You may find the following resources from Harvard Catalyst helpful as well:

- General Overview - https://catalyst.harvard.edu/programs/regulatory/clinical-trial-reg.html
- Registration Tip Sheet - https://catalyst.harvard.edu/pdf/regulatory/CTR3_%20RegistrationTips.pdf
- Required Results Reporting Data Elements Overview - https://catalyst.harvard.edu/pdf/regulatory/CTR3_ResultsReporting.pdf
- Outcome Measure Considerations - https://catalyst.harvard.edu/pdf/regulatory/CTR3_OutcomeMeasures.pdf

For detailed instructions on the IRB clinicaltrials.gov process, please see SOP: clinicaltrials.gov (HRP-102).

Still want to know more?

Check out the NIH policy overview video which may be found here - https://grants.nih.gov/policy/clinical-trials/overview-policies-resp/story_html5.html

Questions?
Contact the IRB Office

Harvard University IRB

Smith Campus Center

1350 Massachusetts Ave

Suite 645 (6th floor)

617-496-3985

cuhs@harvard.edu

Guidance on NIH regulations that may affect your research

Part II: Requirements for research that meets the NIH definition of a clinical trial

Is your study funded by the NIH? This could be through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program. If so, there are additional requirements that you must be compliant with.

NIH REQUIREMENTS FOR RESEARCH THAT MEETS THE NIH DEFINITION OF A CLINICAL TRIAL

The NIH defines a clinical trial as:

A research study in which one or more human subjects are prospectively assigned to 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.

To assist in making this determination, NIH has created a Clinical Trial Decision Tool - https://grants.nih.gov/ct-decision/index.htm.

More information about what NIH considers as a clinical trial may be found on the NIH website here -https://grants.nih.gov/policy/clinical-trials/definition.htm .

If your study meets the NIH definition of a clinical trial, the following requirements must be fulfilled:

TRAINING IN GOOD CLINICAL PRACTICE

All NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials are required to be trained in Good Clinical Practice (GCP). **GCP training is separate and distinct from the standard ethical conduct of human research training.**

The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials.

Please see the Training section of the IRB website for various GCP training options that are available - https://cuhs.harvard.edu/required-ethics-training

More information on Good Clinical Practice training may also be found on the NIH website here - https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

EXPANDED REGISTRATION AND RESULTS REPORTING IN CLINICALTRIALS.GOV

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov (https://clinicaltrials.gov/ct2/home) as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" (https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm) for competing applications and contract proposals submitted on or after 1/18/2017 .

ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

Information on Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov may be found on the NIH website here - https://grants.nih.gov/policy/clinical-trials/reporting/index.htm