

<b>TITLE:</b>	Standard Operating Procedure (SOP) Communication: Research Participants	<b>NUMBER:</b>	NSHA REB-SOP-6-002
Effective Date:	January 3, 2017	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members, and REB Office Personnel.		

## 1. PURPOSE:

This standard operating procedure (SOP) describes the Research Ethics Board (REB) communications with research participants involved in research overseen by the NSHA REB.

## 2. POLICY:

In the interests of enhancing human research participant protection and harmonization of policies and procedure, it is important for the REB to foster collaboration and open communication. Research participants should be able to confidentially voice their concerns or questions, or request information regarding their participation or potential participation in a research project, to an informed individual on the REB or in the Research Ethics Office.

## 3. DEFINITIONS:

See Glossary of Terms

## 4. PROCEDURES:

### 4.1. Communication with Research Participants

- 4.1.1. Research participants are encouraged to contact (telephone or in writing) the Research Ethics Office with questions and concerns. If requested, the identity of the participant will not be recorded or shared;
- 4.1.2. The REB Office Personnel will relay communications promptly to the Manager when the participant shares concerns or problems encountered with a research project or research staff;
- 4.1.3. The Manager (or designee) will promptly communicate participant concerns or problems to the REB Executive Chair;
- 4.1.4. The REB Executive Chair or designee works to resolve participant issues, including follow-up with the Investigator or the Investigators supervisor or institutional official and appropriate federal agencies, as indicated;

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- 4.1.5. The REB Executive Chair or designee documents communication with the research participant and a record of this communication is maintained securely on file at the Research Ethics Office.

## **5 REFERENCES**

- I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 1, Section B;
- II. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;
- III. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115.

## **6 RELATED DOCUMENTS:**

N/A

### Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
September 29, 2017	Original Version	