

Chapter 19

Data Management

Identifying Subjects: Each person enrolled in the study was assigned a randomized 8-digit identifier. New participants in Visit 2 will be assigned a unique randomized 8-digit identifier as well. If the new participant is a refusal from Visit 1 or a known family member in Visit 1 that did not participate, they already have a randomized 8-digit identifier. Potential new marry-ins that participate will receive a unique randomized 8-digit identifier, unless the marry-in participated in Visit 1 and was enumerated, in which case that marry-in already has a randomized 8-digit identifier. This is to ensure that each participant is associated with only one randomized 8-digit identifier. This 8-digit number represents the person on all forms. To reduce the possibility of confusion, the first page of each form should have a label attached containing a code39 barcode, and an acrostic that represents the first 3 letters of the person's last name followed by the first 2 letters of their first name. For example, John Smith's acrostic would be SMIO.

Clinic And Recruitment Staff Identifiers: Every person involved in contact with subjects or prospective subjects will have a 3-digit identifier. This identifier should be present on all data collection forms to identify the person performing the test, administering the interview, or the person responsible for verifying that subjects have completed materials that were not administered by study staff. The master list will be maintained through the REDCap data entry system by the field center manager or a designated alternate.

Field Center Codes: Field center identifiers should be circled on the first page of each form. They are not entered into the data entry system, as the data entry system will automatically keep track of the field center.

Obtaining Study Forms: Forms may be downloaded as PDF files from the study web site at <https://dsgconfluence.wustl.edu/pages/viewpage.action?pageId=7345052>

Data Conventions – General Rules for Completing Forms: The following is a list of all the data conventions for the study when filling out forms.

1. Entering Dates: All dates should be entered in three fields, Day, Month, and Year, separately, except for the Date Form Filled Out on the top of each form. The valid month values are 1 – 12 and valid day values are 1 - 31. All year values should be entered as 4-digit years. The date format is DD-MM-YYYY. As an example, October 22, 2015 would be entered as "22-10-2015". The date may be entered by selecting a date through the calendar pick list in REDCap.
2. Block capital lettering should be used to fill out alphanumeric data fields.
3. Leading zeros are not necessary on the form, or in the data entry system, e.g., if an age field has three spaces, and the person's age is less than 100, it is not necessary to enter 085 for 85.
4. When entering time into REDCap, ensure that both hour and minute fields have a value, even if the value is 0, e.g., 8 hours should be entered as 8 hrs and 0 minutes.
5. Coding Missing data items and/or Missing Forms: Missing items should be coded according to the rules given below for any questions that are asked and not answered. Questions that are not asked due to a skip pattern within a form are the only fields on any given form that should be left completely blank. If a form is not filled out at all, then the date (form filled out) should be coded according to the rules below.

R: *Refused:* Used if subject refuses: to answer a question, fill out a form, or perform a procedure when there is no specified method of handling it in the protocol. If the subject refuses a questionnaire or procedure in its entirety, enter "R" in the date field for that questionnaire or procedure.

- N:** *Not applicable*: Used when subject is unable to perform a procedure, and there is no specified method of handling it in the protocol or form.
- P:** *Missing due to Protocol*: The procedure/question is not relevant (e.g., gender-specific questions, or subject was excluded from answering the question, or performing the test due to a physical condition, and there is no specified method of handling it in the protocol or form.)
- U:** *Unavailable*: Used if a measurement/question is not completed for any reason other than the above three, and there is no specified method of handling it in the protocol or form.
- D:** *Don't Know*: Used sparingly, after all probes have failed. May not be available for some forced choice questions.
- K:** *Unknown*. Used sparingly, and offered as a potential response.
6. **How to correct errors**: Corrections are made by drawing a single line through the incorrect entry such that the original entry is readable and entering the correct data above the incorrect entry. All corrections must be initialed and dated and made only by appropriate site staff (e.g. study coordinator, PI, sub-investigator, pharmacist, neuropsychological examiner) Do not write over the previous entry. Erasures, liquid paper (white-out), correction tape, etc. are not permitted.

The REDCap Data Entry System: The LLFS data entry and management will be done through REDCap (Research Electronic Data Capture; Harris et al. 2009) electronic data capture tools hosted at Washington University in St. Louis. REDCap is a secure, web-based application designed to support data capture for research studies, and it can be used through any device having internet access. It satisfies the HIPAA Privacy Rule requirements. The feature of data validation in REDCap can avoid entering any observations violating the accepted range. A Logging table stores all information about data changes and exports so every operation performed in REDCap is tracked and can be easily retrieved at the project level. Multiple users with an ID and password in REDCap, can use the data entry system at the same time.

Hardcopy output is printed locally at the field center from PDF files. These PDF files are obtained from a web page designated for the field center's use.

System Access And Security: To gain access to the LLFS REDCap data entry system, each user is required to have a valid userid and a pass phrase for that userid. The userids are assigned by REDCap administrators at Washington University. Each individual user should have his or her own userid. In order to obtain a REDCap userid, go to http://www.biostat.wustl.edu/redcap/?page_id=43 and click the link on the bottom of the page that says “[REDCap User Account and Project Account Applications via REDCap Survey](#)”. Once the form opens in the next window, see options in Appendix 1 (below) to complete the application. After submitting the application, send an email to Mike Province (mprovince@wustl.edu) and Rosa Lin (rosa@dsgmail.wustl.edu) at the DMCC stating who you are, what site you are at and that you just completed the online REDCap application. This will allow the DMCC to approve the request quickly. When the account is created, REDCap administrators will send a userid and password via email to the requestor and DMCC. DMCC will then activate the requestor’s account for access to the LLFS REDCap system.

When users log on to the Demo/Test server the first time, they should change the temporary pass phrase to one of their own choosing. The pass phrase should be 10-15 characters long, contain only letters, numbers, and underscores, and it must consist of at least one lower-case letter, one upper-case letter, and one number, as it should not be written down so that other people may see it and use it to gain access to the data and programs. About a half-hour after the pass phrase is changed, the account will be enabled on the REDCap Production server. Users will not have access to any LLFS databases until access is given by the DMCC. The rights of each user who is granted access to LLFS project are defined individually, depending on the user’s profile. When you have finished working on the system, please log out of the system. This will prevent unauthorized people from having access to the system. The system also keeps track of who has

been using it, and this should be as accurate as possible. If you exit the REDCap data entry system, the next person to sign on will have to use his or her own userid.

The REDCap "inactive accounts" suspension program for both the Demo and Production servers prevents system access by users who are no longer associated with LLFS projects. Accounts will be suspended on the Demo server if no activity is detected after 9 months, and on the Production server after 6 months. Users who need to have their accounts reactivated for either server will need to submit an email request to REDCap support queue [redcap@rt.biostat.wustl.edu].

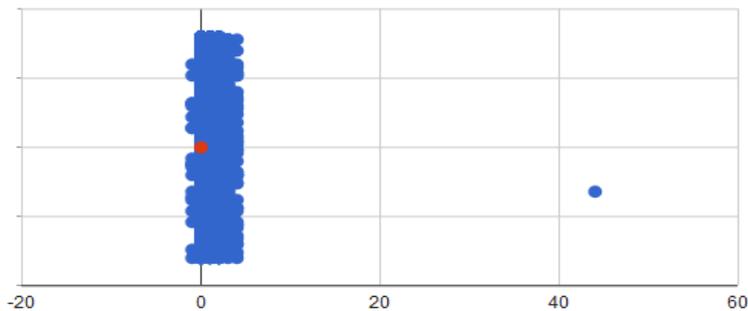
Features and Tools: In addition to the functionality of data entry, including logic skip encoded into the forms and quality checks for data range, REDCap provides other tools and applications to manage data collection and quality. The module of Graphical Data View & Stats can display any project data in aggregative graphical format and as descriptive statistics to assist in data cleaning. For example,

(12j). Leg cramps. 0, Never 1, Rarely (1x/month or less) 2, Sometimes (2-4x/month) 3, Often (5-15x/month) 4, Almost Always (16-30x/month) -1, Refused: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
3737	1220 (24.6%)	7	-1.00	44.00	0.76	1.18	0.00	0.00	0.00	0.00	1.00	2.00	3.00

Lowest values: -1, -1, -1, -1, -1

Highest values: 4, 4, 4, 4, 44



If clicking any of the points on the plot, the data entry form of that exact record will open.

Report Builder: The module of Report Builder allows users to create and save customized data reports, which will query the project and display the resulting data in a table format. Once the report is saved, all users who are granted access to the Report Builder module of the project can view it. To view family member information, we will use this feature to create two reports: one for searching proband ID and the other for displaying family member information (such as relationship to proband, vital status, enrollment status, etc.). Editing the existing family member report and entering the proband ID as a limiter/filter of the report may generate a table including the proband and his/her family member information.

The following documentation should give all the information necessary to use the system, its menus and submenus, data entry screens, and support and management functions. As with any piece of documentation, it is constantly undergoing revision. Should you find any errors, or would like clearer instructions on how to do a task, please contact the DMCC.

Starting the LLFS Data Entry System and Logging In: The URL of the REDCap data entry system is <https://redcap.wustl.edu/>. Obtain access to the web site using any web browser. Clicking on the Production server to open the "Login" screen. This screen has room for two fields: userid and pass phrase. Enter your userid, and then your pass phrase. The pass phrase will NOT appear as you type it. Should you type either the userid or the pass phrase incorrectly, the system will not allow you to log in, but will notify you and ask you to re-enter them. Both the userid and pass phrase are case sensitive.

After successfully logging in, click on the tab "My Projects" on the top of the web page, and then select the project title, either "Visit 2 In-person" or "Visit 2 Follow-up". Clickable project menu items are shown on the left side of the screen. The Application tab contains menu items pointing to general REDCap functions, such as Report Builder and Graphical Data View & Stats. All menu items in the Data Collection tab point to LLFS forms. Click on one of the LLFS forms and you will view an existing record (unique 8-random digit LLFS identifier) by selecting it from a drop-down list. The records are separated into two drop-down lists according to their status (incomplete vs. complete) for this particular data collection instrument. If there is no unique 8-digit random identifier, create a new record by typing a new LLFS study ID in the text box "Enter a new or existing Study ID" and hit Tab or Enter. When the form for a participant you select pops up, please retype the participant ID in the first text box for verification purposes. After entering data in a field, click on the "Tab" key on your keyboard to move the cursor to the next field. If the "Enter" key is clicked, it will close the form.

Initial 3 month Pilot of Visit 2 Forms in REDCap: The first 3 months of Visit 2 will be a pilot phase during which we will assess any potential changes that may be necessary to our forms. At this time we will assess data quality and integrity, and ask feed-back from the field RAs on making the forms better. Since REDCap is a product we are using, and not our own software, it is more difficult to make changes to the forms for Visit 2 as the study progresses, unlike in Visit 1 where we were able to make changes at the DMCC. To make changes to Visit 2 forms, we will need the REDCap administrators to approve them, which is not impossible but adds another barrier to progressing forward. This is the reason for the pilot phase of data collection for Visit 2, to minimize additional form changes after 3 months so that we minimize the burden of accessing the REDCap administrators.

Chapter 19: Appendix 1

Washington University in St. Louis, School of Medicine, Division of Biostatistics**Request for REDCap User Account**

Go to http://www.biostat.wustl.edu/redcap/?page_id=43

Click the link on the bottom of the page that says “[REDCap User Account and Project Account Applications via REDCap Survey](#)”

Options to select in online REDCap user application:

Select **User Account**

Select **Yes for supervisor approval needed**

WU Supervisor/WU collaborator First Name= **Michael**

WU Supervisor/WU collaborator Last Name= **Province**

WU Supervisor/WU collaborator email address= mprovince@wustl.edu

Applicant information: you, the applicant should know this

Email of another person to be notified when account is created (ie WUSM sponsor or project administrator)=

rosa@dsgmail.wustl.edu

Email of another person= **supervisor at field center**