

	Standard Operating Procedures
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Procedure Category:	Study Activities
Procedure CLN-04-06:	Emergency Unblinding Procedures

Procedure Overview

This procedure describes the necessary activities performed by MICHHR personnel in the event that emergency unblinding is required within a controlled clinical trial.

Responsible Individuals

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

Procedure

1. The investigator or designee must review the existing study documentation to determine if there is a defined procedure for emergency unblinding. This procedure should be documented in the protocol and/or in the randomization instructions. The investigator should follow the defined procedure to ensure the randomization code is broken only in accordance with the protocol and IDS policy.
2. The investigator or designee must make every attempt to contact the sponsor/CRO prior to a code break. The protocol should include sponsor/CRO emergency contact information. This contact serves to provide the details of the situation to the sponsor/CRO in addition to obtaining the concurrence of the sponsor/CRO that a code break is indicated.
3. The investigative site personnel must create and maintain documentation regarding the emergency unblinding as defined by the sponsor/CRO and IDS departmental SOPs.
4. In the event that unintended unblinding occurs, the investigative site personnel must create and maintain appropriate documentation of the unblinding in addition to informing the sponsor/CRO as quickly as possible.

Note: See online IDS SOPs for further information.

Documentation

Documentation for this procedure includes the written procedures for emergency unblinding as well as documentation created as a result of the unblinding.

Version Number: 002	Implementation Date: November 17, 2000
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	Review Date: June 30, 2005
Approval Signature, Date:	

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Deviation Approval

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

Procedure Author

Manager, Research Support Core

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