



## Monday Morning Practice Pearls #65

### How do we interact with the Office of Protocol Services (OPS) to register a protocol with clinicaltrials.gov?

The Clinical Center's Office of Protocol Services (OPS) 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 iRIS, OPS will create a lay summary/lay protocol title from the protocol document that is sent to ct.gov. The lay summary is independent from other data the OPS receives via iRIS.

Any modifications to the summary need to be sent via an email to the protocol services mailbox - [CC\\_Protocol\\_Services@cc.nih.gov](mailto: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 OPS.

### Why is it important for the investigator to review the protocol summary before it is registered on CT.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 OPS will register the protocol on clinicaltrials.gov.
- The study can be opened to accrual when the study is posted to CT.gov and other activation/initiation activities are completed, and a change to the accrual status is submitted in iRIS on the Study Status Change form.

\* OPS 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, OPS will not be registering the protocol. As part of the IRB new protocol application process, iRIS asks a question about the responsible party and, if not the NIH, then the NCT number needs to be provided when it is available. This will avoid a double registration for these types of protocols.