

Chapter 19

Data Management

Identifying Subjects: Each person enrolled in the study was assigned a randomized 8-digit identifier. All new participants in Visit 3, including the grandchildren of the probands, will be assigned a unique randomized 8-digit identifier as well. If the new participant is in proband generation or in offspring generation and is a known family member in the previous two Visits 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 participants or prospective participants 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 participants 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://dsproject.atlassian.net/wiki/spaces/LLFS/pages/85819429/Visit+3+MOP+Panels+and+Chapters+Sept+15+2019+to+Present>. Hardcopies of the forms are printed locally at the field center from PDF files.

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. 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.
4. 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.
- C:** *Missing due to Cognitive or behavioral problem*: Used when subjects have a cognitive or behavior problem that prevents them from engaging in the test in a valid manner. This code should not be used if the participants are simply unable to complete the item because they don't know the answer or the task is too difficult.
- H:** *Missing due to Physical or sensory problem*: Used when participants have a physical or sensory problem such as motor, hearing, or vision impairment that prevents them from completing the test item in a valid manner.
- 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 five, 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.
- O:** *Other*. Used when none of the above situation apply.

5. 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.

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

https://redcap.wustl.edu/redcap/srvrs/prod_v3_1_0_001/redcap/surveys/index.php?s=D9YTEAFFYF. Once the account request form opens, 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@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 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. 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 prevents system access by users who are no longer associated with LLFS projects. Accounts will be suspended after 6 months if no activity has been detected on that account. Users who need to have their accounts reactivated need to submit an email request to the REDCap support queue [redcap_helpdesk@wustl.edu].

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 REDCap Production Servers have two versions: version 7 and version 8. In order to have access to version 8 server, field sites users need to request a guest WUSTL key. See instructions in Appendix 2 (below) to complete the request of a WUSTL key. Currently the data collection instrument for the LLFS ancillary study Dementia Review project is in Production Server version 8 and the data collection instruments for all LLFS in person visit forms, annual phone follow up forms and other supporting operations are in Production Server version 7. Eventually REDCap administrators will migrate projects in version 7 to version 8.

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 REDCap Version 7 Production Server to open the "Login" screen. Or clicking on REDCap Version 8 Production Server and then enter WUSTL key account userid and pass phrase 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 REDCap Version 7 Production Server, click on the tab "My Projects" on the top of the web page, and then select the project title, "LLFS", "LengthTrc" or "OpSupport". Similarly, after successfully logging in REDCap Version 8 Production Server, click on the tab "My Projects" on the top of the web page, and then select the project title "Dementiarvw". 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 Calendar and File Repository. 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 and no values have been entered, it will close the form. Otherwise, clicking on "Enter" key, the "NOTE: Some fields are required: message window pops up.

Initial 3 month Pilot of Visit 3 Forms in REDCap: The Visit 3 forms in REDCap are same as the forms used at Visit 2. The first 3 month of Visit 3 will be a pilot phase during which DMCC will add event “v3” in REDCap “LLFS” project, designate Visit 3 forms for “v3”, and assess and fix any form field validations and skip logic issues in event “v3”. We will also ask for feed back from the field RAs on making sure the forms are working well.

Updating the Pedigree (Triplet file)

The TRIPLET dataset reflects the pedigree structures. A triplet is the person, his/her mother, and his/her father. This is all the necessary information needed to determine relatedness. At Visit 3, we will recruit proband grandchildren generation samples. There will probably be a few new participants from proband generation or proband’s offspring generation to enroll in Visit 3. Thus whenever a new participant is enrolled at Visit 3 (either proband grandchild or otherwise), we need to update the pedigree structure for that family and add the new participant’s triplet information into the pedigree triplet file.

1. When to Update Pedigree Structure (Triplet)

If participant has enrolled in Visit 1 and/or Visit 2, then no update to pedigree. However, if participant is new (no visit 1 data and no visit 2 data, new family member interested, new marry-in, or proband’s grandchildren generation) then we NEED to check on and update pedigree structure.

2. How to update Triplet

When a new participant is identified, alert DMCC and tell DMCC the new participant’s pedigree ID. DMCC will then send two files to the field center:

(1) Pedigree plot for that pedigree.

Participant name and date of birth (DOB) are included in the plot.

(2) Pedigree specific triplet file (csv):

- a. column A – subject
- b. column B - pedid (pedigree ID)
- c. column C - id
- d. column D - dadid
- e. column E - momid
- f. column F - Proband_status (1=Yes, 0=No)
- g. column G - Deceased (1=Yes, 0=No)
- h. column H - sex (1=male; 2=female)
- i. column I - Twinstatus (twin status, 1=Yes, 0=No)
- j. column J - adopted (1=Yes, 0=No)
- k. column K - twinrelatn (twin relationship, M=MZ twin, D=DZ twin)

If a new participant’s name and DOB are already on the pedigree plot, there is no need to update the pedigree. If a new participant’s name and DOB are not on the pedigree plot, then the triplet for the pedigree needs to be updated. To update the pedigree, first assign an 8-digit LLFS ID to the new participant from the list of potential new participant IDs from DMCC. This ID is put in column C of the pedigree triplet file, at bottom of existing records. Next, determine the relationship of the new participant to the existing family members. The way to update the triplet depends upon which category of relationship the new participant is to the existing members:

- (1) New marry-in in either proband generation or offspring generation
- (2) New child of proband generation with both parents known in pedigree
- (3) New child of proband generation with only one parent known in pedigree
- (4) Grandchild of proband generation with both parents known in pedigree
- (5) Grandchild of proband generation with only one parent known in pedigree

Directions to update *the pedigree triplet file* for each category:

(1) *New marry-in in either proband generation or offspring generation*

For new marry-in triplet information

- dadid and momid (columns D and E) are empty
- proband status is 0 (Column F)
- Enter data in columns G through K (self-explanatory, sex 1=male; 2=female)

If no children to the ‘new’ couple, need to create a ‘dummy’ child. Enter information for the dummy child of the couple. Complete columns B, D, E, F, G, I, J and K.

(2) *New child of proband generation with both parents known in pedigree*

Create a record for the new child. Assign an LLFS ID to the new child from the list of potential new participant IDs, and put it in column C. Complete column B and columns D through K.

(3) *New child of proband generation with only one parent known in pedigree*

- Create a record for the other parent of the new child. First, assign an LLFS ID to the other parent from the list of potential new participant IDs, and put the ID in column C.
- Create a record for the new child. Assign an LLFS ID to new child from the list of potential new participant IDs, and put it in column C. Next, complete columns B, and columns D through K.

(4) *Grandchild of proband generation with both parents known in pedigree*

- Create a record for the new grandchild. Assign an LLFS ID to new grandchild from the list of potential new participant IDs, and put it in column C. Next, complete columns B, and columns D through K.

(5) *Grandchild of proband generation with only one parent known in pedigree*

- Create a record for the other parent. Assign an LLFS ID to the other parent from the list of potential new participant IDs, and put the ID in column C. Next enter data in column B, and columns D through K.
- Create a record for the new grandchild. Assign an LLFS ID to new grandchild from the list of potential new participant IDs, and put it in column C. Next, complete column B, and columns D through K.

Once the new participant has been added to the triplet file, send it to Rosa (rosa@wustl.edu) at the DMCC for checking and incorporation into the full LLFS triplet.

Chapter 19: Appendices

Appendix 1:

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

Go to https://redcap.wustl.edu/redcap/srvrs/prod_v3_1_0_001/redcap/surveys/index.php?s=D9YTEAFFYF

Options to select in online REDCap Account Request Form:

Select New **User Account**

Select **Accessing an existing project**

Applicant information: you, the applicant should know this

Select **Yes, supervisor or collaborator approval is needed**

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

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

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

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

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

Appendix 2:**Washington University in St. Louis, School of Medicine
WUSTLKey Guest Account Request Form**

Apply for a guest WUSTLkey account:

Go to <https://connect.wustl.edu/guest/guestrequest/> to open WUSTLKey Guest Account Request Form.

Part 1: Guest Information: you, the applicant should know this

Part 2: Account Details

Select **Guest**

Select **6 to 12 months**

Part 3: Sponsor Information

First Name: **Rosa**

Last Name: **Lin**

Email Address: **rosa@wustl.edu**

After receive the guest WUSTL key, call at 314-933-3333 to activate the key.

After get logged into REDCap version 8 with the WUSTL key for the first time, create guest usernames and also email DMCC. DMCC will then activate the requestor's account for access to the LLFS REDCap system.