**NIH Single IRB Policy FAQs for the Extramural Community**: <https://www.aamc.org/download/474322/data/nihfaqsforsingleirb.pdf>

**What types of studies does the single IRB policy affect (new, existing, etc)?**

The policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subject’s research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

The policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018.  Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.  For contracts, the policy applies to all solicitations issued on or after January 25, 2018.  For the intramural program, the policy applies to intramural multi-site studies submitted for initial review on or after January 25, 2018. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

**When (and how) should I submit a request for use of a Single IRB?**

**The earlier you contact the IRB office the better we can assist you. Please contact the IRB Director, Millie Maleckar or email irbreliance@bsd.uchicago.edu.**

**I am applying for a grant and want to comply with the NIH policy, where do I get started?**

**Contact the IRB office so we can assist in providing grant language describing the use of a Single IRB review process.**

**I am writing a grant for a multi-site study. Is there specific language to include in the grant to indicate single IRB review?**

**Yes. We can assist in language describing the use of a Single IRB review process to be included in the grant submission.**

**I already have a grant but wish to comply with the policy.  What do I do?**

**Contact the IRB office as soon as possible so that the reliance process can begin with the relying sites’ IRBs. Provide the IRB number of the currently funded study.**

The NIH policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018.  Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.

**Who decides if University of Chicago will be the IRB of Record?**

**It depends. If the study is a network or consortium funded study, the network will often name the IRB of Record. For NIH funded studies, the lead PI may request his/her institution to be the IRB of Record; however, the institutional official (IO) makes the determination of whether the institution will serve as IRB or Record or not. All requests should be submitted to IRB office for consideration using the proposed reliance form.**

**Are there exceptions to the NIH single IRB review policy?**

**The NIH may grant exception if the use of a single IRB review is prohibited by federal, state, or tribal laws or regulations or where the use of a single IRB review is prohibited by established policy.**

**Who pays for the single IRB review?**

**At this time, the University of Chicago is not charging for single IRB review. The NIH policy states that costs associated with single IRB review may be charged as direct or indirect costs, provided they are well-justified and consistently treated according to applicable cost principles of the NIH. We will have more information forthcoming regarding costs for single IRB review.**

**NIH Guidance:** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html>

**When University of Chicago will be the IRB of Record and I am the lead PI:**

***What are my responsibilities to the University of Chicago IRB?***

**When serving as the lead PI and the University of Chicago is the IRB of Record, you are responsible for contacting the IRB office as soon as possible so that the reliance process can begin with the relying site IRBs. The IRB office will aid in gathering appropriate local context information and can provide assistance to you in submitting the appropriate information via AURA-IRB. You are responsible for submitting all study-related materials based upon University of Chicago policies and procedures, just as you would if you were conducting a single site research project at the University of Chicago. In addition, amendments adding relying sites will need to be submitted so that the relying sites receive the appropriate consent forms and documentation. The IRB office will aid in this process.**

***What are my responsibilities to the participating sites?***

**You are responsible for communicating approvals to the participating site PIs, as well as providing the approved study materials (application, protocol, site consent form, approval letter, measures, etc.). You are also responsible for submitting any study related reports from relying sites to the UChicago IRB for review and approval. Essentially, you are submitting all sites’ study reports, revisions for local context, amendments, continuing reviews, reports of non-compliance, and adverse events as you would if you were conducting the study only at the University of Chicago. The key difference is that you are now reporting for every site to the University of Chicago IRB.**

***What information do I submit for the continuing review?***

**At continuing review, you will submit a continuing review application, along with all continuing review documents for ALL SITES approved by the University of Chicago IRB.**

***If another site experiences an unanticipated problem, what do I do?***

**Report the event to the University of Chicago IRB as soon as possible. The IRB office will facilitate review of this submission and communicate with the relying IRB. As Lead PI, you are agreeing to be responsible for reporting these events in accordance to University of Chicago IRB policies and procedures.**

***What do I do if a participating site needs to amend their study documents?***

**You will need to obtain the study documents from the local site and submit these materials as an amendment to the University of Chicago IRB via AURA-IRB. Please consider whether the participating site’s revisions may also affect the other sites and make revisions, as necessary.**

***What do I do to amend the protocol and informed consent document for all sites?***

 **Submit an amendment to the University of Chicago IRB via AURA-IRB with any revised documents.**

***How do I add a new site to an existing study that has been approved under single IRB review?***

**Submit an amendment to add the site.**

**When University of Chicago is NOT the IRB of Record, but U of C is a participating site and I am the PI:**

***Do I need to submit anything to the University of Chicago IRB?***

**YES! You are required to submit an abbreviated application via AURA-IRB (through the Central IRB pathway). Even though another IRB has taken responsibility for the review of your research under the criteria required by the applicable federal regulations, there are still pieces of review that must occur at the University of Chicago. The IRB also requests copies of the consent document, protocol, and IRB approval letter from the IRB of Record for documentation purposes. An acknowledgement letter will be provided via AURA-IRB once all documentation has been reviewed.**

***What local information do we put in the template ICD?***

**The University of Chicago requires that that consent forms include U of C institutionally approved template language for subject injury and HIPAA authorizations. If you have any questions about language in the consent document, contact the IRB office.**

***Do I need to submit anything to the University of Chicago IRB at continuing review?***

**Yes, after receiving the approved study documents from the Lead site, submit the approved consent document, approval letter from the IRB of Record, and any additional supporting materials related to enrollment at the University of Chicago.**

***What if an unanticipated problem occurs, what do I do?***

**Any adverse event or non-compliance with the protocol that takes place at University of Chicago should be reported via AURA-IRB, as well. This is to ensure that appropriate human subjects protections are in place, and to aid in compliance monitoring for the study and investigator.**

***What do I do if I need to amend the study documents?***

**In AURA-IRB, please utilize the activity “edit study” to revise any documentation, including the protocol, consent form, or other documents consistent with the changes approved in the amendment. The protocol should then return to the “acknowledged” state once all changes have been incorporated.**

***What do I do if University of Chicago staff change?***

**The University of Chicago remains responsible for ensuring all staff listed on a protocol, even one reviewed by another IRB, are appropriately trained in human subject’s research protections. As such, a personnel change amendment should be submitted if new staff are to be added. As with other personnel changes, approval of the personnel changes must be granted before the individuals may begin work on the study.**