Clinical Trials & ClinicalTrials.gov - Changes to the Federal policy and reporting requirements

National Institutes of Health (NIH) and the Food and Drug Administration (FDA)

Purpose: The data must be shared broadly and quickly. The Final Rule clarifies the law previously mandated in September 2000.

Applicable to: All Clinical Trials that are determined to be "Applicable Clinical Trials" (ACT), as defined by the FDA. These are covered by the FDA's Final Rule. In addition, this applies to all NIH Funded Clinical Trials, except for infrastructure grants and trials that were completed prior to January 18, 2017. If the study ends prior to January 18th, 2017, you should enter basic information about the study, but you are not required to submit results. If the study is completing after January 18th, 2017, you must and are required to do the reporting.

To determine if a trial is an "Applicable Clinical Trial" (ACT) for those trials other than NIH, please see the checklist on our website or by following the link here: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

A quick guide is below:

Is the study a CT? - YES

Is the study evaluating an FDA regulated drug or device? - YES

Is the study happening in the United States? – YES

Is there an IND or IDE? – YES

Is the product manufactured in the United States – YES

Is this a Phase I study? – YES

A Responsible Party is determined by the criteria below. In the case of Cooperative Agreements, the PI and study team must agree ahead of time who will be the responsible party. It will not be the NIH.

1) The sponsor - either the holder of the IND or the IDE
2) The person that initiates the Clinical Trial when awarded a grant (i.e. the NIH grantee).
3) The funder of a procurement agreement (i.e. funding by a contract). There are instances with a federal contract that NCI may be the responsible party (this should be identified in advance).
4) The provider of the study drug (typically the industry or pharmaceutical company providing the funding). The contract should clearly outline the responsible party.

Changes to the Policy: There are **new** registration data elements. These data elements are required when registering the trial and you can find them here: https://prsinfo.clinicaltrials.gov/definitions.html. On the next page, you will find links to registering a clinical trial on the clinicaltrials.gov website. Generally, if not a drug or device study, it would be excluded. However, vitamins, etc. are to be included under this rule. **When in doubt – register!!**

1) There must be only be one record per clinical trial

2) The study must be registered in clinicaltrials.gov before 1st participant is enrolled or no later than 21 days after enrollment of 1st participant for "applicable clinical trials." As part of the registration, the NIH grant number must be entered in study record. There must be a statement within the informed consent.

3) The study must be updated at least every 12 months (some information must be updated within 15-30 days of change)

4) Summary results must be reported no later than 1 year after primary completion date. The primary completion reporting refers to the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. This law was written by Congress, the FDA and NIH are just implementing the law. If you are seeking approval for licensing, etc., you are able to request a delay in the submission of this final reporting.

5) ICMJE – the reporting of results of a clinical trial won't interfere with your ability to publish. The ICMJE's criteria can be found here: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Failure to Comply: Institutions are required to implement no later than April 18, 2017.

1) Will result in withholding of clinical trial funding to the institution
2) Fines of up to $10,000 per day for non-compliance
3) Notification on FDP and NIHs website of non-compliance

HELPFUL LINKS:

FAQs (ClinicalTrials.gov): https://clinicaltrials.gov/ct2/manage-recs/faq#applicable

How to Register Your Study: https://clinicaltrials.gov/ct2/manage-recs/how-register

How to Edit Your Study Record: https://clinicaltrials.gov/ct2/manage-recs/how-edit

How to Submit Your Results: https://clinicaltrials.gov/ct2/manage-recs/how-report

The Final Rule, DHHS: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

The Final Rule, Webinar Series (3):

https://www.nlm.nih.gov/bsd/disted/video/clinicaltrials/finalrulewebinar1.html

https://www.nlm.nih.gov/bsd/disted/video/clinicaltrials/finalrulewebinar2.html

https://www.nlm.nih.gov/bsd/disted/video/clinicaltrials/finalrulewebinar3.html

Overview of ClinicalTrials.gov and Related Policies: https://prsinfo.clinicaltrials.gov/webinars/module1/index.html

Key FDAAA Issues: https://prsinfo.clinicaltrials.gov/webinars/module2/index.html