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PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	24 Jun 2020
TO:	Fred Korley
PROTOCOL:	NHLBI - C3PO, Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO) (Pro00044489)
APPROVAL DATE:	17 Jun 2020
EXPIRATION DATE:	17 Jun 2021

IRB APPROVED DOCUMENTATION:

Protocol Version(s):	• Protocol Version 1 (Dated June 12 2020)
Consent Template(s):	• Informed Consent Form (Advarra IRB Approved Version 23 Jun 2020)
Product Information:	• INVESTIGATOR'S BROCHURE for SARS-CoV-2 Convalescent Plasma (COVID-19 Convalescent Plasma) (Edition Number: 1.0, Release Date: 10 June 2020)
Other Material:	• Subject Handout (Dated June 12, 2020) • Standard Operating Procedure Electronic Informed Consent (Version 3, Dated 11-Jun-2020)

The IRB approved the above referenced protocol with the modifications listed below on 17 Jun 2020:

- **Modifications to the Informed Consent Form**

On 23 Jun 2020, the IRB reviewed and approved additional edits to the Informed Consent Form.

The IRB determined that the use of a Legally Authorized Representative (LAR) is approved for this study. During the course of the study, if the subject regains the capacity to consent, informed consent must be obtained from the subject and the subject must be offered the ability to leave the study if desired.

Please Note the following COVID-19 considerations:

1. **Please ensure that you have adequate study staff and resources before you begin conducting the study.**

2. **Please consider delaying enrollment if your study procedures may be impacted by the pandemic; or please submit a modification to change the procedures.**
3. **Please note that screening questions relating to COVID-19 are not considered research questions unless you will be collecting data on COVID-19.**

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

The IRB determined the eConsent process is appropriate. Use of eConsent is Approved. Please submit the following (can be submitted in a subsequent Modification, and does not need to be submitted prior to use of eConsent):

1. An Attestation Letter stating that the eConsent is a complete and exact copy of the IRB approved ICF document OR describing the elements that are different (for example, additional statements, links, graphics);
2. A working link (with login information) to be used by the IRB to review the functionality of the eConsent (may be included in the Attestation Letter, or submitted separately)

Please Note: This approval notice is for the IRB approval of the protocol only. The Principal Investigator <u>for each site</u> must complete a separate site submission to receive an IRB Approval notice allowing them to conduct the study.

Subpart B Determination – Main study
45 CFR §46.204
The Board determined that the research meets requirements under Subpart B and all criteria met to support research in pregnant women/fetuses.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

Approved investigators and sites are required to submit to Advarra for review, and await a response prior to implementing, any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.