Research Record Keeping Requirements

A. Purpose

This procedure outlines the requirements for documentation of the Research and Institutional Review Committee (RIRC) activities at The Queen's Medical Center (QMC).

B. Maintenance of Research Records

Research records shall be legible, identifiable and retrievable. Records are filed by the internal control tracking "RA" number (RA-Year-xxx) in active files and are filed by Principal Investigator and RA number for inactive files. All records are maintained on file in the Research Regulatory Office. Reference to records are identifiable and retrievable via the computerized tracking database.

C. Material required by Federal Regulation to be maintained for a minimum of 3 years after completion of the study (the Research Regulatory Office maintains research files for 7 years from the last correspondence):

a. Copies of all research proposals/protocols reviewed including amendments, changes, and modifications
b. Scientific evaluations, if any, that accompany the proposals
c. Approved informed consent/assent documents
d. Progress reports submitted by investigators
e. Reports of injuries or adverse events or unanticipated events to subjects
f. Records of continuing review activities
g. Copies of all correspondences between RIRC and the investigator
h. Statements of significant new findings provided to subjects
i. Internal or external audit reports on research studies
j. Minutes of RIRC meetings
k. A list of RIRC members
l. Copy of the last page of the consent form on all subjects enrolled from QMC
m. FDA 1572 form
n. Any part of the RIRC submission material
o. Investigator brochures
p. Tools, surveys, study-related documents

D. Minutes of the RIRC meetings

The RIRC Manager or designee is responsible for recording and drafting the minutes of the RIRC meetings. In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the RIRC at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(1) for the categories of research listed in the Federal Register of November 9, 1998 (see 63 FR 60364-60367 at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=98-29749-filed). Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the RIRC may not take further actions or votes unless the quorum can be restored.

The minutes of the RIRC meetings contain the following information:

1. Date and time of the meeting
2. Attendance at the meetings
3. Acceptance or modifications required of previous meeting minutes
4. Discussion of each protocol reviewed
5. Actions taken by the RIRC
6. Vote on actions taken on protocols including the number of members voting for, against and abstaining
7. Indication whether protocols are approved by full or expedited review
8. The basis for requiring changes to a protocol
9. The basis for disapproving research
10. The basis for termination of a research study
11. A written summary of controverted issues and their resolution
12. Discussion of other issues of concern to the RIRC
13. Education material discussed and distributed to RIRC members
14. If a member in attendance has a conflicting interest regarding any protocol for review, minutes shall show that this member did not participate in the review or vote, except to provide information requested by the RIRC.

E. Letter of the RIRC meetings

1. The RIRC Manager or designee will use the minutes of the RIRC meetings for drafting the letters of approval, conditional approval, tabled, or denial to Principal Investigators and their secondary contact person.
2. Letters will be signed by the RIRC Chairman or designee
3. Approved documents will have the RA number and RIRC approval seal place by RIRC staff.
4. Conditional approval, tabled, or denial letters will be accompanied with a list of items that must be addressed with a response by the investigator.

F. Roster of the RIRC Members

A list of RIRC members on file in the QMC Regulatory Office includes details described below:

1. Name of RIRC members
2. Earned degrees
3. Representative capacity on the committee (scientific members, non-scientific members, community representatives with no affiliation with QMC, expertise in different fields of medical care or health care)
4. Indications of experience to describe each member's chief anticipated contributions to RIRC deliberations.
5. Affiliation or relationship of member to QMC

G. Regulations and Education Materials

Federal, State and local regulations and education materials for RIRC members, Research Regulatory Office staff, investigators and study coordinators is on file in the RIRC office.

H. Record Retention by Investigators

1. Record retention requirements for the investigator vary with the type of research conducted and the provisions of the investigator's funding source. RIRC recommends that investigators clearly understand the retention requirements of their sponsors. All records must be accessible for inspection and copying by authorized representative of the QMC

RIRC, department or agency supporting the research. The condition for maintaining confidentiality of the subjects and the research records are required for the life of the data.

2. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations. Investigators shall upon request from authorized FDA officials, sponsors of the study, or QMC RIRC representative, at reasonable times, allow access to records for inspection and copying.
3. The Office of Human Research Protections guidelines for require institutions to retain records of IRC activities and certain other records frequently held by investigators for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representative of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.
4. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution must identify the successor responsible for maintaining those institutional records for the period of time required.