MEMORANDUM

DATE: December 16, 2025

TO: Island Health Research Community

FROM: Research Compliance, Dept of Research at Island Health

RE: Training Requirements for the Implementation of ICH E6(R3)

On January 6, 2025, the International Council of Harmonization (ICH) adopted the newly renovated Guideline for Good Clinical Practice (GCP) – E6(R3). The next step for the ICH members is to implement the new guideline in their respective countries or area of authority. For Canada, ICH E6(R3) will be implemented on April 1, 2026.

As 'Good Clinical Practices' is within the Food and Drug Regulations under Part C Drugs, Division 5 Drugs for Clinical Trials Involving Human Subjects, the law for conducting clinical trials with drugs, there is mandatory training for Island Health Researchers, study team members and service providers conducting human research with drugs that require Health Canada approval.

REQUIREMENTS

1. **GCP – update to E6(R3)**

   All Qualified Investigators, study team members and service providers (as applicable) are required to complete or update their Collaborative Institutional Training Initiative (CITI) GCP before April 1, 2026.

   To support more Learners completing CITI GCP that will generate a new completion certificate and report, notifications have been changed from 90 to 180 days. This step will allow the capture of GCP certificates that are expiring between April 1 and approximately mid-September 2026.

   If you are:

   - Taking GCP for the first time or you receive your notification to retake your GCP (Basic or Refresher) before April 1, 2026:
     - complete the current CITI Canada GCP E6 (*which includes the R3 updates*) course and
     - receive a new completion 'certificate' and 'report' or

If your:

- GCP training is not due to expire before April 1, 2026 and you don't receive a notification to retake your GCP:
  - Re-complete your previously taken GCP course (*which will include the R3 updates*) and
  - Receive an updated completion 'report'

Notes:

- see Appendix A: Steps to Re-Complete the Previous GCP Course When You Will Not Receive a notification before April 1, 2026
- Due to the global nature of clinical trials, some Sponsors may require updated GCP training prior to Health Canada's implementation on April 1, 2026.

2. ICH E8(R1) – General Considerations for Clinical Studies:
ICH's Introductory Overview Video, October 2024

Due to the importance of ICH E8(R1) – General Considerations for Clinical Studies for the implementation of ICH E6(R3), the review of ICH's Introductory Overview Video, October 2024 (via Chrome) will also be completed by April 1, 2026.

As there is no completion certificate generated to confirm the review of the above video, you will need to self-attest to this training.

Please use the provided training record (see Appendix B: Training Record) to capture this training for your records.

RECOMMENDATIONS

1. Health Canada's Guidance Document:
Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100)

Health Canada will be updating 'Guidance 100' with R3 references and releasing it prior to April 1, 2026. This document is important as it supports all those who are involved in conducting clinical trials to interpret the Health Canada Food and Drug regulation, Part C, Division 5 and how it relates to ICH E6.

REFERENCES

- Collaborative Institutional Training Initiative (CITI)
- Health Canada's Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100)
- ICH E6(R3) – Guideline for Good Clinical Practice
- ICH E8(R1) – General Considerations for Clinical Studies
- ICH E8 (R1) Introductory Overview Video, published in October 2024
- Network of Networks (N2). (2025, November). *Guidance for N2 CITI-Canada Institutional Administrators and Others Involved in Training and Quality.* N2 Quality Committee. (email attached)

QUESTIONS

If you have questions regarding the transition to E6(R3), please contact:
ResearchCompliance@islandhealth.ca

Appendix A: Steps to Re-Complete the Previous GCP Course When You Will Not Receive a notification before April 1, 2026

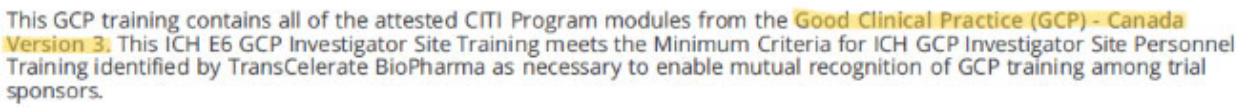
1. Log in to your CITI account
2. Select 'View Courses' under 'Institutional Courses'
3. Select 'Review Course' for your last GCP course under 'Completed Courses'
4. Select 'Review' next to each module you would like to re-complete*
    a. You may see:
        i. Only 'Review' buttons or
        ii. 'Review' buttons mixed with Blue 'Start' buttons
            1. complete only the blue 'Start' buttons

***Important**:

- At the end of each module, to confirm you are in a E6(R3) module, you will see 'Last Updated: October 2025'
- Re-completing modules does not change or extend the Learner certificate's expiration date
- A Part 2 of your Completion Report or 'Coursework Transcript' will be generated to:
    - Reflect the most recent completion date and score for each module:

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Overview of ICH GCP (ID: 14048)	29-Oct-2025	3/5 (60%)
Institutional Review Board/Independent Ethics Committee/Research Ethics Board (IRB/IEC/REB) (ID: 14049)	29-Oct-2025	4/5 (80%)
Investigator Responsibilities and GCP (ID: 16501)	29-Oct-2025	5/5 (100%)
Informed Consent in Clinical Trials of Drugs and Biologics (ID: 14062)	29-Oct-2025	4/4 (100%)
Managing Investigational Products According to GCP Requirements (ID: 14056)	29-Oct-2025	4/4 (100%)
Detection, Evaluation, and Reporting of Adverse, and Serious Adverse Events (ID: 14063)	29-Oct-2025	5/5 (100%)
Sponsor Responsibilities and GCP (ID: 14050)	29-Oct-2025	5/5 (100%)
Monitoring Clinical Trials by Sponsors (ID: 14068)	29-Oct-2025	4/5 (80%)
Audits and Inspections of Clinical Trials (ID: 14141)	29-Oct-2025	5/5 (100%)
Administrative Documents (ID: 14066)	29-Oct-2025	3/4 (75%)

    and
    - Contain updated language confirming alignment with ICH E6(R3) for re-completed modules under 'Description'.


This GCP training contains all of the attested CITI Program modules from the Good Clinical Practice (GCP) - Canada Version 3. This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Appendix B: Training Record

TRAINING RECORD	
Name of Training:	ICH E8(R1) – General Considerations for Clinical Studies: ICH's Introductory Overview Video, October 2024
Provider:	International Council for Harmonisation (ICH)
Date of Training:	

SELF ATTESTATION	
By my signature, I attest to completing the training referenced above.	
Name of Learner:	
Signature of Learner:	
Date of Signature:	