From K Aims to Execution: Building the Behavioral and Implementation Clinical Research Infrastructure as an Early Career Investigator

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Learning Objectives

- Describe the core operational infrastructure required for behavioral or implementation research, including trials
- Identify the key components of a successful study start-up plan
- Identify common roadblocks faced by early-career behavioral trials and potential solutions

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About Me

Implementation scientist

- Understanding determinants
- Testing implementation strategies
- Intervention adaptation

Currently in Year 3 of K23 from NIMHD

- Intervention adaptation
- Focus on populations with non-English language preference

My Research

- TIDE (**T**ools to **I**mprove **D**ischarge **E**quity) pilot trial
- CONNECT (**C**ommunication **O**utreach for **N**avigation and **NE**eds-based **C**are **T**ransitions) pilot of hospital discharge intervention for patients with non-English language preference

Office of Human Research Affairs (OHRA)

- My first trial was selected for a quality assurance review from OHRA . . . While I was 8 months pregnant

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Behavioral Trials

Behavioral trials evaluate interventions that aim to modify individual or system behaviors—such as patient actions, clinician practices, or care workflows—to improve health outcomes.

Behavioral trials are <u>not</u>

- drug/device trials
- observational research

Common designs

- Randomized controlled trials (individual or cluster)
- Pragmatic trials embedded in care
- Stepped-wedge designs
- Pilot/feasibility trials

Examples

- Testing different discharge education approaches
- Evaluating clinician prompts to change prescribing behavior
- Assessing patient navigation or care-coordination programs
- Comparing communication strategies to improve adherence

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Why Planning Matters

Good science requires more than good ideas

- Behavioral and implementation studies are workflow-intensive
- Direct relationship between organization of trial and participant experience
- Fixing things after launch is much, much harder
- As early career faculty you are likely to get a quality assurance review (OHRA)

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Core Operational Infrastructure

1. Data collection systems
2. SOPs
3. Participant recruitment
4. IRB and other approvals
5. Hiring and training staff

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REDCap as Study Management Tool

- COLLECTS AND STORES DATA GENERATED BY STUDY
- TRACKS PARTICIPANT STATUS FROM SCREENING TO CLOSE-OUT
- ACTS AS AN AUDIT TRAIL FOR DATA QUALITY CHECKS
- GENERATE LISTS THAT YOU WILL NEED FOR MONITORING

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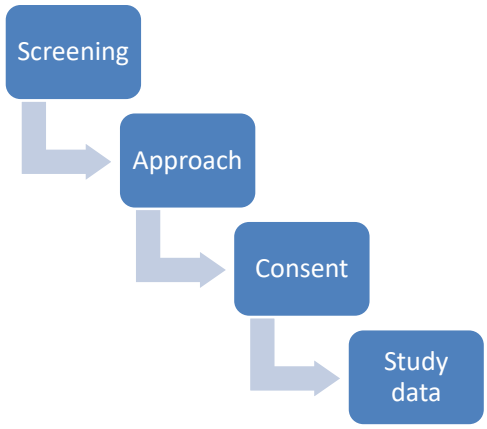
REDCap Build Tips

Separate different types of data that serve different functions:

- *Reduces errors*
- *Improves oversight*
- *Reduces effort in data cleaning and analysis*



Others: Identifiable information, adverse event reporting

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REDCap Build Tips

1. Screening Project

- **Purpose:** Identify and track potentially eligible participants
- **What lives here:** MRN, eligibility determination
- **Why separate it**
  - Most screened individuals are never enrolled
  - Contains PHI that doesn't belong in the analytic dataset
  - Often accessed by a wider group (e.g., screeners)

2. Approach Project

- **Purpose:** Document recruitment activity and consent outcomes
- **What lives here**: documentation of approach, consent status, attestation of consent procedure
- **Why separate it**
  - Recruitment data are operational, not analytic
  - Needed to monitor effectiveness of recruitment
  - Support IRB audits and reporting

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REDCap Build Tips

3. Study Data

- **Purpose:** Capture data used for analysis
- **What lives here**: study ID only, baseline measures, intervention exposure, randomization, follow up outcomes
- **Consider re-confirming eligibility criteria**
- **Why separate it**
  - Cleaner data that is analysis ready
  - Access control
  - Lower risk of accidental PHI exposure

Others Projects to Consider

- Identifiable information
  - Phone number/address for follow up contact
- PI documentation
  - Protocol deviation
  - Adverse events

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Learn From My Mistakes

Do extensive testing while in Development mode

Always label variables that are PHI in REDCap

Build your CONSORT diagram ahead of time and label source of each data point (if needed)

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2. STANDARD OPERATING PROCEDURE (SOP)

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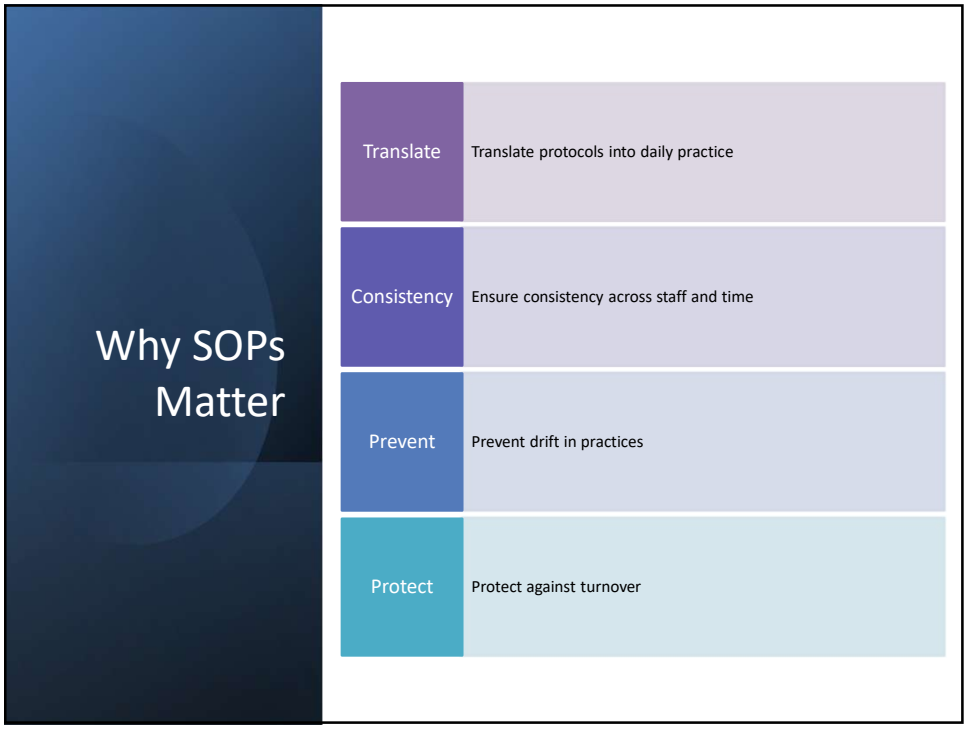
Why SOPs Matter
Translate
Translate protocols into daily practice
Consistency
Ensure consistency across staff and time
Prevent
Prevent drift in practices
Protect
Protect against turnover

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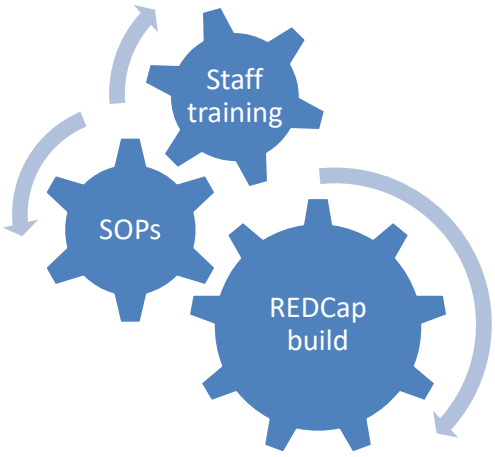
The Approach to SOP Development



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Core SOPs for Behavioral Trials

- Screening and eligibility determination
- Consent and enrollment procedures
- Intervention delivery documentation
- Data entry and correction
- Adverse events and deviations

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Example: SOP Structure

- Purpose and scope
- Roles and responsibilities
- Step-by-step explanation
- Related documentation and forms

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Learn From My Mistakes

- Detailed but as simplified as possible to prevent protocol deviations
- Extensively test the SOP prior to start of trial
- Ask for others to review your definitions for adverse events (AEs) and unanticipated problems (UPs)
- Consider a PI Documentation project to document protocol deviations, AEs and UPs

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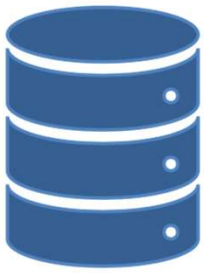

3. PARTICIPANT RECRUITMENT

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Considerations for Recruitment

- How will you obtain screening pool?
  - CDW vs Epic
- How can you most efficiently organize screening?
- Warm hand off required before participant approach?
- Linguistic and cultural concordance between participants and frontline study staff?
  - Disparities in recruitment demographics?

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Example: Screening Workflow

- Early arrival RA uses Epic to carry out screening
  - A series of shared lists that finalize in an approach list for the day
  - Eligible participants entered in REDCap*
  - Outreach attempts (using Epic chat) tracked
- Rescreening at 1pm

*Note: HIPAA waiver needed to do this

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Learn From My Mistakes

Linguistic and cultural concordance is CRITICAL for recruitment success

Don't underestimate the time to recruit your goal sample size

Create reports to quickly generate data prior to weekly study team check ins

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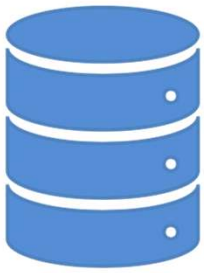

4. IRB (AND OTHER) APPROVALS

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Beyond the IRB

- Clinical Research Resources Office (CRRO)
- Department/Section Chair
- Clinical leads (example: Chief Nursing Office, Inpatient Medical Directors)
- Research and Technology Program (RTP)
- Artificial intelligence (AI) Committee
- BMC legal

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To Consider

- Regulatory binder
- Delegation of Authority log
- Onboarding and training checklists
- Data management plan
- Protocol deviation and adverse event logs
- Close out plan

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Learn From My Mistakes

Think through which non-IRB approvals you need EARLY

Give yourself enough time to build regulatory documents

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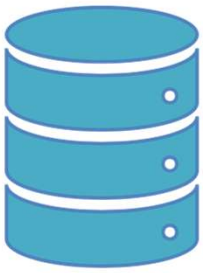

5. HIRING AND TRAINING STAFF

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Considerations in Hiring

Linguistic needs

Non-English language preference?

Experience

Participant interaction

Quant or qual skills

Hire part time or full time

Students

BMC hires

Study timeline

Classroom based training

Observation

Sign off

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Onboarding and Training

Develop onboarding checklist

- Person onboarding is responsible for managing it

Signed agreement between you and RA

- Timeline
- Compensation
- Authorship

Training approach

- Classroom
- Mock/practice
- Observation of senior RA/Project Manager
- Observed by senior RA/Project Manager

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Learn From My Mistakes

Align study timeline with semesters

Hiring one team member with relevant experience saves you time

Get best contact email for each RA prior to end of their time on project

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Take Aways

1. Core operational infrastructure

- Behavioral and implementation research requires **systems** to support consistent execution, data quality, and compliance

2. Successful study start-up

- Strong studies invest early in **study start-up**: iterative development of SOPs, REDCap databases, and training materials
- Pilot workflows *before* enrolling participants
- Onboarding checklists are **key**

3. Common roadblocks and solutions

- Trials can struggle due to underbuilt infrastructure (start building early), overcomplex systems (simplify whenever possible), and time constraints (be realistic)

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