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Summary Edits

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25. Data Management

This chapter outlines the responsibilities of the Clinic Coordinator, data coordinator, and/or data entry technician at each site with regard to data management. In addition to this chapter, information is also available in the user's manuals for the various data entry and data management systems, as well as in the two training slide shows that are posted on the PREMIER web site.

Staff ID's

All PREMIER staff must have a PREMIER staff ID number. To obtain a staff ID number, the Clinic Coordinator should e-mail the Project Secretary at the Coordinating Center with the following information:

- First and last name
- Project job title
- Address (work)
- Phone number (work)
- Fax number (work)
- E-mail address (work)
- Whether or not the staff person will require access to the PREMIER web site

The Coordinating Center will assign a new number within 24 hours of receipt of this information. Web site access will be set up within 7 days.

Quality Control Methods Prior to Data Entry

The Clinic Coordinator will need to manually employ the quality control methods outlined below in real-time before the participant leaves the intervention site for both the batch-entered and centrally entered data. These methods include:

Patient identification and record linkages. The ID in each form needs to be checked for transposition errors. The format must be "aaaaa#####." The initial 3 alpha characters must be the same as the first three letters of the participant's last name. The next 2 alpha characters must be the same as the first two letters of the participant's first name. The last five digits are unique identifying numbers for that participant. Each page of multi-page forms must have the same ID number. ID labels can be generated after each screening visit, before run-in and before each intervention period to help assure accuracy (refer to PREMIER Data Entry System User's Manual for further details on patient identification).

Legibility. All data must be checked for illegible handwritten replies, spelling errors, etc. All checked response boxes must have checks within designated spaces. Check to be sure that the forms are filled out in pen. Forms filled out in pencil are often difficult to read.

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Form admissibility. All forms must be checked to determine if the form was completed within the specified time window. All forms must be checked to assure that the completed form is the correct one for the indicated visit or activity.

Missing information. All forms must be checked for unanswered items or sections of an otherwise completed form. The Clinic Coordinator must assure that all necessary forms have been completed for the indicated visit or activity before entry of the individuals visit data can begin. There are a few forms that are allowed to have missing data (patient history, psychosocial forms). This is indicated in the coding instructions for these forms. All other PREMIER data collection forms must be complete prior to data entry.

Consistency. All data must be checked to assure that information supplied in one section is consistent with data in another section of the same form. All forms for the same participant for a given visit must be checked to assure consistency. Skip patterns on forms should be checked for the correct data flow.

Range and inadmissible codes. All data must be checked to assure they do not contain values either outside specified ranges or undefined alphabetic or numeric codes.

The individual coding instructions that are attached to the relevant forms provide detailed instructions for coding and review procedures for each study form. Be sure to review the coding instructions for the form before completing the review process. See the section below for details on how to correct errors on the forms.

Data Edits on Forms

It is important to use the following process when making corrections to study forms to assure the accuracy and validity of the data.

- Participant responses should never be obliterated.
- A single slash should be made through the incorrect response and the correct response written next to it.
- The reviewer's initials, date of correction and an explanation of the edit should be written next to the data field that is being edited.

For example:

92 90 RL 8/5/99 Addition error

If a participant makes a correction to a form, the Clinic Coordinator should

- Verify that the response is clearly written.
- Make a single slash through the old response.

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- The reviewer's initials, date of correction and the notation "participant correction" should be written next to the data field.

For example:

YES NO
 RL 8/5/99 participant correction

Data Entry

All forms will be batch entered by a PREMIER certified data entry technician. Range and logic checks are built into the system to try to deal with form discrepancies before entry. The data entry technician should enter the data as is from the form. The values not meeting the defined range and logic check criteria normally can not be entered. For some fields, it may be possible to override these checks. See the data entry user's manual for information on overrides.

The goal for data entry is to be current within two weeks in order for reports to be accurate.

Data Entry Flow

All data collection forms for a visit should be entered before the corresponding visit/flow forms. All forms including the visit/flow forms should be entered before any closeout forms.

For example: You just finished SV1 for a participant. The participant was eligible after the visit, but called up a day later and refused to continue.

1. Enter the BP form
2. Enter the Rose Questionnaires
3. Enter the Eligibility Questionnaire
4. Enter the SV1 Visit Form
5. Enter a Participant Closeout Form

The only exception to this is the series of forms collected prior to randomization that do not have to be entered prior to randomization (#20, 21, 23, 24, 25, 26, 27, 45, 46, 47, 48, 49). These forms must be collected/completed prior to randomization, but they do not have to be entered prior to randomization. However, it is recommended that the forms be entered prior to randomization whenever possible.

Quality Control Methods Following Data Entry

As the data entry technician enters the data, any values that do not pass the range or logic checks defined by the system will trigger a prompt to the data entry technician to confirm that it was

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correctly entered. If it is not a data entry error and the technician confirms that it is entered as coded, the form will be rejected. At this point the technician can either flag the form for review, or in some cases, the override function can be used to enter the values as is.

Data Edits to Database

Most corrections can be made at the sites using the data edit feature in the PREMIER Data Entry System. See the Data Entry User's Manual and the Data Management User's Manual for details on these processes. Certain types of corrections will need to be made by the Coordinating Center due to potential conflicts in the data fields (e.g. a participant was closed out in error).

To have a correction made by the Coordinating Center, send an e-mail or fax to the Data Manager at the Coordinating Center with the participant ID, the name of the form, the date on the form, the data field in error and an explanation of the correction. For complex forms/edits, fax a copy of the form along with the request. The Coordinating Center will make the change and send an e-mail confirmation that the change has occurred. The Clinic Coordinator should also make these changes on the relevant participant data form (see "Data Edits of Forms" section above).

Data Validation

The primary measures of data integrity rely on the verification of data. Verification is a comparison of data before a transition (data entry) to the result after the transition to assure a one-to-one correspondence and assure that the transition process was "true". In order to assure the accuracy of the PREMIER data, the Coordinating Center has set up a two step process. 1) Validation of the data by the Coordinating Center completed at the end of each cohort and as a part of a site visit. 2) Validation completed by the individual sites.

Data Validation at the CC

Data validation will be done by the Coordinating Center to assure validity of the data. The Coordinating Center will request the following at the end of each cohort:

- All Blood Pressure forms for randomized participants
- Three charts chosen at random from randomized participants. This includes all clinical and intervention forms entered into the PREMIER data entry system.

Additional validation will occur as a part of site visits. The Coordinating Center will request a random set of forms (from both randomized and non-randomized participants), as well as three random charts from each site.

The site should copy the requested forms and complete the accompanying shipping log (form #36) and send to the Data Clerk at the Coordinating Center. A summary error report and a detailed error report will be compiled for the site. The Clinic Coordinator at the site and the Data

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Clerk and Data Manager at the Coordinating Center will then work together to solve any discrepancies that may have occurred. The Clinic Coordinator is responsible for seeing that corrections are made to the forms if needed (see data edits on forms section). Corrected copies of the forms should be faxed or mailed to the Coordinating Center. Changes that need to be made to the database should be clearly noted on the form. The Coordinating Center will file all copies of the forms in the Coordinating Center's participant chart.

Data Validation by the Site

The Data Management system has several data validation reports available for the sites to validate their own forms. There are reports to view all screening data and all blood pressure data for randomized participants. There is also a report to print all intervention data that is located in the Intervention system. Unblinded staff can only access this report.

Sites also have the option of printing data for specific forms one participant at a time using the view data feature in the Data Entry system.

The following list is a guideline for the amount of data validation to be conducted at the individual sites:

- All screening data for randomized participants
- A random sample of other forms for randomized participants

Archiving

A copy of each site's master database will be transferred nightly via phone lines from the site computer workstation to the coordinating center's file server. Archiving will occur automatically at the coordinating center, which will contain the previous day's data from the sites on-line and all historical data off-line. The historical data is easily obtained if restoration is needed. In addition, all data collection forms need to be archived for the life of the study in hard-copy form so that copies may be sent to the coordinating center as needed for data management. Requests for copies of archived data will be made on a form-by-form basis by the Coordinating Center.

Use of PREMIER Computing Equipment

Kaiser Permanente Center for Health Research (CHR), as PREMIER Coordinating Center, is supplying the following equipment for use by PREMIER Study intervention sites:

- 1 Compaq Deskpro EN 6266
- 1 Lexmark Optra S1855
- 1 APC Universal Power Supply
- All Required peripherals, batteries, cables, and connectors

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CHR retains rights of ownership for this equipment and all installed software. The equipment and software are provided for the sole purpose of conducting PREMIER activities as specified in the PREMIER Manual of Procedures (MOP). These activities include, but are not limited to, study communications, data entry, data transfer, reporting, data edits, and data repairs. This equipment will be returned to the CHR upon demand.

Additional uses or modifications of the equipment, software, and/or configuration, are not authorized, except as approved by the Coordinating Center Data Manager, and are considered a violation of study procedures. Non-authorized use or modification include but are not limited to: personal use of equipment or software, making and/or distributing unlicensed copies of PREMIER study software, installing additional software, making configuration changes to equipment or existing software, or connection to non-study networks.

Prior to action, the PREMIER Coordinating Center Data Manager must authorize any request for exceptions to this policy.

Other PREMIER Technical Manuals

Please refer to the following manuals for technical details/instruction.

- General Instructions for the PREMIER Workstation
- PREMIER Data Entry System User's Manual
- PREMIER Data Management System User's Manual
- PREMIER Intervention System User's Manual
- PREMIER Lab Tracking System User's Manual
- PREMIER Certification System User's Manual

These manuals should be filed in the "Computer Workstation User's Manual" binder supplied by the Coordinating Center. The manual should be updated with any revised manuals shipped by the Coordinating Center. The binder should be located near the site computer workstation for easy access by staff.