

CHAPTER 27

WEBSITE

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CHAPTER 27

WEBSITE

27.1. OVERVIEW

The LIFE Study website was designed to provide the basis of the LIFE Study Data Management System and to serve as a communication tool for study personnel. The site contains a variety of helpful information related to the conduct of the study. It is best viewed using Firefox 3.0 or higher, or Internet Explorer 6.0 or higher.

27.2. NAVIGATION TIPS

Text enclosed within horizontal or vertical scroll bars extends beyond the limits of the computer monitor. Click on these bars with the computer mouse to move the text into view. Web page links may or may not be underlined but can be identified by scrolling over the link with the computer mouse. Selecting a link will take the user to other areas of the website.

27.3. FEATURES OF THE LIFE STUDY WEBSITE

27.3.1. Public Home Page

Once the browser is invoked on the client computer, the following URL (web address) should be entered:

<https://www.thelifestudy.org>

The public home page will then appear, which contains the study logo, description, and sections for Media Coverage and Literature, Study Site Contact information, and the Enrollment Information button. To return to the home page, click on the “Home” link in the top right corner of the screen.



Figure 1. LIFE Study Public Homepage

27.3.1.1. Login Link

From the LIFE Study website homepage clicking the “Login” link in the top right of the screen will take the user to the login screen. This screen prompts 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.

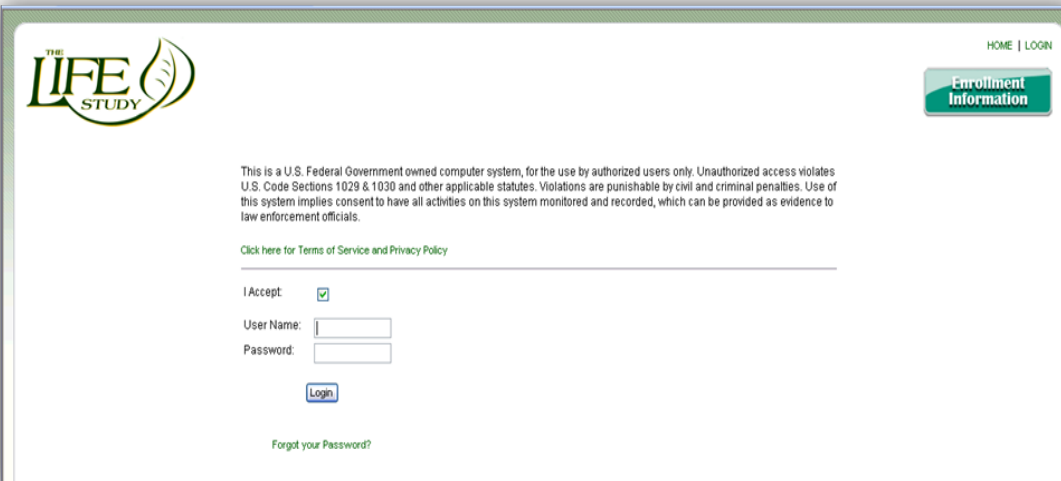
The screenshot shows the LIFE Study login interface. At the top left is the LIFE Study logo. At the top right are links for 'HOME' and 'LOGIN', and a green button labeled 'Enrollment Information'. A disclaimer states: 'This is a U.S. Federal Government owned computer system, for the use by authorized users only. Unauthorized access violates U.S. Code Sections 1029 & 1030 and other applicable statutes. Violations are punishable by civil and criminal penalties. Use of this system implies consent to have all activities on this system monitored and recorded, which can be provided as evidence to law enforcement officials.' Below this is a link: 'Click here for Terms of Service and Privacy Policy'. The login section includes a checkbox for 'I Accept:' which is checked, followed by input fields for 'User Name:' and 'Password:'. A blue 'Login' button is positioned below the password field. At the bottom of the login section is a link: 'Forgot your Password?'

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. A username and temporary password is provided by the DMAQC to all study personnel by email. Users should always log in using their own user name and password.

27.3.1.1.1. Passwords

A username and password is automatically generated once a new user has been added to the website via submission of the “New User Request” form. After setup is

complete the initial password assigned to the user will be randomly generated by the system and emailed directly to the user. The password emailed will be EXPIRED. Upon the users first login they will be taken to a screen that will prompt them to enter a new password of their choosing. The criteria for valid passwords are as follows:

- must be least 6 characters in length AND
- must contain at least one number AND
- must contain at least one UPPER case letter AND
- must contain at least one lower case letter

Passwords will expire every 90 days and users will be prompted to enter a new one when it does. Accounts are allowed six attempts to login. After the sixth failed attempt the account will be locked and the user will need to contact the site administrator to reset the account.

These policies reflect general and minimal Wake Forest University School of Medicine (where this website and data management system resides) security policy and are not set by this particular study.

27.3.1.2. Enrollment Information Button

The Enrollment Information button, located in the top right of the LIFE Study website homepage, will direct the user to the LIFE Study Recruitment page. The direct URL web address is www.thelifestudy.org/enroll.

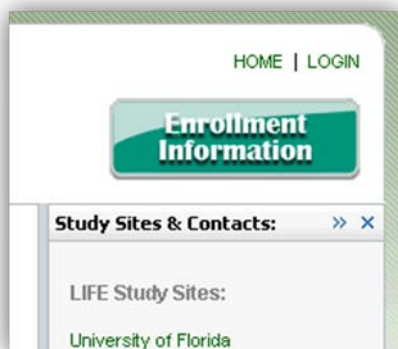


Figure 3. LIFE Enrollment Button

This page is specifically for participants interested in obtaining more information about the LIFE Study. It includes a map of the US with a list of clinical sites, basic eligibility criteria, and basic information about the study. Clicking on the map and list of clinical sites will direct the user to contact information for the site, a phone number and the clinical site website address.



Figure 3. LIFE Enrollment Page

27.3.2. Internal Home Page

The Internal Home Page is the gateway to all areas of the LIFE website. These areas are accessible only to study personnel with a login and password to the LIFE Study website. To return to the internal home page from other areas within the website, click on “Home” in the top right corner of the screen.

Areas accessible from the internal home page through the green Menu bar are:

- Operations
- Reports
- Data Entry
- Intervention
- Old LIFE Site (Pilot) (not pictured)



Figure 4. LIFE Menu Bar

The menu bar is tailored to a specific users permissions and role in the LIFE study (i.e. assessment staff will not see the Intervention tab). Each tab in the Menu bar will

provide access to additional areas of the website. Scrolling over tabs with the down arrow symbol will reveal additional links that a user may have access to.

27.3.2.1. Operations

By scrolling over the Operations tab the user may access the study directory, committees, and documents. This tab also gives access to the tool of “Email Everyone” in the study directory.

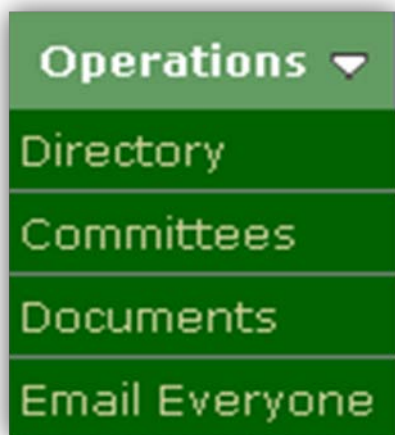


Figure 5. LIFE Operations Menu

27.3.2.1.1. Directory

By clicking on “Directory” from Operations tab, the user will access the LIFE Study Staff directory. Contact information for all LIFE Study personnel are stored and accessible here. Staff are listed alphabetically by last name. Staff full name, email address, and phone number are displayed in the default view. When new study staff are added to the website by the DMAQC the directory is subsequently updated.

To search by last name, click on the letter in the alphabe row that coincides with forst letter of the last name. This will display a filtered list of personnel with last names beginning with that letter. To view all contact information for an individual, click on the name of the individual. If an e-mail address is displayed, the user may click on it and send an e-mail message to that specific person.

To update contact information in the directory, contact the DMAQC.

27.3.2.1.2. Committees

By clicking on “Committees” from the Operations tab, the user will access the list of the Field Centers, Administrative Centers, Committees, and Working Groups of the LIFE

Study. These groups/committees are listed by name alphabetically and sorted by groups. Each group/committee name is a link to detailed information for that group/committee.

Once a group/committee has been selected, the web page for the group/committee is accessed. Details for the group/committee will be listed under tabs on the group/committee page. The tabs are

- Description – a brief description of the group/committee and their role in the LIFE Study.
- Members – a list of individuals assigned to that group/committee.
- Email Group – a function to be used to email the list of individuals listed in “Members”
- Staff IDs (only a tab listed under a Field Center) – a list of the staff assigned to the field center listed with their staff ID. This is also where site project managers can access the certification records for staff.

27.3.2.1.3. Documents

By clicking on “Documents” from the Operation tab, the user will access the central repository for all study related documents. The ‘Document List’ lists collections of documents for the various groups/committees and study wide documents such as the Protocol, Manual of Procedures, Study tools, and Forms. Each committee is provided a repository to store announcements, agendas, minutes and other documents of interest to the committee.

The documents are stored in folders and to access the documents within the folders the user can click on the plus symbol (+) to the left of the document collection folder they wish to access. This will give them access to the categories of documents. Once there, the user can click of the category of documents (i.e. Minutes) and view the list of documents.

27.3.2.2. Reports

By clicking on “Reports” in the menu bar a list of all report collections will be displayed. Numerous reports have been generated and are available. 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. Access to reports is based on study personnel permissions assigned by the DMAQC. Some reports will be viewable only by a specified committee or group of individuals (ie. Sites, site MSO, ACC , Interventionists.)

Reports are stored in folders and to access the reports within the folders the user can click on the plus symbol (+) to the left of the report category name. If no plus symbol is available just clicking on the report category will give access to the list of reports.

27.3.2.3. Data Entry

By scrolling over the “Data Entry” tab in the menu bar the user may access different areas of the LIFE Data Management System. This data management system for LIFE is where all the interaction with participant data will take place. It is accessible only to specific study staff. For more detailed information about the data management system, please refer to MOP Chapter 23.

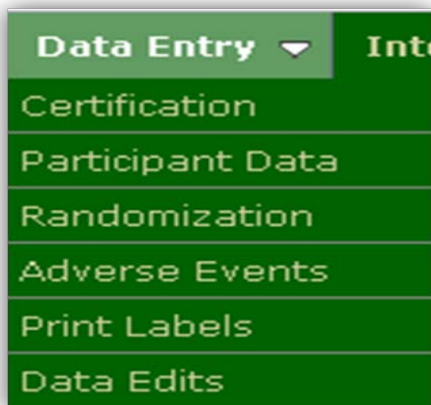


Figure 6. LIFE Data Entry Menu

27.3.2.4. Intervention

By scrolling over the “Intervention” tab in the menu bar the user may access the Intervention tracking system. This area of the website is limited to specific study staff. For more detailed information about the Intervention Tracking system, please refer to MOP Chapters 10 and 23.

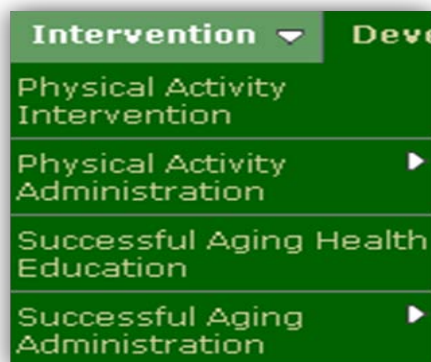


Figure 7. LIFE Intervention Menu

27.3.2.5. Old LIFE Site

By clicking on “Old LIFE Site” in the menu bar the user gains access to the Pilot LIFE website. It allows access to PILOT documents, directories, forms that were used during the Pilot phase of the LIFE study and is provided for reference as we move forward into the main trial of the LIFE Study.



Figure 8. Old LIFE Site Menu Tab