

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-02:	Preparation and Submission of Regulatory Documents

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in preparing and submitting protocol-related documents to the sponsor, CRO, or appropriate regulatory agency.

**Responsible Individuals**

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

**Procedure**

The following tasks are performed by qualified MICHHR personnel:

1. Compile protocol related documents prior to study start up. Such documents may include, but are not limited to:
  - IRB membership roster
  - Two signed original final protocols
  - Two completed and signed original 1572s
  - IRB-approved advertisement, if applicable
  - Two signed original protocol amendment(s), if applicable
  - Two signed original protocol addendum(s), if applicable
  - Two CVs for each staff member listed on the 1572
  - Lab certifications(s) and normal ranges for lab values
  - Two original signature authorization forms
  - Letter from the IRB documenting approval of the protocol and informed consent
2. Submit the study start-up documents to the sponsor or CRO representative during the pre-study visit or study initiation visit. If the documents cannot be hand-delivered, send them to the sponsor or CRO using the study designated courier. Return the customer copy airbill for confirmation and tracking of shipment.
3. Retain one original of all of the documents listed above for filing in the Investigator Study File (ISF).

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Approval Signature, Date:	

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4. Submit any additional documents as requested by the sponsor or CRO. These may include, but are not limited to:
  - Protocol Amendments or Addenda
  - IRB approvals, notifications, and annual approvals
  - Serious adverse experience documents
  - Investigator brochure update notification documents
  - Study close-out forms
  - Signature authorization forms
  - Updated 1572s and corresponding CVs
5. All documents requested should be forwarded within one week of the request unless other arrangements have been made with the sponsor or CRO (i.e. the documents will be provided at the next scheduled monitoring visit).
6. Log the documents submitted on the Administrative Study Checklist; see SOP CLN-02-04.
7. Query study specific operational files at least monthly to verify receipt acknowledgement of submissions and related responses.

### Documentation

Documentation for this procedure includes the documents identified above as well as study correspondence to or from the IRB, the sponsor, or the CRO.

### 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.

### Relevant Definitions

IRB - Institutional Review Board

ISF - Investigator Study File

### Procedure Author

Manager, Research Support Core

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