

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-01:	IRB Submission Procedures (External/Internal)

**Procedure Overview**

This procedure describes the necessary activities performed by the qualified MICHHR personnel to submit protocol-related documents to the Institutional Review Board (IRB) for review and approval, or to provide emergency notification regarding important events.

**Responsible Individuals**

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

**Procedure**

Detailed information regarding submissions to IRB is covered on the University of Michigan Medical School Institutional Review Board (IRBMED) website at <http://www.med.umich.edu/irbmed/>.

The Clinical Research Associate/Assistant compiles documents for submission to the IRB. These documents may include, but are not limited to:

Initial Protocol Documents

- Signed final protocol
- Investigator Brochure
- Informed consent
- Advertisement/solicitation/recruitment materials
- Protocol amendments, if applicable
- Protocol addenda, if applicable
- Protocol synopsis
- Patient education videos
- Survey instruments (questionnaires)
- IDS acknowledgement (may be pending)
- Biomed approval, if applicable (may be pending)

Version Number: 003	Implementation Date: November 17, 2000
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	Review Date: June 30, 2005
Approval Signature, Date:	

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Subsequent protocol amendments / addenda  
Continuing IRB approval requests  
Serious adverse experience / Investigator Brochure update notifications  
Study termination notification  
Informed consent revisions

**Documentation**

Documentation for this procedure includes the IRB Submission Memo, IRB Approval/Confirmation Letter, Emergency IRB Notification Memo, materials submitted to the IRB, documentation of communication with the IRB, the IRB Submission Tracking Notebook and related sponsor or CRO correspondence.

**Deviation Approval**

The Director, MICHIR or designee must approve deviations from this procedure. The Director, MICHIR or designee must store documentation of the deviation approval in the appropriate study file.

**Relevant Definitions**

IRB - Institutional Review Board  
ISF - Investigator Study File

**Procedure Author**

Manager, Research Support Core

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