August 29, 2025

Dear ACT Consortium Partner,

We are writing to seek your support in the promotion and adoption of the World Health Organization's Guidance for Best Practices for Clinical Trials at your respective institutions and REBs. The Accelerating Clinical Trials (ACT) Consortium strongly endorses this guidance.

The Guidance for Best Practices for Clinical Trials was developed in response to the 2022 World Health Assembly resolution (WHA75.8) on strengthening clinical trials. This guidance provides Member States with a framework for integrating robust and ethical clinical trial practices into their national health systems, enhancing the quality, transparency, and inclusivity of trials worldwide.

While there has been an emphasis on adherence to ICH E6 R3 guidelines, it is important to highlight a critical distinction. The WHO Guidance for Best Practices for Clinical Trials notes that trials of new drugs or devices intended for a regulatory indication should follow ICH E6 R3 guidance, whereas all other trials should follow the Guidance for Good Randomized Clinical Trials. Hence, although most trial protocols state they will follow ICH E6 R3, **it is important to encourage investigators at your institutions and REBs to state in their protocols that they are following WHO guidance,** which covers guidance for whatever type of trial is being undertaken. We firmly believe that adoption of these guidelines is in the best interests of Canadian researchers and we urge you to play a crucial role in helping to educate institutions and investigators, particularly around this aspect of the WHO guidance.

For more information on the new clinical trials guidance, please visit the WHO website or view the following webinar: WHO launches new clinical trials guidance – What do I need to know?

Sincerely,

Dr. PJ Devereaux, MD, PhD,
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ACT/AEC Operations Committee Co-Chair

Dr. Guy Rouleau, OC, OQ, MD, PhD, FRCP(C),
FRSC, McGill University
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On behalf of the ACT/AEC Canada Consortium