A study is an "SIR" when the IND or IDE is held by a STANFORD Investigator

Holder of the IND or IDE = "Sponsor" per Federal Regulations

eProtocol Information (Sections 5 and 6):

- Investigational Drug: IND number *(Confirmed with attached FDA documentation)*
- Investigational Device: IDE number *(Confirmed with attached FDA documentation)*
- Holder of IND/IDE must be indicated: If "*The IND/IDE is held by the STANFORD Investigator …*" is selected, then it is SIR.

Attachments for eProtocol (Section 16), as applicable:

- FDA IND letter of acknowledgement and/or documentation of no objection *("okay to proceed")*
- FDA IDE Approval letter (for Significant Risk Devices only)
- Clinical protocol *
- Investigator Brochure or other product information (if IND) *
- Device Manual (if IDE) *
- All correspondence with the FDA on the IND or IDE
- Confirmation of IND/IDE Training - *sent to IRB Manager by RCO-CQI*

* Updates should be submitted to IRB

Additional for IND (Investigational Drug) Section 6:

Pharmacy Dispensing or Security and Controlled Access Plan:
If "No" pharmacy dispensing, a Security and Controlled Access Plan must be described in Section 6 or attached in Section 16.

Reports from IND Holder (attach in Section 16):

➔ **Continuing Review**

- Annual Report to FDA: *Required within 60 days of FDA IND effective date.*

Additional for IDE (Investigational Device) Section 5:

Device Ordering, Storage and Control:
PD confirms that the device will be handled according to the SHC/LPCH policy for Investigational New Devices or provides an explanation, if no.

Reports from IDE Holder (attach in Section 16)

➔ **Continuing Review (Significant Risk Devices):**

- Progress Report to FDA and IRB: *At least annually from FDA approval letter, and/or due date shown on FDA approval letter*

➔ **Modification (prior to Final Report)- Study Closure** [21 CFR 812.150 (b)(7)]

Significant Risk Devices:

- Final Report to FDA: *Required within 6 months of study completion or termination.*
- Final Report to IRB: *Required within 6 months of study completion or termination, should include final report to the FDA.*

Non-Significant Risk Devices:

- Final Report to IRB: *Required within 6 months of study completion or termination.*