UNIVERSITY OF CALGARY

CUMMING SCHOOL OF MEDICINE

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University of Calgary E6 (R3) Transition Training

As part of our ongoing commitment to ensuring research teams are aligned with current regulatory standards, the Calgary Centre for Clinical Research (CCCR) is implementing interim training to bridge the transition from ICH E6 (R2) to ICH E6(R3).

Background

- ICH GCP E6(R3) was released in early 2025.
- Network of Networks hosted a webinar "R2 to R3 Comparison Session" held on October 1st, 2025. The webinar provided essential insights into the key differences between R2 and R3 and their impact on clinical research operations.
- CITI Canada's GCP courses was updated on October 27th, 2025, incorporating updates from the new ICH E6(R3) Guideline for Good Clinical Practice (GCP). The updated content for these courses are available in the University of Calgary's CITI Canada curricula.
- Study teams are not required to complete this training until their current GCP expires, as long as they have completed the transition training (R2 to R3 Comparison Session webinar).

Institutional Decision

- Attendance at the ""R2 to R3 Comparison Sesson" webinar will be recognized by CCCR as bridging training between ICH E6(R2) and ICH E6(R3). For those who were unable to attend the live session (on Oct 1, 2025), the webinar recording will be made available. Click here to view the webinar.
- Attendance confirmation certificates are available here.
- Research team members and investigators must make a personal commitment to review the webinar recording in full and create an internal record confirming completion. They are encouraged to engage with the CCCR team with any questions or clarifications arising from the material.
- Study teams are required to complete this transitional training until their current GCP expires.

Harmonized Research Training Framework and Requirements

- This interim training will serve as a bridge until staff are due for GCP renewal.
- CITI Canada's GCP Course was updated on October 27th, 2025, to include updates from the new ICH E6(R3) guideline.

Next Steps

All research team members and investigators in clinical trials are strongly encouraged to complete this transition training until their current GCP expires — either by attending the live session (Oct 1, 2025) or by carefully reviewing the recording and documenting self- training — to remain current with the evolving GCP framework.

Resources from the R2 to R3 Comparison Session webinar:

- Recording of the R2 to R3 Comparison Session webinar
- ACRP's comparison summary of ICH E6(R2) to ICH E6(R3)
- ICH E6(R3) Final Guideline
- ICH E6(R3) Step 4 Presentation
- ICH M11 Protocol Template (for reference only)
- N2's ICH E6(R3) Comparison with (R2)
- Self Attestation Form

If institutes or centres have identified alternative approaches or training modules for bridging R2 to R3, these should be submitted to the Lead Regulatory Officer – Clinical Research for review and confirmation to ensure that they meet the required fundamental competencies.

For any questions regarding this interim training recognition or documentation, please contact Jenna Dobry-Dub jldobry@ucalgary.ca .

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