Recruitment Methods

Ethical Concerns and Principles

The researcher and the IRB must consider the following ethical concerns when evaluating a recruitment strategy:

Respect for privacy

Does the recruitment strategy respect an individual?s reasonable expectations for privacy? Will patients be upset when they learn researchers not involved in their care have read their medical records without permission?

Lack of pressure

Is the study introduced in a way that allows subjects ample time to consider, with no undue pressure because of timing of the request, who makes the request, how the request is made,

or the offering of excessive inducements? Will patients be put in a situation where they may hesitate to say ?no? to their own physician? How will pressure be minimized?

Unbiased presentation of the study

Is all information accurate, balanced and free of misleading emphases that make the study excessively attractive? Is the information as complete as is appropriate for each stage of recruitment?

Avoiding the therapeutic misconception

Patients tend to believe a clinical trial ? or anything proposed by health care providers ? will benefit them, even if they?re told there is no assured benefit. Does the recruitment strategy work to counteract this misconception?

Conflicting concerns of care providers and patients

Subjects may prefer that someone involved in their care contact them about research, but they may find it hard to say ?no? to a care provider. Clinicians may find their clinical judgment in conflict with a desire to enroll patients in their research.

Also keep the following principles in mind when developing your recruitment strategy:

Avoid initial contact by "unknown" individuals

Prospective research subjects generally should be contacted by people directly involved in their care, not by unknown researchers.

Restrict medical record access

Avoid giving access to medical records and identifiable health information to people not directly involved in a patient?s care.

Minimize use of PHI

Minimize the amount of protected health information (PHI) [1]/identifiable information gathered and the number of people who have access to identifiable information.

Exceptions to these principles may be granted where necessary. The IRB application must explain why exceptions are necessary; approval is not automatic.

Acceptable Recruitment Methods

You will be asked to explain your method(s) of recruiting subjects in the IRB Application. The following recruitment methods have been used in studies conducted at UCSF and its affiliated institutions. Depending on circumstances, any of these methods may be in compliance with both the federal (45 CFR 46) and the federal HIPAA Privacy Rule (45 CFR 164), but there also may be ethical and practical problems with any of the methods.

Click on the proposed recruitment method for more details, important considerations and/or restrictions.

1. Clinics maintain a separate IRB-approved recruitment protocol.

Clinics, departments or other groups asks patients if they will agree ahead of time to be contacted for research. See the sample Consent to Be Contacted For Future Research [2] consent form. Investigators contact patients about particular studies in accord with their signed consent.

2. Study investigators enter basic study info on a searchable public website.

To keep patients informed of potential research opportunities, many departments maintain lists of current studies on their websites or other public websites, such as the NCI's cancer clinical trial listing. Making your study available to the public in this fashion is optional.

Based on FDA guidance [3], you do not need to submit the website text to the IRB if the it only provides basic trial information, such as:

- the title,
- purpose of the study,
- protocol summary,
- basic eligibility criteria,
- study site location(s) and
- how to contact the site for further information.

If the listing contains additional descriptive information about the study, submit the text of the website so the IRB may assure that the description does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

ClinicalTrials.gov and UCSF Clinical Trials [4] Finder: If your UCSF study is open and listed on ClinicalTrials.gov, it will automatically be pulled into the UCSF Clinical Trials [4] website. This new tool lets potential participants search for active studies at UCSF and contact the study team. Study information is extracted at least weekly from ClinicalTrials.gov, so please keep information about your study current [5] on ClinicalTrials.gov and and respond promptly to potential participants.

Learn more about the launch of the UCSF Clinical Trials finder [6], and visit the HUB for ClinicalTrials.gov registration requirements [7]. Please note that the IRB does not need to review submissions to ClinicalTrials.gov, but you must provide the IRB with the clinical trial identifier (NCT#).

Reminder: IRB submission and approval is still required for other types of advertisements [8], including web-based recruitment materials.

3. Advertisements, notices and/or media are used to recruit subjects.

The IRB must first approve the text of these items. Subjects who respond to these will contact the study investigators. See advertising guidelines [8] for more information. Note: No HIPAA-regulated PHI [1] is used in this recruitment strategy.

4. Study investigators provide their colleagues with a "Dear Patient" letter describing the study.

This letter is signed by the treating physician(s) and informs the patients how to contact the study investigators. The study investigators are prohibited from having access to patient names, addresses or phone numbers; patients must initiate contact. The IRB has created a sample recruitment letter [8]. See 8.b below for additional options.

5. 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 (e.g. a note in the medical record that the patient agreed to be contacted). Investigators may give the referring physicians a study information sheet for the patients.

You do not need to submit the "Dear Doctor" to the IRB for review. However, submit any materials that will be distributed to potential subjects.

Note: If the referring health professional will be providing a detailed description of a specific study to patients as part of the recruitment process, the IRB should review the recruitment script/materials.

6. Study investigators who are also clinicians providing direct care recruit their own patients directly.

Investigators, or nurses or staff working with the investigators, approach the patients. This approach respects privacy, but also raises ethical concerns because of the difficulty of saying no and the therapeutic misconception (see the discussion of ethical concerns above). If recruiting by letter, see our sample recruitment letter [8].

7. Study investigators recruit potential subjects who are unknown to them.

Examples include snowball sampling, use of social networks, direct approach to unknown people in public situations, and random dialing.

8. Study investigators request a waiver of consent/authorization for recruitment purposes.

In all cases, the waiver must be justified in the "Waiver of Consent/Authorization for Recruitment Purposes" section of the application. Waivers are granted in four primary situations:

a. Minimal risk, no-subject-contact studies: In minimal risk studies in which subjects will be not be contacted (e.g., many chart review studies) researchers request a complete waiver of consent/authorization. The application must explain why the study cannot be done without the waiver.

b. Review of charts before recruitment: If the study requires researchers to review charts to identify prospective subjects who will then be contacted and asked to be in the study, the

justification for the waiver to review charts must show why the study cannot be done without the waiver. The waiver covers collecting only the minimum amount of information needed to make contact; consent is obtained before additional information is gathered.

The IRB?s usual policy is that patients identified through chart review should be approached by someone already involved in their care. ?Already involved in their care? includes health care professionals directly involved in their care, as well as administrative and research staff working with the health care professionals.

c. Direct approach by someone not involved in the patient?s care: In some circumstances it may be necessary for members of the research team who are not involved in the patient?s care to make the approach, either in person or by phone or letter. The application should explain why the study cannot be done unless the researchers approach subjects directly. Direct approach by someone not involved in the patient?s care is an exception to the usual policy but may be approved in exceptional circumstances such as emergency care research.

d. Large-scale epidemiological studies and other population-based studies: These types of studies may need to identify subjects through registries, medical records in multiple institutions, or other sources. The researchers may need to contact prospective subjects directly rather than through professionals involved in the prospective subjects? health care. This approach involves a greater invasion of privacy than other methods, because researchers without approval from patients gather significant private health information about the patients, and then contact the patients directly.

Because this approach is an exception to the IRB?s usual policies, the application must explain in detail why it is impossible to do the study unless the IRB 1) waives authorization/consent to obtain subjects? identities and 2) allows researchers to contact subjects directly.

Who May Recruit

Individuals initiating contact (in person or by phone) with potential subjects must have basic knowledge about the study (so they can answer questions) and training in the voluntary nature of research participation. They also should be prepared to provide prospective subjects with

- a researcher?s name and phone number (for questions about the study) and
- the phone number of the IRB (for questions about a research subject?s rights).

The IRB?s usual policy is that patients identified through chart review should be approached by someone already involved in their care. See method 8b above for more info.

Recruitment Materials Needing IRB Review

The following types of recruitment materials must be submitted as part of the initial application for IRB review. Any additions or changes to these items must be submitted as modifications [9] of the study.

Letters to subjects

Submit all letters to subjects or their representatives, regardless of who signs the letters, including the PI, a primary care provider or an organization the subject has joined. The IRB has created a sample recruitment letter [8]. You do no need to submit "Dear Doctor" letters for review.

Advertisements

Submit all advertisements in all media, including flyers, posters, newspaper ads, radio or television announcements, and informational videos. Ensure the ads meet the **advertising guidelines[8].**

Note: TV ads or videos used in subject recruitment must be reviewed and approved by the IRB, just like other recruitment tools. Investigators should obtain IRB approval for a concept or script before making a major investment in video production. When a video has been prepared in advance by a sponsor, it should be submitted for review (as a DVD or disc). If the video is not approved, the IRB may allow the study to proceed as long as the video is not used by the local investigator and the local investigator does not accept referrals from any advertising campaign that uses the video.

Do NOT submit the sponsor?s national recruitment materials if they will be reviewed and approved by a central IRB or commercial IRB

The UCSF IRB does NOT have to review a study sponsor?s national recruitment campaign materials ? e.g., TV ads, radio ads, online ads, podcasts, central call center script, etc. ?provided that these materials will be reviewed and approved by a central IRB or commercial IRB. Sometimes the sponsor outsources this work to a company, which acceptable as long as a central IRB or commercial IRB will review and approve the national recruitment campaign.

The investigator should state in the IRB Application that the study sponsor will have a national recruitment campaign and all of the national recruitment materials will be reviewed and approved by _____IRB (name the central/commercial IRB).

The UCSF IRB should still review any local recruitment materials that will have UCSF contact info on it or that will be posted, sent out, or managed by the UCSF investigator.

Recruitment scripts ? New sample script available!

Submit scripts or guides that will be used for in-person or telephone recruitment interviews.

NEW Sample Phone Recruitment Script [10]: We've provided a sample script for you to adapt for your study.

In telephone surveys, the initial recruitment call sometimes leads directly into the consent process. In such studies, the script should include, at least, the names of the persons responsible for the study, reference to UCSF, a description of the types of questions that will

be asked, an estimate of the time it will take to complete the interview, and the direct question of whether or not a person wishes to participate. The interviewers also should have available an investigator's telephone number in case the prospective subjects have questions about the study that the interviewer cannot answer, and the IRB phone number if there are questions about a research subject?s rights.

Web postings or pages

Submit printouts of postings or pages used for direct recruitment. Informational descriptions posted on websites that have policies insuring that study descriptions are accurate and balanced (e.g. clinical trial sites maintained by the UCSF Comprehensive Cancer Center) need not be submitted for review.

Special Cases

CTSI Consultation Services

CTSI's Consultation Services [11]program can implement cohort identification and direct mail campaigns for patient recruitment. Provide the IRB with the following information if you are using this service.

1. IRB Application, "Recruitment" section:

Use the following template language to indicate that you will be using the CTSI Consultation Services:

We are collaborating with the CTSI Consultation Service to provide cohort identification and direct mail for recruitment. The Dear Patient letter (attached) will be sent to individuals identified from the APeX record systems via a data extraction by Academic Research Systems (ARS) of patients with a diagnosis of [XXX]. These patients [are/are not] known to or under the care of the researchers.

Also, the IRB?s usual policy is that patients identified through chart review should be approached by someone already involved in their care (see above). Explain why the study cannot be done unless the researchers approach subjects directly. See the CTSI Consultation Services website [11] for more information.

2. IRB Application, "Waiver of Consent/Authorization for Recruitment Purposes" section: Answer all questions and explain what info will be collected prior to obtaining informed consent.

3. Attach the recruitment letter [8]: This letter must be printed on the PI's departmental letterhead and approved by the IRB.

The CTSI Consultation Service will print, prepare and mail the letter on departmental letterhead on behalf of the study staff. Interested subjects will be able to contact the study staff as described in the letter. The data extract will be delivered to the CTSI Consultation Service?s MyResearch account in order to facilitate the direct mail activities while ensuring

privacy and confidentiality of the patients identified.

Keeping information about individuals who decline participation

In general, no identifiable information may be kept about prospective subjects unless they consent to even this limited participation in the research. The IRB Application should describe how this consent will be obtained. With IRB approval, non-identifying information about refusers may be collected. See the PHI definition and list of 18 identifiers [1] for a description of items that identify subjects. If the research cannot be done if refusers? consent to record basic information is required, the IRB will consider waiving consent [12].

Sponsor?s role in recruitment

- In general, UCSF does not permit its researchers to provide subject contact information to sponsors. Sponsors may not directly contact prospective subjects based on information from UCSF researchers.
- If the sponsor plans a national or local advertising campaign to recruit subjects, all materials must be submitted for IRB review, including any scripts or guides used when prospective subjects call the sponsor?s representatives.

Recruiting researchers? students and staff

Researchers should not directly ask their students or staff to be research subjects, as it may be hard to refuse such a request. The IRB prefers that researchers post flyers and allow volunteers to initiate contact about the study. No pressure should be applied to encourage participation.

Recruitment in classrooms

Potential participation in research must be presented as a voluntary option. Participation cannot be tied to grades. It must be clear that there will be no stigmatization of students who decline to participate. If class time will be taken for research participation, alternative activities should be provided for those who decline (especially in pre-college levels).

Incentives and referral fees

Per-patient incentive payments or referral fees, whether paid for each referral or each enrollment, are **not allowed**. Such payments may encourage recruiters to put inappropriate pressure on prospective subjects and are illegal in California. Lump-sum payments not tied to the number of patients referred or enrolled may be allowed in particular studies. Include all information about incentives and/or referral fees in the recruitment section of the protocol.

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Contact Us
UCSF Main Site

Source URL: http://irb.ucsf.edu/recruitment

Links
[1] http://irb.ucsf.edu/hipaa
[2] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/future-contact-consent.doc
[3] http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm
[4] http://clinicaltrials.ucsf.edu/
[5] http://clinicaltrials.ucsf.edu/about/for-researchers
[6] http://www.ucsf.edu/news/2016/12/405126/dearth-clinical-study-participants-leads-ucsf-launch-new-trial-finder-tool
[7] http://hub.ucsf.edu/clinicaltrialsgov
[8] http://irb.ucsf.edu/advertising-and-recruitment-letter-guidelines
[9] http://irb.ucsf.edu/modification
[10] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/sample-recruitment-phone-script.docx
[11] http://accelerate.ucsf.edu/research/recruitment
[12] http://irb.ucsf.edu/waiving-informed-consent