



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

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

A. General Information

An important issue in human research, especially in the context of clinical trials, is the “therapeutic misconception” associated with new interventions. Clinical studies should be designed with the concept of equipoise in that there should be sufficient data to support the notion that in a randomized clinical trial neither arm is a priori known to be superior to the other. In advertising, the concept of “new” is intentionally made synonymous with “improved” but this is antithetical to the scientific principles underpinning human experimentation.

The FDA considers direct advertisement for research participation to be the start of the informed consent process. For this reason, the IRB will review the content of all submitted proposed advertisements/recruitment materials (flyers, letters, scripts, etc.), proposed recruitment methods, and all other related written material to be provided to subjects.

Guidance from the FDA includes that the “FDA believes that any advertisement to recruit subjects should be limited to the information prospective subjects need to determine their eligibility and interest.”

The IRB reviews “direct advertising for research participants,” which is defined as advertising that is intended to be seen or heard by prospective participants to solicit their participation in a study. When advertisements are easily compared to the approved consent document, the IRB chair, or other designated IRB member, may review and approve by expedited means. When the IRB reviewer has doubts or other complicating issues are involved, the advertising should be reviewed at a convened meeting of the IRB.

When the IRB evaluates the selection of participants and procedures for retaining enrollees, the IRB also considers the influence of compensation. Compensation should be appropriate for the level of risk, discomfort, and/or inconvenience experienced by the participant and not have the potential for coercion or undue influence for a participant to enroll in or remain on the study. The PI must present justification that the compensation offered through these procedures is not inequitable (see also SOPP, section 3.2, [Convened IRB Review](#)).

According to the California Department of Consumer Affairs, “California law prohibits lotteries. A lottery is any scheme for the disposition of property by chance among persons who have paid or promised to pay any value for the chance of obtaining the property, with the understanding that it will be disposed of by chance.” (There are three exemptions to this prohibition including the California State Lottery, bingo for charitable purposes and a raffle conducted by a non-profit, tax-exempt organization for charitable purposes.) “Courts have used certain rules to decide whether a scheme includes consideration because it is not always clear. If a person is eligible to win a prize without purchase, there is no consideration and the contest is legal. In such a case, if some people *may* pay money - for example, an admission charge or a product - there is not necessarily consideration if other people may enter without such a purchase. If eligibility to win a prize is limited to those who have paid money, however, there is consideration. Alternatively, if some persons *must* pay in order to have a chance at a prize while others do not, there is consideration.”

In addition, there is concern that most people overvalue their likelihood of winning, and therefore, offering a valuable prize may serve to undermine the process of informed consent.

In light of this information, a convened IRB will on a case-by-case basis determine whether lotteries, raffles, and/or drawings may be used to recruit or retain participants. In order for the IRB to consider approving the use of lotteries, raffles, and/or drawings, the following must be addressed:

1. The study is minimal risk;
2. Appropriate compensation is being offered;
3. The Research Plan must include the following:
 - a) Procedures to ensure that any individual who is asked to participate in the research study but declines, who consents/assents to enroll in the study, or who fails to complete the study, will be given equal compensation by having an equal chance of winning. In other words, if an individual is eligible to participate in the study, and therefore the lottery, raffle and/or drawing, they do not have to participate in the study to be eligible to participate in the lottery, raffle, and/or drawing;
 - b) Procedures for the inclusion of an individual who is not asked to participate in the study but wishes to be included in the lottery, raffle, and/or drawing;
 - c) A fair method of choosing the winner and how the winner will be notified; and
 - d) Disclosure of the approximate chance of winning (e.g., no less than 1 in 1000).

Institutional Review Board review and approval of listings of clinical trials on the Internet is not required when the system format limits the information provided to basic trial information, such as the following:

1. The title; purpose of the study;
2. Protocol summary;

3. Basic eligibility criteria;
4. Study site location(s); and
5. How to contact the site for further information.

B. Suggested Advertisement/recruiting 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.
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.
6. If compensation is to be made to subjects, the IRB reviews both the amount of compensation 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 compensation were to be contingent upon completion of the study or if the compensation was unusually large. Compensation should reflect the degree of risk, inconvenience, or discomfort associated with participation.

C. Content That Shall Not Be in Advertisement/recruiting material

1. State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
2. Make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation;
3. Make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device;
4. Use terms such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational;
5. Promise “free medical treatment,” when the intent is only to say participants will not be charged for taking part in the investigation.
6. Include compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
7. Make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA (or equivalent regulatory body) labeling.

D Specific submission requirements

The IRB will review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting participants is not coercive. The IRB will review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB -approved text may be accomplished through expedited procedures.

In general, it is best that the proposed advertisement/recruitment material be submitted with the initial IRB application whenever possible. If this is not possible, the submission will be provided as an amendment request following the policies/procedures outlined for such a request using e-IRB services including submission of a cover letter that clearly indicates why the advertisement/recruitment material is being provided for review; what revisions, if any, have been made to the advertisement/recruitment material, the procedures of the use of the advertisement/recruitment material, etc. and revised study documents including a Research Plan to reflect current/proposed recruitment procedures, etc. Per amendment request policies/procedures, two copies of revised advertisement/recruitment materials, as well other study documents, as appropriate, must be provided. One copy will include the revisions highlighted and one “clean” copy.

E Further Information

For further information or clarification regarding the above, please contact the Human Research Protections Program at (858) 246-4777 or visit the HRPP website at <https://irb.ucsd.edu>.