Steps that Precede Clinical Study Initiation (DSMB)

Review, finalize, and submit:
- Protocol
- Response to summary statement concerns
- Human Subjects Protection Plan/Safety Monitoring Plan
- Target Enrollment Form
- Human Subjects Training Certification (delivered to Grants Management Branch)
- Model Informed Consent Form

If NINDS agrees, schedule investigator meeting

Develop or revise study materials and procedures:
- Study organization
- Manual of Operations
- Study forms/CRFs
- Safety monitoring processes/reports
- DSMB report outline

Changes suggested by NINDS/DSMB?

YES

NO

Protocol, Informed Consent, or other study materials require changes

DSMB recommends to NINDS that study can begin

If NINDS agrees, schedule investigator meeting
Steps that Precede Clinical Study Initiation (SMC/IMM)

Review, finalize, and submit:
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- Response to summary statement concerns
- Human Subjects Protection Plan/Safety Monitoring Plan
- Target Enrollment Form
- Human Subjects Training Certification (delivered to Grants Management Branch)
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- Study organization
- Manual of Operations
- Study forms/CRFs
- Safety monitoring processes/reports

Changes suggested by NINDS?

Protocol, Informed Consent, or other study materials require changes

NINDS states study can begin