

Recording Sponsors and Responsible Parties - Include 20170721

Complete this section only if you require an XML document to register your trial with ClinicalTrials.gov.

The Responsible Party can be either a sponsor, principal investigator (PI), or sponsor/investigator. The term "responsible party" is either of the following:

1. **Sponsor.** Name of the primary organization that oversees the implementation of the study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3.
- or -
2. **Principal Investigator.** The individual who serves as the principal investigator and is designated as responsible party, consistent with the conditions described in the statute.
- or -
3. **Sponsor-Investigator:** The individual who both initiates and conducts the study.



For further elaboration on the definition of these roles with respect to responsible party, refer to <http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>.

The fields displayed in the Sponsor/Responsible Party section depend on your selection of the Responsible Party role:

- If you select **Sponsor**, you do not submit any further information about the Responsible Party.
- If you select **Principal Investigator**, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section.
- If you select **Sponsor-Investigator**, this section expands to display the investigator's title and organization affiliation. Although the system populates the Investigator's name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section, you can select another person for this role.

How to Complete the Sponsor/Responsible Party Section

1. Complete the Lead Organization/Principal Investigator section, as described in [Recording Lead Organizations and Principal Investigators](#). Doing so will ensure that the Sponsor/Responsible Party section is pre-populated when applicable.
2. In the Sponsor/Responsible Party section, select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Sponsor	Click Look Up Sponsor and search for the organization as per the instructions in Looking Up Registered Organizations .
Responsible Party	Indicate the party who is responsible for the trial. Select one of the following options: <ul style="list-style-type: none">• Sponsor. Name of primary organization that oversees implementation of study and is responsible for data analysis. If you select this role, you do not submit any further information about the Responsible Party.• Principal Investigator. Primary medical researcher in charge of carrying out a clinical trial's protocol. If you select this role, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section.• Sponsor-Investigator. The individual who both initiates and conducts the study. If you select this role, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section.
Investigator*	If the Responsible Party is the Principal Investigator, you can not change the person's name. If the Responsible Party is the Sponsor-Investigator, you can change the person's name. To do so, click Look Up Sponsor , and follow the instructions in Looking Up Registered Persons .
Investigator Title*	The system populates this field. Enter a new title in the field provided if other than Principal Investigator.
Investigator Affiliation*	If the Responsible Party is the Principal Investigator, you can change the affiliated organization. To do so, click Look Up Organization , and follow the instructions in Looking Up Registered Organizations . If the Responsible Party is the Sponsor-Investigator, you can not change the affiliated organization.