

Procedure Category:	Clinical Management
Procedure CLM-01-10:	Documentation of Substantive Site Communications

Procedure Overview

To define the standard procedures for documenting substantive site communications (letter, memo, fax, telephone report, e-mail, other electronic communications).

Responsible Individuals

Qualified MICHHR personnel (including, but not limited to, Project Manager and Clinical Study Monitor); Contracted Clinical Research Associates; Director, MICHHR

Procedure

Substantive site communications include, but are not limited to, the following:

- Communications pertaining to adverse events;
- Deviations or modifications of inclusion/exclusion criteria;
- Interpretations of protocol procedures;
- Randomization code breaks;
- Significant study site issues.

Documentation regarding such substantive communications is filed in the Investigator Regulatory File and the UM MICHHR files, and is sent to the appropriate study personnel. If appropriate, the site communication is to be immediately reviewed with the sponsor.

Documentation

A letter, memo, fax, telephone contact report, or e-mail printout serves as documentation for this procedure.

Deviation Approval

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

Procedure Author

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Version Number: 004	Implementation Date: February 11, 2000
Page 1 of 1	Revision Date: October 23, 2002
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Approval Signature, Date:	