CHAPTER 23

DATA MANAGEMENT

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CHAPTER 23

DATA MANAGEMENT

23.1. OVERVIEW

The LIFE Study data management system utilizes a Web browser-based interface, with electronic data being stored and managed centrally at the coordinating center. This system facilitates the rapid, efficient collection of clinical information using the existing technology of the Internet as well as the ease of use and familiarity of Web browsers. The data entry screens, which are very similar to the study forms, have been developed using hypertext mark-up language (HTML). Participant data entered by clinic staff will reside on an NT server at the coordinating center, with Cold Fusion middleware providing connectivity to the SQL Server database. Data security in the webbased data system uses 128-bit encryption and Secure Socket Layer (SSL). Recovery from disasters such as natural phenomenon (water, fire, or electrical) is possible through the ability to reconstruct both the database management system and the data up to the last backup through the use of nightly backups. This will ensure optimal recovery of data systems in the event of a disaster. Back-up tapes are kept in a locked, fire and waterproof storage cabinet away from the computer room. Additional back-up tapes are stored at another location on the Wake Forest University School of Medicine campus.

23.2. LIFE Study DATA MANAGEMENT SYSTEM

23.2.1. Login

Microsoft Internet Explorer is recommended for optimal viewing of the LIFE Study Web Site. Once either the Internet Explorer 5.X or Netscape 6.0 is invoked on the client computer, the following URL (<u>web address</u>) should be entered:

http://www.thelifestudy.org/index.cfm

The LIFE Study home page will appear. The user should then click on Login. The login screen will then appear. This screen instructs the user to enter username and password into the appropriate fields. The system is password-protected in order to prevent unauthorized access. Once a valid username and password combination has been entered and verified, the user can click on the login button below those fields and proceed to the study site map. A username and password is provided by the coordinating center to all study personnel. Users should always log in using their own user name and password. Web activity, including access to the data management system, is tracked on an individual basis, using the individual's staff identification number. Passwords may be changed by clicking the Change Password option on the Log In page. Passwords must be at least six characters and contain a minimum of one letter capitalized and one number. To further enhance security, data encryption techniques during transmission have been employed.

23.2.2. Data Entry Screen Layout

A data entry screen is the electronic equivalent of a paper form. It is made up of three sections: 1) the participant identification section, located at the top left side of the screen, displays participant-specific information; 2) the form information section (or header), located at the top right of the screen, where identifying information about the type of form is entered; and 3) the data section, located below the form information header, where the form contents are entered.

23.2.3. System Features

The system allows for data to be entered in HTML fields that are similar in appearance to the hard-copy form. The data management system performs several validation checks upon submission of the form. Data must match the correct type (numeric data in numeric fields), and required fields must be entered. When a form is submitted, an alert message appears on the top left hand side of the form if any required fields have been omitted or are outside a specific range.

Eligibility checks are performed on the screening forms. Each eligibility criterion is validated when a form is submitted. If a value for an eligibility item that has been entered is not in the desired range, an error message will be displayed in red on the top left hand of the screen. The field to be corrected will be marked by a red dot on the form. If a mistake has been made, correct the initial value. If the data entered is not required for study eligibility but is not in the desired range, a warning will be issued on the top left hand screen in orange. Forms with errors (in red) can not be saved. Forms with warnings (in green) can be submitted by left clicking on the submit with warnings tab.

The main types of fields that appear on the data entry screens are:

	Select boxes:	for questions where only one response is acceptable
Text boxes:		for entering text or numeric data such as age, weight,
		height, etc.
	Checkboxes:	for questions where multiple answers are acceptable
	Date fields:	for fields such as date of form or date of birth

Visit types* are indicated by the following codes:

- TSI
- SV1
- SV2
- F03
- F06
- F09
- F12
- F15
- F18
- PRN

* Applicable follow-up visit codes will be added as the study progresses. FV indicates follow-up visits.

Special Use Forms:

The "As Needed" area houses all forms included those not linked to a specific visit. These include, but are not limited to, Participant Status Change, Event Tracking, Unscheduled Visit, Spontaneous Notification of Event, Injurious Fall or Fracture. If the form name has New to the left, this indicates that the form may be completed multiple times for the participant. Previously entered data for the participant may be viewed or edited by clicking on the Form Completed date that is listed to the right of the form name.

Keypad numbers on the right side of the keyboard will select answers in select boxes if "Num Lock" is on, i.e.; 1=Yes, 2=No.

After entering data, use the "Tab" key to move to the next field. To move backwards, press the "Shift" and "Tab" keys simultaneously.

The data management system automatically formats dates with slashes as they are entered. A date that is entered as 060601 will automatically be displayed as 06/06/01. Enter two digits for month and day. Use leading zeros in date fields when appropriate. The year can be two or four digits.

Information in "For staff use only:" boxes should be entered.

In order to distinguish between missing and non-missing data, the data management system sets all blank data items to missing by default when a form is saved. Fields for which no data have been entered are assigned a value of "-9". A code for permanently missing data is a value of "-6. Items that are refused to answer or unknown by the participant are a value of -7.

Items that are answered "yes" are a value of 1, items that are answered "no" are a value of 0.

23.2.4. Accessing the LIFE Study Data Management System

Upon logging on to the LIFE Study Web Site, click on "Data Entry Menu" to the right on the site map. Access to this area is limited to staff members who have completed data entry certification (see Appendix D). The Data Entry Home Page (Figure 1) will appear. The system allows access to Study Forms, the Participant Visit Schedule and the Reports module.

Figure 1

Identify the Field Center location of the Participant to be entered.			
Field Center Location	Participant ID		
0 - Select One	Submit		

Initializing A New Participant

New participant data is entered into the LIFE website by first assigning a PID and an acrostic to the participant. The PID, is assigned using the labels generated by the LIFE Label Program as described in Appendix C. The acrostic is assigned as designated in Appendix C.

Study Forms

Study Forms lists all study forms by visit. By entering a participant identification number (herein called "PID") and the participant's acrostic and selecting a visit on the Forms page, the associated forms for the visit will be displayed. (Figure 2)

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The barcode gun can be used to scan in the PID from the participant label or simply enter the PID and acrostic. If the barcode gun does not scan correctly or if an incorrect PID or acrostic is typed, delete the fields by highlighting with the left button of the mouse and using the delete function on the keyboard.

Return to participant entry					
Participant ID	Acrostic	stic Randomized			
T10001	SMIJA	No Eligible for randomization?			

Visit Name	Date Target
<u>Telephone Screening Visit</u>	
Participant Orientation	
<u>Screening Visit 1</u>]
<u>Transitional</u>]
Screening Visit 2/Randomization]
First Intervention Visit	
<u>3 Month Telephone Follow-up</u>]
<u>6 Month Follow-up</u>]
<u>9 Month Telephone Follow-up</u>]
12 Month Follow-up]
<u>15 Month Telephone Follow-up</u>]
18 Month Follow-up/Close-out]
End Point Status Follow-up]
Non-Scheduled Visit]
<u>As Needed</u>]
SAE Review	

After entering the PID and acrostic the page in Figure 2 will be displayed.

Select type of visit to begin entering forms for the selected participant. Once the visit has been selected, a range of forms for that visit will be displayed. If the form has been entered for the participant a check will be displayed in the column under entered.

Select the form to be entered. Left click on the form name. (Figure 3)

Figure 3

Return to visit menu				
Participant II	Acrostic	Randomized		
T10001	SMIJA	No	Eligible for randomization?	

Visit Detail	
Screening Visit 1	
Forms	Entered
400 Meter Walk (v1.7)	
Ancillary Study Enrollment	
Blood Pressure, Radial Pulse and Weight (<u>v1.5)</u>	
Body Height	
Contact Information (v1.2)	
Demographics (v1.2)	
Disability (v1.2)	
Electrocardiogram (v1.5)	
Main Study (Informed) Consent	
Medical and Hospital Admission History	
Medication Inventory	
Missed Screening Visit	
MMSE (v1.2)	~
Physical Exam (v1.7)	
Process Measures	
Screening Visit 1 Checklist (v1.2)	
Short Physical Performance Battery	1
Short Physical Performance Battery Consent	

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Participants must be randomized within 28 days from the date of main study consent (400 Meter walk) to avoid re-screening the participant. The window is calculated by adding 28 days to the "Date of 400 Meter Walk" entered on 400 Meter Walk Form . This is the estimated date of randomization. If a participant falls outside the 28 day window, a "Re-screen Participant" link appears in the Randomization Status section. Re-screening means that all forms completed up to that point must be re-completed and data entered.

The eligibility status of an entered participant may be checked at anytime by left clicking on "eligibility" next to the PID. The screen will show any items outstanding for eligibility including complete forms and specific values. See Figure 4.

Figure 4

Participant P10002 is NOT eligible for random assignment to treatment arm(s)
Participant is at site 1 based upon the PID.
Participant gender is Male
Form Field Message
frm_400MWalk.cfm No records returned from the DB
frm_shrtPhysPerformBattery.cfm No records returned from the DB

SAE Review:

The SAE (Serious Adverse Event) Review link on the participant's forms page navigates to a listing of forms for a participant that has reported an adverse event. The forms listed are but not limited to: Physical Exam, Medical and Hospital Admission History, SPPB, Adverse Event and Event evaluation. (Figure 5)

Figure 5

Visit Detail	
SAE Review	
Forms	Entered
400 Meter Walk (v1.3)	
400 Meter Walk (v1.7)	
Adverse Event	
Blood Pressure, Radial Pulse and Weight (v1.4)	
Blood Pressure, Radial Pulse and Weight (v1.5)	
Disability (v1.2)	
Electrocardiogram (v1.1)	
Event Evaluation	
Health Care Utilization	
Late Life Disability (v1.2)	
Medical and Hospital Admission History	
Medication Inventory	
Physical Exam (v1.3)	
Physical Exam (v1.4)	
Physical Exam (v1.6)	
Process Measures	
Short Physical Performance Battery	

23.2.5. Randomization

Once eligibility is determined on Screening Visit 1 forms, Screening Visit 2 forms and the Eligibility Checklist, the participant may be randomized into the study. If all screening forms are marked 'Eligible' a "Randomize" link will appear under Randomization Status (Figure 5). Click the "Randomize" link **once** to initiate a request to confirm randomization.

Figure 6

Participant P10003 is eligible for random assignment to treatment arm(s) Participant is at site 1 based upon the PID. Participant gender is Male

Randomize

Left click the "REALLY SURE you want to Randomize", once to randomize to a treatment arm of the study. (Figure 6). At this screen email notifications of randomizations can be entered.

Figure 7

Participant T10368 is eligible for random assignment to treatment arm(s) Participant is at site 1 based upon the PID. Participant gender is Male <u>Return to Visits</u>

Press if you're REALLY SURE you want to Randomize...

Enter any e-mail addresses separated by commas that you would like notified of this event. Remember that in today's increasingly SPAM averse environment, we cannot guarantee that this nofication will be received in every case. Therefore, please depend upon other means for official notification. At most, this notification facility should be considered a convenience only.

Your "from" email address will be included in the list of adressees for confirmation purposes.

То:

From:

Randomization status is displayed once the randomization status is selected.

(Figure 7) Please print the randomization assignment and place in participant's file.

Figure 8

Participant T10372 is eligible for random assignment to treatment arm(s) and has been randomized. Participant is at site 1 based upon the PID. Participant gender is Male <u>Return to Visits</u>

Randomization:	
Site:	Cooper
Gender:	Male
Randomized To:	Education
Additional Sub-randomization:	None
Date of Randomization:	2004-03-08 18:27:17.263

After randomization, the Randomization Status (Figure 7) on the Eligibility Status page will display the date of randomization. Eligibility data on randomized participants may be viewed but not edited.

23.2.6 . Intervention Tracking System

The Intervention Tracking System can be accessed by left clicking on the Intervention Tracking System link on the middle toolbar, right side. This will immediately display the five forms used in the tracking system and the demographic information for the participant. (Figure 8).

Figure 9.0

Physical Activity Session Monthly Physical Activity Log

Information Session Missed Visit Clinical Notes

Demographic Information

Participant ID	Acrostic	
Passed from previous page	Passed from previous page	
Name:		
First: M.I.:	Last:	
Address:		
Address 1: Address 2: City:	State:	Zip Code:
Phone Number:		

Gender:		
Male/Female:		
Age:		
Age:		
Education:		
Years of Education:		
Baseline EPESE Score:		
Score:		

Physical Activity Session Summary

Physical Activity 5	ession Summa	ary				
PID Date	Study Phase	Start Pedometer Reading	Exercise Location	Etc.	Etc.	-
1. P10001 02/18/0	4 2	45,333	Treadmill	blah, blah	blah, blah	
2. P10001 04/18/0	4 2	25,773	Track	blah,	blah,	•

PID	Date	Week 1 Steps	Week 2 Steps	Week 3 Steps	Week 4 Steps	Week 5 Steps
. P10021	02/18/04	40,167	45,333	41,567	37,988	10,230
2. P10021	04/18/04	22,178	25,773	30,981	33,653	34,886

Information	Session	Summarv
n normanion.		o annairte

Missed Visit Summary

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Monthly Activity Log Summary							
PID	Date	Week 1 Steps	Week 2 Steps	Week 3 Steps	Week 4 Steps	Week 5 Steps	4
1. P1002	1 02/18/04	40,167	45,333	41,567	37,988	10,230	
2. P1002	1 04/18/04	22,178	25,773	30,981	33,653	34,886	
							-

Information Session Summary

Missed Visit Summary

Clinical Notes Summary

To access the forms for Intervention Tracking, left click on the form name. Information is entered into the form and when completed, left click on "Submit" at the bottom of the form.

23.2.7. Reporting

Numerous reports have been generated and are available under Reports on the website. The current list of web reports is shown in Figure 9. Each of the web reports covers a different area of concern for the study. Many of the reports contain study-wide data while others_are clinic-specific.

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Figure 10.0

General Reports

<u>(admin)</u>

(1) Recruitment Progress
(2) Weekly Telephone Screening Summary
(3) Cumulative Number Telephone Screened
(4) Weekly Randomization Summary
(5) Randomization Summary
(6) Cumulative Randomization vs. Study Goal
(7) Randomization Summary by EPESE Score
(8) Enrollment vs. Recruitment Goals
(9) Exclusions by Visit
(10) Listing of Exclusions (Screening Visit One)
(11) Breakdown of Race by Gender
(12) Recruitment Strategies for All Participants Eligible After Telephone Screening
(13) Staff Certifications By Site
(14) Form Warnings Frequency by Site
(15) Selected Demographic Characteristics: Screened and Randomized Participants

23.2.8. Data Quality Control

Data quality control is checked during site team visits and periodic document reviews. As detailed in chapter 24, Quality Control, DMAQC site team members review ten percent of randomized participants charts for data accuracy. Online data is preprinted from randomly selected PID's and during the site visit the data is compared with participants charts. Results are reported through the site visit team report prepared at the conclusion of the site visit.

Data Cleaning

The Data Cleaning is a web-based application designed for the purpose of validating data that has been entered into the LIFE study database. It is a streamlined approach that enables the user to match and confirm data entered into the study form with the values recorded on the associated paper Chapter 23 12//06/04 V.1.3 23-16

form. Critical data fields have been selected by the study for validation and will appear by default. The data relayed in the query will always be clinic-specific. Only the fields that require validation are displayed when the Data Cleaning is invoked. This interactive method will not only save time but ensure the integrity of participant data collected.

Instructions

- Log in to the study website and click on Data Cleaning from the menu. If you do not see this link on your Site Map, please notify a member of the LIFE team at the DMAQC.
- 2. A list of all unresolved queries for your clinic will be displayed.
- Select a PID (Participant ID) from the right side of the screen by clicking on the message count to display a list of outstanding queries for that participant.
- 4. One or more query edits will be displayed. You can navigate directly to the form to be verified by clicking on the form link displayed.
- 5. You may either enter the correct value from the paper form or choose from several other options: **a.** If the value displayed in the "Value Entered" column matches the paper form, select "Verified" from the Status dropdown box. **b.** If the "Value Entered: column is blank, the data are missing. If the data exist on the paper form, you may enter it into the "Edited" status. **c.** Select "Form Link" to navigate directly to the corresponding field on the web form. After saving the data on the web form, you will return to the Data Cleaning page instead of the Forms Management page. Please note that the Data Cleaning tool is intended for clarifying discrepancies and not for entering data entry forms in their entirety. It is also recommended that you enter corrected values directly on the list page to streamline the form validation process.
- 6. By clicking the "Save" button in the upper left corner of the query edit list you will save all changes made to the participant's specific list. It is not necessary to click "Save" after each change as you proceed through the list. If you choose to navigate to the web form to make a correction,

make sure you click "Save" before clicking "Form Link". Otherwise, any changes made will not be saved.

7. When there are no unresolved query edits for your clinic, the Data Cleaning will display a message to that effect.

23.2.9 Participant Satisfaction Surveys

Participant Satisfaction Surveys are data entered through The LIFE Study website. Clicking on the "Participant Satisfaction Survey" tab will open the data entry area. (See figure 10). Please note that the form number field on the form is a sequential number assigned at the clinic. This number is only for the purpose of correcting any data that may have been incorrectly entered. It is used for identifying the form if there is a need for a correction.

Figure 11

Participant Satisfaction Surveys

<u>Clinic Visit</u> <u>Physical Activity Intervention</u> <u>Successful Aging Workshop</u> <u>Workshop Session</u>

To select a form for data entry, click on the link for the survey form needed. This form is data entered and submitted.

23.3. Data Management Software Updates

Throughout the LIFE Study, the DMAQC will periodically update the data management system. If significant changes are made to the system requiring downtime, clinic staff will be informed via e-mail with ample lead time.

23.4. Programming Staff Contact Information

Questions regarding the LIFE Study Data Management System may be addressed to:

Appendix A

PC Setup Instructions:

1) Basic setup

After taking the equipment out of the shipping boxes, you will notice that the keyboard and mouse connectors are color coded to match the appropriate connectors on the back of the PC. Attach the monitor, keyboard and mouse to the desktop system.

2) Attaching the barcode reader

To attach the barcode reader, you will need to disconnect the keyboard because the barcode reader attaches to the keyboard cable. Simply plug the keyboard connector into the barcode reader cable and then plug the remaining barcode connector into the keyboard connector on the PC.

3) Power up

Attach the power cables to the PC and the monitor and turn on the power to both pieces. The system should power up and boot into Windows 2000. This system will come configured with a video resolution of 800x600, which is the resolution the web was designed for. If you change this resolution setting, please be aware that you will alter the way the web site is displayed on your system and this may induce functional problems with using the site. If you make any changes to the resolution, please alert the coordinating center (CoC) should you call for support with any web site related issues.

5) Network Configuration

In order to access the LIFE Study web site, you will need to have someone configure network access for this PC. That can be done via setting up an account with an Internet Service Provider (ISP), such as Mindspring, and connecting via the modem; or you can utilize the onboard Ethernet card and connect to some existing network infrastructure. Chapter 23 12//06/04 V.1.3 23-20

Appendix B

LIFE Label Program Download Program Instruction

- 1. Select 'Support/Downloads' from the Sitemap web page.
- 2. Click 'Contact Information Program' under 'Downloads', for your site name.
- 3. Select 'Save ' and click.
- Dialog box will appear prompting for the directory where you would like to save the file. Select a directory and select "Save" button to begin download.
- 5. Create a folder, "LIFE". Move the files downloaded into the "LIFE" folder.
- 6. Once the 'setupcip.zip' file has been saved to your local directory, find the file and double click the file to open WinZip.
- 7. In WinZip double-click the setupcip.exe file.
- 8. Follow the prompts on the screen to complete program installation.
- See "3.1 Starting the Program" in Instructions for LIFE Study Label Program documentation for steps to create a desktop shortcut for this program.
- 10. Download Barcode Font Software: Unzip the files from the barcodesetup.zip. Run the install.exe and a wizard will appear to walk you through the installation. This will install the needed fonts into the appropriate Windows directory.

Appendix C

Instructions for LIFE Study Label Program

1.0. Overview

A participant contact information program is located on each Clinical Center computer. This program is the <u>only</u> way that sites can obtain PIDs for participants in the LIFE Study and allows sites to record information on their recruited participants only.

A participant's ID follows the participant throughout screening and follow-up visits. Participant ID's take the form P10001, where P1 is the clinic code where the participant was initially screened, followed by 4 sequential numbers (i.e., 0001). For example, clinic P1 participant IDs would take the following format: P10001. For the majority of participants, this number will remain constant throughout the study. However, in the event that a participant physically relocates to another area where a LIFE Study clinic is located and wishes to remain in the study, the first two digits will be modified to reflect the clinic code where the participant has moved. The LIFE Study DMAQC should be contacted for assistance should this happen. Clinical Centers are assigned unique blocks of screening IDs that are generated by the Contact Information Program on the Clinical Center computer.

The combination of Participant ID and Acrostic will uniquely identify each participant. Participant name will be captured on the Pre-screening form (although not data-entered). The acrostic will be assigned when the participant information is saved in the Contact Information Program. The acrostic is constructed from the first three letters of the last name, then the first two letters of the first name. For example: John M. Doe would have an acrostic DOEJO. If there are not enough letters to complete each subcomponent of the acrostic, the letter "z" will take the place of the missing letter(s). For example: Jo Ho would have an acrostic of HOZJO.

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2.0. Obtaining an ID for a Participant

The Label Program prints labels with pages of sequential PIDs that are specific to the Clinical Center. Each PID will have one "peel off" label printed for the screening process. These labels are referred to as Screening Labels. The program will not reprint screening labels. If for some reason a page of screening labels has been lost and must be reprinted, then please contact the coordinating center.

Screening Labels contain a barcode representation of the PID and the PID in human-readable format. These labels should be transferred to the screening forms. The barcode for the screening label can be scanned into the Label Program to generate additional form labels to use on forms for future visits.

3.0. Directions for Use of the Label Program

3.1. Starting the Program

Upon installation, you will see a folder named "life" in the directory you specified. Double click this to open the folder and reveal its contents. In this folder there is an icon of a Fox's head, click on this to open the application. (You may want to create a shortcut to this file and place the shortcut on your desktop). To create a shortcut, click the right mouse button on the Windows desktop. A small menu will appear. Under the "New" option of this menu, choose the "Shortcut" option. In the "Create Shortcut" window, type in the full path to (or use the browse button to find) the "life.exe" file. The setup routine defaults this file to the "C:\life" directory, unless another path was specified. Click on the "Next" button. Enter a name for the shortcut. Click on the "Finished" button. You should now see the shortcut on the Windows desktop.

3.2. Choices

Upon starting the program, you will see two menu options: Action and Utilities.

Five choices will appear under the Action menu. These choices include:

- a) Participant Contact Information
- b) Print Screening Label Batches
- c) Print Participant Visit Labels
- d) Initialize Clinic Information
- e) Exit

Two choices will appear under the Utilities menu. These choices include:

- a) Backup Data
- b) Restore Data

3.3. Setting Up Label Program

The first task in setting up the Contact Information Program is entering the clinic information. Choose "Initialize Clinic Information" under the "Action" menu option. Enter the Clinic ID assigned to your specific clinic and click on "Save". This action should only be performed once. When the information has been entered and saved, click on the "Exit" button. The Clinic ID is automatically generated and cannot be changed.

3.4. Printing Screening Label Batches

This is where the screening labels are printed. Thirty labels are printed per page. To print these labels, select the *Print Screening Label Batches* option. Then identify the number of batches of 30 labels that should be generated. Once a page of unique IDs has been printed, you will be unable to re-print this group of unique participant IDs.

3.5. Contact Information

To produce labels for future follow-up visits, <u>it is necessary</u> to enter a minimal amount of information about the participant into the Participant Contact Information screen (Figure 3a). The required pieces of data are: Participant ID, first name, last name and date of visit. All other information that can be entered, saved, and later retrieved, is for the local use of the Clinical Center. It is to be entered only if the Clinical Center finds this aspect of the program useful. The steps to initialize a participant are:

- a) Select the Participant Contact Information option.
- b) Scan in Participant ID from the screening label (or enter manually)
- c) Type in the date that the form was completed
- d) Enter first, middle and last name

Other information can then be entered. This information will not be transmitted to the coordinating center. It is only for the use of the Clinical Center.

The "Undo" button is used to discard any changes made to the record.

The "Save" button will save any changes you have made to the record.

The "Find" button allows you to search for a Participant ID. The list is in Participant ID order. Scan (or manually enter) the Participant ID into the "Search for participant field". As you type, the matching record will be found and shown within the participant list located in the middle of the screen. Click on the participant and hit the "Retrieve" button to pull up the contact information. (Note: You can also use the scroll bars on the participant list to find the participant). Hitting the "Exit" button will close the search screen and return you to the contact information page.

R Life Contact Information						
<u>A</u> ction <u>U</u> tilities <u>A</u> dmin						
Life Participant Contact Information						
Participant 21	2121 Acrostic JZZJZ Date of 02/21/2004 Completed JG					
Participant Information						
Last Name	Mailing Address (street address or P.O. Box)					
First Name Middle Name or						
Maiden Name	City State Zip / PC					
SSN Number						
Home Phone	Work Phone Cell Phone/Other					
Email	JJJJJJJ					
	New Edit Find Undo Save Exit					

Figure 3a. LIFE Study Participant Contact Information Screen

Appendix D

Staff ID and Certification Form Instructions

Staff identification codes and certification status are contained in the Staff List. Staff members are assigned a staff ID when they are certified. The Staff ID is requested by contacting _L.C._ at the LIFE DMAQC. The Staff List contains the staff ID and the certification status for all study components requiring certification. The certification status is noted by entering the date of last certification in the data entry field for that staff member. The date of certification is a validation for the "examiner" field on participant forms. (See fig. 4A.) In order to enter a staff member's ID and certification, select "List of Staff" from the middle bar center menu. To add a staff member, select and left click "New". To revise information for an existing staff member select the staff name and left click. Information is entered into the required fields and left click submit when completed.

Figure 4a.

Staff L	og and Certification	Status
Staff ID:	2	
First Name:		Last Name:
SPPB:		
Blood Pressure:		
Weight, Height Behavioral Run-in Admin and Assessment :		
Weight, Height:		
400M Walk:		
Medication Inventory		
Grip Strength		
Blouse/Shirt Test		
Lateral Mobility Task		
Cognitive Tests (WFU and Standard)		
Blood Collection and Processing		
Interviewing (HRQL and MMSE)		
Data Entry	2/26/2004	
Behavioral Run-in Admin, Assesment		
Physical Activity Intervention		
Successful Aging Intervention		
DXA Scanning		

Staff Log and Certification Status

submit

Appendix E

LIFE Study Computer Equipment Support Clinic Staff

PC, monitor, printer and barcode scanner:

Your PC and monitor are under warranty until 2/26/2005. In the event you experience technical problems with the monitor follow the instructions below. All calls regarding technical assistance with the PC, printer and barcode scanner should be directed to the coordinating center.

If you are experiencing technical difficulty with the monitor:

Please identify the Express Service Code and Service Tag number before you place a call to Dell Technical Support. The numbers can be found on a sticker on the side or back of the PC. If you experience any difficulty trying to place a technical support call, you can call _L.C._ at ____.

The keypad numbers listed in the technical support instructions below will help expedite your call. Please be aware that the voice prompts could change at any time. The instructions reflect the correct order of the voice prompts as of June 8, 2001. If the order of the voice prompts changes listen for the items listed in the parentheses beside steps 5-7 to aid you in your call. Placing a call to Dell Technical Support:

1. Call 1-800-

Press # key if you have located the Express Service Code. Otherwise, stop here and call, _L.C._ at____.

- 2. Enter Express Service Code (numbers only).
- 3. Press 1 when prompted if the number you entered is correct. Press 2 if the number you entered is not correct.
- 4. Press 3 (Hardware technical support menu).
- 5. Press 2 (OptiPlex desktop, etc).
- 6. Press 3 (After 30 days since shipment).

Your call will be placed on hold until a support representative answers your call.

Tracking your support call: Business hours: 8:00am - 6:00pm Central

Call 1-800-. Press 1. Enter extension 26607.

Provide your reference #.