



MEMORANDUM #7

Date: August 11, 2022

To: All EIMPRIS team members

From: MediMergent Project Team

RE: Protocol Amended 08Aug2022, Reconsenting patients who signed the 6May2022 ICF, Pharmacy Manual and SARS-CoV-2 PCR positive patient samples sent to Isoplexis

Hello EIMPRIS Team Members,

ESR 22-21698 Protocol Amended 8Aug2022 (Amendment #3) -

Attached please find the ESR 22-21698 amended protocol dated 8Aug2022. You should have received your Advarra IRB site approval for the amended protocol (protocol Amendment #3 8Aug2022). The changes to this version of the protocol ONLY involve statistics, endpoints, sample size and power calculations. There are no changes to the Informed Consent associated with the 8Aug2022 protocol amendment and no changes to the operational aspect of the study.

- Protocol signature pages for the amendments #2 and #3 will be sent under separate cover for signature by the Principal Investigator (PI) and should be uploaded to your site regulatory portal.
- Attached please find a “Read and Confirm Training Document” for individual protocol training documentation. This needs to be completed by your study personnel once they have reviewed the 8Aug2022 amended protocol. All study personnel should train on the updated protocol and document their training on the form provided. Additionally, a group training log is available should you wish to do group training. The individual and group training documents are available in the EIMPRIS resource library for downloading. Once training documents are signed, please upload them to your EIMPRIS regulatory SharePoint folder.

Re-consenting enrolled patients who signed the 6May2022 consent –

The current IRB approved ICF is the updated ICF dated 22Jul2022 for which your site recently received approval. Any patient that signed the 6May2022 consent needs to re-consent to the study and sign the updated ICF revised 22Jul2022. Re-consenting patients needs to be done

using a paper copy of the Advarra IRB approved consent for your site. You can download a copy of your site ICF from the Advarra Cirbi portal if you haven't already done so.

ESR 22-21698 Study Pharmacy Manual -

Attached please find the ESR 22-21698 study pharmacy manual for your review and reference. A copy of the manual is available in the EIMPRIS resource library for reference and downloading. Please distribute this document to study team members, as needed.

COVID PCR Positive Patient T-Cell Samples sent to Isoplexis -

If you have a patient that is **SARS-CoV-2 PCR positive after Evusheld™ administration**, you must collect an RBD-IgG, serum AZD7442 concentration (PK) sample and T-Cell sample as outlined in the protocol.

Specific to the specimen obtained for the T-Cell sample sent to Isoplexis, please be sure to mark the sample bag/documentation as “**Unscheduled COVID Positive Pt. Sample**”.

Please reach out to us any time at eimpris@eimpris.com or **800-757-7345** if you have any questions.