

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.17
Advertisements, Recruiting Materials, and Procedures and
Procedures Preparatory to Research

Policy

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, proposed recruitment methods, and all other related written material to be provided to subjects. No claims should be made either explicitly or implicitly that the experimental drug or device is safe or effective for the purpose under investigation, or that the drug or device is superior to any other drug or device. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

Advertisements and Recruitment Materials

Guidance from the FDA includes the “FDA believes that any advertisement to recruit subjects should be limited to the information prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that FDA does not require inclusion of all of the listed items:

1. The name and address of the clinical investigator and/or research facility;
2. The condition under study and/or the purpose of the research;
3. In summary form, the criteria that will be used to determine eligibility for the study;
4. A brief list of participation benefits, if any (e.g., a no-cost health examination);
5. The time or other commitment required of the subjects; and
6. The location of the research and the person or office to contact for further information.”

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.

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.

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 should 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. The IRB will review advertising to assure that advertisements do not:

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.

Advertisements may state that participants will be compensated, but should not emphasize the compensation or the amount to be compensation, by such means as larger or bold type. Advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements: the name and address of the clinical investigator or research facility; the condition under study or the purpose of the research; in summary form, the criteria that will be used to determine eligibility for the study; a brief list of participation benefits, if any (e.g., a no-cost health examination); the time or other commitment required of the participants; and the location of the research and the person or office to contact for further information.

No advertisement can include any exculpatory language.

Compensation

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, [Full IRB Review](#)).

Lotteries, Raffles, and Drawings

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).

This information, along with specifically informing individuals that they are not guaranteed to win any prize in the drawing and that the only compensation they will receive is the “1 in X” chance of winning, must be provided in the consent/assent as well as to those who wish to participate in the lottery but not the research study.

Procedures for Purposes Preparatory for Research

It has been a common practice for clinicians who are also doing research to use medical records they have produced, or the clinical information systems of their organization, to identify potential participants for research studies or to find cases for a retrospective chart review. HIPAA distinguishes between the use of medical records for health care — which is a HIPAA covered function — and the use of records for research purposes — which is not covered and must be done only with signed authorization or with a waiver of authorization granted by an Institutional Review Board.

The HIPAA Privacy Rule permits use of PHI for *reviews preparatory to research* however in the University of California system, this is considered part of the overall research plan and requires IRB review prior to the review activity commencing. It is not permissible to begin the research by gathering preliminary data via lookups in clinical information systems, or reviewing clinic appointment logs or other records of clinical care, prior to IRB review and approval of a study.

If procedures for purposes preparatory to research involve review of private information, such as preparing a research protocol, assisting in the development of a research hypothesis, or aiding in research recruitment, for instance identifying prospective research participants who meet the eligibility criteria for enrollment review, consent must be obtained or a waiver of consent must be granted. In order to grant a waiver of consent, this item must clearly describe:

1. Justification why using these procedures would be considered minimal risk to the potential subjects.
2. Justification why a waiver of consent would not adversely affect the rights and welfare of the potential subjects.
3. Justification why these procedures could research not practicably be carried out without the waiver.
4. Whenever appropriate, a procedure for providing potential subjects with additional pertinent information after participation.

If the procedures also include access to PHI, HIPAA authorization must be obtained, or a partial waiver of individual HIPAA authorization must be granted. In order for a partial waiver of HIPAA authorization to be granted, this item must also clearly describe:

1. A plan to a) protect identifiers from improper use and disclosure; and b) destroy identifiers at the earliest opportunity or provide justification for retaining the identifiers;
2. Justification as to why these procedures could not a) practicably be done without the waiver, and b) be done without access to, use, or disclosure of the PHI;
3. Justification that the privacy risk to individuals whose PHI will be used or disclosed is minimal and reasonable in relation to the anticipated benefit, if any, to the individuals; and
4. What PHI will be used and who will access, use or disclose the PHI.

More information about HIPAA and Research at the University of California can be found [here](#).

Note that for studies that involve an FDA-regulated agent, procedures performed in preparation of a clinical investigation would not fall under the definition of a clinical investigation and would not require informed consent.

Procedures

1. IRB members and/or HRPP program staff will review recruitment material, recruitment procedures, and procedures preparatory to research for compliance with applicable policies.

Applicable Regulations and Information Sheet

[21 CFR 50.20](#)

[21 CFR 312.7\(a\)](#)

[21 CFR 812.7\(a\)](#)

[45 CFR 46.116](#)

[UCSD HRPP/IRB SOPPs, section 3.2, Full IRB Review](#)

[State of California, Department of](#)

[Consumer Affairs, Legal Guide U-2 —](#)

[Rules Prohibiting Lotteries](#)

[FDA Recruiting Subjects — Information Sheet](#)

[NIH, IRB, and the HIPAA Privacy Rule](#)