Policy
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Section: Conduct of Research
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Subject: Recruitment/Advertising

Definitions:
1. Advertising: A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. Typically, this is used for recruitment purposes for a research study.
2. Finder’s Fee: Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to residents, physicians, nurses, or others in a position to identify potential participants that might qualify for enrollment into a study. The fee is paid only for participants who are actually enrolled into the study.
3. Bonus Payment: Compensation tied to the rate or timing of recruitment. Examples of bonus payments include but are not limited to the following: The sponsor announces that the highest enrolling site in the nation will receive a $10,000 bonus; The sponsor offers to pay an additional $10,000 to any site that enrolls five participants within a week; The sponsor offers to pay an additional $10,000 to any site that fulfills its recruitment target by the end of the month; The sponsor offers to pay an additional $1,000 for any subject who agrees to enroll within one day of initial contact.
4. Recruitment: Seeking individuals to enroll or participate in a research project.

Policy:
It is the policy of the Human Research Protections Program (HRPP) 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 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 an amendment 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 must 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 must review 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. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.

II. Coupons for use on products once approval for marketing is granted are never an acceptable method as a recruitment incentive.

III. 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 facility or institution of the Investigator or study coordinator (e.g. Vanderbilt);
   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;
   G. The location of the research and the person or office to contact for further information; and
   H. Payment or compensation, but the payment or the amount to be paid is not emphasized by such means as larger or bolded type (See HRPP Policy X.F).

IV. 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. Terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non FDA-approved; or
   D. Promises of "free medical treatment," when the intent is only to say that participants will not be charged for taking part in the investigation.

V. Receptionist Scripts. The first contact prospective study participants make is often with a receptionist who 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.

VI. Internet Recruitment. All advertisements and recruitment methods must be reviewed and approved by the IRB prior to implementation. The only exceptions which do not require
prospective IRB approval are the following listing services: the National Cancer Institute’s cancer clinical trial listing (PDQ), the government-sponsored AIDS Clinical Trials Information Service (ACTIS), Clinicaltrials.gov, and the Vanderbilt University Medical Center’s Clinical Trials Registry. 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.

VII. Vanderbilt Mass Communication E-mail. Advertising submitted through mass email solicitation at Vanderbilt should be simple, readable, and understandable. It should meaningfully and respectfully convey a message to a broad spectrum of the Vanderbilt community. It should be text-based and written in 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 sentences and paragraphs;
   C. Paragraph 1 – include enough information to help readers self-select;
   D. Paragraph 2 – purpose of the study;
   E. Paragraph 3 – requirements of participation;
   F. Paragraph 4 – benefit to the participant or a statement there is no benefit; and
   G. Paragraph 5 – a contact person “for more information”.

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

IX. 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.

X. Inclusion of Women, Children and Minorities. The inclusion of women, men, 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 men, women or minorities denies them the opportunity to benefit. Moreover, for purposes of generalizing research results, Investigators must include the widest possible range of population groups.

XI. 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, and health statuses. 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. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the Investigators must provide a clear rationale for exclusion of this information.

XII. Finder’s Fees and Bonus Payments. 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. In some situations, these payments are prohibited. Each situation should be reviewed to be sure that it complies with Federal regulations, ethical opinions, and HRPP policy.
   A. It is impermissible to pay or accept “finder’s fees”. Additionally, it is impermissible for Vanderbilt University Medical Center employees or students to accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.
B. It is impermissible to accept bonus payments.

C. It is acceptable to receive compensation for recruitment and screening related activities that are unrelated to whether the participant ultimately enrolls in or completes the research study (such as advertising, administrative and personnel costs). Investigators should be sure to determine a reasonable budget amount that is directly related to the value of the services provided to the study, and to document how that amount was determined. For example, individuals could be paid on a flat hourly basis for the time spent recruiting and screening potential research participants (regardless of whether they are successful in recruiting those participants) and time sheets should be kept documenting this effort. Staff should not be paid a fee for every successful recruitment (e.g., $10 for every participant who signs the consent document to participate in the study). Further, this amount should be reflected in a written agreement that is reviewed by the Office of Contracts Management.

D. This policy is not intended to prohibit renegotiation of contract fees when recruitment is progressing much more slowly than anticipated such that additional time and effort are required for recruitment activities than initially anticipated.

XIII. 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. For physicians, the Tennessee Board of Medical Examiners deems certain recruitment incentives to be unethical and unprofessional conduct, and could be subject to physician disciplinary action.

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)
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)
Tennessee Board of Medical Examiners Rule 0880-2-.13(4)(t)
VUMC Social Media Policy