

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

OCT 30 2008

- Federal regulations require IRB approval before implementing proposed changes.
- 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.)
- Complete this form and attach the changed research documents.

OFFICE OF HUMAN SUBJECTS  
REVIEW BOARD

Today's Date: 10/30/08

## 1. Contact Information

Principal Investigator's Name: James K. Kirklin BlazerID: jkirklin E-mail: jkirklin@uab.edu  
 Contact Person's Name: Mary Lynne Clark BlazerID: mlclark E-mail: mlclark@uab.edu  
 Telephone: 4-2555 Fax: 5-0085  
 Campus Address: 790 LHRB

## 2. Protocol Identification

Protocol Title: The Data Coordinating Center for the Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS)  
 IRB Protocol Number: F051228006

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

- Currently in Progress (Number of participants entered: 1113) ✓
- Study has not yet begun (No participants entered)
- Closed to participant enrollment (remains active)—  
 Number of participants on therapy/intervention: \_\_\_\_\_  
 Number of participants in long-term follow-up only: \_\_\_\_\_
- Closed to participant enrollment (data analysis only)—  
 Total number of participants enrolled: \_\_\_\_\_

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

- |                                                                                                                                                                                                                                                                           |                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| <input checked="" type="checkbox"/> Protocol Revision                                                                                                                                                                                                                     | <input type="checkbox"/> Revised Consent Form                        |
| <input checked="" type="checkbox"/> Protocol Amendment                                                                                                                                                                                                                    | <input type="checkbox"/> Addendum (new) consent form                 |
| <input type="checkbox"/> Study Closed to participant entry                                                                                                                                                                                                                | <input type="checkbox"/> Enrollment temporarily suspended by sponsor |
| <input type="checkbox"/> Study Closure                                                                                                                                                                                                                                    | <input type="checkbox"/> Change in protocol personnel                |
| <input checked="" type="checkbox"/> Other, (specify) <u>Revised Appendix C: Adult Blood &amp; Tissue Revoke Authorization; Appendix C: Pediatric Blood and Tissue Revoke Authorization; Appendix: Device Brand List; Appendix D: Participation Agreement Addendum I</u> ✓ |                                                                      |

## 3. Reason for change

Briefly describe, and explain the reason for, the change. If normal, healthy controls are included, describe in detail how this change will affect those participants.  
 Include a copy of the protocol and any other documents affected by this change (e.g., consent form, questionnaire) with all the changes highlighted.

The current protocol amendment was required primarily to clean up the document. We have changed our terminology, provided additional references, and improved our instructions. The majority of the revisions are cosmetic; however, we have added a new section regarding "Site Eligibility and Enrollment". We have also revised Appendix C, D, and K.

Appendix C: The Adult Blood and Tissue Revoke Authorization form and the Pediatric Blood and Tissue Revoke Authorization form was revised to include a section which allows a participant wishing to revoke his/her authorization for participation in the Blood and Tissue repository a choice to end their continued participation in (a) heart failure testing (b) DNA testing or (c) both.

Appendix D: The Addendum to the Participation Agreement was developed to amend the current Participation Agreement replacing the provision entitled, "Information from the registry may be disclosed to third parties" with the provision appearing below:

**Information from the registry may be disclosed to third parties, as follows:**

Statistical summaries and limited access patient-level data will be given to the sponsor (NHLBI, including the OSMB), the FDA, and CMS, as authorized in the Patient Consent and HIPAA Authorization form. De-identified data may be disclosed to industry on a periodic basis. To help participating sites fulfill Medical Device Reporting (MDR) requirements to the FDA, requisite data will be sent to the manufacturer and FDA on a periodic basis.

Appendix K: Section 3 and 4 were deleted removing all unapproved devices from the list.

**4. Does this change 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, or call the IRB office at 934-3789.

**5. Does the change affect subject participation (e.g. procedures, risks, costs, etc.)?**

Yes  No

**6. Does the change affect the consent document(s)?**

Yes  No

If yes, briefly discuss the changes. \_\_\_\_\_

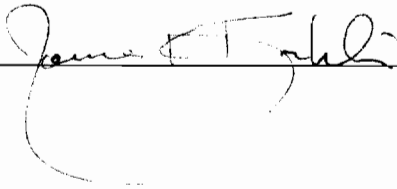
*Include the revised consent document with the changes highlighted.*

Will any participants need to be reconsented as a result of the changes? \_\_\_\_\_

Yes  No

If yes, when will participants be reconsented? \_\_\_\_\_

Signature of Principal Investigator \_\_\_\_\_



Date 10/30/08

Oct 1-16-08

Approved Expedited

To Convened IRB

f. Chhabra MD

Chair or Vice-Chair

Oct 31, 2008 Date