

### **REDCap: Best Practices**

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### Best practices

### The Why?

- Design better studies
- Utilize previously proven techniques and forms
- Effeciencies
- Costs of not following good guidelines

"Given the time and attention usually devoted to protocol development, it is paradoxical that data collection forms are often hastily constructed at the end of that process. – From Data Collection Forms in Clinical Trials, 1991, Raven Press, Spilker and Schoenfelder.





### Standard release vs. LTS

### Standard release (SR):

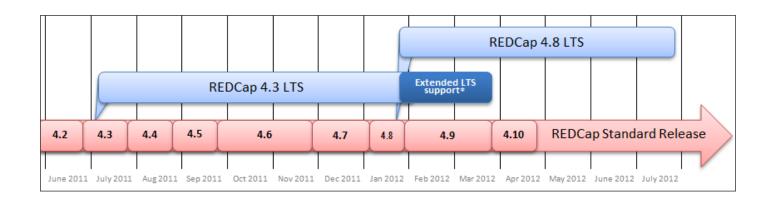
- new features added frequently
- monthly release schedule for new features
- weekly bug fix releases when needed

### Long-term support (LTS):

- major release taken from the standard release
- supported with bug fixes/patches only for an extended period of 6 months
- generally considered to be more stable
- e.g. REDCap 7.0 LTS will be supported from Dec 2016 June
   2017



## Standard release vs. LTS (2)



### Which REDCap product to choose?

- SR is the common choice for most REDCap implementations
- LTS is typically used for specific scenarios
  - environment for regulatory compliance purposes (e.g. FISMA, 21 CFR Part 11)
  - if you are wanting to introduce new REDCap features to your users at a slower pace (every 6 months instead of every month)





## Standard release vs. LTS (3)

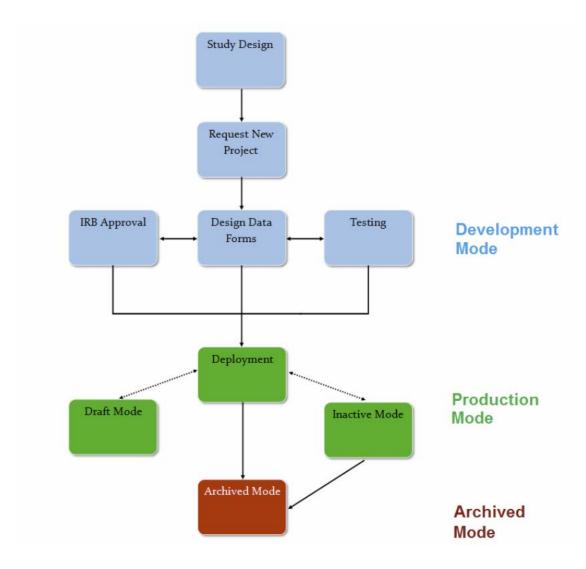
#### Switching between LTS and SR?

- Both directions are possible
- Version you are upgrading to must be a higher number (REDCap itself knows nothing of LTS or SR)
- LTS->SR:
  - If you're currently on LTS, then you can switch to SR at <u>any</u> time since SR is always a higher version number
- SR->LTS:
  - When using SR, you'll only be able to go back to LTS when the new LTS branch is released, which is every 6 months





# Project lifecycle



Source: Center for Health Insights University of Missouri -- Kansas City



### Project setup

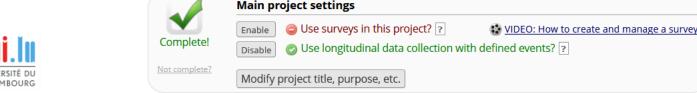
### 'Classic' projects

 Data collection instruments are only used once for each record in project

### Longitudinal projects

- Instruments are utilized repeatedly to collect data
- Events need to be defined (e.g. Visit 1, Visit 2)
- More structured approach
- Export all data collection instruments for one visit together for analysis (one row) = correlated exports
- Scheduling module can be used

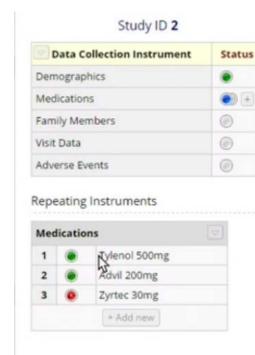


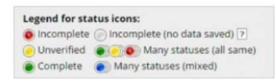




## Project setup (2)

- One-to-many data collection
  - Relatively new functionality
  - "Repeat Entire Event":
    - All the event's instruments will repeat together and stay connected (all instruments in one row in export)
  - "Repeat Instruments":
    - Instruments will repeat separately and independently from each other (each instrument has its own row in export)
  - Custom labels possible









## Project setup (3)

- Repeating instruments or events continued
  - In classic projects:
    - You can only add repeating instruments
    - A very simple way of doing longitudinal data collection
    - Don't need to specify maximum number of events beforehand
  - In longitudinal projects:
    - Repeat instruments (repeat instruments independently of each other)
    - Repeat entire events (repeat all instruments together)

Data Collection Instrument	Enrollment & One- time data	Weekly Visit 80 kg	80.9 kg (#2)	76 kg (#3)	85 kg (#4)	82.3 kg (#5)	80 kg (#6)	45 kg (#7)	kg (#8)	- Add new 175 kg (#9)
Demographics	•									
Medications (survey)	(i) +									
Family Members	• +									
Weekly Visit Form 1 (survey)	•	0					0	0	•	•
Weekly Visit Form 2		0	0	0	0	0	•	0	0	0
Weekly Visit Form 3		0	0	0	0	0	•	0	0	0
Adverse Events	• +									

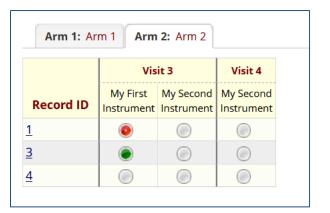




## Study arms

- Only possible in longitudinal projects
- Default: 1 arm and 1 event, you add more
- Arms and their events are independent of each other
- The same Record ID name can be used in multiple arms, but they are associated with independent participants
- Many different use cases possible

Arm 1: Arm 1								
	Vis	it 1	Visit 2					
Record ID		My Second Instrument						
1	•							
<u>2</u>								







## Study arms (2)

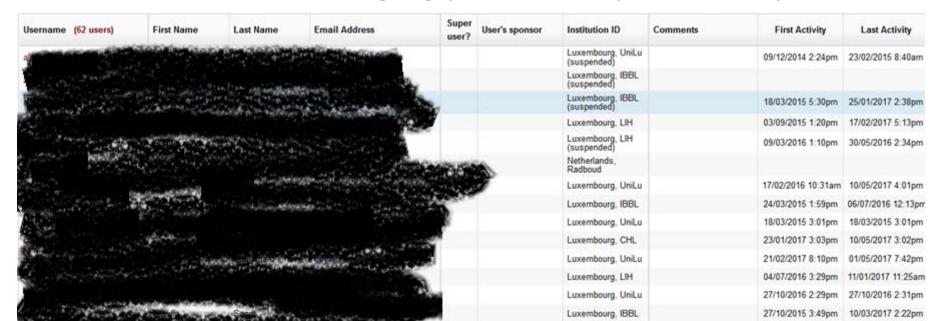
- Some people use arms as "tracks" within research studies
  - different programs and participants can enroll or become eligible for any of them (i.e. they are not mutually exclusive)
- In other studies participants cross over from one arm to the other
  - some participants start out on Arm 1, then cross over to Arm 2 half way through the study when some specified criteria are met
- Moving subjects from Arm 1 to Arm 2 not simple:
  - exporting the data in csv, change it, import it back (no clear audit trail)
  - change in DB (no audit trail)
- My approach: if arm/group assignment can change or is unclear, yet participant can only be in one arm
  - don't use arms i.e. designate via field in form instead





### User management

- Use the Institution ID for a large project
- Regularly check with site leaders on user status
  - Every 6 months
  - Suspend inactive accounts (don't delete)
- Don't enforce changing passwords periodically



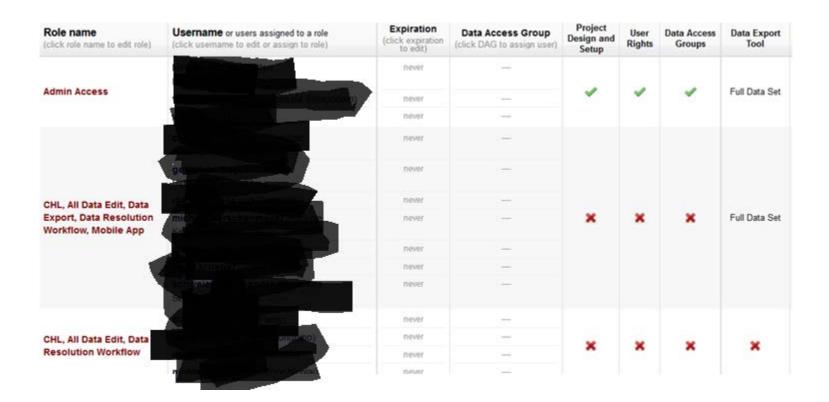
### User application access

- Limit to necessary minimum
- Save time by using user roles (predefine user rights)
- Consider data access groups (DAGs)
  - Useful for separating different sites
- Take special care with allowing users to access:
  - Project design and setup
  - User rights
  - Data exports
  - Data import tool





# User application access (2)

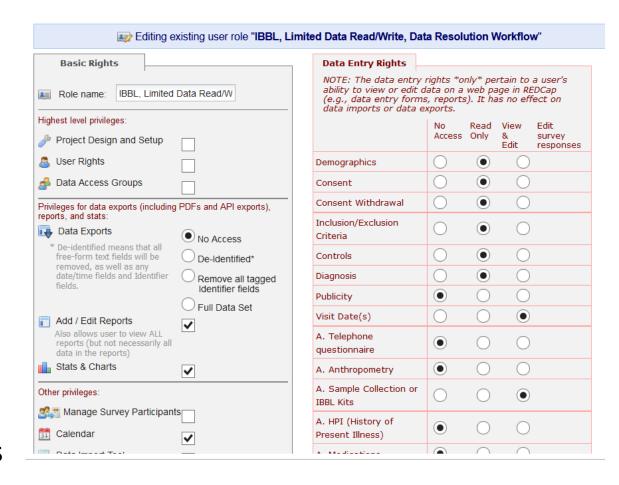






### Form restrictions

- Use restrictions
- Check form
   status when
   creating new
   form or
   renaming form
  - New formdefaults to"view & edit"for all user roles

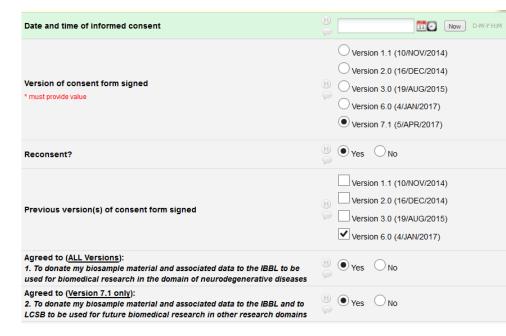






### Consent

- Longer studies often have several iterations of the consent form
- Capture information on:
  - Date of consent
  - Version of consent
  - Reconsent?
  - Specifics of consent
- Don't forget consent withdrawal
- Provide PDF copies of all current consent(withdrawal)
   templates to clinical teams







### Subject identifiers

- Collecting any identifying information is strongly discouraged, unless absolutely necessary
- Best practice: code subject identification, keep key in a separate location
- 18 pieces of information that are considered identifiers (protected health information, PHI) for HIPAA compliance
- Use "Check For Identifiers" module and tag such fields
  - Variables tagged as Identifiers can be "deidentified" when exported.
- Customize the date shift range for date shifting de-identification

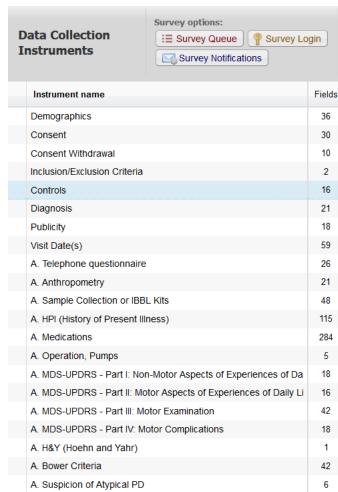
1.	Name
2.	Fax number
3.	Phone number
4.	E-mail address
5.	Account numbers
6.	Social Security number
7.	Medical Record number
8.	Health Plan number
9.	Certificate/license numbers
10.	URL
11.	IP address
12.	Vehicle identifiers
13.	Device ID
14.	Biometric ID
15.	Full face/identifying photo
16.	Other unique identifying number, characteristic, or code
17.	Postal address (geographic subdivisions smaller than state)
18.	Date precision beyond year





### Data collection instruments

- Group related variables on forms (= data collection instruments)
- Keep forms reasonably short to increase usability and minimize potential data loss
  - There is no auto-save function in REDCap data entry forms
- Allows for more flexibility in workflow design
- Use branching logic, where it makes sense, to minimize scrolling







## Fields/variables

#### Naming variables

- Use a new prefix for each data collection instrument (e.g. dm\_ for demographics)
- Keep names short and simple
- Use accepted abbreviations (e.g. dob, dx)
- Make them meaningful
  - Downstream analysis (statistics)
  - Data import functionality
  - Data search; choose a field to search
- Be consistent (e.g. \_med1, \_med2, \_med3)

	14	question2_2	Examiner Last, First Names	text
	15	question6_6	Date of visit	text (date_mdy)
	16	question7_7	Age at visit	calc Calculation: rounddown(datediff([initial_visit_arm_1] [question5_5],[question6_6],"y","mdy",true))
	17	question9_9	Systolic blood pressure mm Hg (sitting)	text (number)
	18	question515_515	Diastolic blood pressure mm Hg (sitting)	text (number)
ĺ	19	question10_10	Pulse per minute (sitting)	text (number)

			2014-09-2
REDC	ар		dcap_v5.11.1/Design/data_di
20	question510_510	Systolic blood pressure mm Hg (standing)	text (number)
21	question511_511	Diastolic blood pressure mm Hg (standing)	text (number)
22	question512_512	Pulse per minute (standing)	text (number)
23	question11_11	Weight (kg)	text (number)
24	question12_12	Height (cm)	text (number)
25	question13_13	ВМІ	calc Calculation: round([question11_11]*10000/([question12_12]),2)





# Fields/variables (2)

- Reduce the use of free-text fields
- Use validation wherever possible
  - Format:
    - e.g. yyyy-mm-dd
    - Hard validation; cannot save if fails
  - Constraints:
    - e.g. min, max
    - Soft validation; can be ignored by user, results in warning
- Don't mix data types
  - Wrong: capturing systolic/diastolic BP in one field
  - Right: create 1<sup>st</sup> field for systolic and 2<sup>nd</sup> for diastolic (and validate with "number")



# Fields/variables (3)

- Avoid requiring respondents to make calculations whenever possible
- Avoid mixing different date formats (e.g. mdy and ymd)
- Identify units of measurement
  - Don't assume everyone knows what unit is being measured
  - Units can change
  - Use field label (included data in export) and field note
- Numerical codes of choices (answer options)
  - Choose them carefully, important efficient for statistical analysis
  - Yes=1, No=0 (when not using the Yes/No field type)

"Match" response options and codes					
Example: What year of residency are you in?					
GOOD	BAD				
1, PGY 1	0, PGY 1				
2, PGY 2	1, PGY 2				
3, PGY 3	2, PGY 3				
4, PGY 4	3, PGY 4				

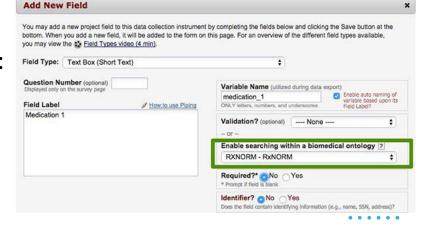
Source: CHEO Research Institute





### Incorporate standards

- Using standard measures will allow you to more easily
  - Compare your findings with those of others
  - Reuse your own datasets later
- Methods
  - Use text fields with biomedical ontology lookups
  - Annotate yourself using "Field annotation" field
  - Use forms from the REDCap Shared Library
- Some standards
  - For laboratory values: LOINC
  - For diseases, symptoms and findings:
     SNOMED-CT
  - For medications:WHO-ATC, RxNorm, MDDB
    - For clinical studies in general: CDISC





## Compliance & regulatory

- "Part 11" = FDA 21 CFR Part 11 Compliance
- Defines criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records
- Is done on a study by study basis
- How to become compliant?
  - 1. Read the guidelines
  - 2. Define how your institution will meet the guidelines
  - 3. Get audited internally, then externally (e.g. FDA)
  - 4. Consider yourself Part 11 compliant, but review at regular intervals

Source: BlueHarbors

21 CFR Part 1





# Compliance & regulatory (2)

#### Further notes:

- A number of US universities have gone to the process using REDCap (Duke, UPenn, etc)
- Validation requires a subjective interpretation of the Part 11 guidelines by each organization.
   There is no template.
- Needs to be reviewed at regular intervals
- All decisions are based on how much risk your institution is willing to take
- Validation goes far beyond REDCap. You need user access agreements, disaster recovery plans, SOPs, etc.
- Very time-consuming for the first project, the next ones are easier



Source: BlueHarbors





# Compliance & regulatory (3)

#### Further notes continued:

- HIPPA is a lower level of compliance than
   Part 11
- Don't document anything you are not prepared to follow
- Keep it as unspecific as necessary
- There are many features in REDCap that have nothing to do with the validation scope of Part 11. New features don't necessarily have to be documented
- Using mobile app: validation will be a problem since PHI is being stored in a phone



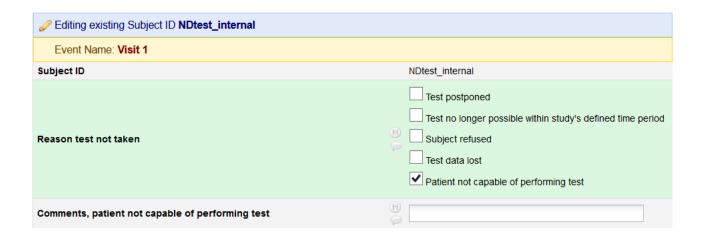
Source: BlueHarbors





### Missing data

- Normal part of data collection
- Plan for it
  - Use required tag (sparingly)
    - Can be ignored in data entry form, but not in survey
  - Define why it is missing within REDCap







## **Testing**

- Prior to moving into production, do as much testing as possible
  - 1. Project designer: add mock data for basic checks
  - Clinical team/data entry staff: add data for 3-5 actual cases
    - Everyone who will be entering data should test
    - Encouragement is often necessary
  - Typical problems encountered: branching logic, calculations, discrepancies btw paper source and eCRF
    - Changing project design in production is not always practical or doable





## Development vs. production modes

- Move project to production mode prior to collecting real data
- Maintains data accuracy and integrity
- Additional checks to avoid data being modified, deleted or overwritten unintentionally
- Check: https://rc.partners.org/kb/article/2093

Metadata	Change Type	Data Impact	Require User Confirmation	REDCap Admin Action	Critical Issue
Variable / Field Name	Add new	No data impact. New field will be added to all records.	No	Commit changes.	
Variable / Field Name	Delete	Possible data loss. Deletes the field and ALL the data entered for that field	Yes, if field contains data. No, if field does not contain any data.	Run Revision Report to verify if field contains data. If field has data, notify requester for confirmation prior to committing changes.	critical
Variable / Field Name	Rename	Possible data loss. REDCap views this action as the equivalent to deleting a variable and adding a new variable. Data is deleted	Yes. Same as deleting variable / field name.	Same as deleting variable / field name.	critical





### Calculations

- Can only produce numbers or "NaN"
- Order of operations: PEMDAS
  - Parentheses (simplify inside them), Exponents, Multiplication and
     Division (from left to right), Addition and Subtraction (from left to right)
- Conditional logic possible (if/then)
- Avoid creating second-level/cascading calculations
  - They will not reliably calculate
  - Hard to troubleshoot
  - Even though values may appear in the field onscreen, blanks may be exported
- Export data to do complex stats in SPSS, SAS, R, Stata





## Data quality & resolve issues modules

#### Data quality module

- Regularly run checks to help track invalid or missing data
- Execute the pre-made rules
- Design your own rules where appropriate

#### Resolve issues module

- Assign issues to users
- Monitor problem resolution

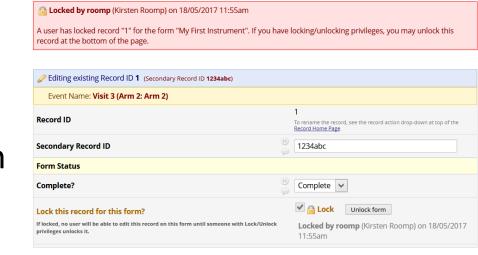
Data Quality	t A&B Clear						
		Apply to: All records 🔻					
Rule #	Rule Name	Rule Logic (Show discrepancy only if)	Real-time execution ?	Total Discrepancies	Delete rule?		
A	Missing values*	-		Execute			
В	Missing values* (required fields only)	-		Execute			
С	Field validation errors (incorrect data type)	-		Execute			
D	Field validation errors (out of range)	-		Execute			
Е	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-		Execute			
F	Hidden fields that contain values**	-		Execute			
G	Multiple choice fields with invalid values	-		Execute			
Н	Incorrect values for calculated fields	-		Execute			





## Locking

- Safeguard data integrity
- Useful in larger projects with multiple data entry users
- All users with locking privileges can unlock each others' records
- You can lock records
  - 1. By individual data entry form
  - By entire record, across all events







### IRB (Institutional Review Board) Approval

- Consider including PDF versions in IRB your submission
  - design your data forms in REDCap before submitting your final protocol for approval
- University of Luxembourg
  - https://intranet.uni.lux
     Search for: Ethics Review Panel
  - http://wwwen.uni.lu/research/chercheurs recherche/stan dards policies





### References

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- "REDCap Best Practices and General Guidelines", UT Southwestern Medical Center, Dallas, TX
- "REDCap Best Practices", Institute of Translational Health Sciences, University of Washington, Seattle, WA
- "REDCap Best Practices for Data Collection of Clinical Trials", School of Medicine, Washington University in St. Louis, MO
- "REDCap Tips", University of Denver, CO



