

**ONTARIO INSTITUT
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Data Quality Framework

REDCap Data Quality Test Project

Version 1.2.1

September 11, 2024

Written and reviewed by the OBI Data Quality Team

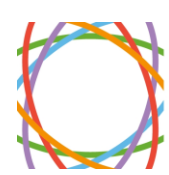
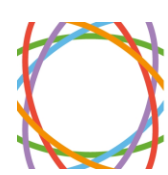


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Purpose and Background

This REDCap project is designed to demonstrate, explore, and test some of the procedures outlined in OBI's Data Quality Framework (DQF) including the use of missing data codes to flag individual fields, the functionality of the Participant Status form (PSF) and Missing Data Flagging form (MDFF), and the automatically generated Form Display Logic that uses the PSF, MDFF, and Form Status data to hide forms on the Record Status Dashboard if participants leave the study.

These forms and form display/branching logic are unique to each study and can be generated by OBI once your REDCap project development is complete. This process involves custom scripts that use the REDCap API to export relevant data and metadata. Minimal input from your research team is needed to 1) determine the timepoint at which the PSF and MDFF should be scheduled, 2) which form-level missing data codes should be included in the MDFF, and 3) which administrative forms can be omitted from the MDFF.

Several OBI Common Data Elements (CDEs) are included in this project to provide a level of form familiarity to its users. Five sample records have been created to demonstrate the functionality of the described features. Project users will be given permissions that allow viewing these records and creating/editing their own records to test the functionality.

The current versions of the Data Quality Framework and Common Data Elements are found on the [Brain-CODE website's Standards page](#). Please refer to the OBI DQF Stage 1 training document "[REDCap Tools & Procedures](#)" for more information on the forms and tools described in this document.

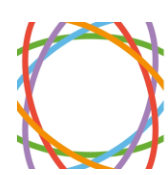
Project Description

FORMS

CDEs

For information on using the CDEs, please see DQF Stage 1 document #3 "[OBI DQF Common Data Elements Guideline](#)" and for the specific details of each form, please see section "Common Data Elements" on the [Brain-CODE website's Standards page](#). The test project contains the following CDEs:

- Adult Demographics form
- Medical History form
- WHOQOL-BREF
- PHQ9
- PSQI



Data Quality Forms

- Participant Status form
- Missing Data Flagging form

Other

- Record Description
 - Repeats the description of each record from this document

STUDY SCHEDULE

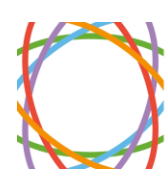
The project has 4 timepoints: “baseline”, “followup1”, “followup2”, “admin”. “baseline”, “followup1”, and “followup2” are used for collecting participant data. The “admin” timepoint is specifically used by research staff for the quality control data forms.

Data Collection Instrument	baseline (1)	followup1 (2)	followup2 (3)	admin (4)
Record Description				✓
Demographics Adult	✓			
Medical History (survey)	✓			
PHQ-9 (survey)	↓	↓	↓	
WHOQOL-BREF	✓		✓	
PSQI		✓	✓	
Participant Status Form				✓
Missing Data Flagging Form				✓

Project-Level Missing Data Codes

Below is the list of core missing data codes included in DQF Stage 2 document #3 “[OBI DQF Data Quality Reporting Guide](#)”.

- “Unable to perform”
- “Task declined”
- “Ran out of time”
- “Administrative error”
- “Technical error”
- “Other”
- (“Unknown value”)



- (“Not applicable”)

Depending on the specifics of your study, all missing data codes may not be applicable and there may be others that would be useful. Furthermore, there may be additional codes that would be useful to flag missing forms in the Missing Data Flagging form but not useful as field-level missing data codes. Please determine with OBI which missing codes you would like included as options on the Missing Data Flagging form.

Participant Status Form

This form is used to track participant’s status (‘Active’, ‘Complete’, ‘Withdrew consent’, ‘Withdrawn by PI’, ‘Lost to follow-up’, ‘Screen fail’) and their progress through the study protocol’s timepoints. Timepoints should be marked as complete once all expected data is collected; this is the case when a) data has been collected for all forms (complete or partially complete), or b) the participant will not provide data for all forms (at the discretion of the researcher or clinician, the participant declines to provide data for a form, following withdrawal from the study, etc.).

In addition to providing a central, standardized method to track participant status, the data from this form is used in the Missing Data Flagging form and Form Display Logic to facilitate the low burden flagging of missing data. This data is critical in OBI’s Data Quality Reporting pipeline (external to REDCap) to determine what data is expected.

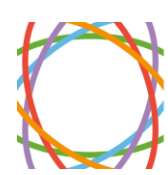
Missing Data Flagging Form

The MDFF can be used in two ways to quickly flag missing data:

- 1) For forms with no data, the selected missing data code is applied in the Data Quality Reporting pipeline to explain why an entire form is missing.
- 2) For partially complete forms (i.e., those with blank fields), the selected missing data code is applied in the Data Quality Reporting pipeline to all blank fields in the form.

For a form to appear in the MDFF, the following branching logic criteria must be satisfied:

- 1) A form’s Form Status is marked as ‘Incomplete’, ‘Unverified’, or is blank (i.e., the form has not been opened)
- 2) The scheduled timepoint for the form is marked as complete in the Participant Status form
- 3) Any other “standard” Form Display Logic criteria are met (see [next section](#))



- 4) The form must not have been specified in the Missing Data Flagging form creation process as a form to ignore (e.g., the Record Description form in this project; these forms are listed in an orange banner at the top of the MDFF)

Additionally, branching logic is built into the dropdown menus. When a participant is marked as Active or Complete in the PSF, the “Participant is no longer in the study” option is hidden but appears when the participant is marked as “Withdrew consent”, “Withdrawn by PI”, “Lost to follow-up”, or “Screen fail”.

If the participant withdraws before completing the final timepoint, there is no need to flag forms at timepoints after the timepoint at which the withdrawal occurred; these will be accounted for in the Data Quality Reporting pipeline.

Form Display Logic

"STANDARD" FORM DISPLAY LOGIC

One form contains Form Display Logic not related to the PSF and MDFF:

- PSQI: enabled only if the calculated age or entered age in Demographics Adult form ≥ 18 years

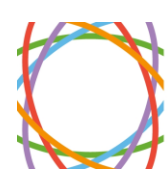
COMPLETION STATUS FORM DISPLAY LOGIC

This Form Display Logic can be used to disable forms after a participant leaves the study so that it is apparent on the Record Status Dashboard that no further data collection is expected for that participant. For a form to remain enabled, the following criteria must be satisfied:

- 1) The participant’s status in the Participant Status form must be “Active” or “Complete”
- 2) If the participant’s status in the Participant Status form is marked as “Withdrew consent”, “Withdrawn by PI”, “Lost to follow-up”, or “Screen fail”, the form’s scheduled timepoint in the checkbox section of the Participant Status form is checked
- 3) Any “standard” Form Display Logic is satisfied

Sample Records

Five sample records are included in the project to illustrate how the Form Status, Participant Status form, Missing Data Flagging form, and Form Display Logic work together in different situations. Each section below has a brief description of what part of the study protocol the participant has completed (this description is also repeated in each record’s Record Description form), followed by three REDCap screenshots showing the Participant Status form, Missing Data



Flagging form, and Form Status dashboard (showing both Form Status and forms disabled through Form Display Logic), respectively, with an explanation of the project’s behaviour in each caption. The first four records are ordered chronologically as if a single participant (sample_001_x_{your IDP name}) was progressing through the study. The fifth record represents a second participant (sample_002_1_{your IDP name}). These records are locked to ensure the data matches the descriptions. Additional records can be created for further testing purposes.

SAMPLE_001_1

This participant just enrolled in the study. They are marked as “Active” on the PSF but have not completed any timepoints. No forms are disabled through Form Display Logic except those that have "standard" Form Display Logic (i.e., the PSQI requires the participant be above the age of 18 years. No age is entered in the Demographics Adult form so the PSQI is disabled).

Record ID	sample_001_1
Participant Status: <u>ACTIVE</u>	
The participant is still actively enrolled in the study.	
What is the status of the participant?	
<small>* must provide value</small>	
<input checked="" type="radio"/> Active <input type="radio"/> Complete <input type="radio"/> Withdrew consent <input type="radio"/> Withdrawn by PI <input type="radio"/> Lost to follow-up <input type="radio"/> Screen fail	
<small>Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn (no longer part of study), Lost to follow-up (unreachable)</small>	
Which timepoints has the participant completed?	
<input type="checkbox"/> baseline_arm_1 <input type="checkbox"/> followup1_arm_1 <input type="checkbox"/> followup2_arm_1	
<small>Please check box if no more data is expected to be collected for the given visit</small>	

Figure 1: sample_001_1's Participant Status form

Record ID	sample_001_1
Excluded form: record_description	
If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form	
Form Status	
Complete?	<input type="text" value="Incomplete"/>



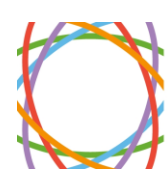
Figure 2: *sample_001_1's Missing Data Flagging form. No forms are displayed since no timepoints are marked as complete in the PSF.*

<input type="checkbox"/> Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				
Demographics Adult				
Medical History (survey)				
PHQ-9 (survey)				
WHOQOL-BREF				
PSQI				
Participant Status Form				
Missing Data Flagging Form				

Figure 3: *sample_001_1's Form Status dashboard. No forms are disabled through Form Display Logic based on PSF or Form Status data. Note: the PSQI is disabled through standard Form Display Logic because no age is entered in the Demographics Adult form.*

SAMPLE_001_2

This participant is active in the study and has completed all forms that they were expected to complete for the “baseline” timepoint; they fully completed the PHQ-9 and PSQI (this form became enabled when an age above 18 years was input in the Demographics Adult form), declined to provide some information in the Demographics Adult form, and declined to provide any responses to the Medical History form. The PSQI and PHQ-9 Form Statuses are both marked as “Complete”. The Demographics Adult’s Form Status is marked as “Incomplete” and the Medical History’s Form Status is left blank since the form contains no data. The PSF is marked as “Active” and the “baseline” timepoint checkbox is selected.



Record ID sample_001_2

Participant Status: ACTIVE

The participant is still actively enrolled in the study.

What is the status of the participant? (H) (M)

* must provide value

Active
 Complete
 Withdrew consent
 Withdrawn by PI
 Lost to follow-up
 Screen fail

reset

Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn (no longer part of study), Lost to follow-up (unreachable)

Which timepoints has the participant completed? (H) (M)

baseline_arm_1
 followup1_arm_1
 followup2_arm_1

Please check box if no more data is expected to be collected for the given visit

Figure 4: sample_001_2's Participant Status form

Record ID sample_001_2

Excluded form: record_description

If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form

BASELINE_ARM_1

Demographics Adult: (H) (M)

Medical History: (H) (M)

Form Status

Complete? (H) (M)

Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

Not a missing form

Unable to perform

Task declined

Out of time

Admin error

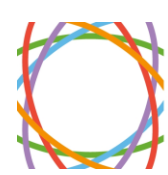
Technical error

Missing other

Not applicable

Save & ...

Figure 5: sample_001_2's Missing Data Flagging form. Fields for Demographics Adult and Medical History at "baseline" are shown because "baseline" is marked as complete in the Participant Status form and the Form Statuses are "Incomplete" and blank, respectively. Dropdown menus do not include the "Participant is no longer in the study" option because their status in the PSF is set to Active. The PSQI and PHQ-9 are not shown because their Form Statuses are both "Complete".



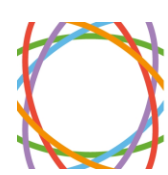
This example demonstrates how the Missing Data Flagging form can be used to flag two types of missing data. In the Demographics Adult form, the selected missing data code will be applied to all blank fields in the Demographics Adult record in OBI’s Data Quality Reporting pipeline since the record is not missing but contains missing items (i.e., partially complete). This removes the need to flag each individual missing item in a form which can be time-consuming. Since the Medical History form contains no data, the missing data code will flag the entire form as missing.

<input type="checkbox"/> Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				<input checked="" type="radio"/>
Demographics Adult	<input checked="" type="radio"/>			
Medical History (survey)	<input type="radio"/>			
PHQ-9 (survey)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
WHOQOL-BREF	<input checked="" type="radio"/>		<input type="radio"/>	
PSQI		<input type="radio"/>	<input type="radio"/>	
Participant Status Form				<input checked="" type="radio"/>
Missing Data Flagging Form				<input type="radio"/>

Figure 6: sample_001_2's Form Status dashboard. No forms are disabled through Form Display Logic based on PSF or Form Status data. Note: the PSQI is now enabled because an age equal to or greater than 18 years was entered in the Demographics Adult form.

SAMPLE_001_3

The participant is still active in the study and is now partway through the “followup1” timepoint. At “followup1”, the participant completed the PHQ-9 (Form Status = “Complete”) and did not start the PSQI (Form Status = blank); the participant ran out of time but said they will complete the PSQI tomorrow. Since PSQI data is expected in the future, the checkbox for “followup1” in the PSF should not be checked.



Record ID sample_001_3

Participant Status: ACTIVE

The participant is still actively enrolled in the study.

What is the status of the participant?

* must provide value

Active
 Complete
 Withdrew consent
 Withdrawn by PI
 Lost to follow-up
 Screen fail

Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn (no longer part of study), Lost to follow-up (unreachable)

Which timepoints has the participant completed?

baseline_arm_1
 followup1_arm_1
 followup2_arm_1

Please check box if no more data is expected to be collected for the given visit

Figure 7: sample_001_3's Participant Status form

Record ID sample_001_3

Excluded form: record_description

If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form

BASELINE_ARM_1

Demographics Adult:

Medical History:

Form Status

Complete?

Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

Not a missing form

Unable to perform

Task declined

Out of time

Admin error

Technical error

Missing other

Not applicable

Save & ...

Figure 8: sample_001_3's Missing Data Flagging form. The PSQI at timepoint "followup1" is not shown because that timepoint is not marked as complete in the PSF and the PHQ-9 is not shown because its Form Status is "Complete".

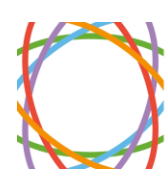


<input type="checkbox"/> Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				<input checked="" type="radio"/>
Demographics Adult	<input checked="" type="radio"/>			
Medical History (survey)	<input type="radio"/>			
PHQ-9 (survey)	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
WHOQOL-BREF	<input checked="" type="radio"/>		<input type="radio"/>	
PSQI		<input type="radio"/>	<input type="radio"/>	
Participant Status Form				<input checked="" type="radio"/>
Missing Data Flagging Form				<input type="radio"/>

Figure 9: sample_001_3's Form Status dashboard. No forms are disabled through Form Display Logic based on PSF or Form Status data.

SAMPLE_001_4

The participant unfortunately had a medical emergency and was withdrawn from the study by the Principal Investigator as a safety precaution. The participant's status in the Participant Status form is set to "Withdrawn by PI" and the date and reason of withdrawal was entered. Because no more data collection is expected at this timepoint, "followup1" is marked as complete in the PSF.



Record ID sample_001_4

Participant Status: WITHDRAWN

The participant has been withdrawn from the study.

What is the status of the participant?

* must provide value

Active
 Complete
 Withdrew consent
 Withdrawn by PI
 Lost to follow-up
 Screen fail

Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn (no longer part of study), Lost to follow-up (unreachable)

Date of withdrawal:

2024-08-06 Today Y-M-D

Reason for withdrawal by PI (select primary reason): Medical reasons unrelated to reported conditi

Which timepoints has the participant completed?

baseline_arm_1
 followup1_arm_1
 followup2_arm_1

Please check box if no more data is expected to be collected for the given visit

Figure 10: sample_004's Participant Status form. Note that the "followup2" timepoint should not be checked even though no data will be collected.

Record ID sample_001_4

Excluded form: record_description

If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form

BASELINE_ARM_1

Demographics Adult: [dropdown]

Medical History: [dropdown]

FOLLOWUP1_ARM_1

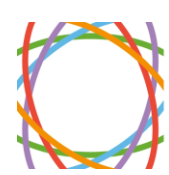
PSQI: Participant no longer in study [dropdown]

Form Status

Complete? Incomplete [dropdown]

- Not a missing form
- Unable to perform
- Task declined
- Out of time
- Admin error
- Technical error
- Missing other
- Not applicable
- Participant no longer in study

Figure 11: sample_004's Missing Data Flagging form. At "followup1", only the PSQI shows up because its Form Status is blank. Because the participant is marked as "Withdrawn by PI" in the PSF, the "Participant no longer in study" option will be available in dropdown menus.

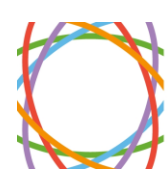


Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				
Demographics Adult				
Medical History (survey)				
PHQ-9 (survey)				
WHOQOL-BREF				
PSQI				
Participant Status Form				
Missing Data Flagging Form				

Figure 12: sample_004's Form Status dashboard. When a participant is marked as withdrawn, lost to follow-up, or as a screen fail in the PSF, all forms (excluding the Participant Status form and Missing Data Flagging form) that are scheduled at timepoints not marked as “complete” in the PSF (i.e., followup2) are disabled through Form Display Logic; these are the greyed out empty circles.

SAMPLE_002_1

sample_002_1 represents data from a different participant. The participant was recently enrolled in the study and has provided all information that will be collected for the “baseline” timepoint. However, the Demographics Adult form had some unanswered fields that are left blank and not populated with missing data codes. The Medical History form and PHQ-9 are fully completed. The WHOQOL-BREF was completed but contains a few blank fields that were all flagged with missing data codes. The Form Status for the Demographics Adult form should be “Incomplete” and the Medical History, PHQ-9, and WHOQOL-BREF should be “Complete”. Please note that all forms without blank fields should be marked as “Complete”; for this use case, missing data codes are treated as data.



Record ID sample_002_1

Participant Status: ACTIVE

The participant is still actively enrolled in the study.

What is the status of the participant? (H) (M)

* must provide value

Active
 Complete
 Withdrew consent
 Withdrawn by PI
 Lost to follow-up
 Screen fail

Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn (no longer part of study), Lost to follow-up (unreachable) reset

Which timepoints has the participant completed? (H) (M)

baseline_arm_1
 followup1_arm_1
 followup2_arm_1

Please check box if no more data is expected to be collected for the given visit

Figure 13: sample_002_1's Participant Status form

Record ID sample_002_1

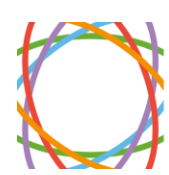
Excluded form: record_description

If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form

BASELINE_ARM_1

Demographics Adult:	<input type="text"/>
Form Status	<div style="border: 1px solid gray; padding: 2px;"> <ul style="list-style-type: none"> Not a missing form Unable to perform Task declined Out of time Admin error Technical error Missing other Not applicable </div>
Complete?	<input type="checkbox"/>
Lock this instrument?	<input type="checkbox"/>
<small>If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.</small>	

Figure 14: sample_002_1's Missing Data Flagging form. Only one form's Form Status was set to "Incomplete" for the "baseline" timepoint, which is marked as completed in the Participant Status form. Since Demographics Adult is a partially completed form, the selected missing code will be externally applied to all empty fields.















 Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				
Demographics Adult				
Medical History (survey)				
PHQ-9 (survey)				
WHOQOL-BREF				
PSQI				
Participant Status Form				
Missing Data Flagging Form				

Figure 15: sample_002_1's Form Status dashboard. No forms are disabled through Form Display Logic based on PSF or Form Status data.