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 study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (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).

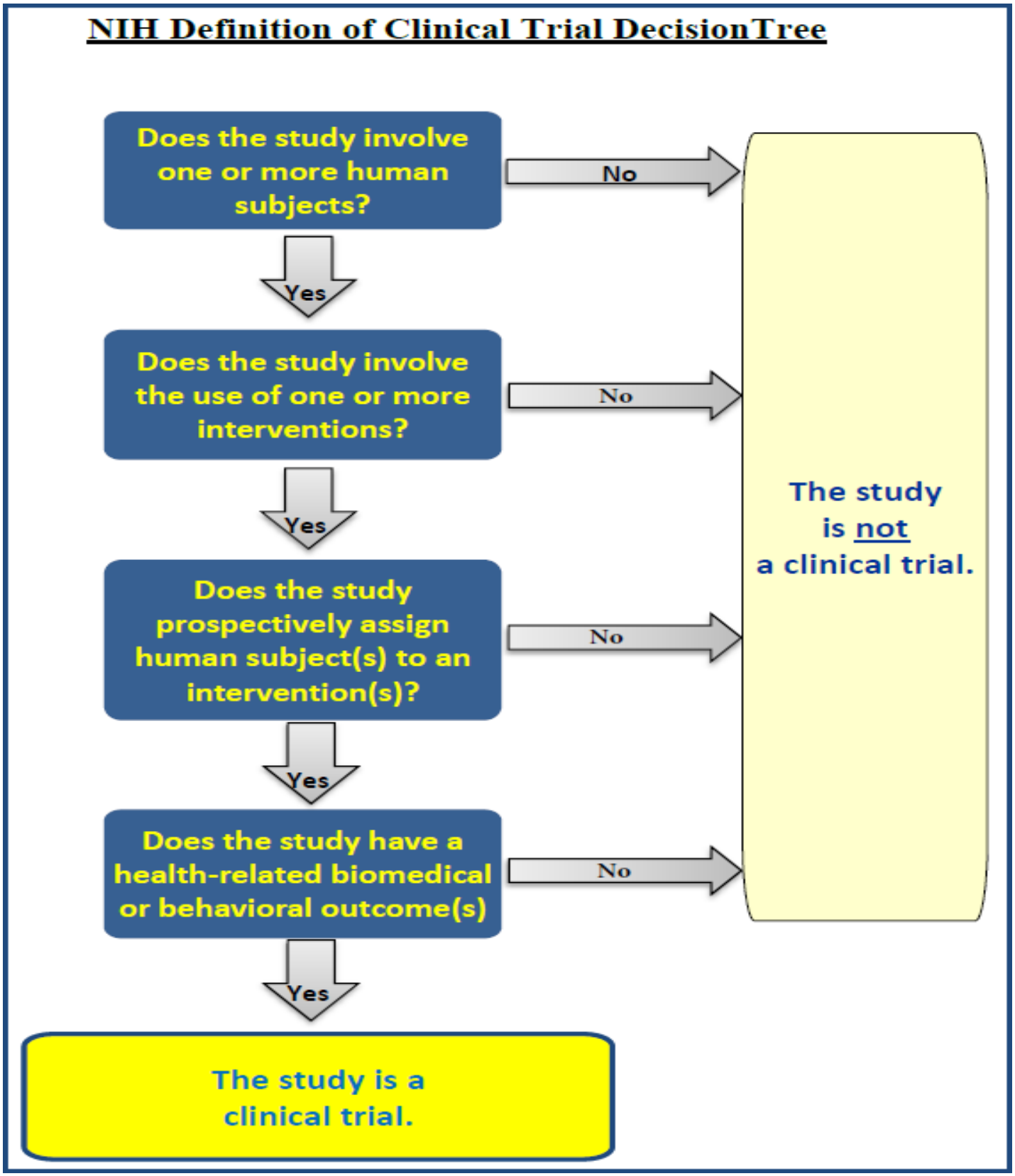
[3] The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[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.

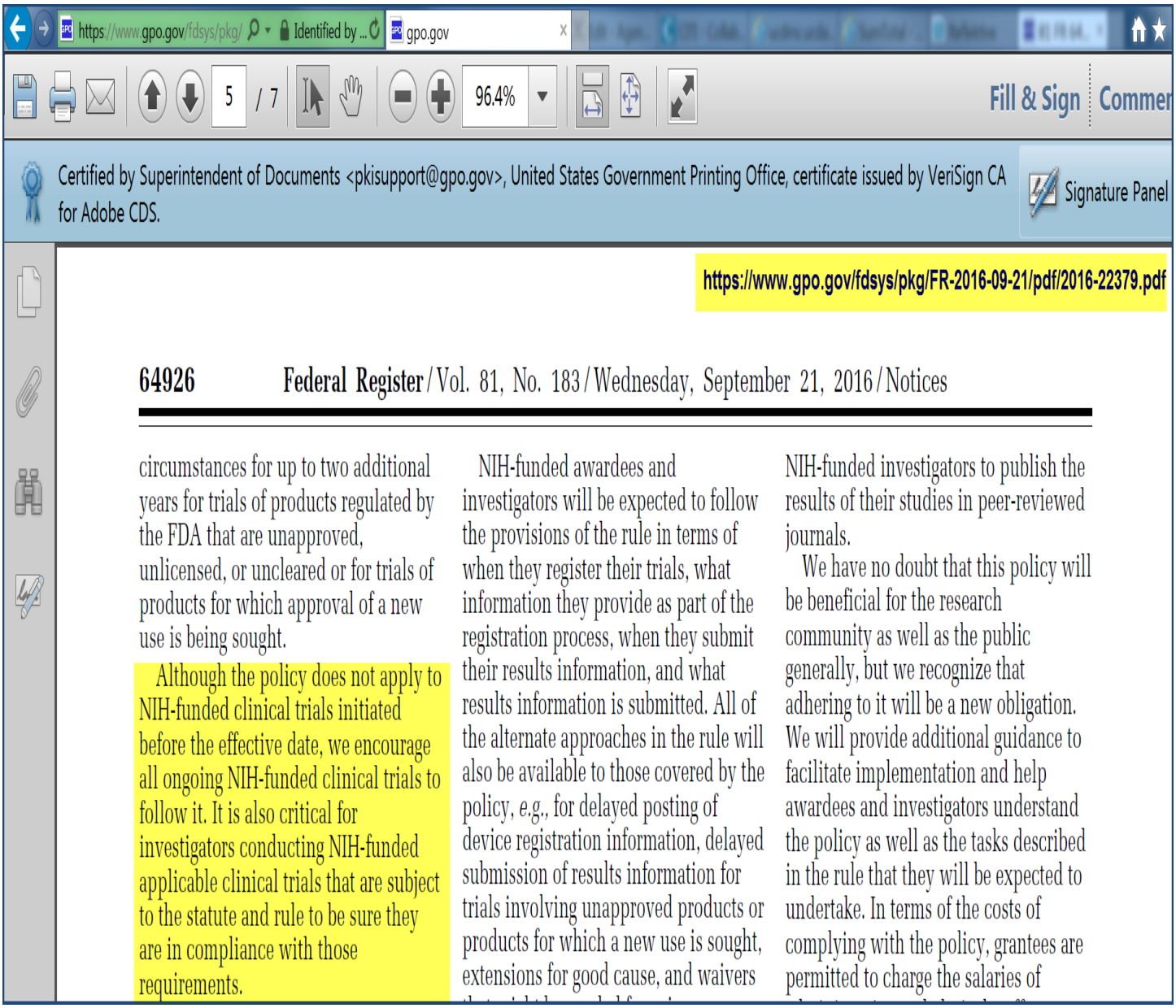
[5] A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or 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

Decision Tree: https://osp.od.nih.gov/wp-content/uploads/2014/11/NIH%20Definition%20of%20%20Clinical%20Trial%20Decision%20Tree-%20UPDATED.pdf



Continuing Review



NIH ClinicalTrials.gov Registration Policy – Checklist

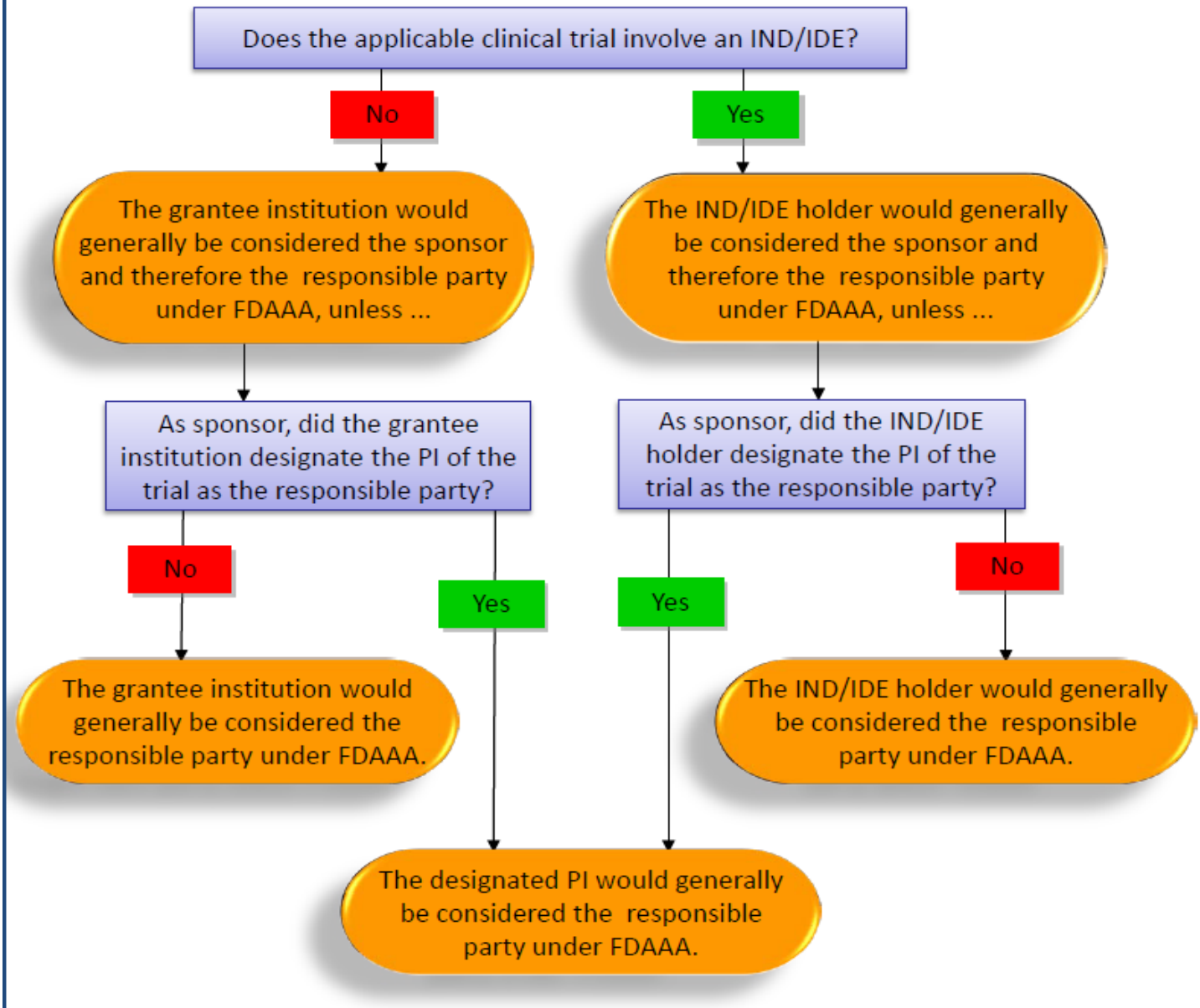
ALL *criteria* below must be true to meet NIH Policy requirement:	
☐	NIH Funded: wholly or partially - *verify the terms and conditions of the NIH award, which should indicate the study is identified as a clinical trial* * *does not* apply to a clinical trial that uses NIH-supported infrastructure, which does not receive NIH funds to support its conduct
☐	Initiated on or after January 18, 2017
☐	Meets definition of Human Subjects Research [45 CFR 46.102(d) and 45 CFR 46.102(f)]
☐	Protocol includes prospectively assigning research participants to one or more arms of an intervention
☐	Protocol includes an intervention with an endpoint of modifying one or more health-related biomedical or behavioral processes *[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)]*
☐	Protocol includes a health-related biomedical or behavioral outcome endpoint(s) resulting from an intervention

LR Responsibilities:	
☐	Informed Consent documents need 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
☐	*Timeline Submission to ClinicalTrials.gov:* Registration: Not later than 21 days after enrollment of the first participant Results: Not later than 12 months after primary completion date

Responsible Party for Registration

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