



Title: [NIH Clinical Trials Registration Policy](#)

Date of Last Revision: 02/21/17

Audience: Office of Research HRP

Definition / Criteria: https://osp.od.nih.gov/wp-content/uploads/2015/04/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf

NIH Definition of Clinical Trial

A research study¹ in which one or more human subjects² are prospectively assigned³ to one or more interventions⁴ (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.⁵

¹ See Common Rule definition of “research” at 45 CFR 46.102(d).

² See Common Rule definition of “human subject” at 45 CFR 46.102(f).

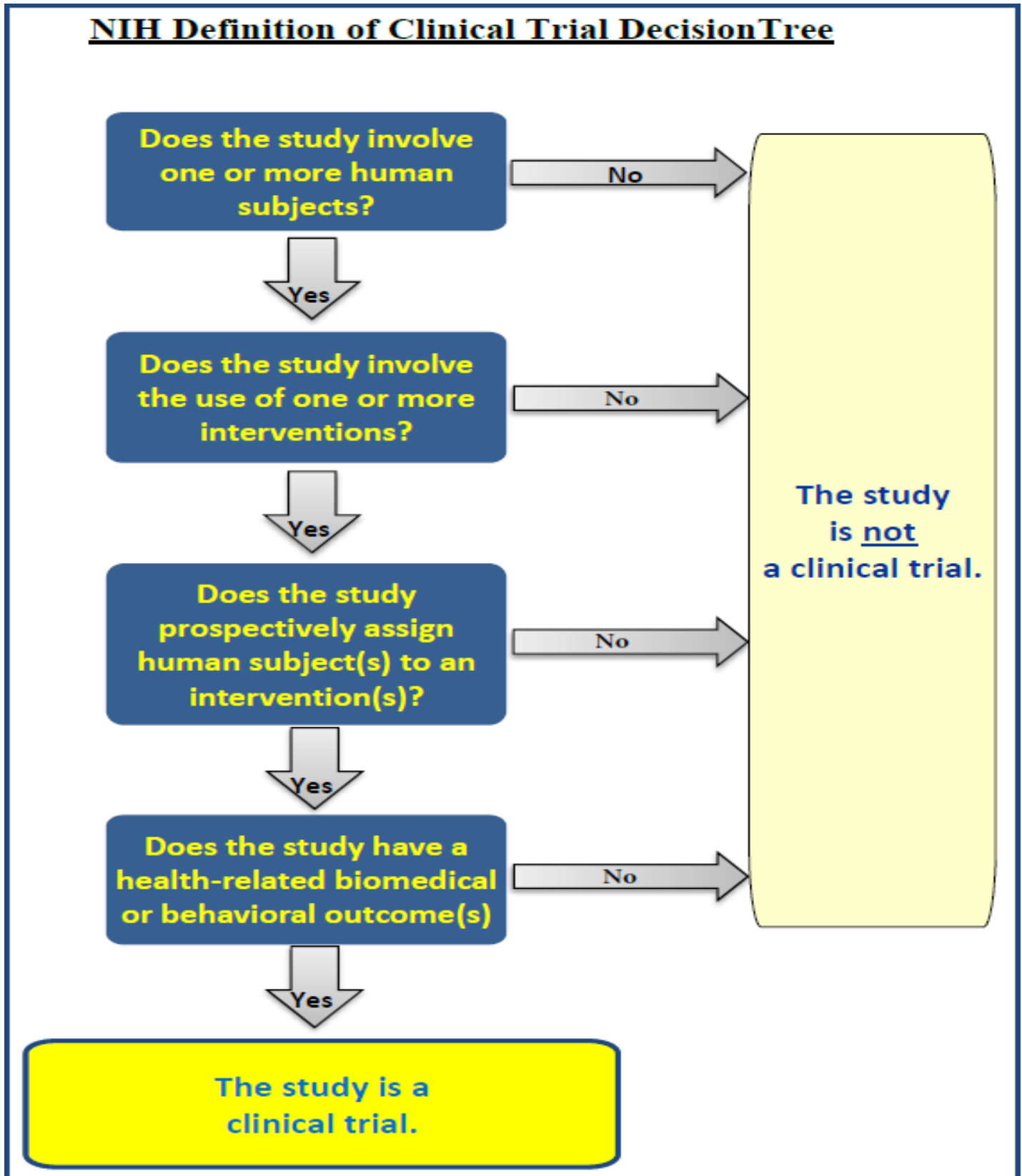
³ The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

⁴ An “intervention” is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

⁵ A “health-related biomedical or behavioral outcome” is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Revised Version Issued October 23, 2014

NIH Definition of Clinical Trial Decision Tree



Continuing Review

The image is a screenshot of a PDF document viewer. At the top, the browser address bar shows the URL <https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf>. Below the address bar is a toolbar with various navigation and viewing controls, including a zoom level of 96.4%. A blue banner at the top of the document area states: "Certified by Superintendent of Documents <pkisupport@gpo.gov>, United States Government Printing Office, certificate issued by VeriSign CA for Adobe CDS." On the right side of this banner is a "Signature Panel" icon. The document content is displayed in a large white area. At the top right of this area, the URL <https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf> is repeated in a yellow box. Below this, the document title "64926 Federal Register / Vol. 81, No. 183 / Wednesday, September 21, 2016 / Notices" is displayed. The main text of the document is organized into three columns. The first column discusses FDA regulations. The second and third columns discuss NIH-funded clinical trials and the requirement to publish results in peer-reviewed journals. A yellow highlight is present in the first column, covering a paragraph that states: "Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, we encourage all ongoing NIH-funded clinical trials to follow it. It is also critical for investigators conducting NIH-funded applicable clinical trials that are subject to the statute and rule to be sure they are in compliance with those requirements."

<https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf>

64926 Federal Register / Vol. 81, No. 183 / Wednesday, September 21, 2016 / Notices

circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval of a new use is being sought.

Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, we encourage all ongoing NIH-funded clinical trials to follow it. It is also critical for investigators conducting NIH-funded applicable clinical trials that are subject to the statute and rule to be sure they are in compliance with those requirements.

NIH-funded awardees and investigators will be expected to follow the provisions of the rule in terms of when they register their trials, what information they provide as part of the registration process, when they submit their results information, and what results information is submitted. All of the alternate approaches in the rule will also be available to those covered by the policy, e.g., for delayed posting of device registration information, delayed submission of results information for trials involving unapproved products or products for which a new use is sought, extensions for good cause, and waivers

NIH-funded investigators to publish the results of their studies in peer-reviewed journals.

We have no doubt that this policy will be beneficial for the research community as well as the public generally, but we recognize that adhering to it will be a new obligation. We will provide additional guidance to facilitate implementation and help awardees and investigators understand the policy as well as the tasks described in the rule that they will be expected to undertake. In terms of the costs of complying with the policy, grantees are permitted to charge the salaries of

NIH ClinicalTrials.gov Registration Policy – Checklist

ALL criteria below must be true to meet [NIH Policy](#) requirement:

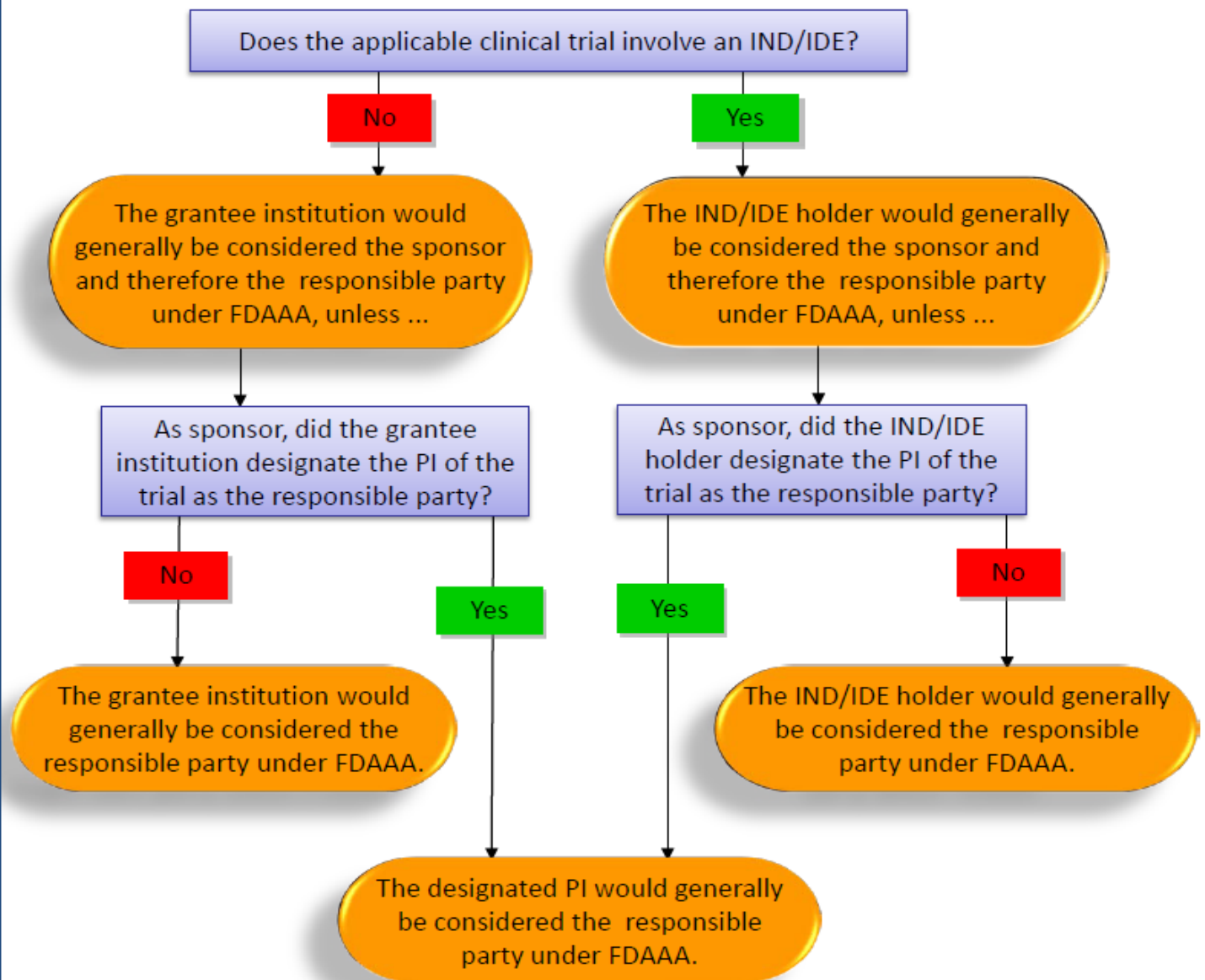
<input type="checkbox"/>	<p>NIH Funded: wholly or partially</p> <p>- verify the terms and conditions of the NIH award, which should indicate the study is identified as a clinical trial</p> <p><i>* does not apply to a clinical trial that uses NIH-supported infrastructure, which does not receive NIH funds to support its conduct</i></p>
<input type="checkbox"/>	Initiated on or after January 18, 2017
<input type="checkbox"/>	Meets definition of Human Subjects Research [45 CFR 46.102(d) and 45 CFR 46.102(f)]
<input type="checkbox"/>	Protocol includes prospectively assigning research participants to one or more arms of an intervention
<input type="checkbox"/>	<p>Protocol includes an intervention with an endpoint of modifying one or more health-related biomedical or behavioral processes</p> <p><i>[Includes 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)]</i></p>
<input type="checkbox"/>	Protocol includes a health-related biomedical or behavioral outcome endpoint(s) resulting from an intervention

LR Responsibilities:

<input type="checkbox"/>	Informed Consent documents need to include a specific statement relating to posting of clinical trial information at <i>ClinicalTrials.gov</i>
<input type="checkbox"/>	Each NIH-funded clinical trial should have only one entry in <i>ClinicalTrials.gov</i> that contains its registration and results information
<input type="checkbox"/>	<p>Timeline Submission to <i>ClinicalTrials.gov</i>:</p> <p>Registration: Not later than 21 days after enrollment of the first participant</p> <p>Results: Not later than 12 months after primary completion date</p>

Identifying the “Responsible Party” Under FDAAA for Applicable Clinical Trials Conducted Under NIH Grants

- This flowchart presents basic guidance on determining what entity or individual would be considered the “responsible party” under FDAAA for applicable clinical trials conducted under NIH grants (including cooperative agreements). It maps out the guidance provided in the “Elaboration of Definitions of Responsible Party and Applicable Clinical Trial”, and is also available as an interactive flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm.
- This flow chart may not address every situation. The grantee institution’s sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.



https://grants.nih.gov/clinicaltrials_fdaaa/docs/registration_flow_chart.pdf

Registration Steps

Steps 1 and 2

1. Responsible Party (RP) will register at ClinicalTrials.gov: system will prompt questions to help determine whether a study is an ACT (applicable clinical trial)
2. PRS (ClinicalTrials.gov team) will review the registration information: 2-5 business days

Steps 3 and 4

3. PRS will provide comments to the RP: completion time depends on the comments and the response time from the RP and PRS *[this is an opportunity to verify the study is an ACT or not]*
*** a registration record can only be deleted if it has not yet been assigned an NCT#**
4. After review of comments are accepted, PRS will assign the registration record an NCT #: study will be posted publicly within 2 business days

Step 5

5. After an NCT # has been assigned (regardless of ACT/non-ACT status), there are obligations for providing system updates; and there are obligations for providing results (*results only for ACTs*)

* Only the RP can approve/release transactions (i.e., register, update, results) in the system; a designated/assigned individual can *prepare* the transactions