Policy Number: 22
Title: Advertisement and Recruitment
Date of Last Revision: 08/10/05, 09/09/10, 02/01/16, 04/06/18

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review and approve all recruitment materials for participants in research conducted under its jurisdiction.

I. All Recruiting and Advertising Materials Must be Approved by the IRB - The IRB must assure that appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB must review all of the research documents and activities that bear directly on the rights and welfare of the participants of proposed research, including the methods and materials that Investigators propose to use to recruit participants.
   A. For example, the Investigator must obtain IRB approval for all final versions of television, radio, videotape or print advertisements, e-mail solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective research participants. All methods of advertisement require approval from the IRB prior to their use.
   B. The following examples do not qualify as an advertisement:
      1. Communications intended only to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters;
      2. News stories, so long as they are not intended for recruitment purposes (e.g. a phone number at the end to contact for more information to participate in a particular study, full details of inclusion/exclusion criteria of a particular study, etc.); and
      3. Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute or physician).
   C. The IRB considers advertising or soliciting for study participants to be the start of the informed consent process and subject selection process. Advertisements must be reviewed and approved by the IRB as part of the package for initial review. When the Investigator decides after the initial approval to advertise for participants or to change the advertisement, the advertising is considered a modification to the ongoing study. The IRB reviews the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence.
   D. When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The IRB reviews 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 reviews the final audio or video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording.

II. Any 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:

A. The name, address, and institution of the Lead Researcher or study coordinator (e.g. UC Irvine);
B. If applicable, include “investigational, meaning non-FDA approved”;
C. The condition under study and the purpose of the research;
D. In summary form, the criteria that will be used to determine eligibility for the study;
E. A brief list of participation benefits, if any (e.g., a no-cost health examination);
F. The time or other commitment required of the participants; and
G. The location of the research and the person or office to contact for further information.

III. Advertising materials should not include the following:

A. Claims, either explicitly or implicitly, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
B. Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
C. Claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling;
D. Allow compensation for participation in a trial offered by a Sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing;
E. Use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non FDA-approved;
F. Promises of "free medical treatment," when the intent is only to say that participants will not be charged for taking part in the investigation;
G. Exculpatory language or
H. An emphasis of payment or the amount to be paid, by such means as larger or bold type.

IV. Recruitment Scripts - The first contact prospective study participants make is often with an administrative staff contact that follows a script to determine basic eligibility for the specific study. The IRB must review the procedures to assure that they adequately protect the rights and welfare of the prospective participants. The IRB must have assurance that any information collected about prospective participants will be appropriately handled.

V. Internet Recruitment - All advertisements and recruitment methods must be reviewed and approved by the IRB prior to implementation except for two specific clinical trial listing services which *do not require* prospective IRB approval as determined by the Food and Drug Administration. These include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). For other Internet recruitment sites, IRB review and approval is required to assure that the information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document. In addition, the Investigator must assure that the information shared for Internet recruitment is in accordance with their signed clinical trial agreement or grant.

VI. UCI Campus Communication E-mail - Advertising submitted through mass email solicitation to the UC Irvine campus community should be simple, readable, and understandable. It should meaningfully and respectfully convey a message to a broad spectrum of the UCI community. It should be text-based and written in block paragraphs. The following format is recommended when utilizing this method of recruitment or advertisement:

A. A headline that describes the study and volunteers needed;

B. Use complete sentences and paragraphs;
C. Statement 1 – include enough information to help readers self-select;
D. Statement 2 – purpose of the study;
E. Statement 3 – requirements of participation;
F. Statement 4 – benefit to the participant or a statement there is no benefit; and
G. Statement 5 – a contact person "for more information".

VII. Students as Participants - The IRB should exercise oversight with the use of students as participants in research.

VIII. Data Base/Primary Care Physician Recruitment - Often times Investigators request to use search methods of particular databases looking for potential participants that may be eligible for their research projects (e.g., disease, age, sex, etc.), or they request to contact primary care providers (PCP) for access to potential participants from the PCP's patient population. These recruitment methods require IRB approval prior to initiation.

IX. Inclusion of Women, Children and Minorities - The inclusion of women, children, and minorities in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. To the extent that participation in research offers direct benefits to the participants, under-representation of children, men, women or minorities denies them the opportunity to benefit. Moreover, for purposes of generalizing research results, Investigators should include the widest possible range of population groups.

X. Involvement of Humans in Research - NIH-supported Investigators must provide to the IRB details of the proposed involvement of humans in their research protocols, including the characteristics of the subject population, anticipated numbers, age ranges. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation.

XI. Finder's Fees and Bonus Payments – Although research sponsors may offer to pay Investigators or study personnel an additional fee to encourage participant recruitment efforts and the timely or accelerated opening of research studies, these payments are strictly prohibited per California Heath and Safety Code Section 445 and UCI IRB policy.
A. It is not permissible to pay or accept a "finder's fees."
B. It is not permissible to accept bonus payments. UCI employees or students cannot accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients. Cash or cash-equivalent payment to health care providers for referral of subjects or potential subjects is not permitted.
C. Other types of compensation (e.g., books, other non-cash gifts) are also prohibited.

XII. Legal Implications
A. The Council on Ethical and Judicial Affairs of the American Medical Association denounced the practice of finder's fees in December 1994;
B. The Federal anti-kickback statute can also be implicated by this practice; and
C. California Health and Safety Code (Section 445) states that "No person, firm, partnership, association or corporation, or agent or employee thereof, will for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition."

## XIII. Use of a Lottery, Raffle or Drawing System

A. 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. If some people may pay money - for example, an admission charge or buy a product - there is not necessarily consideration *if* others may enter the contest without such a purchase. If eligibility to win a prize is limited to those who have paid money, however, there is consideration and the contest is not legal.

Consideration in the context of research applies when subject compensation is a lottery or raffle to win a prize (e.g., gift certificate, iPad, etc.). If eligibility to win a prize is limited to those who participate in the research there is consideration therefore the contest is not legal.

B. The IRB will 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 considered:

1. The study involves minimal risk to participants (Exempt or Expedited).
2. The prize is less than $600 and will not to unduly influence participation in the research.
3. The Subject Compensation Section of the Protocol Narrative 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 are not required 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) in the consent/assent.

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 and recruitment materials for those who wish to participate in the lottery but not the research study.

XIV. When research is sponsored by the Department of Defense (DoD)

A. When research involves U.S. military personnel policies and procedures include additional protections for military research participants to minimize undue influence as follows:

1. Officers are not permitted to influence the decision of their subordinates;
2. Officers and senior non-commissioned officers may not be present at the time of recruitment;
3. Officers and senior non-commissioned officers have a separate opportunity to participate;
4. When recruitment involves a percentage of a unit, an independent ombudsman is present.

XV. When following Department of Justice Regulations and Guidance

A. When research is conducted within the Bureau of Prisons:

1. The selection of participants within any one organization must be equitable;
2. Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered;
3. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
    a) No longer in the Bureau of Prisons custody,
    b) Participating in authorized research being conducted by Bureau employees or contractors.

References:

21 CFR 56.107(a)
21 CFR 56.111(a)(3)
21 CFR 56.111(b)
21 CFR 50.20
21 CFR 50.25
21 CFR 812.20(b)(11)
California Health and Safety Code - Section 445
U.S. Food and Drug Administration Information Sheets: “Recruiting Study Subjects,” 1998 Update
Clarification of Ethics Opinion 6.03, 65. Finder’s Fees: Payment for the Referral of Patients to Clinical Research Studies
42 U.S.C. ‘1320a-7b(b)
SECNAVINST 3900.39D, para. 6a(6)
DoDD 3216.2, para. 4.4.4
DoJ: 28 CFR 512.11 (4,5)

## Procedure Number: 22.A
## Title: Procedure for Advertisement/Recruitment

### Procedure:

This procedure provides guidance for advertising associated with the recruitment of human participants for research conducted under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

I. Lead Researcher (LR) Responsibilities

- A. The LR will submit all types of advertisements (e.g., television ads, radio, videotape, print advertisements, e-mail solicitations, and Internet websites) associated with the recruitment of research participants to the UCI IRB for review and approval. This includes any sponsor-provided advertisements or Investigator-drafted advertisements.
- B. The IRB reviews advertisements in their final form prior to final IRB approval for use.
- C. The UCI IRB considers advertising or soliciting for study participants to be the start of the informed consent and participant selection processes. Therefore, advertisements should be included as part of the initial "Application for Human Research."
- D. IRB review and approval for additional advertisements or changes in currently approved advertisements or recruitment methods will be submitted in the form of a modification request to the IRB for approval prior to implementation.
- E. Campus Community e-mail solicitations are first submitted to the UCI IRB for review and approval. The IRB will provide the Investigator with the approved advertisement with an IRB approval stamp. The Investigator submits the IRB stamped mass e-mail advertisement to their School's Communication Representative for mass e-mail posting.

II. IRB Committee Responsibilities

- A. The IRB will review and approve all advertisements or means of soliciting participants in human subjects research to assure that the rights and welfare of the prospective participants are protected and that information collected about prospective participants will be appropriately handled.
- B. The IRB will review final versions of printed advertisements to evaluate the relative size of type used and other visual effects.
- C. When advertisements are to be taped for broadcast, the IRB will review of script and the final audio or video tape prior to approval.
- D. The IRB Committee Chair or designated Committee Member may review changes to advertisements. However, the Chair or designated Committee Member may refer the advertisement to the full, convened IRB Committee if the advertisement contains subjective material which in his or her opinion needs further review.

III. IRB Analyst or Higher Responsibilities

- A. The Analyst will review all initial study submissions to determine what type of advertisements will be used for recruitment. If advertisements are planned, but not provided, the Analyst will remind the LR that submission for IRB review and approval is required prior to use.
- B. The Analyst will stamp all written forms of advertisement with the official IRB approval stamp.
- C. Advertisements submitted as modifications may be approved by the IRB Chair or designated Committee Member on an expedited basis.

D. If the Chair or designated Committee Member refers the advertisement to the full, convened IRB Committee, the Analyst will facilitate scheduling on the next available agenda.

Procedure Number: 22.B:
Title: Procedure for Advertisement/Recruitment of Students and Employees as Research Participants

Procedure:
This procedure outlines the responsibilities of the UC Irvine (UCI) Institutional Review Board (IRB) and Investigators when recruiting students and employees as participants in research conducted under the UCI IRB's jurisdiction.

I. Lead Researcher (LR) Responsibilities

The LR must take into consideration the following when recruiting students and employees as participants in human subjects research.

A. Recruitment of students by LRs who are also faculty members or instructors at UCI.

1. Lead Researchers are to advertise and recruit student participants generally, rather than recruiting individual students directly.
2. An exception to this rule may be allowed when the use of one's own students is integral to the research. For example, research into teaching methods may be allowed by the IRB when sufficient precautions have been taken to protect the student-participant (e.g., using a third party to obtain informed consent).

B. Student Participation as a Class Component

1. The IRB may approve the giving of course credit or extra credit to students who are expected to participate in research activities as part of a class curriculum only when alternative means of obtaining course credit or extra credit is made available to students who do not wish to volunteer as research participants. Students must be given other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit. For example, short papers, special projects, book reports, and brief quizzes on additional reading may be offered in lieu of research participation.
2. These research studies may not involve more than minimal risk and students must be told that they can withdraw from the study at any time without losing the extra credit.
3. The use of extra credit points for participation in research studies should be limited as a reward, used only when the research is closely tied to the course subject matter, and should not raise the student's grade by more than one-half of a letter grade (e.g., B to B+).
4. Students should be recruited through the Social Sciences Human Subjects Pool, bulletin board postings or online advertisements, rather than individual solicitations.
5. Research interventions should not be conducted during class time.
6. Lead Researchers should be cautious about recruiting students into research of a coercive or sensitive nature, (e.g., drug use, alcoholism, sexual preferences, etc.)

C. Medical School Students

1. Medical school students may only participate in research involving minimal risk and minimal interruption of time.
2. The IRB has the authority to review and approve research involving medical students. However, any IRB concerns regarding the use of medical students should be promptly forwarded to the Senior Associate Dean for Educational Affairs for review.
3. Lead Researchers should be cautious about recruiting medical students into research of a coercive or sensitive nature (e.g., drug use, alcoholism, sexual preferences, etc.)

D. Student Recruitment

Although UCI IRB approval is granted, research activities that are targeted for or designed specifically to address students from a particular Department or School may require the approval of the appropriate Dean or Department Chair before the study may commence.

E. Student Records

1. UC Irvine is subject to the provisions of Federal law known as the Family Educational Rights and Privacy Act (also referred to as FERPA). This act affords matriculated students certain rights with respect to their educational records.
2. Generally, students have the right to consent to disclosures of personally identifiable information contained in the student's education records to third parties (such as researchers). Investigators must obtain student's consent to access personally identifiable information in the student's educational records, even if consent to participate in the research may have been waived by the IRB. There are some exceptions however. See Policy # 32.

F. Employees

1. Lead Researchers should minimize the likelihood that employees who participate in research programs perceive that the decision will affect performance evaluations or job advancement.
2. Employees should be recruited through general announcements or advertisements, rather than individual solicitations.
3. Employees of a particular Investigator or laboratory should not be directly recruited for participation in any study conducted by that Investigator or laboratory, although such employees may, on their own, volunteer to participate.
4. Lead Researchers who include colleagues or subordinates as research participants should be able to provide a rationale other than convenience for selecting those individuals and should show that the recruitment methods do not lead colleagues to think that they will be compromised by not participating.

II. IRB Committee Responsibilities

A. The IRB should exercise oversight with the use of faculty, instructors, students, medical students, and employees as the targeted population in research.

B. The IRB will review the proposed involvement of faculty, instructors, students, medical students, and employees as the targeted population in research activities and when making its final determination assure that:

1. Consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence, which, clearly identify methods used to maintain confidentiality;
2. There are genuinely equivalent alternatives to participation available;
3. The selection of participants is equitable;
4. The risk of undue influence or coercion is minimized; and
5. If applicable, added protections for vulnerable populations have been assured.

C. Any concerns regarding the use of students may be promptly forwarded to the Dean of the appropriate school or Department Chair.

D. Any concerns regarding the use of medical students may be promptly forwarded to the Associate Dean for Medical Education.

III. IRB Analyst or Higher Responsibilities

A. The Analyst will conduct a pre-review of all initial applications or modifications that propose the use of students, medical students, or employees as a targeted population.

B. The Analyst will assure that the IRB Chair or Committee is aware of the inclusion of students, medical students, or employees as a targeted population.

C. If necessary, the Analyst will facilitate communication between the IRB Committee and the Dean of the appropriate school or Department Chair or the Associate Dean for Medical Education.

References:
45 CFR 46.111