

# Extramural Site Activation Reference List

This is a general tool to guide investigators on items that are typically completed prior to study activation; i.e., authorization to recruit participants. An action item tracker that contains the items needed for activation will be tailored for the study and provided closer to the time of the initiation visit or teleconference.

**[ ]** IRB approval received for protocol and consent document(s), and study related materials to conduct the study are on site

**[ ]** Investigator Site File/Essential Documents file is complete

**[ ]** Manual of Procedures is near final

**[ ]** Case Report Forms (CRFs) are complete

**[ ]** Database finalized and available for data entry

**[ ]** Clinical Data Management Plan drafted

**[ ]** Clinical Quality Management Plan drafted

**[ ]** NIDCR has made the determination of safety oversight

**[ ]** Program Official confirmed that documents required for NIDCR Clinical Terms of Award (CToA) are satisfactory:

* + IRB Approved Protocol
	+ IRB Approved Consent Document(s)
	+ Data and Safety Monitoring Plan

**[ ]** Study/Site[[1]](#footnote-1) Initiation Visit (SIV) or Teleconference (SIT) completed

**[ ]** Critical action items identified during the SIV/SIT have been resolved

1. Note that an SIV/SIT is one of the activities needed prior to study activation. SIVs/SITs can occur at the study or site level. [↑](#footnote-ref-1)