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:
	TS-E – Evaluation Training Session
	TS-P – Practice Training Session
	TS-O – 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

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).

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.

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[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. Cick 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.

Figure 3: Participant Enrollment Form

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).
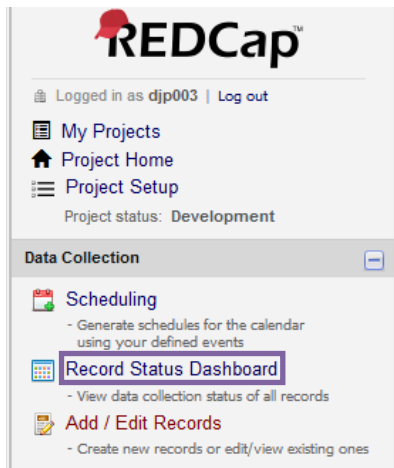

Figure 5: Left-hand Navigation zone

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**.

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).

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).

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.

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 browser[2] 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.

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[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.

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.

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:

Appendix B – Participant Survey

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

Participant Information

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 * must provide value	2017-06-04 [Today] Y-M-D
Participant Age	27-29 ▼ Age of participant (years)
Participant Gender * must provide value	⦿ Female ◯ Male ◯ Unspecified reset
Dominant Hand	◯ Left ⦿ Right reset Right-handed or left-handed?
Level of Training * must provide value	◯ Student ⦿ Trainee / Registrar ◯ Faculty / Consultant reset Completed years of post-graduate surgical training prior to current appointment.
Current Training Year * must provide value	7 ▼ Following graduation from medical school
Past MIS Experience - Basic (e.g., appendectomy, cholecystectomy) - Intermediate (e.g., fundoplication, colectomy, splenectomy) * must provide value	☑ Basic ☑ Intermediate ☑ Neonatal Previous experience with minimally invasive surgery.

Neonatal MIS Experience - Please indicate the number of procedures that have been completed in each category.

	0	1-5	>5
Repair of duodenal atresia * must provide value	◯	◯	◯ reset
Repair of esophageal atresia / tracheo-esophageal fistula * must provide value	◯	◯	◯ reset
Congenital diaphragmatic hernia * must provide value	◯	◯	◯ reset
Pulmonary lobectomy * must provide value	◯	◯	◯ reset
Pyloromyotomy * must provide value	◯	◯	◯ reset
Ladd's procedure for intestinal malrotation * must provide value	◯	◯	◯ reset

[Submit]