Children's Healthcare of Atlanta
Dedicated to All Better

Date: 1/6/2017

NOTIFICATION OF APPROVAL
Children's Healthcare of Atlanta Institutional Review Board

Study Title: Utility and Correlation of Known Anticoagulation Parameters in the Management of Pediatric Ventricular Assist Devices
Principal Investigator: Shri Deshpande, MD
CHOA IRB#: 16-203
Date IRB Approval Issued: 1/5/2017
Date IRB Approval Expires: 1/4/2018
IRB Review Type: ☐ Full Committee ☒ Expedited
Sites Associated with this IRB Approval: ☒ Children's at Egleston
☐ Children's at Scottish Rite
☐ Children's at Hughes Spalding

Risk Category:
☒ 46.404 OHRP (50.51 FDA)
☐ 46.405 OHRP (50.52 FDA)
☐ 46.406 OHRP (50.53 FDA)
☐ 46.407 OHRP (50.54 FDA)

You are approved to review **100** subjects' charts between 1/1/2013 and 6/30/2016. You **MUST** have IRB approval for data collected outside of the approved date range or over the approved number of subjects **PRIOR** to data collection. Failure to obtain prior approval may result in inability to use data.

Children's Healthcare of Atlanta Institutional Review Board approved the above referenced study.

☐ The stamped approved informed consent document for use in this study is attached. Only this original shall be used to make copies for study enrollment. You may not use any informed consent document that does not have this Institutional Review Board's current stamp of approval. The board has determined one parent signature is required.

☒ The requirement for informed consent is waived for this study. The IRB has determined that all specified criteria described in 45 CFR 46.116(d) as necessary to obtain a waiver of informed consent.

☒ The requirement for authorization for the release of protected health information for research purposes is waived for this study. The IRB has determined that all specified criteria in 45 CFR 164.512 as necessary to obtain a waiver of HIPAA Authorization.

☐ The requirement for authorization of release of protected health information is partially waived for this study.

☐ This study is open for data analysis only.

While conducting this research, please ensure that the following occur:

- As applicable, informed consent is sought and appropriately documented from each prospective subject or the subject's legally authorized representative before the subject participates in the research.
- IRB approval for continuation of the study is obtained prior to the above referenced expiration date. Failure to obtain approval for continuation prior to the expiration date results in immediate termination of the research at the above referenced study sites.
- Any modification to the study procedures or documents approved by the IRB are submitted to and approved by the IRB prior to implementing the change.
- Serious adverse events reports are reported to the IRB within ten (10) days of knowledge of them.
- Appropriate study records are maintained as mandated by this institution, the sponsoring agency, and the FDA.
- Hospital staff involved with this study are fully informed and trained regarding their involvement with this research or its subjects.

The IRB office may provide a request for continuing renewal at 60 and 30 days prior to the expiration date indicated above. However, it is the Principal Investigator's responsibility to ensure that the continuing renewal materials are submitted in adequate time to allow IRB review and approval prior to the expiration date. Failure to obtain IRB approval for continuation results in immediate termination of the research. In this case, the study may not be re-opened under this CHOA IRB# unless the continuing renewal materials are received within 90 days of the expiration date and approved by the IRB. Otherwise, the study must be submitted as a new protocol and a new CHOA IRB# will be assigned.

As a reminder, in addition to IRB approval, the PI is responsible for obtaining all applicable organizational approvals for the study (Legal, Clinical Engineering, Sourcing, Departmental, etc.).

Sincerely,

Tom Penna, MTS, CIP
Institutional Review Board Program Analyst

Documents Approved:
Protocol, *version 1/5/2017*