Interagency Registry for Mechanically Assisted Circulatory Support

Intermacs® Manual of Operations and Procedures Version 5.0

Appendix C: Patient Information Forms, Templates, & Guidelines

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Guidelines on Waiver of Informed Consent and HIPAA Authorization

Waiver of Informed Consent

An Institutional Review Board (IRB)/Ethics Board (EB) may approve a consent process that does not include some or all of the elements of informed consent or may waive the process entirely. Generally, there are three sets of circumstances under which United States (US) regulations give an IRB authority to waive the required informed consent, provided the IRB finds and documents that the study/investigation meets criteria identified by regulations:

- **Public Benefit or Service Programs Research** [refer to 45 CFR 46.116(c)]
  - The investigation is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:
    - Public benefit or service programs,
    - Procedures for obtaining benefits or services under those programs,
    - Possible changes in or alternatives to those programs or procedures, or
    - Possible changes in methods or levels of payment for benefits or services under those programs, and
  - The investigation could not practicably be carried out without the waiver or alteration.

- **Waiver for Minimal Risk Studies** [refer to 45 CFR 46.116(d)]
  - The investigation involves no more than minimal risk to participants, and
  - The waiver or alteration will not adversely affect the rights and welfare of the participants, and
  - The investigation could not practicably be carried out without the waiver or alteration, and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  Unless all four conditions are met, informed consent will be deemed feasible.

- **Emergency Situations** [refer to 21 CFR 50.23(a)(b)(c); 21 CFR 312, and 21 CFR 812]

In the US, the request for Waiver of Informed Consent should be submitted to the IRB. If approved, the investigator will get a statement from the IRB indicating that the waiver has been granted.

Outside the US, please check with your country’s regulatory authority/agency for the circumstances under which a Waiver of Informed Consent can be obtained.
Waiver of HIPAA Authorization\textsuperscript{1}

In some situations, an IRB may waive the requirement that study participants sign a HIPAA Authorization Form (for US sites). In general, a Waiver of Authorization may be granted in the same situation where the IRB now grants a Waiver of Informed Consent. A typical example would be an investigation that would use retrospective chart review, where the data are already collected. Investigations that involve a Waiver of Informed Consent and that are approved by the IRB on or after April 14, 2003, must also have a Waiver of Authorization approved by the IRB. For studies that the IRB approved with Waiver of Informed Consent before April 14, 2003 no Waiver of Authorization is required.

A Waiver of Authorization does not mean that an investigation is exempt from HIPAA’s privacy regulations. It only means that you do not need signed authorization from each participant.

To qualify for Waiver of Authorization, investigators should indicate that:

- The registry use of the health information does not represent more than a minimal risk to privacy;
- The investigation could not be done without the requested health information;
- It would not be practical to obtain signed authorizations from the participants;
- The specific elements of health information that are requested are not more than the minimum necessary\textsuperscript{2} to accomplish the goals of the study.

The request for Waiver of Authorization should be submitted to the IRB. If approved, the investigator will get a statement from the IRB indicating that the waiver has been granted. The investigator can take this form to the site (“covered entity”) that is holding the requested health information, indicating IRB approval of its release.

Of note, if investigators who receive health information under a Waiver of Authorization disclose any of that information to other investigators, institutions, or agencies, the investigator is responsible for keeping an accounting of disclosures\textsuperscript{3}. Under HIPAA, subjects can request a record of how often their health information was released to others in the previous 6-year period. For health information obtained under a Waiver of Authorization, it is the investigator’s responsibility to provide this record of disclosures.

\textsuperscript{1}United States DHHS, OCR Privacy Brief: Summary of the HIPAA Privacy Rule, Last updated May 2003 (http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf)\
\textsuperscript{2}Minimum necessary applies: When using or disclosing protected health information (PHI) or when requesting PHI from another covered entity, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.\n\textsuperscript{3}The Privacy Rule allows three methods for accounting for research-related disclosures that are made without the individual’s Authorization or other than a limited data set: 1) a standard approach, 2) a multiple-disclosures approach, and 3) an alternative for disclosures involving 50 or more individuals. Whatever approach is selected, the accounting is made in writing and provided to the requesting individual. Refer to 45 CFR 164.528.
Guidelines on Informed Consent Elements

In the event that Waiver of Informed Consent is not granted by the Institutional Review Board/Ethics Board, then participating sites should follow their local IRB/EB policies in regard to obtaining informed consent. Because participation in Intermacs® and Pedimacs is considered minimal risk (i.e., *no evaluations or tests beyond standard of care are required*), the IRB/EB may approve a consent that does not include or alters some of the following elements:

- Local IRB/EB authorization or approval stamp (required in final Informed Consent)
- NHLBI Contract Number (HHSN268201100025C) and the sponsor’s name, National Heart, Lung, and Blood Institute, preferably on the front page
- Local Principal Investigator listed on the front page
- Purposes of the research
- Expected duration of the subject’s participation
- Approximate number of subjects involved in the study (either locally or combined sites)
- Procedures –
  - Adults: EQ-5D and KCCQ or Quality of Life questionnaires, Neurocognitive test, Functional Capacity test
  - Pediatrics: Quality of Life questionnaires to be completed by patients and Quality of Life questionnaires to be completed by parents, Functional Capacity test for patients over 10 years of age
- Statement that participation is voluntary
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or to others which may reasonably be expected from the research
- No additional costs to the subject that may result from participation in the research
- Statement that the subject will not receive payment for participation in the registry
- Description of extent, to which confidentiality of records identifying the subject will be maintained
- Statement noting the possibility that the local Institutional Review Board/Ethics Board (EB); health authorities (e.g., the Food and Drug Administration); MCSD manufacturers; and the Intermacs® organization or their representatives may inspect participants’ records
- Statement that a Certificate of Confidentiality was obtained
- List of groups or agencies that will receive data, including: Investigators for Intermacs®; the National Heart, Lung, and Blood Institute; device manufacture; other government agencies (such as the Food and Drug Administration and Centers for Medicare and Medicaid Services for patients in the United States)
- Explain whom to contact for answers to pertinent questions about the research
• Explain whom to contact for answers to pertinent questions about research subjects’ rights
• Explain whom to contact in the event of a research-related injury to the subject
• Include a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
• Include the consequences of a subject’s decision to withdraw from the research
• Explain anticipated circumstances under which a subject’s participation may be terminated by the investigator without regard to the subject’s consent
• Description of the registry can be found at www.clinicaltrials.gov
• The following statement in its entirety: “The National Heart, Lung, and Blood Institute will obtain information from this clinical study under data collection authority Title 42 U.S.C. 285b.”
• Statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation, will be provided to the subject or the subject’s legally authorized representative in a timely manner; OR a statement why new findings may not be available
• Subject signature (or subject’s legally authorized representative) and date line
• Statement that a copy of the informed consent will be given to the person signing the form

NOTE:

1. The information given to a subject or the subject’s legally authorized representative shall be in language understandable to the subject or their representative (i.e., lay terms).

2. No informed consent, whether written or oral, may include any exculpatory language through which the subject or their representative is made to waive or appear to waive any of the subjects legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

3. HIPAA authorization may be incorporated into the Informed Consent or may be provided in a separate HIPAA Authorization Form.
Guidelines on Revoking Consent and Authorization

Once a participant has consented to participate in Intermacs®, he/she may choose to withdraw consent at any time. To aid in this process, Revoke Authorization templates are provided for participants to complete if they decide to withdraw from the Registry. To revoke authorization, participants will need to complete the appropriate Revoke Authorization form and provide the completed form to Clinical Center Staff (herein referred to as “Staff”). This form allows participants to officially withdraw consent and authorization for participation in the Registry. At this point, Intermacs® will only use the information already collected from the participant before the written request was made. The Staff will respond to this letter by giving the participant a copy of the completed form. The original will be retained on file by the Principal Investigator and a copy will be placed in the participant’s medical record, if applicable. The Staff will immediately contact the Intermacs® Data and Clinical Coordinating Center (DCC) to inform them to censor the Registry participant.

Some centers do not require a written request for a participant to withdraw from the Registry after he/she consented. At those centers where local Institutional Review Board (IRB)/Ethics Board (EB) review of Intermacs® is required annually, the IRB/EB will set the requirements for a participant to withdraw from Intermacs®. At some institutions, the only requirement for participants to withdraw consent is to verbally inform the Staff of their decision. If this is the case, the Staff will need to request a letter from their local IRB/EB describing their policy. The original letter will be placed in the Center's file for future reference, and a copy will be forwarded to the DCC Regulatory Director. If the participant decides to withdraw his/her consent using this method, the Staff will prepare a memo-to-file stating that the participant has informed them of the intent to withdraw from the study. This memo shall include the date of participant withdrawal, be signed and dated by the preparer, and be retained on file by the Principal Investigator, with a copy placed in the participant’s medical record, if applicable. The Staff will immediately contact the DCC to inform them to censor the participant in the Registry.
List of Templates/Forms Available

Patient Information Sheets

A. Adult Intermacs®

B. Pediatric Intermacs® (Pedimacs)

Informed Consent and Authorization Templates/Forms*

A. Adult Intermacs®
1. Informed Consent Template
2. HIPAA Authorization Template
3. Release of Information Authorization Form

B. Pediatric Intermacs® (Pedimacs)
1. Informed Consent Template
2. HIPAA Authorization Template
3. Release of Information Authorization Form

*These templates/forms apply to pre and post marketing trials sponsored by device manufacturers where a waiver of consent and authorization is granted to participating institutions, but Intermacs® participants (participating in the control arm) are likely to undergo evaluations beyond those required in Intermacs®.

Revoke Authorization Templates

A. Adult Revoke Authorization Form

B. Pediatric Revoke Authorization Form