Certificate of Action

Investigator Name: Leopoldo Cancio, MD	**Board Action Date:** 03/26/2021
Investigator Address: US Army of Institute of Surgical Research, 3698 Chambers Pass JBSA Fort Sam Houston, TX 78234-7767, United States	**Approval Expires:** 03/26/2022 **Continuing Review Frequency:** Annually
Sponsor: Coalition for National Trauma Research (CNTR) **Institution Tracking Number:**	**Sponsor Protocol Number:** CNTR-2020-001 **Amended Sponsor Protocol Number:**
Study Number: 1303590	**IRB Tracking Number:** 20210893
Work Order Number: 1-1405638-1	
Protocol Title: Plasma Resuscitation without Lung Injury (PROPOLIS)	

THE FOLLOWING ITEMS ARE APPROVED:
Investigator
PROPOLIS Research Monitor Duties #30124592.0
Protocol (12-27-2020) Version 1
SITE SPECIFIC Protocol Letter (03-18-2021) Confirmation of pregnant women exclusion, 21 CFR Part 11 Compliance, and confirmation of consent
Consent Form [S0]
Authorization to Use and Disclose PHI [S0]
Telephone Script for obtaining a Signed Consent Form #30207844.0 - As Submitted

Please note the following information:
The Board determined that criterion (iii) is met, and that this research does not require an Investigational New Drug (IND) from the Food and Drug Administration (FDA). "21 CFR 312.2(b): Exemptions. (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply: (i) <Omitted>; (ii) <Omitted>; (iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; (iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and (v) <Omitted>". Please note that criteria (i), (ii), and (v) are under the control of the sponsor, and WCG IRB holds the sponsor responsible for complying with those criteria. Criterion (iv) is satisfied by the fact that the study has been reviewed by WCG IRB.

For this study, the Board approved the enrollment of adult subjects who lack capacity to consent. When an adult subject lacks the capacity to consent, a "legally authorized representative" (LAR) must consent for the subject.

COVID consent - Consent discussions should follow FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic," available on line at https://www.fda.gov/media/136238/download. FAQ 11, 12, and 13 describe acceptable alternative consent processes.

The Board determined this study is greater than minimal risk. The board conducted a scientific review and determined that the requirements of the Common Rule part 111 were met and the research has scientific merit.

Request for Alternative Consent Process

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- For research subject to continuing review, submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - For research subject to federal oversight other than FDA:
        - No additional identifiable private information about the subjects is being obtained
        - Analysis of private identifiable information is completed
- For research subject to continuing review, if research approval expires, stop all research activities and immediately contact the IRB.
- Promptly (within 5 days) report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.
If the IRB approved an e-consent process that involves uploading the approved consent form to an e-consent platform, please ensure that the consent form(s) approved for your site is the version of the consent form that gets uploaded to the platform.
If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by WCG IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. "

For research subject to continuing review, you will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
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