

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-03:	Informed Consent Requirements

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in creating an informed consent document.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHHR

**Procedure**

An IRB approved Informed Consent Document (IDC) must be discussed with and signed by each study subject or the subject's legally authorized representative. MICHHR personnel responsible for obtaining informed consent from a subject must first assure that they are utilizing the most current IRB-approved informed consent document for that study. Federal regulations for the documentation of consent for the involvement of minors in research, including the assent of minors will also be followed when applicable.

An informed consent process shall precede any involvement of the subjects in the research. If an individual expresses interest in a study, an informed consent document can be mailed to the potential subject. Individuals will be provided a private environment while reading/signing consent. Consent will be signed and dated in the presence of investigator or investigator designee after review of informed consent and the opportunity for subject feedback from a member of the study team. The subject will receive a copy of the informed consent document with all required signatures and dated. The original signed informed consent document will be retained in subject's research record. A copy of the informed consent will be placed in the medical record, unless a waiver to include the IDC in the medical record has been granted by the IRB to protect the privacy of the subject. The date of consent signing will be recorded in the medical record or other source document. For protocols where waiver of the documentation of consent is granted by the IRB, then the consent process will follow IRB-specified procedures under this waiver.

The informed consent document and supporting information are available through the University of Michigan Medical School Institutional Review Board (IRBMED)

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	Review Date: June 30, 2005
Approval Signature, Date:	

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Procedure Category:	Administration
Procedure CLN-03-03:	Standard Operating Procedure Format Template

website at <http://www.med.umich.edu/irbmed/>. This website also includes links to numerous related documents and other relevant sources of clinical research and regulatory information.

### **Documentation**

Documentation for this procedure includes the informed consent document and any documentation utilized in creating the informed consent document.

### **Deviation Approval**

The Director, MICHR or designee, must approve deviation from this procedure. The Director, MICHR or designee, must store documentation of the deviation approval.

### **Relevant Definitions**

IC - Informed Consent

IRB - Institutional Review Board

IRBMED - University of Michigan Medical School Institutional Review Board

### **Appendices**

Appendix 1 IRBMED Sample Informed Consent Document

### **Procedure Author**

Manager, Research Support Core

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