2020 Research Boot Camp Series

Presented by:
Research in Outcomes for Children's Surgery (ROCS)
Center for Children's Surgery

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Day 2:
IRB Submission with Human Subjects Research and Data Collection

Claudia Mata, MPH

Maxene Meier, MS

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Series Schedule

- Day 1, Friday August 7th : "**Designing Your Study and Protocol**"
  - Study Design
  - Research Questions and Aims
- Day 2, Friday August 15th : "**IRB Submission and Data Collection**"
  - Human Subject Research
  - Required Training and Submission Guidelines
  - Data Variable Types
  - Collecting Data and Database Building: REDCap
- Day 3, Friday August 21st : "**Data Analysis and Manuscript Writing**"
  - Working with a Statistician
  - Preparing Data for Analysis
  - Presenting Your Results

Thank you Jill!

From Jill:

1) ask people for successful grants, aims pages, and IRB protocols

2) get help with your research idea as soon as you can so that you can have help outing the projects and how to pull together a research program

3) aims and proposals are an interactive process and are done simultaneously throughout the grant writing process

Series Schedule

- Day 1, Friday August 7th : "Designing Your Study and Protocol"
  - Study Design
  - Research Questions and Aims
- Day 2, Friday August 15th : "IRB Submission and Data Collection"
  - Human Subject Research
  - Required Training and Submission Guidelines
  - Database Variable Types
  - Data Management and Database Building: REDCap
- Day 3, Friday August 21st : "Data Analysis and Manuscript Writing"
  - Basics of Manuscript Writing
  - Working with a Statistician
  - Preparing Data for Analysis
  - Presenting Your Results: figures and tables
  - Authorship

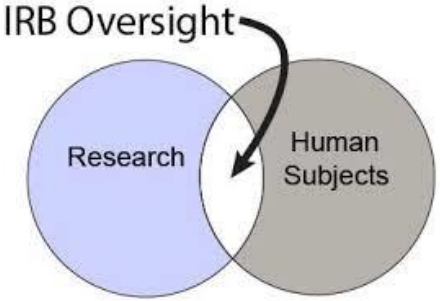
Steps to Complete a Scholarly Project

STUDY DESIGNS

PROTOCOL AND IRB APPLICATION

Human Subject Protections

- IRB is not meant to be difficult or the enemy
- The purpose of the IRB is to ensure that research upholds the following…



Belmont Principle	Application
Respect for Persons	Informed Consent
Beneficence	Risk/Benefit Assessment
Justice	Subject Selection

IRB Process

Before submission

- Complete CITI training
- COI disclosure

Submission process

- Submit through the Human Subject Research Portal
- Feasibility Review (CHCO/RI)
- COMIRB
- OnCore protocol creation

More Info…. https://research.cuanschutz.edu/comirb/home/submissions

CITI Training

For all research personnel involved in the study

Required courses

- Biomedical **or** Social Behavior investigators
- Human Subjects' Protections
- Health Information Privacy and Security (HIPS) for Clinical Investigators

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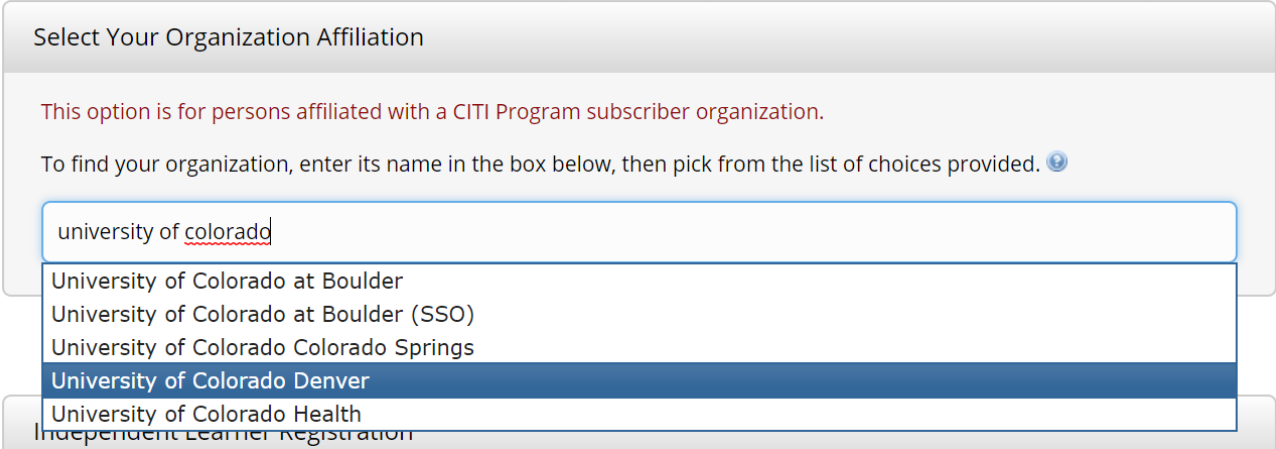
CITI Training

- Create an account on the CITI homepage
- Select *University of Colorado Denver* as organization affiliation
- Use University of Colorado credentials to set up the account



COI Disclosure

- Complete your COI Disclosure Form on the eRA website. Select **Denver** as your campus and login with your CU Denver credentials.
  - Step by step guide on how to complete the COI Disclosure Form
- Complete COI once a year, unless your status changes during the year.

Human Subject Research Portal

HSR Portal Submission

- Complete Clinical Research Protocol Assessment Form
  - https://research.cuanschutz.edu/crs/clinical-research-support/clinical-research-administration/human-subjects-research-portals/hsr-new-protocol-portal
- Clearance letter
  - Receive clearance letter by email
  - Need letter for COMIRB submission

Resize font: Returning?

Clinical Research Administration

Protocol Assessment Form

Email address of person completing form

* must provide value

STUDY INFORMATION

UPDATE: If you have an amendment to add a new study site to an IRB-approved protocol, please note that the submission process for these amendments has changed . Amendments to add study sites should now be submitted through the Amendment Portal.

IRB (COMIRB) Number (xx-xxxx):

* must provide value

Protocol Version Number and/or Date:

* must provide value

Study Title

* must provide value

COMIRB Application Components

- Personnel
- Sites
- Data and Specimen Collection
- Data Management and Security
- Consent/Waiver of Consent/Authorization

COMIRB Submission:

Retrospective Chart Review

Secondary Research Application

- Specific for retrospective chart reviews
- Shorter than full application
- Need to have protocol and list all data variables interested in collecting

COMIRB Application — Secondary Research

Submission Details

Protocol Number: _____ Version Date: _____

Project Title:

Key Study Personnel

Last Name	First Name and MI	Dept/Division	E-Mail Address	VA Employee	Role
				☐	
				☐	

Add one Investigator with the role of PI. Add one Investigator with the role of Primary Contact. **All** other study investigators, including any listed above, must be added on the electronic ***Personnel eForm*** when the protocol is submitted to COMIRB through eRA(InfoEd).

Is the PI a student or trainee [including resident/fellow], or doing this research to fulfill an educational requirement? ◯ Yes ◯ No

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Colorado Multiple Institutional Review Board

- COMIRB Home
- Submissions
- Training
- About COMIRB
- Forms
- Guidance Documents
- Participant Resources
- Policies and Procedures
- Contact Us
- FAQ
- Announcements

COMIRB Forms

Colorado Multiple Institutional Review Board

The following COMIRB forms are the most current forms which have been approved by the Director of Administrative offices, and the Association for the Accreditation of Human Research Protection Program committee.

- "Smart PDF" Initial Application Forms
- Application Attachments
- Advertising Components Submission Form
- PI Attestation Form & Mentor Agreement
- Continuing Review
- Protocol Template

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http://www.ucdenver.edu/research/comirb/Pages/forms.aspx

References

- COMIRB website

https://research.cuanschutz.edu/comirb

- Clinical Research Support Center

https://research.cuanschutz.edu/crs

- ROCS Support Intake Form

https://form.jotform.com/CCS_ROCS/rocs-intake

- ROCS contact info

ROCS@childrenscolorado.org

Questions?

Steps to Complete a Scholarly Project

STUDY DESIGNS

PROTOCOL AND IRB APPLICATION

DATA COLLECTION

DATA ENTRY & CLEANING

Data Variable types

Data?

Data?

Data?

If you google "types of data" you get this:

People also ask

What are the 4 types of data?

What are the 5 types of data?

What are the 3 types of data?

How many types of data types are there?

Feedback

www.forbes.com › sites › adrianbridgwater › 2018/07/05

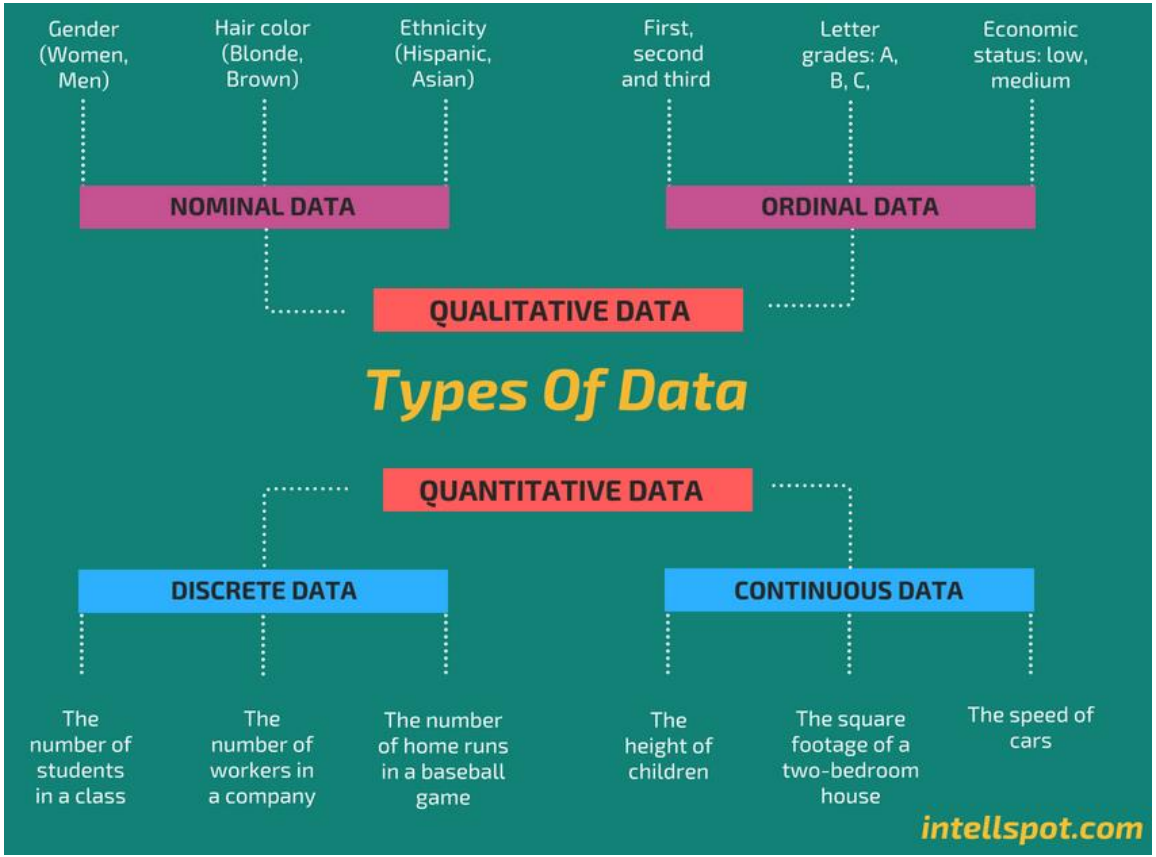
The 13 Types Of Data - Forbes

Jul 5, 2018 - The 13 **Types Of Data** · 1 - Big data · 2 - Structured, unstructured, semi-structured

Types of data

This came from

“6 types of data”



Types of data

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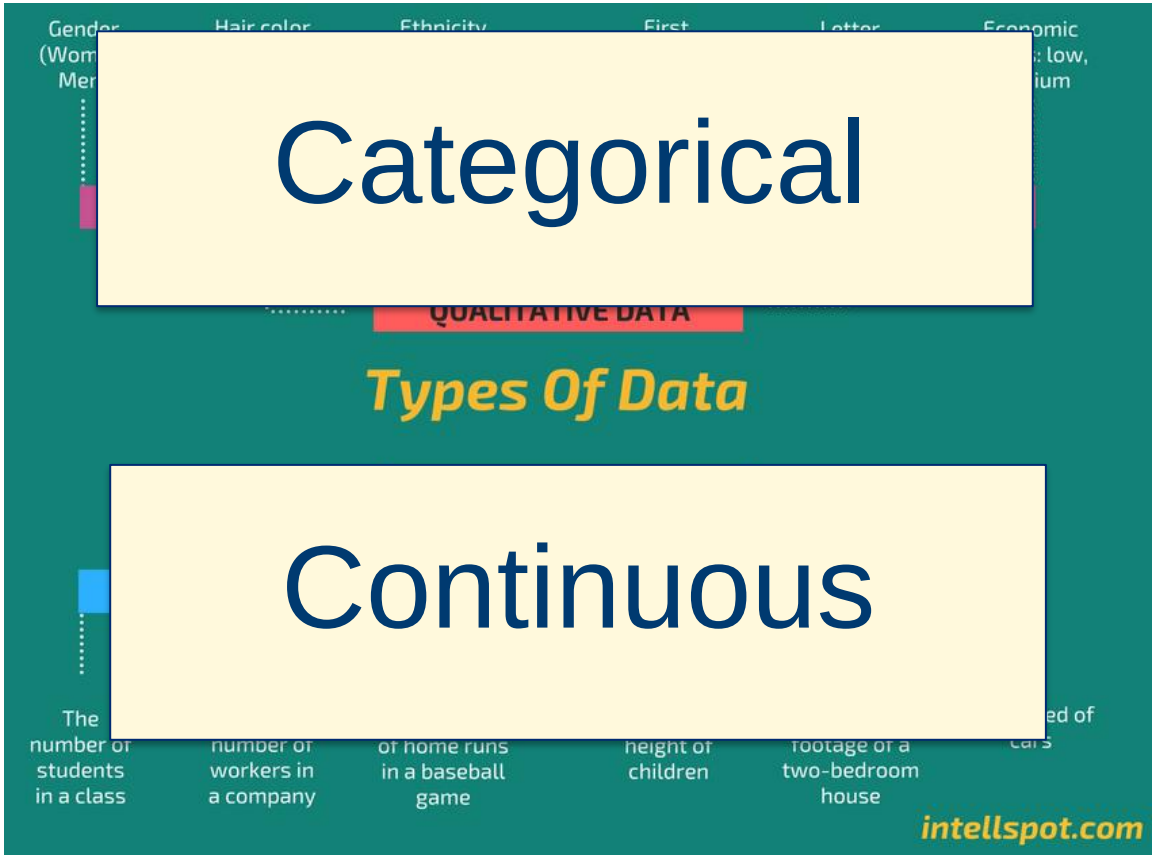
“6 types of data”



Types of data: Categorical

Categories or groups

Examples:

- Gender: Male, Female, Other
- Eye Color: Blue, Brown, Hazel
- Grade: 1st, 2nd, 3rd…

Types of data: Categorical

Categories or groups

Ordinal (rank)

- Eye C[illegible] Blue, Brown, Hazel
- Grade: 1st, 2nd, 3rd…

Types of data: Categorical

Categories or groups

Examples:

- Gender: Male, Female, Other
- Eye Color: Blue, Brown, Hazel
- Grade: 1st, 2nd, 3rd…

Nominal

Types of data: Continuous

Numeric values

Examples:

- Height
- Weight
- Temperature

Types of data: Continuous

Numeric values

Examples:

- Height
- Weight
- Temperature

Can be interval or ratio

What type of data?

1. Age in years

What type of data?

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)

What type of data?

4

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)
3. Blood Pressure

What type of data?

5

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)
3. Blood Pressure
4. Blood type

What type of data?

6

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)
3. Blood Pressure
4. Blood type
5. Income

What type of data?

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)
3. Blood Pressure
4. Blood type
5. Income
6. Income ($30,000 - $50,000, $51,000 - $70,000, etc.)

What type o

1. Age in years
2. Age (0 – 5 ye
3. Blood Pressu
4. Blood type
5. Income
6. Income ($30
   etc.)

Income is a sensitive question
Others include: drug usage, abortion, and sexual behavior

What type o

1. Age in years
2. Age (0 – 5 ye
3. Blood Pressu
4. Blood type
5. Income
6. Income ($30
   etc.)

Income is a sen
question
Others include: drug
usage, abortion, and
sexual behavior

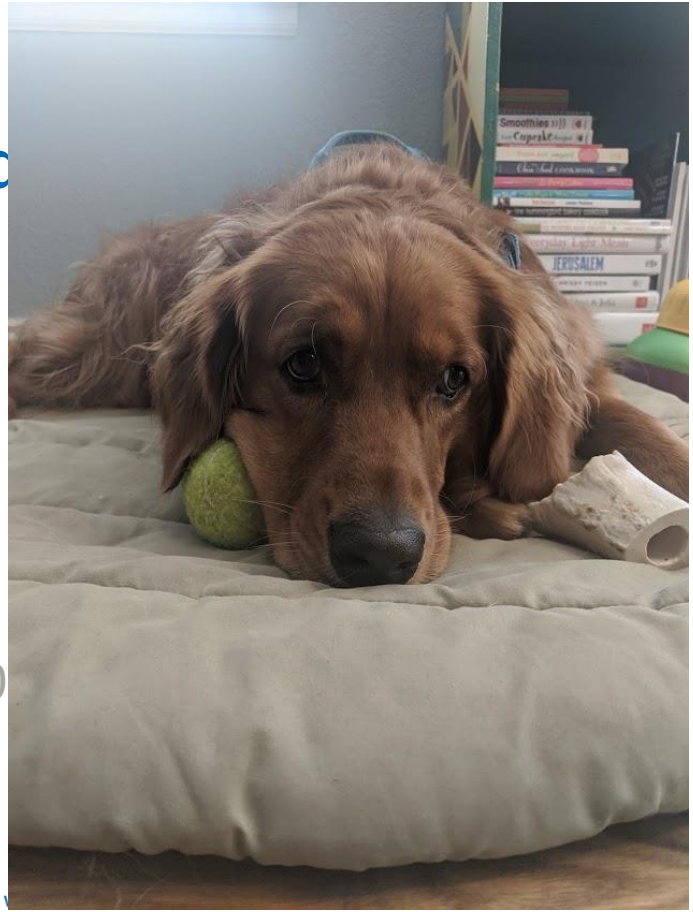
8

What type of data?

1. Age in years
2. Age (0 – 5 years, 6 – 10 years, 11-15 years, etc.)
3. Blood Pressure
4. Blood type
5. Income
6. Income ($30,000 - $50,000, $51,00 - $70,000, etc.)
7. Midge

What type of d

1. Age in years
2. Age (0 – 5 years,
3. Blood Pressure
4. Blood type
5. Income
6. Income ($30,000
   etc.)
7. Midge



9

Data

Continuous → Categorical

Age in years → Age groups

Data

Continuous → Categorical

Age in years → Age groups

1, 2, 3, 3, 3, 4, 5, 7, 10, 11

Data

Continuous → Categorical

Age in years → Age groups

1, 2, 3, 3, 3, 4, 5, 7, 10, 11

Data

Continuous → Categorical

Age in years → Age groups

Under 5	5 and over

Data

Continuous ? ← Categorical

Age in years ? ← Age groups

Under 5	5 and over

Data

Continuous ← / Categorical

Age in years ← / Age groups

Under 5	5 and over

Data

Think about how your question will be answered

Is it a sensitive topic (i.e. will your patient answer it truthfully/at all)? Will they give you the truthful answer or one they think you want to hear?

Will you need to find the mean?

How will you accurately gather it?

Data Management

Data Management Overview

1. PHI
2. Things to consider before patients
3. REDCap
4. Data Hygiene
5. Excel and REDCap
6. HIPAA Compliance
7. Tips and Tricks


I JUST LOVE DATA.
DATA'S MY FAVORITE.
memegenerator.net

1. PHI

- Protected Health Information
- Patients' privacy comes first
- What is PHI?
  - Name, MRN, Birthdate, address (even zip code)
  - Visit Dates, phone numbers, email address
  - Diagnosis, treatment information, medical test results, prescriptions
- Electronic or physical records
- Can you identify someone from it?

1. PHI

- Protected Health Information
- **Patients' privacy comes first**
- What is PHI?
  - Name, MRN, Birthdate, address (even zip code)
  - Visit Dates, phone numbers, email address
  - Diagnosis, treatment information, medical test results, prescriptions
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1. PHI

- Protected Health Information
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  - Name, MRN, Birthdate, address (even zip code)
  - Visit Dates, phone numbers, email address
  - Diagnosis, treatment information, medical test results, prescriptions
- Electronic or physical records
- Can you identify someone from it?

2. Things to Consider Before Patients

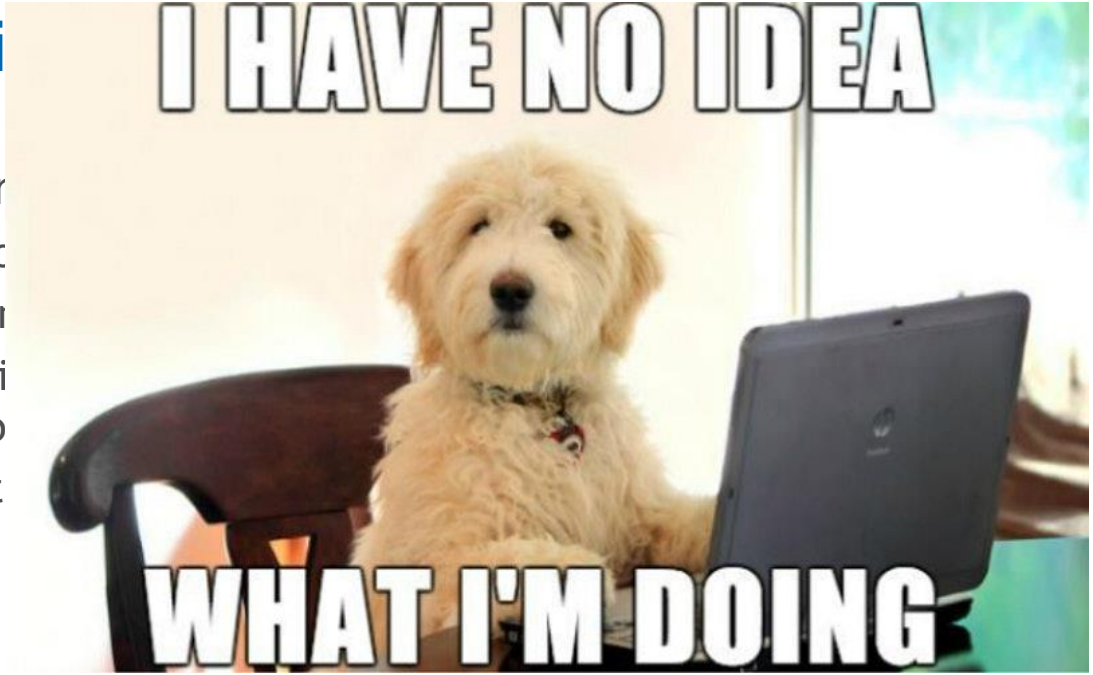
Consider everything you might want to look at

- Any potential confounders?
- Baseline demographics and clinical characteristics
- ID variables – if you have multiple data sources, how will they be linked?
- Longitudinal variables?

2. Thi

Consider

- Any po
- Baseli
- ID vari
  they b
- Longit



2. Things to Consider Before Patients

When in doubt:
CONSULT A BIOSTATISTICIAN

2. Things to Consider Before Patients

Continuous variables

- Anything measured on a numeric scale with an infinite number of possible values – weight, time, concentrations
- Make sure units are consistent throughout the dataset
- Build in range checks, if possible

2. Things to Consider Before Patients

Categorical variables

- Data that can be grouped – race, sex, region
- Two levels = Dichotomous
- Be careful to not breakdown into too many levels (makes it hard to ensure enough data in each level)

2. Things to Consider Before Patients

Before collection, determine how data will be managed

- Does you data have a unique identifier (ideally a study id which is linked to their MRN or HAR)
- Do you have a clear description of how the data were generated and processed – if you were unable to continue for any reason could someone come in and understand exactly what you did? **Also important for methods section!**

2. Things to Consider Before Patients

Before collection, determine how data will be managed

- Where will it be stored?
- Will it be accessible by everyone that needs to access it (and only those individuals)? Do people who are not on your IRB have access to your files?
- Do you have a codebook?

2. Things to Consider Before Patients

Before collection, determine how data will be managed

- Where will it be stored?
- Will it be accessible by everyone that needs to access it (and only those individuals)? Do people who are not on your IRB have access to your files?
- Do you have a codebook?

Describes the contents of the data

2. Building a Data Dictionary/Codebook

- Fill dictionary should be made prior to collection
- Stored on a new sheet or separate excel file

2. Building a Data Dictionary/Codebook

Variable Name	Description	Levels/Categories
record_id	record_id	
pid	pid	
hispanic	hispanic	1 = yes, 2 = no
race	race	3 = black, 4 = white, 5 = other
sex	sex	1 = male, 2 = female
dob	date of birth	
date_appt_1	date of first appt	
age	age at surgery	
insur_type	insurance type	1 = public, 2 = private, 3 = none
graphics_complete		

2. Building a Data Dictionary/Codebook

3. REDCap

Research Electronic Data Capture

- Developed at Vanderbilt University
- Secure way to store data
- Must be invited to access the database
- **HIPAA Compliant**
- On campus: Amanda Miller

REDCap™

Log In

Only IRB-approved protocol data should be stored in REDCap, unless you have received prior approval for an exception. Contact redcap@ucdenver.edu if you have any questions.

For information on obtaining a UCD REDCap account, policies and procedures, and to watch our tutorial videos, please visit our REDCap Info Site.

Please log in with your user name and password. If you are having trouble logging in, please contact REDCap Admin.

Username:

Password:

Log In

Forgot your password?

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3. REDCap

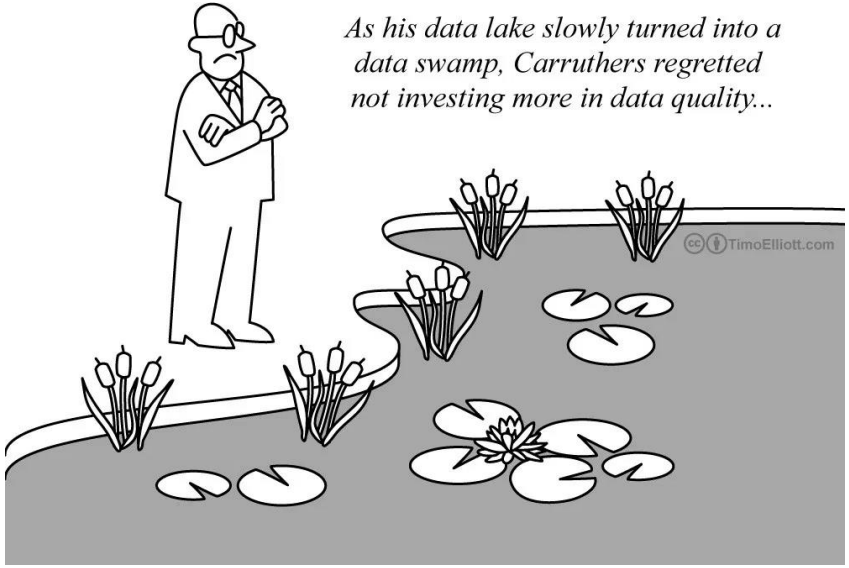
A few capabilities

- Email out surveys (linked to main database)
- Branching logic
- Customize user rights
- Easy to use – tons of online tutorials
- Tracks all changes

4. Data Hygiene

- 10 minutes on the front end saves hours (and $$$!) on the back end
- The first variable on the first form is a unique record identifier
- Create a data dictionary as you go (if not in REDCap)
- Validate and spot check
- Do double data entry if possible

4. Data Hygiene



4. Data Hygiene

- Validate text fields and define minimum/maximum ranges
- Similar variables go together on short, separate forms
- Use field notes to describe units, formats, etc.
- Determine units and coding **before** data collection; don't change halfway through
- BE CONSISTENT

5. Excel vs REDCap

Data Storage

- Most preferred = REDCap
- More convenient = Excel
- More secure = REDCap
- Data dictionary automatic generation = REDCap

5. Excel vs REDCap

Data Storage

- Most preferred = REDCap
- More convenient = Excel
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5. Excel vs REDCap

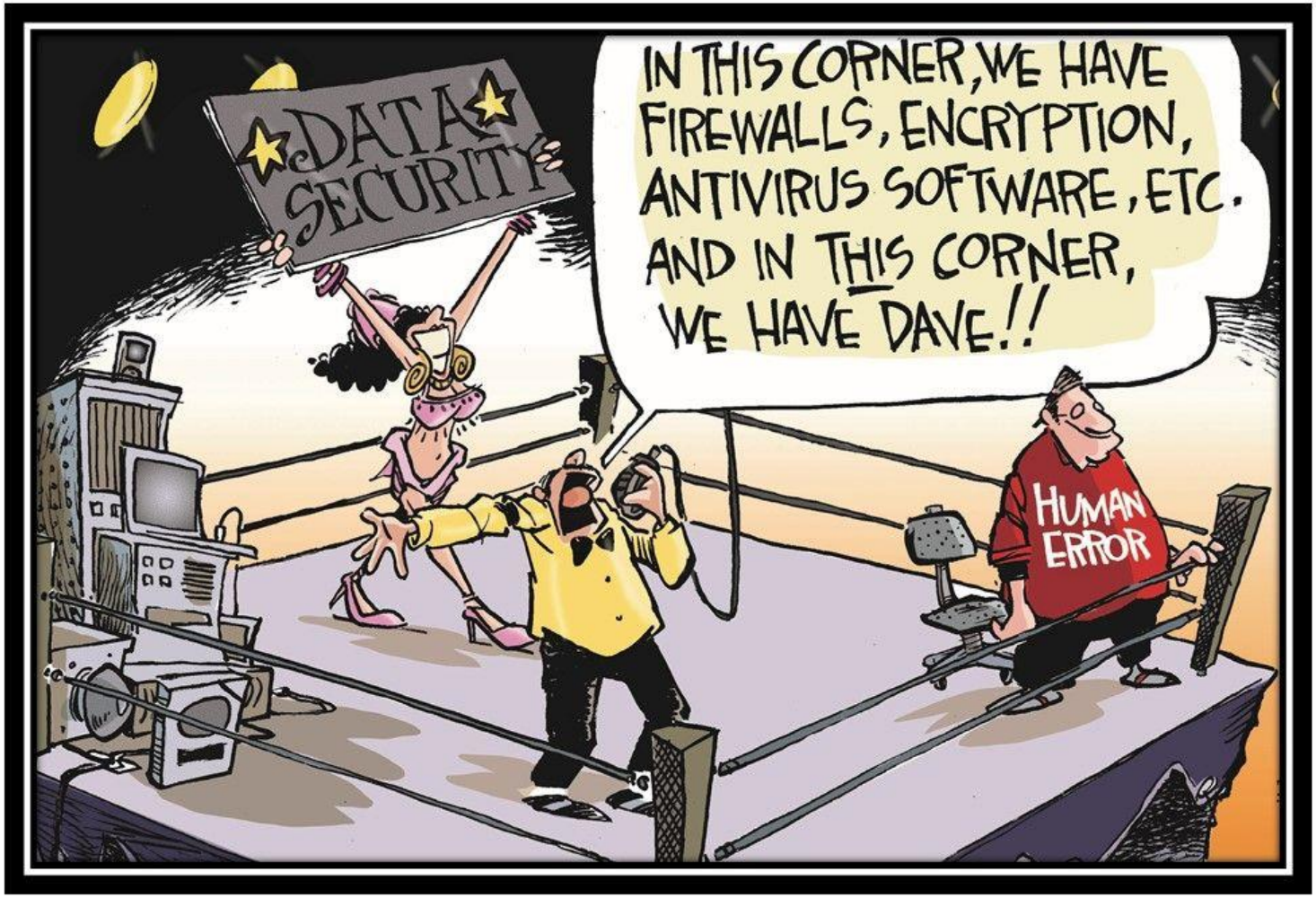
Data Storage

- Most preferred = REDCap
- More convenient = ~~Excel~~ REDCap
- More secure = REDCap
- Data dictionary automatic generation = REDCap

REDCap also automatically tracks changes, can easily adjust user rights, and it automatically HIPAA compliant

6. HIPAA Compliance

- Excel and Access require additional steps
- REDCap is HIPAA compliant automatically
  - Maintained on a secured server, backed up twice daily with off-site back-ups
  - All activity is automatically logged and tracked
  - Secured login and access
  - Easily able to identify and strip PHI identifiers
  - Able to send information in a secure fashion, even to those without accounts


DATA SECURITY
IN THIS CORNER, WE HAVE FIREWALLS, ENCRYPTION, ANTIVIRUS SOFTWARE, ETC. AND IN THIS CORNER, WE HAVE DAVE!!
HUMAN ERROR

6. HIPAA Compliance- Your Responsibilities

- Never share your username or password
- Never share an API token (unique token used to link applications)
- Mark all identifiers as identifiers (PHI)
- Strip identifiers before exporting if not necessary or if exporting to unsecured device
- Give minimum required user rights to all users
- Never give Project Design or User Management rights to users with basic accounts

7. Tips and Tricks

- Provide only Patient ID numbers: Protected Health Information (PHI) should not be included (do NOT include patient names)
- Character (A, AB, O) and numeric values (0, 1, 2) should not be mixed within one column.
- Use range checks when setting up the database
- Missing values should either be marked with "NA" or simply left blank
  - BE CONSISTENT
- No units in continuous variable entries – Should be in data dictionary
  - BE CONSISTENT- units should be same through entire column (“kg” vs “lbs”)

7. Tips and Tricks

- No punctuation or spaces (e.g. commas, quotes, <,>) in data values
- No special formatting:
  - colored text
  - highlighted columns
  - *Italics*
  - **bolding,**
  - ^{super} or $_{sub}$ scripting
  - the “comment” feature
- No capitalization/ spelling variations

7. Tips and Tricks

- No punctuation or spaces (e.g. commas, quotes, <,>) in data values
- No special formatting:
  - colored text
  - highlighted columns
  - *Italics*
  - **bolding,**
  - ^{super} or $_{sub}$ scripting
  - the “comment” feature
- No capitalization/ spelling variations

Programming languages do not recognize these features which could result in lost information

7. Tips and Tricks

- No punctuation or spaces (e.g. commas, quotes, <,>) in data values
- No special formatting:
  - colored text
  - highlighted columns
  - *Italics*
  - **bolding,**
  - ^{super} or $_{sub}$ scripting
  - the “comment” feature
- No capitalization/ spelling variations

Creates additional unintentional levels

7. Tips and Tricks

ID	Sex	Age	Weight
1	Male	12	90
2	male	3	14.2
3	F	2	28
4	Female	50	40
5	Male	5	17.9

7. Tips and Tricks

- Choose appropriate format for the variable (text vs. numbers)
    - Avoid text boxes and un-validated fields
- For categorical variables consider whether a check box (multiple selection) or radio button (single selection) is more appropriate
    - Consider what the variable is asking, can you ‘check’ more than one
- Make sure the variable labels are meaningful

7. Tips and Tricks

- Name – how the computer recognizes the variable
  - **Unique**
  - **Short** but descriptive
  - No spaces
  - No special characters except "_"
  - E.g., SCR_WT
- Label – (slightly) longer description of the variable including units
  - E.g., "screening weight (kg)"
- Format – describes the meaning of categorical variables
  - E.g., 0=no 1=yes

7. Tips and Tricks

This is a learning process and no dataset is perfect (right away)

Questions?

"This is not what I meant when I said 'we need better data cleansing!'"

www.iwaysoftware.com/go/dataquality

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