

PREGTRIAL IN- PERSON MEETING

FROM INCLUSION TO IMPLEMENTATION

DRAFT 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)	Natalie Dayan
8:35	Patient Partner Talk • Talk (10 minutes) • Audience questions/discussion (5 minutes)	Margaret Loniewska

Start Time	Panel 1: Ethical Principles and International Frameworks 8:50–10:05 Moderator: Dr. Emily McDonald (to be confirmed), McGill University	Presenter
8:50	Research Ethics 101 • Presentation (20 minutes)	Jonathan Kimmelman
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
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
9:50	Panel 1 – Question Period • Audience questions/discussion (15 minutes)	Panel 1 speakers
10:05	REFRESHMENT BREAK (15 minutes)	
Start Time	Panel 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 Béard, Université de Montréal	Presenter
10:20	Updates on PregTrial – Time for implementation • Presentation (20 minutes)	Natalie Dayan, Rose Mwangi, McGill University
10:40	Maternal–Child Trials Network – Putting the “M” in MICYRN • Presentation (20 minutes)	Thierry Lacaze-Masmonteil, Aiman Siddiqi
11:00	Training future generations in maternal and pediatric clinical trials – Update on IMPaCT • Presentation (20 minutes)	Lauren Kelly, University of Manitoba, IMPaCT
11:20	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
11:40	Panel 2 – Question Period • Audience questions/discussion (20 minutes)	Panel 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
13:00	NETWORKING LUNCH (45 minutes)	
Start Time	Afternoon Workshops – The Cornerstone of Ethical Research: The Informed Consent Form	Presenter
13:45	Updates to ICH E6(R3) – Health Canada perspectives and insight • Presentation (10 minutes) • Audience questions/discussion (10 minutes)	Adil Nashed, Health Canada
Start Time	Session 4: Consensus-Building Breakout Group Workshops 14:05–17:15 Moderators: Dr. Rose Mwangi (Postdoctoral Fellow) and Dr. Natalie Dayan, McGill University	Presenter
14:05	ICF Toolkit – Presentation of use of the toolkit • Presentation (10 minutes)	PregTrial team member
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 (20 minutes)	
15:35	Report-backs and consensus discussion (70 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 • Group consensus • Summary of consensus points and priority actions • Post-meeting working group commitments and member assignments	
17:15	ADJOURN	