Tool Summary Sheet

Tool: Clinical Quality Management Plan (CQMP) Template

Purpose: MS Word template to be used as a starting point for preparing a Clinical Quality Management Plan

Audience/User: Principal Investigators and other study team members responsible for preparing a Clinical Quality Management Plan

Details: This template includes a proposed structure for a Clinical Quality Management Plan as well as sample language and other guidance.

Best Practice Recommendations:

- Review this draft template and customize to the specific needs and requirements of the study. **Text provided in this template is sample text that should be updated as needed**.
- Tools and templates referenced in this document are available on the NIDCR Toolkit for Clinical Researchers or through your Program Official.
    - QM tools and templates:
        - QM Subject/Participant Data Review Tool
        - QM Quarterly Review Tool
        - QM Annual Review Tool
        - QM Essential Documents Review Tool
        - Quality Management Summary Report Template
    - Other tools:
        - Manual of Procedures (MOP) Template
        - Standard Operating Procedure (SOP) Template
        - Consent Document Review Checklist
- Refer to the 'Introduction to Site-Level Quality Management within the Clinical Research Process' slide set for further details, definitions, and descriptions of tools available to support Quality Management.
- The CQMP can be developed on a site-basis, with each section's text tailored to the study staff at that site, or on an overall study-basis. If one CQMP is developed on a study-basis for a multi-site study, clearly identify within the document any items or tasks that differ by site. Note that sample text in this template is written as if there are multiple sites; please modify as needed.
- The CQMP will include only those activities that are the responsibility of the site personnel. Responsibilities of outside parties, such as clinical research associates monitoring the site, are documented elsewhere (e.g., the Clinical Monitoring Plan). You may find it helpful to refer to those other plans within the CQMP.

- The CQMP typically includes ongoing activities that begin following study initiation. Quality management activities that occur prior to the initiation of the CQMP may include, but are not limited to:
    - Reviewing consent documents against the Consent Document Review Checklist to ensure that all proper elements are included and that the Consent complies with all relevant regulations, local IRB requirements, and Good Clinical Practice, as appropriate
    - Creating a list of required trainings (institution-wide, per protocol) and a method for confirming and documenting staff training
    - Documenting calibration of study examiners or equipment
    - Creating process documents (SOPs, Manual of Procedures, references to the location of details regarding study-specific data collection (e.g., patient-reported, separate source documents)
    - Creating tools, checklists and reminders
- In the template, the instructions and explanatory text are indicated by *{blue italics}* ("CROMS_Instruction" style). Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.
- Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
- Delete template-specific sample and *{instructional text}* as well as this Tool Summary Sheet during the CQMP development process.
- Leave the template version information in the lower left hand corner of the document. You may choose to add "Based on" in front of "Template Version".
- It is easiest and cleanest to use the styles that are embedded in the document, rather than to create your own. (In MS Word 2007: From the Home menu, select the bottom right arrow key to bring up the styles box, select "Options", under "Select Styles to Show" select "in current document".)
- Ensure that all placeholder and example text is replaced with the study-specific information.
- Store all QM materials in a Quality Management Binder, which is maintained separately from the Essential Documents Binder.

Tool Revision History:

Version Number	Version Date	Summary of Revisions Made:
1.0	20Aug2012	First approved version
2.0	13Apr2015	Reorganized by QM activity schedule

Clinical Quality Management Plan

Protocol: <protocol number and protocol title>

Site: <Name of Clinical Site>

{The QM coordinator is the individual responsible for managing QM activities at the clinical site.}

By signing below, I acknowledge my agreement with this plan.

_____

QM Coordinator Name (Printed)

_____ _____

QM Coordinator (Signature) **Date**

_____

Principal Investigator Name (Printed)

_____ _____

Principal Investigator (Signature) **Date**

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{This uses the Table of Contents function in Microsoft Word that will automatically update headings and page numbers used throughout the report. In the body of the report, add, delete, or modify headings as needed. In order to ensure proper updating of the TOC, use the heading styles that are defined in the document: CROMS_Heading 1-CROMS_Heading 9.

To regenerate the Table of Contents and other links and cross-references in the document, Choose "Select all" and then F9.}

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1.0 INTRODUCTION TO THE CLINICAL QUALITY MANAGEMENT PLAN

The Clinical Quality Management Plan (CQMP) establishes the quality management guidelines for tasks related to the NIDCR Protocol <insert protocol full name>. The purpose of the CQMP is to identify and document the ongoing processes and activities that will be used to monitor and facilitate quality protocol execution following study initiation. Quality measures related to study development and start-up are not included in this plan.

1.1 QM Activity Schedule and Tools

{Describe the standard schedule for QM activities, and the tools, checklists, and reminders that will be used in the QM process.}

Quality Management (QM) activities will be conducted at each subject study visit, as well as on a quarterly and annual schedule. Additional QM activities and reviews will be conducted on an as-needed basis in response to staff or process changes.

The following tools will be used to document Quality Management (QM) activities for this study:

- QM Essential Documents Review Tool
- QM Subject Data Review Tool
- QM Quarterly Review Tool
- QM Annual Review Tool

In addition the following checklists and reminders have been developed for this study's QM process:

- Eligibility Checklist
- Calibration Check Log

1.2 Quality Management Documentation and Reporting

{Describe how the results of the internal assessments will be summarized, analyzed, and communicated to staff. Indicate the schedule for quality reviews and for the production of QM Summary Reports.}

Each clinical site will maintain the CQMP and QM tools/logs either in a QM binder (for paper documents) or electronic folder. Site Study Coordinators (SCs) will be responsible for site-specific QM activities. The Lead SC will be responsible for QM activities at the lead study site and will provide oversight for QM activities for the entire study.

Each site SC will provide a Quality Management Summary Report to the Lead SC one month before the Medical Monitor Oversight Report (MMOR) <or CSOC Report, DSMB Report > is due. The Lead Study SC will compile the site reports into a comprehensive, study-wide report that will be provided to the NIDCR. The Lead Study SC will also summarize the information for inclusion in the Medical Monitor Oversight Report <or CSOC Report, DSMB Report>. This summary will document the following:

- QM activities completed since the prior report submittal, including:
    - Frequency of reviews
    - Number of charts reviewed
    - Items covered by the review
- Identification of problem areas
- Corrective Action Plan(s)
- Trend Analysis (if applicable)
- Possible need for revision to CQMP

{Items found in the sections below are offered as a starting point for consideration. Add, delete, or revise as applicable to your study, and move items from one category to another as appropriate (e.g., from quarterly to annually).

Describe study or site-specific quality processes and include references to specific QM tools that will be used in the sections that describe those activities. If there are SOPs or there is a Manual of Procedures (MOP) that addresses items in any section, include a general statement that references those other documents and add references to specific chapters as appropriate.}

2.0 AD HOC QUALITY MANAGEMENT ACTIVITIES

2.1 New Study Personnel

{Describe or provide reference to site processes for ensuring and documenting qualified staff and competency.}

The site SC will ensure that all study personnel have completed all required institution-specific and protocol-specific trainings and that these trainings are documented appropriately on the Training Log. The site SC will also ensure that new personnel are appropriately documented on the Delegation of Responsibilities Log (DOR). While training should be completed and

documented in real time, the Lead SC will verify that all training is current and appropriately documented on a quarterly basis, as noted in section 4.8 below.

Institution-specific Training

{E.g., Human Subjects Protection, Phlebotomy, Dangerous Goods Regulations, research staff training, applicable site policies/procedures.}

All study staff will complete CITI or NIH Human Subjects training prior to commencement of study activities per MOP Section <#>. The site staff is also required to receive HIPAA training. Staff training certificates will be stored in the Essential Documents Binder and documented on the Training Log.

Protocol-specific Training

{List specific trainings, e.g., specimen handling/processing, study product, data management.

Based on site role, and as appropriate to study-assigned tasks as noted on the DOR, new clinical research staff may be evaluated based on specific criteria after a certain timeframe or completion of a certain number of study procedures/dosing, etc., prior to being considered appropriately trained on the study.}

Below is a summary of required training for new study personnel:

- New Clinical Research Staff: Review the SIV training slides maintained on the Study Webpage (<link to study webpage URL>) and the protocol and MOP with the Lead Study Coordinator prior to participating in the study.
- New Research Assistants: Receive training on data collection procedures and data entry. If the research assistant is involved in activities related to administering questionnaires, they will be trained on all of these activities as well.
- New Clinical Examiners: Attend a calibration with the standard examiner and demonstrate inter- and intra-rater reliability per Protocol section <#>.
- Calibrated Examiners: Require recalibration on an annual basis for the duration of the study. Examiners are calibrated on the most current version of the protocol.

3.0 SUBJECT STUDY VISIT QUALITY MANAGEMENT ACTIVITIES

Procedures and processes to ensure protocol adherence at each subject study visit are documented in the Manual of Procedures (MOP).

The following is a detailed description of QM activities that will be performed prior to subject study visits and upon visit completion.

3.1 Subject Record Review

{Examples: Eligibility Criteria; Concomitant/Prohibited Medications; AE/SAE/UP Identification and Reporting; Protocol Visit Compliance (evaluate for missed visits, out-of-window visits, lost to follow-up, etc.); Protocol-specific Procedures (all inclusive); Protocol Deviations; and Study Discontinuation.}

Prior to confirming subject study visits, the site SC will verify that the subject is scheduled for the appropriate appointment as listed on the Visit Window Calculator.

During the visit, the site SC will ensure that the subject still meets the eligibility requirements.

At the completion of each visit, the site SC will review the subject record to identify any needed AE/SAE/UP reporting.

3.2 Consent Process Completion and Documentation

{Explain how the consent documentation will be reviewed after it has been completed, to compare to the established consent processes (which may be described in an SOP or in the MOP) and to review for completeness.}

Prior to the screening and baseline visits, the site SC will verify that the most current IRB-approved study consent/assent documents are available for use. If re-consenting is required throughout the subject's participation in the study, the site SC will verify that the most current IRB approved consent is available prior to the study visit.

Before the subject leaves the clinic, the site SC will review the consent documentation and confirm adherence to the consent processes described in the MOP.

3.3 Source Document Completion

{Describe the checks and cross-checks in place at the site for source document completion.}

At visit completion, all records containing source documentation are reviewed by the clinician for completeness. Source documentation methods are described in the MOP Section <#>.

OR

At visit completion, a reviewer will complete a checklist that captures the required elements of the visit. For training purposes this reviewer will be someone other than the individual who completed the source documents for the first X subjects for each site SC.

3.4 Case Report Form Completion

{If using a paper CRF, suggested quality checks may include similar options as those noted in section 3.3. An additional level of quality review could be added by implementing a second party review of the forms after completion and before review by the clinical monitor and/or submission to the data management group.

If using an eCRF, in many instances inconsistencies or omissions in data entry would be noted with an automatic query that fires based on expected parameters for data entry. Determine if the DCC will be programming these edit checks and performing manual data review, and capture the schedule either here or reference the document that details the query process.}

Procedures for completion of CRFs are described within MOP Section <#>, and data error detection and correction procedures are documented in MOP Section <#>.

Queries and alerts, generated by the electronic data capture (EDC) system, occurring during the clinical visit will be corrected as soon as notified during data entry or as soon as time allows following the visit.

4.0 QUARTERLY QUALITY MANAGEMENT ACTIVITIES

{Modify as needed if it is determined that activities should be completed on a monthly basis.}

The following is a detailed description of the Quarterly Quality Management review activities, which will be documented on the QM Quarterly Review Tool.

4.1 Consent Process Completion and Documentation

The site SC or designee will review X% of the site's executed consents using the Quality Management Subject Data Review Tool.

4.2 Laboratory Specimens

{Reference the sections of the protocol, MOP, or other study documents that detail the protocol required specimens. This section should address all aspects of specimen collection, processing, storage, and shipment to be reviewed. Consider referencing any checklists for specimen

collection or any specimen temperature monitoring for specimen storage. If you have a separate laboratory manual describing specimen management, consider referencing.}

MOP Section <#> describes the labeling, collection, handling, shipping, and storage of the clinical specimens obtained in this study. Every 3 months, the site SC will review laboratory checklists, specimen shipment logs, and temperature logs for completeness.

4.3 Equipment Set-up and Calibration

{If study-specific requirements include the use of medical devices (blood pressure monitors, ECG machines, etc.), consider discussing review of maintenance and calibration records here to maintain data integrity. If these items are noted in other study documents, provide a reference.}

MOP section <#> describes the procedures for setting up, checking calibration, and calibrating the study equipment. Equipment calibration checks and recalibrations will be noted on the Calibration Check Log. The site SC will review the Calibration Check Log every 3 months.

4.4 Source Document Completion

{This may or may not be needed here, depending on the amount of review required following each subject study visit.}

The site SC will use the Quality Management Subject Data Review Tool to review completion and accuracy of the source documents and the eCRFs for 100% of subjects at the site every 3 months.

4.5 Data Queries / Case Report Form Completion

{Describe quality reviews of CRFs if using a paper CRF, or of eCRFs and query reports if using an eCRF. Note if the review should be performed by someone other than the individual(s) initially involved in the process.}

The site SC will cross-check eCRF data for accuracy and completeness every 3 months. The site SC will also review query reports to confirm that all manual and automatic queries have been resolved. The Lead SC will review all system generated and manual queries across all sites to ensure completion and close-out of queries.

4.6 Study Drug/Device

{Describe quality review activities related to study drug (formulation, receipt, storage, dispensing, tracking, destruction) or device (receipt, storage, calibration, dispensing, tracking, destruction, if applicable). Refer to pharmacy or other manuals when useful.}

MOP Section <#> describes the pharmacy's processes for the ordering, maintenance, and dispensing of the study drug. The pharmacy maintains all logs associated with the study drug. The site SC will obtain log information from the pharmacist quarterly and review accountability records for accuracy and completeness. This review will be documented on the QM Quarterly Review Tool.

4.7 <Insert study-specific tests/assessments>

{For example: Quality of Life Measurements, pain scales.}

4.8 Staff Training / Qualifications

Training Logs will be reviewed by the site SC every 3 months to verify training is current and properly documented. This will include a review for institution-specific and protocol-specific trainings. See section 2.0 above for additional information about required training.

4.9 Essential Documents

{Discuss how the site will monitor for current licenses, maintaining current IRB approvals, and appropriate regulatory documents. In determining the review frequency for the Essential Documents Binder (a.k.a. Investigator Binder, Investigator Site File), consider external monitoring that may occur on a regular basis. If your site is monitored by NIDCR or their designee, this external monitoring may be considered sufficient to fulfill the minimum requirements for this review.}

The Investigator Site Files are updated by the site SC when changes to licenses, IRB documents or CVs are made during the study. The site SC will review the Investigator Site File every 3 months to verify that all documents (paper and electronic) are maintained. This review will be documented and summarized in the Essential Documents Review Tool. At least annually, the CROMS CRA will conduct a complete review of the Investigator Site File.

5.0 ANNUAL QUALITY MANAGEMENT ACTIVITIES

The following is a detailed description of the Annual Quality Management review activities, which will be documented on the QM Annual Review Tool.

5.1 Process Documents

{Describe measures that will be used to review process documents (e.g., MOP, SOPs) to ensure they are sufficient and complete. During the execution of the study, these process documents could be reviewed against the actual practice, as a part of the QM program.}

The procedures and processes to ensure protocol adherence among the study personnel are set forth in the Manual of Procedures (MOP). The MOP is reviewed by the Lead SC every 12 months for applicability and accuracy.

This CQMP will be a living document and will be reviewed for applicability and accuracy and updated as necessary every 12 months by the Lead SC. Additional QM needs identified at a study site will be communicated to the study team. The study team will evaluate the need to update the CQMP, tools, and logs.