



# **CTO REB Qualification Process**

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# Agenda

- CTO Qualification Manual
- Pilot of Qualification Process: OCREB
- Lessons Learned
- Next Steps
- Questions

# CTO Qualification Manual

- Why re-invent the wheel?
  - TAHSN Qualification Manual was used as the foundation (CTO REB Streamlining Working Group Recommendation)
  - RER-AG Group aided in refining content
  - Review by External Experts
- CTO Qualification Manual informed by:
  - CGSB
  - TCPS2
  - Health Canada
  - ICH-GCP
  - FDA



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# The Qualification Review Team

- “College of Reviewers”
  - Auditor
  - REB Chair
  - REB Operations Personnel
  - CTO representative



# Pilot of Qualification Process: OCREB

- OCREB volunteered to be the first to go through the CTO REB Qualification Process
  - Collaborative and collegial

# Review Process:

- In preparation, OCREB:
  - Delegated an Operational staff member familiar with all processes as a point person
  - Provided documentation such as SOPs, TORs, CVs etc.

# Onsite Review

- 4 steps
  - Entrance meeting
  - On site review of documents and facilities
  - Meetings with Chairs / Vice Chairs
  - Exit meeting





# Report Issuance



- Report is written and issued within 2 weeks
- REB given up to 3 months to respond to report



# Qualified!

- CTO Qualified status achieved once all observations are responded to and accepted
- Status valid for 3 years
  - Annual report required to provide an update regarding any changes
  - Any major changes should be reported immediately to CTO

# Lessons Learned

- Having the review done by Peer reviews proved to be a good approach
- Create a survey for REB members and staff
- Observe an Board meeting
- Importance of a “CTO Qualified” certificate

# Next Steps

- Further refinement to the Checklist based on Expert Reviews
- Uploading the manual for community feedback
- Currently recruiting Boards to undergo the CTO REB Qualification Process



# Questions



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