National Center for Complementary and Integrative Health

# Tool Summary Sheet

**Tool:** Quality Management Study-wide Review Tool

**Purpose:** To provide a structure for quality management review of study-wide materials and processes

**Audience/User:** Principal investigators (PIs) and other study team members responsible for quality management

**Details:** This tool can be used as a starting point and potential document structure for the development of study- and site-specific quality review of study-wide materials and processes. To document quality management (QM) reviews, the Review Indicators and Criteria should be customized to meet your study-specific needs/requirements.

There is a separate tool for quality management of subject-level data and materials (Quality Management Subject/Participant Review Tool).

**Best Practice Recommendations:**

- Customize this review tool to the specific needs and requirements of the study.
- Thoroughly complete the tool's header information. Even if you are completing the checklist manually, we recommend that you fill out the heading/header information electronically so that it will be carried across all pages of the document.
- The names of the individuals who conducted the reviews should be noted on the tools, so that a subsequent reviewer can follow-up as needed with those individuals. If some items are reviewed by someone other than the individual noted in the header, please indicate in the Comments field associated with each of those items.
- Store all QM materials in a Quality Management Binder, which is maintained separately from the Essential Documents Binder. If filing the paper version, the reviewer should initial each page next to his/her printed name.
- Review of the regulatory file should be completed annually, at a minimum.
- Some of the items noted in this tool may be stored outside of the Regulatory Binder (a.k.a. Investigator Binder). It is helpful to have inserts included in the binder to identify the location of these other items for reviewers.

## Tool Revision History:

| Version | | |
|---|---|---|
| **Number** | **Date** | **Summary of Revisions Made:** |
| 1.0 | 24Apr2013 | First approved version |
| | | |

# Quality Management Study-wide Review Tool

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|---|---|---|---|
| **Protocol Number/ Abbreviated Title:** | | **Date of Review:** | <specify date completed or date range> |
| **Reviewer Name:** | | **Review Period:** | <specify regularity (e.g., annually)> |

**Instructions:** This section is a sample Essential Documents Review Tool, based on ICH-GCP. Mark the appropriate box for each criterion listed. Any issues noted within "Comments" will be summarized in the Quality Management Summary Report. File the completed tool in the study files with other QM materials.

| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
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| **Study Identification** | Identification of the site, including name of PI, study location(s), Protocol Number and title, etc. is present and correct on the study file. | | | | |
| **Protocol** | A current and IRB-approved copy of the Protocol is on file. | | | | |
| | All previous versions of the Protocol are on file. | | | | |
| | Signed versions of the protocol signature page are available for each version of the Protocol. | | | | |
| | Any lapses have been documented properly. | | | | |
| **Consent Document(s)** | A current and IRB-approved copy of the Consent Document is on file. | | | | |
| | All previous versions of the Consent Document are on file. | | | | |
| | Any lapses have been documented properly. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Local Regulatory Approvals** | All local, state, and/or special authorizations related to the protocol are maintained and up-to-date. | | | | |
| **Federal Wide Assurances (FWA)** | Current Federal Wide Assurance and IRB Registration documents for governing regulatory bodies (e.g., IRB), issued from OHRP, are present and include expiration dates. | | | | |
| **IRB Membership** | The IRB Roster or Membership composition is on file and has been updated annually. If the IRB does not provide a roster, official IRB documentation is present stating that names are not released. | | | | |
| **IRB Approvals** | The initial IRB Approval for the Protocol and the Consent Document(s) is present. | | | | |
| | Continuing Review Approval(s) are present (annually). | | | | |
| | IRB Approvals for information given to study subjects are on file (advertisements, recruitment scripts, subject information materials). | | | | |
| | Periodic reports are present (if applicable). | | | | |
| | Approvals for any protocol/consent/assent amendments are present. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Curricula Vitae (CVs) or Biosketches** | Current CVs or biosketches are present for the Principal Investigator and all sub-investigators listed on the IOR/1572.<br>Basic requirements of the CV include current work address, professional title, degrees, current relevant licensure, and clarification of site affiliation. For non-IND studies, CVs should be dated any time on or after the start of the study. For IND studies, CVs should be updated every 2 years. | | | | |
| **Licenses** | Appropriate licenses (dental, medical) are present and current for Principal Investigator and all sub-investigators listed on the 1572/IOR. | | | | |
| **Investigator Brochures/ Package Inserts** | Investigator brochures are present, current, and available for investigational products. Documentation of IRB submission is present (if applicable). | | | | |
| | Package inserts are present, current, and available for approved drugs. Documentation of IRB submission is present (if applicable). | | | | |
| **1572/IOR Agreement** | An Investigator of Record Agreement (IOR) or a 1572 (for IND studies) is present and complete. | | | | |
| | The agreement is current, accurate, and signed by the PI. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Financial Disclosure Forms (IND/IDE)** | Financial disclosure forms for all key personnel are present (if applicable). | | | | |
| **Sponsor Correspondence** | Documentation of correspondence between the site and sponsor is present and current. | | | | |
| **Internal Correspondence** | Documentation of internal correspondence is present and current. | | | | |
| **Telephone Contact Reports** | Telephone Contact Reports are present and current. | | | | |
| **Regulatory Review History** | An up-to-date Regulatory Review History Form is present. | | | | |
| **Final Reports** | The Final Report to the IRB is present (if applicable). | | | | |
| | The Final Report to the sponsor is present (if applicable). | | | | |
| **Notes to File** | Relevant study-specific notes to file/numbered memos are present. | | | | |
| **Delegation of Responsibilities Log** | The Delegation of Responsibilities Log is present and current for all individuals authorized to make entries in study records or participate in protocol execution. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Training: Clinical Research and Study-Specific** | Documentation of Human Subjects Protection Training for all relevant personnel is present and complete. | | | | |
| | Documentation of study-specific training for all relevant personnel is present and complete. Documentation of calibration is present, if applicable. | | | | |
| | Documentation of OSHA training is present for individuals shipping specimens. | | | | |
| **Subject Code List** | The Subject Code List is present. This is a list that links patient names to subject IDs. (It often exists in a secured location separate from the remainder of the study file.) | | | | |
| **Site Screening and Enrollment Log** | The Site Screening and Enrollment Log is present and up-to-date. | | | | |
| **Investigational Product** | Investigational Product Accountability Records are present, accurate, and current. Records reconcile with current IP inventory. (Records must be able to link batch numbers to subjects.) | | | | |
| | Instructions (protocol-specific MOP) for the storage, mixing, and handling of Investigational Product are present, or their location is specified and easily accessible. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| | Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers of all test articles (if open-label study) are present and current. | | | | |
| | Randomization list and decoding procedures for Blinded Investigational Product are present. | | | | |
| | Investigational Product Temperature Logs are present, or their location is specified and easily accessible. | | | | |
| **Laboratory Normals and Accreditations** | Laboratory certifications and accreditations are present for U.S. labs. (CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.) | | | | |
| | If not a U.S. lab, appropriate certificates of qualification for the lab are present. If not present, a statement is present explaining the reason and a description of the standard being used. | | | | |
| | Approvals from collaborating research laboratories are present. | | | | |
| | Current and historical Normal Ranges for all protocol-required tests are present. This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. | | | | |

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| Document | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Specimen Tracking Logs** | Specimen Tracking Logs or Retention Records are present, or their location is specified and easily accessible. | | | | |
| **Unanticipated Problems (UPs)** | All UPs are identified and reported according to protocol and IRB requirements. | | | | |
| **Serious Adverse Events (SAE) and other Safety Reports** | All SAEs that have been reported to NCCIH/CROMS and the IRB are present. | | | | |
| | Copies of all study issue "Dear Doctor" letters are present. | | | | |
| | Copies of all IND Safety Reports are present. | | | | |
| **Protocol Deviations** | All Protocol Deviations are present, and all relevant deviations that have been reported to the IRB according to IRB requirements are present. | | | | |
| **Monitoring Visit Logs and Associated Visit Documents** | Monitoring Visit Logs and associated visit documentation are present (site initiation, interim monitoring, close-out). | | | | |
| **Study-specific Procedures / Manual of Procedures** | Current and historical study-specific procedures or the Manual of Procedures (MOP) are present and clearly identifiable as current or historical. | | | | |
| **Sample Case Report Forms (CRF)/eCRF(s)** | If data are captured on paper CRFs, a blank copy of each approved version is present and easily identifiable as current or historical. | | | | |

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| **Reviewer Name:** | | **Review Period:** | <specify regularity (e.g., annually)> |

**Instructions:** This section is for other QM reviews of study-wide processes and for QM reviews of materials that are maintained outside of the Essential Documents Binder. Mark the appropriate box for each criterion listed. Any issues noted within "Comments" will be summarized in the Quality Management Summary Report.
This table will require significant customization to meet the needs of the study. Items included herein are merely examples.
File the completed tool with other QM materials.

| Item | Criteria | YES ✓ | NO ✓ | N/A ✓ | Comments |
|---|---|---|---|---|---|
| **Procedural Document <Name Procedural Document> Content Review** | Procedural documents have been reviewed by those with relevant expertise and have been deemed sufficient for use in the study. | | | | |
| **Procedural Document <Name Procedural Document> Process Review** | Processes described in the procedural document are being followed. Any relevant checklists or supplemental documentation, prescribed by the procedural document, are available and have been properly completed and signed, as applicable. Purposeful deviations from the designated procedures are documented. | | | | |
| **Calibration Process Reviewed** | Processes associated with the calibration of individuals conducting study assessments are completed according to the written plan. Tools documenting calibration activities are complete and accurate. | | | | |
| **Adjudication Process Reviewed** | Processes associated with study adjudications are completed according to the written plan. Materials documenting adjudication activities are complete and accurate. | | | | |