SOP Title	**NMREB Communications – Other Entities**
Number.Version	N603.002
Effective Date	05/11/2018

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		2019-02-26
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		2019-03-06

1. PURPOSE

This Standard Operating Procedure (SOP) describes the Non-Medical Research Ethics Board (NMREB) communications with various parties, aside from the Investigator, involved in research overseen by the NMREB.

2. GENERAL POLICY STATEMENT

In the interest of enhancing human research participant protection and the harmonization of policies and procedures, it is important for the NMREB to foster collaboration and open communication with the local NMREB and its various institutional representatives and departments.

The NMREB is required by federal regulations to ensure that specific reports and actions are communicated to entities that may have an interest in the status of the research being conducted, including institutional officials and regulatory authorities.

3. RESPONSIBILITY

This SOP applies to all NMREB members including the Chair and Vice-Chair(s) and to all Office of Human Research Ethics (OHRE) staff.

The Investigator is responsible for informing the NMREB of study related correspondence to and from the regulatory agencies including notification regarding any planned inspections or audits.

The OHRE staff are responsible for notifying the NMREB Chair or Vice-Chair(s) of any communication to or about the NMREB from regulatory agencies.

The NMREB Chair or Vice-Chair(s) is responsible for requesting that the Investigator communicate any reportable events to the NMREB, the sponsor, and Institutional Official as appropriate. The NMREB Chair or Vice-Chair(s) may choose to notify the Institutional Official directly.

The Institutional Official is responsible for communicating required reportable events to the regulatory authorities in accordance with applicable laws, or the terms and conditions of research agreements or contractual arrangements.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Communication with Institutional Contacts

5.1.1. The OHRE staff will provide to the designated institutional representative(s), access to and notification of all NMREB approvals for all initial and continuing approvals (as applicable);

5.1.2. The Investigator must communicate any reportable events occurring during the conduct of the study to the NMREB, the sponsor and the appropriate Institutional Official. The NMREB Chair or Vice-Chair(s) may choose to notify the Institutional Official directly;

5.2. Communication with Institutional Departments

5.2.1. If during its review the NMREB has concerns with the Investigator's application (e.g., conflicts of interest), the NMREB may contact the applicable institutional contact (e.g., contract office);

5.2.2. Reciprocal communication is desirable between the NMREB, the contracts office, the research office, or other departments as applicable, on various matters related to or unrelated to the reviewed research.

5.3. Communication with External Bodies

5.3.1. The NMREB Chair or Vice-Chair(s) may communicate with the regulatory agencies to discuss research projects when appropriate, to seek guidance as needed, or to report the termination or suspension of the NMREB approval of a research study;

5.3.2. The NMREB Chair, Vice-Chair(s) or designee is the point of contact for any inspections or audits by regulatory bodies. The NMREB Chair or Vice-Chair(s) notifies the NMREB members, the applicable Investigators and the OHRE staff of any planned inspections or audits.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
6.2. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.115.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N603.001	Original	07/08/2016
N603.002	Update to NMREB Chair	05/11/2018