9. Chapter 9: Data Management Procedures

9.1 General Instructions for Completing Forms

All ENRICHD study data should be recorded on official ENRICHD data collection forms provided by the coordinating center. Data will be recorded by study nurse-coordinators, investigators, therapists, or other trained Clinical Center staff. The study case coordinator should check the forms for accuracy, completeness, and legibility, before mailing to the CSCC for data processing and analysis.

Use **black ball point pen** for completing all interview based forms. The first page of all the self-administered forms will contain both general instructions on completing mark-sense forms, and specific instructions to the participant on how to respond to the questionaire. An administrative area is also on the first page of each booklet or individual form for identification and linkage of the instrument to a particular timepoint (see section 9.5 below). The administrative section should be completed before giving the questionnaire to the patient. Make no erasures and do not use correcting fluid. The optical mark read (OMR) formatted self-administered psychosocial forms should be completed in **#2 pencil**. OMR form corrections can and should be via erasure since the optical scanner and processing software can only correctly score one mark per item. This is an important factor in correctly processing the psychosocial forms, so all self-administered forms should be carefully checked once returned for incomplete erasures, stray marks, skipped items, and items with more than one response indicated.

Print all text responses legibly; do not use cursive writing. Always retain a copy of each form completed either by interview, or self-administered, in the permanent ENRICHD patient file.

Record all times in 24 hour format (also called international time, e.g., 00:00=12 Midnight, 06:00=6AM, 20:00=8PM, etc.).

9.2 Missing Data

Do not leave responses blank on a Form. Unanswered responses embedded in question sequence that was validly skipped because the items were not applicable are permitted. Blank responses are not automatically assumed to be “Unknown” or “No”. Be explicit in the recording and entry of data on the study forms. When information is unavailable and will never be known, place a double horizontal line through the space. For example:

```
Height ========= in.
```

9.3 Permanently Missing Forms

A list of expected forms that have not been received by the CSCC will be generated periodically and sent to the clinical centers. Information necessary for tracing the missing forms will be provided. Included on the expected not received listing will be the patient ID number, the form code, and the visit number for the missing form. When possible, an approximate visit date based on other forms
received for that same patient and visit will be included. Clinic staff are asked to respond promptly regarding the status of the missing form(s).

Locate the copy of the requested form from the patient file, and follow the procedures for re-transmitting a form to the CSCC located in the ENRICHD Data Transfer section of the manual of operations.

If no copies of the form in question can be located but the information on the form can be recovered (from lab reports, medical records, etc.), complete a blank form. The clinic should write "Replacement" in the status field of the missing forms report, and also write "Replacement" on the top of the form. Transmit the replacement form to the CSCC.

If an entire form cannot be located and the information cannot be recovered, write "Permanently missing" in the status report. Complete the header section of a blank form and write "Permanently Missing" across the top of the form. Transmit the missing form to the CSCC.

9.4 Correcting Errors

Corrections should be made in the following manner:

− Cross out the original response with a single line in such a way that it is still legible.
− Write the correct response above or to the side of the original response.
− Date and initial the correct response.

For example:

What is the patient’s Gender?  Male  X  Female __

Do not use white out or erasures at any time.

9.5 Completing the Form Header Fields

Enter the Center ID Number on each participant Form in the administrative use area. A table of the clinical center numbers appears at the end of this chapter for reference. Patient ID Numbers should be transcribed from the ENRICHD Screening ID list provided by the Coordinating Center. The ID numbers will be grouped by hospital within clinical center. The Patient Number consists of the 2 digit hospital identification number followed by the 5 digit patient sequence number, which when combined gives a 7 digit patient ID (see below). The combination of the Center number and the Patient ID together is referred to as the Study ID, and it is this 9 digit form (2 + 7) that the ENRICHD Data Management System (DMS) uses to uniquely identify patients participating in the study. The first patient eligible for the study will be given the first number in sequence from the center specific list supplied by the coordinating center. The second patient eligible will be next
number from that list, etc. For Investigators that have more than one site, each sites should use sequence numbers generated by the CSCC for that site.

ENRICHD

FOLLOW-UP EXAMINATION FORM (FUX, Version A)

Center: □□□ Patient ID: □□□□□□□□□□ Patient Initials: □□□ Visit: □□□

Sequence #: □□□ Date: ___/___/19___ Staff ID#: □□□

Enter the patient initials. If the middle initial is unknown or does not exist, enter the letter "X" in that box. All 3 boxes for the patient initials must be completed. See the detailed instructions for completing each form to assign the appropriate 2 digit visit number. Some Visit numbers will be preprinted or automatically completed by the data entry software (e.g. eligibility or randomization visits). The date field appearing in the header is "today’s date", the date the information was collected or transcribed, not the date keyed. Date formats will always appear in month/day/year order. The final item in the header area is the staff ID#, which will be assigned by the CSCC for each member of the participating clinical center who is authorized to record study information on a paper form or electronic data entry screen. The CSCC must be prospectively informed of any ENRICHD clinical center personnel changes and the need for staff ID# assignment. Valid code numbers for the ENRICHD clinical centers appear below:
<table>
<thead>
<tr>
<th>Clinical Center</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke University Medical Center</td>
<td>01</td>
</tr>
<tr>
<td>Rush-Chicago</td>
<td>02</td>
</tr>
<tr>
<td>Stanford University</td>
<td>03</td>
</tr>
<tr>
<td>University of Alabama, Birmingham</td>
<td>04</td>
</tr>
<tr>
<td>University of Miami</td>
<td>05</td>
</tr>
<tr>
<td>University of Washington, Seattle</td>
<td>06</td>
</tr>
<tr>
<td>Washington University</td>
<td>07</td>
</tr>
<tr>
<td>Yale-Harvard center</td>
<td>08</td>
</tr>
</tbody>
</table>
9.6 ENRICHD Data Transfer Procedures

Patient information will be transferred to the Coordinating Center in 3 different modes during the course of the study. Diskettes containing electronic versions of the data and any changes (transactions) related to processing that data at the central database will be shipped on a biweekly basis and can be included with the transfer of paper forms (see section 3.2 of DMS Users Guide in Appendix for discussion of those procedures). Self-administered psychosocial questionnaires (such as BDI, ESSI, SEM) recorded on optical mark sense paper forms will be batched and shipped for centralized reading and scoring of those data. Event specific end points documentation materials (enzyme lab sheets, discharge summaries, ECGs, etc.) as described in medical measures (see Chapter 5) will also be forwarded to the Coordinating Center for use by the study end points classification committee. Refer to section 5.8 for procedures related to collection and transfer of end points materials.

9.7 Transfer of Forms to the Case Coordinator

9.7.1 Collecting and Batching Completed Form Pages

The Case Coordinator will visit each clinical center at least twice monthly. During that visit, the coordinator will review all the data forms that have been completed since the last clinic visit for completeness and correspondence to the patient's clinical record. The coordinator will collect the original and make a photocopy of each completed, reviewed form. The original copy of the form will be sent to the Collaborative Studies Coordinating Center (CSCC) for processing. A copy of each form will remain at the clinic in the patient form binders for at least two years after conclusion of the study. The set of forms collected from a clinic at a monitoring visit will be referred to as a "batch" of forms.

9.7.2 The Batch Inventory Sheet

For each batch collected, the case coordinator should complete a Batch Inventory Sheet (BIS). The BIS is a form used to document the number and type of forms in a batch. It provides each center with a record of the forms it sent to the Coordinating Center. Finally, the inventory sheet provides the CSCC with a valuable tool to trace forms in its filing and processing system.

Section 1: BATCH IDENTIFICATION

Item 1) Print the two-digit clinic code (see Appendix A).

Item 2) Print the name of the case coordinator who is collecting the copies of the forms.

Item 3) Fill in the month, day and year of the date which the batch was compiled.

Item 4) Print the name of the person at the clinical center who is giving the copies to the case coordinator.
**ENHANCING RECOVERY IN CORONARY HEART DISEASE**

**ENRICHD**

**FORMS BATCH INVENTORY SHEET (BIS)**

**Section 1: Batch Identification**

The original and first copy of the following forms are being transferred from clinic/hospital

☐ ☐ (2-digit clinical center number) to the case coordinator ______________________ on

____/____/19____ by the clinic/hospital representative ___________________________.

mo. day yr.                                                          (NAME)

______________________________

**Section 2: Inventory of Forms**

<table>
<thead>
<tr>
<th>7-digit patient number</th>
<th>Data forms</th>
<th>Clinic form count</th>
<th>CSCC form count</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

TOTAL: _______ _______

COMMENT: (Have you included a data diskette?)  YES  NO  (Please circle.)

**Section 3: Batch Processing History (to be completed by CSCC)**

CSCC Batch Number: ____________ Date Rec’d at CSCC: __ / __ / ____ Rec’d by:

**Section 2: INVENTORY OF FORMS**
Fill out one line of the BIS for each patient included in the batch being sent to the CSCC for data processing.

1) Enter all seven digits of the Patient ID Number in which the first 2 digits are the hospital code number, and the last 5 digits are the sequential patient number (see example below).

2) For the given patient number, note which forms are being transferred. Form codes appear in the upper right center of each page heading.

Only completed forms that have been filled out legibly and checked by the investigator and Case coordinator are to be collected and recorded on the BIS.

3) Finally, for the given Patient Number, enter the number of forms sent in the boxes provided. For example, below is one line of a completed BIS showing forms collected from hospital 1 for patient 24:

<table>
<thead>
<tr>
<th>7-digit patient number</th>
<th>Data forms</th>
<th>Clinic form count</th>
<th>CSCC form count</th>
</tr>
</thead>
<tbody>
<tr>
<td>002400000</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4) After completing as many lines as required, record the total number of forms being shipped with the BIS. This total is obtained by summing the column entitled "Clinic Form Count."

Section 3 BATCH PROCESSING HISTORY

This area is to be used by CSCC. DO NOT complete this section, leave blank.

9.7.3 Preparing the Batch

The batch should always begin with its corresponding BIS. At the clinic, the case coordinator should place the original BIS on top of the original forms, and place the first copy of the BIS on top of the corresponding photocopies of forms. Do not staple forms together. The forms should be ordered by Patient Number and then by Form type as they appear on the BIS. The direct correspondence between the inventory sheet and the collection of forms facilitates processing and confirmation by the CSCC that the data transfer is complete.

Each batch of forms and the corresponding cover BIS should be joined together by a paper clip, rubber band or placed in a manila envelope. No two batches should be joined together to avoid introducing any potential processing errors with inventory of the batch.
9.7.4 Disposition of copies

The original BIS will be mailed to the CSCC and one photocopy will be retained by the case coordinator with the copies of corresponding data forms. A second copy of the BIS should be filed in the clinical center site for future reference.

9.8 Transfer of Forms to the CSCC

9.8.1 Shipping the Batches to the CSCC

The batches collected during case coordinator visits should be sent to the CSCC as soon as possible and at least twice per month. Batches should be sent by an express package delivery service (e.g. Airborne Express, Federal Express, United Parcel Service, U.S. Postal Service next day delivery). More than one batch may be sent in one envelope. However, each batch should be separate from the other batches within the envelope because each batch is checked and inventoried as a unique collection of data forms for tracking and processing.

Each mailing should contain the following items together in one envelope: (1) the batched group of forms; (2) the corresponding BIS; and (3) any letters or notes about these batches that would explain any discrepancies and relate to the processing of the batch.

Mailing envelopes with data forms should contain only the items mentioned above. Extraneous materials such as letters to investigators or research staff at the CSCC should be sent under separate cover. It is permissible to include data transfer diskettes with paper forms; however, please note the inclusion in the comments area of the BIS.

All batch data mailings should be addressed to:

ENRICHD Central Receiving  
Collaborative Studies Coordinating Center  
University of North Carolina  
137 East Franklin Street, Suite 203  
Chapel Hill, North Carolina  27514-4145

9.8.2 Acknowledgment of receipt of batches

Once a month the CSCC will fax to the Case Coordinator an acknowledgment of batches received by the CSCC. This correspondence will contain identifying information for each batch received since the previous acknowledgment. If this acknowledgment is not received within 3 weeks of the shipment of a batch, the Case Coordinator should contact the CSCC to investigate why confirmation for the batch shipment is overdue.

9.9 Questionable Data Queries

The majority of missing, illegible, and incorrect data values are expected to be discovered and corrected by the clinic staff and the Case Coordinator during their review of the completed ENRICHD data forms prior to their collection. These corrections are made on the original forms
(see General Instructions for Completing Forms section elsewhere in the operations manual for details on how to correct an entry).

After the original forms have been transferred to the CSCC, further problems may be discovered by the Case Coordinator or the clinic staff. In addition, when the data are processed at the CSCC, the editing software will identify missing, extreme, and inconsistent values. In these cases, a Query Log Report (QLR) is used to identify the suspect value, and to document the resolution of the issue.

For problems discovered manually, blank Questionable Data (QDA) forms are provided for use by Case Coordinator and CSCC staff as appropriate.

No matter who discovers the questionable data, only clinical center staff are authorized to determine the appropriate resolution.

The QDAs and QLRs have a separate batch inventory form that should be completed and submitted with each batch of query forms.

**9.9.1 Completing the Manual Questionable Data Form**

The person identifying the questionable value completes the header section of the QDA form, and section 1 (Identification of Value to be Corrected). The clinic staff member who determines the appropriate resolution (correction, confirmation, etc.) completes Section 2 (Problem Resolution).

**9.9.1.1 Form Header Information**

Enter the Patient Number of the patient whose data are in question. Enter the date that this Questionable Data Form is being initiated.

**9.9.1.2 Identifying Information (items 1-7)**

This section of the form should be completed by the person detecting a problem with a data value on a form already collected from the investigator or center staff member. The patient's forms binder should be checked to confirm that a Questionable Data Form has not already been generated for this problem. All items should be completed to insure a proper resolution.

Items 1-3: Enter the Form type and date from the original data form containing the item being questioned.

Item 4: Enter the item number and a brief description of the item to be investigated.

Item 5: Enter a brief description of the problem.

Item 6: Enter the name of the person detecting the problem.

Item 7: Enter the current value of the item to be investigated.
ENHANCING RECOVERY IN CORONARY HEART DISEASE (ENRICHD)

QUESTIONABLE DATA FORM (QDA)

Code#:  

Patient ID#:  

Section 1: Identification of Value to be Corrected

1. Form Code:  

2. Visit Number:  
   Sequence Number:  

3. Form Date:  
   mo.  da.  yr.  

4. Item Number:  
   Description of Item:  

5. Description of problem:  

6. Name of Person Detecting Problem:  

7. Current Value of Item:  

Section 2: Problem Resolution

8. CORRECT Value of Item:  
   (Note: The Correct value must fit into the space allocated in the original question)

9. Comments:  

10. Name of Person Providing Correction:  

11. Date of Correction:  
   mo.  da.  yr.  

9-10
9.9.1.3 Problem Resolution (items 8-11)

This section should be completed by the person providing the corrected value. This must be a
member of the staff at the clinical center where the original data collection form was completed.

Item 8: If the current value is determined to be incorrect, enter the corrected value for the item.

If the current value is missing, enter the value if available from the subject chart. If the value is unavailable, enter the word "missing."

If the current value is confirmed to be correct, enter the word "correct."

Item 9: Enter explanation, justification, etc. if appropriate.

Item 10: Enter the name of the person responsible for resolving the question. This must be a
member of the staff at the clinical center where the original data collection form was completed.

Item 11: Enter the date the Problem Resolution section of the form was completed.

9.9.1.4 Updating the original Form

After completing the Questionable Data Form, the investigator's copy of the original form page
should be updated as appropriate. The investigator or their designate must initial and date all
changes made to Forms.

9.9.1.5 Handling the Completed Questionable Data form

All three copies of the Questionable Data Form should be stored in the patient's file. The Case
Coordinator will collect the first two copies of the form at the next visit. The third copy is retained
permanently in the patient's ENRICHD file.

9.9.2 Completing the Computer Generated Questionable Log Report

The header section of the QLR form, and section 1 (Identification of Value to be Corrected) are
generated from the records processed by the CSCC. The clinic staff member who determines the
appropriate resolution (correction, confirmation, etc.) completes only Section 2 (Problem
Resolution).

9.9.2.1 The Data Query Form Checklist

When the CSCC generates a set of QLRs from a batch of forms that have been processed and
edited, a summary of the items flagged in question will be listed. This list contains the patient
number, form, and item for each data QLR generated. There is also a check box for the person
completing the QLR to use in tracing the completion of query logs. This checklist is for internal use
by the Case Coordinator and clinical center and does not have to be returned to the CSCC.
ENRICHD Questionable Log Report (QLR) Checklist

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Form &amp; Check</th>
<th>Item#</th>
<th>Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>0101401</td>
<td>MHA</td>
<td>3</td>
<td>[]</td>
</tr>
<tr>
<td></td>
<td>BDI</td>
<td>6</td>
<td>[]</td>
</tr>
<tr>
<td>0101502</td>
<td>PSS</td>
<td>3</td>
<td>[]</td>
</tr>
<tr>
<td></td>
<td>BDI</td>
<td>4</td>
<td>[]</td>
</tr>
<tr>
<td>0101603</td>
<td>MEA</td>
<td>4</td>
<td>[]</td>
</tr>
<tr>
<td>0101707</td>
<td>ESS</td>
<td>5</td>
<td>[]</td>
</tr>
<tr>
<td></td>
<td>BDI</td>
<td>6</td>
<td>[]</td>
</tr>
<tr>
<td>0101809</td>
<td>BEA</td>
<td>3</td>
<td>[]</td>
</tr>
<tr>
<td></td>
<td>MHA</td>
<td>4</td>
<td>[]</td>
</tr>
</tbody>
</table>
9.9.2.2 Form Header Information

The patient number of the patient whose data are in question and the date that the QLR was initiated are pre-entered.

9.9.2.3 Identifying Information (items 1-7)

This section of the form is generated from records processed by the CSCC in which a problem is detected with a data value on a form already collected from the investigator. The patient's file should be checked to confirm that a previous QDA or QLR has not already been generated for this problem. The original batch identification number is provided to assist the tracing of the data form in question.

Items 1-2: The form type and form date from the original data form containing the item being questioned.

Items 3-4: The item number and its current value to be investigated.

Item 5: A brief description of the problem.

9.9.2.4 Problem Resolution (items 6-9)

This section should be completed by the person providing the corrected value. This must be a member of the staff at the clinical center where the original data collection form was completed.

Item 6: If the current value is determined to be incorrect, enter the corrected value for the item.

If the current value is missing, enter the value if available from the patient's chart. If the value is unavailable, enter the word "missing."

If the current value is confirmed to be correct, enter the word "correct."

Item 7: Enter the name of the person responsible for resolving the question. This must be a member of the staff at the clinical center where the original data collection form was completed.

Item 8: Enter explanation, justification, etc. if appropriate.

Item 9: Leave blank, the CSCC will complete this item when the returned QLR is processed.
ENRICHD Manual of Operations, Chapter 9:  Data Management Procedures

ENRICHD DMS Questionable Log Report Page 1

07/14/96 All Records for Patient

Section 1: Identification of Value to be Corrected

1. Patient Number: 0200105 Form: BDI Version: A Visit: 01
2. Date of log: 07/16/96 FormSeq#: 00 Line#:000
3. Field: BDIA002
4. Value: 7
5. Description of Problem: Out of edit range

Section 2: Problem Resolution

6. Correct Value of Item: ______________
7. Reviewer Initials: _____ Review Date: ______________
8. Comments: _______________________________________________________

Section 1: Identification of Value to be Corrected

1. Patient Number: 0201011 Form: MHA Version: A Visit: 01
2. Date of log: 07/16/96 FormSeq#: 00 Line#:000
3. Field: MHAA06D
4. Value: 60
5. Description of Problem: Out of edit range

Section 2: Problem Resolution

6. Correct Value of Item: ______________

9-14
7. Reviewer Initials: ______  Review Date: ______________

8. Comments:____________________________________________________________________
____________________________________________________________________

9. Data Entry Operator initials: ______ Date Corrected in DMS: ______

===============================================================================

9.9.2.5 Updating the Original Form

After completing the Questionable Data Form, the clinical center copy of the original data form
should be updated as appropriate. The investigator or their designate must initial and date all
changes made to data forms.

9.9.2.6 Handling the Completed Data Query Form

All three copies of the Questionable Data Form should be stored in the subject's file. The Case
Coordinator will collect the first two copies of the form at the next data collection visit. The third
copy is retained permanently in the patient's forms file.

9.9.3 Transfer of Forms to the Case Coordinator

9.9.3.1 Collecting and Batching Completed QDA and QLR Forms

The Case Coordinator will visit the clinical center at least twice monthly. During those visits, the
case coordinator will review all the QDA and QLR forms that have been completed since the last
clinic visit for completeness and correspondence to the patient's clinical record. The case
coordinator will collect the original of each completed, reviewed form. The copy of each form will
remain at the clinic in the case binders for at least two years after completion of the study. The set
of forms collected from a clinic at a will be referred to as a "batch" of forms.

9.9.3.2 The Query Inventory Sheet (QIS)

The Questionable Data Forms (QDA) and the Questionable Log Reports (QLR) should be batched
separately from the regular data forms. For each batch collected, the case coordinator should
complete a QDA & QLR Query Inventory Sheet (QIS). The QIS is a form used to document the
number of QDAs and QLRs in a batch. The QIS provides the clinic with a receipt for the queries
already forwarded to the CSCC. It also an indirect record of the forms it sent to CSCC. Finally, it
provides the CSCC with a valuable tool to trace queries in its filing and processing system.

Section 1: BATCH IDENTIFICATION

Item 1) Print the two-digit clinic code, listed in the Appendix.
Item 2) Print the name of the Case Coordinator who is collecting the copies of the forms.

Item 3) Fill in the month, day and year of the administrative visit at which the batch was collected.

Item 4) Print the name of the person at the clinical center who is giving the copies to the Case Coordinator.

Section 2: INVENTORY OF QDA AND QLR FORMS

Item A) Fill in the number of QDA forms included in this batch.

Item B) Complete the page count of the QLRs included in the batch.

Section 3: BATCH PROCESSING HISTORY

This area is to be used by CSCC. DO NOT complete this section; leave it blank.

9.9.3.3 Preparing the Batch

The batch should always begin with its corresponding Query Inventory Sheet (QIS). At the clinic, the Case coordinator should place the original QIS on top of the original QDA and QLR forms, and place the first copy of the QIS on top of the corresponding first copies of QDA and QLRs. Do not staple forms together. The QDAs should be ordered by patient number. The QLRs should also be ordered by patient numbers as they appear on the batch inventory sheet (QIS).

Each batch of QDAs and QLRs and the corresponding covering QIS should be joined together by a paper clip, rubber band or placed in a manila envelope. No two batches should be joined together.

9.9.3.4 Disposition of Copies

The original QIS will be mailed to the CSCC and the first copy will be retained by the Case Coordinator with the copies of corresponding forms. The second copy of the QIS should be filed in the clinical center for future reference.
ENHANCING RECOVERY IN CORONARY HEART DISEASE (ENRICHD)
QDA & QLR BATCH QUERY INVENTORY SHEET (QIS)

Section 1: Batch Identification

The original copy of the following QDA and QLR forms are being transferred to the

Case Coordinator ______________________ on ____/____/19____
(NAME)                          mo.    da.         yr.

by the Clinic representative ______________________
(NAME)
-----------------------------------------------------------------------------------

Section 2: Inventory of QDA and QLR Forms

A. Questionable Data Forms (QDA) Clinic page count       CSCC page count

B. Questionable Logs (QLR)

-----------------------------------------------------------------------------------

Section 3: Batch Processing History (To Be Completed by CSCC):

CSCC Batch Number: _____________

Date received at CSCC: ____/____/19____
mo.    da.         yr.

Received by: ______________________
9.9.4 Transfer of QDAs and QLRs to the CSCC

9.9.4.1 Shipping the Batches

The batches collected during case coordinator visits should be sent to the CSCC as soon as possible. Batches should be sent by an express package delivery service. More than one batch may be sent in one envelope. However, each batch should be separate from the other batches within the envelope. Shipments may include batches of data queries as well as Forms.

Each mailing should contain the following items together in one envelope: (1) The batches; (2) the corresponding QIS; and (3) any letters or notes about these batches.

All batch data mailings should be addressed to:

ENRICHD Central Receiving
Collaborative Studies Coordinating Center
University of North Carolina
137 East Franklin Street, Suite 203
Chapel Hill, North Carolina  27514-4145

9.9.4.2 Acknowledgment of Receipt of Batches

Twice a month the CSCC will fax to the Case Coordinator an acknowledgment of batches received by the CSCC. This correspondence will contain identifying information for each batch received since the previous acknowledgment. If this acknowledgment is not received within 3 weeks of the shipment of a batch, the Case Coordinator should contact the CSCC to investigate why the query data transfer batch was not confirmed on time.

9.10 Problem Clarification Requests

A Problem Clarification Request is used to document and resolve issues which are not related to specific data fields on the case report forms. For example, if duplicate forms are received, a Problem Clarification Request would be completed at the CSCC asking for verification of the correct form.

9.10.1 Completing the Problem Clarification Request

The Case Coordinator should research the problem with the investigator or his/her designate, and print the response to the question in the section of the form labeled THE SOLUTION. Enter the date the problem was resolved and the name of the person who resolved the problem in the corresponding spaces.

9.10.2 Disposition of copies

The original Request (top page) should be addressed to:
The copy of the Problem Clarification Request should be maintained by the Case Coordinator. When applicable, a photocopy should be stored in the patient's forms binder.
ENHANCING RECOVERY IN CORONARY HEART DISEASE  
(ENRICHD)  

PROBLEM CLARIFICATION REQUEST

TO:

-------------------------------------------------------------------

THE PROBLEM:

Date Detected: ___/___/19___  Detected By: ___________________________

Mo  Da  Yr

Problem Location and Description:

-------------------------------------------------------------------

THE SOLUTION:

Date Resolved: ___/___/19___  Resolved By: ___________________________

Mo  Da  Yr

Solution (Please print a response to the problem described above. Use the back of this paper, if necessary):

Please return the completed clarification request to:
ENRICHD Central Receiving
Collaborative Studies Coordinating Center
Suite 203, NCNB Plaza
137 East Franklin Street
Chapel Hill, NC  27514-414
APPENDIX A.

Table of Clinical Center Code Numbers

<table>
<thead>
<tr>
<th>Clinical Center</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke University Medical Center</td>
<td>01</td>
</tr>
<tr>
<td>Rush- St. Luke's Medical Center</td>
<td>02</td>
</tr>
<tr>
<td>Stanford University</td>
<td>03</td>
</tr>
<tr>
<td>University of Alabama, Birmingham</td>
<td>04</td>
</tr>
<tr>
<td>University of Miami</td>
<td>05</td>
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<td>University of Washington, Seattle</td>
<td>06</td>
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<tr>
<td>Washington University</td>
<td>07</td>
</tr>
<tr>
<td>Yale-Harvard</td>
<td>08</td>
</tr>
</tbody>
</table>