

APPROVAL LETTER

TO: Kirklin, James K

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 11-Jun-2019

RE: IRB-051228006
The Data Coordinating Center for the Interagency Registry of Mechanically Assisted Circulatory Support (Registry of Mechanical Circulatory Support Device for End-Stage Heart Failure - Phase 2) (Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Renewal)

The IRB reviewed and approved the Continuing Review submitted on 10-Jun-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Expedited
Expedited Categories: 8a
Determination: Approved
Approval Date: 11-Jun-2019
Approval Period: One Year
Expiration Date: 10-Jun-2020

The following populations are approved for inclusion in this project:

- Children – CRL 1

The following apply to this project related to informed consent and/or assent:

- Waiver of Informed Consent
- Waiver of HIPAA

Documents Included in Review:

- ipr.response.190610