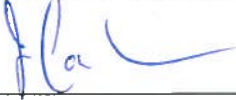




<b>Section 100:</b>	<b>General Administration</b>
<b>Title:</b>	<b>Research Activities Requiring HSREB Review</b>
<b>SOP Code:</b>	<b>102.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

## Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

The purpose of this SOP is to describe research activities that require HSREB review and research activities that do not.

## 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.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

All research involving human participants must be reviewed and ethically cleared by a REB. No intervention or interaction with human participants in research, including recruitment, may begin until a REB has reviewed and ethically cleared the research protocol, consent documents and recruitment materials.

## **5.1 Research that Requires HSREB Review**

5.1.1 The following requires review and ethical clearance by the HSREB before the research commences:

- a) Research involving human participants,
- b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

## **5.2 Research that may be Exempt from HSREB Review**

5.2.1 The HSREB chair will make the decision regarding submitted research projects that may be exempt from HSREB review,

5.2.2 Research that relies exclusively on publicly available information may not require HSREB review when:

- a) The information is legally accessible to the public and appropriately protected by law,
- b) The information is publicly accessible and there is no reasonable expectation of privacy;

5.2.3 HSREB review may not be required for research involving the observation of people in public places where:

- a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,
- b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
- c) Any dissemination of research results does not allow for identification of specific individuals;

5.2.4 The opinion of the HSREB chair should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

## **5.3 Activities that may not Require HSREB Review**

5.3.1 Activities outside the scope of research subject to HSREB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than the HSREB;

5.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal

educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and may not fall within the scope of HSREB review; however HSREB ethics clearance is required if results are to be disseminated and/or published;

5.3.3 Creative practice activities, in and of themselves, do not require HSREB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to HSREB review.

#### **5.4 Exceptions that may require HSREB Ethics Clearance**

5.4.1 Internet chat rooms and self-help groups with restricted membership access;

5.4.2 Linking data from multiple sources of publicly available information may require ethics clearance.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICES**

None.

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Research Activities Requiring HSREB Review	v.102.001 2015MAY25	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.

