SOP Title	Communication – Study Participants
Number.Version	602.002
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Approvals

Name and Title of Signatories	Signature	Date yyyy/mm/dd
Janet Manzo Executive Director, OCREB		2013/06/25
Jack Holland Chair, OCREB		2013.06.26

1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the Ontario Cancer Research Ethics Board (OCREB) communications with study participants.

2.0 GENERAL POLICY STATEMENT

Research participants should be able to voice their concerns or questions, or to request information regarding their participation or potential participation in a research project, in confidence, to an informed individual on the REB or in the REB office.

3.0 DEFINITIONS

See glossary of terms.

4.0 RESPONSIBILITY

This SOP applies to all OCREB members including the Chair and Vice-Chair and to all OCREB office personnel including the Executive Director and the Research Ethics Officer.

The OCREB office personnel are responsible for immediately responding to, or directing research participant communication to the OCREB Chair, as appropriate.

The OCREB Chair is responsible for responding to research participant communication.

5.0 SPECIFIC POLICIES AND PROCEDURES

5.1 Communication with Research Participants

5.1.1 Research participants are encouraged to contact (by telephone or in writing) the OCREB office with questions and concerns, using the contact information provided in the informed consent document. If requested, the identity of the participant will not be recorded or shared;

5.1.2 The OCREB office personnel must document all initial communication with the research participant using the *Research Participant Communication Contact Form*. This form, which contains contact information, is stored securely in a locked file;

5.1.3 The OCREB office personnel must immediately relay information to the Chair when a participant indicates that they would like to speak with the Chair to share concerns or problems encountered while participating in a research project;

5.1.4 In the absence of the Chair, the OCREB office personnel will immediately relay all communication from participants to the Vice-Chair;

5.1.5 The Chair or designee works to resolve participant issues, which may include a follow-up with the Investigator or the Investigator's supervisor or other institutional representative, and with appropriate federal agencies, as indicated;

5.1.6 If the local REB Chair or another individual at the institution is listed in the consent form and is contacted by a research participant, OCREB should be notified of information relevant to studies overseen by OCREB;

5.1.7 The Chair documents all communication with the research participant and a de-identified record of this communication (*Research Participant Communication Reporting Form*) is maintained in a secure electronic file and in the relevant study file in the online system (when applicable).

6.0 REFERENCES

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans*, December 2010 (TCPS2);
2. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 56.109, 56.115;
3. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.115.

7.0 SOP HISTORY

SOP Number	Version	Key Changes
602	001	Original
602	002	• Approvals section – signatory was changed to the curent OCREB Chair; • Section 3 – definitions are provided in a separate glossary of terms; • Section 5 – modified slightly to note the details of the separate contact and reporting forms; • Section 6 - reference to TCPS2 was added.