MIRECC UNIT SPECIFIC
QUALITY MANAGEMENT PROGRAM

I. POLICY

The Mental Illness Research, Education and Clinical Center (MIRECC) will establish and maintain a specific and comprehensive quality management (QM) program as an adjunct to the VA Maryland Healthcare System Research and Development (R&D) Service quality management program. Modifications to the written plan may be made as MIRECC needs warrant. The plan will be reviewed annually by the QM Committee and updated as necessary.

II. PURPOSE

A. To establish a defined guidance in the conduct and operation of MIRECC research on human participants.
B. To support the mission and philosophy of the MIRECC.
C. To implement the requirements of the VAMHCS R&D Service quality management program.
D. To provide evidence of a structured and effective MIRECC quality management program.

III. STRUCTURE

This plan will outline the following:

A. Program direction and oversight
B. Reporting structures
C. Individual Study Requirements
D. Audit Process
E. Staff Education
F. Clinical, Administrative and Technical quality controls and measures

IV. QUALITY MANAGEMENT PROGRAM

A. Program Direction and Oversight

The MIRECC Director has the overall responsibility for the monitoring of MIRECC studies and their compliance with the MIRECC QM program. The MIRECC Associate Director for Research will collaborate with the Director in the overall conduct and reporting of the QM Program. The Director of Research Quality Management (DRQM) for the MIRECC will coordinate the day-to-day operations of the QM Program in collaboration with the Associate Director for Research with oversight by the MIRECC Director.

The QM Committee will meet on a monthly basis, or more often if the Committee deems necessary, to review and support the quality management process.

B. Reporting Structures

Quarterly QM reports will be given to the MIRECC Steering Committee. A copy will also be forwarded to the VA Research Services office.

C. Individual Study Requirements

1. All MIRECC research protocols involving human participants should have quality controls and measures in place to assure compliance with the conduct of the approved research and the VAMHCS R&D Service quality management program. This includes the storage of information such that patient identifiers and data are kept in separate, secure locations. Additional controls and measures should include, but not be limited to, those listed below in the section entitled “Clinical, Administrative and Technical Quality Controls and Measures”.

2. At the beginning of a MIRECC study, the Principal Investigator or Project Coordinator will customize the Medication and Equipment Audit and the Internal Source Documents Audit forms to their protocol and submit these forms to the MIRECC Research Administrator. These forms will be used by the MIRECC QM Auditor (see Audit Process) when reviewing that protocol.

3. Studies already underway when the MIRECC QM Program is approved will customize the MIRECC Medication and Equipment Audit and the Internal Source Documents Audit forms to their protocol and submit these forms to the MIRECC Research Administrator within three weeks after implementation of this Program.

D. Audit Process

1. At least on an annual basis, every active MIRECC study will be reviewed by a qualified auditor. The auditor will review a *minimum* of five random study charts, or 100% of the study charts if less than five participants are enrolled. The auditor will use forms that correspond to items listed in the MIRECC Clinical, Administrative and Technical Quality Controls and Measures section as a guideline.

2. Protocol Violations

   a. If a protocol violation is discovered which poses an increased risk to a human participant, the auditor will immediately bring it to the attention of the MIRECC Director and the appropriate principal investigator (PI), either by phone or email. The MIRECC Director and PI will then contact the IRB and VA Research Services office, if required.

b. Other protocol violations, which do not involve a risk to a human participant, will be listed, along with the corrective action required, in the first section of the Problem Resolution Worksheet. If the auditor discovers a missed SAE or an undocumented, unexplained or unreported missed study event, these are listed in the second section of the Problem Resolution Worksheet.

c. The auditor will schedule a follow-up review of the Problem Resolution Worksheet for two weeks from the date the worksheet is given to the principal investigator. In that two-week period, the investigator and study coordinator should resolve the problems OR document why the problem cannot be resolved and what plan is in effect to prevent future problems. Resolutions are listed in the appropriate sections of the Problem Resolution Worksheet. When the investigator feels that all possible problems have been resolved, s/he completes the bottom section of the Problem Resolution Worksheet.

d. At the two-week time point, the auditor follows-up on Problem Resolution Worksheets. If the auditor feels that all possible problems have been resolved, s/he completes the bottom section of the Problem Resolution Worksheet and files it with the Internal Source Documents Audit in the source documents chart.

e. If the auditor feels that further action is warranted, s/he will attach a note to the Problem Resolution Worksheet outlining the actions needed and return it to the investigator with another two-week timepoint in effect. The investigator proceeds as in 2b. except that resolutions are now documented as signed narrative notes. The Worksheet continues to pass back and forth between the auditor and the investigator until all problems have been resolved or documented.

3. Audit findings will be summarized and given to the principal investigator within two weeks of the audit. A copy of the report will be filed in the MIRECC.

E. Staff Education

1. To ensure that all MIRECC investigators and research staff adhere to the Training and Education requirements as outlined in the VAMHCS R&D Service quality management program, proof of completion of required human research subject trainings should be submitted to the MIRECC Research Administrator. Proof of completion of these trainings by new staff should be submitted within two weeks of their start date.

2. All MIRECC staff are required to complete on-going mandatory trainings as required by the VA Research Service office.

3. All MIRECC investigators should have a plan for educating their research staff about their specific study prior to implementation of that protocol.

F. Clinical, Administrative and Technical quality controls and measures

1. All MIRECC research protocols should have quality controls and performance measures appropriate to their individual protocol. Audits will be performed in the following domains:

    a. Regulatory Documents
        1) IRB communications
            a) Initial approval
            b) Annual reports and approval
            c) Consent form (current)
            d) Other
        2) Form FDA 1572 (if applicable)
        3) Confidentiality Certificate (if applicable)
        4) VA Research & Development Committee approval

    b. Study Protocol Procedure
        1) Screening (paper and electronic forms)
        2) Eligibility
        3) Randomization
        4) Medications (if applicable)
        5) SAE reporting
        6) Endpoints
        7) Follow-up
        8) Progress notes
        9) CPRS warning (if applicable)

    c. Medications and Equipment (if applicable)
        1) Medications
            a) Blinding
            b) Security/Storage
            c) Dispensing

    d. Staff
        1) Credentialing
        2) Study specific training
            a) Obtaining consent
            b) Reliability
        3) UMMS human research subjects training(s)
        4) VA human research subjects training program(s)

2. The following standardized QM forms will be used by the MIRECC auditor. These forms will be made relevant to each study by collaboration with the PI.

    a. Regulatory Documents Audit
    b. Internal Source Documents Audit
    c. Medications and Equipment Audit
    d. Staff Credentials/Training Audit
    e. Problem resolution worksheet

3. Regulatory documentation

    A Regulatory Binder should be maintained in each laboratory conducting a MIRECC study. In addition, a copy of all regulatory documents should be sent to the MIRECC Research Administrator. Documents may include the following, depending on the type of research being conducted.

    a. Binder Contents:
        1) Regulatory documents should include:
            a) The IRB protocol approval letter, copy of the approved informed consent(s), copy of the approved protocol and any approved revisions/amendments, IRB continuing review approvals, safety reports, and appropriate IRB correspondence regarding Serious Adverse Events (SAE).
                i) FDA 1572, if applicable, or Investigator Letter of Agreement for non-industry-sponsored studies
                ii) Laboratory certificates, if applicable
                iii) Investigator Curriculum Vitae (CV)
                iv) Pharmacist's CV, if applicable
                v) Annual reports to the IRB
                vi) All protocol communications (in correspondence section of binder)
                vii) All external and internal monitoring reports and logs
                viii) Completed regulatory checklist
        2) Documentation of submission of all SAE reports to the IRB
        3) Documentation of submission of targeted SAEs to Research Office
            a) All deaths
            b) SAE possibly, probably, definitely related to study agent
            c) SAE prompted changes in protocol or informed consent
        4) Completed Research Methods Accountability Form
        5) Maintenance of a file to record any SAE or protocol deviation is recommended. Contents should include:

a) SAE/Protocol Deviation & Unanticipated Problem Checklist, & Adverse Events Form

b) A copy of the SAE or protocol deviation report should also be filed in each applicable participant file to facilitate tracking

6) IRB requires a research chart be maintained for each participant

4. Computerized Patient Record System documentation

All MIRECC research protocols will comply with VAMHCS policies regarding the documentation of contacts with VA patients. In particular, all patient contacts will be documented electronically as “research notes” in the appropriate virtual clinic in the Computerized Patient Record System (CPRS). In general, notes should briefly reflect the nature and duration of the contact (e.g., “one hour research assessment”), comment on the patient’s cooperation with and reactions to any procedures or interventions, document study-defined endpoints (e.g., dropout, completion), and note significant incidental information (e.g., suicidal ideation).