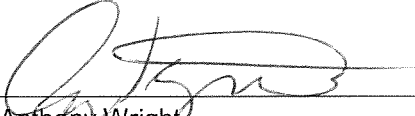
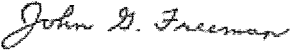



Section 400:	Review of Research
Title:	Research Requiring Federalwide Assurance (FWA)
SOP Code:	409.001
Effective Date:	2016March07

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR07
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR07
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR07
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP pertains to GREB and its authority to review and approve human participant research in compliance with applicable United States (US) Federalwide Assurance (FWA) of Protection for Human Subjects regulations, policies, and current and emerging best practices.

2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen's University. The scope of GREB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants."

3.0 RESPONSIBILITIES

All GREB members and GREB office personnel are responsible for ensuring that the requirements of this SOP are met. Researchers are responsible for complying with FWA regulations when receiving funding from any US federal department or agency that has adopted the Common Rule.

The Ethics Compliance Advisor (ECA) is responsible for ensuring that all updates and renewals are reported to the US Office of Human Research Protection (OHRP).

4.0 DEFINITIONS

“Federally supported” is defined in this SOP and in the FWA as the US Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves US Government employees.

FWA Adverse Event ([FWA]AE) is defined in this SOP as “any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms.”¹

5.0 PROCEDURES

All research engaged in US federally supported human participant research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects,

¹ Although the HHS regulations do not define or use the word adverse event, this is the common definition of this term across government and non-government entities modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practices. (See <http://www.hhs.gov/ohrp/policy/advevntguid.html>)

must comply with the US Federal Policy for the Protection of Human Subjects, known as the Common Rule. All US federally supported human participant research must also comply with any additional human participant regulations, policies, and current and emerging best practices. All human participant research conducted or supported by the US Department of Health and Human Services (DHHS) must comply with all subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

The US Federal Office for Human Research Protections (OHRP) requires that (US) federally supported (i.e., conducted or supported) research involving human participants only be conducted at facilities covered by a Federalwide Assurance (FWA). Through the FWA, GREB commits to the Department of Human Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

- Queens' University FWA number is: **FWA00004184**
- Queens' University GREB IRB number is: **IRB00003062**

5.1 Update or Renewal of Institutional Review Board (IRB) Registration

- 5.1.1 IRB registration update must be made within 90 days after changes regarding the contact person (i.e., the ECA) who provided the IRB registration information, the GREB Chair, or GREB membership;
- 5.1.2 If Queens' University decides to disband a registered IRB that it is operating, it must be reported in writing within 30 days after permanent cessation of the IRB's review of US Department of Health and Human Services (HHS) conducted or supported research;
- 5.1.3 IRB Registration is effective for 3 years and must be renewed every 3 years, even if no changes have occurred, to maintain an active FWA. Any renewal or update that is submitted electronically and

approved by US Office for Human Research Protections (OHRP) begins a new 3-year effective period.

5.2 Federalwide Assurance (FWA) Clearance

- 5.2.1 Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all US federally supported human participant research will be reviewed, prospectively approved, and subject to continuing oversight and review (depending on the degree of risk) at least annually by GREB;
- 5.2.2 GREB Members should identify and bring to the attention of the GREB Chair, Ethics Coordinator, or the Ethics Compliance Advisor (ECA) ethics applications that receive US government funding or that identify the study as requiring Federalwide Assurance (FWA) compliance. The Chair or ECA will determine if the research study and ethics application meet the criteria for ethics clearance according to FWA regulations, policies, and current and emerging best practices;
- 5.2.3 For FWA clearance, the typical GREB clearance steps must be followed, namely: a completed submission and reviewed by GREB delegated or full board review. GREB and/or GREB Office Personnel may consult researchers for additional information as necessary (see SOP 402.001 GREB Delegated Review or 403.001 GREB Full Board Review);
- 5.2.4 Following initial review of the research, the GREB shall make a determination as to the compliance of the research with FWA and communicate this determination to OHRP;
- 5.2.5 Participant recruitment/registration, pilot studies, obtaining informed consent, access or collection of data and collection of data cannot start prior to receiving written ethical clearance by GREB and FWA.

- 5.2.6 In addition to GREB and FWA Ethics Clearance, the requirements of where the research will be conducted must be met before the research can begin (e.g., department approvals, adequate resources);
- 5.2.7 In accordance with FWA regulations, policies, and current and emerging best practices, researchers shall report to GREB any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants, any unanticipated events, and any serious or continuing non-compliance, including reportable events that meet the reporting criteria as outlined in this SOP and/or in the research protocol;
- 5.2.8 Unexpected Adverse Event Reports² must be reported to US Office for Human Research Protections (OHRP) according to the required time-line for reporting incidents (see "Guidance on Reporting Incidents to OHRP" - <http://www.hhs.gov/ohrp/compliance/reports/index.html>). Incident reports include reports of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance, the requirements or determinations of the GREB, and suspension or termination of GREB approval;
- 5.2.9 GREB will have authority to approve, suspend, terminate, require modifications in, or, where it deems the risks to participants exceeds the benefits of the research, not grant ethical clearance.

² See U.S. Department of Health and Human Sciences (HHS) "Unanticipated Problems Involving Risks and Adverse Events Guidance" (2007) - <http://www.hhs.gov/ohrp/policy/advevntguid.html> (accessed 2016FEB29)

5.3 Update of Renewal of Federalwide Assurance (FWA)

- 5.3.1 Each institution must complete and submit its FWA updates and renewals using the electronic submission system available through the OHRP Web site at <http://ohrp.cit.nih.gov/efile/>;
- 5.3.2 The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement;
- 5.3.3 Incident reports, which include reports of unanticipated problems involving risks to participants or others; Serious Adverse Events³, serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of GREB; and suspension or termination of GREB clearance of a research study must be reported to OHRP. See Guidance on Reporting Incidents to OHRP at: <http://www.hhs.gov/ohrp/compliance/reports/index.html>;
- 5.3.4 Renewal/update is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, to maintain an active FWA. Any renewal or update that is submitted electronically and approved by US Office for Human Research Protections (OHRP) begins a new 5-year effective period.

5.4 Non-exemptions from FWA Compliance

- 5.4.1 Research that is not exempt from FWA Compliance:
- Intervenes or interacts with human participants for purposes of US federally-supported research,

³ U.S. FDA defines a Serious Adverse Event as any undesirable experience associated with the use of a medical product in a patient [or participation in research – my brackets] that results in the following outcomes: death, life threatening experience, hospitalization (initial or prolonged), disability of permanent damage (i.e., substantial disruption of a person's ability to conduct normal life functions), congenital anomaly/birth defect, or other serious medical outcomes. See <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm> (accessed 2016FEB29)

- Obtains individually identifiable private information about human participants for purposes of US federally-supported research, or
- Receives a direct US federal award to conduct human participant research, even where a subcontractor or collaborator carries out all activities involving human participants.

6.0 REFERENCES

US Federal Policy for the Protection of Human Subjects, known as The Common Rule; and all subparts of DHHS Regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its subparts A, B, C, and D).

U.S. Department of health and Human Sciences (HHS) “Unanticipated Problems Involving Risks and Adverse Events Guidance” (2007) -

<http://www.hhs.gov/ohrp/policy/advevntguid.html> (accessed 2016FEB29)

HHS, “Guidance on Reporting Incidents to OHRP” (2011) -

<http://www.hhs.gov/ohrp/compliance/reports/index.html> (accessed 2016FEB29)

7.0 APPENDICES

1. OHRP Guidance on Reporting Incidents

8.0 REVISION HISTORY

SOP Title	Version	Updates
Research Requiring Federalwide Assurance (FWA)	v.409.001 2016MAR07	Original: This SOP was developed based on information from the US Federalwide Assurance (FWA) documents, and the US Office for Human Research Protections (OHRP) documents as well as Queen's University previous documents or policies (using the format of CAREB/N2).