NATIONAL INSTITUTE OF HEALTH (NIH) COLLABORATIVE STUDIES:

RESOURCES FOR ENHANCING ALZHEIMER'S CAREGIVER HEALTH

Reach

Resources For Enhancing Alzheimer's Caregiver Health

Data Management Manual

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REACH Data Management Manual

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REACH II Overview

REACH II Overview

Resources for Enhancing Alzheimer's Caregiver Health (REACH II) was funded in 2001 to design and test a single multi-component intervention among family caregivers of persons with Alzheimer's Disease or related disorders. Built upon the findings of REACH I, the overall objectives of REACH II are to 1) identify and reduce modifiable risk factors among diverse family caregivers of patients with Alzheimer's Disease or a related disorder, 2) enhance the quality of care of the care recipients, and 3) enhance the well-being of the caregivers.

The Coordinating Center will facilitate coordination and cooperation across the five intervention sites. Along with ensuring the successful administration of cooperative activities, the Coordinating Center will develop and maintain a common database from measures collected across the sites. To manage this data the PoP Software System will be employed. Each site will enter the study forms using the PoP data entry system. Interactive data type verification and range checks will be employed through PoP to help prevent entry errors. Data are then verified using double-entry and discrepancies are resolved. Edits will be run on each of the clinical site microcomputers using PoP for intra-form logic and consistency verification. Data that have passed edits at the intervention sites will then be electronically transmitted to the Coordinating Center.

Chapter 2

PoP Overview

The PoP Software System (PoP) is designed to address issues related to data collection in multi-centered clinical trials. The objective of PoP is to provide investigators with secure, accurate, and consistent data. With PoP, a form developer is able to design a system that will yield clean data within a well-formed protocol.

PoP is composed of two interdependent systems: a development system and a data entry system. The development system operates within PoP to allow for customization of a data entry system for use in a research study or a clinical trial. The PoP data entry system is a multi-purpose, screen oriented, menu driven system designed for multi-site research studies and clinical trials. The Data Entry cycle includes the entry of data collected on paper forms; the verification of this data through a double entry process; an edit function that runs the data through defined checks; and error correction modules.

Chapter 3

About the Microcomputer

Unpacking the Computer System

The components of the computer system will be shipped in 4 separate boxes. One box will contain the *Gateway PC*. Another box will contain the *Color Monitor.* Another box will contain the Ancillary Equipment. The last box will contain the *hpdeskjet 940c Printer*.

Checklist

A checklist will be placed inside each box that lists all components and parts that should be contained within. Once a box is opened, the checklist should be immediately visible. Please remove the checklist and fill in the check boxes as you unpack each item. If for some reason a checklist has not been enclosed, please refer to Appendix F where you will find a copy of all 4 checklists.

If you have reached the end of the checklist and some items have not been checked, please circle the appropriate site at the bottom of the checklist. Please fax this form to the Coordinating Center and the unchecked component/part will be shipped out to your site immediately.

Computer System Installation

Once you have verified that all equipment has been correctly shipped and you have placed the equipment in its desired location, you may begin the installation.

The installation of the REACH computer system is relatively easy. However, it is important to perform the following steps in the listed order. Refer to the illustration above for help.

Step #1. ***Place the AMERICAN POWER CENTER/UNIVERSAL POWER SUPPLY (APC/UPS) in the desired location.***

Step #2. ***Place the Gateway CPU in the desired location close to the APC/UPS.***

Step #3. ***Insert the KEYBOARD cable (purple plug) into the port with the purple label around it on the back of the CPU.***

Step #4 ***Insert the MOUSE CABLE into (green plug) the port beside the keyboard cable into the back of the CPU.***

Step #5 ***Insert the MONITOR CABLE (blue plug) into the port with the etched inscription "TV-OUT" next to it on the back of the CPU.***

Step #6 ***Insert the 5 FOOT Phone Cable into the CPU and the APS/UPS. Insert the end of the phone cable into the phone port labeled "modem" (GREEN LABEL) in the back of the CPU. Insert the end of the phone cable into the "Modem Port" on the back of the APS/UPS.***

Step #7 ***Plug the end of the 25 FOOT PHONE cable into the APS/UPS and the phone wall jack. Insert the end of the phone cable into the "wall outlet" on the back of the APS/UPS. Insert the other end of the phone into the phone wall jack on the wall.***

Step #8 ***Insert the end of the WHITE cable into the back of the monitor. Insert the other end of the WHITE cable into the APS/UPS.***

step #9 ***Insert the end of the BLACK cable into the back of the CPU. Insert the other end of the BLACK cable to the APS/UPS.***

Step #10 ***Connect the HPDESKJET 940. The printer power cable should be connected to the APS/UPS to the port below the keyboard port.***

However, if the printer power cable is not long enough to reach the APS/UPS it may be connected to a power strip or wall outlet. Connect the printer cable to the maroon port on the back of the CPU.

Step #11 ***Insert one end or the white MODEM cable into the white modem parell port. Insert the other end of the cable into the serial port of the CPU. Plug the modem into the APS/UPS.***

Step #12 ***Insert the APS/UPS power cord into a power strip or wall outlet.***

Step #13 ***Press the "On/Off" switch on the APS/UPS to power-up.***

Step #14 ***Turn on power switches to all individual pieces of equipment (i.e., CPU, monitor, and printer).***

You have completed the installation of the REACH computer system.

Equipment Description

The REACH II computer configuration consists of many system components. A brief description is provided to answer commonly asked questions.

Gateway 700S Value Enhanced Processor - Tower Case

The Gateway Processor (1.8 GHz) was selected to provide sufficient processing power for the PoP Data Entry System and other software currently used for this project. Additionally, it provides adequate processing power for possible future system enhancements that may occur during the life of the project.

17" DiamondTron Monitor

The Diamondtron was selected as a suitable size for performing data entry procedures. This particular monitor has proven to be reliable and durable over an extended period of time.

Hewlett-Packard DeskJet 940C Printer

A Hewlett Packard DeskJet 940c Printer has been selected to provide dedicated print capability for generating PoP and data management reports.

APS/UPS Electronic Power Center

The Electronic Power Center device provides several important services for this project. 1) It protects the computer equipment against power line irregularities such as brownouts, dropouts, and surges. 2) Also, it protects the telecommunications line from destructive transient voltage surges. 3) It provides the unattended remote access capability to each clinical center microcomputer.

Keyboard Extension Cable

A keyboard extension cable is provided to allow greater distance between the keyboard and the processor. Only use this cable if necessary.

Monitor Extension Cable

A monitor extension cable is provided to allow greater distance between the monitor and the processor. Only use this cable if necessary. Use of this cable may cause information on the monitor screen to appear blurred.

Phone Cable (25 feet in length)

A 25 foot cable has been provided to allow that distance between the APS/UPS and the phone connection wall plate.

Phone Cable (5 feet in length)

A 5 foot cable has been provided to allow that distance between the APS/UPS and the modem connection on the back of the Processor.

Zip Disks

Zip Disks necessary for the PoP Backup Procedure will be purchased at each clinical center. An additional disks has been provided for use with the PoP Backup Procedure only if other tapes have become damaged.

Zip Disk Labels

2 Sets of Tape Labels (4 total) are provided with each computer system. The second set of labels will be used for new tapes replacing old ones if they become damaged.

Computer System Boot Procedure

"BI-Boot" Procedure

A "BI-Boot" menu has been configured to protect the integrity of the REACH II data as well as permit the computer system to perform several independent functions.

A. Windows XP

The Windows XP Selection is used to access two primary applications - PoP and PCAnywhere. This selection the drivers necessary for these two applications to function properly. This safeguard will ensure that the Data Entry System and related files will be free from any unknown or undocumented causes of corruption.

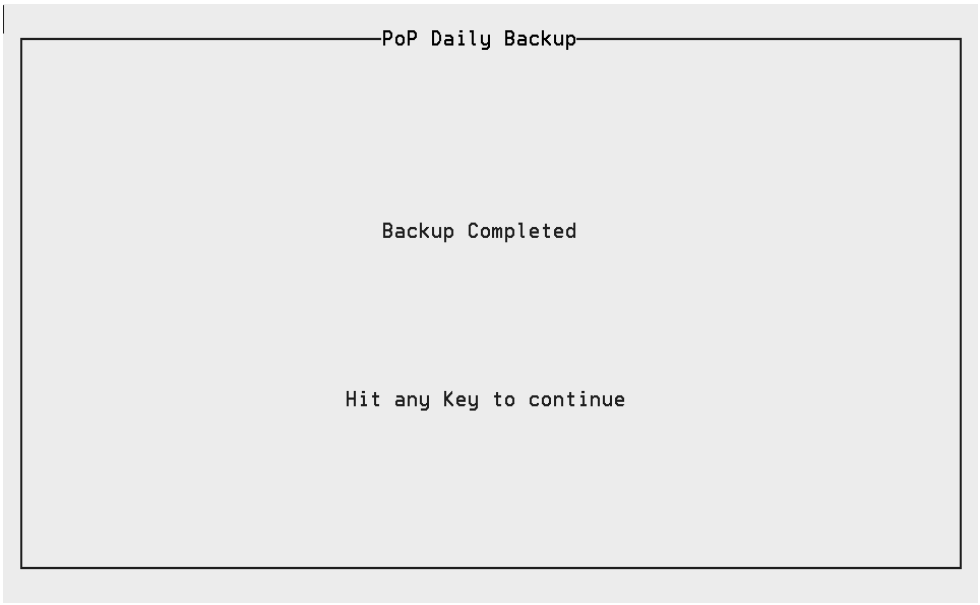
Please Note: **DO NOT START PoP FROM DOS**. All necessary Windows drivers will not be loaded and as a result Windows software may not function properly.

Automated Backup Procedure (PoPBACK)

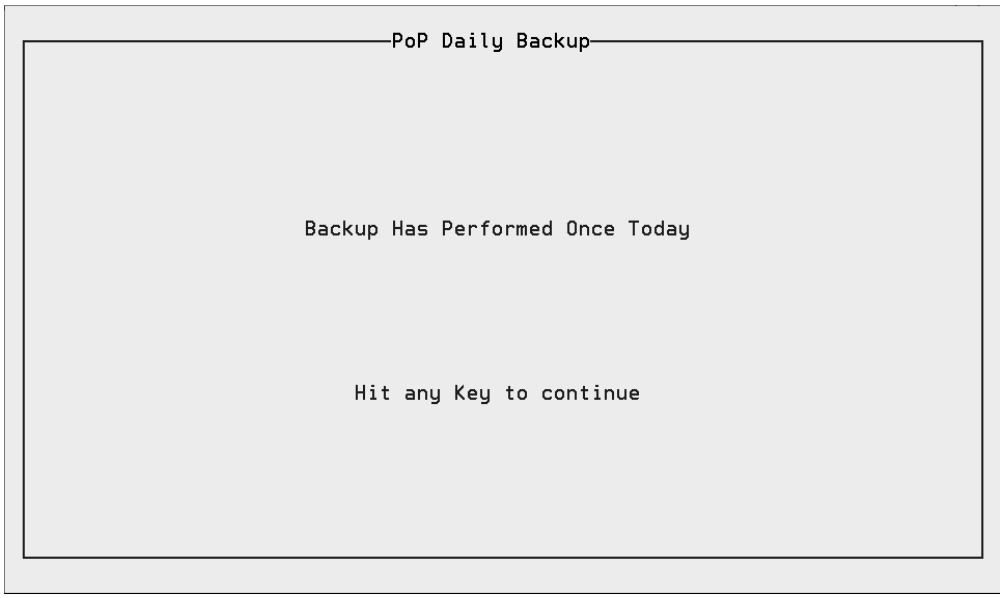
Backups are enforced only through the *PoP Data Entry* selection. Each time *PoP Data Entry* is selected, the automated backup procedure will be executed. However, PoPBACK will only copy PoP files to tape the first time *PoP Data Entry* is selected each day. A PoP Daily Backup screen appears with instructions regarding the backup procedure.

In addition a screen will appear indicating that the backup procedure has completed successfully. However, if the zip disk has stopped and it appears that the backup procedure is halted for more than 10 minutes AND the following screen has not appeared, please contact the Data Coordinating Center for assistance. If possible, please leave the information on the screen (or copy it to paper) so that it may be relayed to the Data Manager assisting you.

Please Note: Do not perform any data entry until the backup problem has been resolved. However, you may reboot the computer into the Windows environment by pressing Ctrl-Alt-Del.



If subsequent backups are required on the same day, then a “manual” backup may be executed through the PoP Main Menu. It is good practice to perform a manual backup after a large amount of data has been entered. To initiate a manual backup following a data entry session select the System environment in PoP and then select “Daily Backup.” You will be prompted for the appropriate diskset and disk to insert into the zip drive.



Zip Disks

The backup procedure uses two disksets (labeled Diskset1 and Diskset 2) to accomplish the PoP monthly and daily backup and archive processes. Typically,

a diskset consists of 2 disks for a total requirement of 4 Zip disks to accomplish the full and daily archive process. However, the number of disks required per diskset may vary depending on the number of forms and the size of the PoP data files. The backup procedure is designed to provide at least one full month of backups in reserve.

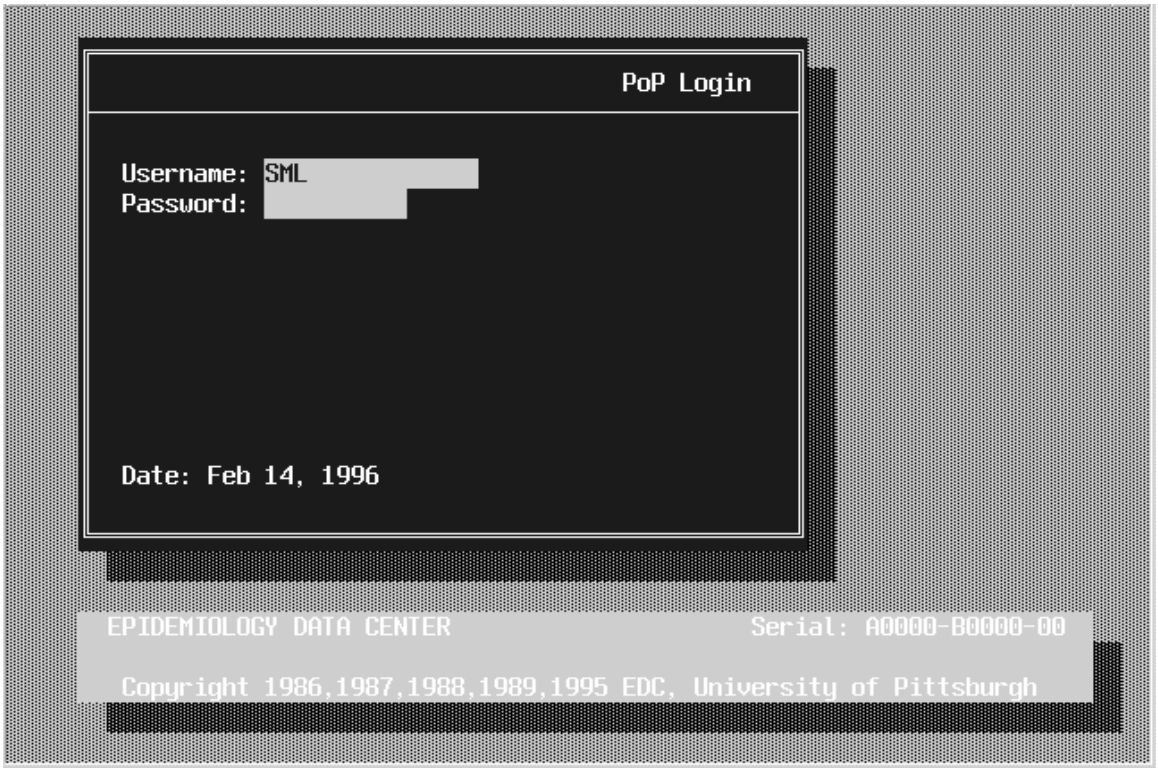
The backup reserve is achieved through a diskset rotation. Diskset rotation occurs when a new month or year is encountered. For example, in January Diskset 1 may be used. In February Diskset 2 will be requested for use. In March of the same year Diskset 1 will be requested again. Diskset 1, at this time, will be initialized (erased) and reused again.

On a daily basis, a user is prompted to insert the disk that is labeled with a specific diskset and disk number. **NOTE:** *When a disk's capacity is exceeded, the user is asked to insert a new disk (within the current diskset). At the beginning of each month (or a new year), a user is prompted for a new diskset*.

Whenever a new disk is inserted, the backup procedure initializes (erases) the disk and the user will see the message "Initializing Media….". **WARNING:** Inserting a disk other than the one indicated will result in the loss of archived data and could affect the recovery process. This version of the backup procedure does NOT verify the physical disk label. It is the sole responsibility of the PoP software user to ensure that the correct disk has been inserted.

PoP Startup Login

After the PoPBACK procedure has completed, the PoP Login screen will appear.



1. Type your Username and press *Enter*.

2. Type your Password and press *Enter* (the password is not visible).

3. If the Login procedure is incorrect, the message *"Login Incorrect"* appears. PoP allows three attempts to login correctly before exiting to DOS.

4. If the Login procedure is correct, the Main Menu (see Chapter 5) appears and PoP is ready for use.

B. Hyperpop

Hyperpop is telecommunications software for multi-site data transfer. Site information such as site name, site number, and modem phone number are stored in this system. One key feature of HyperPoP is the ability for unattended "overnight" communication and unattended data transfer at a designated time.

By employing HyperPoP, the Data Coordinating Center computer calls the site computer. The site computer, being in the "Power-Down" position, will "wake-up" and run an ancillary program to HyperPoP. The program will "answer" the call, hang-up, and then call the Coordinating Center back. At this time, various actions can occur, such as file copying and data transfer.

Note: As described earlier under BI-Boot procedure:

HyperPoP menu selection is the default boot option for the REACH II computer. When the BI-Boot Menu appears on the screen and the warning beep occurs, the user has 4 seconds to Hyperpop or Windows XP boot options, otherwise the computer automatically boots into the HyperPoP "waiting for a call" mode. To select the Pop or Windows XP boot option, use the *up arrow* and *down arrow* keys to highlight the desired boot option and press e*nter*.

Other than for its intended telecommunications procedure, there is no reason to select the HyperPoP boot option. If the computer has booted into this selection inadvertently, the computer prompt eventually will read "C:\HA5>". At this point, simply press the *Ctrl Alt Del* keys simultaneously to return to the computer system BI-Boot Menu.

NOTE: DO NOT START THE PoP SOFTWARE or WINDOWS XP from *Hyperpop*. All necessary PoP and Windows XP drivers may have not been loaded and as a result the systems may not function properly. If you want to load PoP or Windows XP, boot the computer by pressing Ctrl Alt Del keys simultaneously and then select PoP or Windows XP from the Tri-Boot menu.

Chapter 4

Data Forms

The REACH II clinical trial will employ many different forms to collect information on the study subjects. These forms, when combined together, will comprise an interview battery. For the REACH II study, the interview batteries are considered "core" data collection tools and have been tailored to specific interview time points. For REACH II, there is a Core Baseline and Follow-up battery. Additionally, there will be a need for transition batteries if care recipients become placed into an institution or are deceased prior to the follow-up anniversary date. Lastly, if participants elect to drop out of the study prior to the follow-up anniversary date, a discontinuation battery has been developed to meet this event.

All of the batteries have some identical features. For example, every battery requires the REACH II ID, which uniquely identifies every REACH II participant. In addition, the date of the interview, along with the interviewer's name and certification number, are include on the forms. Along with the core interview batteries, REACH II has incorporated data management forms and evaluation forms. Below is a list of forms for the REACH II project.

Core Forms

The Core Forms are used to collect information during scheduled events (interviews) and at screening. Each form is identified by a 2 letter form code.

SCREENING BATTERY

FORM NAME	FORM CODE
Screening	SC
SPMSQ	SP

BASELINE BATTERY

FORM NAME	FORM CODE
Mini-Mental State Examination	MM
Personal Appearance	PA
CG/CR Sociodemographic Information	SO
ADL/IADL	AD
Vigilance	VG
Revised Memory And Behavior Checklist	MB
Burden Inventory	BI
Formal Care And Services	FC
Positive Aspects Of Caregiving	PC
Desire to Institutionalize	DI
Caregiver Health And Health Behaviors	CH
CES-D	SD
Social Support	SS
Religiosity/Spiritual Coping	RG
Social Activities	SA
Quality of Care	QC
Risk Appraisal	RA
Caregiver Medications	GM
Care Recipient Medications	RM

FOLLOW-UP BATTERY

FORM NAME	FORM CODE
Mini-Mental State Examination	MM
Personal Appearance	PA
Follow-up Sociodemographic Information	FS
ADL/IADL	AD
Vigilance	VG
Revised Memory And Behavior Checklist	MB
Burden Inventory	BI
Formal Care And Services	FC
Positive Aspects Of Caregiving	PC
Desire to Institutionalize	DI
Caregiver Health And Health Behaviors	CH
CES-D	SD
Social Support	SS
Transition Religious/Spiritual Coping	TR
Social Activities	SA
Quality of Care	QC
Risk Appraisal	RA
Caregiver Medications	GM
Care Recipient Medications	RM
Project Evaluation	PE

BEREAVEMENT BATTERY

FORM NAME	FORM CODE
Bereavement Sociodemographic Information	BS
Transition Formal Care And Services	TF
Caregiver Health And Health Behaviors	CH
CES-D	SD
Transition Social Support	TS
Transition Religious/Spiritual Coping	TR
Social Activities	SA
Bereavement	BF
Bereavement Risk Appraisal	BA
Caregiver Medications	GM
Project Evaluation	PE

PLACEMENT BATTERY

FORM NAME	FORM CODE
Placement Sociodemographic Information	PS
Placement RMBPC	PR
Placement Burden Inventory	PB
Transition Formal Care And Services	TF
Caregiver Health And Health Behaviors	CH
CES-D	SD
Social Support	SS
Transition Religious/Spiritual Coping	TR
Social Activities	SA
Placement	PL
Placement Risk Appraisal	PR
Caregiver Medications	GM
Project Evaluation	PE

DISCONTINUED BATTERY

FORM NAME	FORM CODE
Transition RMBPC	TM
Transition Burden Interview	TB
Preventative Health	PH
CES-D	SD
Transition Social Support	TS

Data Management Forms

The Data Management Forms include forms used during interviews to collect information of unscheduled events and data management bookkeeping.

FORM NAME	**FORM CODE**
Off-Protocol	OP
Care Recipient Tracking	RT
Participant Information*	PI

**Not collected by the Coordinating Center*

Evaluation Forms

The Evaluation Forms include forms used to evaluate certain segments of the REACH project.

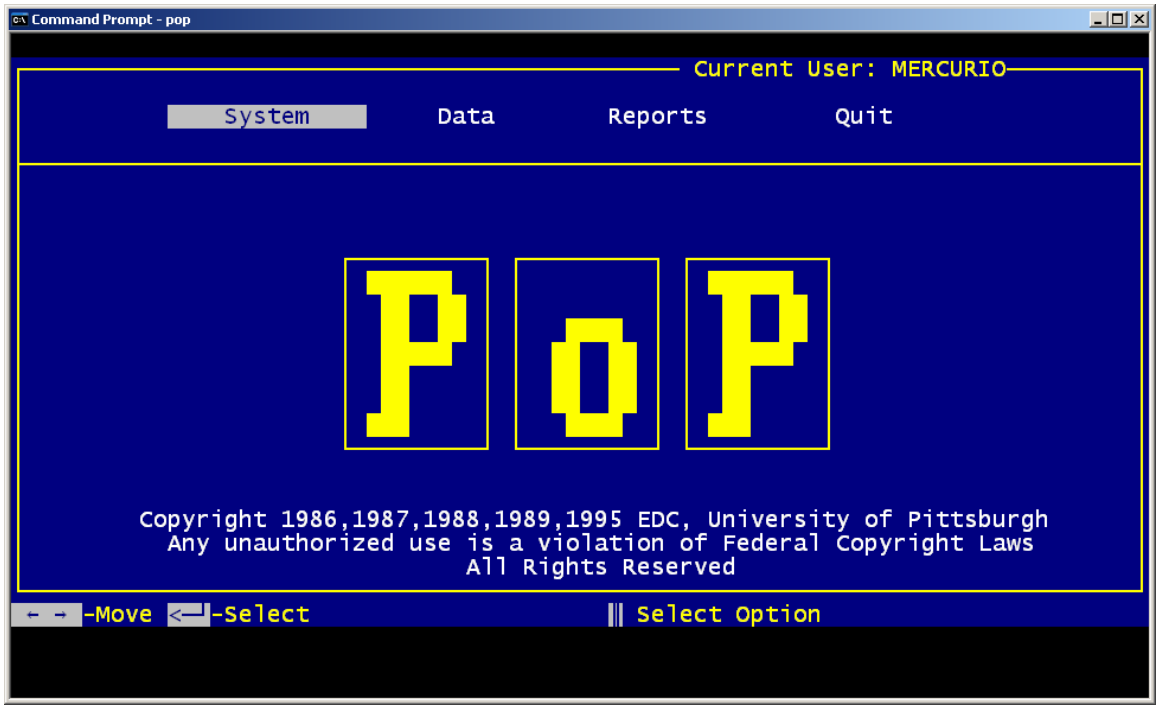
FORM NAME	**FORM CODE**
Interventionist Characteristics	IC
Intervention Delivery Assessment	DA
Caregiver Adverse Events	AG
Care Recipeint Adverse Events	AR
Adverse Events Follow-up	AF

Chapter 5

PoP Data Entry

PoP Data Entry Main Menu

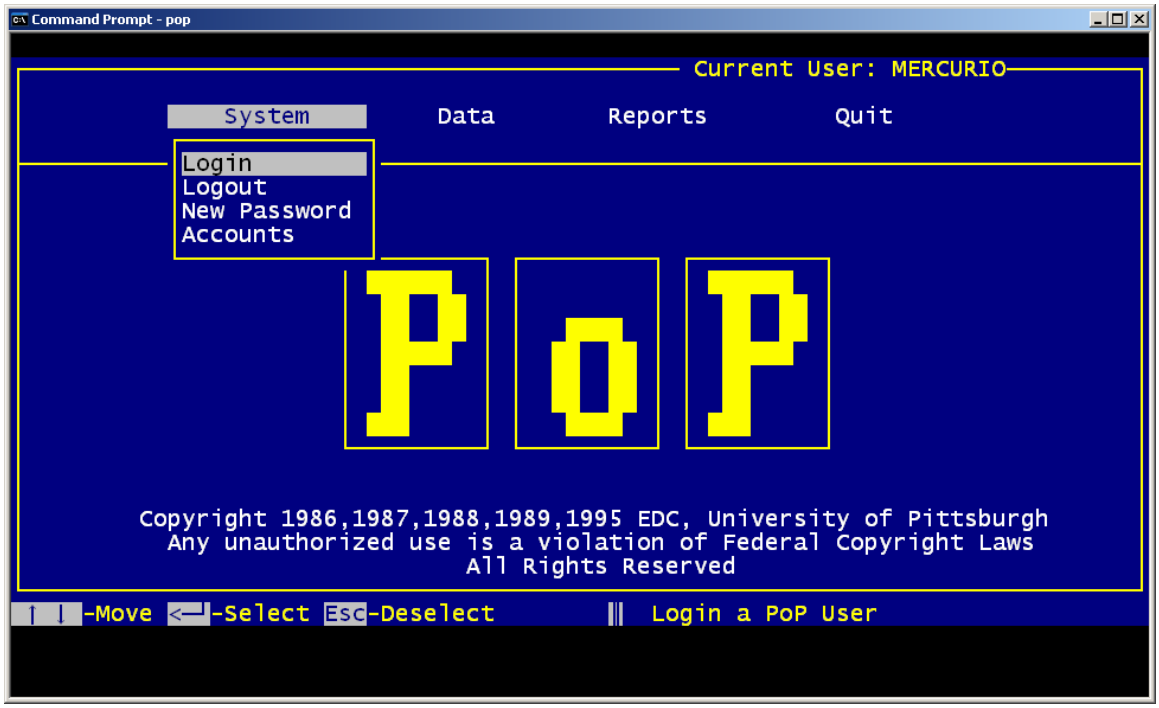
The PoP Data Entry System is a menu-driven system which provides the structure that allows the user to process information or data through the defined entry cycle. All activity within PoP begins at the first menu level, the PoP Data Entry Main Menu. The PoP Data Entry Main Menu contains three environments and ***Quit***. The environments are ***System***, ***Data***, and ***Reports***. Each environment contains subsystems that control data entry functions in PoP. The subsystems are revealed in drop-down menus when a highlighted environment is selected.



*When **Quit** is selected from the Main Menu, your computer will re-boot and the "TRI-Boot" menu will appear.*

PoP System Environment

The **System Environment** contains subsystems that control ***Accounts*** and ***Security***.



Login

PoP recognizes two types of login procedures: the Startup Login (see Chapter 3) and the System Login. The System Login procedure initiates a new session without exiting PoP.

To initiate a System Login and begin a new PoP session, select **Login** from the PoP Main Menu. Enter your Username and Password.

If an attempt is made to login while another user is currently logged into PoP, a message indicating the current user appears on the PoP Login screen. Press any key to return to the Main Menu and follow the **Logout** procedure (see below) to end the PoP session of the current user, if necessary.

Logout

Select **Logout** to end a PoP session without exiting out of PoP.

*It is important to use the **Login** and **Logout** subsystems because PoP maintains audit trails that include the Username.*

New Password

Select ***New Password*** to assign a new Password to an existing Username.

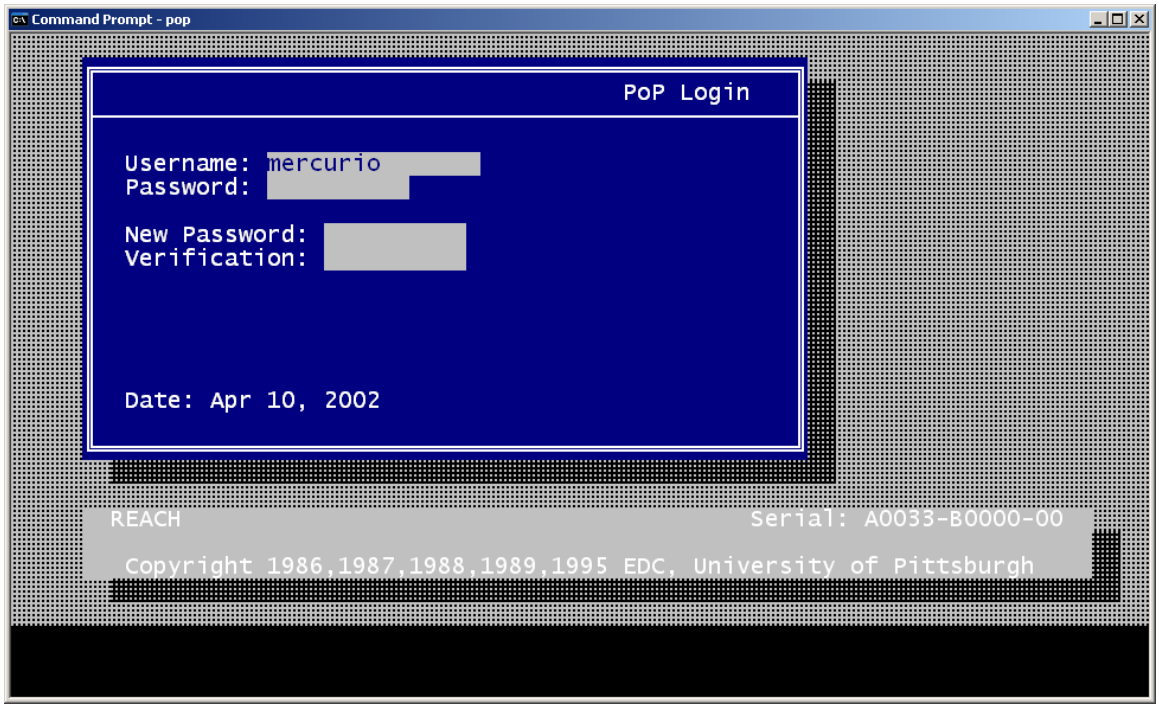
1. Move to ***New Password*** and press *Enter*.

2. The PoP Login screen appears.

3. Type your Username and press *Enter*.

4. Type your current Password and press *Enter* (your password is not visible).

5. If your Username and Password have been entered correctly, the system prompts for a New Password and Verification.



6. Type your new password at the New Password prompt and press *Enter* (the password will not be visible).

7. Type your new password again at the Verification prompt and press *Enter* (the password will not be visible). A correct verification returns the user to the Main Menu.

8. If the new password is typed incorrectly at the Verification prompt, the message "*Verification Incorrect*" appears. Press any key to return to the Main Menu and try again.

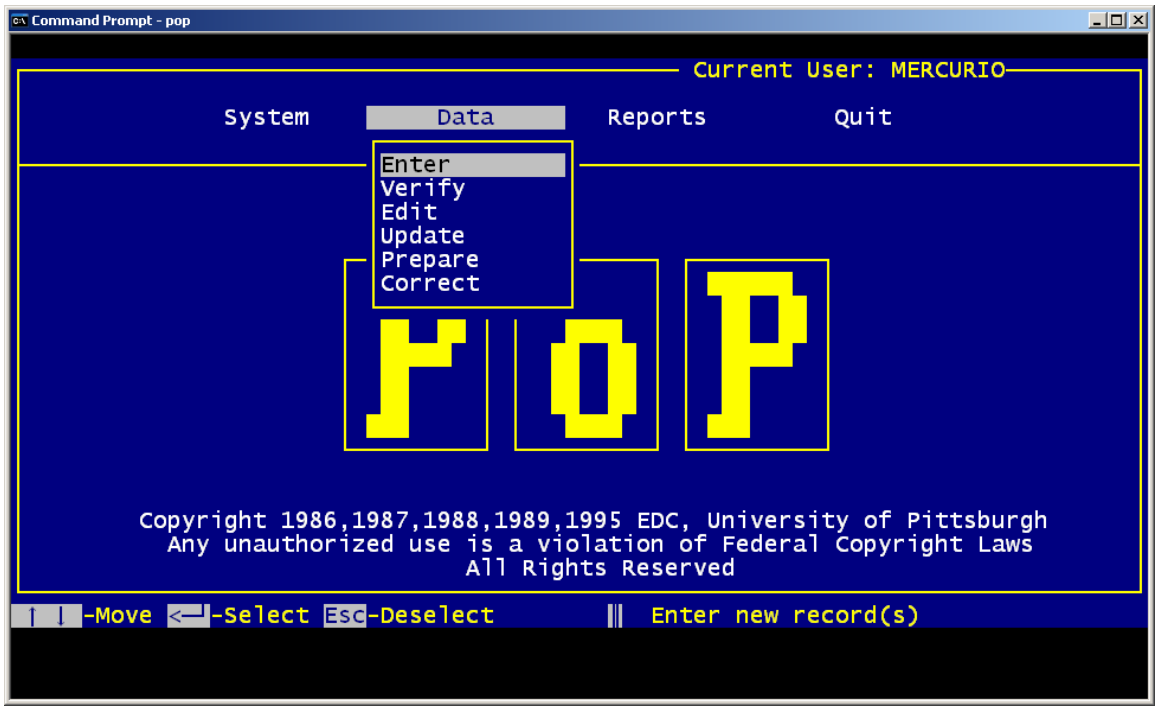
Accounts

This subsystem is selected to ***Add***, ***Edit***, ***Show*** or ***Remove*** users. The Data Coordinator is responsible for maintaining the User Accounts.

To use PoP, a user must have an account with a registered Username and Password.

PoP Data Environment

Any process which creates, changes, edits, reports, or prepares data files is included in the **Data Environment**. The **Data Environment** contains the ***Entry, Verify, Edit, Update, Prepare,*** and ***Correct*** subsystems.



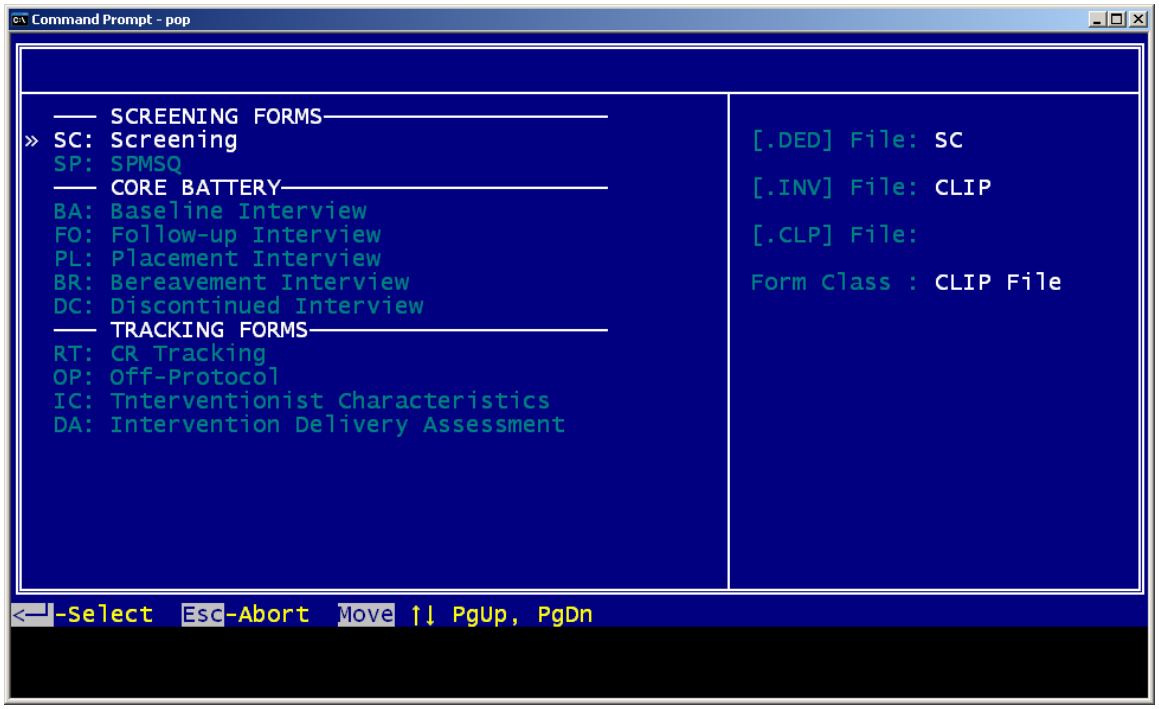
Entry

Select the ***Entry*** subsystem under the **Data Environment** to enter the data from paper data collection forms. Each form is identified by its name and 2-character code.

1. Move to ***Entry***, press *Enter*, and the Study Selection screen appears.

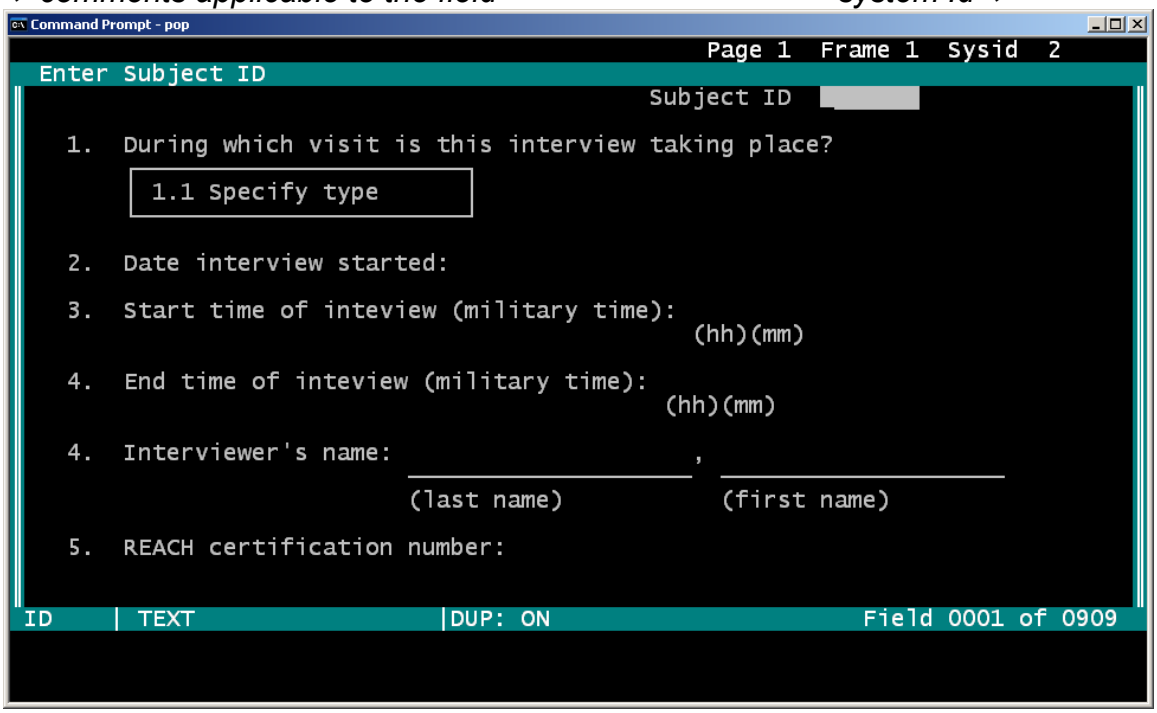
2. Choose the appropriate study and press *Enter*. The Form Selection screen appears.

3. Move the cursor to the applicable form/battery or select it by typing the first letter of the form code. Press *Enter*.



The first frame of the selected form appears and is ready for entry.

comments applicable to the field *system Id*



short name of variable *type of variable*

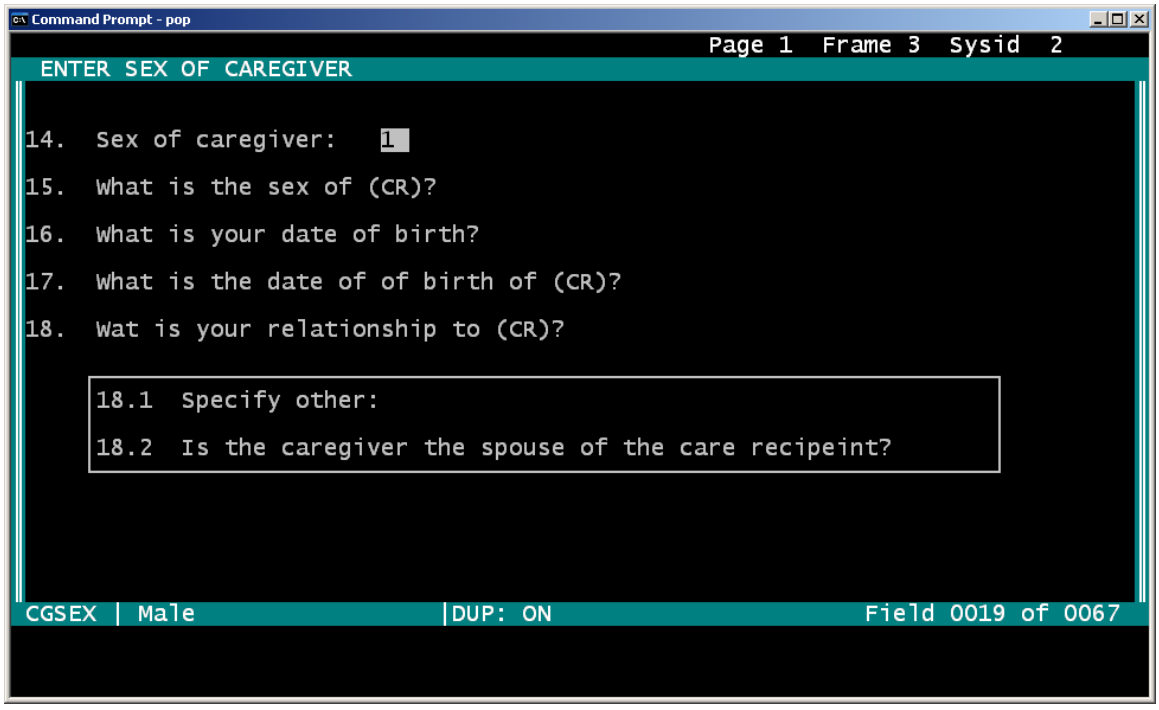
Although PoP maintains an electronic inventory file, it is highly recommended that each record and the history of its data process be logged. This manual contains instructions for completing a sample Data Processing Log and for recording the history on the actual data collection form (Appendix A).

Data Processing Log: ❶ Record the 2-character form code next to "Form:".
❷ Record your reach certification number. ❸ Copy the Sysid (System ID) which appears in the upper right-hand corner of the screen into the first column of the log. The Sysid is a PoP generated consecutive record identifier. ❹ Record the subject ID. ❺ Record the date the form was administered.

Data Collection Form: In the designated area on the front of the form, record the Sysid.

4. The first entry field is highlighted. Type the information as it appears on the paper collection form. Press *Enter* to record the data and move to the next field.

5. Enumerated Types: An enumerated type is defined when the responses to a question or item are categorical and can be assigned a numeric value or code. Each enumerated type is given a name which uniquely identifies it. This name will appear at the bottom of the screen where "type" is listed. Press the *left arrow* or *right arrow* to view each response and its assigned code. As each response/code is accessed, the code will appear in the current field and the accompanying response will appear in place of "type" at the bottom of the screen (see example below).



↑ *response*

6. Press the *up arrow* cursor key to move backwards to a previous field, if necessary (the missing value is entered into the vacated field).

7. Continue entering the information until the record is completed.

8. Function Keys within ***Entry*** (for a complete listing of PoP function keys, see Appendix B):

[F5] enters the Missing value as defined for the study, when pressed.

[F6] enters the Not Applicable value as defined for the study, when pressed.

[F7] toggles the Message Bar at the top of the screen from the field COMMENT display mode to the field RANGE display mode, when pressed. Whichever mode is activated remains active until *F7* is pressed again or a new record is selected.

[Alt][F5] enters the Missing value for the remaining fields in the frame, when pressed.

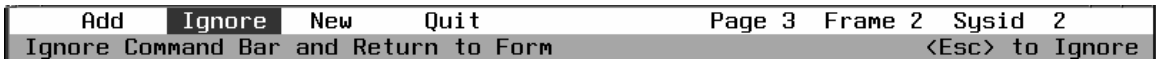
[Alt][F6] enters the Not Applicable value for the remaining fields in the frame, when pressed.

[Esc] places the cursor at the Command Bar at the top of the screen, when pressed.

9. A Command Bar appears at the top of the screen with the options Add, Ignore, New, and Quit when a record is complete or when *Esc* is pressed.

Add: Select Add after entering all data for a given record to save that record and continue entering records of the same form type.

Ignore: Select Ignore to disregard a previous command and return to the form.



New: Select New to switch to a new form with the option to save or not save the previously entered data.

Quit: Select Quit to return to the Main Menu with the option to save or not save the previously entered data.

10. If a value entered in a particular field does not fall within the defined range of values, the entry specialist will receive an error message and that value will not

be accepted. If the data coordinator is not available, the missing value should be entered or entry can be aborted for that particular record. PoP will automatically insert the missing value in a field when a value is not entered.


Data Processing Log: ❻ Record date of entry in the 4th column of the log.


Data Collection log: Record the date of entry and your initials in the designated area on the front of the form.

Each paper form that is entered creates one computer record.

With the entry of each record PoP references two inventory files, a master inventory file and a form specific inventory file.

The master inventory file runs a CASE LOGIN PROGRAM (CLIP) as each new record is entered. This program confirms that the ID entered is a valid study ID. This process is initiated as soon as the ID is entered. If it is not valid, the following error message will occur:

```
  Error (031): '10002MARTI' not Logged into CLIP
 ENTER ALPHANUMERIC PATIENT ID
```

Entry for that particular record cannot continue and the data coordinator should be notified.

An individual inventory file, maintained for each form type, runs a FORM LOGIN PROGRAM (FLIP) as each new record is entered. Once the key field(s) is/are entered (PoP allows up to three keys to identify a unique record), PoP will initiate FLIP. If a record already exists with the entered key(s), the following error message will appear at the top of the entry screen:

```
  Error (037): Record Already Exists
 ENTER ALPHANUMERIC PATIENT ID
```

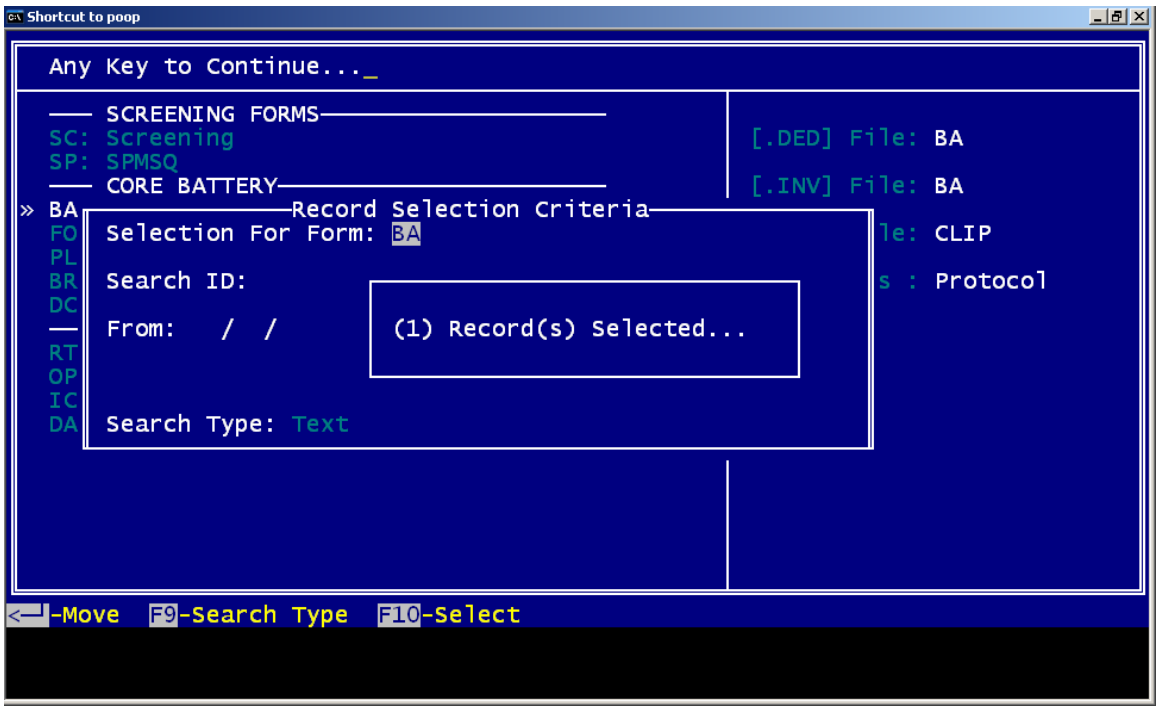
Again, entry for that particular record cannot continue until the key conflict is resolved. The data coordinator should be notified.

Verify

The ***Verify*** subsystem is selected to re-enter data from the paper collection form in an effort to confirm that the data entered in ***Entry*** are correct and free from typographical errors. Ideally, the person verifying the data should not be the same person who entered the data. If this is not possible, it is recommended that verification should be initiated no earlier than 24 hours after entry.

1. Select ***Verify*** and the Study Selection screen appears. Select the appropriate study and press *Enter*.

2. The Form Selection screen will appear (see Entry). Select the form with records to be verified and press *Enter*. The Record Selection Criteria window appears.



3. Select all records (F10), or a particular record(s) using the Search ID which is the unique ID assigned to each study participant, or a subset of IDs using the * in the Search ID field, or the From and To dates of data entry for the form.

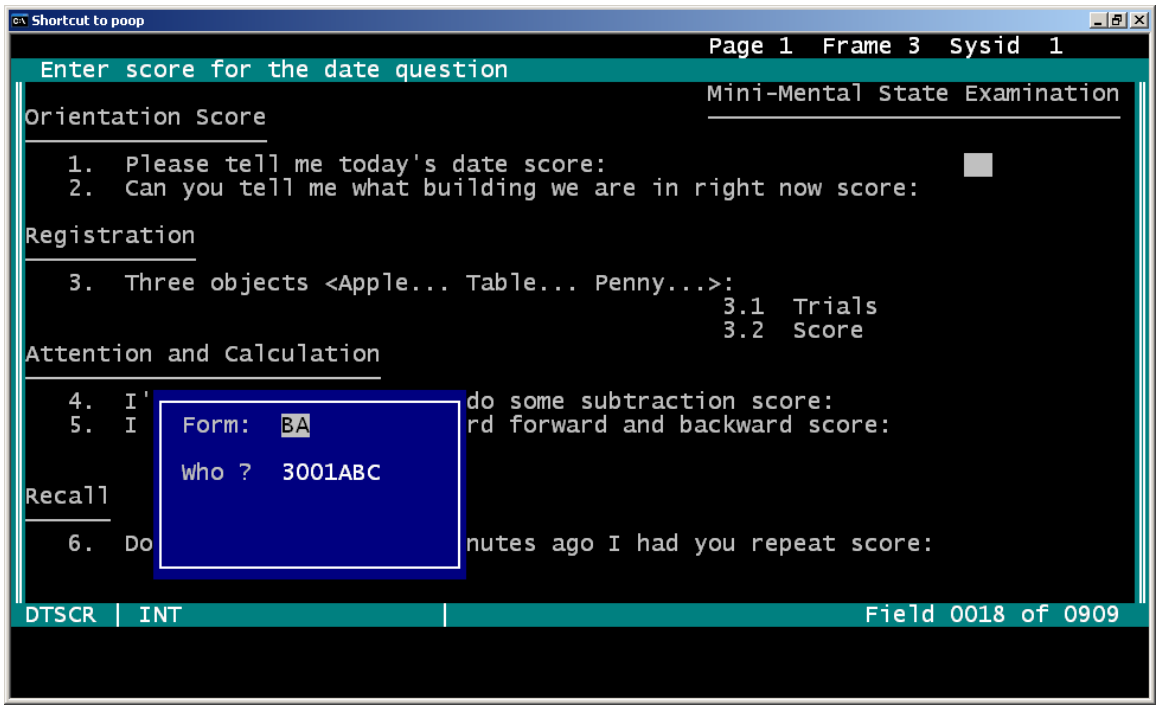
> All records: press *F10*. (This is recommended to avoid inadvertently skipping a record(s).)
>
> Particular record(s) for a unique ID: Enter the Search ID and press *F10* to select all records of that form type for one participant. If the ID is not Text, press *F9* to switch from Text to the correct data type before entering the Search ID.

Subset of records using *: Sometimes it is useful to select a subset of records. Enter the first identifying characters of the subset and add "*". Press *F10* to select.

From and To dates for entry: Press *Enter* to skip the Search ID field and enter the dates on which the appropriate records were entered. Press *F10* to select all records for the dates entered.

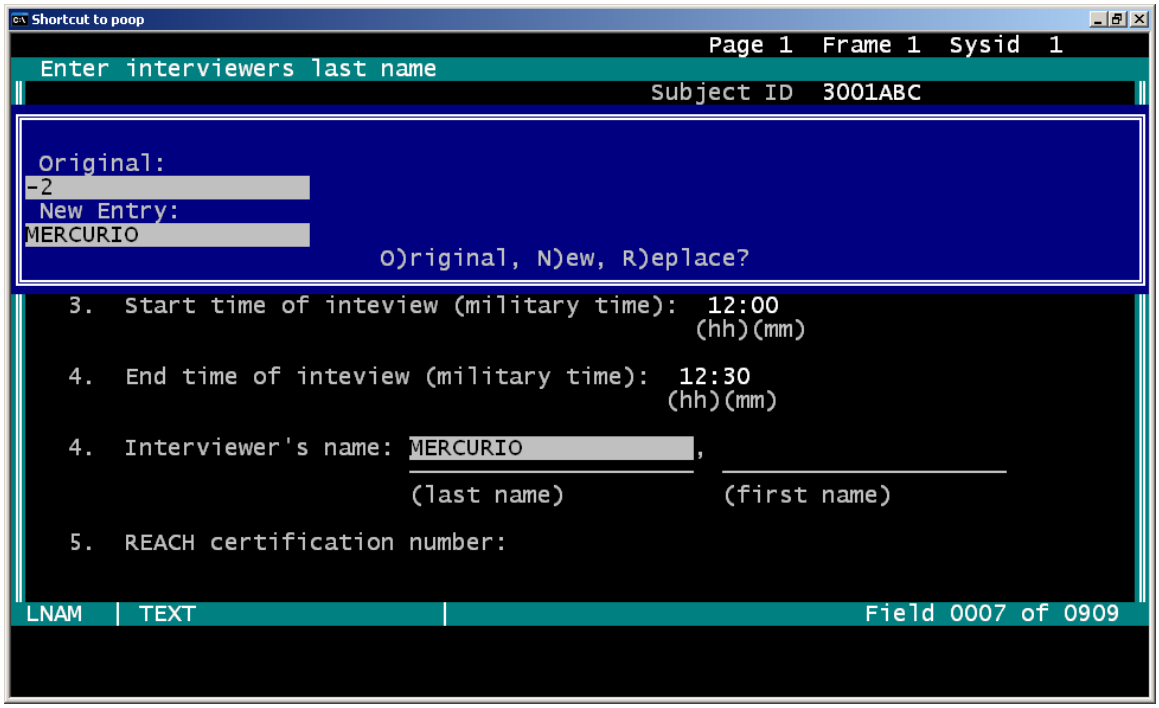
4. The number of records selected appears within the window. Press any key to continue the ***Verify*** process.

5. Compare the Sysid and keys that appear on the cover page of the form with those on the computer screen before continuing. To quickly identify the key fields, press *F9.* A window will appear with the identifying information. Once this information has been compared to the cover page of the form, press *F9* to close the window. If the Sysid and keys do not match, do not continue the verification process and contact the data coordinator if the issue cannot be resolved.



6. Note that the ID appears on the screen and cannot be verified/changed. If the ID which appears is incorrect, abort verify by pressing *Esc* and selecting Quit, and notify the data coordinator.

7. Re-enter the data as in ***Entry***. If the data re-entered in ***Verify*** are not identical to the data entered in ***Entry***, the confirmation screen appears.



8. The system asks for confirmation of the correct data. The Original (from ***Entry***) value and New (from ***Verify***) value appear along with an option to Replace the value with a different value.

Press “O” to select the original value and move to the next field.

Press “N” to select the new value and move to the next field.

Press “R” to enter a different value and move to the next field.

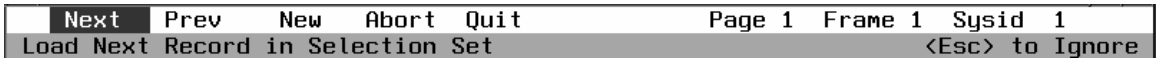
9. Continue entering the data until verification for the record is completed. It is not possible to “backup” to a previous field in ***Verify***. If data entered/changed in ***Verify*** are not correct, they have to be changed in ***Update***.

10. A [.VRP] file is created/appended to which captures all changes made during the verify session. These reports can be accessed through ***Print*** or ***View*** as described in the **Reports Environment** section.

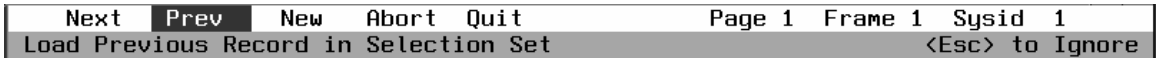
11. A Command Bar appears at the top of the screen with the options Next, Previous, New, Abort, and Quit when a record has been verified.

Within ***Verify***, the Command Bar is activated by pressing *Esc*. The commands are defined as follows:

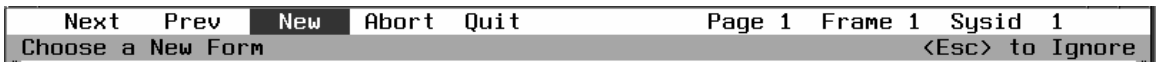
Next: Select Next to load the next record in the selection set and save the previously verified data.



Prev: Select Prev to load the previous record in the selection set with the option to save the previously verified data.



New: Select New to choose a new form from the Form Selection screen with the option to save the previously verified data.



Abort: Select Abort to end the current ***Verify*** session without saving the current data (record).

Quit: Select Quit to return to the Main Menu with the option to save or not to save the previously verified data.

Data Processing Log: ❼ Record the date the record was verified.

Data Collection Form: Record the date the record was verified and your initials in the designated area on the front of the form.

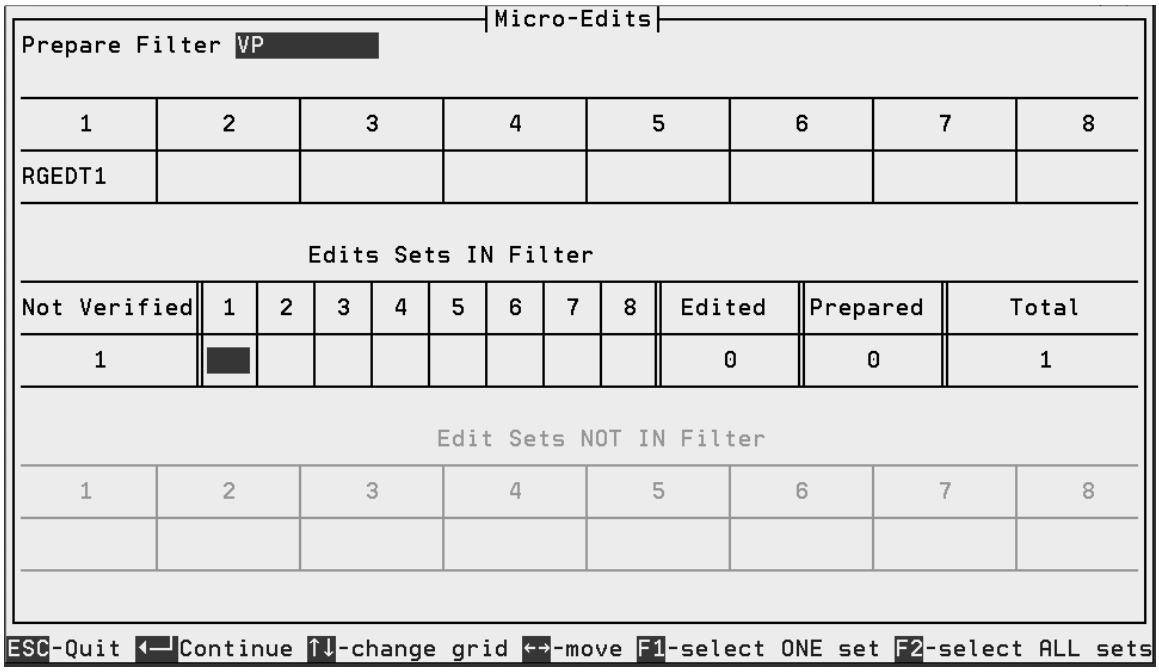
Edit

Form edits are a series of conditions defined for each form that individual records must pass through successfully before the record is considered “clean” and ready for the next step in the data process. The ***Edit*** subsystem is selected to check for errors in records that have been entered and verified. ***Edit*** contains one or more edit sets defined for each form that all records must pass through to

ensure the accuracy and quality of the data. Each record must pass all of the edit sets consecutively to be considered an error free record.

1. After ***Edit*** is selected, the Study Selection screen appears. Select the appropriate Study and press *Enter*.

2. The Form Selection screen will appear. Select the form with records to be edited and press *Enter*. The Micro-Edits screen appears.



3. The Micro-Edits screen contains information about the edit sets and shows the status of all records entered for that form. The first row of information shows the edit sets defined for the selected form (in this example, RGEDT1). The second row shows the status of the records of the selected form.

The Not Verified block shows the number of records entered but not verified.

The Edit Sets in Filter blocks show the location of records within the edit sets.

The Edited block contains the number of records that have successfully passed through the required edit sets.

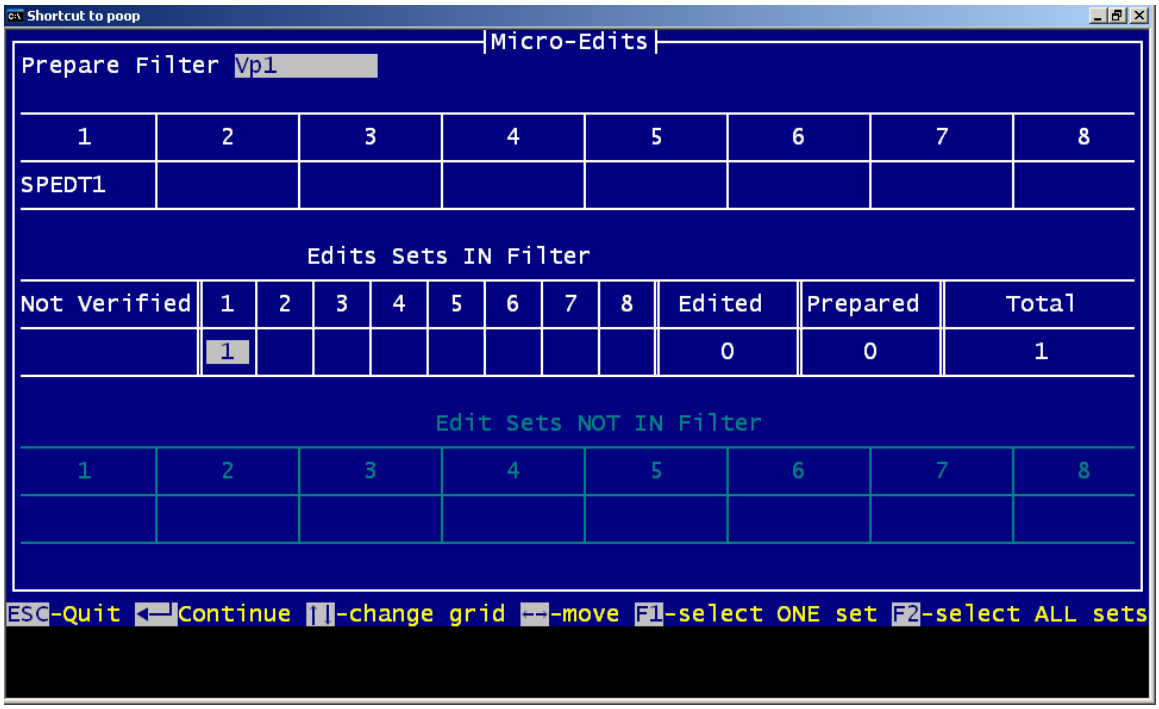
The Prepared block contains the number of records for which an ASCII file has been created (either batched or currently waiting to be batched).

The Total block is the sum of the records in the Not Verified block, the Edit Sets in Filter blocks, the Edited block, and the Prepared block.

The third row of information is for Data Coordinating Center use only.

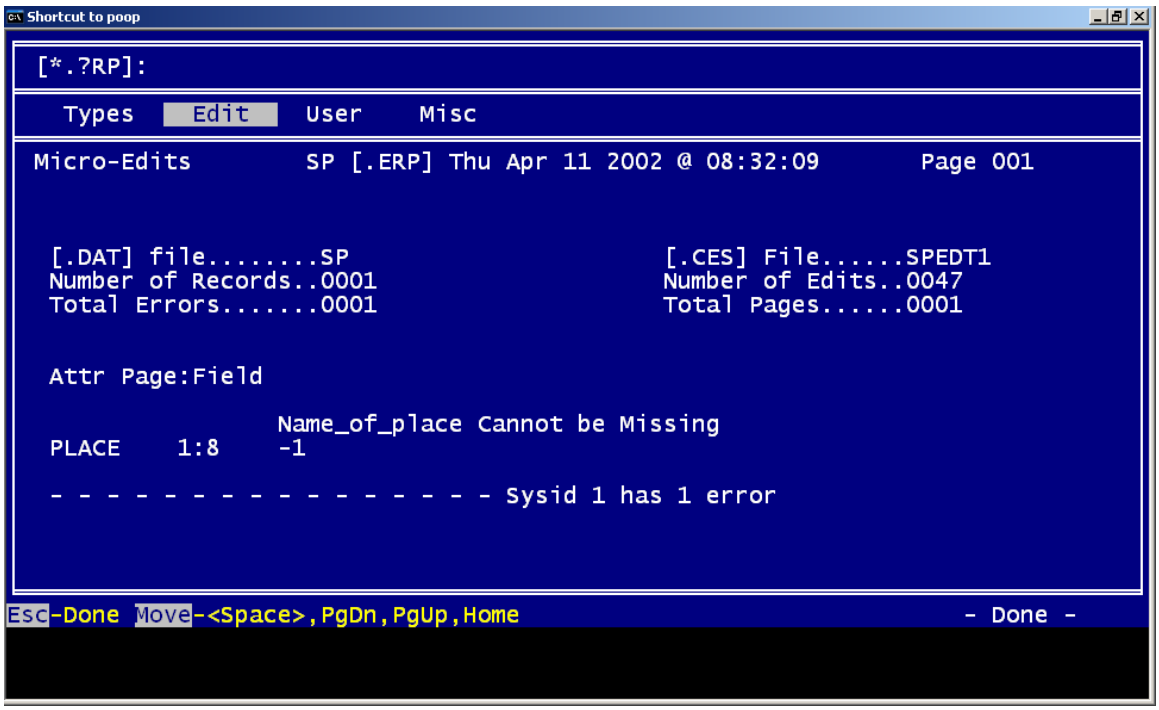
4. The Help Line at the bottom of the screen displays the keyboard keys that are active in ***Edit*** and their associated actions. Move the cursor to highlight the desired edit set. Press *F1* to process all records in the selected edit set or press *F2* to process all records in ALL edit sets. These keys toggle the edits on and off.

5. Press *Enter* to call "Run Edits? no yes". Select "no" to cancel the editing process and remain in the Micro-Edits screen or select "yes" and the Micro-Edits Status screen appears as the records are processed.



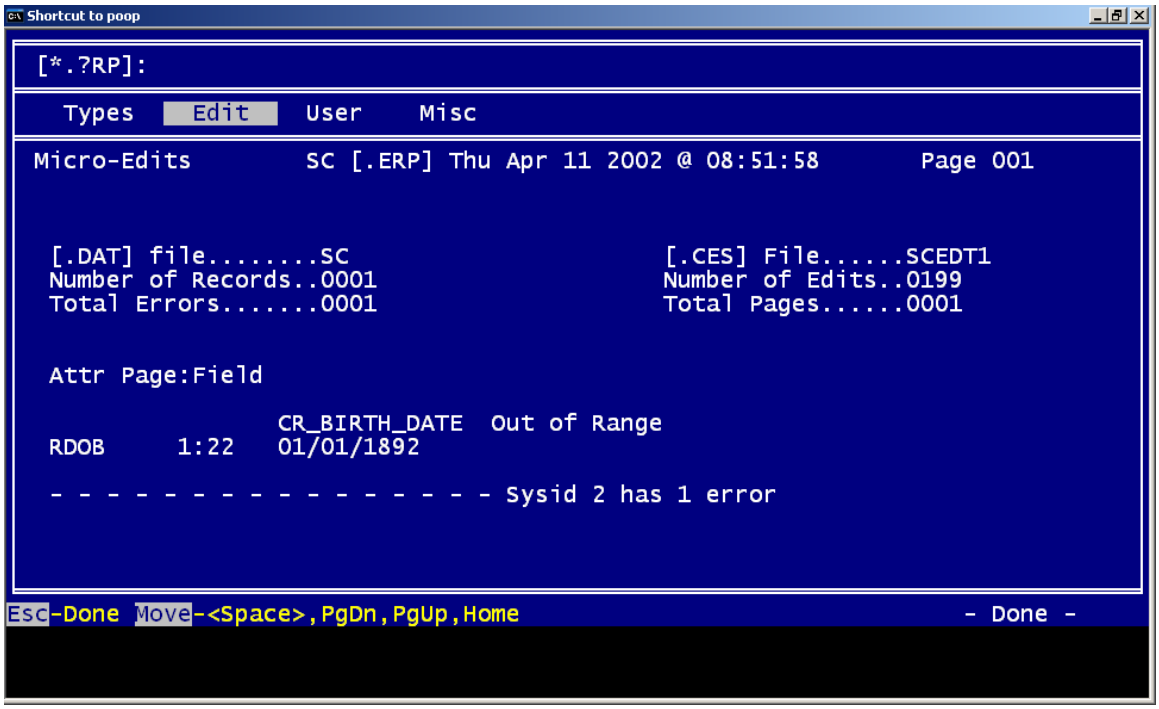
6. Follow the instructions displayed in the Message Window to return to the Micro-Edits screen and review the status of the edited records.

7. An Edit report [.ERP] is created each time edits are processed. The fields associated with the edit error along with the associated keys or record identifiers can be viewed or printed from the **Reports Environment** (see next section). The following is an example of an Edit Report as viewed from the screen.



On the top of the first page of every Edit Report appears the name of the file and the run date. Also listed is the form name, edit set name, number of records edited, number of edits the record is required to pass, total errors, and total pages.

To aid in the resolution of error(s), for each record the edit error report contains the record identifiers (ID, date of visit, and visit number in the above example), an error message and the attribute names for the relevant fields and their current value. Each attribute is also defined by the page on which it appears and its field number on the screen.




Data Processing Log: ❽ Record the date the ***Edit*** process was initiated.

8. The information on the Edit Report should be compared to the paper data collection form. Corrections should be noted on the Edit Report (as well as the paper data collection form, if necessary). Corrections to errors are made in ***Update***. The record must then be processed through ***Edit*** again.

9. If the error is a "false" error (i.e., no correction is required), the data coordinator will bypass (push that record through the edit set) the appropriate edit set for that record. An Edit Bypass Request form (Appendix C) is completed when edit sets are bypassed.

Updates made to records turn "passed" edit sets to "fail"; if updates have been made, previous bypasses for a particular record will no longer be in effect and the bypass procedure will have to be repeated.

Update

The ***Update*** subsystem is selected to make corrections to participant records at any point *prior to* ***Prepare***. Most corrections are a result of errors found during the ***Edit*** process. The ***Update*** subsystem looks and operates like the ***Entry***

subsystem. The status of the record (active/deleted, verified) is displayed at the bottom of the screen along with the information appearing on the entry screen.

*The only field which cannot be changed/corrected during **Update** is the unique ID. Notify the data coordinator if the ID must be corrected.*

1. Select ***Update*** and the Study Selection screen will appear. Select the appropriate study and press *Enter*.

2. When the Form Selection screen appears, select the form with records to be updated. The Record Selection Window appears.

3. Select the relevant record(s) using the Search ID, or the From and To dates of data entry, or *F10* to select all forms.

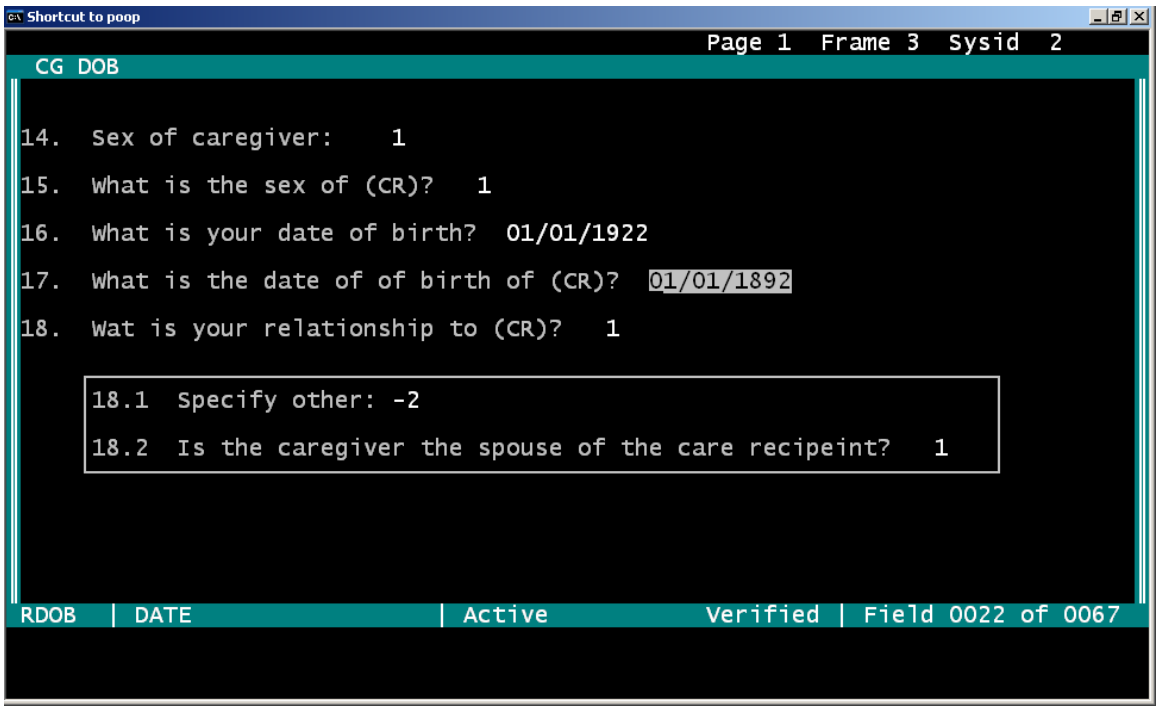
> Enter the Search ID or a portion of the Search ID and press *F10* to select all records of that form type for one participant or a subset of participants, or
>
> Press *Enter* to skip the Search ID field and enter the dates on which records were entered. Press *F10* to select all records for the applicable dates, or
>
> Press *F10* to select all records for the form (excluding those which have been prepared).

Select only those records that require corrections.

4. The number of records selected appears within the window. Press any key to continue and the first frame of the first record in the selection set appears.

5. Compare the Sysid and keys that appear on the cover page of the form with those on the computer screen before continuing. If they do not match, do not continue the update process and contact the data coordinator if the issue cannot be resolved.

6. To make a change, move the cursor to the field that is incorrect and enter the correct information. (Note that all entered values are visible. However, the ID field cannot be changed by the entry specialist.) Press *Enter* to apply the change to the field. Before moving to another field/page, *Enter* must be pressed to save the change to that field.



7. Change only the applicable fields; unlike ***Entry*** and ***Verify***, only the fields to be corrected have to be re-keyed. Use *Page Down* to move to later screens. When the record is correct, press *Esc* to reveal the Command Bar which contains Next, Prev, [Un]Del, New, and Quit. All of the commands, except [Un]Del , are defined in the previous Command sections

> [Un]Del: Select [Un]Del to change the status of the current record from Active to Deleted. Select [Un]Del again to change the status of the deleted record from Deleted to Active. The action taken is reflected in the Status Bar at the bottom of the screen.
>
> A record can be changed from Deleted to Active during the current ***Update*** session only.
>
> *Deleted records will not be prepared. Once saved as deleted, the record can only be restored by the data coordinator through the Inventory Editor (by Sysid).*

8. During ***Entry*** and ***Verify***, range checking occurs. Occasionally, a true value for a field is “out of range” as defined by the system. An “out of range” value can be entered during an ***Update*** session. Most “out of range” values entered through ***Update*** will require an edit bypass.

9. A [.URP] file is created/appended to which captures all changes made during the ***Update*** session. These reports can be accessed through ***Print*** or ***View*** as described in the **Reports Environment** section.

10. After the ***Update*** process has been completed, the ***Edit*** process must be re-initiated for the updated records.

 Data Processing Log: ❾ Record the date when the record is "clean" or has passed all edit sets.

 Data Collection Form: Record the date when the record is "clean" or has passed all edit sets and your initials in the designated area on the front of the form.

11. As an aid to correcting errors identified in ***Edit***, the Edit report for a form type can be viewed from ***Update***. To view an Edit report from within ***Update***, press *F9*, select Edit and press *Enter*. Select the appropriate Edit report and press *Enter*. The Edit report appears on the screen for viewing. Press *Esc* to return to the record in ***Update*** and make the required changes.

Prepare

The ***Prepare*** subsystem is selected to create or append to an ASCII file the data which have passed through all phases of the PoP Data Entry System. Once a record has been processed through ***Prepare***, any additional changes must be made through ***Correct***.

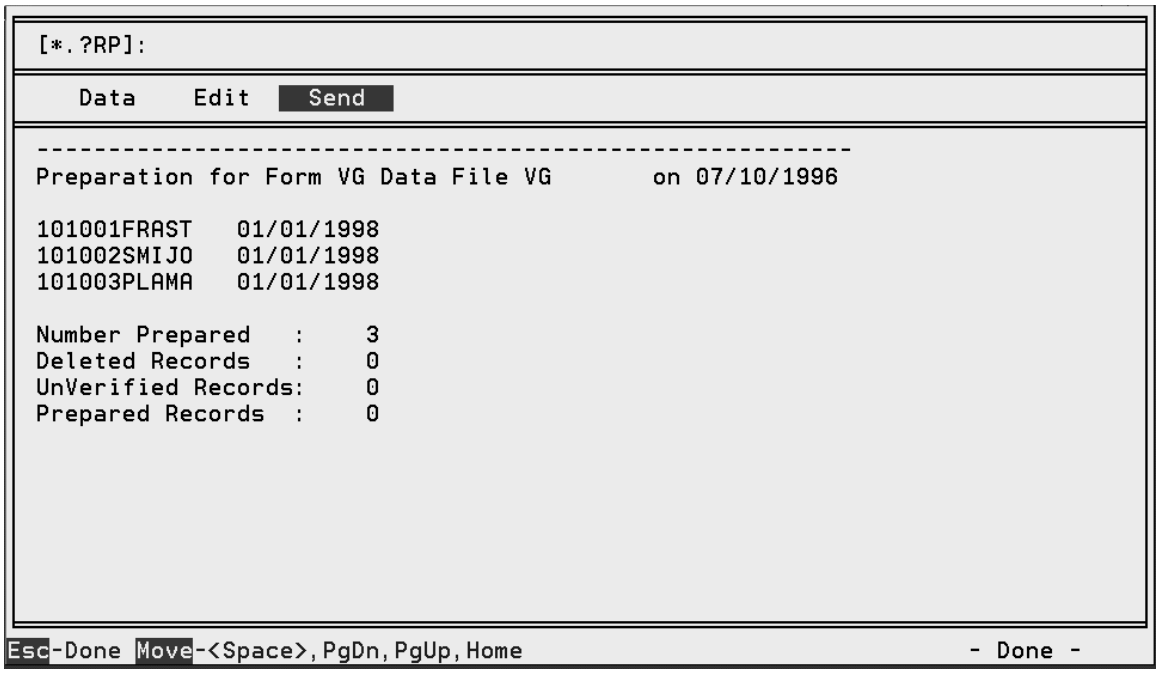
1. Select ***Prepare*** and the Study Selection screen appears. Select the appropriate study.

2. When the Form Selection screen appears, move to the relevant form(s), press *Enter* to mark the form(s). An asterisk indicates that the form is marked for Prepare. (Press *Enter* to remove the asterisk, if necessary). Press *F10* to begin ***Prepare*** processing for the marked forms.

3. If you wish to select ALL forms, hold down the *left Alt* key and press *F10* to begin ***Prepare*** processing for ALL forms.

4. A Prepare Report [.MRP] is generated which includes diagnostic information regarding prepared forms, as well as the Key fields for the records which were

prepared during the process. Every time records are prepared the relevant information is appended to the Prepare Report. The data coordinator may request or access this report to verify record counts in the main database as well as the data files. Below is an example of a Prepare Report (through the ***View*** subsystem of the **Reports Environment**):



5. **Prepare** records as needed to exit them from the PoP cycle (inaccessible in anything but ***Correct***).


Data Processing Log: ❿ Record the date the record was prepared.

Export

The ***Export*** subsystem is selected to 'export' all of the data to an ASCII file which have passed through any phases of the PoP Data Entry System. Any changes made through Update or Correct will be included in the exported data sets.

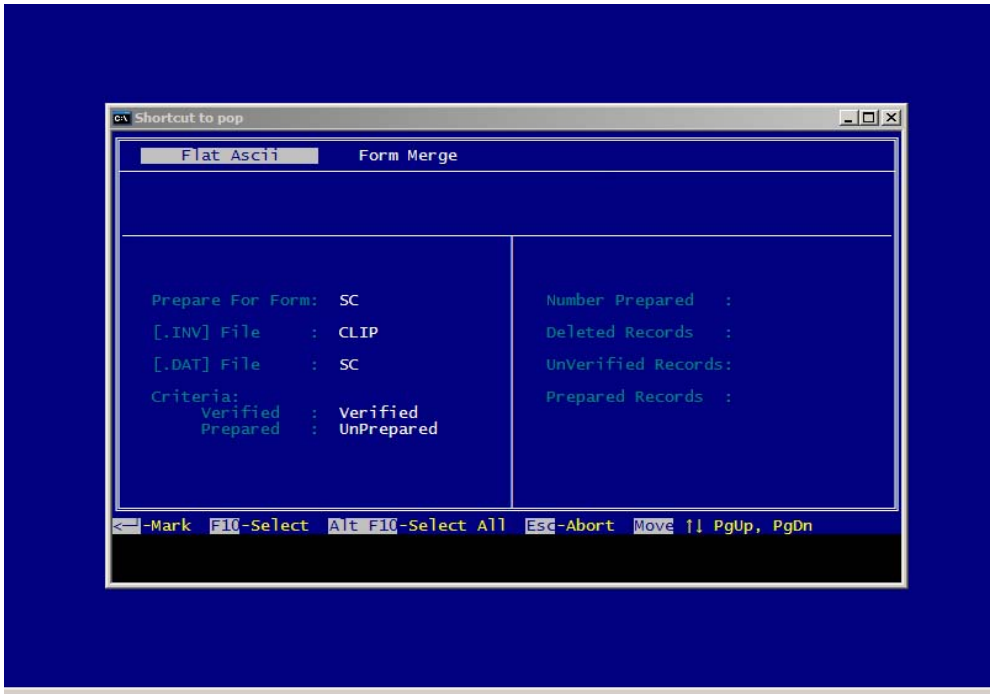
1. Select ***Export*** and the Study Selection screen appears. Select the appropriate study.

2. When the Form Selection screen appears, move to the relevant form(s), press *Enter* to mark the form(s). An asterisk indicates that the form is marked for

Export. (Press *Enter* to remove the asterisk, if necessary). Press *F10* to begin *Export* processing for the marked forms.

3. If you wish to select ALL forms, hold down the *left Alt* key and press *F10* to begin ***Export*** processing for ALL forms.

4. After selecting the forms and striking F10, the below window will appear with the option to select Flat Ascii or Form Merge. **Always select Flat Ascii.** Note that if a form has no data entered, an error message will appear. This message simply means that Export cannot locate any data.



Correct

The ***Correct*** subsystem is selected to make corrections to participant records *which have already passed through the* ***Prepare*** *process*. The ***Correct*** subsystem looks and operates like the ***Update*** subsystem. The status of the record (active/deleted, prepared, verified) is displayed at the bottom of the screen along with the information appearing on the entry screen.

The only field which cannot be changed/corrected during ***Correct*** *is the unique ID. Notify the data coordinator if the ID must be corrected.*

1. Select ***Correct*** and the Study Selection screen will appear. Select the appropriate study and press *Enter*.

2. When the Form Selection screen appears, select the form with records to be corrected. The Record Selection window appears.

3. Select the relevant record(s) using the Search ID, or the From and To dates of data entry, or *F10* to select all forms.

> Enter the Search ID or a portion of the Search ID and press *F10* to select all records of that form type for one participant or a subset of participants, or
>
> Press *Enter* to skip the Search ID field and enter the dates on which the records were entered. Press *Enter* to select all records for the applicable dates, or
>
> Press *F10* to select all records for the form (excluding those which have not been prepared).

Select only those records that require corrections.

4. The number of records selected appears within the window. Press any key to continue and the first frame of the first record in the selection set appears.

5. Compare the Sysid and keys that appear on the cover page of the form with those on the computer screen before continuing. If they do not match, do not continue the correction process and contact the data coordinator if the issue cannot be resolved.

6. To make a change, move the cursor to the field that is incorrect and enter the correct information. (Note that all entered values are visible. However, the ID field cannot be changed by the entry specialist.). Press *Enter* to apply the change to the field. Before moving to another field/page, *Enter* must be pressed to save the change to that field.

7. Change only the applicable fields; unlike ***Entry*** and ***Verify***, only the fields to be corrected have to be re-keyed. Use *Page Down* to move to later screens. When the record is correct, press *Esc* to reveal the Command Bar which contains Next, Prev, [Un]Del, New, and Quit. All of the commands are defined in previous command sections.

8. A [.XRP] file is created/appended to which captures all changes made during the ***Correct*** session. These reports can be accessed through ***Print*** or ***View*** as described in the **Reports Environment** section. The [.XRP] file is batched along

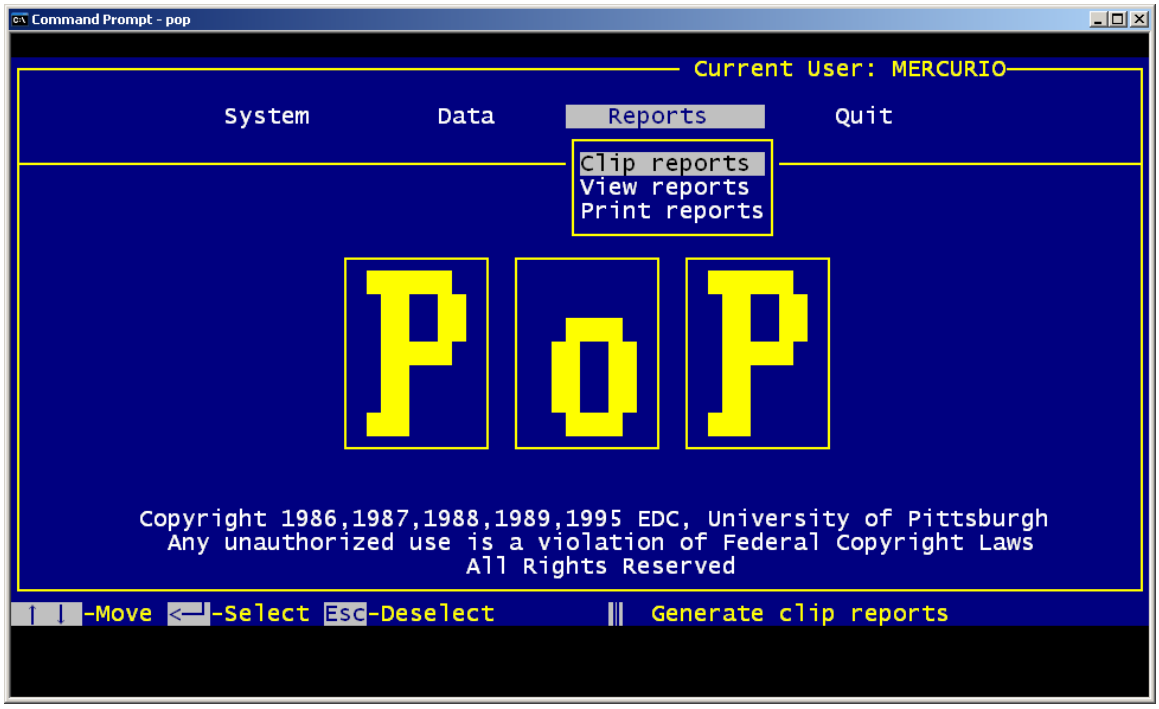
with the data files and only the corrections made to records are appended to the database. The records are not “prepared” again.

All changes should be noted on the data collection form by crossing out the old value, writing in the new, and initialing and dating the change.

Chapter 6

PoP Reports Environment

The **Reports Environment** contains the ***CLIP Report, Print, View***, subsystems. The ***CLIP Report*** subsystem is selected to create reports that show the status of records within PoP. The ***Print*** subsystem is selected to print [.?RP] files under Data, Edit, and Send categories. The ***View*** subsystem is selected to view [.?RP] files under Data, Edit, and Send categories on the screen.



CLIP Report

Select ***CLIP Report*** under the **Reports Environment** to create a CLIP report [*.IRP] file. An [.IRP] file is a Case Status inventory file, a Database Status inventory file, or a Database Summary inventory file. Each of these files provide information about the status of forms and participant records in the system.

A Case Status inventory report contains data about study participants and the status (entered, verified, prepared) of the forms that have been entered for these participants in the PoP system.

The left column shows the short name of each form followed by the second and third key values, if applicable. The right column shows the status of the record within the PoP

Entry cycle *('----------'=entered, 'V'=verified, '-12345678'=passed edit sets, 'Prepared'=prepared).*

Case ID: 010025SMI

SL:	1 2	----------
CE:	10/20/91	V----------
FS:	. . . . .	Prepared----
QA:	2 3	V-12---------

A Database Status inventory report contains data regarding the status (prepared/not prepared) of all forms entered in the system for all participants *(records prepared : records in Entry cycle).*

Forms:	SL	CE	FS	QA	Totals
010025SMI	0:1	0:1	1:0	1:1	2:3
010026JON	1:0	1:0	0:0	1:0	3:0
010027FUR	0:1	1:1	1:0	0:1	2:3

A Database Summary inventory report contains summary data regarding the status (prepared/not prepared) of all forms entered for each form type *(records prepared : records in Entry cycle).*

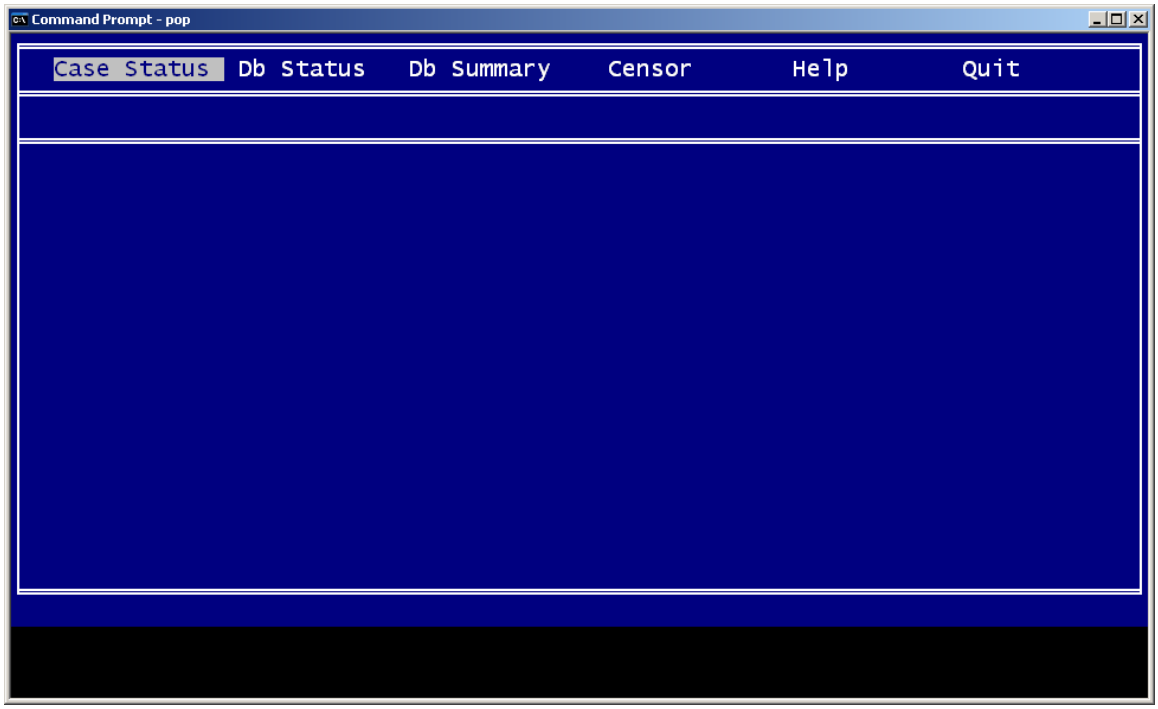
Forms	Count
SL	1:2
CE	2:2
FS	2:0
QA	2:2

To create a report for Case Status:

1. Move to ***CLIP Report***, press *Enter* and the CLIP report selection screen appears.

2. Move to Case Status and press *Enter*. The Form Selection Screen appears.

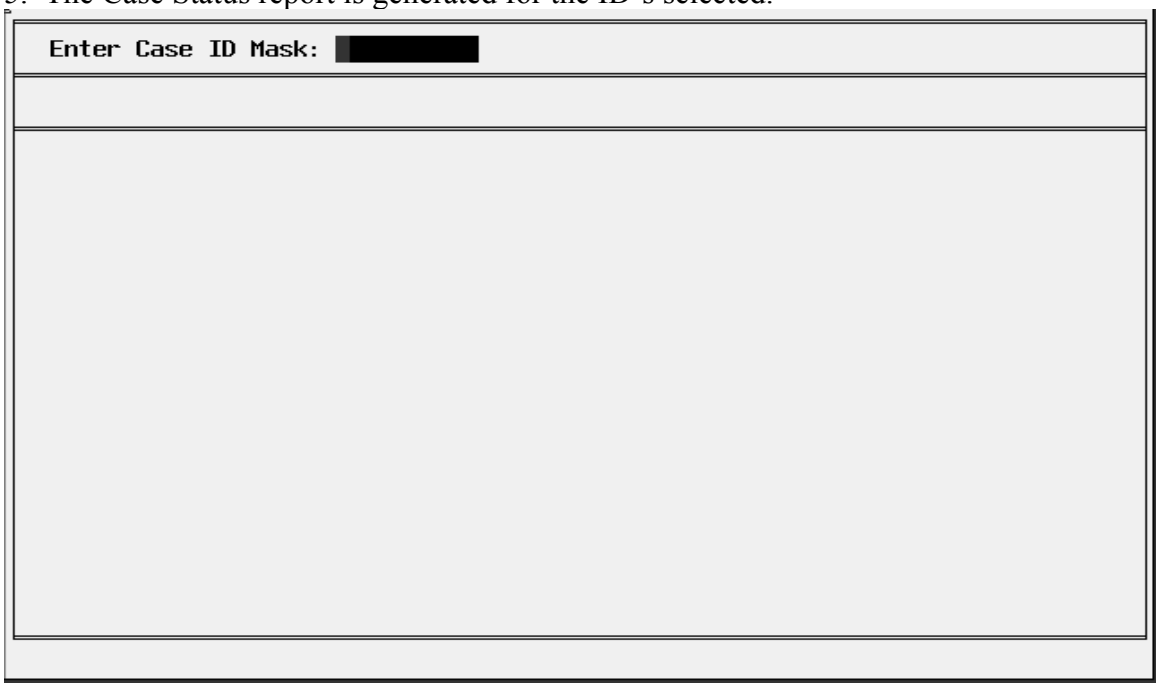
3. Select the CLIP form and press *Enter*. The ID selection screen appears.



4. Determine the Case (participant) ID numbers to be included in the file and enter the Case ID Mask.

The Case ID Mask is created using the wildcard characters "?" and "" and as much of the study ID as necessary to create the mask. A question mark (?) in the mask means that any character can occupy that position. An asterisk (*) in the mask means that any character can occupy that position or any other of the remaining positions in the mask.*

5. The Case Status report is generated for the ID's selected.



6. The PoP Main Menu appears after the file is complete.

7. ***Print*** or ***View*** the report from the appropriate subsystem.

To create a Db Status or Db Summary report:

1. Move to ***Clip Report***, press *Enter*, and the Clip report selection screen appears.

2. Move to Db Status or Db Summary, press *Enter*, and the form selection screen appears.

3. Select the CLIP form and press *Enter*.

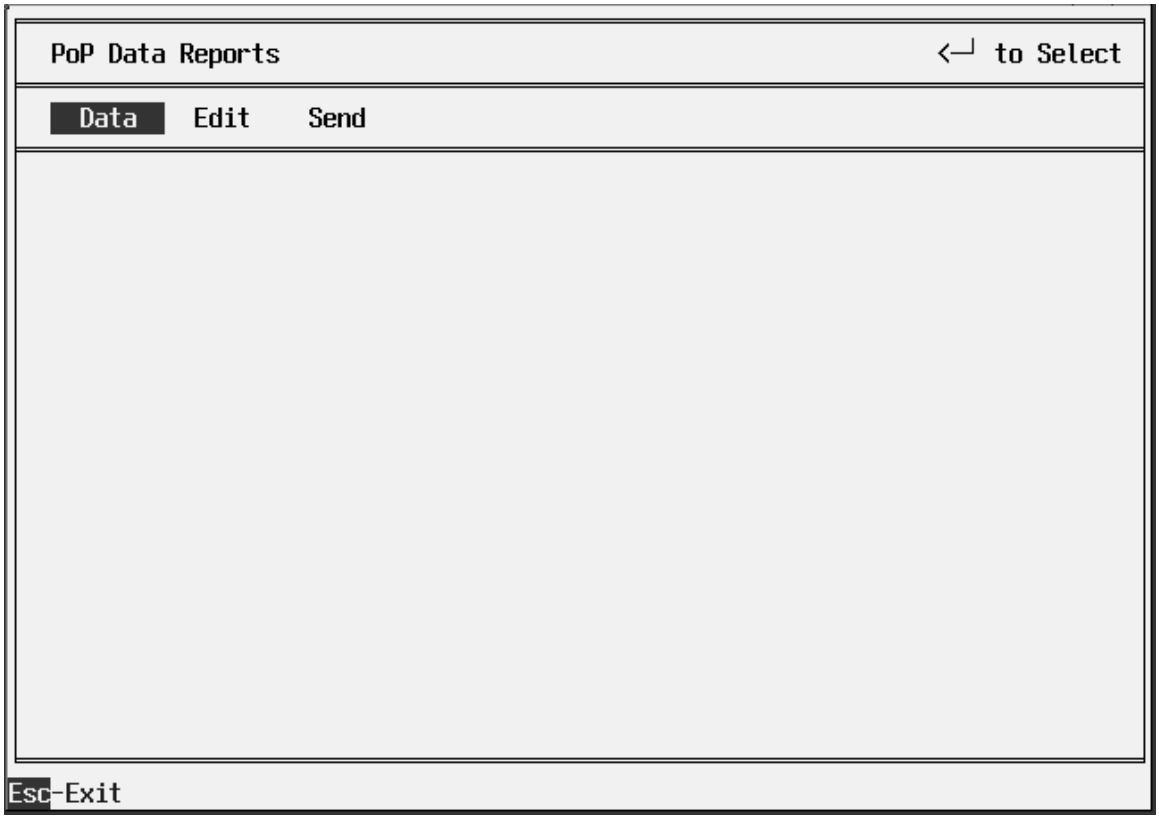
4. The appropriate report is generated and the PoP Main Menu reappears.

5. ***Print*** or ***View*** the report from the appropriate subsystem.

The **CLIP Report** subsystem contains a censor module which is used to mark a particular case ID as inactive. For example, when a patient dies or is lost to follow-up, their ID could be marked as censored for future reporting and data entry purposes. Once a case has been censored, attempts to enter a record for that case will invoke a warning message giving the data entry person the option to abort or continue with the entry process. Also, CLIP Reports generated after censoring will identify censored cases.

Print

This subsystem is selected to print files [.?RP] under Data, Edit, and Send categories.



The Data [*.?RP] category contains the audit trail for ***Verify*** [*.VRP], ***Update*** [*.URP] and ***Correct*** [*.XRP] files; and inventory [*.IRP] files.

The Edit [*.?RP] category contains Edit [*.ERP] files that are used when correcting errors detected during the ***Edit*** process.

The Send [*.?RP] category contains Prepare [*.MRP] files that hold data regarding records that have been processed through the ***Prepare*** subsystem.

1. Move to ***Print***, press *Enter*, and the PoP Data Reports screen appears.

2. Move to the appropriate category and press *Enter.*

3. Move to the desired file and press *Enter* to generate the printed copy of the report. (The filename begins with the 2-character form code and ends with the applicable extension.)

4. Press *Esc* to return to the PoP Data Reports screen.

5. Press *Esc* again to return to the PoP Main Menu.

View

This subsystem is selected to view files [.?RP] under Data, Edit, and Send categories.

The Data [*.?RP] category contains the audit trail for ***Verify*** [*.VRP], ***Update*** [*.URP] and ***Correct*** [*.XRP] files; and inventory [*.IRP] files.

The Edit [*.?RP] category contains Edit [*.ERP] files that are used when correcting errors detected during the ***Edit*** process.

The Send [*.?RP] category contains Prepare [*.MRP] files that hold data regarding records that have been processed through the ***Prepare*** subsystem.

1. Move to ***View***, press *Enter*, and the PoP Data Reports screen appears.

2. Move to the appropriate category and press *Enter.*

3. Move to the desired file and press *Enter*. (The filename begins with the 2-character form code and ends with the applicable extension.)

4. The file appears on the screen for viewing. Use the cursor keys as indicated at the bottom of the screen to move through the report.

5. Press *Esc* to return to the PoP Data Reports screen.

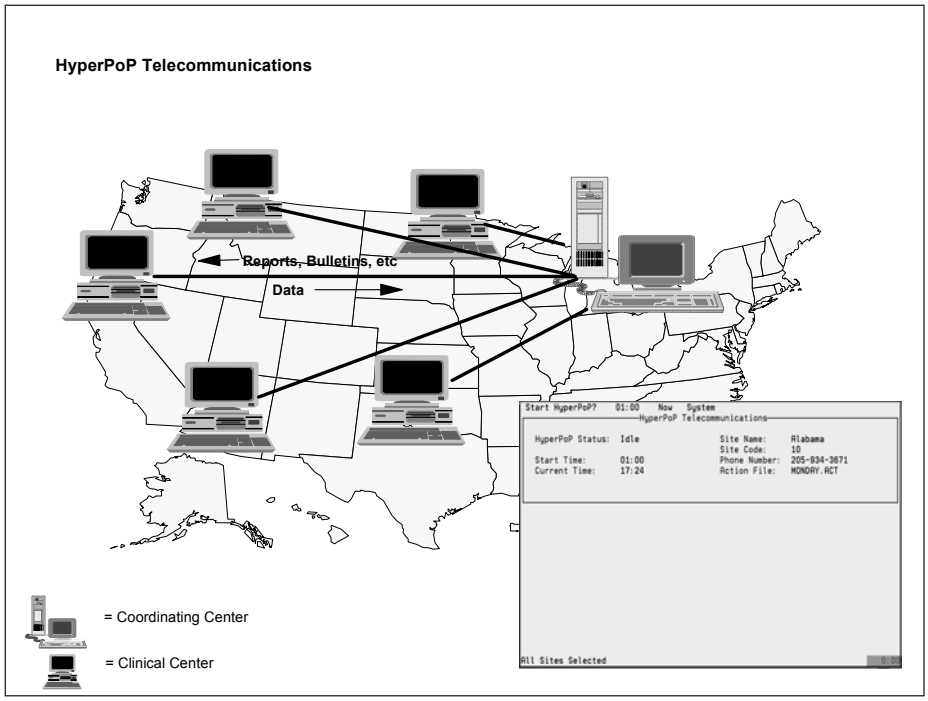
6. Press *Esc* again to return to the PoP Main Menu.

Chapter 7

Telecommunications Procedures

HyperPoP - Unattended Information Transfer

The HyperPoP telecommunications process facilitates information transfer between the Clinical Center and the Data Coordinating Center (DCC). On Monday evenings, new data entered during the previous week will be transferred to the DCC.



It is extremely important to the success of this unattended telecommunications process that the REACH computer system be powered up and down in the appropriate manner. If the computer is powered up or down by any other means, it may cause the telecommunications process to fail. In case of failure, you will be contacted by the DCC and telecommunications will performed at an alternative time.

How to power down the computer for evening transfer

1. Reboot the computer into DOS (the default for the BI-boot menu) and wait for the DOS prompt to appear.

2. Press the on/off switch, on the mini-tower, to the off position.

pcAnywhere - System Maintenance & Troubleshooting

During the course of this project, upgrades to forms and other PoP system files may be necessary. These upgrades, as well as certain technical support, will require that the Data Coordinating Center (DCC) have access to the Clinical Center computer system. pcAnywhere is telecommunications software which provides complete, high-speed PC-to-PC remote computing and general communications capabilities. The REACH computer system includes this software to be used for routine system maintenance and troubleshooting.

Use of pcAnywhere will be initiated in one of two ways: the Clinical Center will be contacted by the DCC to schedule a convenient time to perform system upgrades *or* the Clinical Center will contact the DCC to report a problem with the computer system.

To "Wait for a Call" from the DCC:

1. To initiate pcAnywhere, boot the computer in Windows XP. **Do NOT start Windows from either the *PoP Data Entry* or *DOS 6.22* boot options.**

2. Double click on the PCAnywhere folder and then click onto the icon labeled "modem."

3. The DCC can now initiate remote access to the center's computer and perform system maintenance or troubleshooting.

4. After the DCC has completed the remote operation, the Clinical Center should terminate or cancel the pcAnywhere session. The DCC will end the remote session and the center's PC will remain in the "pcAnywhere Waiting..." mode.

To "Cancel" pcAnywhere:

1. Click on the "pcAnywhere Waiting..." icon in the bottom left-hand corner of the monitor.

Chapter 8

Problem Reporting

Who to Call?

If you are experiencing any problems with the PoP Data Entry Software or the REACH computer system equipment, please contact the Data Coordinating Center (412) 624-4435.

Computer System Maintenance

Preventive and common sense maintenance must be exercised in caring for the equipment. The equipment should be protected as much as possible from dust and dirt. Please keep food and beverages away from the REACH computer system.

All on-site hardware service must be cleared with the Data Coordinating Center (DCC). The DCC will assist you with diagnosing the problem. If it is determined that a hardware error exists, you will be provided with instructions for obtaining on-site maintenance and repair.

Chapter 9

Edit Reports from the Coordinating Center

On a monthly basis, the Coordinating Center will execute editing programs on all data in the REACH database.

Edit types

Intraform Edits: The Intraform Edit reports check for missing values, inappropriate not applicable values, out of range values, and logical inconsistencies within forms. These edit reports are similar to those in PoP but more extensive.

Interform Edits: The Interform Edit reports check for logical inconsistencies between forms and time points..

These edits will search the data for problems such as:

- **missing** data
- **out-of-range** data points
- **dependency/logical mismatches** (e.g. The question "Does patient consent to be in study?" is marked "Yes", but data collector has checked some reasons for refusing consent)
- **Unresolved temporary data codes** (e.g. If a drug is not listed on the code list, the temporary code of "9999" will be recorded until a code is assigned)
- **Chronological inconsistencies** (e.g. An interview is after the date of data entry)
- **Calculation inconsistencies** (e.g. Errors in math calculationhese programs will search for both intraform (within a single form) and interform (across several different forms) inconsistencies.

The Edit Report

The report includes the Participant ID, an abbreviation of the form name/identifier, the variable name and label, the value recorded on the form, and a brief explanation of the error. However, when a 'Logic Check ' is recorded, the label does not match the variable name. For these checks information is provided to explain the 'Logic Check' instead of the variable name (see the REACH Code book for the form name/identifiers and variable names)

The reports also list information on data inconsistencies between data collection forms. For example, if there is an inconsistency between data recorded on the PR and the LE, the Form Name will be reported as PR/LE. Any Form Name that contains two form names is identifying an inconsistency between data recorded on those two forms.

Inconsistencies between initial Baseline data and Follow-up data are also contained in this report. Any Form Name that contains a number is identifying the order of the hospitalization. For

example, BA1/BA2 is a comparison where the number '1' represents the initial Baseline Form and the number '2' represents the first repeat form.

Values of A, B, C, and D represent missing, not applicable/not done, unknown, and refusal data, respectively. A response on a form that is left blank will be entered as missing (A) data. If you record not done or unknown for a response, the data are entered as B and C respectively. Our editing systems will always report missing (A) values as errors. Reporting of not applicable/not done, unknown and refusal responses is most often dependent on the question.

Resolving Edits

Reports detailing any inconsistencies will be e-mailed to the Data Manager every month for resolution. Reports will list the patient ID, the form(s) in question, the variable(s) in question, the current value, and a message indicating the problem (see Appendix ??? for sample Edit Reports).

Data collectors are to printout the Edit Report, retrieve the original form(s) from the patient file, review the problem(s) as stated on the report, consult the appropriate REACH personnel to correct the problem and make changes to the form(s) as necessary.

The method for making changes to a data collection form are as follows:

- Draw a large "X" through the incorrect answer
- mark and circle the correct answer on the form
- initial and date the correction

NOTE: If an item is determined to be correct as originally coded, the data collector should write "Bypass" on the Edit Report, initial and date it, and fax the report back to the data center. As with PoP bypasses, an Edit Bypass request form should be completed. Subsequent edit programs will not repeatedly report the inconsistency.

Any discrepancies, delinquencies, or errors which are included in the above reports will require the attention of the Data Manager, Data Collector and/or any certified REACH personnel who has authorization to make corrections. These issues must be resolved and the appropriate corrections made to the database. Unresolved issues will remain on the report until corrected. The Data Coordinating Center should be contacted if additional information is required.

Appendix A

Data Processing Log &
Cover Sheet of Data Collection Form

Data Processing Log

Form/battery: ❶____ ____

CERT. NUMBER	SYSID NO.	ID NO.	DATE OF FORM	ENTRY DATE	DATE VERIFIED	PoP EDIT DATE	CLEAN DATE	PREPAR E DATE	COMMENTS
❷	❸	❹	❺	❻	❼	❽	❾	❿	⓭

Cover Sheet of Data Collection Form

Completion Log		
	Person	Date
Data collected		__ __/ __ __/ __ __
Data entered		__ __/ __ __/ __ __
System ID		
Data verified		__ __/ __ __/ __ __
Data cleaned		__ __/ __ __/ __ __
Data transferred		__ __/ __ __/ __ __
Subject ID		

Appendix B

PoP Commands Quick Reference

Within PoP, the function keys (F1 through F10) execute specific functions within the various PoP environments. Sometimes the function keys are used in conjunction with other keys, such as the Alt, Shift, and Ctrl keys. When a function key is used in conjunction with another key, hold down that key and press the function key.

Data Environment

Entry, Verify, Update, Correct Subsystems

The following is a description of the functionality of specific keys within the Entry, Verify, and Update subsystems in the Data environment. The following function keys are active after a form has been selected.

[F5] enters the Missing value as defined for the study, when pressed.

[Alt][F5] enters the Missing value for the remaining fields in the frame when pressed.

[F6] enters the Not Applicable value as defined for the study, when pressed.

[Alt][F6] enters the Not Applicable value for the remaining fields in the frame when pressed.

[F7] toggles the Message Bar at the top of the screen from the field COMMENT display mode to the field RANGE display mode when pressed. Whichever mode is activated remains active until F7 is pressed again or a new participant record is selected.

[F8] within the ***Entry*** subsystem only, allows the user to toggle between DUP:ON and DUP:OFF

[F9] within the ***Verify*** subsystem only, allows the user to view identifying information about the current record in the Verify selection set.

[F9] within the ***Update*** subsystem only, allows the user to view any report in the Data, Edit, or Send print/view modules. Press Esc to return to the Update subsystem. (This feature is especially useful when editing participant records).

[Esc] places the cursor at the Command Bar at the top of the screen when pressed.

Cursor Keys

[→] the right arrow key is used to edit a highlighted field. Use [→] to move the cursor to the right within a highlighted (reverse video) field.

[←] the left arrow key is used to edit a highlighted field. Use [←] to move the cursor to the left within a highlighted (reverse video) field of a participant record.

[↑] the up arrow key is used to move the cursor within frames and pages of a participant record. Use [↑] to move the cursor up to the previous field. If the current field is empty, the Missing value is entered in that field when the up arrow key is pressed.

[↓] the down arrow key is used to move the cursor within frames and pages of a participant record. Use [↓] to move the cursor down to the next field. If the current field is empty, the Missing value is entered in that field when the down arrow key is pressed.

[Page Up] the Page Up key allows movement between frames and pages of a participant record. Use [Page Up] to move the cursor up to the last field on the previous frame. If the current field is empty, the Missing value is entered only in that field when Page Up is pressed.

[Page Down] the Page Down key allows movement between frames and pages of a participant record. Use [Page Down] to move the cursor down to the first field on the next frame. The Missing value is entered into all the empty fields in a frame when Page Down is pressed.

[Home] the Home key is used to edit a highlighted field. Use [Home] to move the cursor to the beginning of a highlighted field.

[End] the End key is used to edit a highlighted field. Use [End] to move the cursor to the end of a highlighted field.

[Delete] the Delete key deletes the character immediately above the cursor.

[Insert] the Insert key toggles the typewriter keys from typeover mode to insert mode. Whichever mode is activated remains active until the Insert key is pressed.

Numeric Keypad

The Num Lock key activates the numerals on the keypad. If the Num Lock key is not active, the numeric keypad supports the cursor movement function.

[+] the plus key is used to browse the list of values (codes) for an enumerated type in a forward direction.

[-] the minus key is used to browse the list of values (codes) for an enumerated type in a reverse direction.

[/] the backslash is used to separate the month, day, and year of a date

[Enter] the Enter key enters the data in a highlighted field.

[Del] the Del key deletes the character immediately above the cursor

Typewriter Area

The typewriter keys operate like the keys on a standard typewriter. The default status of the typewriter keys is typeover mode. The Insert key is pressed to toggle the typewriter keys between insert mode and typeover mode.

[Enter] the Enter key enters the data in a highlighted field.

[Backspace] the Backspace key deletes the character to the left of the cursor.

[Ctrl][Backspace] the Backspace key is used in conjunction with the Ctrl key to deletes all the data in a highlighted field.

The numeric keys in the typewriter area of the keyboard can also be used to select numeric values. Use the plus [+] and minus [-] keys to browse the list of values (codes) within an enumerated type. (The Shift key must be depressed for the plus [+] key to operate with enumerated types).

Edit Subsystem

The following is a description of the functions of specific keys within the Edit subsystem in the Data environment. Once the Edit subsystem and the applicable form type have been selected, these keys perform the functions indicated when processing edits for participant records that have been processed through the Verify subsystem.

[Esc] presents the option to quit edits (yes) or return (no) to the Micro-Edits screen.

[Enter] presents the option to run edits (yes) or return (no) to the Micro-Edits screen.

[→] the right arrow cursor key moves the cursor to the edit set to the right of the cursor.

[←] the left arrow cursor key moves the cursor to the edit set to the left of the cursor.

[F1] selects the edit set at the cursor location for all records of the selected form that are ready to be edited.

[F2] selects all edit sets for all records of the selected form that are ready to be edited.

Prepare Subsystem

The following is a description of the functionality of specific keys within the Prepare subsystem in the Data environment. These keys are active after Prepare is selected and the Form Selection screen appears.

[Enter] marks the selected (highlighted) form with an asterisk (*). Depressing the Enter key again removes the asterisk. The asterisk indicates that participant record(s) for this form are ready to be Prepared.

[F10] processes the participant record(s) as Prepared for the forms marked with an asterisk (*).

[Alt][F10] processes all participant records that have passed through the Entry cycle (Entry, Verify, Edits) as Prepared for all forms.

[Esc] places the user at the Main Menu.

[↑] moves the cursor up through the Forms Selection screen

[↓] moves the cursor down through the Forms Selection screen

[Page Up] moves the cursor to the first form on the previous page of the Form Selection screen

[Page Down] moves the cursor to the first form on the next page of the Form Selection screen

Reports Environment

Print and View Subsystems

The Print subsystem allows the user to print reports. The View subsystem allows the user to view reports. These reports are grouped as Data, Edit, Send, User, and Misc. Within these subsystems, the cursor keys, the space bar, and the first letter of the preferred report group are pressed to position the cursor at the appropriate group. The Enter key enters the selected report group for printing or viewing.

Within a report group inside of View, the down arrow [↓], Page Up, Page Down, Home, and End cursor keys are the only active keys.

Data

The Data report group allows the user to print or view Verify audit [*.VRP] reports; Update audit [*.URP] reports; Correct audit [*.XRP] reports; and Inventory status [*.IRP] reports. Select the 2-character form code with the appropriate extension to print or view the desired report.

Edit

The Edit report group allows the user to print or view edit [*.ERP] reports. Select the 2-character form code with the applicable edit set to print or view the desired report. (e.g., XXEDIT1.ERP to print or view the edit status and errors for all XX Form records for the first edit set).

Send

The Send report group allows the user to print or view send [*.MRP] reports. Select the 2-character form code and extension to print or view the desired report.

Appendix C

Edit & MMSE Bypass Request Forms

Edit Bypass Request

Date __ __ / __ __ / __ __ __ __ **Site Number** ___ **Initiator** __ __ __

Sysid	Key1	Key2	Key3	Battery/ Form	Attribute name	Value	Explanation
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____
_____	______	______	______	______	______	______	____

EDC use only:

Date bypassed __ __ / __ __ / __ __ __ __

Initiator: ____________________________

Bypass Request for (CR) with MMSE score = 0 and bed bound

Date __ __ / __ __ / __ __ __ __ **Site Number** ___ **Initiator** __ __ __

Subject ID __ __ __ __ __ __ __ **SysID** __ __ __

1. Does question 15 and 15.1 of the MMSE equal "YES"? ( ) No ( ) Yes

2. Verify that the total MMSE score equals zero by entering the values of all of the sub-scores.

Sub-score variable	Value	Sub-score variable	Value
DTSCR	_____	NTSCR	_____
BLSCR	_____	RTSCR	_____
OBSCR	_____	PPSCR	_____
MHSCR	_____	EYSCR	_____
LDSCR	_____	WTSCR	_____
APSCR	_____	CPSCR	_____

EDC use only:

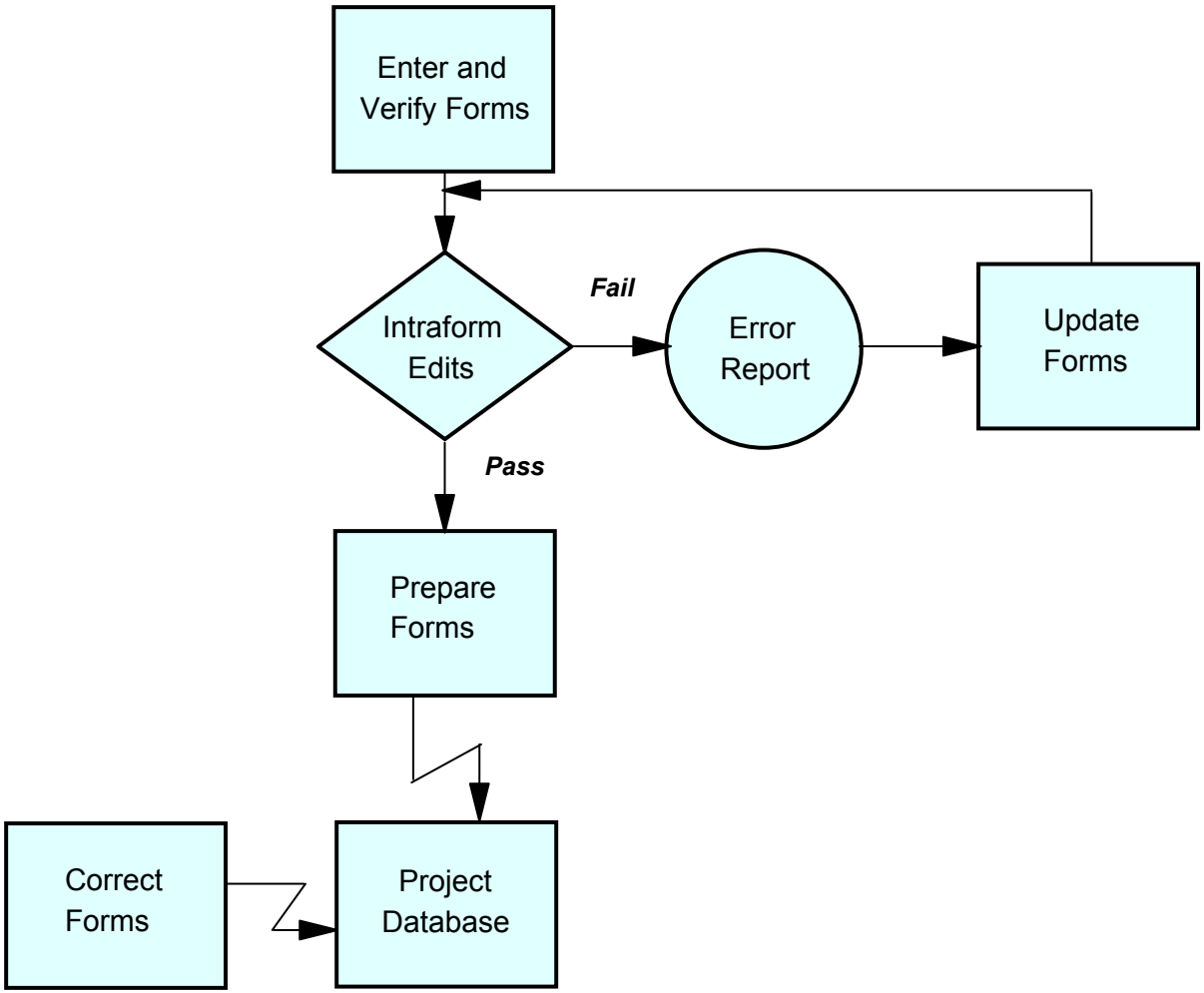
Date bypassed __ __ / __ __ / __ __ __ __

Initiator: _____

Appendix D

PoP Data Flow

PoP Data Flow



Appendix E

Missing, N/A, Unknown Values
Example Table

Missing, Not Applicable, Unknown Values
Example Table

		F5 key	F6 key		
Variable Type	Explanation	Missing Value	Not Applicable Value	Unknown Value	Refused
Integer	Whole Number	-1	-2	-3	-4
Real	Number with a Decimal Point	-1	-2	-3	-4
Text	Alphanumeric Characters	-1	-2	-3	-4
Date	mm/dd/yy	01/01/1801	02/02/1802	03/03/1803	04/04/1804
Time	hh:mm	99:00	98:00	97:00	96:00
Enumeration	Integer	-1	-2	-3	-4

Appendix F

Unpacking Checklists

Carton Checklist

Carton 1 of 4

Site: _____

Name of Data Manager: _____

(If there are missing or damaged items…)

Please return to:

REACH II Coordinating Center
Attn: Rocco Mercurio

Facsimile: 412-624-5268

- ☐ PC
- ☐ MOUSE
- ☐ MOUSE PAD
- ☐ KEYBOARD
- ☐ POWER CORD (BLACK)
- ☐ 6 FT TELEPHONE CORD
- ☐ 2 ZIP DISKS
- ☐ 1 MODEM CABLE
- ☐ 1 PARELLEL PRINTER CABLE
- ☐ 1 U.S. ROBOTICS EXTERNAL FAX MODEM

Comments:

(If there are missing or damaged items…)

Please return to:

REACH II Coordinating Center
Attn: Rocco Mercurio

Facsimile: 412-624-5268

Carton Checklist
Carton 2 of 4

Site: _____

Name of Data Manager: _____

☐ MONITOR

☐ MONITOR CABLE

☐ POWER CORD (WHITE)

Comments:

(If there are missing or damaged items…)

Please return to:

REACH II Coordinating Center
Attn: Rocco Mercurio

Facsimile: 412-624-5268

Carton Checklist

Carton 3 of 4

Site: _____

Name of Data Manager: _____

☐ APC UPS (MUST CONNECT BATTERY)

☐ SPEAKERS

Comments:

(If there are missing or damaged items…)

Please return to:

REACH II Coordinating Center
Attn: Rocco Mercurio

Facsimile: 412-624-5268

Carton Checklist

Carton 4 of 4

Site: _____

Name of Data Manager: _____

☐ HP DESKJET 940C PRINTER

☐ 1 BLACK TONER CARTRIDGE

Comments:

Appendix G

Reordering Supplies

Details on this process will be available upon completion of the site PC configuration.