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Recruitment: Ethics, Regulations and Practical Solutions



Class Outline

- Recruitment regulations and ethical concerns
 - Foundations
 - Principles in Action
- Generally accepted recruitment methods
 - Overview of standard methods from IRB application
 - Guidelines for Advertisements/Flyers
- Guest Presentations
- **▶** Panel Q&A



Guest Presenters

Jennifer Creasman

Director of Recruitment Services, CTSI

Natalie Nardone, PhD

Project Manager, Tobacco Research Center

Byron Mason

 Director of Research Partnerships for the Technology & Information Exchange (TIE) Core, Center for AIDS Prevention Studies (CAPS)

Mary Koestler, RN, PhD, CRC

 Clinical Trials Project Administrator and Trials Nurse, Memory and Aging Center

Carol Maquire, RN

 Admin. Director of Clinical Research, Health eHeart Study, Cardiology



Ethical Foundations

Back to the Basics:

Ethical Principles of *The Belmont Report*

1. Respect for Persons

-Voluntary Participation, Informed Consent

2. Beneficence

-Favorable Risk/Benefit Ratio

3. Justice

-Fair Selection of Subjects, Sharing of Risks/Benefits



Ethical Principles in Action

Respect for Privacy

- -Does the recruitment method keep privacy in consideration?
- -Are subjects being contacted by researchers not involved in their care?

Lack of Pressure

- -Is there time allowed to consider participating?
- -Are they being recruited by someone in a position of authority (i.e. teacher/employer)?
- -Is the compensation so high that participants agree to the risks only for the payment?



Ethical Principles in Action

Unbiased Presentation

- -Is the information accurate, balanced and complete?
- -Is information 'left out' to make the study sound better?

"Therapeutic Misconception"

- -Are you using words like 'treatment' or 'therapy' inaccurately?
- -Are you actively countering this common misconception?

Conflicting Concerns

- -Do subjects prefer to be contacted by someone involved in their care, but find it hard to say 'No' to care providers?
- -ls a researchers' clinical judgment in conflict with a desire to enroll more patients?



WE WANT YOU...

to share your time, blood, sweat and tears (and other bodily specimens) for the advancement of science, while incurring a uncertain amount of risk to your well-being and/or privacy, with or without any direct benefit to yourself.





Ask yourself...

- Do participants know their role in the project?
- How are they approached and treated?
- Why should people care?
- What's in it for them?
- Is overcoming mistrust an issue?



Generally Accepted Recruitment Methods

17.0 Recruitment

17.1 * Methods (check all that apply):

- Study investigators (and/or affiliated nurses or staff) recruit their own patients directly in person or by phone.
- Study investigators recruit their own patients by letter. Attach the letter for review.
- Study investigators send a "Dear Doctor" letter to colleagues asking for referrals of eligible patients. If interested, the patient will contact the PI or the PI may directly recruit the patients (with documented permission from the patient). Investigators may give the referring physicians a study information sheet for the patients.
- Study investigators provide their colleagues with a "Dear Patient" letter describing the study. This letter can be signed by the treating physicians and would inform the patients how to contact the study investigators. The study investigators may not have access to patient names and addresses for mailing
- Advertisements, notices, and/or media used to recruit subjects. Interested subjects initiate contact with study investigators. Attach ads, notices, or media text for review. In section below, please explain where ads will be posted.



Generally Accepted Recruitment Methods (continued)

- Study investigators identify prospective subjects through chart review. (Study investigators request a Waiver of Authorization for recruitment purposes.)
- Large-scale epidemiological studies and/or population-based studies: Prospective subjects are identified through a registry or medical records and contacted by someone other than their personal physician. (Study investigators request a Waiver of Authorization for recruitment purposes.)
- Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program develops a CHR-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another CHR-approved study.
- Study investigators list the study on the School of Medicine list of UCSF Clinical Trials website or a similarly managed site. Interested subjects initiate contact with investigators.
- Study investigators recruit potential subjects who are unknown to them through methods such as snowball sampling, direct approach, use of social networks, and random digit dialing.
- Other

Human Research Protection Program

If Other, explain:



EARN up to \$500!

If you are over age 18 and have Multiple Sclerosis...

WE WANT YOU

For a Research Study Be a hero. Join the study.

Free Medication, not yet available on the market



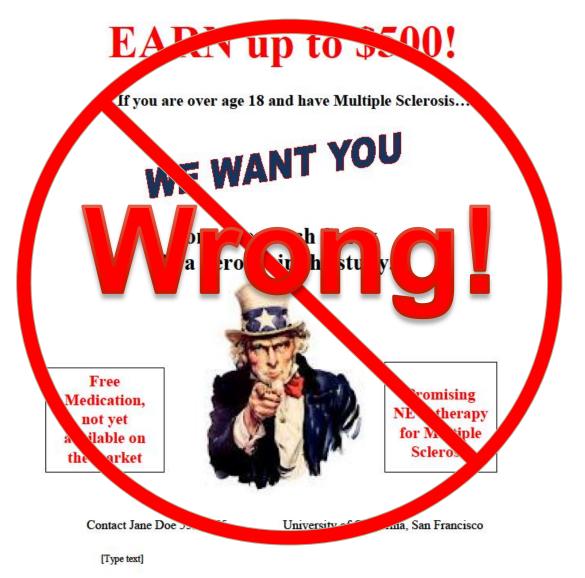
Promising NEW therapy for Multiple Sclerosis

Contact Jane Doe 555.5555

University of California, San Francisco

[Type text]







Multiple Sclerosis Research Study If you are over age 18, have MS and were diagnosed less than 2 years ago...

WE WANT YOU

For a Research Study looking at how an investigational drug effects the immune system of people with MS

Earn up to \$500 for the 1 year study (12 monthly visits required)

You will receive an investigational drug



We will monitor your MS symptoms

Contact Dr. Jane Doe 555.5555 Department of Neurology

UCSF Medical Center 400 Parnassus Avenue

Human Research Protection Program

[Type text]



Ads, Flyers and Media Guidelines- "Do's"

- Name and address (PI or Institution)
- Condition under study
- Purpose of the research
- Summary of eligibility criteria
- Brief list of participation benefits, if any (e.g. no-cost health examination)
- Time or other commitment required
- Locations Person/office to contact



Ads, Flyers and Media Guidelines-"Don'ts"

- Benefits beyond what is in the consent
- Claims that procedures are safe/effective
- Claims that procedures are equivalent or superior to others
- Terms such as "new treatment," or "new medication," without explaining that the test article is investigational
- Promises of "free treatment"
- Payment emphasized with larger or bold type
- Language that the PI cannot be held liable for any research related event



Questions & Resource Information

Recruitment section of HRPP Website:

http://www.research.ucsf.edu/chr/Recruit/chrRecruit.asp

UCSF CTSI Consultation Services:

http://ctsi.ucsf.edu/about-us/programs/consultation-services

 AccrualNet: Tools, Strategies, and Resources to Support Accrual

https://accrualnet.cancer.gov/

Social Media Best Practices

http://www.ucsf.edu/about/social-media-best-practices

Healthy Kids in Research

http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php

Writing Clear Advertisements

http://hub.ucsf.edu/sites/hub.ucsf.edu/files/Writing_Clear_Advertise ments.pdf

Advertising Strategies for Clinical Trials

http://www.slideshare.net/bodekerk/advertising-clinical-trials



Guest Presenter

Jennifer Creasman

Director of Recruitment Services, CTSI



CTSI Consultation Services

Recruitment Services for Study Coordinators

Jennifer Creasman Director, Data Management and Participant Recruitment Units CTSI Consultation Service

8/10/2015



CTSI facilitates the rapid translation of research to improvements in patient and community health. It is a cross-school, campus-wide institute with scientist leaders at its helm.

CTSI accomplishes this mission by:

- Offering Expert Advice to Researchers at Every Stage
- Steering Scientists Toward Inventions
- Training the Next Generation of Translational Scientists
- Providing Critical Support for Clinical Research



CSF Clinical & Translational Science Institute

Consultation Services (CS) - Expert advice is provided in a wide range of subject areas, including:

- ✓ Bioinformatics Data Analysis
- √ Biostatistics
- ✓ Data Management
- ✓ Study Design & Implementation
- ✓ Recruitment Services

All services are available on a fee-for-service basis, after the initial consultation, which is free.





Consultation Services (CS) - Recruitment Services

- ✓ Cohort identification & direct mail
- ✓ Recruitment methodology
- ✓ Developing a recruitment plan
- ✓ Social Media recruitment and intervention.





Consultation Services (CS) - Recruitment Services

Recruitment Services Partners:

- Human Research Protection Program
- Academic Research Services (ARS) cohort ID and Research Data Browser

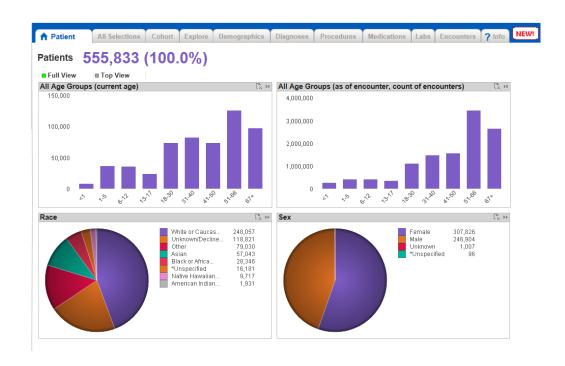




Clinical & Translational Science Institute

ARS: Research Data Browser

https://myresearch.ucsf.edu/research-data-browser







Do Not Contact Request Process

Opting out of research at UCSF

- Contact ARS with all contact preference updates
- Do not manage opt-out lists locally

Discussion:

- How do you handle patient requests not to be contacted?
- How many requests do get?
- Is this a problem for you or your study?





CSF Clinical & Translational Science Institute Science Institute

Molly Belinski



Title CS/SOS Program Coordinator School UCSF School of Medicine Department CTSI Address Phone 415-514-6206 Email Molly.Belinski@ucsf.edu

Auto-populated fields from HR data

Self-populated and customizable fields

Education and Training

University of San Francisco

Northern Michigan University

Master of Public Adminstration (in progress)

Bachelor of Science

vCard Download vCard

2015 School of

Management International Studies 2003

Websites

CTSI Strategic Opportunity Support

CTSI Consultation Services

To request a UCSF Profile, visit http://tinyurl.com/ucsfprofiles





Current Future CTSI-PRS Initiatives

- TrialSpark: data-driven clinical trial recruiting tool
- Public facing clinical trial list to launch July 2016
- Opting out of research process development
- CRC training and outreach



For more information on any services offered by CTSI Consultation Services, visit http://accelerate.ucsf.edu/consult or contact CTSI.Consulting@ucsf.edu





Guest Presenter

Natalie Nardone, PhD

 Project Manager, Tobacco Research Center

RECRUITMENT STRATEGIES

Natalie Nardone, PhD Manager, UCSF Tobacco Research Center Department of Medicine

natalie.nardone@ucsf.edu

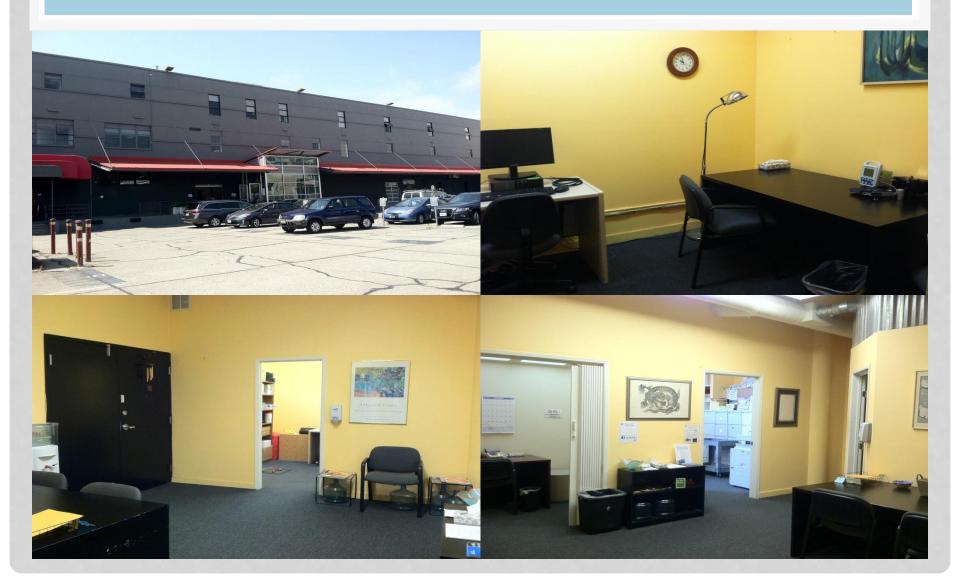
OUTLINE

- Who we recruit, studies we run
- Recruitment strategies we use
- Pros/Cons of each & helpful tips

WHO WE RECRUIT & STUDIES WE RUN

- Healthy Volunteers
 - 18-70, males/females all ethnic/racial backgrounds
 - Cigarette Smokers
 - Electronic Cigarette Users
- Outpatient & Inpatient Studies
 - Observational
 - Clinical trials
 - Longitudinal
 - Cross-sectional

UCSF TOBACCO RESEARCH CENTER



STRATEGIES WE USE

- Craigslist Ads
 - Paid and Free
- Local Flyers & Postcards
- Taxicab Ads
- Newspaper Ads
- UCSF Resources
 - Clinical Trials Webpage
 - Shuttle

*We obtain IRB approval for all recruitment methods before we use them.

CRAIGSLIST ADS

Pros:

- Attracts locals
- Quick response
- Free section
- Fairly inexpensive

Cons:

- Section Specific
- Specific population

Tips:

- Keep it short
- Find out what section works & stick with it.

★ Paid Study: E-Cigarette Users (mission district)

UCSF / San Francisco General Hospital research team is looking for paid volunteers for a clinical research study on the impact of flavors on nicotine delivery and effects in electronic cigarette (ecigarette users).

Qualified participant must be:

- o E-cigarette user
- o Use the e-cigarette at least once daily for the last 3 months or longer
- o Has tried various e-juice flavors
- o Healthy
- o Male or female
- o 18-70 years old
- o No active drug use (except marijuana)

More details:

- 1 Screening visit to determine eligibility
- o 1 Inpatient hospital visit lasting 3 days
- o Saliva, urine, and blood will be collected
- o This is NOT a treatment or smoking cessation study
- o E-cigarettes will be provided for the hospital visit
- o Compensation up to \$800 for completing the study

For more information please call the Tobacco Research Clinic at 415-476-3555 or fill out a brief survey !

Some, but not all criteria

What happens in the study

LOCAL FLYERING & POSTCARDS

SMOKERS NEEDED

UCSF Smoking study

UCSF Research studying the effects of nicotine metabolism rate on smoking behavior

Study Requires 2 Clinic visits & 1 overnight admission
Reimbursement: up to \$300

Eligibility:

- Healthy
- Age 18-70
- African
 American
 and
 Caucasians
- NO Drugs



UCSF Tobacco Research Center Call: 415/476-3555





Please leave your name,

phone number, age, and

number of cigarettes

smoked per day

UCSF-SFGH Division of Clinical Pharmacology and Experimental Therapeutics

SMOKERS NEEDED FOR NICOTINE RESEARCH STUDY



SMOKERS

Generally Healthy Age: 18-70 Men and Women

CALL OUR RECRUITMENT LINE:

415-476-3555

Monetary compensation provided

Pros:

Inexpensive, target a population

Cons:

Time, can be moved & tampered with

Tips:

Keep track of successful flyering spots

TAXICAB ADS

Pros:

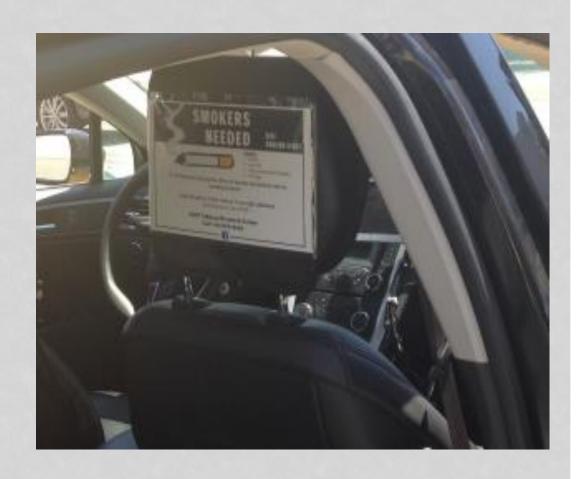
- Large audience
- Demographic of working professionals

Cons:

- Expensive (\$2,000-\$2,500 a cycle)
- Low call volume

Tips:

 Know the cab route



NEWSPAPER ADS

- **News Sources**
 - SF Chronicle, Online local newspapers (Mission) Local, Veteran's View), SF Weekly

Planned Parenthood in 2012, it was an extremely important signifier to women voters that he was deeply out of touch with their lives," says Geoff Garin, president of Hart Research, a major national polling firm that recently conducted a nationwide survey for Planned Parenthood on the controversy. "There's no reason to think the

dent of the Planned Parenthood Federation of America, insists that the videos were "heavily edited" and that her organization has never profited from the sale of fetal tissues. She said the video releases are the work of a "militant" antiabortion faction linked to groups like Operation Rescue, some of whose members have been acunderstanding and prevention of maternal and fetal health conditions.' But her arguments

have not calmed the increasingly fierce reactions from Republicans, including former Arkansas Gov. Mike Huckabee, a staunch social conservative who has made headlines with the Planned Parenthood controversy. The latest

Francisco, has vowed that her party will "overwhelmingly" fight any government spending bill that defunds Planned Parenthood — a signal that the partisan divide has already upped the stakes for a government shutdown if Congress can't pass a stopgap mea-

California Sens. Dianne Feinstein and Bar-



DONATE YOUR CAR



Pros:

Fairly inexpensive

Cons:

Reaches older population (more likely to be unhealthy)

Tips:

Keep message brief



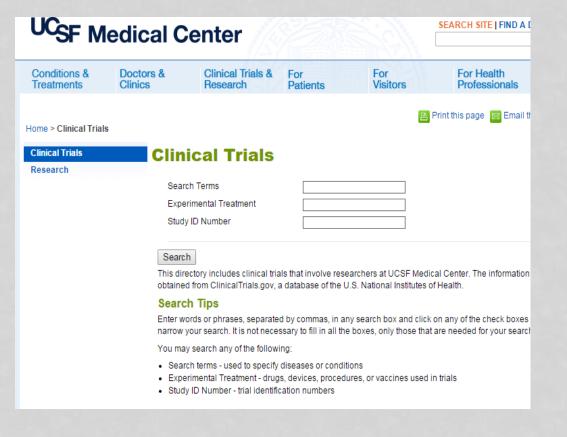
The Decision is Black & White

When it comes to White Marbles, it's easy to decide where to buy, IRG has the best selection of Calacatta, Carrara, and Statuary—all under one roof—and in-stock today!

415.657.0280 Brisbane | 925.829.1133 Dublin | www.marblecompany.com | [] [] [] []

UCSF RESOURCES

- UCSF Medical Center Clinical Trials List
- UCSF Shuttles





ADDITIONAL INFO

We also recruit participants from:

- Word of mouth and referrals
- Clinicaltrials.gov
- Previous participants

Other things we have tried:

- Email blasts
- Radio Ads
- Facebook
- Backpage.com
- Barefoot student

CONSIDERATIONS

- Keep track of what works
- Know your population
- Keep it varied
- Expect an ebb and flow

Questions?



Guest Presenter

Byron Mason

 Director of Research Partnerships for the Technology & Information Exchange (TIE) Core, Center for AIDS Prevention Studies (CAPS)

Human Research Protection Program

UCSF HRPP Meeting

August 25, 2015 Byron Mason, Research Partnerships Director Center for AIDS Prevention Studies (CAPS) University of California, San Francisco

CAPS Technology and Information Exchange (TIE) Core

Center for AIDS Prevention Studies (CAPS) Technology and Information Exchange (TIE) Core





Tying research and community together

www.caps.ucsf.edu

Our Primary Objectives

- Science to Community: Facilitate access to and use of HIV prevention science by stakeholders (i.e., community-based organizations [CBOs], health departments, funders and policy makers);
- **Community to Science**: Support CAPS scientists' use of community expertise;
- Foster Collaborative Research: Support communityinvolved research and ongoing collaborative research partnerships between CAPS scientists and diverse communities.

Community-Engaged Research

- Meaningful collaboration between researchers and community leaders to address communities' needs
 - CBOs/HDs/CPGs
 - Develops important inroads to diverse communities
- Interdependent, mutually beneficial relationship that pursues a common goal
- The process of community engaged research exists on a continuum

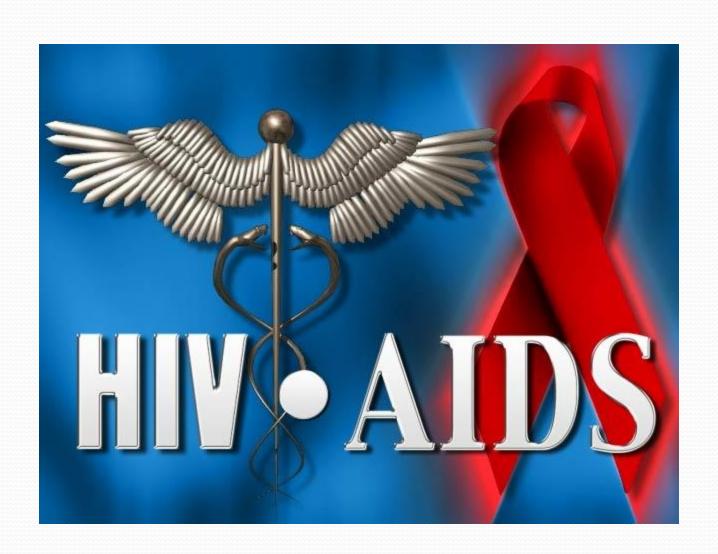


Why Community Engaged Research?

There is a growing recognition that traditional research approaches, while appropriate for many research questions, have failed to solve complex health disparities.

Health problems exist within the context of people's lives, and the explanations will likely be found in the messy complexity of real life.

A community-engaged approach can enable us to conduct research and produce results which may be directly translated to improve human health.



What we know...

- SF/US HIV epidemic is fueled by social determinants of disparities, which calls for a better understanding of how these forces interact.
- The high rates of HIV/AIDS we see, especially among communities of color, are not the result of high-risk behavior in these communities, but social determinants/structural inequalities that make them more likely to come in contact with the disease and less likely to treat it.
- The intersection of race, poverty, stigma, socio-economic status and sexuality among other factors—becomes the embodiment of health inequities.
 - Many populations exist "within the margins" (homelessness, incarceration, commercial sex work)
 - Outlets for social support and community capital are lacking.

What impact does this have on recruitment?



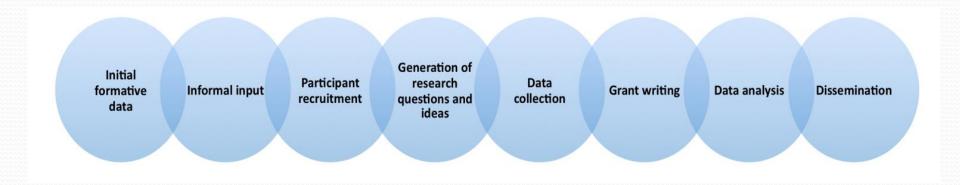
Recruitment and Engagement Barriers from Community Perspective





- Serious barriers in gaining access to "hard to reach" populations
- Often disenfranchised and marginalized
 - Continued underrepresentation of persons of color in research.
- Sustained mistrust of research by communities most in need.
 - Experience with researchers fosters mistrust and poor relations between researchers and community members.
 - Sense that researchers are more interested in professional advancement than in improving conditions.
 - Suspicion that researchers are "using" communities by collecting data with no return of information and no shared credit.

Spectrum of Engagement—Collaborative Activities



Spectrum of Engagement—Community Roles



Important Considerations

- Think differently/look over walls/break down silos/speak out
 - Studies consistently show that low income, unemployment, food insecurity and lack of access to education and health care, among other factors, increase vulnerability to a myriad of health conditions.
 - Social determinants are sometimes a better predictor of health outcomes than risk behaviors.
 - Target inequalities
 - Addressing the structural forces that shape the spread of disease represents a fundamental and necessary shift from the historic approach to health promotion.
- Start early / Build trust / Show up
- Expect to learn, not only to teach

Successes and Challenges

- Highly "functional" and motivated infrastructure
 - Diversity of disciplines and backgrounds
 - Close ties to a range of communities
 - Synergy between provider (CBO), consumer, government (local, state and federal) and corporate
- Engagement challenges
 - General communication between community & science
 - Motivating academics to engage with community
 - Establishing a mutual beneficial relationship
 - General lack of understanding of social context of diverse communities

Resources

- CAPS Website (<u>www.caps.ucsf.edu</u>)
 - Fact Sheets
 - Research Instruments
 - Tool Box
 - "Working Together" Manual
 - Recommendations for Research Dissemination
 - Social Media (Facebook, Twitter, LinkedIn)

Collaboration Resources

- Clinical and Translational Science Institute: http://ctsi.ucsf.edu/
- University Community Partnerships (UCP) site http://partnerships.ucsf.edu/
- Community-Campus Partnerships for Health Resources: http://ccph.info/
- Community Based Participatory Research (CBPR) http://www.cbprcurriculum.info/

Thank you!



Guest Presenter

Mary Koestler, RN, PhD, CRC

 Clinical Trials Project Administrator and Trials Nurse, Memory and Aging Center

Human Research Protection Program

UCSF Memory & Aging Center

Clinical Trials Program:

Recruitment Challenges & Solutions

University of California San Francisco



Department of Neurology Memory and Aging Center Mary Koestler, RN, PhD, CCRC Administrator MAC Clinical Trial Program 27 August, 2015

Overview:



- About Memory and Aging Center (MAC)
- Our Research & Clinical Trials
- Recruitment Sources
- Recruitment Challenges
- Solutions
- Summary

UCSF Memory and Aging Center (MAC) Sandler Neurosciences Building

675 Nelson Rising Lane, Suite 190 UCSF Mission Bay Campus



- Division Department Neurology
- Bruce Miller, M.D., Medical Director MAC
- Adam Boxer, M.D., Ph.D., Clinical Trials Director
- ~ 175 Employees

UCSF MAC Trials Team

Adam Boxer, M.D., Ph.D. Principal Investigator

Mary Koestler, R.N., Ph.D.

Clinical Trials Administrator & Trials Nurse

Clinical Research Coordinators:

Emma Hare, Sr. CRC Emmeline Chuu Noelle Ohanesian Ryan Powers June Jung, Ph.D.

Neurocognitive Raters:

Christine Walsh, Ph.D.

Melanie Stephens, Ph.D.

Christa Watson, PsyD.

Jennifer Richards, Psychometrist

Sub-Investigators:

Richard Tsai, M.D.
Julio Rojas-Martinez, M.D., Ph.D.
Zachary Miller, M.D.
Cynthia Barton, N.P.

Trials Administrative Support
Caitlin Glennon

Eye Movement Specialist Hilary Heuer, Ph.D.

Patient Population MAC Trials

- Neurodegenerative Conditions
 - Alzheimer's Disease (AD)
 - Mild Cognitive Impairment (MCI)
 - Frontotemporal Lobar Dementia (FTLD)
 - Progressive Supranuclear Palsy (PSP)
 - Corticobasal Degeneration Syndrome (CBS)
 - Progranulin Mutation; Carrier or Symptomatic
- Healthy Elders AD Trial

What type Trials?

• FDA Trials - Phases 1, 2, 3

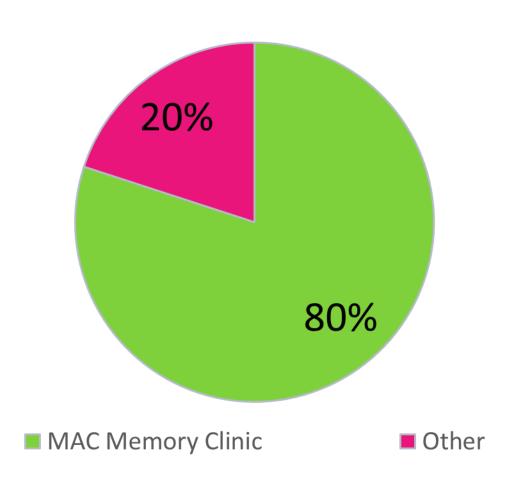
- Investigational New Drug (IND) Industry-Sponsored
- IND Investigator-Sponsored
- Randomized, Placebo-Controlled
- Single Multiple Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Open-Label

Where do we conduct visits?

- Neurosciences Clinical Research Unit (NCRU)
- Parnassus Clinical Research Unit (Outpatient)
- Parnassus Moffitt 12th Floor (Inpatient)
- Gateway Building Mission Bay

Primary Recruitment Source

Institutional Versus Outside



"Other" Recruitment Sources

- Community Colleagues Referrals
- ClinicalTrials.gov Website
- UCSF/MAC Websites
- Brain Health Registry

*Recruitment Challenges

- Cognitively Impaired 'Vulnerable' Population
- Communication of complex concepts
- Patient & Caregiver Expectations
 - Clinical Care vs. Clinical Research
- Competitive Enrollment & Maintaining Quality Standards
- Promoting Optimal Decision-Making Environment
 - Information and Time for Contemplation

*Other Recruitment Challenges

- Subject & Caregiver Barriers to Participation
 - Travel to UCSF
 - Time commitment
 - Economic factors
 - Study procedures
 - Placebo
 - Narrow Inclusion & Exclusion Criteria
 - Stable Medications

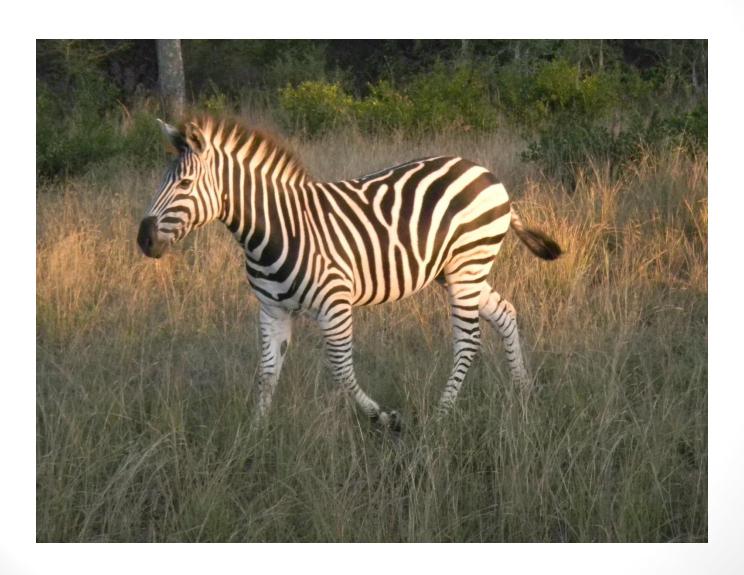
*Tip: Recruitment Solution

- CHR-Approved Recruitment Protocol
- Identifies potentially eligible patients
 - 'Phone Screen Project'
 - Interested patients contact MAC Trials Staff
 - Research Staff Conducts Telephone Interview
 - Approved Script Sequenced questions
 - Minimal Data Collection
 - Information about currently open trials

Summary

- CHR-Approved Recruitment Project:
 - Demonstrated Recruitment Strategy for MAC Trials
 - Identifies potentially eligible patients for enrolling & future trials
 - Minimal PHI collection
 - Starts communication between researchers and interested patients
 - Reduces Subject burden
 - Minimal Data Collection
 - Information about currently open trials

Thank you...





Guest Presenter

Carol Maquire, RN

 Admin. Director of Clinical Research, Health eHeart Study, Cardiology

Human Research Protection Program



Q&A Panel Forum

Jennifer Creasman

- Director of Recruitment Services, CTSI
- Natalie Nardone, PhD
 - Project Manager, Tobacco Research Center
- Byron Mason
 - Director of Research Partnerships for the Technology & Information Exchange (TIE) Core, Center for AIDS Prevention Studies (CAPS)
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