**Tool Summary Sheet**

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| **Tool:** | Quality Management Annual Review Tool |
| **Purpose:** | To provide a structure for quality management review of study-wide materials and processes to be completed on an annual 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 annually. 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 Quarterly (QM Quarterly 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 an annual 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 |

**Site: <Enter site>**

| **Instructions:** This tool is for the annual QM review. Mark the appropriate box for each criterion listed. Any issues noted within “Comments” will be summarized in the Annual QM Review Summary.  This table can be modified to meet additional needs of the study.  File the completed tool with other QM materials. |
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| **Item** | **Criteria** | **YES**  **√** | **NO**  **√** | **N/A**  **√** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **MOP Content Review**  \**Lead site only* | Procedural documents have been reviewed by those with relevant expertise and have been deemed sufficient for use in the study. |  |  |  |  |
| **MOP 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. |  |  |  |  |
| **CQMP, QM Tools/Logs Review**  \**Lead site only* | Quality Management documents have been reviewed and have been deemed sufficient for use in the study. |  |  |  |  |
| **Protocol-specific Training** | Training Logs have been reviewed to verify training is current and documented. |  |  |  |  |

SAMPLE

Annual QM Review Summary

**Site: <Enter site>**

| Category |  | Clarification |
| --- | --- | --- |
| **MOP** |  | MOP content was reviewed and updated to version x.x. |
| **Protocol-specific Training** | Issue | The Training Log was not updated to document new Study Coordinator Training. |
| Corrective action | The lead study coordinator verified that new Study Coordinator Training was complete and documented the training. |