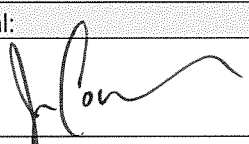
Section 400:	**Review of Research**
Title:	**Research Requiring Federalwide Assurance (FWA)**
SOP Code:	**409.002**
Effective Date:	**2016SEP12**

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor	 Name: Jennifer Couture	Date: 2016 Sep 14
Approval Authority:		
Chair, HSREB	 Name: Dr. Albert Clark	Date: Sept 14, 2016
Approval Authority:		
Director, Research Ethics Compliance	 Name: Dr. Andrew Winterborn	Date: 2016 Sep 15

1.0 PURPOSE

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.

2.0 SCOPE

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

3.0 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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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.**

5.1 Update or Renewal of HSREB Registration

5.1.1 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;

5.1.2 Any updates or renewals must be reported using the electronic submission system available through the Electronic Submission System (ESS) on the OHRP website;

5.1.3 HSREB registration updates must be made in the electronic system within ninety days;

5.1.4 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;

5.1.5 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;

5.1.6 Any renewal or update that is submitted and approved electronically will re-start a new three year active FWA;

5.1.7 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;

5.1.8 The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

5.2 Incident Reports

5.2.1 The Ethics Compliance Advisor or designee is responsible for sending incident reports to OHRP;

5.2.2 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,

5.2.3 Additional guidance on reporting OHRP incidents can be found on the OHRP website;

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Guidance on Reporting Incidents to OHRP.

8.0 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	1. Numerous revisions to Purpose, Scope and Procedures. 2. Definitions removed and added to glossary of terms. 3. Hyperlinks added for website references. 4. All references to IRB changed to REB.

Section 400:	**Review of Research**
SOP Title:	**Research Requiring Federalwide Assurance (FWA)**
SOP Code:	**409.002**
Effective Date:	**2016SEP12**

Appendix 1

GUIDANCE ON REPORTING INCIDENTS TO OHRP (2011)

NOTE: THIS GUIDANCE REPLACES OHRP'S MAY 27, 2005 GUIDANCE ENTITLED "GUIDANCE ON REPORTING INCIDENTS TO OHRP". This guidance has been updated to clarify what information regarding serious or continuing noncompliance by the institutional review board needs to be reported, to include an e-mail address to report incidents to OHRP, and to update OHRP's contact information.

This guidance represents OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

Date: June 20, 2011

1. Scope:

This document provides guidance about procedures institutions may use to file incident reports with OHRP. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. In particular, OHRP offers guidance on the following topics:

I. Applicability of incident reporting requirements;

II. Information to be included in incident reports;

III. Time frame for reporting incidents;

IV. OHRP focus on corrective actions when reviewing incident reports;

V. OHRP's response to incident reports;

VI. Where to send incident reports; and

VII. Additional guidance.

Target Audience: IRBs, institutional officials and institutions that may be responsible for review, oversight, or conduct of human subjects research covered by an OHRP-approved assurance.

Regulatory Background:

HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to regulatory requirements pertaining to research conducted under an OHRP- approved assurance are promptly reported to OHRP:

a. **Any unanticipated problems involving risks to subjects or others;**

b. **Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and**

c. **Any suspension or termination of IRB approval.**

Guidance:

I. Applicability of incident reporting requirements

In general, these reporting requirements apply to all nonexempt human subjects research that is:

a. conducted or supported by HHS;

b. conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or

c. covered by an FWA, regardless of funding source.

Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. OHRP notes that these incident reporting requirements are **not** applicable to such research. In such cases, the institution should contact the non-HHS department or

agency that supports the research about reporting requirements. See the decision chart below.

II. Information to be included in incident reports

To fulfill the regulatory requirements for reporting incidents, OHRP would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in an incident report submitted to OHRP:

A. For unanticipated problems involving risks to subjects or others:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem; and
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

B. For serious or continuing noncompliance:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved;
- Name of the principal investigator on the protocol, if applicable;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);

- A detailed description of the noncompliance; and

- Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

C. For suspension or termination:

- Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;

- Title of the research project and/or grant proposal that was suspended or terminated;

- Name of the principal investigator on the protocol;

- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);

- A detailed description of the reason for the suspension or termination; and

- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

III. Time frame for reporting incidents

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or

- when an investigation has been completed or a corrective action plan has been implemented.

IV. OHRP focus on corrective actions when reviewing incident reports

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of non-compliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of the corrective actions taken by the institution. In particular, OHRP assesses whether or not the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution-wide.

V. OHRP response to incident reports

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will either state that the report was adequate or request additional information. For questions on reporting, please contact the Director of the Division of Compliance Oversight, 240-453-6900 or 866- 447-4777.

VI. Where to send incident reports

Please send reports (PDF or Word documents preferred) to the following email address:

IRPT.OS@hhs.gov

VII. Additional guidance

Please see OHRP guidance on continuing review regarding the distinction between suspension and expiration of IRB approval and OHRP guidance on unanticipated problems.

Content created by Office for Human Research Protections
Content last reviewed on March 19, 2016