	901.004

PURPOSE

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

SCOPE

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

RESPONSIBILITIES

All REB members, Research Ethics staff and the Director, Research Ethics, are responsible for ensuring that the requirements of this SOP are met.

DEFINITIONS

See Glossary of Terms.

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.



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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.

Documentation

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

REFERENCES

See References.

REVISION HISTORY

SOP901.001	15-Sept-2014	Original version
SOP901.002	08-Mar-2016	No revisions needed
SOP901.003	08-Oct-2019	5.2.5: addition of the following in the fifth bullet – vulnerable ‘(in the context of research)’
SOP901.004	15-May-2023	No revisions needed