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.