

Procedure Category:	Clinical Management
Procedure CLM-01-06:	Records of CRA Visits to Investigative Sites

**Procedure Overview**

To define record-keeping requirements for Clinical Research Associate visits to investigative sites.

**Responsible Individuals**

Clinical Research Monitor; Contracted Clinical Research Associates; Director, MICHHR

**Procedure**

Records of visits to investigative sites by CRAs are produced and maintained as agreed to by UM MICHHR Research Support Division (MICHHR/RSC) and the sponsor. The sponsor’s SOPs for reporting monitoring activities are followed if requested by the sponsor. MICHHR/RSC standard visit reports include the following (Federal Register Vol. 60, No. 159, August 17, 1995):

- Date(s) of the visit
- Name of the CRA
- Name and address of the investigator or other individuals visited
- Summary of the findings which describe the investigator's ability to fulfill or actual fulfillment of their obligations
- Summary of the findings sufficient to describe the acceptability of the investigative site facilities
- A statement describing any actions taken by the CRA and/or investigator to remedy any deficiencies noted during the visit

Additionally, the CRA signs the Monitor Visit Log located in the investigator's study file notebook.

**Documentation**

The CRA submits a written report to the sponsor after each site visit or study-related communication. Visits include, but are not limited to, the following:

- Investigator/site qualification visits
- Site initiation visits
- Routine site (monitoring) visits

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- Study close-out visits

The standard report templates for these monitoring visits may be found as appendices to the corresponding SOPs that cover these visits.

### 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.

### Relevant Definitions

CRA - Clinical Research Associate

### Procedure Author

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