

	Standard Operating Procedures
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Procedure Category:	Protocol Review
Procedure CLN-01-03:	Assessing Workload/Staff Requirements

Procedure Overview

This procedure describes the necessary activities performed by the MICHHR to determine the necessary staff and amount of work required for a targeted protocol.

Responsible Individuals

Qualified MICHHR personnel; Investigator; Laboratory Manager; Pharmacy Manager; Director, MICHHR

Procedure

1. MICHHR personnel reviews and records the key elements for all newly submitted protocols and/or case report forms utilizing MICHHR's Budget Spreadsheet, found in Appendix 1.
2. MICHHR personnel uses the Workload Worksheet found in Appendix 2 to create a summary of the workload.
3. MICHHR personnel forwards the protocol, completed Workload Worksheet, Budget Spreadsheet, and related study material to the MICHHR Business Manager for review and approval.
4. MICHHR personnel and the investigator utilize the results in budget and contract negotiations (see SOP CLN-02-02).

Documentation

Documentation for this procedure includes the Workload Worksheet and the Budget Spreadsheet.

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.

Appendices

- Appendix 1 Budget Spreadsheet
- Appendix 2 Workload Worksheet

Version Number: 002	Implementation Date: November 17, 2000
Page 1 of Error! Bookmark not defined.	Revision Date: June 30, 2004
Review Date: June 30, 2005	
Approval Signature, Date:	

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Procedure Author
Manager, Research Support Core

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Page 2 of Error! Bookmark not defined.	Revision Date: June 30, 2004
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