

**NIH-Sponsored Research Requirements:**

**Clinical Trials**

The NIH has instituted a number of requirements for clinical trials sponsored by NIH.  The intent of these new requirements is to improve the quality, consistency, efficiency, and transparency of clinical trials sponsored by the NIH. A summary is found on the NIH website at <https://grants.nih.gov/policy/clinical-trials/why-changes.htm>.

These requirements apply to IRB-HSBS investigators who conduct behavioral research that falls within the definition of a clinical trial. This guidance is intended to assist IRB staff in the review of research applications and in consultations with study teams. **Key Information**

1. **Definition of a Clinical Trial**

[NIH definition of a clinical trial](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) is:

*A research studyin which one or more human subjectsare prospectively assignedto one or more interventions(which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.*

The NIH Clinical Trials website <https://grants.nih.gov/policy/clinical-trials.htm> provide resources, including FAQs and case studies, to determine whether a particular project meets the definition of a clinical trial.

Projects funded after January 25, 2018, already include an indicator in the award notice (see screenshot below) to identify those projects that are subject to NIH Clinical Trials requirements. The IRB staff does not make this determination.

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**NOTE:** the exception to this would be for program or center grants. Although the indicator might be “no”, the projects funded under the grant could be required to register (as determined by NIH).

1. **ClinicalTrials.gov \***

As of January 18, 2017, a [new policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) requires that all new NIH-funded clinical trials, or those receiving a competing renewal, must be registered on [ClinicalTrials.gov](https://clinicaltrials.gov/), a website designed by the NIH and the FDA, and maintained by the National Library of Medicine that provides public access to information about clinical trials conducted in the United States and abroad.  Investigators are also required to submit results of the trial at the conclusion of the research.

Investigators are required to include the following information about ClinicalTrials.gov registration in the informed consent document (this text is included in IRB-HSBS consent templates):

*A description of this clinical trial will be available on* [*www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time*

**\* NOTE:**For research identified as Basic Experimental Studies with Humans (BESH) and submitted to those FOAs, the NIH will continue to expect registration and results reporting for these studies but is allowing additional flexibility to report on alternative portals instead of [ClinicalTrials.gov](https://clinicaltrials.gov/).

Administrative liaisons trained to assist investigators have been designated for schools and colleges that expect to obtain NIH funding for clinical trials.  In addition, the Medical School Research Regulatory Affairs team offers training in use of the ClinicalTrials.gov registration system and on the relevant policies.  See: <http://ttc.iss.lsa.umich.edu/ttc/?s=clinicaltrials.gov&submit=Search>.

**NOTE:** IRB-HSBS PI questions about NIH-funded clinical trials registration and reporting may be directed to Kate Sasamoto at orcr-deptemail@umich.edu.

Please note that investigators whose research involves clinical trials of investigational drugs and medical devices (FDA-regulated research that is reviewed by IRBMED), are required by [law](https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission) to register and report results on ClinicalTrials.gov.  In addition, investigators wishing to publish in [ICMJE](http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/) journals must also register their clinical trials at the website.

1. **Good Clinical Practice (GCP) Training**

As of January 1, 2017, [National Institutes of Health (NIH) policy (NOT-OD-16-148](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html)) requires investigators involved in the conduct, oversight, or management ofNIH-funded clinical trials to be trained in GCP principles which constitute international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials.  The GCP training requirement for NIH-funded clinical trials is in addition to (and does not replace) required basic human subjects protection training (e.g. U-M’s PEERRS human subjects modules).  All NIH-funded clinical trial study team members, except administrative staff, are required to complete GCP training.

GCP training modules for social and behavioral researchers can be found in the MyLinc system under the MICHR, [Social and Behavioral Research Best Practices](https://maislinc.umich.edu/maislinc/learner/search/catalog?RootNodeID=-1&NodeID=464&UserMode=0).

**NOTE:** Currently, U-M cannot support non-U-M research partners’ use of MyLinc to complete this training. However, the Society of Behavioral Medicine is hosting the same training on their site. Non-U-M partners may be referred to the site link (below) for access to the training after setting up a free account.

<http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>.

For a fee, this training is also available through the CITI program <https://about.citiprogram.org/en/course/gcp-social-and-behavioral-research-best-practices-for-clinical-research/>.

1. **Single IRB for Multi-Site Studies**

Effective September 25, 2017, NIH policy requires the designation of a [single IRB-of-Record](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) for multi-site clinical trials where the same non-exempt protocol will be implemented at multiple sites.  A plan designating a single IRB must be included in proposals submitted to the NIH as of the effective date.  Investigators planning multi-site studies should check with the IRB as part of early planning. In some cases, it may be appropriate for a commercial IRB to provide oversight for multi-site studies. The policy includes links to information on how costs may be charged as direct versus indirect costs.

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