

Section 400:	Review of Research
Title:	Research Requiring Federalwide Assurance (FWA)
SOP Code:	409.003
Effective Date:	2022JAN06

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
Albert F Clark		06JAN2022
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This standard operating procedure (SOP) describes the requirements for conducting federally funded research involving human participants. Under the United States Department of Health and Human Services (DHHS) Code of Federal Regulations 45 Part 46 A Protection of Human Subjects ([Section 46.103](#)) any institution conducted or supported by any United States Federal Department or Agency that has adopted the [Common Rule](#) must have assurance of compliance with the United States Office for Human Research Protections (OHRP) when conducting research using human participants.

1.0 SCOPE

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

2.0 RESPONSIBILITIES

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

The Researcher is responsible for complying with FWA regulations when receiving funding from any U.S. Federal Department or Agency that has adopted the Common Rule.

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURES

The U.S. Federal Office for Human Research Protections (OHRP) requires that all U.S. Federally supported or conducted research involving human participants must be conducted at facilities covered by a Federalwide Assurance (FWA). The HSREB is compliant with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46 and its Subparts A, B, C, and D, and has been assigned the following FWA numbers:

- Queens' University and Affiliated Teaching Hospitals' FWA number is: **FWA00004184.**
- Queen's University's HSREB REB number is: **IRB00001173.**

4.1 Update or Renewal of HSREB Registration

- 4.1.1 The Ethics Compliance Advisor or designee is responsible for ensuring that all updates and renewals are reported to the U.S. Office of Human Research Protection (OHRP) in a timely manner;
- 4.1.2 Any updates or renewals must be reported using the electronic submission system available through the Electronic Submission System (ESS) on the [OHRP website](#);
- 4.1.3 HSREB registration updates must be made in the electronic system within ninety days;
- 4.1.4 Any disbandment of the HSREB must be reported to OHRP in writing within thirty days after the permanent cessation of the HSREB's review of DHHS conducted or supported research;
- 4.1.5 HSREB registration is effective for three years and must be renewed every three years, even if no changes have occurred, in order to maintain an active FWA;
- 4.1.6 Any renewal or update that is submitted and approved electronically will re-start a new three year active FWA;
- 4.1.7 The FWA renewal/update is effective for five years and must be renewed every five years, even if no changes have occurred, in order to maintain an active FWA. Any FWA renewal or update will require the VP of Research's approval. Any renewal or update that is submitted electronically, and approved by OHRP, begins a new five year effective period;
- 4.1.8 The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

4.2 Incident Reports

- 4.2.1 The Ethics Compliance Advisor or designee is responsible for sending incident reports to OHRP;
- 4.2.2 Incident reports may be related to the following:

- Unanticipated problems involving risks to participants or others,
- Serious Adverse Events (SAEs),
- Serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46,
- Suspension or termination of HSREB ethics clearance of a research study,

4.2.3 Additional guidance on reporting OHRP incidents can be found on the [OHRP website](#);

5.0 REFERENCES

See References.

6.0 APPENDICES

1. [Guidance on Reporting Incidents to OHRP](#).

7.0 REVISION HISTORY

SOP Title	Version	Updates
Research Requiring Federalwide Assurance (FWA)	v.409.001 2015OCT22	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.
Research Requiring Federalwide Assurance (FWA)	v.409.002 2016SEP12	<ul style="list-style-type: none"> • Numerous revisions to Purpose, Scope and Procedures. • Definitions removed and added to glossary of terms. • Hyperlinks added for website references. • All references to IRB changed to REB.
Research Requiring Federalwide Assurance (FWA)	v.409.003 2022JAN06	<ul style="list-style-type: none"> • Site Approval updated