

Who is responsible for registering the trial on ClinicalTrials.gov?

The individual/entity responsible for registering the trial is the “[Responsible Party](#)”. The statute defines the responsible party as:

- The *sponsor* of the clinical trial, (as defined in [21 C.F.R. 50.3](#))
-OR-
- The *principal investigator (PI)*, if the PI:
 - Is so designated by a sponsor, grantee, contractor, or awardee,
 - Is responsible for conducting the trial,
 - Has access to and control over the data,
 - Has the right to publish the results of the trial, and
 - Has the ability to meet all of the requirements for the submission of clinical trial information.

[Click here for NIH Flowchart Identifying the “Responsible Party” for Applicable Clinical Trials.](#)

[Click here for Elaborations of Definitions of Responsible Party.](#)

*The guidance below provides a few categories of trials under which the **sponsor/funding agency** should be the “responsible party” to register the trial on Clinicaltrials.gov:*

- Industry sponsors should take responsibility to register the trial if:
 - The study/protocol is **industry-initiated** (industry-written protocol), or
 - The industry sponsor is the **applicant/holder of an Investigational New Drug (IND) or Investigational Device Exemption (IDE)**.
- For **multi-site** and **subaward** trials, the lead sponsor/site should take responsibility to register the trial. *If the USC PI is not the lead sponsor/site, he/she should consult with the lead sponsor/PI to ensure registration is competed and to avoid duplicate registrations.*

*The guidance below provides a few categories of trials under which the **PI** is the “responsible party” to register the trial on Clinicaltrials.gov:*

- The PI is considered the responsible party for registering the trial for:
 - **Investigator-initiated** trials, regardless of the funding source, including unfunded studies (e.g., gifts, departmental funds, etc.), and those funded by non-profit organizations.
 - Studies involving an application where the PI is the **holder of an IND or IDE**.