Clinical and Translational Science Institute / CTSI
at the University of California, San Francisco

Welcome to Online Training for Clinical Research Coordinators

ROLE OF THE RESEARCH COORDINATOR

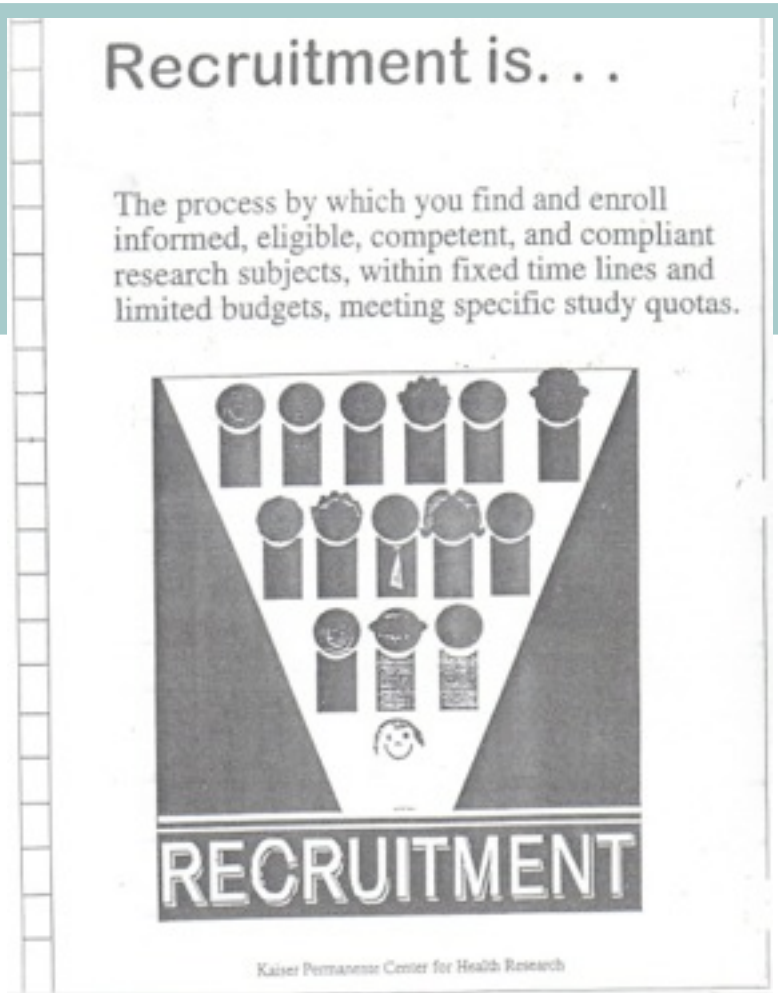
Recruitment of Subjects Best Practices

Objectives

- Definitions
- Goals and Barriers
- Recruitment Guidance
  - Ethical Concerns
  - Acceptable Methods
  - Who may recruit subjects
- Eligibility and Recruitment

Definition of Recruitment

Most investigators believe, it is just this easy….



The Reality is that Recruitment Barriers Exist

Examples

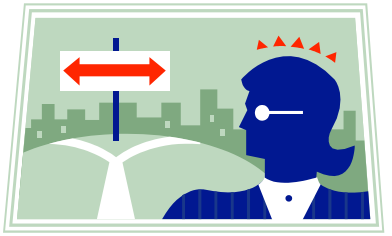
- Fear of receiving a placebo and other misunderstanding of research design terminology
- Patient's reluctance to go against their primary doctor's recommendations
- Fear of being treated like a guinea pig
- Distance subject/patient would have to travel to participate
- What will it cost for the person to participate
- Family objections

Surveys of subjects have identified these common barriers to participation.

Investigator: "Where are the subjects?"

Understand the Positive Reasons Subjects DO Join a Clinical Trial

- Access to best care and doctors for their condition
- Belief they would benefit future patients
- Belief they would get more care and attention
- Belief/Hope that they will benefit



Remember: The research team has an obligation to remain supportive while allowing independent decision-making by the subject.

Recruitment Goals

How many participants need to be contacted to meet your enrollment goals? This applies to small or large studies, and particularly if you have stringent eligibility criteria..more on that later!

3%-20% OF POTENTIAL SUBJECTS WHO UNDERGO SCREENING, ARE FINALLY ENROLLED

Particularly important to keep this in mind when considering the cost of recruitment in time and energy!

Recruitment Goals

Tamoxifen vs. Raloxifene (STAR) breast cancer prevention trial

Enrollment data two years from start:

- 96,244 women took risk assessment
- 54,890 were eligible
- 11,307 chose to participate

Minority Data (all races and ethnic backgrounds)

- 15,022 minority women took risk assessment
- 3,781 were eligible
- 636 chose to participate

Definition of Recruitment

Another definition of Recruitment experienced by research teams; budget, budget, budget!

Recruitment is…The desperate, frustrating, costly search for participants who obviously reside in some other place than where you are searching. And whose enrollment cost may become comparable to the national debt!

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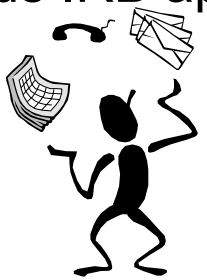
Recruitment Goals

Implement recruitment strategy that meets UCSF CHR/IRB approval:

- ✓ Newspapers/radio is costly and needs IRB approval.



- ✓ Local support group meetings provide a safe opportunity to ask questions and hear from other participants.
- ✓ Flyers need IRB approval but are good to reach many and protect privacy since the subject contacts you.
- ✓ Track recruitment efforts for sponsor and audit.
- ✓ Develop a script for phone recruitment that can be approved by the UCSF CHR/IRB. Any staff doing phone screening will have the same conversation with potential subjects.
- ✓ Tumor boards or clinical staff meetings work best with the use of a 'fast facts' description of open studies with a partial eligibility criteria.

Recruitment Guidance!

No matter the method, all recruitment documents MUST be submitted with the initial application for UCSF CHR review along with a description of your recruitment plans. If you modify the documents or the plan, it must return for re-approval!

For additional recruitment guidance-see the HUB
hub.ucsf.edu/recruitment-strategy

Recruitment Guidance

Ethical Concerns

All research staff must remember that Recruitment is a very important step in the management of a clinical trial.

- If you cannot recruit the number of subjects proposed for adequate analysis, the study was in vain.
- When recruiting, subjects are not yet on a clinical trial. How the research staff handles the act of approaching directly or indirectly the people who can be considered for a study, has its own set of guidelines from the UCSF CHR/IRB and the IRB will want to know your recruitment plans in the initial protocol submission, or if you later modify this plan.

Recruitment Guidance

Ethical Concerns

- Careful respect for privacy of the individual
- Minimize pressure to comply with the researcher
- Show an awareness of conflicts:
- Patients might be uncomfortable saying no to a physician, or
- Having to sign the consent immediately is more uncomfortable, than being able to take a copy home. Best option is for the subject to have time to decide or discuss the decision with friends/family before signing.

Recruitment Guidance

Ethical Concerns

Use of Protected Health Information by researchers must be minimized in their recruitment strategy.

- Access medical records only after the subject signs a HIPAA authorization for the research study
- Researchers at the time of the study application to the UCSF IRB can request an exception to HIPAA authorization, but it must be justified and can be denied by the IRB.
- Even phone or email contact with subjects by research staff to recruit subjects must be avoided prior to HIPAA authorization.

Recruitment Guidance

Ethical Concerns

The consent form is approved for language that removes bias and presents both benefit and risk.

- When the subject is approached, keep verbal explanations unbiased by avoiding language that makes the study seem excessively attractive or providing money or items as inducement to participate. Inducements given to the subject require CHR approval.
- Patients who are ill want to believe the study treatment will benefit them. This is called 'therapeutic misconception.' Clinicians in particular must guard against promising benefits for a treatment under study.

Recruitment Guidance

Acceptable Methods of Recruiting Research Subjects

- All methods may have compliance issues to both the federal Common Rule (45 CFR Part 46) or the HIPAA Privacy Rule (45 CFR Part 164) so it is necessary to discuss how subjects will be recruited within the UCSF CHR/IRB application and noted on the HIPAA Supplement.
- Methods can be divided into direct contact or indirect contact

Recruitment Guidance

What is “Direct “contact?

- Clinics maintain a separate CHR approved recruitment protocol with consent asking for the person’s agreement to be contacted for future research.
- Study investigators who are also clinicians recruit their own patients.
- Study investigators recruit directly people unknown to them via social networks, or public meetings..
- No matter the recruitment method, **all recruitment documents MUST be submitted** with the initial application for UCSF CHR review. If you modify the documents, it must return for re-approval.

Recruitment Guidance

Then what is "Indirect" contact of potential subjects?

- Posting the study on the School of Medicine list of UCSF Clinical Trials web page and subjects can choose to use contact information if interested.
- Advertisements, or notices, or other media, such as television, allow subjects who are interested to contact the investigator on their own.
- Study investigator provides their colleagues a CHR approved 'Dear Patient' letter giving details about the study and who to contact if interested; or provides colleagues a 'Dear MD' letter so that the patient's physician can decide to refer his patient to the study.

No matter the recruitment method, **all recruitment documents MUST be submitted** with the initial application for UCSF CHR review. If you modify the documents, it must return for re-approval.

Recruitment Guidance

Waiver of Consent/Authorization for recruitment purposes

- Are you identifying subjects through chart review to collect minimal amount of information to determine eligibility?
- Is your study a minimal risk study in which subjects will not be contacted and perhaps even de-identified?
- Have another reason to request a waiver?

Explain in detail why it is necessary **not to consent or impossible to obtain subject consent or HIPAA authorization. UCSF CHR will review your recruitment details with the federal regulations to determine if your plan can move forward.

Recruitment Guidance-Lessons Learned

Office of Inspector General for the Department of Health and Human Services released a report on recruitment practices and found two industry recruitment practices that are against the regulations:

- Enrollment incentives, and
- Breaches of patient confidentiality by using individuals listed in databases where they have not consented to being contacted

**Remember that recruitment procedures need review by CHR and there are guidelines that must be followed!!

Recruitment and Eligibility

- Develop screening forms to:
  - Assist investigator with subject identification/enrollment
  - Keep everyone on track as to all tests needed for eligibility are completed
- Make patient responsible for medical records when possible
- Obtain informed consent for any eligibility screening tests required.

Recruitment and Eligibility
Tips and Tricks

SOURCE DOCUMENT CHECKLIST

- Create a source document checklist to make this process easier AND will assist during the audit
  - review all data that you have collected during screening the attending physician/nurse prior to registering a patient
  - **have the investigator sign and date the eligibility checklist.**

Answers to the eligibility checklist questions are viewed as an oath that the patient meets the criteria for entry to the study.

Recruitment and Eligibility

WHAT IF YOUR SUBJECT DOES NOT QUALIFY?

Typically, there are NO exceptions to the eligibility criteria!

- National Cooperative groups will follow this rule
- Some industry studies will allow minor deviations but they must do the approval, CHR must be notified, and document, document, document what is being allowed, who, and why.

Save any signed informed consents from screen failures; remove any data in the database; file the eligibility criteria checklist with the consent to identify why the subject is not going to be enrolled; if your investigator wants to track screen failures, use a separate document and enter subject's initials only.

Recruitment Guidance

The website below is the location of the CHR (UCSF IRB) guidance for clinical research recruitment guidance…or call 415-476-1814

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

or Email: chr@ucsf.edu

Takeaways…

- Recruitment is a very important step in the management of a clinical trial. If you cannot recruit the numbers of people required as written in the protocol, you will not be able to analyze your hypothesis.
- No matter the method, all recruitment documents MUST be submitted with the initial application for UCSF CHR review. If you modify the documents, it must return for re-approval.
- Create an eligibility checklist that is signed by the Principal Investigator; document screening failures.
- Recruitment can often be thought of as easy, with lots of subjects waiting to join; but the reality is that it can be costly, time-consuming, and will require thoughtful care to federal regulations.