

Single IRB-of-Record: What Research Administrators Should Know Questions & Answers

When should investigators contact IRB if they want to use U-M as the SIRB?

Requests must be approved in advance by IRB leadership. We ask that investigators contact the U-M IRB **at least 8 weeks prior** to the grant or contract application due date.

When will the IRB inform the investigator of the decision regarding U-M serving as sIRB? How long before the deadline for the grant submission?

We typically can provide the decision within a week or two. It depends on the clarity of the information provided in the request form, and if we have any follow up questions.

Will this information be presented to investigators as well?

We have shared this information with investigators for several years, and the new PAF questions will remind them again. IRBMED has a dedicated presentation on sIRB. We encourage you to look for that presentation and encourage your study team(s) to attend an offering. Both IRBs have information about the process on their websites:

- [IRBMED](#)
 - [IRB-HSBS](#)
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Please clarify whether protocols at the multiple sites need to be the same in order to require the sIRB?

No, they do not need to be the same. If you are funded by a Common Rule agency it just needs to be a collaborative relationship to require an sIRB to be designated. For example, an NSF political science study could potentially require an sIRB to be designated. Or there may be a situation where each site is performing a different function. However, the sIRB requirement does not apply to research conducted by collaborators outside the U.S.

When will NIH require sIRB information with the application? What is required to submit with the application?

The IRB plan goes in at the time of award notice and does not need to be included with the application.

We have an ongoing multi-site study that has been receiving individual site IRB approvals. However, we've applied for additional NIH funding - would we need to convert our multi-IRB system to a sIRB?

Yes, if you acquire new funding, you will fall under the sIRB requirements.

If we will be a performance site for a consortium with another IRB being the sIRB of record, but we will also be coordinating with other hospitals across the state, should we do a multi-site application or just a performance site?

Clarify the expectation with the lead site as to how they intend to consider the relationships between U-M and other hospitals. Generally if ceding oversight, a ceding application would be required for U-M IRB acknowledgement of ceding to an external IRB.

Does the CTSU determine the costs for the IRB when they put together a budget for us?

The IRB offices do not work directly with the CTSU. We recommend that you contact the CTSU regarding their process.

I was told that the FDA doesn't follow the sIRB requirements that other federal sponsors do, but it wasn't clear when reviewing the FDA website. Can you clarify if FDA-funded grants require sIRB for multisite studies?

At this time there is no existing or pending FDA regulation requiring single IRB review of FDA sponsored multi-site research.

Will the new sIRB questions also appear on UFAs?

No. The new sIRB questions will appear only on PAFs in the [eResearch Proposal Management system](#) beginning September 14, 2020.