Tool Summary Sheet

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| **Tool:** | Quality Management Quarterly Review Tool |
| **Purpose:** | To provide a structure for quality management review of study-wide materials and processes to be completed on a quarterly basis |
| **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 that will be completed quarterly. To document quality management reviews, the Review Indicators and Criteria should be customized to meet your study-specific needs/requirements.  There are separate tools for quality management of subject-level data and materials (QM Subject/Participant Review Tool), Essential Documents (QM Essential Documents Review Tool), and for QM reviews to be completed Annually (QM Annual Review Tool). |
| **Best Practice Recommendations:** | * Customize this review tool to the specific needs and requirements of the study. **Text provided in this template is sample text that should be updated as needed.** * Refer to your Clinical Quality Management Plan (CQMP) for the key quality indicators that will be assessed for your study on a quarterly schedule**.** Add or remove items from the checklist to coincide with the CQMP. * 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. * Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate. * 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. * Some of the items noted in this tool may be stored outside of the Essential Documents 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:**

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| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 14Apr2015 | First approved version |
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| **Instructions:** This tool is for the quarterly QM review. Mark the appropriate box for each criterion listed. Any issues noted within “Comments” will be summarized in the Quarterly QM Review Summary.  This table can be modified to meet additional needs of the study.  File the completed tool with other QM materials. |

| **Item** | **Criteria** | **YES**  **√** | **NO**  **√** | **N/A**  **√** | **Comments** |
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| **Consent Process Completion and Documentation** | The QM Subject Data Review Tool was used to review X% of the site’s executed consents. |  |  |  |  |
| **Laboratory Specimens** | All laboratory checklists, specimen shipment logs, and temperature logs were reviewed for completeness. |  |  |  |  |
| **Equipment Set-up and Calibration** | The Calibration Check Log was reviewed for completeness and all required calibrations were confirmed. |  |  |  |  |
| **Source Document Completion** | All eCRFs have been reviewed against the source documents. |  |  |  |  |
| **Case Report Form Completion** | eCRF data have been cross-checked for accuracy and completeness. Query reports have been reviewed to confirm that all manual and automatic queries have been resolved. |  |  |  |  |
| **Study Drug** | Study drug logs were obtained from the pharmacy and accountability records were reviewed for accuracy and completeness. |  |  |  |  |
| **Institution-specific Training** | Training Logs were reviewed to verify that training is current and documented for all study staff for CITI/NIH Human Subjects Training and HIPAA Training. |  |  |  |  |
| **Protocol-specific Training** | Training Logs were reviewed to verify that training is current and documented for all study staff for required trainings listed in the CQMP. |  |  |  |  |
| **Essential Documents** | The Essential Documents Review Tool was used to verify that all documents are maintained. |  |  |  |  |
| **<Procedural Document Name> Review** | This procedural document has been reviewed by those with relevant expertise and has been deemed sufficient for use in the study. |  |  |  |  |
| **<Procedural Document Name> 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. |  |  |  |  |

SAMPLE

Quarterly QM Review Summary

**Site: <Enter site>**

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| Category |  | Clarification |
| **Consent Documentation** | Issue | 8 of 15 subjects reviewed had incomplete consent process documentation, including lack of date/time in the consent note and no indication of whether or not the subject had his/her questions answered. |
| Corrective actions | Introduced consent note template to consenting process (used tool from NIDCR-CROMS website entitled “Documenting the Consent Process”) on 16JUL2014. |
| Updated the Manual of Procedures (MOP) amendment tracker on 19JUL2014 to clarify the updated consenting process. This change will be made to the MOP during the next regularly scheduled MOP amendment cycle (slated for Q4 2014). |
| Completed re-training on 16JUL2014 for all staff responsible for consenting, per the protocol. Re-training documented in the Training Log. |
| **Equipment Set-up and Calibration** | Issue | Equipment calibration checks were not noted on the Calibration Check Log for a period of two weeks. |
| Corrective action | The lead study coordinator added this item to the visit checklist. |
| **Protocol-specific training** | Issue | According to the calibration plan, clinicians are to be recalibrated annually. It has been 14 months since the original calibration, but no new training has occurred. |
| Corrective action | Team recalibration scheduled for 14NOV2014. Also, based on Team discussions and agreement, the calibration plan will be updated to indicate that recalibration is only required every 2 years. |
| **Subject Questionnaire Process Review** | Issue | Two of the Subject Questionnaires were saved on the computer desktop and not on the server. |
| Corrective action | The files were moved to the appropriate folder on the server. |