correct a problem record for which they are the RP, removing the RP for an Administrator to correct a problem record is the only way the record can be released for PRS review.

Record Owner- PRS account holder who creates a study record in the PRS**.** Record Owners can maintain the record themselves or give one or more users access to a record to make changes. An Administrator can change the Record Owner after the record has been created. At Ohio State, record owners are often research coordinators, co-investigators, or the Principal Investigator (PI) of the protocol.

Responsible Party (RP)-FDAAA 801 and NIH state that the entity or individual responsible for registering a clinical investigation and submitting clinical trial Information to the ClinicalTrials.gov Registry Data Bank is known as the Responsible Party. The Responsible Party for a particular study may be the Sponsor (as defined in section 50.3 of Title 21, Code of Federal Regulations (or any successor regulation), Sponsor-Investigator, or Principal Investigator if so designated by a Sponsor, grantee, contractor, or awardee, so long as the Principal Investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements (under the regulation) for the submission of clinical trial information. When the Responsible Party is the Sponsor, an Administrator performs these record functions. The person identified as the Responsible Party for the Sponsor Organization account acts as the official contact person for that account and full contact information for that person must be listed in the PRS account. At Ohio State, the PI should be listed as the Responsible Party.

Sponsor Organization- A company, university, medical center, or other research organization that conducts clinical trials. Each study record has a Sponsor Organization, and all PRS accounts associated with that record should be under the Sponsor Organization. Investigators apply to be users of the Sponsor Organization's PRS account. (If an investigator is conducting trials for more than one Sponsor Organization, he or she will need an account from each of those organizations to register the studies properly.)

User- Any PRS account holder who is authorized to enter information into the PRS, including investigators or research assistants. Users create and modify their own records but cannot access other users' records unless authorized by the Record Owner or by an Administrator.