

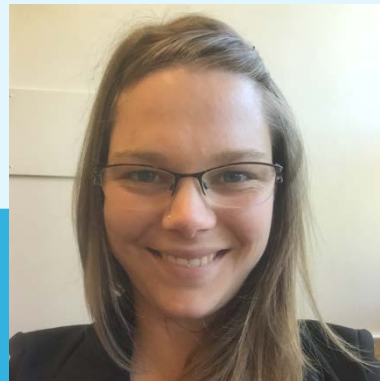
GENOME-SpecTRA Project

Spectrometry in IIA Rapid Assessment



Kaitlin Blackwood, Clinical Research Assistant

Jaclyn Morrison, Project Manager



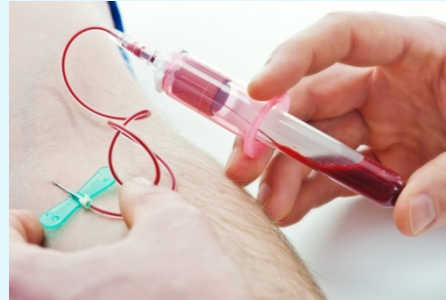
Island Health REDCap Day

March 3, 2016

GOALS OF THE PROJECT

Goal One:

Develop an inexpensive blood test that can be used in the ED to identify patients with TIA.



Goal Two:

Develop a clinical decision support tool that is driven by both clinical and proteomic algorithms.

Clinical Information
(from clinician assessment &
the patient's story)
+
Proteomic Information
(from blood test)



MULTIPLE STUDIES

Study 1 Verification

✓ Recruitment Completed

- Protein Identification
- 560 patients

Study 2 Validation

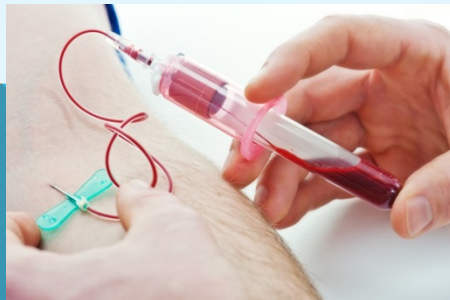
Recruitment Underway

- Validate Protein List
- 1200 patients

Study 3 Clinical Utility

Study Planning Underway

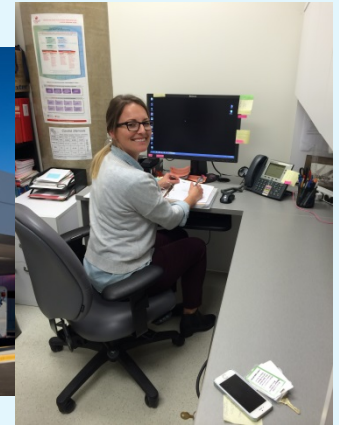
- Testing of the Tool
- 2000 patients



MULTIPLE SITES



Nanaimo Regional General Hospital



Victoria General Hospital

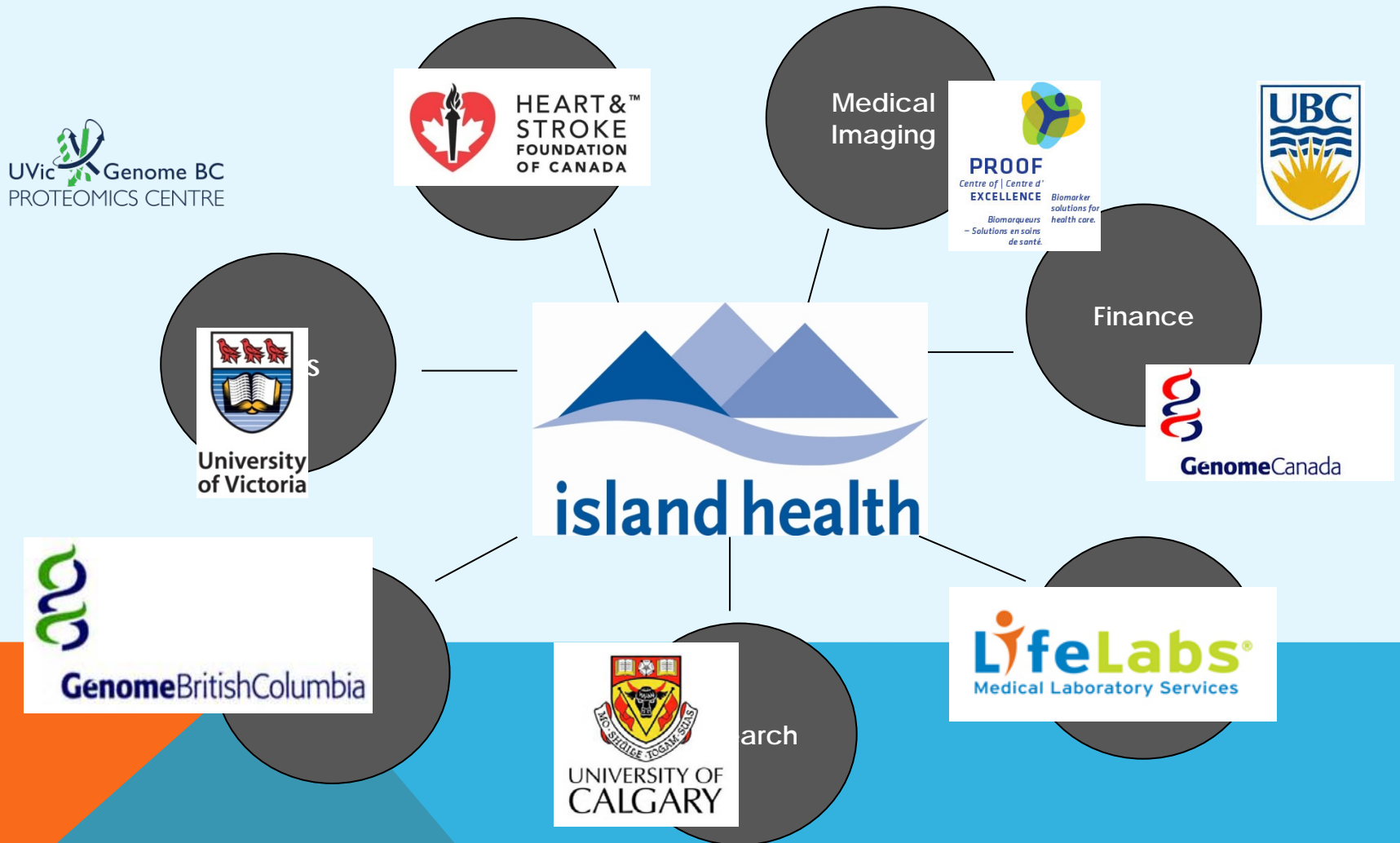


Royal Jubilee Hospital



Foothills Medical Center

MULTIPLE COLLABORATORS




Over 40 individual and institutional collaborators.

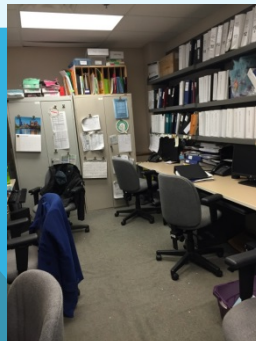
PROJECT DATA COLLECTION

CLINICAL DATA

- Paper based (source document)
- ~20-25 pages of data per patient
- CRF is completed by physicians, nurses and clinical research assistants

Case Report Form (CRF)

		Subject ID: <input type="text"/>	
Name of Interviewer(s) completing ED sections 1-9 (CRF pages 1-5) <i>(Please record your name below)</i>			
Name		Date	
<input type="text"/>		<input type="text"/>	
ED - Section 1			
a) Inclusion Criteria		b) Exclusion Criteria	
Patient referred with suspected TIA or mild stroke (NIHSS <4)	<input type="checkbox"/> Yes <input type="checkbox"/> No	Isolated monocular blindness	<input type="checkbox"/> Yes <input type="checkbox"/> No
< 24 hours from onset	<input type="checkbox"/> Yes <input type="checkbox"/> No	Unable to obtain either MRI (within 7 days) or CT/CTA (within 24 hours)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Age ≥ 18	<input type="checkbox"/> Yes <input type="checkbox"/> No		
English speaking or translator available	<input type="checkbox"/> Yes <input type="checkbox"/> No		
ED - Section 2 - Informed Consent			
Study Arm Consent (either)		Date and Time	
Study 2 (Single Blood Draw)	<input type="checkbox"/> Yes <input type="checkbox"/> No	DATE/TIME	DATE/TIME
mRNA Sub-Study	<input type="checkbox"/> Yes <input type="checkbox"/> No	DATE/TIME	DATE/TIME
ED - Section 3 - Subject Encounters Times			
Visit		Date and Time	
ED Triage	<input type="checkbox"/> Yes <input type="checkbox"/> No	DATE/TIME	DATE/TIME
Single Blood Draw in ED	<input type="checkbox"/> Yes <input type="checkbox"/> No	DATE/TIME	DATE/TIME
Stroke neurologist's assessment, usually in SRAU	<input type="checkbox"/> Yes <input type="checkbox"/> No	DATE/TIME	DATE/TIME
If NO, indicate why:			



PROTEOMIC DATA

- Analysis completed at the UVic-Genome Proteomic Center
- Many data points for every sample (large protein panel)
- Prepared as Excel files



SECURE

WEB-BASED

AUDITABLE

HOW & WHY DO WE USE REDCAP?

EXTRACTABLE

ACCESSIBLE

CENTRALIZED

REPUTABLE




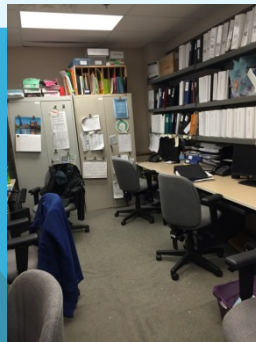
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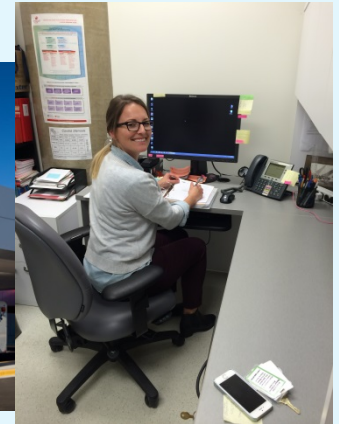
MULTISITE PATIENT ENROLMENT



Nanaimo Regional General Hospital



Victoria General Hospital

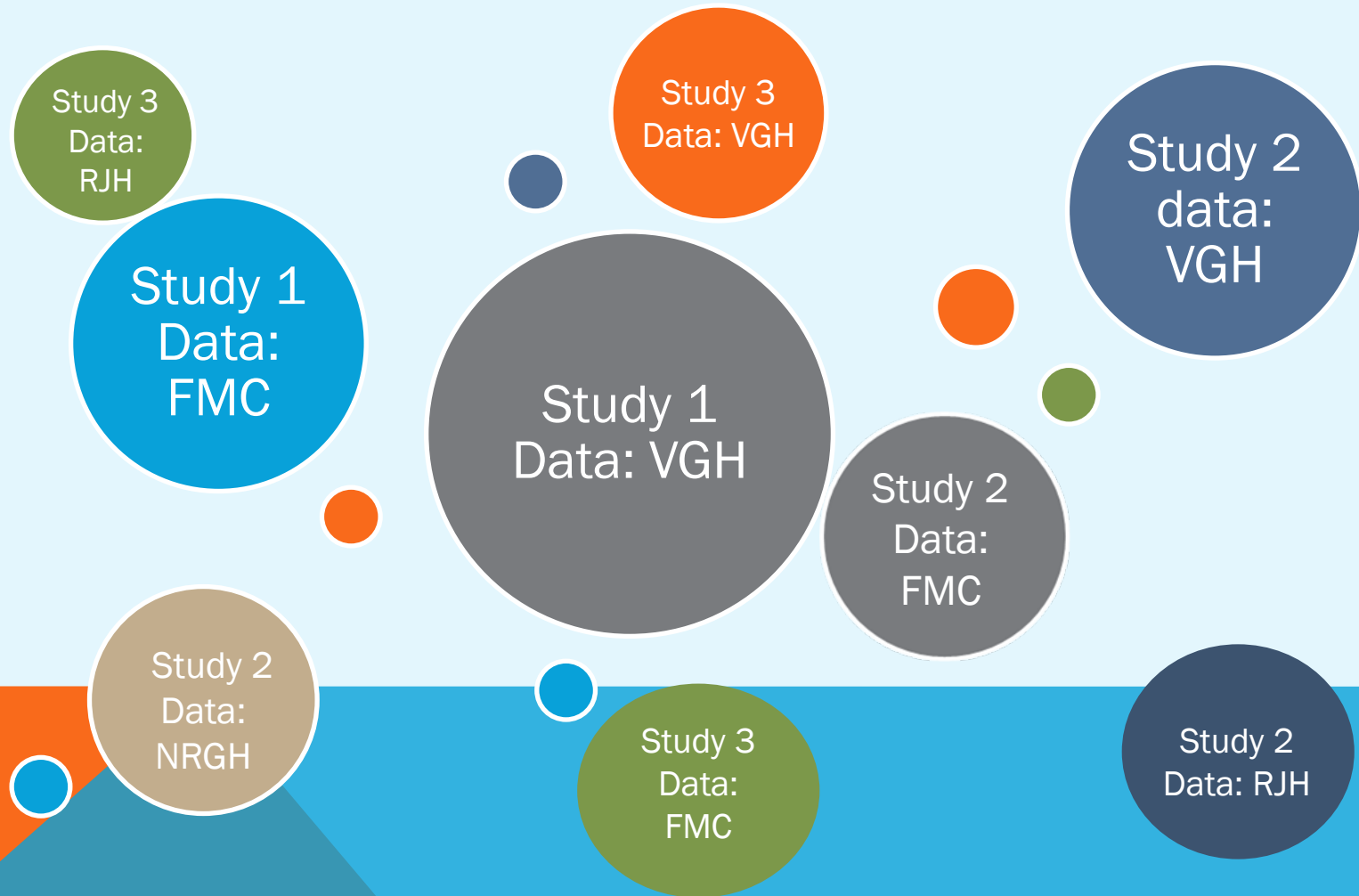


Royal Jubilee Hospital

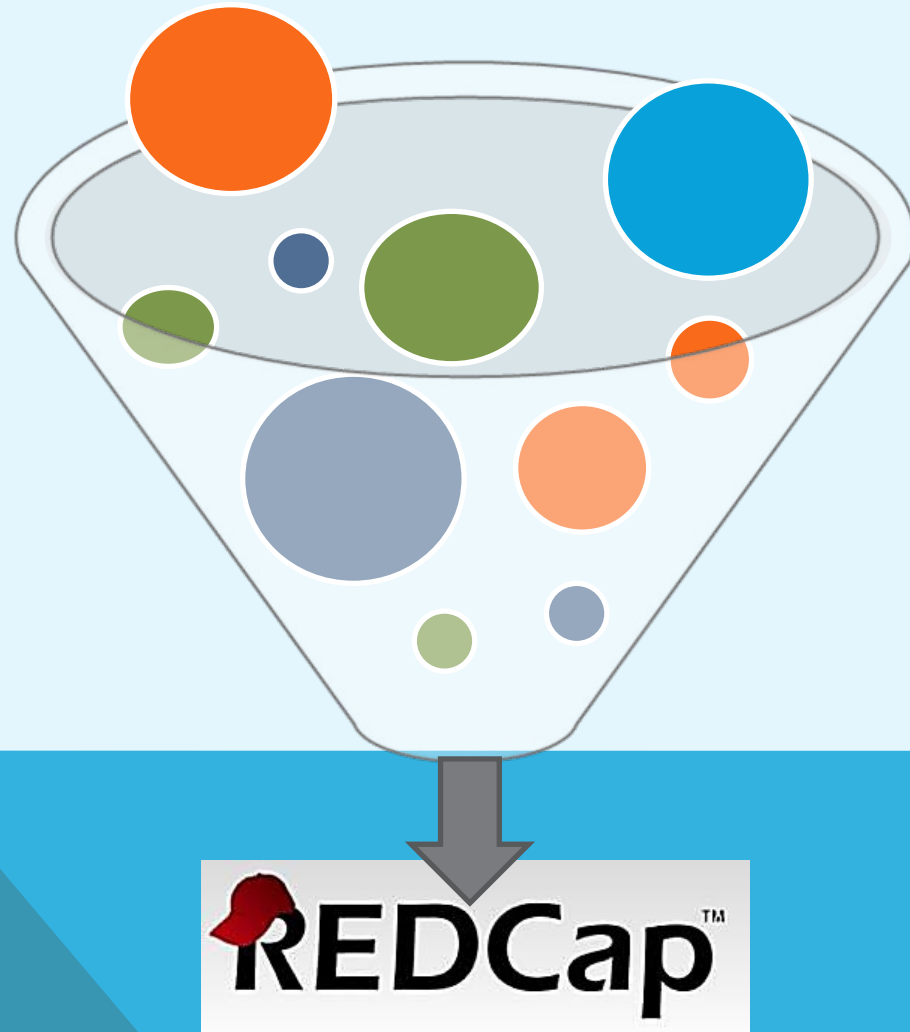


Foothills Medical Center

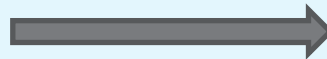
CENTRALIZED BACKDROP FOR DATA



CENTRALIZED BACKDROP FOR DATA



REPUTABLE



PubMed

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- ☐ [Ninety-day perioperative complications of pediatric robotic urological surgery: A multi-institutional study.](#)
1. Dangle PP, Akhavan A, Odeleye M, Avery D, Lendvay T, Koh CJ, Elder JS, Noh PH, Bansal D, Schulte M, MacDonald J, Shukla A, Kim C, Herbst K, Corbett S, Kearns J, Kunnavakkam R, Gundeti MS. J Pediatr Urol. 2015 Oct 9. pii: S1477-5131(15)00359-9. doi: 10.1016/j.jpurol.2015.08.015. [Epub ahead of print]
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2. Dugas M, Neuhaus P, Meidt A, Doods J, Storck M, Bruland P, Varghese J. Database (Oxford). 2016 Feb 11;2016. pii: bav121. doi: 10.1093/database/bav121. Print 2016.
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PMID: 26746621
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ACCESSIBLE: Secure, Web-Based Interface



USER PERMISSIONS

(i) Different permissions can be given to different team members

- From Read-only to full view of data and user management

“Data access groups (DAGs)”

Role name (click role name to edit role)	Username or users assigned to a role (click username to edit or assign to role)	Expiration (click expiration to edit)	Data Access Group (click DAG to assign user)	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Calendar	Data Import Tool	Cc
—	jmorrison3 (Jaclyn Morrison)	06/30/2016	—	✗	✓	✓	Full Data Set	✓	✓	✗	✓	
—	llu (Linghong Lu)	12/31/2016	—	✗	✗	✗	Full Data Set	✗	✗	✗	✗	
—	mbibok (Maximilian Bibok)	12/31/2016	—	✓	✓	✓	Full Data Set	✓	✓	✓	✓	
—	vespinosa (Victor Espinosa)	never	—	✓	✓	✓	Full Data Set	✓	✓	✓	✓	
Data Coordinator	ckenney (Carol Kenney)	05/31/2015	Calgary									
	Eklourfeld	06/30/2016	Calgary									
	kblackwood (Kaitlin Blackwood)	08/10/2016	—	✗	✗	✗	Full Data Set	✓	✓	✗	✓	
	LBilston (Lisa Bilston)	02/02/2016	MovedToStudy2									
Data Entry	jlcook	08/10/2016	Victoria	✗	✗	✗	Full Data Set	✓	✓	✗	✗	
Neurologists	APenn	06/30/2016	Victoria									
	ATrivedi (Anurag Trivedi) [account suspended]	08/31/2016	Victoria	✗	✗	✗	Full Data Set	✓	✓	✗	✗	
	SCoutts	05/31/2016	Calgary									
Project Managers	kvotova (Kristine Votova)	05/31/2016	—	✗	✗	✗	Full Data Set	✓	✓	✗	✗	

(ii) Reminders to review the User Access Dashboard:

ATTENTION REQUESTED: You last accessed the User Access Dashboard 50 days ago. It is recommended that you access the User Access Dashboard at least once a month to review which users still have access to your projects.

Go to [User Access Dashboard](#)

(iii) Automatic suspension of accounts due to inactivity

EXTRACTION ABILITY

(1) Export Data:

Quick Tasks

- Codebook
- Export data**
- Create a report
- Check data quality

The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing field attributes.

Export your data from REDCap to open or view in Excel or various stats packages.

Build custom reports for quick views of your data, and export reports to Excel/CSV.

Build or execute data quality rules to find discrepancies and errors in your project data.

My Reports & Exports

	Report name	View/Export Options	Management Options
A	All data (all records and fields)	View Report Export Data Stats & Charts	
B	Selected instruments (all records)	Make custom selections	

[+ Create New Report](#)

Exporting "All data (all records and fields)"

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and whether or not to perform de-identification on the data set.

Choose export format

- ☐ CSV / Microsoft Excel (raw data)
- ☒ CSV / Microsoft Excel (labels)**
- ☐ SPSS Statistical Software
- ☐ SAS Statistical Software
- ☐ R Statistical Software
- ☐ Stata Statistical Software

De-identification options (optional)

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply.

Known Identifiers:

- ☐ Remove all tagged Identifier fields (tagged in Data Dictionary)
- ☐ Hash the Record ID field (converts record name to an unrecognizable value)

Free-form text:

- ☐ Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
- ☐ Remove Notes/Essay box fields

Date and datetime fields:

- ☐ Remove all date and datetime fields
- OR
- ☐ Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) [What is date shifting?](#)

[Deselect all options](#)

Export Data **Cancel**

EXTRACTION ABILITY

(2) Create a Report

My Reports & Exports

	Report name	View/Export Options	Management Options
A	All data (all records and fields)	View Report Export Data Stats & Charts	
B	Selected instruments (all records)	Make custom selections	
+ Create New Report			

DISPLAY OPTIONS

Select a data collection instrument to view

Demographics

Optional: Select a record to overlay onto the plots below

-- select record --

Viewing options:

[Show plots & stats](#)

[Show plots only](#)

[Show stats only](#)

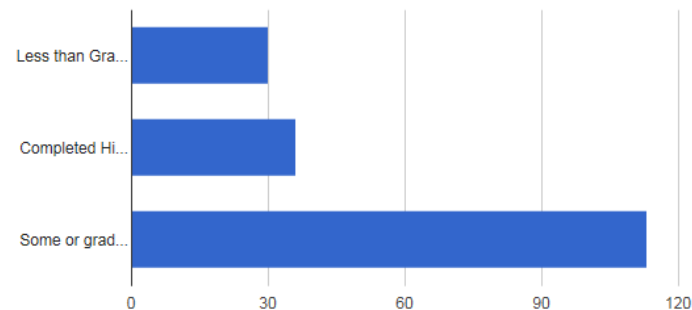
Educational Attainment (highest)

[Refresh Plot](#)

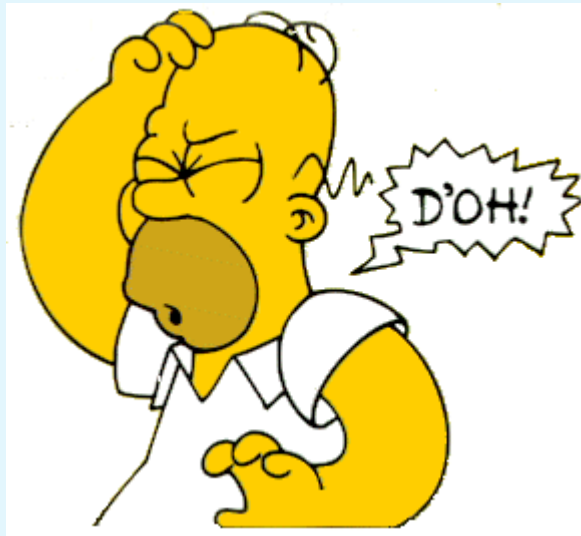
[View as Bar Chart](#)

Total Count (N)	Missing	Unique
179	106 (37.2%)	3

Counts/frequency: Less than Grade 12 (30, 16.8%), Completed High School (36, 20.1%), Some or graduated post-secondary (113, 63.1%)



DOUBLE DATA ENTRY (DDE)



User Beware!

DDE needs to be enabled at the beginning of a new project... It will not work if you try to reinstate it later!



Subject_id	cta_dn (set A)	cta_dn (set B)
1	0	0
2	0	0
3	1	1
4	0	1

AUDIT INFORMATION

- Compliant with Good Clinical Practice
- If you accidentally overwrite a data point, you can look back and find your earlier data value.

Logging [Download entire logging record to Microsoft Excel](#)

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users.

Filter by event: All event types (excluding page views)
Filter by user name: All users
Filter by record: All records
Displaying events (by most recent): 1 - 100
Filter by time range from to

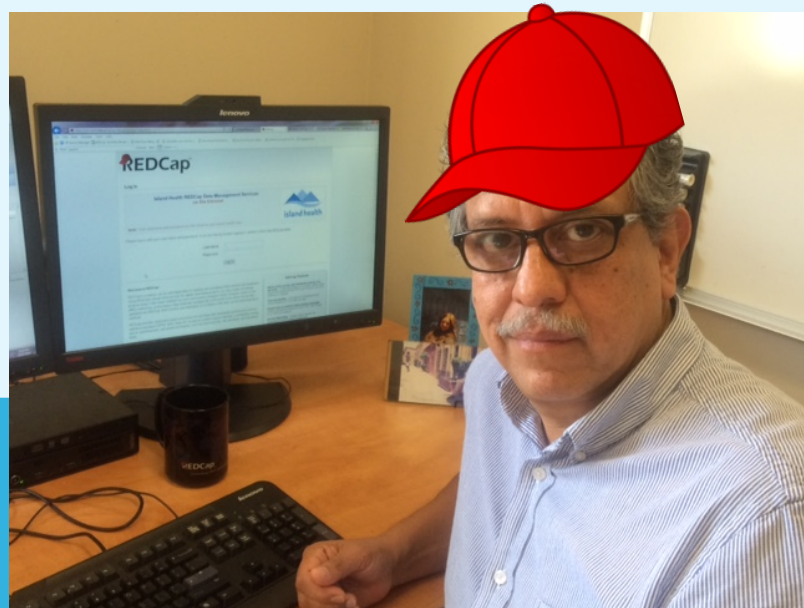
Time / Date	Username	Action	List of Data Changes OR Fields Exported
02/25/2016 4:00pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	brthdtc = '1965-06-03', sex = '0', race = '1', education = '2', demographics_complete = '2'
02/25/2016 3:59pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	sv_ed_triage = '1', sv_ed_triage_dt = '2016-01-08 10:12', sv_strktm_assess = '1', subject_encounter_complete = '0'
02/25/2016 3:58pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	rficdtc_dt = '2016-01-08 14:07', ic_mrna_dn = '99', informed_consent_complete = '2'
02/25/2016 3:57pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	pe_yn = '0', previously_enrolled_complete = '2'
02/25/2016 3:57pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	scrm_failure = '0', screen_failure_complete = '2'
02/25/2016 3:57pm	KBlackwood	Updated Record SpecTRA-SUBJID-70248	grf_vrs = '5', interviewer = 'Carolyn Grant Kaitlin Blackwood', interview_dt = '2016-01-08', inc_nihss_l4 = '1', inc_sx_onset_24hrs = '1', inc_age_g18 = '1', inc_eng_trans = '1', exc_iso_monoblind = '0', exc_mri_contra = '0', inclusion_exclusion_criteria_complete = '2'
02/25/2016 2:51pm	KBlackwood	Updated Record SpecTRA-SUBJID-70247	sv_bp_ed_dt = '2016-01-02 14:41', sv_bp_systol_ed = '203', sv_bp_diastol_ed = '114', sv_pulse_ed = '107', ed_examination_complete = '0'
02/25/2016 2:50pm	KBlackwood	Updated Record SpecTRA-SUBJID-70247	su_tobacco = '1', su_alcohol_g2d = '0', su_illicit_drug_use = '0', substance_use_complete = '2'
02/25/2016 2:50pm	KBlackwood	Updated Record SpecTRA-SUBJID-70247	rx_statin = '0', rx_antipatelet = '0', rx_beta_blocker = '0', rx_ca_blocker = '0', rx_diuretic = '0', rx_ace_inhib = '0', rx_angiotensin_antag = '0', rx_k_antagonist = '0', rx_novel_anticoagulant = '0', concomitant_medications_complete = '2'

EXCELLENT SUPPORT TEAM



- Phone/email support
- User training
- Database back-up

Hats off to Victor & Nathan!



THANK YOU!



Island Health REDCap Day

March 3, 2016