CHAPTER 23

DATA MANAGEMENT

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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 Data Management, Analysis, and Quality Control Center (DMAQC). 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 a server at the DMAQC, with Cold Fusion middleware providing connectivity to the SQL Server database. Data security in the web-based 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. All servers are located in one of two secure data centers while back-up tapes are kept in a secure vault in a separate location from the servers.

23.2. LIFE Study DATA MANAGEMENT SYSTEM

23.2.1. Login

Either Firefox 3.x (or later) or Internet Explorer 6.x or later is recommended for optimal viewing of the LIFE Study Web Site. Once the web browser is invoked on the client computer, the following URL (web address) should be entered:

https://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. The user must also agree to the Terms of Service (TOS) that govern this site. A link to the TOS is provided. The TOS briefly describes that this is a federal information system

and that we expect the users to act responsibly as they interact with this system and that they understand that their activity will be monitored and audited. If the user agrees to abide by all the rules in the TOS, then they check the box accordingly and login can proceed. If not, they can uncheck the agreement button but login to the site will be disabled.

Figure 1. LIFE Study Homepage
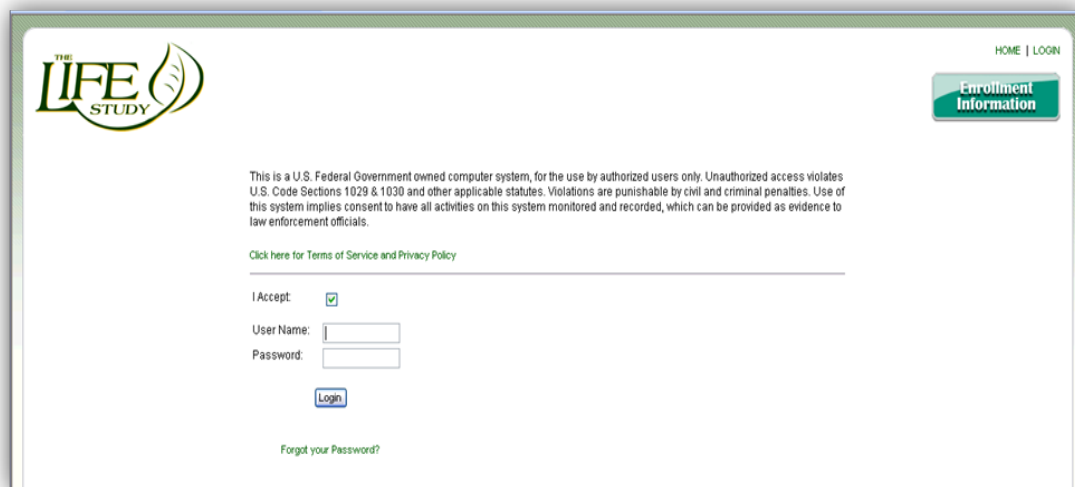
Figure 2. LIFE Login Screen

Once a valid username and password combination have been entered and verified, the user can click on the login button below those fields and proceed to the secure LIFE website. For more information regarding login, obtaining a username and password, and the format of passwords, please see Chapter 27 – Website.

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. Data Management System Features

The data management system allows for data to be entered in HTML fields that are similar in appearance to the paper 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. Forms with errors (in red) cannot be saved. Forms with warnings (in orange) can be submitted and saved by clicking on the "save with warnings" button.

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 question/field to be corrected will be marked by a red X on the form. If a data entry error has been made, the staff can correct the initial value and save the form. 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 and an orange checkmark will appear next to the question/field on the form.

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 used on the paper forms are indicated by the following codes and coincide with the area where data entry of the form will occur:

TSI	F24
SV1	F30
SV2	F36
F06	F42
F12	CLS
F18	NSV

The "As Needed" or "Non-Scheduled Visit "(NSV) forms are all forms that are not linked to a specific visit. These include, but are not limited to, Participant Status Change, Outcome Event Tracking, Unscheduled Visit, 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 will not automatically format date fields. All date fields must be entered MM/DD/YYYY, using leading zeros when appropriate.

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

If data is mistakenly not collected, and cannot be collected, the site should select "Permanently Missing" in the drop down in the select boxes on most forms. This will indicate to the DMAQC that the data was not collected and will not be collected in the future.

23.2.4. Accessing the Data Management System

To access the Assessment Data Management System, after logging into the LIFE Study Web Site, click on the "Data Entry" tab in the menu at the top of the screen and a drop down menu for the different areas will appear.

Figure 3. LIFE Data Entry Menu

The data management systems under the Data Entry tab are:

- Certification

- Participant Data

- Randomization

- Adverse Events

- Print Labels

- Data Edits

These systems can only be accessed by approved staff and is controlled through permissioning by the DMAQC. Access to most of the menu items is limited to staff who have completed Assessment Data Entry Certification (see Appendix D).

Initializing A New Participant ID

Participant IDs (PID) are assigned to a participant after verbal consent prior to conducting the Telephone Screening Interview over the phone. Screening IDs are generated by the Print Labels program (see Appendix C) and then assigned to each screened participant. Before data entry of any data can occur the participant screening ID must be initialized in the data management system.

In order to initialize a new participant ID the site would

1. Click on "Participant Data" in the Data Entry menu

2. Enter the Participant ID in the Participant ID field and click Submit

3. The message "Participant has not been initialized. Click here to go into initialization procedure." will appear and the site will click on the "here" link.

4. They will then enter the Participant's acrostic twice and click Submit.

After initializing the Participant ID the Participant Homepage will appear with access to the data entry screens for visits. Until a participant is randomized only the links to screening visit will be accessible.

Figure 4. LIFE Participant Homepage

The Participant Homepage will list the Participant ID, Acrostic, Randomization Status, and their Follow-up Visit Schedule after randomization. Note until the participant is successfully randomized the follow up visits are inactive. These will become active after randomization. Each visit can be data entered by clicking on the respective link for the visit to be data entered. For example, the Telephone Screening Interview form can be data entered by clicking on the visit link for "Telephone Screening".

Assessment Forms

LIFE Assessment Forms will be listed and accessed under each visit for each participant. The barcode scanner can be used to scan in the PID from the participant label or simply enter the PID.

To access the assessment forms after a PID is initialized:

1. Click on "Participant Data" in the Data Entry menu

2. Enter the Participant ID in the Participant ID field and click Submit and the Participant Homepage will appear with the Visit Menu.

3. Click on the visit link in the Visit Menu to access the assessment forms associated with that visit.

To change visits click on the "Go back to Visit Menu" and then click on another visit.

Forms appear in alphabetical order under each of the visits. Screening forms required to determine eligibility for randomization are bolded in the list. These bolded forms are included in the eligibility checks referenced below.

Adverse Events

The Adverse Event link in the Data Entry menu is where all Adverse Event forms are data entered by blinded (masked) and unblinded (unmasked) staff. This is also where the site Medical Safety Officer (MSO) and Study Physician will access the Adverse Event Evaluation forms for follow-up of all Adverse Events.

The Adverse Event system can only be accessed by approved staff and is controlled through permissioning by the DMAQC. Access to the Adverse Event Evaluation Form is is limited by permissioning through the DMAQC to only the site MSO, study physician, and project coordinator where applicable.

To access the system the site will:

1. Click on "Adverse Events" in the Data Entry menu

2. Enter the Participant ID in the Participant ID field, then click Submit and the Adverse Events system wil appear

See Chapter 22 for details on entering the Adverse Events forms.

23.2.5. Randomization

In order to randomize a participant, all eligibility forms must be data entered and the eligibility criteria must be met on all forms. Data entry of all eligibility forms is done under "Participant Data" in the "Data Entry" menu. Eligibility froms can be found under the Telepohone Screening Visit, Screening Visit 1, and Screening Visit 2. An automatic eligibility check will be performed as forms are entered.

In order to check the randomization status and perform the eligibility criteria check on a participant the site would:

1. Click on "Randomization" in the Data Entry menu

2. Enter the PID in the Participant ID field and click Submit

3. After Submitting the PID the "Randomize Participant" Eligibility Check Screen will appear (Figure 5)

Figure 5. LIFE Randomize Participant/ Eligibility Check Screen

The "Randomize Participant/Eligbility Check" screen will indicate if a participant has any outstanding eligibility forms or if any eligibility criteria makes them ineligible. If an eligibility form is missing or if there is a temporary exclusion then the site can go back to Data Entry/Participant Data to enter the missing form or enter rescreening data.

If all of the participant's eligibility forms have been entered and all forms have an "eligible" status, after entering the PID under "Randomization" the site will get the "Eligible for Randomization Screen" with a Randomize button. Click the "Randomize" link **once** to initiate randomization, and click once to confirm randomization.The participant's randomization status is displayed in the top right section of the Participant Homepage once they are randomized to an arm of the study. Please print the randomization assignment for the participant's intervention file to protect againt unblinding.   An automatic email is generated to the site's Project Coordinator and the lead Successful Aging and Physical Activity Interventionists with the randomization status of the participant.

Notes:

- Participants must be randomized within 28 days from Consent for the Main Trial and 45 days from Telephone Screening to avoid re-screening the participant. The window is calculated by adding 28 days to the "Date of Main Informed Consent" entered on Informed Consent Form and 45 days from the "Date of Telephone Screening".

- After randomization, if the participant's ID is entered again under "Randomization" it will indicate that the participant ID is already randomized. The Randomization Status will also appear on the Participant Homepage as "Yes" with the date of randomization in the table.

- Eligibility forms for randomized participants are locked and may be viewed but not edited.

23.2.6. Intervention Tracking System

To access the Intervention Tracking System, after logging into the LIFE Study Web Site, click on the "Intervention" tab in the menu at the top of the screen and a drop down menu for the different areas of Intervention Tracking will appear (See Figure 6.).
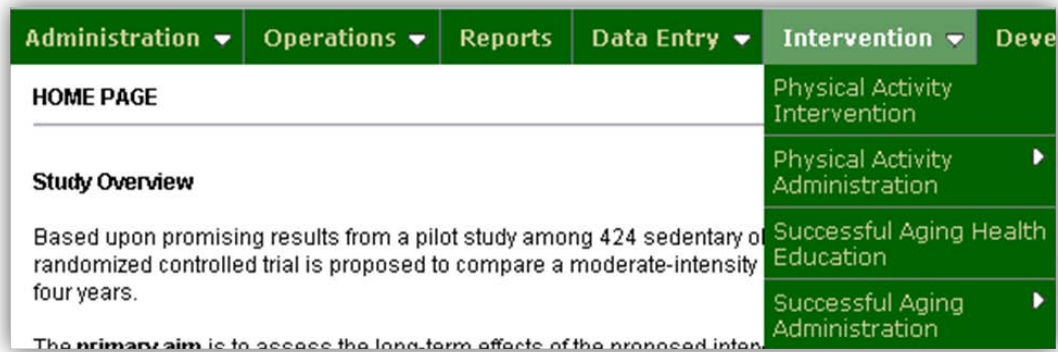
Figure 6. LIFE Intervention Tracking

The LIFE Intervention Tracking System is made up of 4 parts:

1. Physical Activity Intervention

2. Physical Activity Administration

3. Successful Aging Health Education

4. Successful Again Administration

The Intervention Tracking System can only be accessed by approved staff and is controlled through permissioning by the DMAQC. Only unblinded staff will have access to the Intervention Tracking System.

This system allows interventionists to assign randomized participants to groups and to track a participants progress and attendance by individual and by group. The tracking system contains all data entry screens for group session forms and all individual intervention forms such as face-to-face forms, home logs, and extended leave forms. Baseline participant information and contact information will be displayed for the interventionists to reference as needed during the intervention sessions.

The Intervention Tracking System will also provide a number of reports and intervention tools to assist the sites in monitoring their participants.

23.2.7. Reporting

Numerous reports have been generated and are available under Reports on the website. These reports categorized by different areas of concern for the study. Many of the reports contain study-wide data while others are clinic-specific.

To access the LIFE Reports, after logging into the LIFE Study Web Site, click on the "Reports" tab in the menu at the top of the screen. After clicking on the Reports tab a list of categories of reports can be viewed. Some reports will be viewable only by a specified committee or group of individuals (ie. Sites, site MSO, ACC , Interventionists.)

Figure 7. LIFE Reports Menu tab

23.2.8. Data Quality Control

Data quality is checked during team site visits and periodic document reviews. As detailed in Chapter 24-Quality Control, DMAQC site team members will review a number of randomly selected randomized participants' charts for data accuracy on all critical forms related to the primary outcomes and on a random sample of forms related to the secondary outcomes. Online data is preprinted from randomly selected PID's and during the site visit the data is compared with participant's charts. Results are reported through the site visit team report prepared at the conclusion of the site visit.

Data Edits

The Data Edits 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 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.

To access and navigate the Data Edits system:

1. Click on "Data Edits" in the Data Entry menu

Figure 8. Data Edits Menu

2. A list of unresolved Data Edit queries for your site will be displayed.

3. Select a PID to display a list of outstanding queries for that participant.

4. One or more data edit queries will be displayed. You can:

   a. Verify the data entered by checking the paper form against the data display in the "Value Entered" column. If data is correct as entered, selected "Verified" in the status dropdown box.

   b. Enter the data into the "Edited" status in the "Value Entered" column.

   c. Select the form link to navigate directly to the corresponding field on the web form data entry page and edit the data. After saving the data on the web form, you will return to the Data Edits instead of the Participant Homepage/Visit list.

To save the edits or verifications entered on the Data Edits screen, click the "Save" button in the upper left corner. 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. However, if you choose to navigate to the web form to make a correction (option c above), make sure you "Save" the form, otherwise, any changes made, will not be saved.

Note: The Data Edits system is intended for clarifying discrepancies in the data and not for entering data entry forms in their entirety. It is also

recommended that you enter corrected values directly on the participant specific data edits query page to streamline the process.

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

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: at the DMAQC.

Appendix A

PC Setup Instructions:

Basic setup

After taking the desktop equipment out of the shipping boxes, you will notice that the keyboard and mouse connectors are USB connectors and will attach to any open USB port. Attach the monitor, keyboard and mouse to the desktop system.

Power up

Attach the power cables to the PC and the monitor then turn on the power to the monitor and the computer. The system should power up, boot up and prompt you for a username and password.

Network Configuration

The DMAQC IT will be in touch with the site IT to complete the set up of all LIFE computers. Network configuration is required for connection to the Internet using either Wi-Fi or an Ethernet connection. Consult your local networking staff for the proper settings.

Contact the DMAQC Project Manager with questions.

Barcode scanners

Barcode scanners can be attached to any of the six systems sent to the site. To attach the barcode reader, simply plug the USB connector into any vacant USB port on the back of the system.

Printers

Contact your local IT for set up of printers on your local networks

Appendix B

LIFE Study Computer Equipment

Each site received:

- 2 desktop computers with monitor, keyboard, and mouse.

- 2 desktop printers

- 4 handheld barcode scanners

- 4 laptops (2 for intervention only, 2 for assessment only)

PC, monitor, printer and barcode scanner:

Your PC and monitor are under warranty from the original manufacturer. Each system is under warranty for a period of 3 years from the date of purchase. Exact dates can be obtained from the DMAQC but all systems, monitors and printers will be covered until at least December, 2012. 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 DMAQC.

**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, contact the DMAQC for assistance.

Appendix C

Instructions for LIFE Study Website Label Applications

There will be two label applications on the LIFE website to be used to generate; 1) screening labels to be assigned to participants at the telephone screening visit and, 2) individual participant labels after a PID has been initialized.
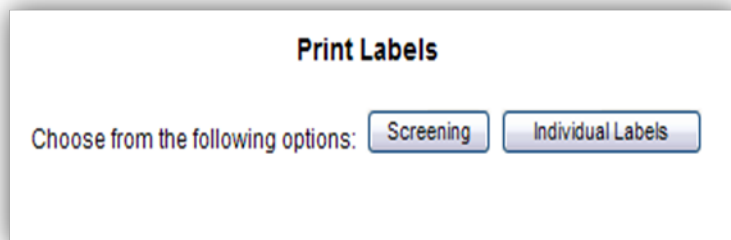
Figure 9. Print Label Screen

Screening Labels

Screening Labels are a set of 30 unique PIDs and used as the telephone screenting visits occur. Once generated, the PIDs on the labels cannot be generated again for screening purposes.

In order to print Screening Labels:

1. Click on "Print Labels" in the Data Entry menu

2. Click on "Screening"

3. Accept the download of the PDF file of the screening labels.

4. Load the appropriate label stock (Avery 5160) into the printer and click on "Print"

Note: We recommend that you not close the PDF until you have retrieved the printed version off the printer and have verified it printed correctly. If not, destroy the labels and reprint via the PDF. Once the PDF file is closed, you will NOT be able to reopen or regenerate those same ID numbers.

Individual Labels

Individual Participant Labels are sheets of 30 PIDs assigned to an individual participant which displays their ID, a barcode, the site ID, and the participant's acrostic. These labels are expected to be applied to each page of all data collection forms completed for a given participant.

In order to print Individual Participant Labels:

1. Click on "Print Labels" in the Data Entry menu

2. Click on "Individual Labels"

3. Scan or Type in the Participant ID

4. Accept the download of the PDF file of the individual labels.

5. Load the appropriate label stock (Avery 5160) into the printer and click on "Print"

Unlike the screening labels, if more individual labels are needed, they can be generated and printed as needed.

Appendix D

## Staff ID Assignment and Certification Status

Staff IDs

Staff ID codes are assigned when a user account is created on the LIFE Study website and is unique to that individual. To obtain a new user account the site Project Manager must complete a "New User Request Form", which is posted to the website, and send it to the DMAQC. The request will be reviewed and the new user will be entered into the system. After the account is set up, an email with the users temporary password and instructions for logging onto the website and changing the password will be sent. Any questions about obtaining a staff ID or a new user account contact the DMAQC.

Staff Certification Status

Staff certifications are collected, data entered, and monitored by the Administration Coordinating Center (ACC). After receiving confirmation of certification status from the site or other central agency (ECG center, Spirometry center, etc.) the date of certification is entered into the LIFE website by the ACC. This information is tracked and email reminders for recertifications will be generated.

To review a staff person's certification status for all measures:

1. Click on "Committees" in the Operations menu
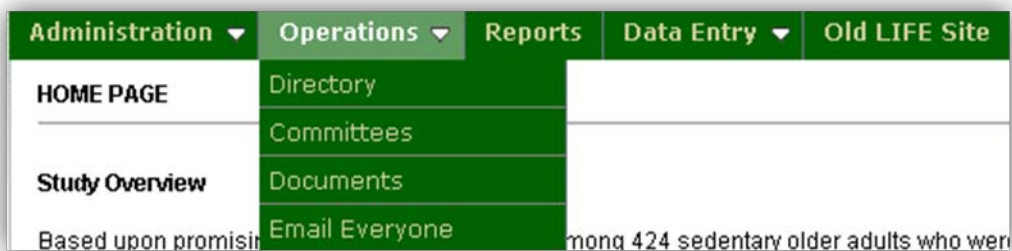
Figure 10. LIFE Operations Menu

2. Click on the Field Center to view

3. Click on "Staff IDs" tab on the Committee/Field Center Page

Figure 11. LIFE Committee Staff ID Page

4. Click on the name of the staff person whose certification status you would like to view

Figure 12. LIFE Staff Certification Status Page

Appendix E

Assessment Data Entry Certification Instructions

For any LIFE staff who will be data entering assessment data it is required that Data Entry Certification be completed before access to edit forms in the assessment data entry system is granted.

To access Data Entry Certification:

1. Go to Data Entry Menu tab

2. Click on Certification and get the "Data Entry Certification" page (see Figure 13)

3. Click on "Instructions" to get full instructions on the process

4. The #1 "Download File" link – This link is for use by the site project manager who will download the file and assign a certification ID to each staff member needing to be certified. (the ID can only be used once and will not work for multiple staff). Site staff should request an ID from their project manager before moving to Item #2.

5. Click on the pdf document link under Item #2 "Visit 1" to download and print the paper forms to data enter for certification.

6. Click on Item #3 "Enter" to data enter all 5 forms and save each

   a. Forms saved will have a checkbox in the "entered" column

   b. The forms should be data entered exactly as recorded on the paper form. If an Error is received something must be fixed. If you received Warnings check the paper form to ensure that the form was data entered correctly. If it was then the form can be "Save[d] with Warnings".

7. After Data Entering all the forms check your certification status by clicking on Item #4 "Check Status"

   a. If you are certified you will get a screen that will indicate you are certified and an email notification will be sent of certification status to the site project manager.

   b. If you are NOT certified you will get a screen that will indicate which forms were not saved successfully. This screen indicates anything that does not meet the data entry certification criteria.

8. After Certification is obtained, permission will be granted for the staff member to access and edit LIFE Assessment Participant Data.

If you have any problems with these steps or with certification please contact the DMAQC.

DATA ENTRY CERTIFICATION

USER: Cindy Stowe   STAFF ID: 00008

********** INSTRUCTIONS **********

1. Download list of Certification Participant IDs:
   (PROJECT MANAGERS ONLY)

   [DOWNLOAD FILE]

2. Print forms for Data Entry Certification:

   VISIT 1

3. Access Data Entry Certification:

   ENTER

4. Check Certification Status:

   CHECK STATUS

Figure 13. LIFE Data Entry Certification Page