

⊦aculty of Medicine and

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September 21, 2023

Dr. Raphael F. de Souza Faculty of Dental Medicine and Oral Health Sciences 2001, ave McGill College, Suite 534 Montreal, QC H3A 1G1

RE: A00-M29-23B (22-07-089)

> 3D printing vs traditional workflow for the fabrication of implant mandibular overdentures: A randomized cross-over clinical trial

Dear Dr. de Souza,

On September 11, 2023, at a meeting of the Institutional Review Board, the above-referenced resubmitted study received a full Board review.

The Committee identified the following concerns for your response.

Study Protocol

a) Science of the study is acceptable.

Consent form

- b) Consent form needs to be on letterhead.
- c) Please clarify if data is coded or anonymized. If the data is to be kept for 25 years, it needs to be anonymized.

The study was approved for a period of 12 months, pending the submission of an appropriate response and revisions to the above concerns.

Please send all correspondence to submit2irb.med@mcgill.ca.

Kind regards,

Roberta Palmour, PhD

Robata M. Palmour

Chair

Institutional Review Board

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