

## **Reporting and Handling Non-Compliance (or Deviations) to the QMC Research and Institutional Review Committee Requirements**

### **Purpose**

This procedure outlines QMC RIRC's requirement for Noncompliance reporting for research studies. RIRC requires reporting of noncompliance which may take the form of protocol violations or deviations. Such reports are considered possible noncompliance until a determination has been made by the RIRC.

### **Definitions**

**Deviation:** Any change, or departure from approved study design or research protocol procedures that has not been approved by the RIRC, and *does not* affect the subject's safety, rights, or welfare and/or the completeness, accuracy and integrity of the study data. These are usually considered minor protocol violations.

**Noncompliance:** Failure to comply with the requirements of an applicable law, regulation or institutional policy, requirements or determinations of the IRB, any variation and/or omission from what is approved.

**Protocol Violation:** Any deviation that *may* affect the subject's safety, rights, or welfare and/or the completeness, accuracy and integrity of the study data. This term usually refers to a major, more serious deviation and may be considered serious noncompliance.

**Serious Noncompliance:** This is noncompliance that has substantive potential or actual increased risk to the subject's safety, rights, or welfare and/or the completeness, accuracy and integrity of the study data.

**Continuing Noncompliance:** This is repeated or a pattern of noncompliance that indicates a disregard or inability to comply with the requirements of an applicable law, regulation or institutional policy, requirements or determinations of the IRB, any variation and/or omission from what is approved.

**Complaint:** An expression of dissatisfaction that may or may not involve noncompliance. Complaints may be from research subjects, subject's families or subject's significant others, staff, RIRC members, principal investigators, and any other person. All complaints and criticisms not covered by the Adverse Event Reporting procedures must be reported to the QMC RIRC.

### **Reporting**

Reports of noncompliance of a particular research protocol or proposal may arrive to QMC RIRC from various sources – subjects, subject's families, investigators, study coordinators and study staff, or through monitoring or by other individuals, and may be done anonymously via telephone, email or letter.

Research staff who become aware of noncompliance or protocol deviation/violation should notify the Principal Investigator as soon as possible. There may be cases when research staff prefer not to notify the PI; reports should be submitted directly to the Manager, Research Regulatory Office

### **Reporting Timeframes**

Initial report of noncompliance or protocol deviation/violation should be made to the Manager, Research Regulatory Office within one week of the PI becoming aware of the event, and followed by a formal report within 2 weeks of the discovery.

### **Content of Reports**

Reports of noncompliance or protocol deviation/violation should include the following elements:

- Date of report
- RA# with study title
- Funding source
- Principal Investigator, contact information and signature
- The study's enrollment status and number enrolled to date
- Detailed description of noncompliance with dates, location, personnel
- Description of factors leading to noncompliance
- Description of any impact to patient rights/safety/welfare or to integrity of study data
- Indicate where else this is being reported
- A description of corrective actions already taken to date, dates of implementation, and whether and how participants were informed of the violation, and outcomes.
- Proposed corrective action plan to prevent recurrence.

### **Investigation and Action**

For all categories listed above, the RIRC Manager will evaluate reports with RIRC Chair. RIRC staff may collect and collate additional information. The RIRC Chair with input from RIRC members will review the report and findings. Additional information may be requested in order to appropriately evaluate the event.

QMC RIRC will respond to a report of noncompliance relative to the level of severity. Potential actions may include, but are not limited to:

- An acknowledgement of review will be provided and no further action is required for events not considered serious or continuing noncompliance.
- Accept, or require modifications to the investigator's corrective action plan
- Establish a corrective action plan
- Request additional information
- Require investigator(s)/staff to complete training
- Require re-consenting of subjects
- Permitting or disallowing the use of data collected during noncompliance
- Monitoring of research
- Require modifications to protocol or informed consent form
- Suspension of all or parts of the research study
- Termination of the research study
- Apply corrective action to all similar protocol
- Referral to appropriate institutional Official

QMC RIRC will notify the PI of their determination within a reasonable timeframe, generally less than 10 business days from the determination.

Findings of serious or continuing noncompliance will be reported to the appropriate institutional officials and the federal agency (e.g. OHRP, FDA, etc) and/or appropriate funding agency.

Any noncompliance that appears to be perceived or actual misconduct must also follow the QMC Administrative policy 610-xx-126B Process for Handling Allegations of Misconduct in Research.