



Monday Morning Practice Pearls #65

[How do we interact with the Protocol Services Section \(PSS\) to register a protocol with clinicaltrials.gov?](#)

The Office of Research Support and Compliance (ORSC) Protocol Services Section (PSS) provides centralized support services for clinical researchers. One of their services is to register protocols with the National Library of Medicine on clinicaltrials.gov.*

While some of the data that is needed for registration is in PROTECT and the CC Protocol Query System (PQS), PSS will create a lay summary/lay protocol title from the protocol document that is sent to clinicaltrials.gov.

Any modifications to the summary need to be sent via an email to the CC protocol services mailbox - CC_Protocol_Services@cc.nih.gov.

[Who receives the lay summary?](#)

The summary is routed through Stacie Jeter in the Protocol Support Office (PSO) to the PI for input/edits and then returned to PSS.

[Why is it important for the investigator to review the protocol summary before it is registered on Clinicaltrials.gov?](#)

- The lay summary informs clinicians and the public about the clinical research trial
- The lay summary protocol endpoints, drug administration, completion dates and arm/groups will be reviewed prior to results reporting per the Food and Drug Administration Amendments Act of 2007 (FDAAA).

[What happens after the lay summary is sent to OPS?](#)

- The PSS will register the protocol on clinicaltrials.gov.
- The study can be opened to accrual when the study is posted on clinicaltrials.gov, other activation/initiation activities listed the Study Status Change form are completed (see [SOP PM-7 Clinical Research Study Initiation](#)), and a change to the accrual status is submitted in iRIS.
- If changes to the information posted on clinicaltrials.gov are needed, see [M2P2 #11](#).

* PSS will provide registration when the NIH is the responsible party. For industry-sponsored protocols or other multi-site protocol in which the NIH is not the lead site/coordinating center, PSS will not be registering the protocol.