

**Protocol  
Letter of Amendment**

**SARS-CoV-2 Vaccination  
Strategies in Previously  
Hospitalized and Recovered  
COVID-19 Patients**

**3 August 2021**

**NCT04969250**

## Letter of Amendment #1

**Date:** 03 August 2021

**To:** Site Investigators and Study Staff  
Institutional Review Boards/Ethics Committees

A handwritten signature in black ink, appearing to read 'Jens Lundgren'.

**From:** INSIGHT 016 Study Team (Jens Lundgren, Protocol Chair)

**Protocol:** INSIGHT 016 Protocol (VATICO)

Version 1.0, 07 June 2021

Vaccination for Recovered Inpatients with COVID-19 (VATICO)

**Subject:** Letter of Amendment to (1) Clarify Visit Schedule and (2) Correct Informed Consent

The following information impacts the INSIGHT 016 (VATICO) study and must be forwarded to all responsible Institutional Review Boards (IRBs) and Ethics Committees (ECs) as soon as possible for their information and review. This Letter of Amendment (LOA) must be approved by all responsible IRBs/ECs, as well as any other entities as applicable to each site, and per the policies and procedures of each site.

### Information to be Clarified:

#### (1) Protocol:

In Section 9.1 (Screening/Baseline and Follow-up Assessments), the description of Figure 2 includes the text, "Every 4 weeks from baseline through Week 24, all participants will be contacted either for a face-to-face visit (indicated in figure) or by phone." It then refers the reader to Appendix B (Schedule of Assessments), but the contacts are not listed. These 4-weekly contacts are referenced in the sample informed consent (Appendix A), and are the intent of the protocol.

As shown in Figure 2, in-person visits are required for all participants at Weeks 12, 24, and 48. Additional in-person visits are required for vaccination at Week 4 or Week 16, for those randomized to receive two doses of vaccine. Otherwise, 4-weekly contacts will be by phone or other electronic means at Weeks 4 (all except group I2, being seen in person for vaccination), 8, 16 (all except group D2, being seen in person for vaccination), and 20. There is no structured data collection or study procedures to be conducted at these contacts; they are intended to maintain contact with the participant and guide them through the protocol.

#### (2) Informed Consent Form:

Under WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?" (page 41 in the main protocol document) the last sentence of the first paragraph states, "If you have already been

vaccinated, you cannot be in this study.” This is incorrect. Per exclusion criterion 1 (Section 7.2), individuals who were vaccinated before randomization into TICO are eligible to participate in VATICO.

#### Amendment

##### (1) Protocol:

In Section 9.1.2 (Follow-up Assessments) the following is added as paragraph 4:

**Participants will be contacted every 4 weeks through Week 24. At 4-weekly timepoints where there is not already participant contact for vaccination or data collection, this will occur by phone or other electronic medium. These contacts are intended to keep participants engaged and assist them in following their randomized vaccination schedule.**

Footnote 7 is added to the table in Appendix B (Overview of Study Procedures):

**7. All participants will have study contact every 4 weeks. This will occur by phone or other electronic medium if there are no other study requirements at that timepoint.**

##### (2) Informed Consent Form:

The Sample Informed Consent (Appendix A) has been amended as follows

Under WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?” (page 41 in the main protocol document) the last sentence of the first paragraph now reads, **“If you got vaccinated after you joined the TICO study, you cannot be in this study.”** Version 1.1 of the Sample Informed Consent, dated 03 August 2021, accompanies this LOA.

#### Implementation:

- This amendment will be incorporated into the next formal protocol revision (version 2.0).
- This LOA and revised consent should be submitted to the IRBs/ECs per institutional policy and approved prior to implementation.
- A copy of this LOA should be filed in the site study binders along with the current protocol.