**Tool Summary Sheet**

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| **Tool:** | **Essential Documents Checklist – NIDCR Clinical Trial (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 interventional human research project (whether IND-regulated or not).** |
| **Audience/User:** | **Clinical Investigators, site study coordinators, OCTOM, and CROMS.** |
| **Details:** | **The documents listed here are among the core documentation required by Good Clinical Practices (GCP) before a study is initiated. Additional GCP-required documents not included here are excluded because they will have been otherwise collated or submitted previously to satisfy NIH grant documentation requirements. OCTOM, or designee, will review the listed documents to ensure all GCP required essential documents are in place and in order for the clinical trial before the site is formally activated.**  [**See NIH Glossary for definition of Clinical Trial**](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 trial initiation.** |

**Tool Revision History:**

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| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 13DEC2010 | Approved version |
| 2.0 | 19DEC2013 | Added ‘Interventional’ to document name, removed IoR Form requirement, and revised ICF reference to Consent Document. |

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

**CHECK TYPE OF SUBMISSION:**

Initial Submission  Annual Renewal Submission

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

**DOCUMENTS TO BE COMPLETED BY SITE:**

For IND studies: Form 1572 dated \_\_\_\_\_\_

For intramural studies: Form 1195 dated\_\_\_

Principal Investigator Curriculum Vitae (CV) and/or appropriate Sub-Investigator (e.g., the Medical Advisory Investigator)

Copy of clinical licensure of PI and/or appropriate Sub-Investigator (e.g., the Medical Advisory Investigator)

For IND studies: CVs for other Sub-Investigator(s)

Financial Disclosure Statements for IND studies and potentially other studies (PI and Sub-Investigators)

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

IRB Approval letter of Final Protocol Ver. \_\_\_

IRB Approval letter of Protocol Amendment Ver. \_\_\_

IRB Approval letter of Protocol Annual Renewal

IRB Approval letter of other information given to Trial Subjects

IRB Approval letter of Advertisement for Subject Recruitment

IRB Approval letter of Consent Document(s) Ver. \_\_\_

IRB Approved Consent Document(s) Ver. \_\_\_

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

Information Given to Trial Subjects (if applicable)

Pertinent IRB Correspondence relating to protocol

Other NIH Approval (where required, e.g., OBA: RAC and IBC)

Lab Normal Value(s) or Range(s) for Medical, Technical, or Laboratory Tests and Procedures

Laboratory Certifications/Qualifications for Procedures and Tests

Investigational product documentation (handling instructions, randomization code [if applicable], instructions for breaking blind [if applicable], shipment/accountability records; if drug is investigational: CofA, sample of container label)

For IND studies: Evidence that protocol has been submitted to FDA

Copy of Investigator’s Brochure, package insert, or other product summary as applicable

Human Subject Protections training for all staff working on research

Other (e.g., DEA license) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

NAME

ADDRESS