

Category:	Study Conduct	Page 1 of 1
Title:	Monitoring of Sites	SOP #: 01. 01.1
Date First Effective:	October 3, 2002	Revision Date:

OBJECTIVE

This standard operating procedure (SOP) describes the responsibilities of the coordinating center for managing and monitoring the participating sites. These procedures apply to all research studies conducted under the direction of the EMNet Coordinating Center.

PROCEDURES

- Project Coordinator
 1. Contact the participating sites once every 2 weeks by email to see how the study is proceeding. Ask about number of patients enrolled and if the site has run into any problems.
 2. Be available to answer any questions regarding the study including but not limited to inclusion/exclusion criteria.
 3. Monitor through email and telephone correspondence the procedures used by the sites to be sure there are no protocol violations.

Category:	Study Conduct	Page 1 of 1
Title:	Adverse Event Monitoring	SOP #: 01. 02.1
Date First Effective: October 3, 2002	Revision Date:	

OBJECTIVE

This standard operating procedure (SOP) describes the responsibilities of the coordinating center for managing, reporting, and documenting adverse events from the time an adverse event is identified until all follow-up activities associated with its resolution have been completed. These procedures apply to all research studies conducted under the direction of the EMNet Coordinating Center.

PROCEDURES

- Project Coordinator
 1. Ensure that all sites are aware of their responsibility to not and report to appropriate study personnel all adverse events reported by the subject or directly observed.
 2. Make sure that all sites contact the coordinating center within 48 hours of a serious adverse event and complete the serious adverse event form.
 3. Contact the sponsor regarding any serious adverse events that are reported.
 4. Make sure that all sites complete the adverse event form for adverse events that are not of a serious nature. The coordinating center does not need to be contacted regarding these adverse events.
 5. Keep track of all serious and non-serious adverse events so that they can be reported to the sponsor at the end of the study.

Category:	Study Closure	Page 1 of 1
Title:	Data Collection	SOP #: 02. 01.1
Date First Effective:	October 3, 2002	Revision Date:

OBJECTIVE

This standard operating procedure (SOP) provides guidelines for accurate and timely data collection by the EMNet Coordinating Center. These procedures apply to all research studies conducted under the direction of the EMNet Coordinating Center.

PROCEDURES

- Project Coordinator
 1. Once the study is over, contact all sites to send in their data forms.
 2. All sites should send in data before the due date listed in the protocol. Sites who do not make this due date will not be paid their stipend.
 3. Remove all materials from packaging.
 4. Initially process forms by confirming that all materials are present and give a total count. Make sure all enrolled patients were eligible for the study using the inclusion/exclusion criteria.
 5. Record in the EMNet database the date of form arrival and the total number of forms.
 6. Place all forms in an interoffice envelope labeling the outside with study name, site number, form type, and envelope number.
 7. Give processed forms to form reviewer.
 8. Email site contact to let them know that the forms have been received and that the form reviewer will contact them with any queries.

Category: Study Closure	Page 1 of 1
Title: Form Review/Query Resolution	SOP #: 02.02.1
Date First Effective: October 3, 2002	Revision Date: October 2004

OBJECTIVE

This standard operating procedure (SOP) provides guidelines for accurate and timely resolution of data clarifications (queries) identified by the EMNet Coordinating Center. These procedures apply to all research studies conducted under the direction of the EMNet Coordinating Center.

PROCEDURES

- Form Reviewer (MD level)
 1. Review all forms received from the sites.
 2. Check for any and all discrepancies.
 3. Flag each page of the form that contains a discrepancy.
 4. Send an email to the site contact informing them of the discrepancies on the forms that they sent. Include all patient identifiers and demographic information so the site contact can access the patient information.
 5. If the site contact does not respond within a week, send another email. If they still do not respond, call them regarding the queries.
 6. When the site responds correct the discrepancy on the form with red ink. Keep all email correspondence with the site regarding queries.
 7. On a case by case basis and with IRB approval, audit a sample of de-identified charts from any participating site.

Category:	Study Closure	Page 1 of 1
Title:	Data Entry/Data Cleaning	SOP #: 02. 03.1
Date First Effective:	October 3, 2002	Revision Date:

OBJECTIVE

This standard operating procedure (SOP) provides guidelines for accurate and timely data entry and cleaning by the EMNet Coordinating Center. These procedures apply to all research studies conducted under the direction of the EMNet Coordinating Center.

PROCEDURES

- Project Coordinator
 1. Once all forms have been reviewed by the form reviewer and all queries are resolved, all forms must be sent to data entry.
 2. All forms should be placed in their original interoffice envelopes.
 3. Forms should then be taken to the data entry company for double data entry.

- Research Assistant
 1. Once all data has been entered and brought back from the data entry company, the excel spreadsheet must be examined for discrepancies that may not have been picked up during form review.
 2. Each variable must be cleaned by determining if all answers are applicable.
 3. Any discrepancies should be flagged in red and the form should be consulted to determine the correct answer.
 4. The site contact should be emailed if the answer on the form is also a discrepancy. Once a response is received, the answer should be changed on the form and in the excel spreadsheet.
 5. Once all variables have been cleaned, then the data is ready to be analyzed.