THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Policy on Advertising and Recruiting for a Research Study

PURPOSE

It is the policy of The University of Texas M.D. Anderson Cancer Center Institutional Review Board System (UTMDACC IRB System) to review and approve advertisement material and recruitment methods for protocols enrolling human subjects.

POLICY STATEMENT

The IRB must assure that appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB will review all of the research documents and activities that bear directly on the rights and welfare of the participants in the proposed research, including methods and materials proposed for recruitment (e.g., advertising).

The purpose of this policy is to define the criteria investigators must utilize when advertising and/or recruiting for research studies.

SCOPE

This policy applies to all human subjects research at (or conducted with) UTMDACC.

DEFINITIONS

Advertisement - A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. Typically used for recruitment purposes.

Recruitment – Seeking individuals to enroll or participate in a research project.

RECRUITMENT & SELECTION

Recruitment and selection of participants must be **equitable** within the confines of the study. Researchers may not exclude participants on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. Recruitment methods should protect participant's confidentiality at all times.

The IRB will review recruitment methods during the initial IRB review and throughout the course of the study. Recruitment methods and the amount and type of compensation should be

described in the protocol body or a supplementary document and the informed consent document. Changes in recruitment methods will be included in an amendment to the protocol and submitted to the IRB for review and potential approval. M. D. Anderson considers recruitment materials to be part of the consent process. As such, all recruitment materials must be submitted to the IRB for review prior to use.

When obtaining the names of potential participants from third parties (e.g., private physicians office), the investigator should consider confidentiality and privacy issues. For example, private physicians must initially contact their patients for permission to release information to the M. D. Anderson investigator. Alternatively, the private physician may also request that their patient contact the M. D. Anderson investigator directly for information regarding the research.

RECRUITING M. D. ANDERSON PERSONNEL

The IRB considers this group as a population vulnerable to inducement. The recruitment of M. D. Anderson personnel into a research study is generally acceptable provided the research outlines the protections which are in place to safeguard against potential inducement to participate in the research.

The IRB generally does not allow recruitment methods to include the recruitment of staff that report directly to the investigator. If a research study must include this population, then the investigator must assure that safeguards exist in the study to protect against unfair inducement. Recruitment methods should be designed so that participation is truly voluntary and not required by the investigator.

All reasonable efforts should be made to keep the participation of M. D. Anderson personnel participating in research confidential.

COMPENSATION

Monetary or other incentives may be offered to participants, however, the amount of incentive should not be so large that it could have a potential to induce a subject into participating in the research. The crucial principle in providing compensation to research participants is the avoidance of inducement to participate in the research.

Issues the IRB will consider when reviewing recruitment incentives include:

- An evaluation of the risk of harm and benefit ratio
- Study population (e.g., MDACC patient population, public registry, relationship to investigator)
- The inclusion or absence of vulnerable populations

<u>Prorating Compensation</u>

It is appropriate to prorate compensation such that payment is provided only for those portions of the study in which the participant participated and not for those portions in which the participant did not participate.

> For example, in a study where participants are potentially compensated $60 for completing questionnaires on three occasions (i.e., $20 per occasion), it is acceptable to provide a payment of $20 for completing questionnaires on only one occasion or $40 for completing questionnaires on only two occasions.

It would even be acceptable to hold the payments until the end of the study, as long as the participants were clearly informed that if they dropped out before the final assessment point, they would receive $20 for each set of questionnaires they had completed up to that point. Recruitment materials and the consent document should be clear not to promise the total compensation where compensation is prorated per visit/procedure.

> For example, using the amounts listed above, the consent language would state “Compensation up to $60”.

The main judgment for the IRB to make in such a case is to ensure that the amount of the payment is commensurate with time and effort, and not large enough to be inducive. Any special vulnerability of participants, such as economic deprivation or age should be taken into account in such a judgment.

The principle of prorated payment is applicable regardless of the assessment modality whether it includes blood draws, medical procedures (e.g., colonoscopies), questionnaires, telephone interviews and/or computer-administered assessments.

That is, it is acceptable to provide a flat fee for each assessment commensurate with the time, inconvenience, and discomfort involved in completing that assessment.

<u>Determining the Amount of Compensation</u>

The objective of compensation is to compensate volunteers so that they are no worse off than if they had not participated in the study, rather than as an inducement to participate. There are at least four issues to be considered in determining the amount of compensation: time, inconvenience, discomfort, and the target population. Compensation should be commensurate with the amount of time, inconvenience, and discomfort involved in participating in the study. It is acceptable to provide participants

with higher compensation for participating in studies where there are larger amounts of time involved, where participation is inconvenient (e.g., utilizing ambulatory assessment strategies that require participant responding at random moments throughout the day, or requiring travel to distant study sites), and discomfort (e.g., blood draw, bronchoscopy). In addition, the amount of compensation should avoid inducement of vulnerable target populations to participate in the research. That is, compensation should not be so high as to result in a disproportionate representation from vulnerable populations (e.g., homeless or very low income populations).

Gifts and gift cards will be assessed based on their cash value. Lotteries or drawings are discouraged. It is preferred that the cash value be distributed evenly.

Additional Safeguards

It should be made clear in both the consent form and in the protocol that payment to the participant is compensation for their time, inconvenience, and discomfort only. Compensation is not to be listed as a benefit of participation, and should not be described as an incentive, or as earnings. Procedures or drugs provided without cost should not be considered a benefit or a form of compensation. Such items should be described as "provided without cost" or "at no cost to you". The word free should not be used.

Recruitment Bonuses

Payment in exchange for referral of potential participants and payment tied to the rate of timing of enrollment (e.g., a bonus payment) is prohibited.

ADVERTISMENT GUIDELINES

Advertising or soliciting for study participants is the start of the informed consent process and subject selection process. Advertisements must be reviewed and approved by the IRB during the initial review of the study. Following initial review, if an investigator decides to advertise for participants or to change the advertisement, a study amendment should be submitted for IRB approval.

The IRB will review the advertising to assure that it does not unduly influence research participants 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.

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 inducive 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 IRB will review each submission to assure that advertisements contain basic elements. Advertisements should be limited to the information the prospective participants need to determine their eligibility and interest. The following is a list of the basic elements that must be included in material when advertising for a research study.

1. Written in simple language (6-8th grade reading level).

2. Include the name, phone number and address of the clinical investigator and/or research facility.

3. State the condition under study and/or the purpose of the research. .

4. State, in summary form, the criteria that will be used to determine eligibility for the study.

5. State briefly any benefits to participation in the study. Do not overstate.

6. The time or other commitment required of the participants (e.g., number of visits, duration of study, etc.).

7. Advertisements may state that participants will be paid but should not use bold or enlarged print or other means to emphasize payment. Do not refer to payment in the header of the ad.

8. Must not promise “free medical treatment”, when the intent is only to say participants will not be charged for taking part in the investigation.

MODES OF ADVERTISING MAY INCLUDE

1. Television
2. Radio
3. Videotape
4. Print (e.g., flyers, brochures, letters to participants, newspaper articles, surveys)
5. E-mail solicitations

6. Internet websites
7. Interviews
8. Phone Calls
9. Receptionist Scripts
10. Initial Public Offering advertisements that includes language that could lead to potential recruitment of research subjects

THINGS TO AVOID WHEN ADVERTISING

The following should be avoided when advertising for a research study:

1. Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation.

2. Use of the term “new” in reference to a drug or device without explaining that the test article is investigational. A phrase such as “receive new treatment” implies that all study participants will be receiving newly marketed products of proven worth.

3. Do not use the word “medicine” when a drug is investigational or when the randomization schema includes a placebo.

4. Should not include preliminary clinical or animal data.

5. Use of the term “free” in reference to treatment or procedures.

6. Do not over-emphasize compensation or use catchy words such as fast, exciting, cutting-edge, and free.

7. Do not use extravagant attention-getting devices such as extremely large, bold typefaces and dollar signs.

8. Do not use language that may pressure readers into participating.

ITEMS THAT MAY NOT REQUIRE IRB APPROVAL

IRB approval is generally not required for the following and thus these items do not need to be submitted to the IRB for review prior to posting or distribution:

1. Communications intended to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters (even when soliciting for study participants)

2. News stories without recruitment material.

3. Publicity intended for other audiences, such as financial page advertisements directed towards prospective investors.

4. Clinical Trial listing services as outlined below:

- National Cancer Institute's Cancer Clinical Trial Listing (PDQ)
- AIDS Clinical Trials Information Service (ACTIS)
- National Institutes of Health (clinicaltrials.gov)
- M. D. Anderson Cancer Center (clinicaltrials.org)

These sites only contain basic necessary information about a clinical study (e.g., title, purpose of the study, study summary, eligibility, study site(s), and contact information) and thus IRB review and approval of listings on these sites would provide no additional safeguard.

However, when the opportunity to add additional descriptive information is not precluded by the database system, IRB review and approval may be required to assure that the additional 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.

PROCEDURES FOR INVESTIGATORS

Submit a copy of advertisements to the IRB for approval prior to dissemination. Investigators may utilize the Advertisement Form (located in the HSRM, Chapter 29).

Advertisements may be submitted either during the initial IRB review process or as an amendment to an ongoing study.

Investigators are responsible for assuring that the information listed in the advertisement contains the basic elements as outlined above.

Investigators are responsible for assuring that Sponsor approval is obtained prior to submission to the IRB, when necessary.

REQUIREMENTS FOR LISTING A PROTOCOL ON A PUBLIC WEBSITE PRIOR TO PUBLICATION

To comply with U.S. Public Law 110-85§§801, M. D. Anderson will automatically list IRB approved protocols on the www.clinicaltrials.org homepage. Information is limited to basic data contained in the M. D. Anderson abstract (e.g., study objectives, eligibility, treatment location, home care required, etc), and thus does not require IRB approval.

Industry sponsors may opt out and choose not to have their protocol listed on this site. The research staff should send an email to IRB Help@mdanderson.org and request that the protocol listing is removed.

POSSIBLE ACTIONS THE IRB MAY TAKE

The IRB may approve, approve contingent or disapprove an advertisement or recruitment method.

The IRB will issue an official approval letter to the investigator. This approval letter should be retained in the investigator's regulatory binder.

Should the IRB find that an investigator has not complied with this policy, the IRB may require actions that include but are not limited to:

- Temporary or permanent suspension of the investigator's research privileges
- Close the study to new patient entry
- Revision of the protocol and informed consent document to address additional risks or safety concerns
- Notification of research subjects
- Assignment of additional oversight of the protocol to an independent monitoring board (e.g., Data Safety and Monitoring Board or outside entity, if appropriate).

REFERENCE:

21 CFR 56.111(a)(3)
21 CFR 56.111(b)
21 CFR 50.20
21 CFR 50.25

University of Texas M. D. Anderson Cancer Center- Office of Public Affairs
http://inside.mdanderson.org/departments/public-affairs/index.html

University of Texas M. D. Anderson Cancer Center- Office of Medical Graphics & Photography
http://inside3.mdanderson.org/faculty/medgraphics/index.htm

STRATEGIC VISION: From the following, please select the appropriate goal(s) applicable to this policy and identified in the 2005-2010 Strategic Vision:

Goal 2: Enhance the quality of existing research programs and develop priority programs for the future.

Approvals:

Committee Review

Committee:	Names:	Date:
Institutional Review Board 3	Ralph S. Freedman, M.D.,	1/23/2007

	Ph.D.	