Concept Approval

Protocol Development

With OPEN Text

Group submits EC to EMMES for CDE review.

Group submits

Protocol to CTEP for approval

EC form is revised

Protocol is revised

Data Management/IT

OPEN Administrator

Protocol Coordination

Protocol is activated and enrollments are processed in OPEN

Form is downloaded into OPEN by OPEN Administrator

EC form is loaded in CaDSR

Protocol is

Approved

CDE review is completed and form is not approved

Protocol Requires Revisions

CDE review is completed and form is approved

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Form set up completed/edits applied/form tested/end to end testing completed in OPEN