participating in NIH funded multi-site studies (participating site), where each site will conduct the same protocol for non-exempt human subjects research (multisite study), to propose and use a single IRB of record (sIRB) to conduct the ethical review required by 45 CFR 46. Policy applies to cooperative agreements, contracts, and the NIH Intramural Research Program. Policy does NOT apply to career development, research training or fellowship awards.

Topic	Summary	Principal Investigator Action	IRB or ORC Action	OSP or CLD Action
Implementation	**NIH proposed competing grant applications (new, renewal, revision, or resubmission) subject to the policy with the receipt date on or after January 25, 2018.** Ongoing, non-competing awards are not expected to comply until the grantee submits a competing renewal application.	PI completes sIRB Form and submits to ORC at least 3 weeks prior to NIH submission deadline to allow time to coordinate with other participating institutions. (See Applicant/Offeror Role and Responsibility for details on sIRB proposal submission)	After submission of sIRB Form by PI, ORC works with PI and other participating sites to develop sIRB Plan. IRB reviews and approves (or requests changes to) sIRB Form and/or proposed sIRB Plan. ORC will provide approved sIRB Plan to PI with copy to OSP/CLD.	OSP/CLD verifies that PI has completed sIRB Process for projects subject to the policy and sIRB Plan or IRB approved exceptions are included in the proposal.
	NIH applications (subject to the policy) to contract solicitations issued on or after January 25, 2018.			
	NIH applications for intramural multisite studies subject to the policy submitted for initial review after January 25, 2018.			
Exceptions	1. Prohibited by a federal, tribal, or state law, regulation, or policy. 2. Other compelling justification may be considered	PI proposes exceptions in sIRB Form. With IRB concurrence, PI may request exception in proposal.	IRB reviews sIRB Form and determines if exceptions should be requested in proposal.	OSP/CLD verifies IRB concurrence with exception request.

Created by: AU Office of Research Compliance – 10.11.2017

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Applicant/Offeror Role and Responsibility	1. In proposal, include plan describing use of a sIRB (IRB of record) sIRB Plan includes: • statement that all participating sites will adhere to sIRB Policy • description of how sIRB will communicate with sites 2. In proposal for delayed-onset research, include: • statement that awardees will follow sIRB Policy • statement that use of registered IRB of record will be communicated to NIH prior to initiation of multisite study. 3. Direct costs: may request additional costs associated with sIRB if justified, reasonable, and consistent with cost principles (FAR 31.302 and FAR 31.203)	1. PI completes sIRB Form and submits to ORC 3 weeks prior to proposal deadline. After IRB approval, PI includes description of sIRB Plan or exceptions in proposal. 2. For delayed-onset research, PI includes required statements in proposal unless PI has requested and obtained concurrence from AU IRB to propose exceptions. 3. As necessary, evaluated in collaboration with ORC and OSP/CLD.	1. After submission of sIRB Form, ORC works with PI and other sites to develop sIRB Plan. IRB reviews and approves (or requests changes to) sIRB Form and sIRB Plan. 2. IRB reviews sIRB Form and determines if exceptions may be appropriate for proposal. No ORC or IRB action required to include standard statements. 3. As necessary, evaluated in collaboration with PI and OSP/CLD.	1. OSP/CLD verifies approved sIRB Plan or exceptions are included in the proposal. 2. Verifies exceptions have been approved by IRB or provides sample delayed-onset language for PI. 3. As necessary, evaluated in collaboration with PI and ORC.
Awardee Role and Responsibility	1. Executing and maintaining Authorization Agreements as evidence of compliance with policy • Documents respective authorities, roles, responsibilities, and communication between sIRB and participating sites 2. Establishing mechanism for communication between sIRB and participating sites	1. PI assists ORC as needed to facilitate execution of Authorization (Reliance) Agreements with all participating sites. 2. Follow communication plan established by ORC and participating sites.	1. Following IRB approval of sIRB Plan, ORC will draft, negotiate, execute, and maintain Authorization (Reliance) Agreements with all participating sites. 2. ORC establishes communication mechanism with sites for compliance purposes.	No action required.

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sIRB "Reviewing IRB" or "IRB of Record" Role and Responsibility	1. Conduct ethical review in accordance with 45 CFR 46 2. May serve as Privacy Board for use or disclosure of protected health information for HIPAA Privacy Rule 3. Work with Awardee to establish mechanism for communication with participating sites	1. Submits AU IRB Protocol for all sites. 2. Includes request for any Privacy Board review in AU IRB Protocol. 3. Follow communication plan established by ORC and participating sites.	1. IRB reviews and approves (or requires changes). 2. IRB serves as Privacy Board when required or requested. 3. ORC establishes communication mechanism with sites.	1. OSP verifies IRB approval prior to account setup. 2. No action required. 3. No action required.
Participating Site "Relying Institution" Role and Responsibility	1. Rely on sIRB for 45 CFR 46 review 2. Meet other regulatory obligations • Obtaining informed consent • Overseeing implementation of approved protocol • Reporting to sIRB - Unanticipated problems - Study progress • Note: May serve as Privacy Board for HIPAA compliance. 3. Provide information to sIRB: • Local context • State/local regulations 4. Not prohibited from duplicating sIRB review, NIH funds may not be used for duplicate review	1. PI follows sIRB Plan. 2. PI works with AU IRB and ORC to address other regulatory obligations. 3. PI includes relevant local context and/or state/local laws in sIRB Form. 4. If applicable, PI submits protocol for AU only to AU IRB.	1. IRB/ORC follow sIRB Plan. 2. IRB and ORC work with PI to fulfill other regulatory obligations. 3. IRB determines local context. ORC communicates to sIRB. 4. AU IRB reviews and approves (or requires changes).	1. OSP verifies IRB approval prior to account setup. 2. No action required. 3. No action required. 4. No action required.