N2 NETWORK OF NETWORKS RÉSEAU DES RÉSEAUX

CAREB ACCER

SOP 901.002

Title	**Quality Assurance Inspections**
SOP Code	901.002
Effective Date	08-Mar-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
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1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for monitoring, evaluating and improving the effectiveness of the human research protection enterprise.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and the QA officer, if separate from the REB Office Personnel, are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Quality Management programs, Quality Assurance (QA), and Quality Control (QC) activities, such as inspections of the REB 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 REB Quality Assurance Inspections (Internal)

5.1.1 The QA Officer will develop a schedule for routine QA inspections or initiate ad hoc inspections in response to complaints or other concerns;

5.1.2 QA inspections may include the REB and the REB office;

5.1.3 When the QA Officer conducts a QA inspection of the REB and the REB office the inspection may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of research files, REB membership rosters, REB attendance records, and REB 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 REB members, REB 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 deviations from ethical, legal, or regulatory requirements, or deviations from the organization's policies, and whether the deviations require remediation,
- An assessment of compliance with all applicable requirements;

5.1.4 The QA Officer compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

5.1.5 The QA Officer prepares a written summary of the inspection, including areas requiring improvement;

5.1.6 The QA Officer reports the findings to the REB Chair or designee, and to the REB and/or to the appropriate Organizational Official as required;

5.1.7 The QA Officer works with the REB 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 Inspections

5.2.1 The QA Officer will develop a schedule for routine QA inspections and implement inspections in response to Researcher requests;

5.2.2 The QA Officer will work with the REB and the organization at which the research is being conducted to determine if and when a for-cause inspection of a Researcher is warranted;

5.2.3 The REB may direct the QA Officer to conduct for-cause inspections;

5.2.4 The QA Officer or designee may request copies of the sponsor's monitoring reports for a designated research project or that a questionnaire from the REB is completed;

5.2.5 The criteria for selecting Researchers or research projects for inspection 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 vulnerable populations,
- Studies in which Researchers are enrolling large numbers of participants,
- Suspected noncompliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Participant complaints,
- Research Staff complaints,
- Any other situation that the REB deems appropriate;

5.2.6 The QA Officer or designee will notify the Researcher of the inspection and a mutually acceptable time will be scheduled. It may be necessary to schedule an inspection without first obtaining the formal consent of a Researcher (e.g., participant safety or suspected non-compliance);

5.2.7 The QA Officer or designee will conduct the inspection using designated/ appropriate evaluation tools;

5.2.8 When the QA Officer conducts an inspection of the Researcher, the inspection 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 REB approval documentation, REB approved consent documents, signed consent documents, 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 REB or the QA Officer 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 QA Officer or designee will discuss the findings with the Researcher;

5.2.11 The QA Officer or designee will draft a report or provide a summary of the inspection including: positive findings, areas for improvement and recommendations for corrective action, and submit the report to the REB 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 specified by the REB;

5.2.13 The QA Officer or designee will send a copy of the final report to the Researcher and the REB. When applicable, the REB Chair or designee will provide the findings to the local Organizational Official.

5.3 Corrective Action

5.3.1 The QA Officer 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 QA Officer will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4 The QA Officer will follow-up with the Researcher in a timely manner to determine if the corrective actions have been implemented by the Researcher following a Researcher audit or inspection.

5.4 Documentation

5.4.1 The QA Officer or designee files all reports and correspondence concerning QA inspections in the appropriate QA Files.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP901.001	15-Sept-2014	Original version
SOP901.002	08-Mar-2016	No revisions needed