**Tool Summary Sheet**

|  |  |
| --- | --- |
| **Tool:** | Extramural Site Activation Checklist |
| **Purpose:** | To clarify the items required prior to site activation for an NIDCR Extramural study. Explicitly included are more than minimal risk studies.  |
| **Audience/User:** | Lead Investigators and study team members of NIDCR Extramural studies, the Clinical Research Operations and Management Support team (CROMS), NIDCR’s Office of Clinical Trials Operations and Management (OCTOM), and Program Officials of the NIDCR |
| **Details:** | This checklist will be prepared by CROMS, and used by the NIDCR Program Official to determine when all requirements have been met for site activation. When all of these requirements have been met, CROMS will send the completed checklist to the OCTOM Director or designee for signature. The OCTOM representative will then forward the checklist to the appropriate NIDCR Program Official for signature. Upon approval, the NIDCR Program Official will send a Site Activation letter to the site PI and will provide copies of the letter and the Checklist to CROMS for the study file.  |
| **Best Practice Recommendations:** | * This checklist should be reviewed with the site investigator to ensure understanding of items required prior to site activation approval.
* The site may not begin enrollment until the site activation letter from the NIDCR Program Official is received by the site.
* Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
* Items in *blue italics* and enclosed in braces *{ }* are instructional text that should be deleted prior to use.
* Remove this Tool Summary Sheet prior to use of the Checklist.
 |

**Tool Revision History:**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 23Feb2012 | Separate document of the Checklist approved through the Guideline tool |
| 2.0 | 19Dec2013 | Added a footnote with final processing / storage instructions. |

|  Protocol <#> EXTRAMURAL SITE ACTIVATION CHECKLIST |
| --- |
| <Protocol title> |
| Site Name: |  | Site #: |  |
| Protocol Version and Date: |  |
| Item | Date |
| 1. IRB Approval Received for Protocol, Consent Form, and Other Applicable Documents
 |  |
| 1. NIDCR Safety Committee (e.g., CSOC, DSMB, DSMC) review complete or confirmation that no Safety Committee will be required
 |  |
| 1. Site Essential Document File Approved
 |  |
| 1. Case Report Forms Final
 |  |
| 1. Data Management System Ready for Data Entry and Clinical Data Management Plan Drafted
 |  |
| 1. Study Materials on Site

{Instruction: List types of required materials separately (e.g., specimen labels and tubes, questionnaires, supplies for procedures).} |  |
| 1. Site Initiation Visit Completed
* Trained on protocol, study procedures (MOP), electronic systems. (Note this requirement includes re-training, if site activation is more than 8 weeks after the site initiation visit.)
* Facilities deemed acceptable
 |  |
| 1. Action Items from Site Initiation Visit Required for Site Activation Completed
 |  |
| 1. Study Specific Requirements Met

*{Instruction: Update with relevant list.}* |  |
| 1. CToA Met and Notification of Award Sent
 |  |
|  |  |  |  |
|  |  |  |  |
| CROMS/DCC Representative Completing the Checklist |  |  | Date |
|  |  |  |  |
| Activation Recommended by <OCTOM Representative>, OCTOM |  |  | Date |
|  |  |  |  |
| Activation Approved by <NIDCR Program Official>, NIDCR[[1]](#footnote-1) |  |  | Date |

1. Forward an electronic version of this document that includes all signatures to the CROMS representative for storage in the study file. [↑](#footnote-ref-1)