

SWOG

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Policy Memorandum No. 42
Subject: Advertising for Subject Recruitment
Departments Affected: All

Page 1 of 5 pages
Original Release Date: May 2007
Revision Date: October 2011

POLICY ON ADVERTISING FOR SUBJECT RECRUITMENT AND TRIAL PROMOTION

When Federal human subject protections were established in the 1970s, a key principle was that there should be clear distinctions between research and industry. Subjects should participate in research out of a desire to contribute to generalizable knowledge and they should understand that any personal benefits were secondary. Central to participation was an assurance that the subjects understood the risks inherently involved in research. Since these protections were created, the lines of distinction have blurred, with subjects now often viewing access to clinical trials as the best hope for effective therapy, and with the growth of multi-site trials making it ever more imperative to recruit large numbers of research subjects.

To ensure that subject protections remain forefront, the U.S. Food and Drug Administration (FDA) requires that an Institutional Review Board (IRB) review and have authority to approve, disapprove, or require modifications in activities covered by the IRB regulations and that appropriate safeguards exist to protect the rights and welfare of research subjects. Such responsibilities require IRB review of all the research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research. Federal regulations consider advertising for subject recruitment to be the first step in the informed consent process, so an IRB must review and approve all methods and materials used to recruit research subjects.

This policy addresses the handling of patient recruitment methods and materials concerning SWOG-coordinated or endorsed studies where such advertising will be part of the protocol package or amendment or will be used at any additional time during the trial, and where these advertisements are either 1) distributed or funded by a pharmaceutical company (see Collaborating with Industry Partners on Trial Promotion below) for use by all sites, or 2) where Group funds are used for the cost of creating or employing study advertising. As a reminder, in addition to any Group review process, each Participating Investigator must submit subject recruitment information to his/her institution's IRB for review and approval. Member or affiliate sites may have policies or procedures that must be followed in addition to, or that may be more restrictive than, this Group policy concerning advertising for subject recruitment.

While it is common for investigators to discuss proposed or potential SWOG clinical trials with their patients, it is requested that investigators make no guarantees of trial activation. On occasion, Group clinical trials are not activated or have a delayed activation for various reasons including based on the Group's main concern for the safety of study participants.

The Group Review guidelines described in this policy do not apply to individual advertising efforts which a participating investigator may utilize at his/her own site outside of Group-sponsored, required or subsidized advertising; rather, such individual advertising would only require the review of the IRB at the participating investigator's site.

Collaborating with Industry Partners on Trial Promotion

SWOG and industry partners often have a shared interest in enhancing accrual to a given clinical trial, but differing goals of each side can make it a challenge for SWOG to ensure its own interests and priorities remain paramount when collaborating in this area.

The following principles should guide SWOG collaboration with industry partners on accrual enhancement and marketing efforts:

- SWOG is not a contract research organization (CRO) available for hire to industry.
- Communications, advertisements, accrual enhancement activities, and educational efforts related to SWOG trials must be controlled by SWOG.
- Industry representatives should not be seen as representing SWOG at member institutions or as acting on SWOG's behalf.
- Industry representatives should not approach SWOG sites on SWOG trial business unless invited to do so by the site or by SWOG's leadership.
- SWOG will decide internally which trials are highest priority for accrual enhancement efforts. Industry support alone should not privilege a trial among SWOG's portfolio of studies.

Below are some specific guidelines based on these principles governing collaboration in marketing SWOG trials.

Industry Interaction with SWOG Clinical Sites

Industry partner representatives may not approach SWOG sites with the primary purpose of promoting a SWOG trial, though they may incidentally discuss SWOG trials at a site when they are there for purposes of their own commercial relationship with the site.

Industry partner representatives may not distribute SWOG literature at SWOG sites.

If an industry partner would like to approach SWOG sites to conduct training related to a SWOG trial, the SWOG Group Chair's Office will first query sites as to their preferred training venue – a site visit from an industry representative, or a group training session online or at the semiannual group meeting. SWOG will then send to the industry partner the contact info for those sites that have requested a visit and/or will work with the partner to schedule a group training session.

Industry Support for SWOG Educational and Promotional Efforts

SWOG welcomes industry collaboration in developing strategy and content for educational and trial promotion efforts.

Industry partners may provide direct funding to the Group Chair's Office to support specific SWOG education and trial promotion efforts, or with SWOG review and approval, they may undertake such efforts directly themselves (e.g., running trial ads).

For large-scale efforts involving significant industry partner support, SWOG may propose that the partner make a restricted grant to The Hope Foundation to fund those efforts.

Partners may not engage outside consultants to conduct marketing efforts for SWOG trials without written approval from the SWOG Group Chair's Office.

Forms of Subject Recruitment:

Direct advertisements for recruiting potential research subjects can take many shapes. Examples include: flyers in a hospital hallway or on a student union bulletin board; newspaper, radio or television ads; direct mailings; electronic mail announcements; postings on websites; brochures in a patient waiting area; communications to referring physicians designed to be passed on to potential subjects; and automated telephone message systems that play outgoing recruitment messages to patients while they are on hold or that are programmed for study subject triage and intake. Yet another form would be a press release designed to publicize a trial that is open to new or ongoing subject accrual. Not included, however, in the perimeter of direct advertising are 1) communications intended to be seen or heard only by health professionals (e.g., "dear doctor" letters and doctor-to-doctor letters, even when soliciting for study subjects) and 2) clinical trial listings on the internet where the system format limits the notice to basic trial information (title, purpose, protocol summary, basic eligibility, study site location, and contact information), e.g., CTSU, PDQ, etc.

By Federal law, an IRB is required to protect the welfare of human subjects participating in research and, specifically, to determine that the selection of subjects to participate in the project is equitable and free from coercion. As an essential part of this process, an IRB must review and approve any advertisement for recruiting subjects to a research project before it can be distributed to potential participants. FDA guidance advises that, "The IRB should review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects."

Group Review:

At the point that it is determined (either by the applicable Disease Committee or Study Coordinator) that subject recruitment for a particular trial would be best implemented through use of advertising, this decision should be communicated to the applicable Protocol Coordinator. The Protocol Coordinator will then report the decision to both the Director of Operations and the Group Chair or his/her designee so that such parties can make a decision concerning the request for the use of advertising for the particular study. If the advertising request is approved, the Director of Operations and Group Chair/designee will be involved in the handling of requests or allocation of Group funds and/or negotiating of any advertising contracts, letters of agreement, invoices, etc.

To best ensure that any study advertising appropriately protects potential subjects, that it fits the intent and requirements of the protocol, that the Group's image is not jeopardized, and that Group resources are used efficiently, any and all subject recruitment or study advertising which is provided or intended for Group-wide use or created using Group funding or resources, shall be first reviewed and approved by the Group Chair, or his designee(s), located at the Group Chair's Office.

Specifically, the Group Chair/designee must review the information contained in the advertisement and the mode of its communication to determine that the procedure for recruiting subjects 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 Group Chair/designee 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 Group Chair/designee must be provided the opportunity to review and approve the script of the advertisement prior to the taping to preclude re-taping because of inappropriate wording and must review the final audio/video tape as well.

Any required modifications or further inquiry into the advertisement will be communicated from the Group Chair/designee to the relevant Disease Committee Chair or Study Coordinator, with simultaneous notification to the Protocol Coordinator and Operations Office Director. The Group

Chair/designee must approve the advertisement, either in its original or modified state, before the advertisement may be forwarded for review to any IRB.

Advertisement Guidelines:

The general tenets of review to be applied by the Group Chair/designee are based on FDA commentary. Specifically, the FDA believes that any advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the FDA has determined that the following items, although not required, may be included in advertisements:

- Name of research facility/clinical investigator;
- Purpose of the research and eligibility criteria (briefly stated);
- Time commitment and remuneration/benefits;
- Contact person for more information;
- The word "research" somewhere prominent in the advertisement.

Advertisements should not include: (1) Claims, explicit or implicit, that the drug, biologic procedure or device is safe or effective for the purposes under investigation or that the test article (drug, biologic, procedure, device) is known to be equivalent or superior to any other drug, biologic, procedure or device; and (2) References to "new treatment", "new medication", "new procedure" or "new drug" without explaining that the drug, biologic, procedure or device is investigational. All advertisements should be tastefully composed and not inappropriately emphasize monetary remuneration. The following is a list of some of the dos and don'ts of subject recruitment advertising:

Do:

- Use the word "Research" in your advertisement, the terms "Study" or "Treatment Study" do not convey the same message
- Provide information prospective subjects need to determine interest, such as eligibility, significant study procedures, and time commitment
 - males, females, adults, children, age range, taking no medications, etc.
 - x-rays, MRIs, exercise testing, overnight stays, frequent blood sampling, etc.
 - duration of study, number of visits and/or length of visits, if only one or two visits
- Use "healthy volunteers" instead of "normal volunteers"
- Use simple lay language without acronyms or abbreviations unless these are well known to the public or to the special patient group you are targeting, e.g., patients with ALS or women with PMS will understand these abbreviations
- Provide simple symptom complexes if you are looking for subjects who do not already carry the diagnosis
- Provide basic exclusion criteria whenever possible to reduce unnecessary calls
- Use the word "investigational" rather than "experimental"
- Name drugs used if approved and/or known to the public, e.g., aspirin, St. John's Wort
- Use the words "at no cost" rather than "free" where relevant
- Specify amount of monetary compensation (if you wish)
- Use the words "up to" if pro-rated compensation is likely
- Specify hospital affiliation (e.g. Cardiovascular Division)
- Indicate where the ad is going to be placed/posted, if the same text will be used for email, newspaper, fliers, etc.
- Submit printed ads as they will appear in print (or as close as possible) so a review can assess the visual impact, emphasis and graphic message

- Submit the full text of radio or television ads

Don't:

- Feature monetary compensation as a lead-in before the description of study purpose and procedures
- Bold, italicize, underline or enlarge fonts on type describing monetary compensation
- Imply treatment benefit if the primary focus of the study is safety and tolerability, drug kinetics, or basic physiological processes rather than efficacy
- Imply treatment benefit for chronic problems if the study involves only short-term interventions
- Emphasize no cost treatment if a placebo is involved (you don't need to explicitly state that placebos are used in ads) and/or the protocol involves drugs, biologics, or devices not FDA approved for the condition under study
- Provide detailed lists of risks and benefits (this should be done in person)
- "Hype" the study with overly optimistic or effusive language implying benefit (commercially designed radio ads occasionally do this)
- Use words describing broader affiliations which tend to mistakenly convey endorsement and/or direct oversight of study treatments and procedures by a university, hospital, clinic or medical school

Again, in addition to any Group review process, each participating investigator must submit subject recruitment information to his/her institution's IRB for review and approval. Member or affiliate sites may have policies or procedures that must be followed in addition to, and that are possibly more restrictive than, this Group policy concerning advertising for subject recruitment.

For additional information regarding federal guidance see:

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>.