

Committee on Developing a Framework to
Address Legal, Ethical, Regulatory, and Policy
Issues for Research Specific to Pregnant and
Lactating Persons

Meeting #2



THURSDAY, MARCH 23, 2023

CLOSED SESSION – COMMITTEE MEMBERS ONLY

9:30–10:00 Closed Session Deliberations

OPEN SESSION – PUBLIC WORKSHOP

WELCOME AND INTRODUCTION

10:00–10:10 Opening Remarks

MIMI FOSTER RILEY, *Committee Chair*
Professor of Law
University of Virginia

SESSION I – PRODUCT LIABILITY CONSIDERATIONS

Session Objectives

- Discuss the role of product liability considerations in creating incentives and/or disincentives for medical product companies to generate evidence for the safety and efficacy of their products in pregnant and lactating populations; and
- Consider what incentives and accountability measures may be effective in generating evidence for pregnant and lactating populations.

10:10–10:25 Fireside Chat

BRUCE KUHLIK, *Moderator*
Former General Counsel
Merck & Co.

Defense Attorney Perspective

JOHN BEISNER
Partner
Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates

10:25–10:45 Discussion with Committee

SESSION II – THE ROLE OF RISK MANAGEMENT & TRIAL INSURANCE

Session Objectives

- Understand what factors or considerations influence decisions to include or exclude pregnant and lactating populations from clinical research;
- Discuss how risk and benefit are assessed for populations that are being considered for inclusion in a clinical research study, as well as for the institutions conducting, funding, or insuring the study; and
- Examine opportunities to apply risk mitigation strategies to clinical research that includes pregnant and lactating populations.

10:45–11:10 Panel Discussion

PATRICIA DANZON, *Moderator*
Celia Moh Professor of Healthcare Management
University of Pennsylvania

Trial Insurance Perspective

SARA DYSON
Vice President of Underwriting Operations & Risk Management
Medmarc

Academic Medical Center Perspective

HILLARY NOLL KALAY
Principal Counsel
University of California

Institutional Review Board Perspective

ELISA HURLEY
Executive Director
Public Responsibility in Medicine and Research

11:10–11:45 Discussion with Committee

11:45–12:45 LUNCH BREAK

SESSION III – EQUITY CONSIDERATIONS FOR INJURY COMPENSATION

Session Objectives

- Understand how research participants view and make decisions regarding participation in clinical research while pregnant or lactating;

- Consider various perspectives on what constitutes fair and just compensation for participants harmed in the course of clinical research;
- Examine the benefits and drawbacks to different injury compensation schemes in the context of promoting fairness and justice; and
- Discuss opportunities to improve upon existing compensation schemes to make them more equitable.

12:45–1:00 **Presentation**

JASON MALONE
Director of the Human Subjects Division
University of Washington

1:00–1:45 **Panel Discussion**

ANNE CC LEE, *Moderator*
Director of Global Newborn Health
Brigham and Women’s Hospital
Harvard Medical School

Research Participant Perspective

MARCELA SMID
Research Participant

JILLIAN BROWN
Research Participant

No Fault Compensation Perspective

EFTHIMIOS PARASIDIS
Chief Justice Thomas J. Moyer Professorship for the Administration of Justice and Rule of Law
Ohio State University

RENÉE GENTRY
Principal Partner
The Law Office of Renée J. Gentry

Tort Perspective

MICHELLE MELLO
Professor of Law and Health Policy
Stanford University

1:45–2:30 **Discussion with Committee**

2:30–3:00 **BREAK**

SESSION IV – CASE STUDIES IN RISK MITIGATION

Session Objectives

- Consider approaches that various institutions have adopted to mitigate risk and liability in clinical research that includes pregnant or lactating persons;
- Discuss challenges and successes of adopting and implementing risk and liability mitigation strategies for research involving pregnant or lactating persons; and
- Discuss opportunities to scale risk and liability mitigation strategies to other clinical research studies that could include pregnant or lactating persons.

3:00–3:20

Panel Discussion

ANNA MASTROIANNI, *Moderator*
Research Professor
Johns Hopkins University

Nonprofit Perspective

METIN GÜLMEZOĞLU
Executive Director
Concept Foundation

NIRANJAN BHAT
Senior Medical Officer
PATH

Industry Perspective

LORIEN URBAN
Senior Medical Director, Clinical Development
Ferring Pharmaceuticals

3:20–4:00

Discussion with Committee

WORKSHOP ADJOURNS

CLOSED SESSION – COMMITTEE MEMBERS ONLY

4:15 – 4:30

Closed Session Deliberations

4:30

ADJOURN DAY 1

FRIDAY, MARCH 24, 2023

CLOSED SESSION – COMMITTEE MEMBERS ONLY

9:30–4:00 **Closed Session Deliberations**
