CLINICAL TRIALS ONTARIO

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NOTICE OF CHANGE TO THE CLINICAL TRIALS ONTARIO REB OF RECORD STUDY AGREEMENT TEMPLATE

NOTICE EFFECTIVE DATE: 12/06/15

RE: Requirements related to US Federalwide Assurance

Please be advised that a clause in the REB of Record Study Agreement, included as Schedule E of the Clinical Trials Ontario (CTO) Participation Agreement, has been revised as follows in this notice. An updated version of the Participation Agreement template [Version Date: 28/05/15], incorporating this change, is available at www.ctontario.ca.

Background

A Federalwide Assurance (FWA) is required for institutions that are engaged in research that is funded or supported by the United States (US) Department of Health and Human Services (HHS). The FWA is an agreement where the institution commits to the HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. As part of the FWA, the institution designates at least one REB (IRB) responsible for reviewing research for the institution.

CTO sought clarification from the Office of Human Research Protections (OHRP) in the US regarding which REB(s) must be designated on the FWA. OHRP confirmed that **institutions are only required to designate their internal REB**. If an institution does not have an internal REB, only one external REB (e.g., the REB that usually provides oversight for the research conducted at the institution) needs to be designated.

What this means for you as the Participating Institution in the CTO Streamlined System

The Participating Institution is not required to designate the REB Host Institution's REB under the Participating Institution's FWA if it does not normally do so.

These revisions will be included in the REB of Record Study Agreement that is posted on the CTO website and signed for each study using the CTO Streamlined System.

Please advise CTO if your organization requires a formal amendment to the Participation Agreement to authorize this change.

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Revision

SCHEDULE 1, Section II: The Responsibilities of the Participating Institution

Original clause (Version date: 27/03/15)

2. The Participating Institution shall maintain a Federal Wide Assurance (**FWA**) and designate REB Host Institution's REB as responsible to the Participating Institution under the Participating Institution's FWA.

Revised clause (Version date: 28/05/15)

2. The Participating Institution shall maintain a FWA.

CLINICAL TRIALS ONTARIO

By: _____
Susan Marlin, President and CEO

Date: June 12/15