Clinical Research Seminar: Case Report Form Design

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Learning Objectives

- The necessity of incorporating data sharing requirements
- **Key design elements and inclusion of standard measures**
- Importance of pilot testing, change management and optimization of data architecture
Good News: Every one can create a Case Report Form (CRF)!
Bad News: Not everyone can create a “reliable and valid” CRF?
Case Report Form (CRF)

- A printed, optical or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject (ICH E6 GCP Guidelines)
- An informative and well-structured CRF simplifies database design and data validation processes as well as manipulation of data during statistical analysis

\(^1\)
CRF Design

- Collect data specified by the protocol. Ideally CRFs should be developed concordantly with the protocol (and statistical analysis plan if available)
  - Assemble multidisciplinary team to provide input (investigators, biostatistician, data manager)
  - Focus on primarily on safety and efficacy endpoints
  - Implement standards where possible (more on this later)
  - Ensure questions, prompts, instructions are clear and concise
  - CRF questions flow in logical order and are culturally and individual/condition sensitive
  - Instruments created by independent source (validated measures), licensed for use (e.g., Beck Depression Inventory) and follow prescribed formatting/copyright requirements

- Ensure the process for design, development, approval and version control documented
## Schedule Evaluation and Events (SOEE)

<table>
<thead>
<tr>
<th>Construct/Domain</th>
<th>Measures</th>
<th>Visit (Days from Hospital Discharge Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SCRN</td>
</tr>
<tr>
<td><strong>Participant Characteristics</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Consent/Eligibility</td>
<td>Date of Consent, Inclusion/Exclusion Criteria including toxicology (urine)</td>
<td>X</td>
</tr>
<tr>
<td>Demographics &amp; SES</td>
<td>Age, Sex, Race, Marital/Partner Status, Health Insurance and Living Situation (homeless)</td>
<td>X</td>
</tr>
<tr>
<td><strong>Health Characteristics</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Co-Morbidities</td>
<td>Charleson Index (EMR)</td>
<td>X</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Depression (PHQ)</td>
<td>X</td>
</tr>
<tr>
<td><strong>Substance Use, Motives, Consequences, Cravings, Readiness and Biomarkers</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Alcohol Severity</td>
<td>AUDADIS</td>
<td>X</td>
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<tr>
<td>Alcohol Use</td>
<td>Timeline Follow-back (TLFB)</td>
<td>X</td>
</tr>
<tr>
<td>Consequences</td>
<td>Short Inventory of Problems – Revised (SIP-2R)</td>
<td>X</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NTX Route</td>
<td>Randomization Group (XR-NTX – PO-NTX)</td>
<td></td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications</td>
<td># of RW-MM visits with nurse or PO med mailing</td>
<td></td>
</tr>
<tr>
<td>Visit</td>
<td>Research Visits</td>
<td>X</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Patient reported side effects, problems during RW-MM visits –opioid meds</td>
<td></td>
</tr>
<tr>
<td>Labs</td>
<td>Liver Tests (ALT, AST, GGT*), Pregnancy Test (SCRN as indicated)*</td>
<td>X</td>
</tr>
</tbody>
</table>

Modified from the NIAAA Alcohol Disorder hospital Treatment (ADOPT) Study
What is the difference between an assessment and an unscheduled event?
Why does it matter?
Data Management Minimum Requirements

CRFs are not developed in a silo, majority of data is typically captured using CRFs or Forms and is integral to study success and part of the data management plan. Minimum requirements for data management:

- Traceability
- Data Quality
Risk Assessment – how good is good enough – what rigor is required?

- Consider:
  - Ethics
  - Regulations
  - Institutional policies
  - Sponsor requirements
  - Plans for data use and reuse

- Ensure three tenets:
  - the rights and well-being of human subjects are protected,
  - the reported data are accurate, complete and verifiable from source,
  - the conduct of the trial is in compliance with the protocol, Good Clinical Practice guidelines and the applicable regulatory requirements
Proactively Determine Plans for Data use and Reuse/Data Sharing

- Data sent to FDA likely using CDISC standards
- Mandated for NIH sponsored research awards (> $500,000)
- In RFA/RFP often will state use of standards (PhenX) or CDISC
- Data sent to sponsor or regulatory agency should require minimal data manipulation
- Using standards will save time (data build and analysis) and improve data quality and traceability since it will minimize harmonization and documentation required
Sample Annotated Demographics Case Report Form - CDISC

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>SITEID</th>
<th>SUBJID</th>
<th>SUBJINT</th>
<th>VISITNUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAP-001</td>
<td>Site Number</td>
<td>Patient Number</td>
<td>Patient Initials</td>
<td>Visit Number</td>
</tr>
</tbody>
</table>

**Demographics**

1. Date of Birth: 
   - BBRTHDAT
   - DD MON YYYY

2. Biological Sex at Birth: 
   - Male
   - Female
   - CHILDNY
   - *If Female, is the patient of child-bearing potential?* 
     - No
     - Yes

3. Ethnicity: 
   - ETHNIC
   - Hispanic or Latino
   - Not Hispanic or Latino

4. Race: 
   - RACE
   - American Indian or Alaska Native
   - Asian
   - Black or African American
   - Native Hawaiian / Pacific Islander
   - White
   - Other: 
     - (specify)
### CDISC - Demographics Example (Data Dictionary)

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td>Identifier</td>
<td>Unique identifier for a study.</td>
<td>Req</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>Char</td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain.</td>
<td>Req</td>
</tr>
<tr>
<td>SUBJID</td>
<td>Subject Identifier for the Study</td>
<td>Char</td>
<td>Topic</td>
<td>Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.</td>
<td>Req</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Char</td>
<td>Identifier</td>
<td>Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.</td>
<td>Req</td>
</tr>
<tr>
<td>DMGRPID</td>
<td>Group ID</td>
<td>Char</td>
<td>Identifier</td>
<td>Used to tie together a block of related records for a subject within a domain.</td>
<td>Perm</td>
</tr>
<tr>
<td>RFSTDTC</td>
<td>Subject Reference Start Date/Time</td>
<td>Char</td>
<td>Record Qualifier</td>
<td>Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone date requires, such as screen failures or unassigned subjects.</td>
<td>Exp</td>
</tr>
<tr>
<td>RFENDTC</td>
<td>Subject Reference End Date/Time</td>
<td>Char</td>
<td>Record Qualifier</td>
<td>Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects</td>
<td>Exp</td>
</tr>
<tr>
<td>SITEID</td>
<td>Study Site Identifier</td>
<td>Char</td>
<td>Record Qualifier</td>
<td>Unique identifier for a site within a study.</td>
<td>Req</td>
</tr>
<tr>
<td>INVID</td>
<td>Investigator Identifier</td>
<td>Char</td>
<td>Record Qualifier</td>
<td>An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.</td>
<td>Perm</td>
</tr>
<tr>
<td>INVNAM</td>
<td>Investigator Name</td>
<td>Char</td>
<td>Synonym Qualifier</td>
<td>Name of the investigator for a site.</td>
<td>Perm</td>
</tr>
<tr>
<td>BRTHDTC</td>
<td>Date/Time of Birth</td>
<td>Char</td>
<td>Record Qualifier</td>
<td>Date/time of birth of the subject.</td>
<td>Perm</td>
</tr>
<tr>
<td>AGE</td>
<td>Age</td>
<td>Num</td>
<td>Record Qualifier</td>
<td>Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).</td>
<td>Exp</td>
</tr>
<tr>
<td>AGEU</td>
<td>Age Units</td>
<td>Char</td>
<td>Variable Qualifier</td>
<td>Units associated with AGE.</td>
<td>Exp</td>
</tr>
</tbody>
</table>
Primary Data Collection - Consent CRF

- What information is required?
- Who is answering the questions?
- How do we collect and store this information?
- How do we check that this information is accurate (reliable) and valid?
- What information is protected or confidential?
- What information can be shared and under what circumstances?
- What would a “data collection” form or screen shot look like to collect this information?
- How do we account for changes in the consent form versioning changes?
Sample Patient Enrollment Case Report

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>—— ——</th>
<th>01</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAP-001</td>
<td>Site Number</td>
<td>(Assigned by System)</td>
</tr>
</tbody>
</table>

Patient Enrollment

1. Patient Number: _____ _____ _____

2. Patient Initials: F M L

3. Date Informed Consent Signed: DD / MON / YYYY

4. If child < 18, Date Assent Signed: DD / MON / YYYY

5. Protocol Version Number of Executed Informed Consent: _____
## MAIN STUDY CONSENT TRACKING FORM

### Recruitment Location:
- (use codes)
  - BISH Location Codes
    - 01=Belhar Antenatal Clinic
    - 02=Bishop Lavis Midwife Obstetric Unit
    - 03-Tygerberg Hospital
  - RAPD Location Codes
    - 00=Native Women’s Health Center
    - 14=Black Hills OB/GYN
    - 15=Midland Office

### 1. Consent signed
   - a. Date Consent signed or refused
   - b. If not signed, please specify reason for refusal

### 2. Addendum signed for Embedded Study
   - a. Date Addendum signed or refused
   - b. If not signed, please specify reason for refusal

### 3. May collect maternal saliva

### 4. May collect maternal blood

### 5. May review maternal medical records

### 6. May collect placental tissue

### 7. May collect cord or infant blood sample (Guthrie card)

### 8. May collect baby’s stool

### 9. May collect brain tissue

### 10. May take photo of infant

### 11. May take video recordings of baby’s movement

### 12. May review baby’s medical records

### 13. Willing to participate in genetics studies

### 14. May use specimens for future studies

### 15. May measure baby’s brain activity and hearing

### 16. May contact for future studies

### 17. May take 3D photo of infant

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Biostatistics and Epidemiology Data Analytics Center (BEDAC)

**Boston University** School of Public Health
CRF Design

- Gather relevant reference documents (e.g., protocol, CRF reference library, Statistical Analysis Plan (SAP), data requirements from Sponsor or regulatory agency, review standards (C-DASH, PhenX), most recent versions of measures (don’t modify an independent or validated scale)
- Develop CRFs, CRF form completion guidelines concurrently
- Cross-check information from CRF, protocol and consent form and SAP
- Visually appealing (uncluttered, organized by construct of measurement)
- Written at 5-8th grade reading level, clear instructions provided, clear and unambiguous questions and response options (limit text responses)
- Parsimony (questions asked once and required for research)
- Traceability (map origin)
- Language translation and back-translation (reliability and validity)
Response Options: Simplistic View

- **Structured**
  - Name (categorical)
  - Categorical (dichotomous, categories order doesn’t matter)
  - Ordinal (order matters, Likert scales)
  - Interval (quantitative)

- **Unstructured**
  - Open text
    - Qualitative
Design and Development Process

All data attributable to a subject with sufficient identifiers to link data with page numbers and if applicable provides provision for signature

<table>
<thead>
<tr>
<th>Catalyst</th>
<th>Site Number</th>
<th>Patient Number</th>
<th>Patient Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAP-001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adverse Event Log

List all Serious Adverse Events (SAEs) the patient experiences after signing the Informed Consent Form. List all other Adverse Events (AEs) the patient experiences after the first administration of amifampridine phosphate. Follow each SAE/AE through 4 weeks after last dose, until each SAE/AE is resolved or stabilized, the patient becomes lost to follow-up, or it has been determined that amifampridine phosphate is not the cause of the event. Use the Adverse Event Log within the Clinical Data Management System (CDMS) to monitor and follow-up on existing events, and to determine the Adverse Event Number. Check the box for "Not an Adverse Event" if the event automatically generated from the CDMS is subsequently determined to be not adverse. If the adverse event is serious, complete the BioMarin SAE Form. Print additional pages, as needed.

**Description:**

*Not an Adverse Event*

<table>
<thead>
<tr>
<th>Adverse Event Number</th>
<th>Visit Number</th>
<th>Date Onset</th>
<th>Serious Event</th>
<th>CTCAE Grade</th>
<th>Attribution to Amifampridine</th>
<th>Action Taken</th>
<th>Outcome of Event</th>
<th>Date Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If Yes, Criteria:

- [ ] No
- [ ] Yes

If 99, Specify:

- (separate by comma)

**Action Taken**

Amifampridine: 

Other Action: 

If 99, Specify:

**Outcome of Event**

- DD/MON/YYYY

- ONGOING

**Coding Key:**

- [ ] = Unknown

**Serious Criteria Codes:**

- 1 = Death
- 2 = Life-Threatening
- 3 = Hospitalization
- 4 = Disability/Incapacity
- 5 = Congenital Anomaly
- 6 = Requires Cancer
- 7 = Other
- 99 = Other Important Medical Event

**CTCAE Grade Codes:**

- 1 = Mild
- 2 = Moderate
- 3 = Severe or medically significant but not immediately life-threatening; hospitalization; or prolonged hospitalization; disability
- 4 = Life-threatening consequences

**Attribution Codes:**

- 1 = Not Related
- 2 = Possibly Related
- 3 = Probably Related
- 4 = Not Applicable

**Other Action Codes:**

- 1 = None
- 2 = Concomitant Medication
- 3 = Hospitalization
- 4 = Surgical/Diagnostic Procedure
- 5 = Patient Withdrawn
- 99 = Other

Investigator Signature: ___________________________  Date: __/__/____

Coding Key: [ ] = Unknown
Clarity of Use

- CRF Layout
- Wording
- Coding
- Use of minimal referential questions (e.g., skip logic)
- Minimize redundancies (collect data once unless for validation purposes)
- Distinction between paper-based CRFs, eCRFs and Patient Reported Outcomes (PRO)
### The SAFE PASSAGE Study

#### Edinburgh Depression Scale

<table>
<thead>
<tr>
<th>Date of Interview:</th>
<th>Interviewer Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language of Interview:</td>
<td>Location of Interview:</td>
</tr>
<tr>
<td>Contact:</td>
<td></td>
</tr>
<tr>
<td>Time Interview Began:</td>
<td>Time Interview Ended:</td>
</tr>
</tbody>
</table>

#### Instructions for the Clinical Coordinator

Complete this questionnaire by marking each statement to the participant. Be sure to read each response option to the participant and have the participant circle the numbers that are in each cell. Mark responses with an X in the circle to indicate the closest to how they felt about the following statements in the past seven days.

1. **I have been able to laugh and see the funny side of things:**
   - As much as I always could: 0
   - Not quite as much now: 1
   - Definitely not as much now: 2
   - Not at all: 3

2. **I have looked forward with enjoyment to things:**
   - As much as I ever did: 0
   - Rather less than I used to: 1
   - Definitely less than I used to: 2
   - Hardly at all: 3

3. **I have blamed myself unnecessarily when things went wrong:**
   - Yes, most of the time: 3
   - Yes, some of the time: 2
   - Not very often: 1
   - No, never: 0

#### Recruitment Interview

**Date of Interview:**

**Interviewer Name:**

**Language of Interview:**

**Location of Interview:**

**Time Interview Began:**

**Time Interview Ended:**

#### Background Information

1. **What is your marital status now (in the last month):**
   - Married: 1
   - Partnered in a marriage or partnership: 2
   - Partnered in a marriage or partnership, not living together: 3
   - Separated: 4
   - Divorced: 5
   - Widowed: 6
   - Single: 7
   - Other: 8

2. **How many years of formal education have you completed:**

<table>
<thead>
<tr>
<th>School Type</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kindergarten</td>
<td>0</td>
</tr>
<tr>
<td>Grade 1</td>
<td>1</td>
</tr>
<tr>
<td>Grade 2</td>
<td>2</td>
</tr>
<tr>
<td>Grade 3</td>
<td>3</td>
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<td>Grade 4</td>
<td>4</td>
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<td>Grade 15</td>
<td>15</td>
</tr>
<tr>
<td>Grade 16</td>
<td>16</td>
</tr>
<tr>
<td>Grade 17</td>
<td>17</td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

3. **When did you find out you were pregnant:**

   - Week(s) of month: __________
   - Week(s) of year: __________
Wording, Coded Responses and Redundancy (minimize)

Reproductive History

Instructions for the Clinical Coordinator

This information must be obtained directly from the mother. Do not obtain any of this information from the medical record. Use as many additional sheets (page 6) as needed to record the participant's complete Reproductive History.

Interviewer's Script

Now, I would like to ask you a few questions about each of your previous pregnancies. Please begin with your first pregnancy:

1. On what date did your first (second, etc.) pregnancy end?
2. Did this pregnancy end in a live birth, stillbirth, spontaneous abortion (miscarriage), therapeutic abortion, ectopic pregnancy, or molar pregnancy?
3. How many weeks were you pregnant? (If precise weeks and days unknown, approximate using Gestational Age Code)
4. How much did your baby weigh? (Mostly likely only completed for live birth and the occasional stillbirth)
5. Did you experience any complications during your pregnancy or delivery? (SHOW CARD 3)
6. Did the baby experience any complications during this pregnancy or delivery? (SHOW CARD 3)
7. If live birth and the child is not living: (SHOW CARD 4)
   a. What was the date of your child's demise?
   b. What was the reason for your child's demise?
   c. Was an autopsy performed?

15. Check if this is the participant's first pregnancy: ☐ (Questionnaire is complete – enter Time Interview Ended on page 1)

OR

Please list your past pregnancy history, starting with your first pregnancy:

Pregnancy Outcome

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: <em><strong>/</strong></em>/___</td>
<td>GA: __ weeks</td>
<td>___ g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome: ___</td>
<td>OR</td>
<td>OR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

6. Do you currently have:

<table>
<thead>
<tr>
<th>(circle one for each item)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Electricity</td>
</tr>
<tr>
<td>b. Working phone service or cell phone service</td>
</tr>
<tr>
<td>c. Running water (inside house)</td>
</tr>
<tr>
<td>d. Toilet (inside house)</td>
</tr>
</tbody>
</table>

7. Including yourself, how many people currently live in your home: [ ]

8. How many times have you moved within the past 12 months: [ ]
Referential Questions

Interviewer’s Script
Now, I am going to ask you some questions about smoking. Because these questions are personal, any information you share with me will be kept confidential. You will be identified by a number only, not by name. Your name will not be placed on this form. Here is a calendar for you to refer to. (SHOW CALENDAR)

Smoking and Tobacco Use History – Section A (Cigarettes)

10A. If you [ever] smoked, when was your last cigarette: [___ / ___ / ___] (check all that apply) ________________ (year) ________________ (month) ________________ (day)

OR

NEVER SMOKED CIGARETTES: [ ] If checked, SKIP TO (Section B – top of page 4)

Instructions for the Clinical Coordinator

Determine the following date range: [___ / ___ / ___] (LMP date, mm/dd/yyyy) to [___ / ___ / ___] (LMP date from Eligibility Form, mm/dd/yyyy)

Based on the participant’s response to Question 10A, check here if the date of the last cigarette was [more than one year] before the LMP date: [ ] If checked, SKIP TO Section B – top of page 4

11A. In the [year] before you became pregnant, how often did you smoke a cigarette: (SHOW CARD A)

(circle one)

None .......................................................... 0 If checked, SKIP TO (Interviewer’s Script A)
Monthly or less ........................................... 1
2 to 4 days a month (approx. once a week) ........ 2
2 to 3 days a week.......................................... 3
4 to 6 days a week....................................... 4
7 days a week............................................ 5

12A. How many cigarettes did you smoke on a [typical day] when you were smoking in the [year] before you became pregnant:

Number of cigarettes: [ ___ ] (specify number or range)
A few notes about Modality and Patient-Reported Outcomes

Paper: Greater potential for missing data, particularly if poorly designed and not administered. Use common format (date fields, headers, response options, shading), page numbering (e.g., 1 of 5), large font, avoid referential questions

EDC: Build in edit checks, picture fields, calendar pop-up, better for referential questions (dependent on whether CRF is paper or electronic) source or paper)

PRO: Content should be clear and understandable to the subject population
Review and Quality Control Process

- Before finalized - all CRFs should be reviewed by multi-disciplinary team, new forms pilot-tested
- CRFs translated into multiple languages should be translated and back translated
- Paper-based CRFs should be carefully reviewed prior to release using version control
- Electronic CRFs must undergo user acceptance testing
- All should ensure participant confidentiality and change control/versioning
CRF Completion Guidelines and Edit Checks

CRF Completion Guidelines designed from user perspective, written when creating CRFs and Edit Checks

Edit Check Categories¹:
- Manual: CRF review prior to entry
- Programmed in Database: majority of checks where possible
- Endpoint: missing, out of range
- Safety: ensure timely reporting of SAE and PV
- Protocol Compliance: adherence to visit schedule
- Listings: discrepancies in redundant data, free text
- External: data transferred from outside source

<table>
<thead>
<tr>
<th>CRF</th>
<th>Field Name (Number)</th>
<th>Check Name</th>
<th>Edit Check</th>
<th>Edit Check Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENROLL</td>
<td>Subject ID (2)</td>
<td>DUP_REC</td>
<td>Duplicate subject ID number</td>
<td>This subject ID number has already been assigned for this site. Please confirm correct ID number.</td>
</tr>
<tr>
<td>DEMOG</td>
<td>Subject ID (2)</td>
<td>NO_SUBI_ID</td>
<td>Missing subject ID number</td>
<td>A subject ID number has not been entered for this record.</td>
</tr>
<tr>
<td>DEMOG</td>
<td>Subject DoB (6)</td>
<td>INVLD_AGE</td>
<td>Subject age is out of range</td>
<td>The date of birth value entered may be invalid. Please confirm correct date of birth.</td>
</tr>
</tbody>
</table>
Good Data Reporting Practices

- Foundation for using research data to support research decisions
- Applies to manual, instrument and computer systems
- FDA took lead with respect to aspects to recording of data (ALCOA) to represent the principles for data quality
  - Attributable: Data values associated with individual or device which observed, recorded and changed (audit trail) information (traceability)
  - Legible: Readable/Legible, long term storage mechanism
  - Contemporaneous: Data recorded at time of observation or measurement
  - Original: Data traceable back to origin
  - Accurate: reflects truth; data errors - inaccuracy, Data discrepancies - suspected or possible data errors

*one ten – one hundred rule: Costs $1 to identify and resolve discrepant data at origin, $10 to resolve during processing, $100 at later stages
Sample Patient Enrollment Case Report

1. Patient Number: ________________________________

2. Patient Initials: F M L

3. Date Informed Consent Signed: DD / MON / YYYY

4. If child < 18, Date Assent Signed: DD / MON / YYYY

5. Protocol Version Number of Executed Informed Consent: _______
# Main Study Consent Tracking Form

**Recruitment Location:**
- 01 = Belbar Antenatal Clinic
- 02 = Bishop Lavis Midwife Obstetric Unit
- 03 = Tygerberg Hospital

## Consent signed

1. a. Date Consent signed or refused
2. b. If not signed, please specify reason for refusal

## Addendum signed for Embedded Study

1. a. Date Addendum signed or refused
2. b. If not signed, please specify reason for refusal

## May collect maternal saliva

- Q No
- Q Yes

## May collect maternal blood

- Q No
- Q Yes

## May review maternal medical records

- Q No
- Q Yes

## May collect placental tissue

- Q No
- Q Yes

## May collect cord or infant blood sample (Guthrie card)

- Q No
- Q Yes

## May collect baby’s stool

- Q No
- Q Yes

## May collect brain tissue

- Q No
- Q Yes

## May take photo of Infant

- Q No
- Q Yes

## May take video recordings of baby’s movement

- Q No
- Q Yes

## May review baby’s medical records

- Q No
- Q Yes

## Willing to participate in genetics studies

- Q No
- Q Yes

## May use specimens for future studies

- Q No
- Q Yes

## May measure baby’s brain activity and hearing

- Q No
- Q Yes

## May contact for future studies

- Q No
- Q Yes

## May take 3D photo of infant

- Q No
- Q Yes

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**Biostatistics and Epidemiology Data Analytics Center (BEDAC)**
**Boston University School of Public Health**
Learning Objectives

- The necessity of incorporating data sharing requirements
- Key design elements and inclusion of standard measures
- Importance of pilot testing, change management and optimization of data architecture
Thank you!!!!

References:
2. The *Data Book Collection and Management of Research Data*, by Meredith Zozus. CRC Press, 2017