EIMPRIS
ENGAGING IMMUNO-PROTECTION INTERVENTION STUDY

MEMORANDUM #8

Date: August 30, 2022

To: Investigators and Coordinators

From: MediMergent Project Team

RE: ESR 22-21698 Study ICF Versions in the EIMPRIS System, Reconsenting, ICF Footer and ICF QOL Day 30 Missing

A. ESR 22-21698 ICF versions in the EIMPRIS system:

The first Master Informed Consent (ICF) template for study ESR 22-21698 was approved by Advarra IRB on 06May2022 (Advarra IRB approved Version 06 May2022). This document was uploaded onto the EIMPRIS clinical trials management system on 08May2022. The site information was inserted on the ICF as each site received IRB approval to take part in the study and enroll patients. The first patient enrolled in the study on 4Jun2022 electronically signed this version of the ICF.

On 22July2022 an updated Master ICF was approved by Advarra IRB (Advarra IRB Approved Version 22 Jul 2022) This version of the ICF was uploaded into the EIMPRIS clinical trials management system on 05August at 1:00 PM EST. It replaced the 06May2022 ICF version. Note, the 06May2022 version of the ICF was deactivated in the system.

ICF Version Timeline Summary:

06May2022 – Initial ICF version approved (Advarra IRB approved version dated 06May2022)

08May2022 – 06May2022 IRB approved ICF uploaded into the EIMPRIS system

04Jun2022 – First patient consented and enrolled in the ESR 22-21698 (EIMPRIS) study

22Jul2022 – Updated ICF approved by Advarra IRB (Advarra IRB approved version dated 22Jul2022)

05Aug2022
1 pm EST – 22Jul2022 IRB approved ICF uploaded and "live" the EIMPRIS system (replaced 06May2022 ICF as current version)

B. Required consent process once the 22Jul2022 Advarra IRB approved ICF was uploaded into the EIMPRIS platform:

The EIMPRIS data collection platform requires that patients consent to participate in the study before they can access the surveys used for data collection. Only one version of the consent can be active in the EIMPRIS system at a time. Once the 22Jul2022 version of the ICF was uploaded on 05Aug2022 at 1 pm EST, re-consenting of previously enrolled and consenting newly enrolled patients was handled in the following manner:

- Any patient that electronically consented and signed the ICF in the EIMPRIS system prior to 05Aug2022 at 1pm EST signed the 06May2022 ICF version of the consent. These patients are required to re-consent using a paper copy of the current IRB approved ICF version dated 22Jul2022. At this time, it isn't possible to re-consent electronically in the EIMPRIS system.
- As of 05Aug2022 at 1:00 pm EST (when the 22Jul2022 ICF was uploaded into the EIMPRIS system) any new patient that consented to the study, electronically signed the 22Jul2022 ICF consent. No further action regarding consent is required for these patients as they have signed the current IRB approved ICF.

C. EIMPRIS system ICF footer missing:

On 18Aug2022, it was realized that the footer with the Advarra IRB version of the ICF was missing from the EIMPRIS system consent. This issue has been corrected as of 26Aug2022. The version of the ICF electronically signed by a patient in the EIMPRIS system to date is as follows:

- ICF electronically signed prior to 05Aug2022 at 1:00 pm EST was the Advarra Master ICF dated 06May2022.
- ICF electronically signed on or after 05Aug2022 at 1:00 pm EST to present is the Advarra Master ICF dated 22Jul2022.

D. ICF QOL Day 30 missing on ICF:

- The ICF description of when the QOL is administered is missing "30" from the following statement regarding when the QOL assessment will occur: "You will complete Quality of Life (QoL) assessments on days 2, 90, 180, 270, and 360 post-baseline at home".
- Advarra IRB has been informed of this typographical error and has instructed MediMergent that this does not require an amended ICF at this time, however, patients should be informed of the error.
- Please inform your patients of this error and document that they were informed.
- The QOL missing Day "30" will be incorporated into the ICF during a subsequent ICF update.