Yukon University

SOP 901

Procedures: Human Research Ethics	SOP 901 Quality Assurance Visits
Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research
Executive Lead	Research Services
Approval Authority	President
Original Date	Replaces AR-03 procedures (May 2009, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

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

2.0 SCOPE

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

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel and YukonU members responsible for quality assurance are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Quality Assurance (QA) activities, such as periodic assessments of REB and research activities, 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 Assessments of the REB

5.1.1 The YukonU Quality Assurance (QA) officer or designee will develop a schedule for routine QA assessments of the REB and the Research Ethics Office in response to requests from the REB, Researcher or Organizational representatives;

5.1.2 QA assessments may be conducted by members of the Research Ethics Office, or by other YukonU personnel. REB members may be directly or indirectly involved;

5.1.3 When the QA Officer or designated individual conducts a QA assessment of the REB and the Research Ethics Office the evaluation may including the following:

- An assessment of the SOPs and compliance with applicable policies, guidelines and regulatory requirements,
- 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 and Researchers,
- 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 or designate, compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

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

5.1.6 The QA Officer or designate reports the findings to the REB Co-Chairs or designee, and to the REB and/or to the appropriate YukonU Official as required;

5.1.7 The QA Officer or designee works with the REB Co-Chairs 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 Visits

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

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

5.2.3 The REB may direct the QA Officer /designee to conduct for-cause visits;

5.2.4 The QA Officer or designee may request that a pre-visit questionnaire is completed by the Researcher;

5.2.5 The criteria for selecting Researchers or research projects for visit may include:

- The results of a previous QA visit,
- 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 non-compliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Research terminated by the REB due to failure by the investigator to submit the study for continuing review or failure to respond to a request for information from the REB,
- Studies reporting a large number of serious adverse events/unanticipated problems and/or 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 visit to review the research project and a mutually acceptable time will be scheduled. It may be necessary to schedule a visit 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 a review of the research project using designated/appropriate evaluation tools;

5.2.8 When the QA Officer or designee conducts a review of the research project, the review may include some or all of the following (as applicable):

- An assessment of the SOPs and compliance with applicable policies and guidance,
- A review of REB approved documentation,
- Interviews with the Researcher and research team,
- 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 documents and/or processes including eligibility requirements,
- A review of data collection mechanisms,
- A review of appropriate source material (e.g., participant medical records), and
- A review of other documentation, as relevant and available;

5.2.9 The REB or the QA Officer/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 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 Co-Chairs 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 Co-Chairs. When applicable, the REB Co-Chairs or designee will provide the findings to the Associate Vice-President Research (AVPR).

5.3 Corrective Action

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

5.3.4 The QA Officer 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 research project quality assessment visit.

5.3.5 Upon completion of the review, the collected data will be analyzed and a written report generated. The report will specifically address all findings, itemizing and describing all of the observations of non-compliance (if any) made during the conduct of the inspection, along with the corresponding regulatory references and required remedial actions, if necessary. For directed audits, the report will include an assessment of whether the preponderance of evidence shows that any of the allegations of noncompliance are findings of non-compliance. If the audit results in findings of noncompliance, the Research Ethics Coordinator will recommend an appropriate course of action to the applicable REB Co-Chairs and, if appropriate, the AVPR;

5.4 Documentation

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

6.0 6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 901	July 2022	YukonU version adapted from N2/CAREB SOP 901.003 (October 8, 2019) and CAREB 901.001 (2021)