**Tool Summary Sheet**

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| **Tool:** | **Essential Documents Checklist – NIDCR Clinical Research (Non-Interventional) Protocols** |
| **Purpose:** | **This checklist can be used to guide collection of documents to be reviewed by OCTOM, or designee, for activating a clinical research site planning to engage in an NIDCR-funded, more-than-minimal-risk, non-interventional human research project.** |
| **Audience/User:** | **Clinical Investigators, site study coordinators, OCTOM, and CROMS.** |
| **Details:** | **The documents listed here are the minimum documentation required by Good Clinical Practices (GCP) that will not have been otherwise collated or submitted previously to satisfy other NIH grant documentation requirements. OCTOM, or designee, will review the listed documents to ensure core aspects of GCP paperwork requirements are in place and in order for the clinical research project before the site is formally activated.**  **See** [**NIH Glossary for definition of Clinical Research**](http://grants.nih.gov/grants/glossary.htm#C) |
| **Best Practice Recommendations:** | * **This form includes a placeholder for the name and address of the individual/group who will be receiving and reviewing the documents. Replace with the appropriate name and contact information upon study specific implementation.** * **Unless otherwise instructed, provide photocopies of the listed documents; originals should be retained in the study trial master file (or equivalent) maintained for the project.** * **Communicate early with OCTOM representatives to clarify documentation obligations; doing so will minimize the risk of delays in clinical study initiation.** |

**Tool Revision History:**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 21DEC2010 | Approved version |
| 2.0 | 19DEC2013 | Revised document name, removed trial references and IoR Form requirement, and revised ICF reference to Consent Document. |

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| --- | --- |
| **Study Principal Investigator:** |  |
| **Clinical Site:** |  |
| **NIDCR Protocol Number and Title:** |  |

**CHECK TYPE OF IRB SUBMISSION:**

Initial Submission  Annual Renewal Submission

Amendment Submission  Other Submission (i.e., Revised Documents, Updated Versions)

**DOCUMENTS TO BE COMPLETED AND SUBMITTED BY SITE:**

Copy Form 1195 (intramural studies), dated \_\_\_\_\_

Copy of Protocol and/or Protocol Amendment(s) Signature Page (if applicable)

Information Given to Subjects (if applicable)

IRB/IEC Approval letter of Final Protocol Ver.

IRB/IEC Approval letter of Protocol Amendment Ver.

IRB/IEC Approval letter of Consent Document(s) Ver.

IRB/IEC Approved Consent Document(s) Ver.

IRB/IEC Approval letter of other information given to Subjects

IRB/IEC Approval letter of Advertisement for Subject Recruitment

IRB/IEC Approval letter of other materials, as required (e.g., CRF)

IRB Approval of Other IRB-required documents (e.g., CRF; specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**Check off document(s) enclosed and forward to the attention of:**

NAME

ADDRESS