

The Use of Non Proprietary Information Management Systems (IMS) for Operational Metric Analysis in the National Children's Study (NCS): *A Review of Experiences by The Children's Hospital of Philadelphia's Study Center*

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Objective & Goals

- SC IMS for Management of Operations
- Our Goals for the IMS are to provide:
 - Analysis of SC Operational Systems
 - System Standards from Metric Analysis
 - Real Time Monitoring of SC activities
 - Targeted Process Improvements



IMS Requirements

- IMS Requirements:
 - Easily Programmed
 - Managed Internally
 - Low Cost
 - Secure
 - Ability to Provide Data Driven Reports



REDCap

- Can non-proprietary software meet the requirements and objectives?
 - We selected REDCap for testing:
 - CHOP is a REDCap consortium partner
 - REDCap is non-proprietary software
 - REDCap's menu of capabilities
 - REDCap's "easy to use" reputation



REDCap Capabilities

- REDCap (Research Electronic Data Capture)
 - A secure, web-based application designed to support data capture for research studies that provides:
 - An intuitive interface for validated data entry
 - Audit trails for tracking data manipulation and export procedures
 - Automated export procedures for seamless data downloads to common statistical packages
 - Procedures for importing data from external sources.



Methods–Staff REDCap Training

- Training via Vanderbilt University tutorials
- Available online:
 - 11 tutorials, 1 to 50 minutes in duration
 - Average 1-2 days to complete



REDCap Training

REDCap

Home My Projects **Create New Project** Training Resources Help & FAQ Send-It

REDCap Training Resources

Just Getting Started?
 In you are new to REDCap, this first set of videos below can help you get started to learn the basics of REDCap and provide a general overview for some of REDCap's preliminary concepts and features.

Title	Description	Watch Video
REDCap Overview	This video provides an overview of basic functions and features within a REDCap project. It will serve as a starting point for learning about the basic concepts of REDCap, what REDCap projects are, how to create them, and how to use them.	50 minutes
Building Your Data Collection Forms	The Online Designer Use this online method for making modifications to project fields and data collection instruments very easily using only your web browser. Changes can be made quickly and viewed immediately as you build your data collection forms in real time.	5 minutes
	The Data Dictionary Use this offline method, called the 'Data Dictionary', which is a specifically formatted Microsoft Excel file within which you may construct your project fields and afterward upload the file into REDCap to commit the changes to your project. If you wish to view an example of how your Data Dictionary may be formatted, you may download the Data Dictionary demonstration file .	14 minutes
The Scheduling Module	If you elect to utilize the Scheduling module in your REDCap project, you may then generate schedules based upon pre-defined events/time-points, after which the scheduled events get added to your project calendar. Scheduling may be done in conjunction with proper data collection, or scheduling may be performed on its own.	6 minutes

Types of REDCap Projects
 There are several flavors of REDCap projects to choose from as you begin thinking about building your own project. Each type of project has its advantages and disadvantages, and may fit the specific needs better of one type of project over another. Please review the different types below, and you may even view a live example of each project type in action or view a short video about it.

Project Type	Description	View Example	Watch Video
	The traditional project is typically used for the primary purpose of		



Background – Proposed IMS

- Proposed IMS systems to assess REDCap:
 - A direct mail campaign system
 - An instrument tracker & quality assurance system
 - A staff hours and expenditures tracking system



Background- REDCap Interface

REDCap™

Logged in as **lillyj** | [Log out](#)

- My Projects
- Project Home
- Project Setup

Project status: **Production**

Data Collection

- Data Entry

Applications

- Calendar
- Data Export Tool
- Data Comparison Tool
- Logging
- File Repository
- Record Locking Customization
- Graphical Data View & Stats
- Report Builder

Reports

- 7.20.11 QC Report Date
- Daily Update
- Problem Forms

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your [REDCap administrator](#).

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Hope lives here.

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Center for Biomedical Informatics (CBMI)

NCS CRF

[Project Home](#) [Project Setup](#)

Quick Tasks

- [Export data](#) Export your data from REDCap to open or view in Excel or various stats packages.
- [Create a report](#) Build custom reports for quick views of your data, and export reports to Excel/CSV.

Project Dashboard

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users	
User	Expires
hardingi (Jennifer Harding)	never
kuklisgormanr	never
lillyj (Jena Lilly)	never
mackts (Tatiana Mack)	never
mcdonaldk (Kenyetta McDonald)	never
skaroffj (Joshua Skaroff)	never

Project Statistics	
Records in project	116
Most recent activity	07/26/2011 9:36am
Space usage for docs	0.39 MB
Project status	Production

Upcoming Calendar Events (next 7 days)

Time	Date	Description
		No upcoming events

CHOP SC NCS Mailing IMS

- Record, track and report on mailing operations
 - REDCap forms:
 - #1: Mailing Coordination
 - Demographics
 - Dates sent & receive
 - Form dispositions
 - #2: Quality Control- Undelivered Mail
 - Tracing methods and status
 - Updated addresses
 - Documentation of resolution
 - Trend Analysis and Reports



REDCap Mailing IMS Form #1

Children's Hospital of Philadelphia
Center for Biomedical Informatics (CBMI)

NCS CHOP Mailing entry page!

SAQ Entry Page

Modify this instrument

Download PDF of

- select PDF download option -

Editing existing PID

Event Name: **June 2011**

PID		(To rename this record, modify the value immediately below.)
PID	<input type="text"/>	
Full Name	<input type="text"/>	
address	<input type="text"/>	
city	<input type="text"/>	
state	<input type="text"/>	
zip	<input type="text"/>	
County	<input type="text"/>	
* must provide value		
Batch	<input type="text"/>	
Was this PID sent a SAQ?	<input type="text"/>	reset value
* must provide value		
Date Sent	<input type="text"/>	
* must provide value		
Date Received	<input type="text"/>	
* must provide value		
Was this SAQ returned undelivered?	<input type="text"/>	reset value
* must provide value		
Form Status		
Complete?	<input type="text"/>	
Save Record		
Save and Continue		
Save and go to Next Form		



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THE NATIONAL
CHILDREN'S
STUDY

REDCap Mailing IMS Form #2

Undelivered Mail [Modify this instrument](#) [Download PDF of](#) - select PDF download option -

[Editing existing PID](#)

Event Name: **June 2011**

PID

Does this PID have any undelivered mail? Yes No [reset value](#)

PSU [reset value](#)

Name

Street Address

apt/suite/ other

City

State

zip

Mailing Type [reset value](#)
* must provide value

Tracing Method? Google USPS White Pages Spokeo SMS Other

Final Status [reset value](#)
* must provide value

Forward to Call Center? Yes No [reset value](#)

Updated address available? Yes No [reset value](#)
* must provide value

SMS Updated? Yes No [reset value](#)
* must provide value

Form Status



CHOP SC CRF Tracking IMS

- Capture and report Study forms by Participant and Visit
- REDCap form:
 - SC details
 - Visit details
 - Forms disposition
 - Quality assurance review
 - Final query resolution



CHOP SC CRF Tracking IMS

Modify project settings

Project title:
Title to be displayed on project webpage

Purpose of this project:
(How will it be used?)

Name of P.I. (if applicable):

IRB number (if applicable):

Please specify:

- Basic or bench research
- Clinical research study or trial
- Translational research 1 (applying discoveries to the development of trials and studies in humans)
- Translational research 2 (enhancing adoption of research findings and best practices into the community)
- Behavioral or psychosocial research study
- Epidemiology
- Repository (developing a data or specimen repository for future use by investigators)
- Other

Design your project:

STEP 1: Choose the type of project you want to build [Tell me more](#)

- Single Survey
- Data Entry Forms (e.g. traditional database)
- Single Survey + Data Entry Forms (e.g. pre-screening survey with follow-up data capture)

STEP 2: Choose collection format for data entry forms [Tell me more](#)

- Classic (each form available for use once for each subject/record)
- Longitudinal / repeating forms (each form available for use one or more times for each subject/record)

Enable the scheduling module? [Tell me more](#)



REDCap CRF Tracking IMS

Data Entry: Event Grid

The grid below displays the form-by-form progress of data entered into the project for one particular PID for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

PID XX

Data Collection Instrument	Events for Arm 1: Women															
	Pregnancy Screener (1)	Pre-Pregnancy Visit (2)	Baby Consent (3)	Consent Non Pregnant (4)	Consent Pregnant (5)	Pregnancy Visit 1 (6)	Pregnancy Visit 2 (7)	Birth Consent (8)	Birth Visit (9)	3 Month Call (10)	6 Month Visit (11)	9 Month Call (12)	12 Month Visit (13)	18 Month Call (14)	24 Month Call (15)	M (16)
Data	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Query Information Collectoin	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Demographics																



REDCap CRF Tracking Form

Event Name: Pre-Pregnancy Visit (Arm 1: Women)

PID (To rename this record for the current arm ONLY, modify the value immediately below.)

Participant Information

PID

PSU

In-House ID

Event Name

Data Collection Information

Visit/Call Coordinator

Another Coordinator? Yes No

Date of Visit M-D-Y

Language of Interview?

Case Report Forms

How many forms were received for this visit?

QA/QC

Quality Control QC of form QC of Instrument Data (excel sheet) QC of SMS

Storage Information

Filed Date M-D-Y

Upload Date M-D-Y

Form Status

Complete?

Programmable Field



REDCap Form Fields

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will automatically be appended to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(5 min\)](#).

Field Type: Multiple Choice - Drop-down List (Only One Answer)

Field Label
Why was this visit not complete?

Variable Name (utilized during data export)
why_visit_not_comp
ONLY letters, numbers, and underscores

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g. name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Field Note (optional)
Small reminder text displayed underneath field
Looking for Branching Logic? Try clicking the  icon for this field after clicking the Save or Cancel button below.

[How do I manually code the choices?](#)

Choices (one choice per line)
1, Due date in within the 60 day window
2, Pregnant prior to consent
3, Study Refusal
4, Visit could not be scheduled: No contact made
5, Pregnancy Loss
6, Participant refused visit

Save **Cancel**



REDCap Branching Logic

Add/Edit Branching Logic [X]

Branching Logic may be employed when fields/questions need to be hidden under certain conditions. If branching logic is defined, the field will only be visible if the conditions provided are true (i.e. show the field only if...). You may specify those conditions in the text box below for the Advanced Branching Logic Syntax or by choosing the Drag-N-Drop Logic Builder method, which allows you to build your logic in a much easier fashion by simply dragging over the options you want. You may switch back and forth between each method if you wish, but please be aware that since the advanced logic allows for greater complexity, it may not be able to be switched over to the Drag-N-Drop method if it becomes too complex.

Choose method below for the following field: **study_id - PID ID**

Advanced Branching Logic Syntax [\(How do I use the advanced syntax?\)](#)

Show the field ONLY if...

— OR —

Drag-N-Drop Logic Builder

Field choices from other fields
(drag a choice below to box on right)

- first_name = (define criteria)
- last_name = (define criteria)
- dob = (define criteria)
- sex = Female (0)
- sex = Male (1)
- address = (define criteria)
- phone_number = (define criteria)
- demographics_complete = Incomplete (0)
- demographics_complete = Unverified (1)

Drag and Drop

Show the field ONLY if...

ALL below are true

ANY below are true

Clear logic

Save Cancel

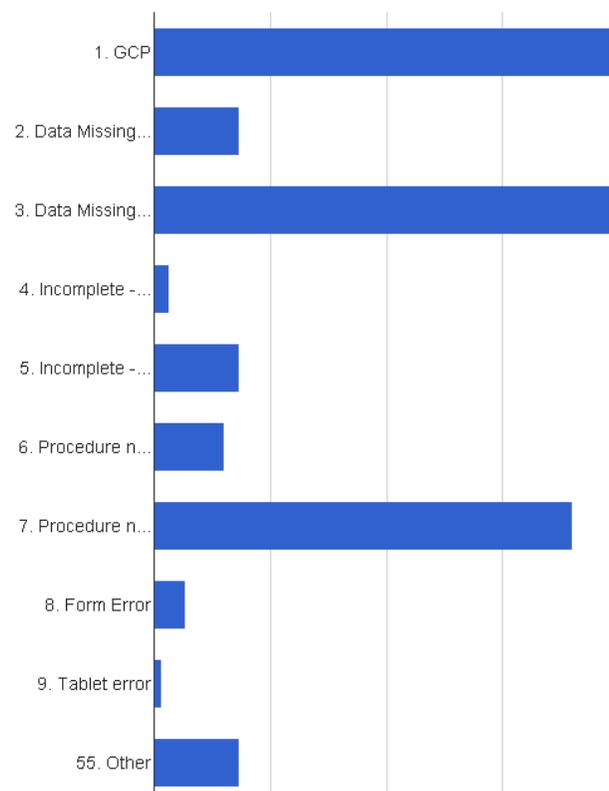
Easy Programming



REDCap Report Example

Situation: [Refresh Plot](#) | [View as Bar Chart](#) ▼

Total (N)	Missing	Unique
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CHOP SC Staff Hours & Expenditures IMS

- Capture and report staff hours and expenditures
- REDCap form:
 - Staff hours, expenses by staff & segment
 - Uses calculated fields
 - Ability split hours by contract



REDCap Hours & Exps Form

NCS Staff Weekly Expenses

Staff Weekly Expenses [Share this instrument](#) [Download PDF of](#) - select PDF download option -

Adding new Last name and week start date in format LASTNAMEYYYYMMDD. Date must always be a Sunday. .

Last name and week start date in format LASTNAMEYYYYMMDD. Date must always be a Sunday. (To rename this record, modify the value immediately below.)

Last name and week start date in format LASTNAMEYYYYMMDD. Date must always be a Sunday. * must provide value

PSU - Montgomery [View equation](#) [Disclaimer](#)
Sets to 20000018 unless staff member is not listed in Staff table for Montgomery County.

PSU - Schuylkill [View equation](#) [Disclaimer](#)
Sets to 20000018 unless staff member is not listed in Staff table for Schuylkill County.

Choose staff member. * must provide value

Week Start Date * must provide value Y-M-D
Must be a Sunday. (Week runs Sunday through Saturday.) Ex: 2011-06-26

Dollar reimbursement/mile [View equation](#) [Disclaimer](#)
For weeks beginning before 7/1/11, staff member is reimbursed \$0.51/mile. After 7/1/11, staff members are reimbursed \$0.55/mile.

Hours

Total hours staff member worked during the week Total hours worked should reflect the actual number of hours worked (excluding sick time, vacation). Decimal format. Ex: 40.0

Staff Hours (Montgomery) [View equation](#) [Disclaimer](#)
Hours worked on Montgomery County activity during the week

Staff Hours (Schuylkill) [View equation](#) [Disclaimer](#)
Hours worked on Schuylkill County activity during the week

Staff Hours (Burlington) [View equation](#) [Disclaimer](#)
Hours worked on Burlington County activity during the week

Staff Hours (Study Center) [View equation](#) [Disclaimer](#)
Hours worked on Study Center activity during the week

Staff Hours (LOI) [View equation](#) [Disclaimer](#)
Hours worked on LOI activity during the week

Staff Hours (Non-NCS) [View equation](#) [Disclaimer](#)
Hours worked on Non-NCS activity during the week

Staff Total Hours Verification [View equation](#) [Disclaimer](#)
Should match "total hours" above

Calculated Fields

Calculated Fields



REDCap Hours & Exps Form

Local Travel - Montgomery County	
Did staff member have local travel in Montgomery County?	<input type="text"/>
Local Travel - Schuylkill County	
Did staff member have local travel in Schuylkill County?	<input type="text"/>
Long Distance Travel	
Did staff member have long distance travel related to Montgomery County during the week?	<input type="text"/>
Did staff member have long distance travel related to Schuylkill County during the week?	<input type="text"/>
Totals	
Weekly Expenses - Montgomery County	<input type="text" value="0"/> View equation Disclaimer
Weekly Expenses - Schuylkill County	<input type="text" value="0"/> View equation Disclaimer
Weekly Miles - Montgomery County	<input type="text" value="0"/> View equation Disclaimer
Weekly Miles - Schuylkill County	<input type="text" value="0"/> View equation Disclaimer
Comments (Optional)	
Comment - Montgomery County	<input type="text"/> <small>Qualitative information (notes) about the staff member's weekly hours, miles, and expenses in Montgomery County. Example: Expenses include per diem for 1-day NCS meeting</small>
Comment - Schuylkill County	<input type="text"/> <small>Qualitative information (notes) about the staff member's weekly hours, miles, and expenses in Schuylkill County. Example: Expenses include per diem for 1-day NCS meeting</small>
Form Status	
Complete?	<input type="text" value="Incomplete"/>
<input type="button" value="Save Record"/>	
<input type="button" value="Save and Continue"/>	

Calculated Fields

CHOP SC REDCap IMS Results

Three functional databases created

- Staff trained in less than 2 days
- 2 weeks to program
- Acceptable Functionality:
 - Assess costs, feasibility & coordination of projects
 - Collect and report key operational data
 - Manage data and quality assurance



Conclusion

- REDCap
 - Can assist in operational management
 - Can be used by staff of all skill sets
 - No cost: non-proprietary software
 - Capable of future enhancements
 - Provides Data Driven metrics



REDCap

- Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr; 42(2): 377-81.

