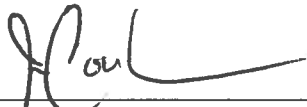




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| Section 900: | Quality Management |
| Title: | Quality Assurance Review Program |
| SOP Code: | 902.001 |
| Effective Date: | 2017APR21 |

Site Approvals

| | | |
|--------------------------------------|--|------------------------|
| Signature of Responsible Individual: | | |
| Ethics Compliance Advisor |  | April 21, 2017 Date |
| | Name: Jennifer Couture | |
| Approval Authority: | | |
| Chair, HSREB |  | April 21, 2017 Date |
| | Name: Dr. Albert Clark | |
| Approval Authority: | | |
| Director, Research Ethics Compliance |  | April 24, 2017 Date |
| | Name: Dr. Andrew Winterborn | |

1.0 PURPOSE

This SOP describes processes for monitoring, evaluating and improving the effectiveness of the human research protection enterprise.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Quality Management programs, Quality Assurance (QA), and Quality Control (QC) activities, such as reviews of the HSREB and of Researchers, allow for a continuous evaluation and subsequent assurance of the human research protection enterprise.

Findings are measured against established policies and procedures and all of the applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

5.1 Quality Assurance Review Program (Internal)

5.1.1 The Ethics Compliance Advisor or designee will develop a schedule for routine QA Reviews or initiate QA Reviews in response to complaints or other concerns;

5.1.2 QA Reviews may include the HSREB and the HSREB office;

5.1.3 When the Ethics Compliance Advisor or designee conducts a QA Review of the HSREB and the HSREB office the review may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of research files, HSREB membership rosters, HSREB attendance records, and HSREB agendas and minutes,
- A review of workload, performance metrics and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with HSREB members, HSREB Office Personnel, Researchers, sponsors, and regulators,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any feedback from sponsors, funders, research participants, and from regulators relevant to the protection of the rights, safety and well-being of research participants,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from Queen's University or

Affiliated Teaching hospital(s) policies, and whether the deviations require remediation,

- An assessment of compliance with all applicable requirements;

- 5.1.4 The Ethics Compliance Advisor or designee compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;
- 5.1.5 The Ethics Compliance Advisor or designee prepares a written summary of the review, including areas requiring improvement;
- 5.1.6 The Ethics Compliance Advisor or designee reports the findings to the HSREB Chair or designee, HSREB members, and to the appropriate Queens University and Affiliated Teaching Hospital Official(s) as required;
- 5.1.7 The Ethics Compliance Advisor or designee works with the HSREB Chair or designee to implement improvements (e.g., new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

5.2 Researcher Quality Assurance Review Program

- 5.2.1 The Ethics Compliance Advisor or designee will develop a schedule for routine QA Reviews and implement QA Reviews in response to Researcher requests;
- 5.2.2 The Ethics Compliance Advisor or designee will work with the HSREB and the appropriate Queen's University and/or Affiliated Teaching Hospital Official(s) where the research is being conducted to determine if and when a for-cause review of a Researcher is warranted;
- 5.2.3 The HSREB and/or the HSREB Chair may direct the Ethics Compliance Advisor or designee to conduct for-cause QA Reviews;
- 5.2.4 The Ethics Compliance Advisor or designee may request copies of the sponsor's monitoring reports for a designated research project or request that a questionnaire be completed;
- 5.2.5 The criteria for selecting Researchers or research projects for QA Reviews may include:
 - The results of a previous external audit or inspection,
 - The results of a sponsor audit,
 - Researcher-initiated studies (i.e., where the Researcher is also the sponsor),
 - Studies that involve a potentially high risk to participants,
 - Studies that involve populations with special considerations,
 - Studies in which Researchers are enrolling large numbers of participants,
 - Suspected non-compliance,

- Unanticipated problems involving risks to participants or others,
 - Suspected or reported protocol deviations,
 - Participant complaints,
 - Research Staff complaints,
 - Any other situation that the HSREB deems appropriate;
- 5.2.6 The Ethics Compliance Advisor or designee will notify the Researcher of the QA Review and a mutually acceptable time will be scheduled. It may be necessary to schedule an on-site review without first obtaining the formal consent of a Researcher (e.g., participant safety or suspected non-compliance);
- 5.2.7 The Ethics Compliance Advisor or designee will conduct the QA Review using appropriate evaluation tools;
- 5.2.8 When the Ethics Compliance Advisor conducts a QA Review of the Researcher, the QA Review may include some or all of the following (as applicable):
- An assessment of the SOPs and compliance with applicable regulations and guidance,
 - A review of all regulatory binders including the HSREB ethical clearance documentation, all versions of HSREB ethically cleared consent documents, signed consent documents, research protocols and amendment documentation, documentation for renewal of ethics clearance, correspondence between the Researcher and sponsor, etc.,
 - Interviews with the research staff and/or the Researcher,
 - A review of test article accountability,
 - A review of specimens and associated collection processes,
 - A review of computer hardware and/or software associated with the research,
 - A review of the consent form(s) and associated processes including eligibility requirements,
 - A review of the completed case report forms (CRFs) or other data collection mechanisms,
 - A review of appropriate source material (participant medical records), and
 - A review of other documentation, as relevant and available;
- 5.2.9 The Ethics Compliance Advisor or designee may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;
- 5.2.10 At the conclusion of the evaluation, the Ethics Compliance Advisor or designee will discuss the findings with the Researcher;

- 5.2.11 The Ethics Compliance Advisor or designee will draft a report or provide a summary of the QA Review including: positive findings, areas for improvement and recommendations for corrective action, and submit the report to the HSREB Chair or designee for review;
- 5.2.12 The Researcher will be given an opportunity to respond to the report with responses and/or corrective action plans within a time frame specified by the HSREB;
- 5.2.13 The Ethics Compliance Advisor or designee will send a copy of the final report to the Researcher and the HSREB. When applicable, the HSREB Chair or designee will provide the findings to the local Queen's University and/or Affiliated Teaching Hospital Official(s).

5.3 Corrective Action

- 5.3.1 The Ethics Compliance Advisor or designee may recommend corrective action based on the findings;
- 5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;
- 5.3.3 The Ethics Compliance Advisor or designee will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;
- 5.3.4 The Ethics Compliance Advisor or designee will follow-up with the Researcher in a timely manner to determine if the corrective actions have been implemented by the Researcher following a QA Review.

5.4 Documentation

- 5.4.1 The Ethics Compliance Advisor or designee files all reports and correspondence concerning QA Reviews in the appropriate QA Files.

6.0 REFERENCES

See References.

7.0 APPENDICIES

None.

8.0 REVISION HISTORY

| SOP Title | Version | Updates |
|----------------------------------|------------------------|---|
| Quality Assurance Review Program | v.902.001 2017APR21 | Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. No revisions to CAREB/N2 SOP 902 since initial effective date. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies. |