

Letter to McMaster

Accessible edition. Sent 11 October 2026. Original wording retained; layout reformatted.

11 October 2026

To: Office of the Vice-President, Research | yprsrch@mcmaster.ca

Re: FALCON (NCT07697261): review and documents before recruitment

Dear Office of the Vice-President, Research,

I am writing on behalf of Long COVID Action Canada to ask McMaster to keep recruitment for FALCON (NCT07697261) on hold pending an independent scientific, ethical and patient-led review.

FALCON proposes to compare the commercially branded Lightning Process with activity pacing for people with Long COVID. Concerns about participant selection, reliance on self-reported outcomes, participant safety and commercial relationships warrant independent review and a public institutional response before recruitment begins.

Please ensure an independent review addresses the following:

1. Whether the design can establish meaningful benefit.

How will the study distinguish changes in symptom reporting or treatment expectations from improvements in everyday function? Please assess the justification for relying on self-reported outcomes and the feasibility of adding an objective functional measure that participants can complete safely.

2. Eligibility and selection bias.

Why is a "readiness to change" questionnaire appropriate for determining eligibility in Long COVID? Please clarify which scoring rule applies, reconcile differing public descriptions, and explain how this selection could affect the interpretation and generalizability of results.

3. Protection against deterioration.

Please explain how post-exertional malaise and sustained worsening will be detected, assessed and acted upon, including stopping criteria, independent safety oversight and follow-up after withdrawal. The registry lists adverse-event outcomes; the question is how these protections will operate in practice.

4. Informed consent.

NICE's ME/CFS guideline advises against offering the Lightning Process to people with ME/CFS. Please explain how this guidance will be considered for participants who also meet ME/CFS criteria, and how consent materials will communicate uncertainty, relevant concerns and the right to withdraw without blame or pressure.

5. Commercial interests and independence.

Please disclose practitioner payments, licensing or materials costs, relevant financial and non-financial interests, and how these will be managed. Reviewers should be independent of the trial team and the intervention's commercial providers, with meaningful, accessible participation by people living with Long COVID.

Please publish the full protocol, statistical analysis plan, participant information and consent materials, and the independent review's findings before recruitment begins.

LCAC's campaign record acknowledges replies from Dr. Jason Busse and HiREB. Those replies should inform the review, alongside the questions that remain unresolved.

Please provide a public, point-by-point written response, identify who is responsible for these decisions, and give an expected response date. If any request has already been addressed, please link to the relevant documents.

People with Long COVID deserve research that can produce trustworthy findings while protecting participants.

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>