RESEARCH QUALITY ASSURANCE (DSMB)

Responsible Administrator: Dr. Barbara Given, Interim Associate Dean for Research
Sponsoring Unit: Research & PhD Program
Effective Date: 02/21/2008
Last Reviewed Date: 12/28/2017
Next Scheduled Review Date: Inactivated Date:

POLICY STATEMENT

To support University and federal recommendations for research oversight, and to assure that all clinical and clinical trial research and the data generated by CON faculty/students are of high quality, reliable and verifiable, the CON Deans, with recommendations from the Research Committee, will institute regularly scheduled review mechanisms. A Research Quality Assurance Group (RQA) will work with investigators to ensure safe and appropriate conduct of research. The frequency and depth of the review will be determined by the RQA group, and will depend on the level of intervention, degree of risks (single site vs. multiple sites), complexity of the study and experience of the Principal Investigator (PI).

The RQA group will function similarly to an NIH Data Safety & Monitoring Board. Per the NIH Policy for Data Safety and Monitoring released June 10, 1998, individuals or groups monitoring data and safety of interventional trials will perform the following activities.

- Review the research protocol and plans for data and safety monitoring.
- Evaluate the progress of interventional trial(s), including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.
- Make recommendations to the IC, IRB, and investigators concerning continuation or conclusion of the trial(s).

Review checklists have been prepared to guide the RQA review following the recommendations from NIH above. It is our hope that faculty/students researchers welcome this constructive mechanism as an opportunity to discuss their project with research colleagues and brainstorm around implementation concerns as they arise.

Recommended by Research Committee: 2/21/08
Approved by Dean’s Office: 2/21/08
Revised by Associate Dean for Research: 12/28/17
Composition of the RQA:
The RQA will be identified by the Associate Dean for Research & Doctoral Program in consultation with the CON Research Committee, and will be comprised of a senior researcher, a junior researcher, and an appropriate methodologist with the expertise to provide appropriate oversight and advice. In addition, the Associate Dean for Research & Doctoral Program and the CNRSI Coordinator will participate. Conflicts of interest will be examined in each case.

RATIONALE

The University claims ownership and stewardship of the scientific records for projects conducted at the University, under the auspices of the University, or with University resources (available at: http://rio.msu.edu/research-data).

Michigan State University’s responsibilities in this regard include, but are not limited to:
- Complying with terms of sponsored project agreements
- Ensuring the appropriate use of animals, human subjects, recombinant DNA, etiological agents, radioactive materials and the like
- Protecting the rights of faculty, students, postdoctoral scholars, and staff, including but not limited to, their rights to access data from research in which they participating.
- Securing intellectual property rights
- Facilitating the investigation of charges, such as misconduct in research and financial conflict of interest
- Responding to legal actions involving the University related to research carried out under its auspices.

University level departments have been created and assigned responsibility for monitoring specific activities identified above, e.g., Contract & Grants monitors compliance with sponsored project agreements, the IRB monitors appropriate use of animals, human subjects, etc.

As administrators within the University, the Deans within each College are charged with responsibility for comprehensive oversight of research conducted within their unit. While oversight of all research studies is important, the NIH places special emphasis on monitoring of clinical studies and clinical trials due to their involvement of animals or human subjects. NIH policy states that each Institute and Center (IC) should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data. The data and safety monitoring functions and oversight of such activities overlap with, but are more comprehensive than the requirements for study review and approval by an Institutional Review Board (IRB) (NIH Guide: Notice OD-98-084).

Currently, the establishment of the data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. Phase I or II trials may be monitored by individuals or monitoring groups.

In 1994, the Office of Extramural Research established the Committee on Clinical Trial Monitoring to review the oversight and management practices of the ICs for phase III clinical trials. One of the
outcomes of this Committee's review was a strong recommendation that "all trials, even those that pose little likelihood of harm, should consider an external monitoring body".

SCOPE

This policy applies to all federally funded clinical research projects administered by the College of Nursing. Projects with a federally mandated DSMB will be exempt from RQA monitoring.

RELATED POLICIES, PROCEDURES OR REGULATIONS

- Each NIH institute/center has an institute/center policy, which is available at: [http://grants.nih.gov/grants/policy/hs/data_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm).

CONTACTS

Questions, comments or concerns should be directed to the Associate Dean for Research & PhD Program.

DEFINITIONS

Adverse events are defined as any untoward medical occurrence that may present itself during treatment or administration of an intervention, and which may or may not have a causal relationship with the treatment.

Serious adverse events are defined as any medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defects.

A clinical trial is a prospective biomedical or behavioral research study involving human subjects, which is designed to answer questions about the effects of a biomedical or behavioral intervention. This includes interventions whose goal is to initiate or change behavior (diet, physical activity, cognitive therapy, etc.) in a target population (such as physicians or consumers) by introducing information resources and services.

Clinical research is research with human subjects that is:
1) Patient-oriented. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) where an investigator directly interacts with human subjects.
2) Epidemiological and behavioral studies.
3) Outcomes research and health services research.
RESPONSIBILITIES

The Associate Dean for Research & PhD Program has responsibility for oversight of this policy.

Principal Investigators have responsibility for submission of required materials to facilitate a timely, efficient review of their project.

Research Administrators have responsibility for scheduling meetings, requesting materials from Principal Investigators, distribution of materials to RQA members prior to meetings, and preparation and distribution of meeting minutes.

PROCEDURES

RQA meetings will be coordinated by the CNRSI Research Administrator(s). All materials will be housed in confidential research administrative files.

Initial review:

1. Upon funding of an RQA eligible project, the Research Administrator will consult the Associate Dean for Research & PhD Program for a recommendation of RQA members.
2. Following identification of RQA members, the Research Administrator will contact RQA members to schedule the first meeting (within 3 months of funding).
3. Approximately 2-4 weeks prior to the meeting, the Research Administrator will send the project PI, an “Initial Meeting Preparation Checklist”.
4. The Project PI will return the Meeting Preparation Checklist along with requested items.
5. Approximately 1 week prior to the meeting, the Research Administrator will distribute to all RQA members an agenda along with supporting documents (identified on the Meeting Checklist). Meeting materials will be organized into a single PDF with page numbers and a cover Table of Contents.
6. At conclusion of the meeting, the PI and the RQA group will make a determination about the degree of monitoring, using the complexity of the study, the level of intervention, degree of risks to the subjects, the number of recruitment sites and experience of the PI as criterion. Training may be recommended, along with additional mentorship.
7. The Research Administrator will attend each meeting to take notes. Minutes, marked draft, will be distributed by the Research Administrator to RQA members within one week of the meeting for review. Final minutes will be distributed by the Research Administrator within 3 weeks of the meeting.

Annual/Follow-up review:

1. A follow-up to the Initial RQA will occur 9 months later.
2. Approximately 3 months before the next requested meeting, the Research Administrator will consult RQA members to schedule the next meeting (should not be more than 1 year from after prior meeting). If an RQA member has left the University, the Research Administrator will consult the Associate Dean for Research & PhD Program for recommendation of a new member.
3. Approximately 4 weeks prior to the meeting, the Research Administrator will send the project PI,
an “Annual Meeting Preparation Checklist”.

4. The Project PI will return the Meeting Preparation Checklist along with requested items.

5. Approximately 1 week prior to the meeting, the Research Administrator will distribute to all RQA members an agenda along with supporting documents (identified on the Meeting Checklist). Meeting materials will be organized into a single PDF with page numbers and a cover Table of Contents.

6. During the meeting, the PI and the RQA group will make a determination about the degree of monitoring, using the complexity of the study, the level of intervention, degree of risks to the subjects, the number of recruitment sites and experience of the PI as criterion. Training may be recommended, along with additional mentorship.

7. The Research Administrator will attend each meeting to take notes. Minutes, marked draft, will be distributed by the Research Administrator to RQA members within one week of the meeting for review. Final minutes will be distributed by the Research Administrator within 3 weeks of the meeting.

FORMS OR TOOLS
The following forms/tools are available on the CON Research website under “Resources for Researchers”:

- RQA Initial Meeting Preparation Checklist
- RQA Initial Meeting Agenda and Minutes Template
- RQA Annual Meeting Preparation Checklist
- RQA Annual Meeting Agenda and Minutes Template
- RQA Narrative Template