Policy on Clinical Trial Registration and Results Dissemination for Federally Funded Studies

This policy was taken from the following sites:

Effective for grant applications submitted on or after January 18, 2017, that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date, the NIH Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting.

The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded in whole or in part by the NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.
The signature of the AOR on the grant or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient’s clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.

2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.

3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the applicable clinical trial to comply with this policy.

Definitions

Clinical Trial. For purposes of this policy, a "clinical trial" means "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."3 This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions. This definition of "clinical trial"4 is broader than the term "applicable clinical trial" as defined in the regulation.5

Responsible Party. In the policy, the awardee or the investigator is responsible for meeting the expectations of this policy. In the regulation, a "responsible party" means, in part, "with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the
Primary Completion Date. In the policy, this term has the same meaning as the term "primary completion date" in the regulation, which is "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated."\(^7\)

Registration Information. In the policy, this term has the same meaning as the term "registration information" in the regulation. In the regulation, registration information consists of descriptive information, recruitment information, location and contact information, and administrative data.\(^8\)

Results Information. In the policy, this term has the same meaning as the term "results information" in the regulation. In the regulation, results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.\(^9\)

Compliance

If the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award. Failure to comply with the terms and conditions of the NIH award may provide a basis for enforcement actions, including termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

Effective Date
This policy is effective January 18, 2017.

Footnotes
1. ClinicalTrials.gov is operated by the National Library of Medicine within the NIH.
2. The Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11 was issued in the Federal Register in September 2016. The regulation implements section 402(j) of the Public Health Service Act.
4. Note that the regulation also includes a definition of "clinical trial." That definition is "a clinical investigation or a clinical study in which human subject(s) are prospectively
assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health related outcomes" (see 42 CFR 11.10 (a)). For the purposes of this policy, the regulatory definition and the definition in this policy are treated as synonymous.

5. In the regulation, applicable clinical trial is defined as an applicable device clinical trial or an applicable drug clinical trial. The regulation defines an applicable device clinical trial to mean, in part, "a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." The regulation defines an applicable drug clinical trial to mean, in part, "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase 1" has the meaning given in 21 CFR 312.21 (or any successor regulation).

6. See 42 CFR 11.10 (a) and 42 CFR 11.4.

7. See the complete definition at 42 CFR 11.10 (a).

8. See 42 CFR 11.10 (b) and 42 CFR 11.28 for the specific data elements.

9. See 42 CFR 11.28 for complete results information and specific data elements.