RECRUITMENT

This document provides guidance to investigators on recruiting human subjects for research. Should you need additional assistance please contact the Office for the Protection of Human Subjects (OPHS) at 510-642-7461 or at ophs@berkeley.edu.

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A. General Information

Informed consent is a process that continues throughout the course of the study. The first part of this process begins with *recruitment*, when initial contact is made with a subject. As such, it is the responsibility of the Committee for Protection of Human Subjects (CPHS) to review recruitment methods and materials with regard to the manner and context in which information is conveyed, to ensure that the possibility of coercion or undue influence and other risks, such as loss of privacy, are minimized.

Per the federal regulations governing human subjects research, 45 CFR 46, all recruitment materials, including *verbal scripts, web postings, correspondence, advertisements,* and *flyers,* must be submitted for CPHS review and approval before use in the field. Any *changes* to previously approved recruitment procedures or materials must also be submitted for CPHS review and approval prior to implementation.*

*While recruitment materials need not be submitted or reviewed at the exempt level, investigators conducting exempt-level research should still adhere to the below points when recruiting subjects.

B. Points to Consider

1. ***Respect for privacy:*** The recruitment method should respect an individual's reasonable expectation of privacy. When identifying and recruiting subjects, researchers should take into account whether subjects might feel that the recruitment method represents an invasion of privacy. Under certain circumstances, such as research targeting gang members as a subject population, it is not appropriate for researchers to ask participants for the contact information of other potential subjects. Instead, researchers should give their contact information to participants to pass along to other potentially interested individuals. Under other circumstances, such as research involving interviews with experts in a particular field, asking for the names of other experts would probably not constitute an invasion of privacy.

2. ***Vulnerable subjects:*** Additional safeguards may be necessary if the study population is likely to include persons particularly susceptible to coercion or undue influence. Examples of vulnerable subjects include: children, prisoners, pregnant women, mentally incompetent persons, persons with little or no literacy, etc.

3. ***Cultural considerations:*** Researchers need to consider the customs of the subject population in order to develop a culturally appropriate recruitment method. For example, in some cultures a researcher may enter into a community to approach prospective subjects *only after obtaining permission* from a community leader, a council of elders, or another designated authority.

4. ***Private medical information:*** Medical records, patient registries, clinical databases and referrals from treating physicians can be useful resources to identify potential subjects; however, researchers should be aware that certain health information is protected under the Health Insurance Portability and Accountability Act (HIPAA) "Privacy Rule." Under the Privacy Rule, it is generally not appropriate for researchers to identify and contact subjects through their private health information. For purposes of recruitment, only *(a) health care professionals* involved in the patient's care and/or *(b) administrative staff* working with the professionals involved in the patient's care *are eligible to review HIPA- protected information without an authorization or waiver*. For additional information, see http://cphs.berkeley.edu/hipaa/hipaa.html/

5. ***Conflicting roles:*** Individuals may prefer to be contacted about participation in a research study by someone with whom they have an established relationship. However, if this person holds a position of authority in relation to the prospective subject, such as employer or professor, that may have a significant influence over the subject. For example, the prospective subject may fear that refusal to participate could damage the relationship, and consequently feel pressured to take part in the research. *In this context, CPHS prefers that researchers distribute flyers or brochures allowing interested persons to initiate contact and that, in addition, a neutral third party obtain consent.* In general, researchers should not directly approach their students or staff about being research subjects.

6. ***Therapeutic misconception:*** In the context of medical care and the physician-patient relationship, there is the possibility of *therapeutic misconception*. Patients have a tendency to believe that a research study proposed to them by their health care provider(s) will benefit them directly, even if they are informed that the research may offer them no benefit. Researchers should consider whether their recruitment methods adequately deter this misconception.

C. Content for Recruitment Materials

1. When developing recruitment materials, take care to ensure that the content is neither misleading nor coercive, and does not make any false or exaggerated claims. It should be clear that "research" is involved.

2. Consider the need for confidentiality in the design of the materials. A sign-up sheet exposing subjects' names and contact information to public view is not appropriate.

3. Use language that is simple, straightforward, and appropriate to the subject population. As with consent forms, an 8th grade reading level is generally recommended.

4. Include the name of the institution, department, lead investigator and/or a contact person along with the relevant contact information.

5. State the purpose of the research in summary form and the eligibility criteria that will be used to admit subjects into the study. *Give individuals the opportunity to screen themselves out whenever possible, by clearly stating study requirements in the recruitment materials*.

6. Studies involving experimental drugs or devices must clearly state that they are experimental or investigational. *No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would not only be misleading to subjects, but would also violate FDA regulations.*

7. Provide the location of the research and time commitment, if appropriate.

8. Include a brief, accurate description of the benefits of participation, if any.

9. Include a straightforward and accurate description of compensation for participation in the study, if any. *If payment is to be made to the subjects, the Committee reviews both dollar amount and method of disbursement to assure that neither entails problems of coercion or undue influence.*

Example of Acceptable Wording:

VITAMIN B_2 RESEARCH STUDY
You are invited to participate in a study evaluating the effects of Vitamin B_2,
conducted by Dr. Cando at the University of California, Berkeley, Department of Nutrition.
The study involves 6 one-hour visits over 3 months, having blood drawn,
and drinking Vitamin B_2 mixed in different beverages.
Compensation available.
If you are at least 18 years old, do not smoke, are right handed,
and would like more information about participating, contact:
Investigator/Graduate Student at 510-333-4444 or Investigator/GraduateStudent@berkeley.edu

Example of Unacceptable Wording:

EARN $500! Get FREE Medical Care!

SAMPLE RECRUITMENT FLYER

Research Study

University of California, Berkeley
Department of [XXXXXX]

[Brief explanation of study]

Who is Eligible?

- XXXXXXXXXX
- Ages XX - XX
- XXXXXXXXXX

What will you be asked to do?

- Spend XX hours at the XXXXXX on XX occasions
- XXXXXXXXXX
- XXXXX
- XXXXXXXXXXXX

Compensation

You will receive up to $$ for your participation in this study.

If you have any questions or are interested in participating, please contact:

Investigator at (510) xxx-xxxx or Email: investigator@berkeley.edu

[TITLE] RESEARCH STUDY
Phone (510) xxx-xxxx
Email: investigator@berkeley.edu