

Investigator completes **Concept Sheet (CS)** template and submits via email to stictg@fhi.org by deadline listed on website

Concept Sheet Review Process

The STI CTG **Executive Committee (EC)** screens the **CS** and then forwards them with comments to the **Scientific Review Committee (SRC)**. The **SRC** reviews and scores the **CS's** and forwards scores to the **EC**. Final approval/disapproval decision is made by the **EC**.

Investigator is notified of the STI CTG's decision within 2 months of the submission deadline.

Investigator may submit a **new** or **revised** **Concept Sheet** template for the next review

Approved

Investigator completes **Protocol Outline (PO)** and associated documents (budget, etc), and submits electronically to STI CTG.

**Assistance may be requested from the STI CTG in Protocol Outline development.*

Investigator completes a **Full Protocol (FP)** and associated documents (budget, etc), and submits electronically to STI CTG.

**Assistance may be requested from the STI CTG in Full Protocol development.*

Protocol Outline Review Process

The EC reviews the PO and forwards with comments to the SRC. A SRC subcommittee (assigned by area of expertise) reviews PO documents, and provides feedback to author as appropriate (iterative process may apply). Final recommendations sent to the EC. The EC makes a final decision. Investigator is then notified of the STI CTG's decision.

Full Protocol Review Process

The EC reviews the FP and forwards with comments to the SRC. A SRC subcommittee (assigned by area of expertise) reviews FP documents, and provides feedback to author as appropriate (iterative process may apply). Final recommendations sent to the EC. The EC makes a final decision. Investigator is then notified of the STI CTG's decision.

EC **Disapproved**

Investigator may submit a **new** **Concept Sheet** for the next review deadline

EC **Disapproved**

Investigator **revises FP** and **resubmits** to the EC for continuing review

Approved

Investigator, EC, the STI CTG Protocol Specialist, and other STI CTG affiliates work together to develop and conduct the trial.

