



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

**Submitting Ads/Recruitment Materials Related to a Research Plan
(Protocol)**

A. GENERAL INFORMATION

Institutional Review Boards (IRBs) are responsible for ensuring equitable selection of research subjects. In fulfilling this responsibility, the IRB reviews advertisements for equitable selection, and to determine whether the procedure for recruiting subjects affords adequate protection. In general, it is best that the proposed ad copy be submitted with the initial IRB application whenever possible.

NOTE: Recruitment materials involving VMRF funding must be submitted separately from UCSD recruitment materials. Usually joint recruitment materials are not authorized, per the VMRF/UCSD Agreement. The UCSD logo or name cannot appear on a VMRF study recruitment advertisement and visa versa.

B. SPECIFIC SUBMISSION REQUIREMENTS

1. The request must be clearly marked as an “Expedited Ad/Recruitment Copy Review” and must be related to an established approved protocol.
2. It must list the IRB approved project number and Research Plan title.
3. A listing of specific potential sources for the ad copy (e.g., radio, TV, newspaper, direct mail to physician, direct mail to patients, etc.) should be provided.
5. One copy of the proposed ad copy must be submitted.
6. Provide the return route for reviewed ad (for example, call for pick up or mail).

C. SUGGESTED RECRUITMENT MATERIAL CONTENT

1. The name and address of the Principal Investigator or the department.
2. The purpose of the research and, in summary form, the eligibility criteria that will be used to admit the subjects into the study.
3. A straightforward and truthful description of the incentives to the subject for participation in the study (e.g., payment or free treatment).
4. The location of the research and the name of the person or the telephone number to contact for further information.
5. Studies involving experimental drugs or devices must clearly state that they are experimental or investigational. Do not use terms such as a

“new” drug or device since the word new can imply "approved" or even better and not investigational, which is considered coercive. In medical studies no claims should be made, either explicitly or implicitly, that any experimental drug or device is safe or effective, or equivalent or superior to any other drug or device. Such representation would not only be misleading to subjects, but would violate FDA regulations concerning promotion of investigational drugs [21 CFR 312.7(a)] and investigational devices [21 CFR 812.7(d)].

6. If payment is to be made to subjects the IRB reviews both the amount of payment and proposed method of disbursement to assure that neither entails problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were to be contingent upon completion of the study or if the payment were unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation.

D. FURTHER INFORMATION

For further information or clarification regarding the above, please contact the Human Research Protections Program at (858) 455-5050 or visit the website at irb.ucsd.edu.