



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Heart, Lung, and Blood
Institute Management Policy Admin
Services Branch
Building 31, Room 5A33
Bethesda, Maryland 20892-2490

February 22, 2007

James K. Kirklin, M.D.
Professor and Director
Division of Cardiothoracic Surgery
Department of Surgery 760 THT
1530 3rd Avenue South
Birmingham, AL 35294-0007

Dear Dr. Kirklin:

Enclosed is the Certificate of Confidentiality to protect the identity of research subjects in your multi-site research project entitled, "Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS)." Please note that the Certificate expires on May 30, 2010.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, May 30, 2010, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise either Alesha Hopkins or myself of any situation in which the Certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the Certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to either Alesha Hopkins or myself at: The National Institutes of Health, the National Heart, Lung, and Blood Institute, Building 31, Room 5A21, 9000 Rockville Pike, Bethesda, Maryland, 20892-2486, phone number 301-496-5931 and fax number 301-402-0299.

Sincerely,

A handwritten signature in cursive script that reads "Donna Jones".

Donna Jones
NHLBI Certificate of Confidentiality Coordinator

CERTIFICATE OF CONFIDENTIALITY

NHLBI 07-07

Issued to

University of Alabama at Birmingham

Conducting research known as

“Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS).”

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, James K. Kirklin, M.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Kirklin is primarily responsible for the conduct of this research, which is funded by the National Heart, Lung, and Blood Institute (HV058198).

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the University of Alabama at Birmingham and its contractors or cooperating field centers; and
2. have, in the course of their employment or association, access to information that would identify individuals who are the subjects of the research pertaining to the project known as “Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS)”

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

This registry includes patients with a mechanical circulatory support device, implanted on or after 3/1/2006, intended as destination therapy for end-stage heart failure or bridge to transplantation, provided hospital discharge is feasible. The registry will collect data, blood, and optional tissue samples from approximately 80 participating hospitals and 2,000 new patients per year for a period of four years. Data collected are: patient demographics and profile prior to implant, including a quality of life questionnaire and neurocognitive tests; device and operative details; post-implant follow up at one week, one month, three months, six months and every six months thereafter; and adverse events such as infection, device failure, neurological events, and death.

The Certificate of Confidentiality will protect against disclosure of confidential personally identifiable information gathered as part of this research project that could be linked, directly or indirectly, to individual people. Confidential information is information about a person that, if disclosed, could reasonably be expected to place the person at risk of criminal or civic liability, or be damaging to financial standing, employability, insurability, or reputation. Thus, the Certificate will ensure the privacy of registry enrollees in civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level.

Data collection takes place at multiple recruitment sites. Data are stored as paper documents at each site and electronically in the INTERMACS, web-based, data entry system maintained by the United Network for Organ Sharing (UNOS). Any optional tissue samples collected will be stored at the SeraCare NIH biospecimen repository.

To protect enrollees' identities:


1. Paper registry records will be maintained at each recruitment site through use of assigned access passwords, with access limited to registry research personnel only. Records, including signed Health Insurance Portability and Accountability Act (HIPAA) authorizations for release of data to INTERMACS, will be kept secure (locked up).
2. Electronic registry data (both confidential and non-confidential) will be entered into the INTERMACS database. Confidential information will be available only to UNOS employees who work directly with the registry and to designated INTERMACS researcher personnel. UNOS complies with all national patient privacy regulations. All of their data systems feature multiple levels of security, which protect patient data according to the most stringent requirements. They are fully compliant with HIPAA and are certified by the Health Resources and Services Administration (HRSA). All UNOS employees have obtained government security clearance and are audited annually by HRSA for compliance. Monitors and printouts are located in secure areas and access is limited to security badge holders only. Access to the production databases is restricted and on a need-to-know basis only.
3. Tissue samples stored at the SeraCare NIH biospecimen repository will be assigned an ID number and only the site investigator or senior researchers will possess the linkage code to patient identifiers.
4. No published or unpublished report or visual or speaking presentation about this study will include any material that will identify a participant in this study.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on May 30, 2010. The protection afforded by this Certificate of Confidentiality is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date: 2/26/07


Elizabeth G. Nabel, M.D.
Director