

DATA ENTRY USING REDCAP DATABASE

Neonatal Minimally Invasive Surgery Trainer Project

Data Entry Using REDCap Database
Document Version 1.0 (21 November 2017)



Introduction

This document contains information and instructions to assist Site Directors (SD) and Site Coordinators (SC) participating in the Neonatal Minimally Invasive Surgery Trainer Project (NMTP), sponsored by the International Pediatric Endosurgery Group. Information pertaining to data entry and maintenance using the project's REDCap database is provided, together with answers to frequently asked questions.

Abbreviations Used in this Document

IPEG	International Pediatric Endosurgery Group
IS	Information Services
MIS	Minimally Invasive Surgery
NMTP	Neonatal MIS Trainer Project
PC	Program Coordinator (IPEG)
REDCap	Research Electronic Data Capture
SC	Local Site Coordinator
SD	Local Site Director
TS	MIS Training Session
	Further subdivided as:
	<i>TS-E</i> – Evaluation Training Session
	<i>TS-P</i> – Practice Training Session
	<i>TS-O</i> – Optional Training Session

REDCap

REDCap is an application that enables investigators to design databases and maintain research data using the world wide web. The software is produced and maintained by the [REDCap Consortium](#) with support from [Vanderbilt University](#) and is widely used for clinical research at academic medical centers worldwide. The REDCap server hosting data for this project is maintained by [The Research Institute](#) at Nationwide Children's Hospital. The study data can be accessed by authorized users using a compatible web browser by visiting the following URL:
https://redcap.nchri.org/redcap_v7.1.2/index.php?pid=1162

In the current project, REDCap will be used by the SC or SD to enter details regarding participants in the NMTP as well as performance data from the individual TS completed by participants.

User Accounts

User accounts are necessary to access REDCap. As local project sites are enrolled, requests for SC and SD accounts will be referred to the Technical Coordinator at Nationwide Children's Hospital to be approved by the IS team managing REDCap. Login credentials will then be emailed directly to the local project staff. Usernames and passwords provided to an SC or SD are **not to be shared** with others. Failure to maintain security of REDCap login credentials will be grounds for account termination and exclusion from further participation in the NMTP. Please review the information presented on the REDCap login screen for the details of the REDCap Data Use Agreement, which is required to participate in the NMTP.

REDCap Interface

The screenshot displays the REDCap interface for a project titled "Surgical Training Program Utilization of Simulation Models in Minimal Access Surgery". The interface is divided into three zones:

- Zone 1 (Left-Hand Navigation):** A vertical sidebar on the left containing navigation options such as "My Projects", "Project Home", "Project Setup", "Data Collection", "Applications", "Project Bookmarks", and "Help & Information". The "Add New Participant" button is highlighted with a purple box.
- Zone 2 (Title Bar and Page Description):** The top section of the page, including the browser address bar, the REDCap logo, the project name, and the project title.
- Zone 3 (Data Entry and Editing):** The main content area, which includes a "Quick Tasks" section with a "Codebook" link, a "Project Dashboard" section with a table of "Current Users", and a "Project Statistics" table.

Current Users	
User	Expires
beb003 (Beth Burkhart)	never
bourgeotadm (Tran Bourgeois)	never
djp003 (Dominic Papandria)	never
kad006	never
rccxh001	never
rcdxd001	never
rclxb002	never

Project Statistics	
Records in project	Total: 5 / In group: 1
Most recent activity	05/10/2017 2:42pm
Space usage for docs	0.00 MB

Figure 1: REDCap User Interface Zones

The web pages of the REDCap project site are divided into three zones as shown in Figure 1:

- Zone 1: **Left-Hand Navigation**
- Zone 2: **Title Bar and Page Description**
- Zone 3: **Data Entry and Editing**

Color-coded boxes are used for clarity in this guide although the boxes will not be present when using REDCap.

Participant Enrollment

As local participants are identified, the SC / SD will enter basic information to begin the enrollment process. A new participant can be added by clicking on the **Add New Participant** link in the Left-Hand Navigation zone (Figure 1). A new database record will be generated for the participant.

Record Home Page

The (initially empty) web page is then displayed as a table in the Data Entry and Editing zone. This view is called the Record Home Page and is unique to each Participant. The page presents a grid of buttons, with columns representing events in the NMTP and rows representing data to be collected. Clicking on the buttons enables the SC/SD to enter data into the REDCap database for the selected Participant. The buttons change color, depending on whether data has been entered and whether the data are complete (Figure 2).

The SC / SD will then click on the **top button** in the “Program Enrollment” column (Figure 2).

Record Home Page

Record "194-3" is a new Record ID. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved) ?
- Partial Survey Response
- Completed Survey Response
- ● ● Many statuses (all same)

NEW Record ID 194-3

Data Collection Instrument	Program Enrollment	TS-E (Baseline)	Training Session	TS-E (6 month)	TS-E (12 month)	TS-E (18 month)	TS-E (24 month)
Enrollment	●						
Participants (survey)	●						
Session Reminder (survey)				●	●	●	●
Training Sessions		●	●	●	●	●	●

Figure 2: Record Home Page for new Participant record.

On the following Enrollment form, the SC / SD will:

1. Select the **host program**
2. Enter the participant's **email address**
3. **Randomize the participant** by clicking the **Randomize** (Figure 3).¹
 - a. Confirm participant randomization in the dialog box displayed (Figure 4), which will re-display the enrollment form.

¹ Group assignment to early or late TS-P sessions is pre-determined in REDCap for each site, but the SC / SD will need to obtain group assignment at enrollment. Note that the Randomization Group assignment cannot be changed.

4. Change the record status to **Complete**
5. Click on the **Save & Exit Form** button (Figure 3).

At this point, enrollment is complete and the participant will receive an email prompting him or her to complete the Participant Survey.

Enrollment

Adding new Record ID 194-2

Event Name: **Program Enrollment**

Record ID: 194-2

Program Name: USA - Nationwide Children's Hospital
* must provide value
Name of training program

Participant email address: Dominic.Papandria@nationwidechildrens.org
* must provide value
Email address for the training program participant

Participant Group Assignment
 - Group A: initial mandatory training followed by optional training
 - Group B: initial optional training followed by mandatory training
* must provide value

Form Status

Complete?: Incomplete

Save & Exit Form Save & ...

-- Cancel --

Figure 3: Participant Enrollment Form

Randomizing Record ID "194-2"

Below you may perform randomization for Record ID "194-2" on the field **Participant Group Assignment - Group A: initial mandatory training followed by optional training - Group B: initial optional training followed by mandatory training** (*group_assignment*). Please note that the fields below will become permanently locked and uneditable on the data entry form once this record has been randomized.

Provide any missing values below for Record ID 194-2, then click the Randomize button below.

Program Name: USA - Nationwide Children's Hospital
* must provide value
Name of training program

REMINDER: This project is still in development status, so you should NOT be randomizing real subjects yet. You should only be randomizing real subjects after moving the project into in production status.

Randomize Cancel

Figure 4: Participant Enrollment Form

The Enrollment button will now be green on the Record Home Page, indicating that enrollment of this participant is complete. The SC / SD will then await completion of the survey and plan for a TS-E training session.

Participant Survey

The REDCap site will automatically email a survey link to the address provided at the time of enrollment. The message will contain information identifying the participating program and an invitation to the recipient to participate in the NMTP. By completing the survey, the person agrees to participate in the NMTP. A sample of the email content is provided as Appendix A at the end of this document. Participants will answer questions in the linked survey, identifying demographic variables and previous MIS experience. A sample of this survey is also provided as Appendix B at the end of this document. If the participant wishes to complete the survey, but is unable to do so, the SC / SD can directly enter the survey responses (with the participant present) by clicking on the **second button** in the Program Enrollment column on the Record Home Page (Figure 2). Once the responses to the survey are completed and submitted, the Participants (survey) button on the Record Home Page will be green, indicating the participant is ready to begin training sessions.

Navigating Participant Records

Site Directors and Site Coordinators will maintain program data for each participant in REDCap. To select a specific participant's record, select the **Record Status Dashboard** link in the Left-Hand Navigation zone (Figure 5).

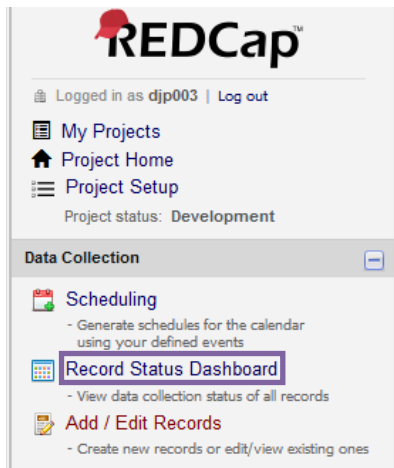


Figure 5: Left-hand Navigation zone

This will display a full list of participant records entered into REDCap at the user's site (Figure 6). Each row in the table represents a participant and each column provides a link to data within a participant's record. The full Record Home Page (Figure 2) for each participant can be accessed using the links in the **Record ID column**.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved) ?
- Partial Survey Response
- Completed Survey Response
- ● ● Many statuses (all same)

Displaying record Page 1 of 1: "194-1" through "194-2" of 2 records ALL (2) records per page

Displaying: Instrument status only | Lock status only | All status types

Record ID	Program Enrollment		Baseline Exercise	Training Session	Evaluation (6 month)		Evaluation (12 month)		Evaluation (18 month)		Evaluation (24 month)	
	Enrollment	Participants	Training Sessions	Training Sessions	Session Reminder	Training Sessions	Session Reminder	Training Sessions	Session Reminder	Training Sessions	Session Reminder	Training Sessions
194-1	●	●	●	●	○	○	○	○	○	○	○	○
194-2	●	●	●	○	○	○	○	○	○	○	○	○

Figure 6: Record Status Dashboard

Training Sessions

Site Directors and Site Coordinators will coordinate completion of proctored Training Sessions (TS) according to the *User Manual for Neonatal MIS Trainers* and the *Neonatal MIS Trainers Data Sheet*. Three types of TS can be completed:

1. Mandatory Evaluation Sessions (TS-E) conducted shortly after enrollment (Baseline) and semi-annually (at 6, 12, 18, and 24 months) following enrollment. These exercises are used to determine the effectiveness of the NMTP at improving MIS skills.
2. Mandatory Practice Sessions (TS-P) – these are completed monthly over a six-month period dictated by the Group Allocation (randomization) of the Participant.
3. Optional / Elective Sessions (TS-O) – additional proctored training completed at the Participant’s request, in excess of the mandatory TS.

TS-E Events

Reminder emails will be sent to participants to confirm that scheduled training sessions have been arranged in accordance with this schedule. Columns are defined for each of these scheduled sessions on the Record Home Page. The **Session Reminder (survey)** row is used only for the generation of reminder emails and changes to these data forms is not necessary. Data for each TS-E is entered by clicking on the button in the **Training Sessions** row corresponding to the training event defined in the schedule (Figure 7). This will open the Training Sessions form (Figure 9).

Record ID **194-1**
zz_Program04

Data Collection Instrument	Program Enrollment	TS-E (Baseline)	Training Session (#1)	+ Add new (#2)	TS-E (6 month)	TS-E (12 month)	TS-E (18 month)	TS-E (24 month)
Enrollment	●							
Participants (survey)	●							
Session Reminder (survey)					○	○	○	○
Training Sessions		●	●	●	○	○	○	○

Figure 7: Record Home Page for enrolled Participant.

TS-P Events

The SC / SD can enter data for TS-P events by clicking a blank (gray) button in the corresponding column. Additional columns can be added for each new TS-P event by clicking on the **+ Add new** button in the column header (Figure 8).

Data Collection Instrument	Program Enrollment	TS-E (Baseline)	Training Session (#1)	+ Add new (#2)	TS-E (6 month)	m
Enrollment	<input checked="" type="radio"/>					
Participants (survey)	<input checked="" type="radio"/>					
Session Reminder (survey)					<input type="radio"/>	
Training Sessions		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	

Figure 8: Record Home Page - adding columns for TS-P or TS-O events.

TS-O Events

The SC / SD can enter data for TS-O events by taking the same steps as those described above for TS-P events. When entering the performance data for the TS, the **Session Type** can be selected (Figure 9).

Training Sessions Form

The following steps are used to enter data for each TS (Figure 9):

1. Select a **Timing Method** to use when reporting time elapsed for each exercise (see below).
2. Choose a **Session Type**
3. Select the **Training Exercises attempted** (all exercises should be completed for each TS-E and TS-P session)
4. Enter the times elapsed for each exercise (see below)
5. Record the count of errors made for each exercise (see the companion document: *Neonatal MIS Trainers data collection* for specific instructions describing how to identify and count errors).
6. At the completion of the training session, record the total time elapsed (see below).
7. Indicate **Training Exercises successfully completed** within the goal time.
8. Scroll to the Form Status section at the bottom of the form and change the **Complete?** field to Complete, then click on the **Save & Exit Form** button.

Training Sessions

Editing existing Record ID 194-2

Event Name: **Baseline Exercise**

Record ID 194-2

Timing Method

Time exercises using web browser
 Enter times manually

* must provide value

Designate how times will be measured and recorded.

Session Date (Calculated)

Type of Training Session

* must provide value

Was a faculty member present during the training exercise?

Training Exercises

	Attempted	Completed within time allotted
Dexterity	<input type="checkbox"/>	<input type="checkbox"/>
Running bowel	<input type="checkbox"/>	<input type="checkbox"/>
Laparoscopic suturing	<input type="checkbox"/>	<input type="checkbox"/>
Thoracoscopic suturing (esophagus)	<input type="checkbox"/>	<input type="checkbox"/>
Thoracoscopic suturing (congenital diaphragmatic hernia)	<input type="checkbox"/>	<input type="checkbox"/>

Training Session Time (calculated)

Training Session time (total seconds)

Form Status

Complete?

Figure 9: Training Sessions Form – new.

Timing Method

There are two methods that the SC/ SD can use to record the time elapsed for the participant to attempt each exercise.

1. Web Browser (**recommended**) – using this method, the browser² will be used to collect starting and stopping times for the session as well as for each exercise and calculate the intervening time automatically. Buttons on the Training Sessions form labeled **Now** will record the current time in the relevant fields.
 - a. When the participant begins each exercise, click the **Now button** in the appropriate Exercise Start row.

² Recommended browsers include Google Chrome, Microsoft Internet Explorer 11, and Mozilla Firefox 54 (Microsoft Windows 7 and 10) as well as mobile Google Chrome and Apple Safari (iOS 10 on iPad). **Please note** that REDCap login sessions for RedCAP are limited to 20 minutes of inactivity before users are automatically signed out and **any unsaved data are discarded**. Any activity (data entry or modification) will reset this time. For longer TS and exercises, users are cautioned to maintain session activity (such as repeatedly clicking on the **Now** button to update the current exercise Stop time – see below). This will avoid data loss from accidental REDCap session termination.

- b. When the exercise attempt is completed or abandoned, click the **Now button** in the appropriate Exercise Stop row (Figure 10). The total completion time (in seconds) will be calculated and entered automatically. This result cannot be edited directly, but starting and stopping times can be changed to correct any errors.

The screenshot shows a web browser interface with several rows of exercise data. The first row is 'Exercise Start: Dexterity (transfer washers)' with a date/time of '2017-06-25 11:50:40' and a 'Now' button highlighted with a red box. Below it is 'Exercise Stop: Dexterity (transfer washers)' with a date/time of '2017-06-25 12:06:14' and a 'Now' button also highlighted with a red box. The next row shows 'Dexterity - Transfer Time (calculated)' with a value of '934'. The following row is 'Exercise Start: Dexterity (string beads)' with a date/time of '2017-06-25 12:06:20' and a 'Now' button highlighted with a red box. Below it is 'Exercise Stop: Dexterity (string beads)' with an empty input field and a 'Now' button highlighted with a red box. The final row shows 'Dexterity - String Time (calculated)' with an empty input field.

Figure 10: Session and exercise times calculated using web browser.

2. Manual Entry – using this method, the user will be prompted to enter the time to complete each exercise in **minutes** and **seconds**. The total completion time will be converted into seconds and entered automatically (Figure 11). Total time for the TS will also be manually entered in minutes and seconds.

The screenshot shows a web browser interface with several rows of exercise data. The first row is 'Dexterity - Time to Transfer - Minutes' with a value of '15' in a red-bordered input field. Below it is 'Dexterity - Time to Transfer - Seconds' with a value of '34' in a blue-bordered input field. The next row shows 'Dexterity - Transfer Time (calculated)' with a value of '934'. The following row is 'Dexterity - Time to String - Minutes' with an empty input field highlighted with a red border. Below it is 'Dexterity - Time to String - Seconds' with an empty input field highlighted with a blue border. The final row shows 'Dexterity - String Time (calculated)' with an empty input field.

Figure 11: Session and exercise times entered manually.

Data Reports

Instructions concerning generation of site-specific reports of participant performance data will be addressed in a future revision of this document.

Technical Support

Questions or problems related to REDCap should be directed to the Technical Coordinator, Dominic Papandria via email at Dominic.Papandria@nationwidechildrens.org.

REDCap FAQ

Questions or problems related to REDCap should be directed to the Technical Coordinator,

Appendix A – Sample Email

Text similar to the following is sent to participants at the time of enrollment:

Dear Colleague,

You have been identified by your training program in Minimally Invasive Surgery (MIS) as a potential participant in a research study, called the Neonatal MIS Trainer Project.

Training Program: ***USA - Nationwide Children's Hospital***

The next step in the process of study enrollment is to complete the attached survey by clicking on the link below. More information regarding the study is also provided.

This investigation examines the use of structured exercises using a standardized neonatal MIS model to improve surgical skills. The study is sponsored by your training program, as well as the International Pediatric Endosurgery Group and Karl Storz, GmbH & Co. KG. The study has been deemed exempt from regulation as Human Subjects Research by the Institutional Review Board of Nationwide Children's Hospital.

Your participation in the Neonatal MIS Trainer Project is *voluntary*. If you decide to participate, you will be asked to complete an online survey, followed by several laparoscopic and thoracoscopic exercises designed to improve surgical performance. You will be assigned to one of two training schedules to determine if either is more effective. Your performance of the exercises will be objectively assessed, recorded, and tracked over time.

There is no penalty for deciding not to participate and the performance data collected cannot be used to determine any benefit or penalty by your training program. You will be provided with performance data to track your progress at regular intervals. We expect that your performance will steadily improve and that your performance in actual MIS procedures will also improve, but the current study will not assess performance in the operating theater.

If you have any questions or concerns regarding this study, please reply to this message to contact the study coordinator.

Warmest regards.

You may open the survey in your web browser by clicking the link below:
Participant Information

If the link above does not work, try copying the link below into your web browser:

https://redcap.nchri.org/surveys/?s=xxxxxxxxxx

This link is unique to you and should not be forwarded to others.

Appendix B – Participant Survey

The following 6-12 question survey is completed by enrolled persons that elect to participate:

Participant Information

Resize font:
🔍 1 🗨

Thank you for agreeing to participate in the Neonatal MIS Trainer Project.

Please provide the following information that will be used to produce anonymous statistical analysis of participant performance.

Thank you!

Enrollment Date	2017-06-04	Today	🔍
* must provide value			
Participant Age	27-29	Age of participant (years)	
Participant Gender	<input checked="" type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Unspecified	reset	
* must provide value			
Dominant Hand	<input type="radio"/> Left <input checked="" type="radio"/> Right	reset	
Right-handed or left-handed?			
Level of Training	<input type="radio"/> Student <input checked="" type="radio"/> Trainee / Registrar <input type="radio"/> Faculty / Consultant	reset	
Completed years of post-graduate surgical training prior to current appointment.			
Current Training Year	7	Following graduation from medical school	
* must provide value			
Past MIS Experience	<input checked="" type="checkbox"/> Basic <input checked="" type="checkbox"/> Intermediate <input checked="" type="checkbox"/> Neonatal	Previous experience with minimally invasive surgery.	
- Basic (e.g., appendectomy, cholecystectomy) - Intermediate (e.g., fundoplication, colectomy, splenectomy)			
* must provide value			
Neonatal MIS Experience - Please indicate the number of procedures that have been completed in each category.			
	0	1-5	>5
Repair of duodenal atresia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			
Repair of esophageal atresia / tracheo-esophageal fistula	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			
Congenital diaphragmatic hernia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			
Pulmonary lobectomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			
Pyloromyotomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			
Ladd's procedure for intestinal malrotation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* must provide value			

Submit