Clinical Trial Informed Consent Form Posting Requirements

Posting and Ensuring the ClinicalTrials.gov Statement is Included

to set a new account email: ctvgov@ucsd.edu

Revised Common Rule or 2018 Requirements to post the ICF applies if:

Clinical Trial:
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 the interventions on biomedical or behavioral health-related outcomes.

Funded or conducted by a Federal Agency:
Such as: NIH, DoD, FDA, CDC, etc.

IRB-Approved on or after 01/21/2019:
Will apply to clinical trials approved prior to this date when the (still active) trials are in transition to comply with the Revised Common Rule (AKA 2018 requirements)

*Post applicable trials within 21 days of enrollment of the first participant.

Case studies and other information at http://grants.nih.gov/policy/clinical-trials/definition.htm

ICF Posting Basics

- Awardees or the responsible party **(RP)** must publicly post on clinicalTrials.gov, one **blank** IRB-approved ICF.
- Post after the trial is closed to recruitment and no later than 60 days after the last study visit.
- Even if more than one IRB approved ICF exists, only one IRB approved ICF must be posted.

Determine whether a study is an NIH-funded clinical trial and/or an ACT!

A study is an **NIH-funded Clinical Trial** if you answer yes to ALL of the following questions or go: NIH Clinical Trial

Does the study…

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the effect of **intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?

A study is an **FDA Applicable Clinical Trial (ACT)** if you answer yes to ALL of the following questions

Is the study…

- ✓ Interventional?
- ✓ With at least one facility in the U.S. or U.S. territory? **OR** With FDA-regulated product manufactured in U.S. or U.S. territory and exported for study in another country? **OR** Conducted under an IND or IDE?
- ✓ Evaluating one drug, device, or biological product regulated by the FDA?
- ✓ NOT phase 0, NOT phase 1, NOT device feasibility study

Whereas the definition of ACT excludes phase 0 and phase 1 studies, the NIH definition of clinical trial does not

If the study you're reviewing is an NIH-funded clinical trial that is phase 0 or phase 1, the ClinicalTrials.gov statement is still required in the ICF

The ClinicalTrials.gov Statement

Certain clinical trials require an exact, unaltered statement in the ICF, which IRB Analysts will check for during pre-review

- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information available here
- Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) available here

While a statement is already included in the UCSD ICF template in the "What else is important for me to know?" section, Investigators must edit the statement appropriately depending on the following guidelines provided below.

If the study is interventional and evaluating an FDA-regulated product (regardless of funding source):

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

If the study is an NIH funded clinical trial that is not evaluating an FDA-regulated product:

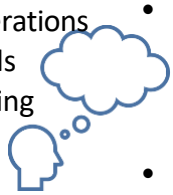
"A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

*Note: If the study is NIH funded **AND** interventional **AND** evaluating an FDA-regulated product, use the FDA-regulated product language above instead.*

If the clinical trial (per ICMJE) is to be published in an ICMJE Journal but is not an intervention of an FDA-regulated product, nor a clinical trial funded by NIH:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. You can search this website at any time.".

Considerations for Trials Evaluating Devices



- A study evaluating a device would only qualify as an ACT if the device must receive any of the following:
  1. A finding of substantial equivalence under section 510(k) of the FD&C Act; or
  2. An order under section 515 of the FD&C Act approving a pre-market approval (PMA) application for the device product; **or**
  3. A Humanitarian Device Exemption under section 520(m) of the FD&C Act
- Most Class I devices and some Class II devices are exempt from the requirements for a finding of substantial equivalence under section 510(k) of the FD&C Act and do not require a premarket approval order.
- By contrast, most Class II and all Class III devices require either clearance under section 510(k) of the FD&C Act or premarket approval under section 515 of the FD&C Act.

NIH Definitions

Health-related biomedical or behavioral outcome

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

- positive or negative changes to physiological or biological parameters (e.g., reduction of inflammatory markers, or gene expression with DBS for Parkinson's disease)
- positive or negative changes to psychological or neurodevelopmental parameters (e.g., cognitive function intervention for Alzheimer's disease participants, mood management intervention in multiple sclerosis)
- positive or negative changes to disease processes
- positive or negative changes to health-related behaviors
- positive or negative changes to quality of life

Prospectively assigned

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

Note: Single arm trials still qualify as prospective assignment if assignment is pre-defined in the protocol

Intervention

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

- 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

ACT Clarifications

ACTs are interventional studies that evaluate FDA-regulated drugs, devices and biologics (approved or not; with or without an IND or IDE). Details https://cdn.clinicaltrials.gov/documents/ElaborationsOnDefinitions.pdf

- **Does not include Phase 0 or Phase 1 studies**

  Although the term ''phase 0'' is used in practice (e.g., to refer to clinical trials that are exploratory in nature and are not designed to evaluate therapeutic or diagnostic intent), any trial that would be referred to as ''phase 0'' meets the definition of a phase 1 trial under FDA regulations (21 CFR 312.21).

  View the Phase 1 definition at here

- **Does not include device feasibility studies, which constitute:**
  - Evaluation of a device product in a small study (generally fewer than 10 participants) to determine the feasibility of the product; or
  - A study to test a prototype device for feasibility and not health outcomes.
    Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

?	**UCSD**: UCSD Clinical Trials FAQ Learn about ClinicalTrials.gov Process and Registration Registration Instructions and obtaining an account Factsheet Decision Tree for Registration and Results **ClinicalTrials.Gov:** ClinicalTrials.Gov FAQ Elaboration on Definition of ACT and Responsible Party ACT Checklist **NIH:** NIH Clinicaltrials.gov FAQ Case Studies to Determine if Study is a Clinical Trial Requirements for Reporting NIH Funded Clinical Trials
	Potential Consequences of Not Reporting to ClinicalTrials.gov **Risks:** Reputation Loss of Funding Potential Fines (up to $14,724/per study/per day) Investigators may face restrictions on publishing their studies in certain journals, as some have specific requirements for study registration with ClinicalTrials.gov prior to publication.
CONTACTS	**UCSD:** Research Compliance and Integrity Tel: 858 822-4939/Email: rci@ucsd.edu or ctgov@ucsd.edu **ClinicalTrials.Gov:** Contact ClinicalTrials.gov at register@clinicaltrials.gov team for assistance particularly when it comes to complex study designs or issues with submitting summary results information into The Protocol Registration and Review System (PRS). Note: A “Contact ClinicalTrials.gov PRS” link is available in the PRS system.

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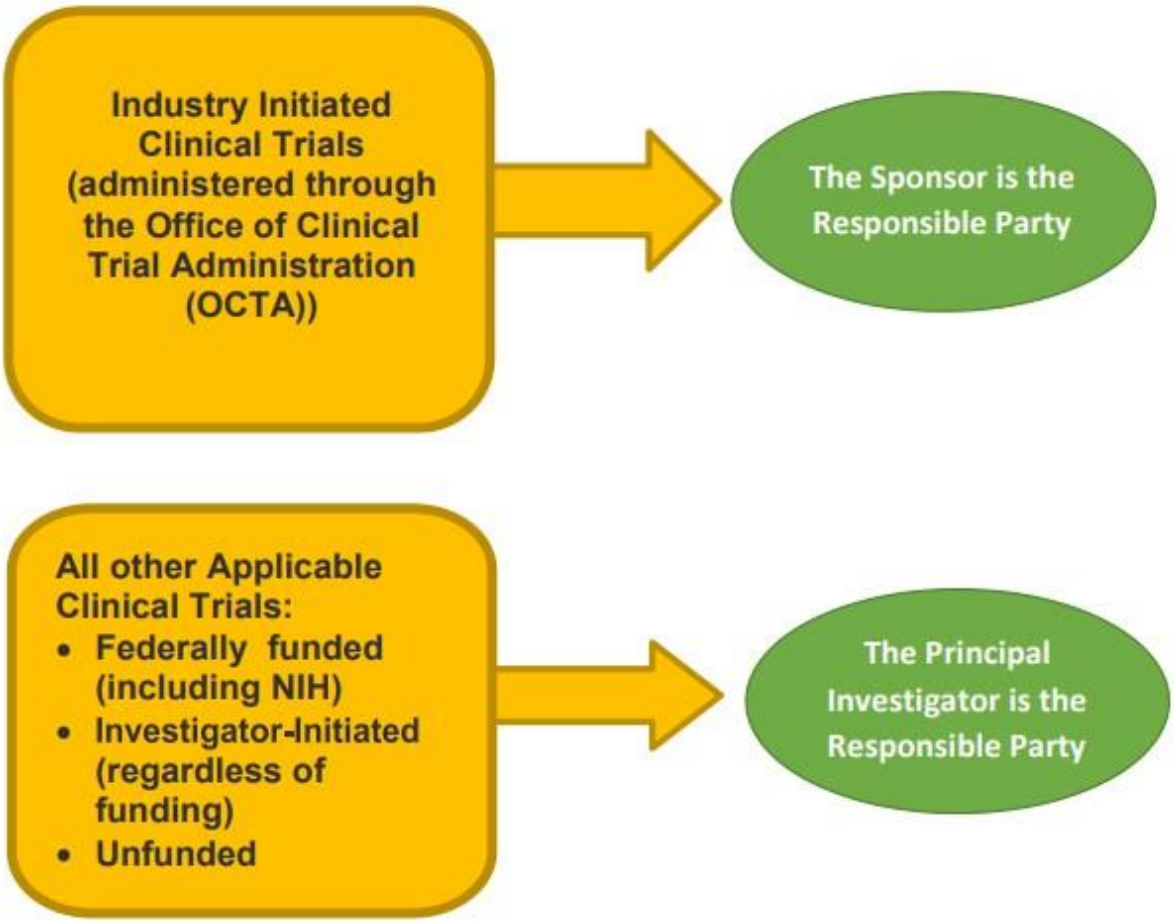
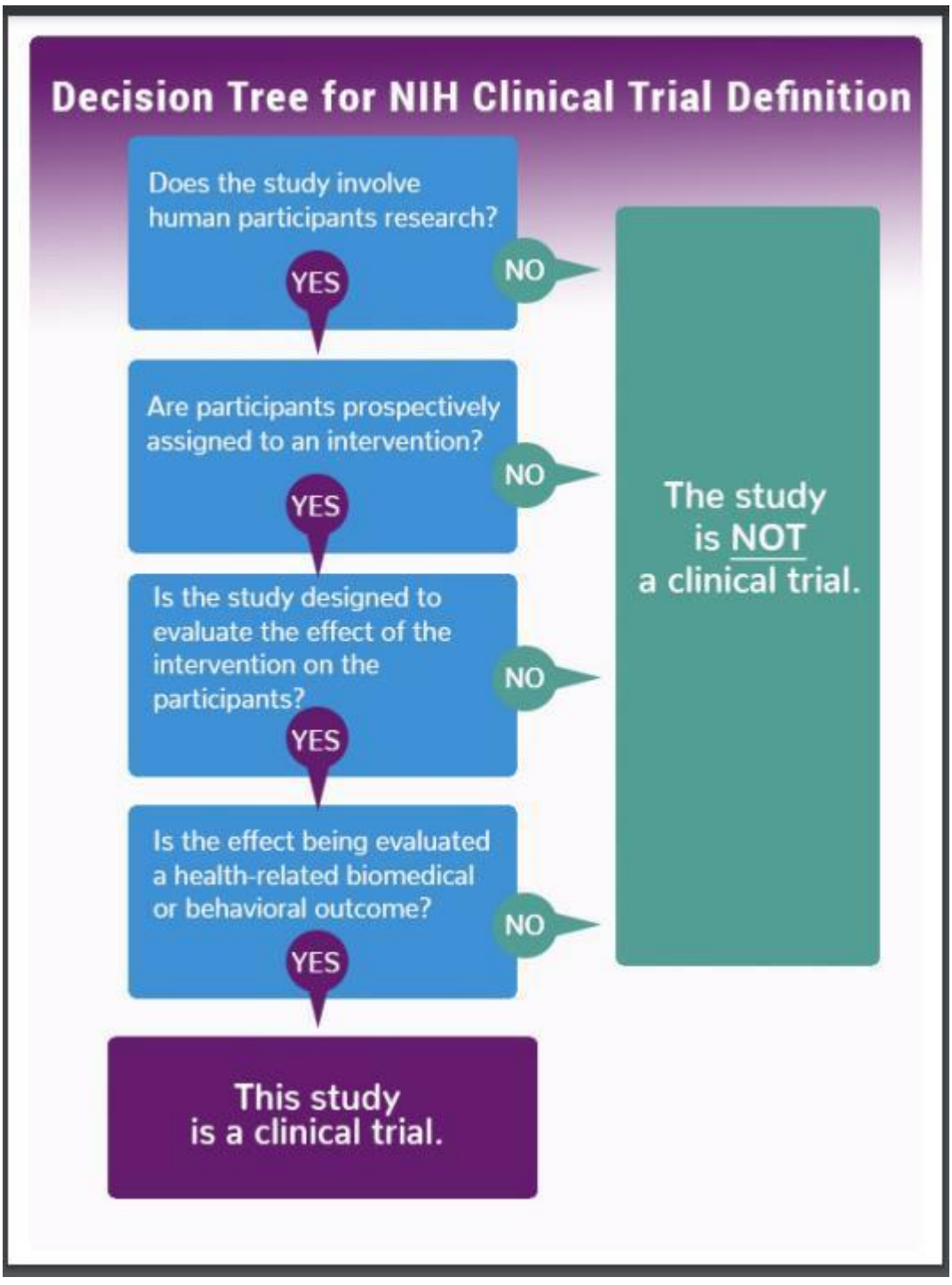
CLINICALTRIALS.GOV DETERMINING THE RESPONSIBLE PARTY DECISION TREE

The "Responsible Party" refers to the entity or individual who is responsible for registering a trial in a clinical trial registry data bank (i.e. ClinicalTrials.gov). The Responsible Party is the only user who is able to "release" the initial record and future updates for public view. The Responsible Party is also responsible to ensure that the trial registration stays accurate and up-to-date. There can only be one Responsible Party per trial registration.



Research Compliance and Integrity
Tel: 858 822-4939 / Email: rci@ucsd.edu
https://blink.ucsd.edu/sponsor/rci/index.html

https://cdn.clinicaltrials.gov/documents/ElaborationsOnDefinitions.pdf



NIH Clinical Trial