



ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)

Regulatory Guidelines

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Title of the project:

ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)

Registry Principal Investigator:

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Regulatory Considerations:

In order to be activated in IMACS, your institution will need to all of the required documentation to the IMACS Project Manager at IMACS@uab.edu and complete data entry training. The required documents are as follows:

IMACS Institutional Enrollment Form

A completed Enrollment Form with basic contact information is the initial requirement in the activation process.

IMACS Memorandum of Agreement

The Memorandum of Agreement must be completed and signed by a representative of your institution that has contractual or **signing authority**.

Regulatory or Ethics Board Approval

IMACS requires documentation from the hospital's regulatory or ethics board that all local requirements for participation in the registry have been met. It is the responsibility of the participating site to determine and adhere to those requirements. For participating groups, or collectives, IMACS will require documentation of regulatory procedures required of the collective.

Note: All documentation must be provided from an authority or representative on the Ethics Board in writing (preferably on official letterhead), rather approval is needed or not.

Informed Consent

It is the responsibility of the participating site to determine if Informed Consent for participation is required. Documentation is required from the regulatory or ethics board as to their policy on the Informed Consent process.

Note: All documentation must be provided from an authority or representative on the Ethics Board in writing (preferably on official letterhead), rather approval is needed or not.

Training

At least one IMACS staff member at the institution must complete the IMACS training process. A live web-based entry training session will be scheduled with the designated staff members at each institution. The training will be conducted in English.