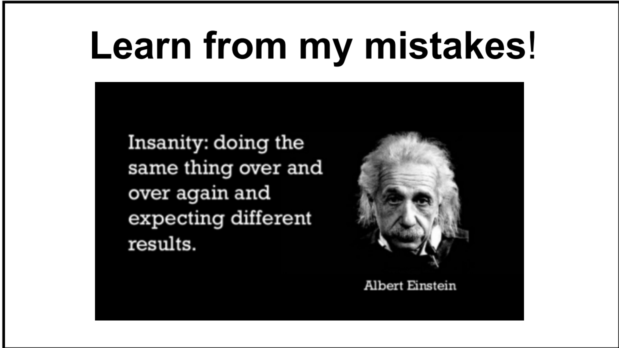
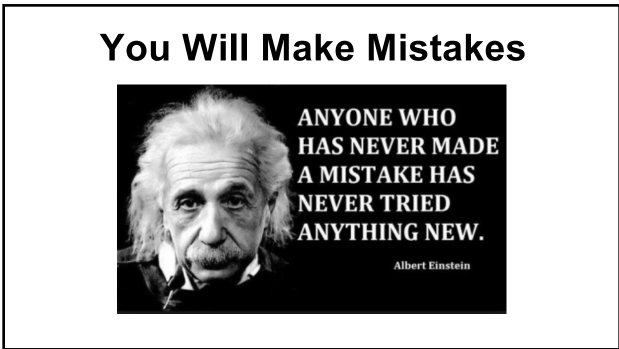


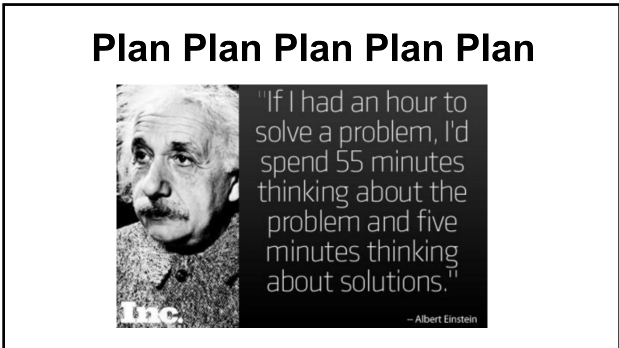
PLAN!! Common (my) Mistakes

- 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



Outline

- Some Set Up Tips
- Recruitment
- Consent
- Retention



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

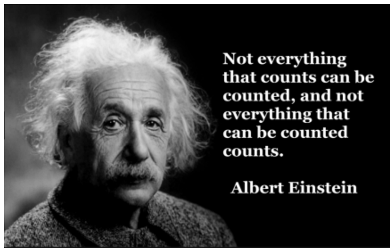
IRB Considerations

- 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

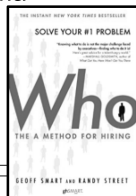


Optimizing:

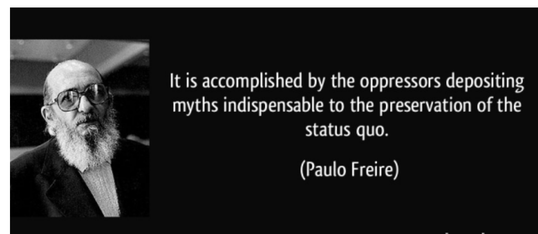
- **Recruitment**
- **Consent**
- **Retention**

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!!



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

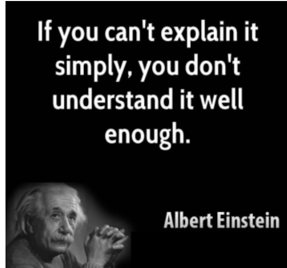
Recruitment Logistics

- 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



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

SAN FRANCISCO GENERAL HOSPITAL
2789 25th St., Suite 350
San Francisco, CA 94110

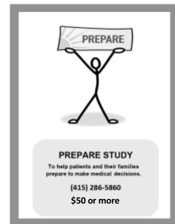
[PATIENT NAME]
[PATIENT ADDRESS]
[DATE]

Dear [PATIENT NAME],

Your Doctor or Nurse Practitioner, [CLINICIAN NAME], said it was OK to tell you about a research study.

The SFGH-PREPARE Study is trying to help people prepare to make good medical decisions.

We are offering patients **$50** or more to be in the study.



Monitoring Accrual: Milestones

- All require, some hold feet to fire

	2011				2012				2013			
Quarter	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Quarterly Target	0	0	6	18	36	43	43	43	43	43	43	43
Quarterly Enrollment	0	0	1	9	15	29	26	50	41	53	33	32
Cumulative Enrollment	0	0	1	10	25	54	80	130	171	224	257	289

	2014				2015				2016
Quarter	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Jan**
Quarterly Target	43	43	43	43	43	16	46	46	15
Quarterly Enrollment	38	42	39	17	32	28			
Cumulative Enrollment	327	369	408	425	457	485			

Table courtesy Nate Goldstein

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

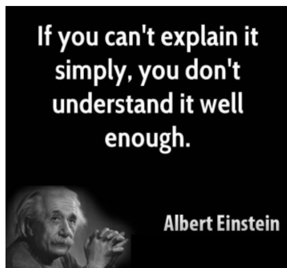
Monitoring Accrual Weekly

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

Optimizing:

- Recruitment
- **Consent**
- Retention

Health Literacy Principles



Informed Consent

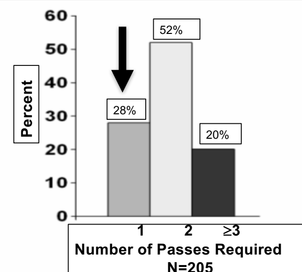
- Just because someone makes a choice does not mean they fully understand the meaning and ramifications
- **Need to confirm understanding**

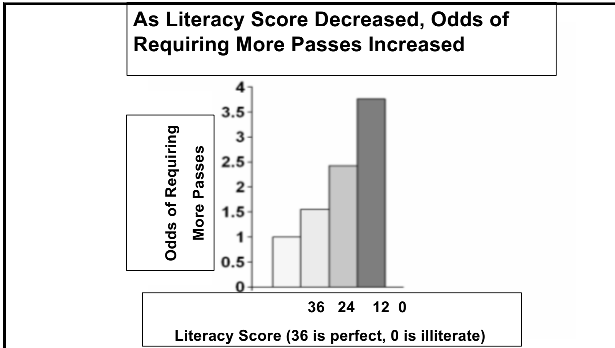
Modified Consent Process

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

Sudore RL, et al. J Gen Intern Med. 2006 Aug;21(8):867-73

Number of Passes Required to Complete Consent Process

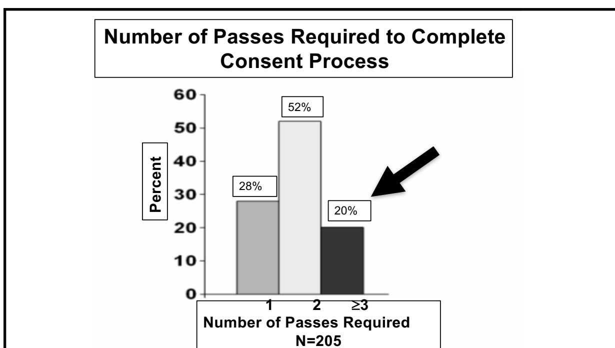




Consent Given in Non-native Language = More Passes

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

Sudore RL, et al. J Gen Intern Med. 2006 Aug;21(8):867-73; **Sudore RL**, et al. Patient Educ Couns. 2009 Jun;75(3):398-402



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

•**Paasche-Orlow,** et al. Am J Respir Crit Care Med. 2005 Oct 15;172(8):980-6. **Fink AS**, et al. Ann Surg. 2010 Jul;252(1):27-36. **Prochazka AV**, et al. J Patient Saf. 2014 Feb 11.

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**

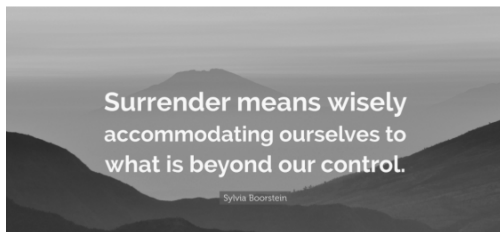
Retention: Review Your Methods

- 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?



Retention: Accommodating

- 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?