

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)
IORG Registration # IRB00012550 (IRB 03)

DATE: 12-Apr-2022

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 06-Apr-2022 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-Apr-2022
Approval Period: One Year
Expiration Date: 10-Apr-2023

Linked Records:

- 000513394
- 000233064

- 000506414
- 000526426
- 000518144
- 000526403
- 000383981
- 000517598

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 HIPAA
- Waiver of Informed Consent

Documents Included in Review:

- CONTINUING REVIEW EFORM

To access stamped consent/assent forms (full and expedited protocols only) and/or other approved documents:

1. Open your protocol in IRAP.
2. On the Submissions page, open the submission corresponding to this approval letter. NOTE: The Determination for the submission will be "Approved."
3. In the list of documents, select and download the desired approved documents. The stamped consent/assent form(s) will be listed with a category of Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)