Randomized Trials
Recruitment, Consent, & Retention for Vulnerable Populations

Learn from my mistakes!

PLAN!! Common (my) Mistakes
• Too restrictive inclusion/exclusion criteria
• Inadequate personnel budget
• Unrealistic accrual rates
• Not understanding IRB constraints
• Participant burden from many measures
• Not including the community/stakeholders

You Will Make Mistakes

Outline
• Some Set Up Tips
• Recruitment
• Consent
• Retention

Plan Plan Plan Plan Plan
### Set up Tips

- Patient/Clinical advisory board
- Sites
- DSMB
- Budget
- IRB, Clinicaltrials.gov
- Measures

### CBPR: A guide to success

- A partnership approach to research that equitably involves community members, organizational representatives, and researchers where all partners contribute expertise, share decision making & ownership.

### Stakeholder Advisory Board

- Highly recommend: budget to pay them
- Need buy-in and champions
- How to engage in workflow plans
- What has worked and not worked
- What messages work best
- Starting to be required

### Choose Sites Wisely

- Working in off-site locations
  - Who is your CHAMPION?
  - Are they committed? What will they do for you?
  - Track record (prelim info needed in grants)
- Will your Co-I’s WORK for you?

### DSMB

- You create the DSMP (the Plan)
- DSMB (Board) Safety, stopping rules, and provide unbiased input about ethical conduct → you propose institute approves
- Required for grant and publication
- Help to get advice from people w/ experience

### Budget

- DO NOT over promise
- Use LOWEST n possible
- Use GREATEST possible recruitment time
- DO NOT under budget project management
- Do NOT under budget for subjects
- If multi-site, consider go > $500K cap/year
**IRB Considerations**

- Site specific IRB requirements
  - Work with yours (others) before grant funded
  - Local approval can convince o/s IRBs
  - May consider meeting with IRB personnel

**ClinicalTrials.gov**

- Register early, painful
- As soon as obtain IRB approval
- Required by journals before 1st enrollment
  - Worst case: w/in 21 days of 1st enrollment

**Lowest # of Measures & Follow-ups**

- Not everything that counts can be counted, and not everything that can be counted counts.
  - Albert Einstein

**Optimizing:**

- Recruitment
- Consent
- Retention

**Recruitment: Staff Hiring Key**

- Hire carefully → make or break recruitment
- High emotional intelligence, charisma
- Fluency in language/cultural
- Willing/able to do what it takes
  - home visits, homeless populations
  - alternative hours
- Study volunteers

**Standardization: Be the Oppressor!!**

- It is accomplished by the oppressors depositing myths indispensable to the preservation of the status quo.
  - (Paulo Freire)
### Create a Written Protocol
- May be asked to submit for publication
  - Often different from IRB applications
- Look for good examples:
  - Laura Hanson: https://www.ncbi.nlm.nih.gov/pubmed/27893884
  - Ask PCRC for other templates
- Why pilot testing is so important
  - Revise over time

### Data Collection Musts
- Study Scripts and Checklists
- Web-based systems w/ built in checks
- Obtain 2-3 close/alternative contacts at baseline (see retention)

### Recruitment: Staff Training
- Create study scripts
  - Standardize so maintain fidelity
  - Continuous improvement on what is working
  - Create a bank of “example situations”
- Create YouTube channel videos
  - Have new staff view videos
  - Must pass role play exercises 1st
  - Review 10% of recruitment

### Recruitment: IRB Constraints
- Find out your IRB/site constraints
  - e.g., new UCSF letter-only recruitment
  - What incentive amounts are allowable?
- Plan for recruitment flexibility
  - Flyers, calling, in-clinic recruitment etc.
- HIPAA waiver for screening
  - Up front screening

### Recruitment Logistics
- Site constraints
  - Who is your champion?
- Active controls or cross over

### Recruitment Logistics
- Site constraints
  - Clinicians don’t have time to help you
  - Clinicians don’t have time to help you
    - Bypass at all costs
    - e.g., asking to give patients information
Health Literacy Principles

If you can't explain it simply, you don't understand it well enough.
Albert Einstein

Recruitment Materials

- All about marketing
  - Use color, logos, 5th-grade reading level
- Permission & using doctor/clinic name
- Letters versus opt-out post cards
- In-person versus phone recruitment
- Incentives

Materials

[Image]

Monitoring Accrual: Milestones

- All require, some hold feet to fire

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Monitoring Accrual

- Assign staff targets to reach
  - Document need by week, think about holidays
  - Be realistic, and then divide by half
  - Assign RA caseload, ownership model

- If not met, why? What are the challenges?
  - e.g., started with in clinic recruitment, wasting RA time. Cold calling bigger bang for buck

Accrual is Low?

- Do you need to pivot?
  - Advice from stakeholder advisory group
  - Is your inclusion/exclusion too restrictive?
  - Alternative approaches, dates/times
    - e.g., elderly populations working, grandchildren
  - Are your RA’s burned out?
  - Update your written protocol & retrain

[Table courtesy of Nate Goldstein]
Monitoring Accrual Weekly

• Weekly meetings (database & automatic):
  – # screened
  – # eligible, # ineligible and why
  – # offered participation
  – # refused and why
  – # consented
  – # withdrew and why

Optimizing:

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Informed Consent

• Just because someone makes a choice does not mean they fully understand the meaning and ramifications
• Need to confirm understanding

Modified Consent Process

1. Consent form written at 6th grade reading level in English & Spanish
2. Read verbatim in English or Spanish
3. Knowledge assessment:
   – 7 true/false questions about consent content
4. “Teach-to-goal”; repeated, targeted education until comprehension was achieved

Number of Passes Required to Complete Consent Process

As Literacy Score Decreased, Odds of Requiring More Passes Increased

Consent Given in Non-native Language = More Passes

- All Non-native English speakers required > 1 pass
- Low health literacy + language discordant provider = poor ratings of doctor patient communication


Number of Passes Required to Complete Consent Process

Other Teach Back Studies

- MDI use & DC info: literacy is “surmountable”
  - MDI mastery: 21% 2nd pass, 10% 3rd pass
  - DC info: 25% 2nd pass, 0.6% 3rd pass
- Surgical IC at 7 VAs: “repeat back”
  - Improves comprehension 53%-70%, key risks
  - Pt reported better understanding alternatives
  - Takes about ~ 2.6 min longer


Palliative Care: Proxy Consents

- Dementia, seriously ill or close to death
- Proxy’s need to teach to goal as well
- Recruiting dyads
  - Simultaneously consenting or referred

Optimizing:

- Recruitment
- Consent
- Retention
### Retention: Review Your Methods
- Decrease response burden, smallest # of items
- Keep follow-up’s to a minimum
- Review study scripts and RA’s experience
- Switch to a different RA caseload
- Send reminder letters
- Check if contact info has changed
- Follow up with alternative contacts

### Retention: Are Participants Engaged?
- Using an active control: all get something
- Incentives
- Remind of the importance (letters, postcards)
- Personal relationships, RA caseloads
- Thank frequently

### Who are you accommodating?

> Surrender means wisely accommodating ourselves to what is beyond our control.

- Accommodate THEIR schedule
- Home visits, Clinic visits,
- Seriously ill, engage the family and caregivers
- Consider proxy measures if needed
- Offer to skip a follow-up, permission to contact for next

### Allow Them an Out

### Questions?

Do you know about any RCTs that provide evidence that we should use RCTs?