

PREGTRIAL IN-PERSON MEETING

FROM INCLUSION TO IMPLEMENTATION

AGENDA

Building Consensus and Advancing Guidelines for Pregnant and Lactating People in Clinical Trials

Monday, October 26, 2026 | Montréal, Quebec | Thomson House, McGill University

GENERAL OBJECTIVES AND OUTCOMES

1. Review ethical principles and frameworks relating to the inclusion of pregnant and lactating individuals in clinical trials
2. Discuss Canada-specific barriers and facilitators in the implementation of ethical frameworks supporting enhanced inclusion of pregnant and lactating individuals in clinical trials
3. Develop consensus through the application of a draft informed consent toolkit facilitating inclusion of pregnant and lactating individuals in clinical trials

OUTPUTS AND DELIVERABLES

1. Stakeholder-informed pregnancy-specific informed consent form toolkit
2. Manuscript of proceedings of meeting
3. Development of an engaged network focused on inclusive clinical trials for women/individuals across the reproductive lifespan

Start Time	Opening: 8:00–8:50	Presenter
8:00	**BREAKFAST & REGISTRATION**	
8:30	**Opening address, land acknowledgment, and introductions** • Opening remarks (5 minutes)	Emily Doerksen
8:35	**Patient Partner Talk** • Talk (10 minutes) • Audience questions/discussion (5 minutes)	Margaret Loniewska

Start Time	Session 1: Ethical Principles and International Frameworks | 8:50–10:05 Moderator: Dr. Emily McDonald, McGill University	Presenter
8:50	**Research Ethics 101** • Presentation (20 minutes)	Benjamin Carlisle, McGill University
	LEARNING OBJECTIVES • Describe key ethical principles guiding the design of clinical trials • Evaluate the ethical considerations of including vulnerable groups in clinical trials • Apply these principles to the inclusion of pregnant and lactating individuals in clinical trials	
9:10	**Health Canada perspective and updates on the ICH E21 document – Priority areas for adaptation and rapid implementation in Canada** • Presentation (20 minutes)	Lindsay Patrick, Health Canada
	LEARNING OBJECTIVES • Describe the ICH-E21 guidelines and their relevance to the inclusion of pregnant and lactating individuals in clinical trials • Identify approach for implementing ICH-E21 that meets the needs of the Canadian research community	
9:30	**A review of disease-specific and agnostic toolkits as part of the WHO Task Force on Inclusion of Pregnant and Breastfeeding Women in Clinical Trials** • Presentation (20 minutes)	Martina Penazzato, WHO
	LEARNING OBJECTIVES • Define the objectives of the WHO task force on inclusion of pregnant and lactating women in clinical trials • Compare disease-specific and disease-agnostic toolkits for pregnant and lactating women inclusion • Propose strategies for international uptake in view of local guidelines and ICH-E21 WHO recommendations	
9:50	**Session 1 – Question Period** • Panel format – audience questions/discussion (15 minutes)	Session 1 speakers
10:05	**REFRESHMENT BREAK** *(15 minutes)*	

Start Time	Session 2: Insights from Canadian Initiatives to Enhance Representation of Reproductive-Aged, Pregnant and Lactating Women in Clinical Trials | 10:20–12:00 Moderator: Dr. Anick Bérard, Université de Montréal	Presenter
10:20	**Updates on PregTrial – Time for implementation** • Presentation (20 minutes)	Natalie Dayan, Rose Mwangi, McGill University
	LEARNING OBJECTIVES • Summarize the current state of the PregTrial initiative and its key outputs to date • Identify opportunities for implementation of PregTrial tools and frameworks in Canadian clinical research settings • Outline next steps for national scale-up of PregTrial recommendations	
10:40	**Accelerating Clinical Trials in Canada – How a national network can be leveraged to move the needle forward on inclusion of under-represented groups** • Presentation (20 minutes)	P.J. Devereaux, McMaster University / ACT
	LEARNING OBJECTIVES • Describe the structure and mandate of the Accelerating Clinical Trials (ACT) national network • Identify how national trial networks can be leveraged to improve inclusion of under-represented groups including pregnant and lactating individuals • Evaluate the potential of coordinated national infrastructure to accelerate implementation of the guidelines discussed in panel 1	
11:00	**Training future generations in maternal and pediatric clinical trials – Update on IMPaCT** • Presentation (20 minutes)	Lauren Kelly, University of Manitoba, IMPaCT
	LEARNING OBJECTIVES • Develop a shared understanding of how clinical trials inform optimal care during pregnancy and beyond • Understand how gaps in investigator training feed the systematic exclusion of pregnant and lactating people from clinical trials • Describe how the three components of the IMPaCT clinical trials training program create capacity for meaningful inclusion	

Start Time	Session 2 (continued) Moderator: Dr. Anick Bérard, Université de Montréal	Presenter
11:20	**Maternal–Child Trials Network – Putting the "M" in MICYRN** • Presentation (20 minutes)	Thierry Lacaze-Masmonteil, Aiman Siddiqi, MICYRN
	LEARNING OBJECTIVES • Describe the development of a Canada-wide Maternal-Child Trials Network within MICYRN • Identify how a dedicated maternal-child trials network can address gaps in representation of pregnant and lactating individuals in clinical research • Discuss opportunities for collaboration between MICYRN and other Canadian clinical trial initiatives	
11:40	**Session 2 – Question Period** • Panel format – audience questions/discussion (20 minutes)	Session 2 speakers

Start Time	Session 3: Keynote Address | 12:00–13:00 Moderator: Dr. Natalie Dayan, McGill University	Presenter
12:00	**Keynote Speaker – "Words Matter: The Ethics of Misclassifying Pregnant Participants as Vulnerable in Clinical Trials"** • Presentation (45 minutes) • Audience questions/discussion (15 minutes)	Dr. Stephanie Morain, Johns Hopkins University
	LEARNING OBJECTIVES • Explain how the classification of pregnant individuals as "vulnerable" in research ethics frameworks has historically shaped their exclusion from clinical trials • Critically evaluate the ethical implications of misclassification and its downstream effects on evidence generation for pregnant populations • Apply an ethics-informed lens to the language and framing used in trial protocols and informed consent documents involving pregnant participants	
13:00	**NETWORKING LUNCH** *(45 minutes)*	

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Start Time	Afternoon Session – The Cornerstone of Ethical Research: The Informed Consent Form | 13:45–14:00 Moderator: Dr. Natalie Dayan, McGill University	Presenter
13:45	**Updates to ICH E6(R3) – Health Canada perspectives and insight** • Presentation (10 minutes) • Audience questions/discussion (5 minutes)	Adil Nashed, Health Canada
	LEARNING OBJECTIVES • Describe the requirements for an Informed Consent Form based on ICH e6r3 requirements • Explain consenting pregnant and lactating participants according to the ICH E6 R3 updates.	

Start Time	Session 4: Consensus-Building Breakout Group Workshops | 14:00–17:00 Moderators: Dr. Rose Mwangi (Postdoctoral Fellow) and Dr. Natalie Dayan, McGill University	Presenter
14:00	**ICF Toolkit – Presentation of use of the PregTrial ICF toolkit** • Presentation (15 minutes)	Amy Choi, Emily Doerksen
14:15	**Workshop – Concurrent group sessions** • Application of a pregnancy-specific informed consent form toolkit to a research scenario requiring inclusion of pregnant and lactating people in trials (60 minutes)	Breakout groups
15:15	**BREAK WITH REFRESHMENTS** *(30 minutes)*	
15:45	**Report-backs and consensus discussion** *(60 minutes)* • Each workshop group presents (5–10 minutes each) • Facilitated discussion to identify consensus points • Nominal group voting on priority areas/actions	Workshop groups
16:45	**Closing Remarks and Commitments** *(15 minutes)* • Group consensus • Summary of consensus points and priority actions • Post-meeting working group commitments and member assignments	
17:00	**ADJOURN**	