Brigham and Women's Hospital
Founding Member, Mass General Brigham

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

22 August, 2022

Bikash Mahato
Under Secretary (Drugs Regulation)
Ministry of Health and Family Welfare
Room No. 434, C Wing
Nirman Bhawan, New Delhi - 110011

Submitted by email to: drugsdiv-mohfw@gov.in

Re**: Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022**

Dear Mr. Mahato,

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) appreciates the opportunity to comment on the Ministry of Health and Family Welfare's request for input on its **Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022** published on 08 July, 2022. It is a timely and important draft guidance.

The MRCT Center is a research and policy center that addresses the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. In addition, the Center has been involved in several focused country engagements, such as India, China, Mexico and the countries of Africa. The MRCT Center is committed to capacity-development and is an ICH-training partner and APEC Center of Excellence Center. Since 2009, the MRCT Center's efforts have resulted in the implementation of best practices, greater transparency, and improved safety for research participants. The majority of our resources and tools are freely and openly available.

The MRCT Center supports the new proposed provisions in Section 73, which indicate that compensation for injury to a clinical trial participant should be awarded only if there is a direct causal link between participation in the trial and the injury. Previous legislative and executive measures had made sponsors and trial sites liable for any injury to a participant in a trial, regardless of any causal link between study procedures and the injury. As the MRCT Center, in coalition with our colleagues active in clinical research in India, has repeatedly emphasized, compensation would be fairly awarded is such a causal link does exist, but awarding compensation for any injury that occurs to a clinical trial participant, regardless of its causal connection to the trial, is fundamentally unfair to sponsors, clinical trial sites and researchers; burdens the research enterprise in India; and discourages vital clinical research that, in many cases, allows the people of India access to important experimental therapies for fatal and life-threatening conditions. The MRCT Center salutes the Ministry for this important and welcome proposed revision to clinical trial regulations in India.

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We are available to discuss our comments with you if that would be helpful and would be happy to work with you on any of the aforementioned items. Please feel free to contact the MRCT Center at bbierer@bwh.harvard.edu, sawhite@bwh.harvard.edu, mark.barnes@ropesgray.com, and david.peloquin@ropesgray.com.

Respectfully submitted,

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