THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 202505671

To: Nicholas Mohr

From: IRB-01 Univ of Iowa, DHHS Registration # IRB00000099, DHHS Federalwide Assurance # FWA00003007

Re: Characterizing a High-Reliability Implementation Program for Sepsis: Sepsis Tools AND Accurate Reporting of Outcome Differences (STANDARD) Study - Qualitative Site Visits

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 10/06/25

Next IRB Approval Due Before: 06/03/27

Type of Application:

☐ New Project
☐ Continuing Review
☐ Biennial Review
☒ Modification

Type of Application Review:

☐ Full Board:
Meeting Date:
☒ Expedited

☐ Exempt

Approved for Populations:

☐ Children
☐ Prisoners
☐ Pregnant Women, Fetuses, Neonates

Source of Support: US Department of Health & Human Services, National Institutes of Health

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

The following documents have been submitted for the above review and approval:

Recruitment Script: Email	recruitment-email_institution STANDARD_2025-10-03.docx

This approval has been electronically signed by IRB Chair:
Brian Bishop, CIP, MA
10/06/25 1540

As Principal Investigator, you are responsible for ensuring this project is conducted in compliance with all applicable federal, state, and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. The research is approved to be conducted as described in the HawkIRB application. The addition or omission of study activities is not permitted without prior IRB review and approval. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. The IRB has approved all recruitment strategies described in the application. It is not necessary to use all of thesestrategies, but no additional recruitment strategies may be used without IRB approval.

Consent: Consent must be obtained using the method(s) described in the application. Consent must be obtained and documented as required prior to certain screening or study procedures/activities. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document must be given to the subject if your Consent contains a HIPAA authorization section.)

Biennial Review: Eligible, non-exempt, studies that do not require an annual continuing review will require a Biennial check in until the project is closed in HawkIRB by the Principal Investigator. The required Biennial check in will include a very brief, seven question check every other year. You are responsible for submitting a Biennial Review in sufficient time for review.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards tosubjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for

reporting to the IRB. Reports from the investigator to the IRB must be submitted via HawkIRB within ten working days of the event or within 10 working days of the PI becoming aware of the event.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained fora period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application. For research that involves Protected Health Information(PHI) under HIPAA, the research records must be kept for a period of six (6) years folling the close of the research project.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the “Investigator’s Guide to Human Subjects Research.” Research investigators are expected to comply with these policies and procedures, and to be familiar with the University’s Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.