**Tool Summary Sheet**

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| **Tool:** | Site Close-out Visit Readiness Checklist |
| **Purpose:** | To clarify the items required prior to scheduling a site close-out visit for an NIDCR supported study. |
| **Audience/User:** | Investigators and study team members of NIDCR studies, the Clinical Research Operations and Management Support team (CROMS), NIDCR’s Office of Clinical Trials Operations and Management (OCTOM), NIDCR Program Officials and DIR Clinical Research staff |
| **Details:** | This checklist will be prepared by CROMS, and used by OCTOM in coordination with the Program Official or DIR Clinical Research Staff to determine when all requirements have been met for a site close-out visit. |
| **Best Practice Recommendations:** | * This checklist provides sample standard items that are required prior to close-out. Customize or add to the list as appropriate for the specific needs of the study (e.g., additional pre-close-out data or regulatory reconciliations). * Add text to the checklist to clarify unusual circumstances as needed. * This checklist should be reviewed with the site investigator to ensure understanding of items required prior to site close-out. * The close-out visit may not be scheduled until all items on the close-out readiness checklist have been completed, including notification of approval for close-out. * Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate. * Remove this Tool Summary Sheet prior to use of the Checklist. |

**Tool Revision History:**

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| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 02Oct2012 | First approved version |
| 2.0 | 05Jul2013 | Revised item listing and removed requirement to enter item completion dates |
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| Protocol <#> SITE CLOSE-OUT VISIT READINESS CHECKLIST | | | | |
| --- | --- | --- | --- | --- |
| <Protocol title> | | | | |
| Site Name: |  | | Site #: |  |
| Final Protocol Version and Date: | |  | | |
| Item | | | | Yes/No |
| 1. Final subject has completed all visits. | | | |  |
| 1. Final site-level Quality Management activities have been completed per site Quality Management Plan, as applicable. | | | |  |
| 1. All site data for all subjects have been entered in database/CRFs.   Examples:   * All Adverse Events (AEs)/Serious Adverse Events (SAEs)/Unanticipated Problems (UPs) have been entered, events resolved, follow-up completed, and documentation reconciled. * Missing Forms lists have been provided to site study teams and all missing forms have been entered into the clinical database, or noted as not expected, and reviewed by the CRA and study/data management. * Concomitant medications have been entered in the clinical database and reconciled with medical history forms and/or AE forms, as appropriate. | | | |  |
| 1. Confirm with DCC that all queries (both auto and manual) are considered to have been resolved/closed. | | | |  |
| 1. Final Interim Monitoring Visit conducted per approved Clinical Monitoring Plan. | | | |  |
| 1. All action items identified during previous monitoring visits addressed and resolved. | | | |  |
| 1. Trial Master File review completed by owner and ready for reconciliation by CRA at close-out visit. | | | |  |
| 1. Notification provided by OCTOM / Program Official / DIR Clinical Director that site is approved for close-out visit. | | | |  |
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