



11 October 2026

To: Hamilton Integrated Research Ethics Board | hireb@hhsc.ca

Re: FALCON (NCT07697261): participant protections and ethics review

Dear Hamilton Integrated Research Ethics Board,

I am writing on behalf of Long COVID Action Canada to follow up on the participant-protection concerns previously raised about FALCON.

I am writing about participant protections in FALCON (NCT07697261), the trial comparing the Lightning Process with activity pacing for people with Long COVID. LCAC's campaign record notes your 24 August acknowledgment of concerns and your undertaking to share them with the board.

I ask that these concerns be resolved before recruitment begins. Please confirm the current ethics-review status and explain how the following questions have been addressed:

- 1. Informed and voluntary consent.** How will participants be told about uncertainty over benefit, relevant safety concerns and alternatives to participation? NICE advises against offering the Lightning Process to people with ME/CFS; how will this be considered and explained to participants who also meet ME/CFS criteria? Will consent materials clearly distinguish symptom-management research from evidence of recovery or cure?
- 2. Post-exertional malaise and sustained deterioration.** How will baseline symptoms and activity limits be recorded, and how will delayed or cumulative worsening be detected during and after sessions? What thresholds trigger a pause, withdrawal from the intervention or suspension of recruitment? Who makes these decisions, and what clinical assessment, referral or support is available if a participant deteriorates?
- 3. Independent monitoring and reporting.** Who reviews adverse events independently of intervention providers, how often, and for how long after treatment? How will harms be captured from people who miss sessions, cannot complete questionnaires or withdraw? How can participants report worsening confidentially without going through their practitioner? Please explain how safety concerns are escalated to HiREB.
- 4. Freedom to stop without pressure or blame.** How will participants be protected from encouragement to exceed their limits, minimize symptoms or attribute a lack of improvement to insufficient motivation? Will they be clearly told they may pause or leave without penalty or effects on their usual care? How will payment, reimbursement and optional safety follow-up be handled if they withdraw?
- 5. Accessible participation.** What adjustments will be available for cognitive difficulties, sensory sensitivity and limited energy, including breaks or shorter sessions? How will the burden of consecutive sessions and questionnaires be assessed, and how will consent remain an ongoing process?



6. Conflicts and participant information. How will practitioner payments, commercial relationships and relevant financial and non-financial interests be disclosed and managed? Will participants have an independent contact for questions or complaints, and access to information about arrangements for research-related injury?

The registry lists adverse-event outcomes. I am asking how safeguards will work in practice, rather than assuming that no protections exist.

Please provide a point-by-point response using information that can be made public, and support publication of the participant information and consent materials before recruitment. If details cannot be shared, please explain the limitation and provide a public summary of the safeguards. Please identify the responsible contact and an expected response date.

Sincerely,

Robert DeRosa

Founder, Long COVID Action Canada

Long COVID patient advocate

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Referenced records

FALCON trial registration

<https://clinicaltrials.gov/study/NCT07697261>

LCAC campaign record

<https://longcovidaction.ca/falcon>

NICE ME/CFS guidance: Lightning Process

<https://www.nice.org.uk/guidance/ng206/chapter/recommendations#lightning-process>