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# Project Revision/Amendment Form



(Rev. 4/7/2004)

(PLEASE TYPE: In MS Word, highlight the shaded, underlined box and replace with your text; double-click checkboxes to check/uncheck.)

[Link: Project Revision/Amendment Form](#)

Federal regulations require IRB approval before implementing proposed changes. Please complete this form and attach the changed research documents. Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.)

Principal Investigator: James K. Kirklin, M.D. Date: 12/21/06

Contact: Mary Lynne Clark Phone #: 4-2555 Fax #: 5-0085 E-mail: mlclark@uab.edu

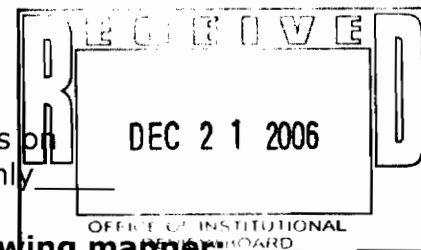
Campus Address: 790 LHRB

Study/Protocol Title: The Data Coordinating Center for the Interagency Registry of the Mechanically Assisted Circulatory Support (INTERMACS)

IRB Protocol #: F051228006

### Current Status of Project: (check only one)

- Currently in Progress (# participants entered: 184)
- Study has not yet begun (no participants entered)
- Closed to participant enrollment (remains active); # participants therapy/intervention \_\_\_\_\_; # participants in long-term follow-up only \_\_\_\_\_



### This submission changes the status of this study in the following manner: (check all that apply)

- Protocol Revision
- Protocol Amendment
- Study Closed to participant entry
- Study Terminated
- Revised Consent Form — Cannot issue until e of Conf. received
- Addendum (new) consent form
- Enrollment temporarily suspended by sponsor
- Other, (specify) \_\_\_\_\_

1. Briefly describe, and explain the reason for, the revision or amendment. Include a copy of supportive documents with changes highlighted. Please highlight changes/revisions/additions to the consent form, protocol, research questionnaire, etc.

The amendment is being submitted for several areas: 1) Four IRB approved Informed Consents are being submitted for amendment (Attachment I). Note: The Certificate of Confidentiality mentioned in the revised consents is pending. 2) New Revoke Authorization forms (Attachment II). 3) The amendment of the informed consent constitutes changes in the Manual of Operations Table of Contents (Attachment III), User's Guide (Attachment IV), and \*Protocol (Attachment V). A Summary of Changes and Additions (Attachment VI) explains the amendment(s) and additions to each document. Also included is a new document to be added to the User's Guide titled 'Informed Consent Required Elements' (Attachment VII) which will assist the sites in drafting their informed consent(s). \*Protocol changes enable the DCC to review and approve all informed consents being used by the participating sites. The changes consists of: Section 1.0 - from "Patients at centers that require informed consent will be consented prior to case data being included in the registry" to "Patients will be consented prior to case data being included in the registry." Section 4.3 - from "Patients at centers that require informed consent will be consented prior to case data being included in the registry. Informed consent documents will not be sent to the DCC" to "Patients will be consented prior to case data being included in the registry. Informed Consent documents with patient signatures will not be sent to the DCC." Section 8.0 - from "Each participating hospital shall: (1) send at least one person to attend training, (2) provide dated proof of initial and annual IRB approval or exemption, (3) enter data on all MCSDs implanted at the site (if consent is not given or if device is part of an ongoing clinical trial, then the site shall provide the name of the device and the date of implant only), (4) enter complete follow-up on all consenting patients, (5) submit to regular and "for cause" data audits by UNOS, (6) correct identified

errors in a timely fashion, (7) attend annual scientific meeting” to “Each participating hospital shall: (1) send at least one person to attend training, (2) provide dated proof of initial and annual IRB approval, IRB approved Informed consent and proof of Human Subjects training for the principal staff (to include the Principal Investigator and site Coordinator), (3) enter data on all MCSDs implanted at the site (if consent is not given or if device is part of an ongoing clinical trial, then the site shall provide the name of the device and the date of implant only), (4) enter complete follow-up on all consenting patients, (5) submit to regular and “for cause” data audits by UNOS, (6) correct identified errors in a timely fashion, (7) attend annual scientific meeting.” ✓

2. Does this revision/amendment revise or add a genetic or storage of samples component?  Yes  No

If yes, please see the Guidebook to assist you in revising or preparing your submission documents or call the IRB office at 4-3789.

3. Does the change affect subject participation (e.g. procedures, risks, costs, etc.)?  Yes  No

4. Does the change affect the consent document?  Yes  No

If yes, briefly discuss the changes. Following approval from the UAB IRB, the amended informed consent templates will be distributed by the Data Coordinating Center (DCC) to the participating sites. Each participating site that does not currently meet the informed consent elements will submit an amended informed consent to their local IRB. Following approval at the local site, the site will forward a copy of their approved amended informed consent to the DCC. ✓

Include the revised consent form with the changes highlighted.

Will any participants need to be reconsented as a result of the changes?  Yes  No

If yes, when will participants be reconsented? The UAB DCC will not be reconsenting participants. Reconsenting participants will occur at the local level. The DCC does not collect copies of informed consents signed by participants.

Signature of Principal Investigator J. K. Kuhl Date 12/21/06

FOR IRB USE ONLY  
dob 2-22-06

APPROVED  
F. Urthaler  
Ferdinand Urthaler, M.D.  
Chairman-IRB  
May 30, 2007