



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Executive Committee Meeting

October 24, 2023
Virtual meeting

Today's Agenda

- Welcome & Updates
- Considering new geographic regions for clinical research
- ORI's NPRM Public Health Service Policies on Research Misconduct : Key Issues
- India: The Digital Personal Data Protection Act, 2023



New MRCT Center Team Members



Jack Ferdman, JD, MPH
Research Analyst



Carolyn Chapman, PhD
Member of the Faculty

New EC Member and Representatives

- ICON
 - Greg Licholai, Chief Medical & Innovation Officer
- Mayo Clinic
 - Owen Garrick, Dean of Clinical Trials
- Johnson & Johnson
 - Ginny Beakes-Read, Head, Global Regulatory Policy and Intelligence



Considering new geographic regions for clinical research



Considering new geographic regions for clinical research

- We have previously discussed our work in capacity building, in Africa, India, and elsewhere.
- We have discussed with sponsors that they are:
 - Looking for new international clinical research sites (and replacing some previously located in Ukraine and Russia and elsewhere).
 - Interested in developing clinical research sites in Africa, Southeast Asia, and South America.
- Is there an opportunity to align efforts collaboratively to build and sustain capacity in these new regions?
- Does (or could) the MRCT Center have a useful role in this process, and if so:
 - Which regions?
 - How can we assist sponsors?
 - What are the most critical needs in capacity training?
 - Are there other organizations with whom we should be collaborating?



ORI's NPRM Public Health Service Policies on Research Misconduct: Key Issues



**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

42 CFR Part 93


RIN 0937-AA12

**Public Health Service Policies on
Research Misconduct**

AGENCY: U.S. Department of Health and
Human Services (HHS).

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: In this Notice of Proposed Rulemaking (NPRM), the Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) proposes to revise the Public Health Service (PHS) Policies on Research Misconduct. The proposed revisions are based on the experience ORI and institutions have gained with the regulation since it was released in 2005. This NPRM seeks comment from individuals, institutional officials, organizations, institutions, research funding agencies, and other members of the public on the proposed revisions and how to improve the clarity of substantive and non-substantive.



The comment period ends 12/5/2023

SUMMARY:

In this Notice of Proposed Rulemaking (NPRM), the Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) proposes to revise the Public Health Service (PHS) Policies on Research Misconduct. The proposed revisions are based on the experience ORI and institutions have gained with the regulation since it was released in 2005. This NPRM seeks comment from individuals, institutional officials, organizations, institutions, research funding agencies, and other members of the public on the proposed revisions and how to improve the clarity of substantive and non-substantive.



INDIA: THE DIGITAL PERSONAL DATA PROTECTION ACT, 2023



THE DIGITAL PERSONAL DATA PROTECTION ACT, 2023

रजिस्ट्री सं० डी० एल—(एन)04/0007/2003—23

REGISTERED NO. DL—(N)04/0007/2003—23



भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-12082023-248045
CG-DL-E-12082023-248045

असाधारण

EXTRAORDINARY

भाग II — खण्ड 1

PART II — Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं० 25] नई दिल्ली, शुक्रवार, अगस्त 11, 2023/ श्रावण 20, 1945 (शक)
No. 25] NEW DELHI, FRIDAY, AUGUST 11, 2023/SRAVANA 20, 1945 (SAKA)

“An Act to provide for the processing of digital personal data in a manner that recognises both the right of individuals to protect their personal data and the need to process such personal data for lawful purposes and for matters connected therewith or incidental thereto.”

Signed 8/11/2023

<https://www.meity.gov.in/writereaddata/files/Digital%20Personal%20Data%20Protection%20Act%202023.pdf>



Questions, Comments, Suggestions



2023 Executive & Steering Committee Meetings

2023 Executive and Steering Committee Meetings

- January 31, 11-12 PM
- April 25, 11-12 PM (virtual)
- September 12, 11-12 PM (virtual)
- December 12-14, EC/SC meeting, Annual Meeting with R3 meeting, Bioethics Collaborative (preferred in-person, hybrid planned)

Executive Committee Meetings

- March 21, 11-12 PM
- June 22, 9 AM-2 PM (preferred in-person, hybrid)
- October 24, 11-12 PM





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2023 Annual Meeting

REGISTER NOW

December 12 - 14,
Virtual & In-Person

Tuesday, December 12th

1:00 - 4:00 PM: EC/SC Meetings

4:00 - 5:30 PM: EC/SC Discussion with Peter Arlett (EMA)

6:00 - 9:00 PM: Cocktails and Dinner

Wednesday, December 13th

8:00 AM: Breakfast

8:30 AM - 12:30 PM: Keynote: Peter Arlett, Head of Data Analytics and Methods (EMA); Detailed programmatic discussions and updates (agenda forthcoming)

Lunch

1:30-4:45 PM: Research, Development, and Regulatory Roundtable (R3) Topics: Update on the GDPR, including discussion of the EU/US data privacy framework; Considerations in Ensuring Accurate Clinical Trials Data

5:00-6:15 PM: Cocktails and Appetizers

Thursday, December 14th

8:30 AM: Breakfast

9:00 - 11:45: Bioethics Collaborative (BC)
Topic: Cell and Gene Therapy: Probing the Ethics (open to all)



UPCOMING MEETINGS

December 14, 2023, 8 AM – 12 PM ET

- Cell and Gene Therapy: Probing the Ethics

2024 Meeting Dates: coming soon!

UPCOMING MEETINGS

November 13, 2023, 1:30PM - 4:00PM ET

- Recent Regulatory Developments Affecting Clinical Trials in the EU and UK:

December 13, 2023, 1:30PM – 4:30PM ET

- 1) Update on the GDPR, including discussion of the EU/US data privacy framework; 2) Considerations for ensuring accurate clinical trials data

2024 Meeting Dates:

March 14, 2024, 12:00-3:30 PM ET

May 2024: TBD

October 10, 2024, 1:00-3:30 PM ET

December 12, 2024, 1:00-3:30 PM ET



Please follow the MRCT Center:



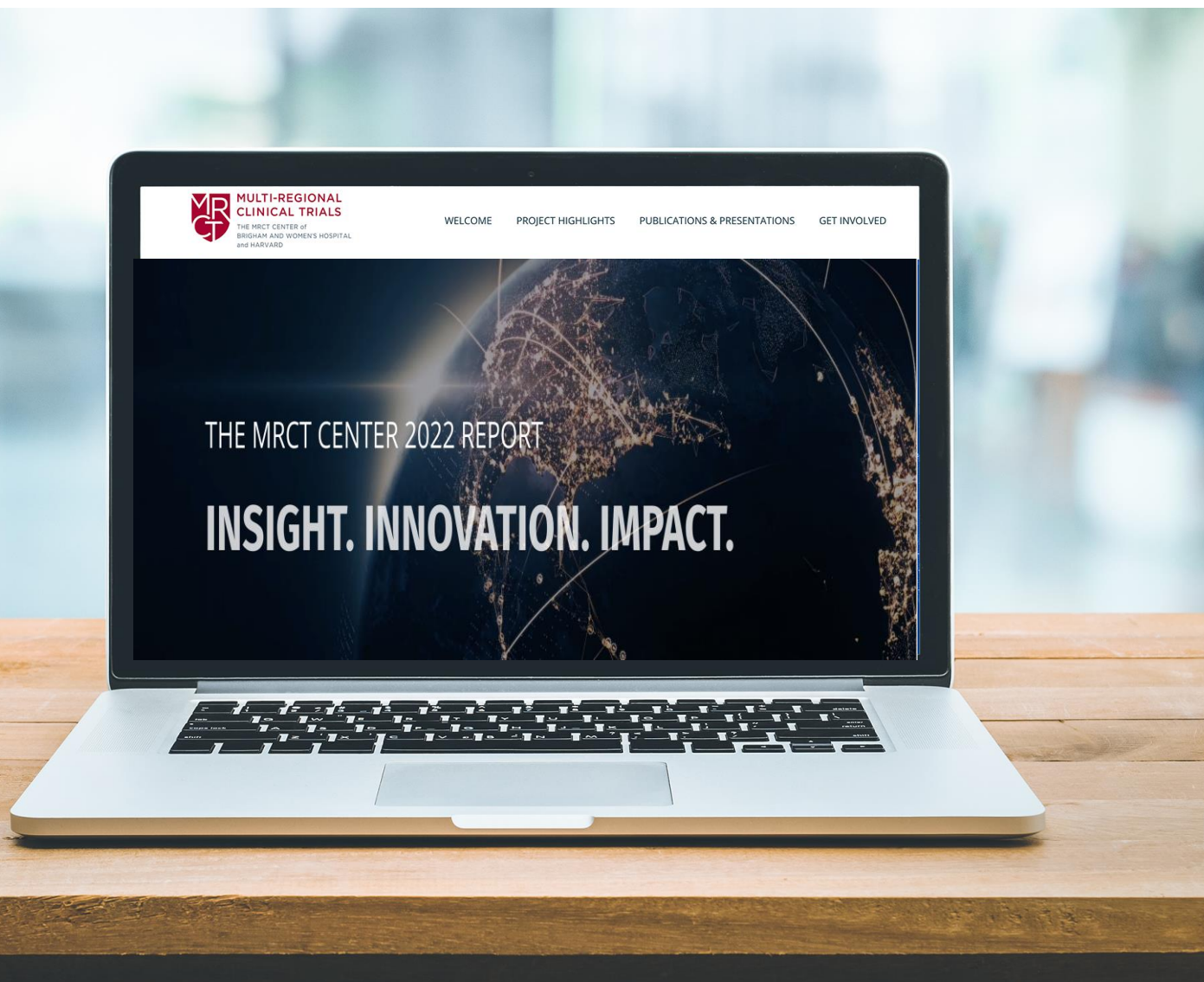
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Thank you for
your support and
collaboration



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