

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input type="checkbox"/> ORIGINAL <input checked="" type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity 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)		5. Name of Principal Investigator, Program Director, Fellow, or Other KIRKLIN, JAMES K

6. Assurance Status of this Project (*Respond to one of the following*)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
 Assurance Identification No. FWA00005960, the expiration date 09/29/2013 IRB Registration No. IRB00000196
- This Assurance, on file with (*agency/dept*) _____, covers this activity.
 Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (*if applicable*)
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (*Respond to one of the following IF you have an Assurance on file*)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
 by: Full IRB Review on (date of IRB meeting) 11/10/2010 or Expedited Review on (date) _____
 if less than one year approval, provide expiration date _____
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments Protocol subject to Annual continuing review.	Title <u>F051228006</u> 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)
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IRB Approval Issued: 11-18-10

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution University of Alabama at Birmingham 701 20th Street South Birmingham, AL 35294
11. Phone No. (<i>with area code</i>) (205) 934-3789 12. Fax No. (<i>with area code</i>) (205) 934-1301 13. Email: <u>smoore@uab.edu</u>	15. Title Chairman, IRB
14. Name of Official Ferdinand Urthaler, M.D.	17. Date <u>11/18/10</u>
16. Signature <u>Ferdinand Urthaler, MD/PhD</u>	

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