



## Tool Summary Sheet

**Tool:** Quality Management Subject/Participant Data Review Tool

**Purpose:** To provide a structure for quality management review of subject data and associated materials

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

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

There are two versions of the same tool provided. One version is a subject-specific checklist, whereas the other is formatted to capture multiple subject reviews on the same form. See additional use instructions at the top of each tool.

**Best Practice Recommendations:**

- Customize this review tool to the specific needs and requirements of the study.
- Refer to your Data Safety Management Plan (DSMP) for the key quality indicators that will be assessed for your study and the frequency of review. Add or remove items from the checklist to coincide with the DSMP.
- When completing a multiple-subject review, use additional pages or add/delete columns as needed, depending on the number of subjects being reviewed. Use the Review Summary column to enter the overall review information for each row (e.g., enter the ratio of subjects with no issues over the total number of subjects reviewed).
- 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.
- 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(s) should initial each page next to his/her printed name.

**Tool Revision History:**

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

## Quality Management – Subject/Participant Data Review Tool (Single Subject)

<b>Protocol Number/ Abbreviated Title:</b>		<b>Date(s) of Review:</b>	<Specify date review completed or date range, if multiple days>
<b>Reviewer Name(s):</b>		<b>Subject ID:</b>	

**Instructions:** This tool will be used for the review of source documentation (SD) compared to case report forms (paper or electronic) and protocol for agreement. Reviews may include lab reports, diagnostic reports, etc. Mark the appropriate box for each question listed. Any issues and resolutions noted in “Comments” will be summarized in the Quality Management Summary Report. File the completed tool with other QM materials.

Indicator(s)	Criteria	YES ✓	NO ✓	N/A ✓	Comments
<b>Informed Consent and Assent Process and Documentation</b>	Current, approved version(s) of the Consent and/or Assent Document have been signed and dated in ink by participant or legally authorized representative and, if required, appropriate site staff or witness.				
	Documentation in subject’s record or medical chart regarding the process/components of informed consent is present, including: the participant and/or legally authorized representative received a full explanation of the study, and adequate time was given for consideration and questions regarding study participation.				
	The participant and/or legally authorized representative signed and dated the Consent Document prior to initiation of study-specific procedures.				

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<b>Indicator(s)</b>	<b>Criteria</b>	<b>YES ✓</b>	<b>NO ✓</b>	<b>N/A ✓</b>	<b>Comments</b>
<b>Eligibility Criteria</b>	The participant has met all Inclusion Criteria and none of the Exclusion Criteria for the study.				
	A chart note or eligibility checklist addressing each specific criterion has been completed.				
	The note or checklist has been signed, credentialed, and dated by the clinician (or investigator) responsible for assessing eligibility for enrollment of the study subject.				
<b>Prohibited/ Concomitant Medications</b>	Recording of Prohibited/Concomitant Medications is consistent and complete between Source Documentation and Case Report Forms (CRF/eCRF).				
	Protocol-prohibited medications are found in Source Documentation/(e)CRF. If yes, reviewed protocol and eligibility.				
<b>Study Product Administration Processes</b>	Study product has been administered per protocol/MOP and documented accordingly.  Note: This includes a review of the documentation supporting correct mixing procedures, labeling, cold and custody chain, licensed personnel, and blinded/unblinded handling and administration.				

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<b>Indicator(s)</b>	<b>Criteria</b>	<b>YES ✓</b>	<b>NO ✓</b>	<b>N/A ✓</b>	<b>Comments</b>
<b>Unanticipated Problem (UP), Adverse Event (AE), and/or Serious Adverse Event (SAE) Identification and Reporting</b>	UPs, AEs, and SAEs have been identified, recorded, and reported properly and within the specified timelines.				
<b>Missed Visits and Followup</b>	The participant has missed one or more study visits.				
	If yes, missed visits are documented according to protocol and institutional requirements. Documentation of attempts to contact the participant is present (i.e., phone call, certified mail, etc.). If missed visits resulted in a protocol deviation, they have been recorded as protocol deviations.				
<b>Missed Lab Tests/Procedures</b>	All protocol-required lab tests and procedures have been performed.				
	If no, missed tests/procedures have been reported as Protocol Deviations.				
<b>Study Product/Study Discontinuation</b>	If the participant has discontinued study product or study visits, all protocol-required steps have been followed.				

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<b>Indicator(s)</b>	<b>Criteria</b>	<b>YES ✓</b>	<b>NO ✓</b>	<b>N/A ✓</b>	<b>Comments</b>
<b>Miscellaneous</b>	Source Documentation Standards are being followed.				
	If CRFs are used as source documentation, they have been signed/dated and credentialed as required. Documentation of CRFs serving as source documents is noted in the Protocol, MOP, or SD agreement/statement at the beginning of the study.				
	All entries are signed and dated.				
	Signatures of personnel signing are present in the Staff Signature List in the Regulatory File.				
	Error corrections are properly executed.				

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**Instructions:** This tool will be used for the review of source documentation (SD) compared to case report forms (paper or electronic) and protocol for agreement. Reviews may include lab reports, diagnostic reports, etc. Please indicate the subject identification numbers in the column headers. For each criterion, indicate Yes, No, or NA (i.e., not applicable or not done). If an item requires further elaboration, use the comments table on the final page of this tool. Consider numbering the comments and cross-referencing that number in the relevant criterion cell. Use the Review Summary column to enter the overall review information for each row (e.g., enter the ratio of subjects with no issues over the total number of subjects reviewed). Issues and resolutions will be summarized in the Quality Management Summary Report. File the completed tool with other QM materials.

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		<b>Yes/No/NA</b>					
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<b>Comment Number</b>	<b>Comment</b>

**NA=Not Applicable or Not Done**

Comment page \_\_\_\_ of \_\_\_\_