

HAC Policies and Procedures

Recruitment Process (Advertisements, Flyers, Brochures, and Recruitment Plans)

Can We Advertise For Subjects?

Yes. Under Federal Regulations [21CFR 56] all announcements and advertisements including e-mail and bulletin board notices, posters, etc., involving research study subjects must be reviewed and approved by the HAC.

What Is The Recruitment Process?

The recruitment process includes all aspects of recruiting and retaining subjects in the research study. Examples of recruitment processes that must be approved by the HAC in their dual role as the IRB and the privacy board are:

- Advertisements (e.g., printed ads newspapers, fliers, inserts, bulletin boards notices, etc., or ads for the radio, television and/or web postings).
- Subject testimonials or experience sharing for a specific study.
- Community organization speaking about a specific study.

Is Advertisement Part Of The Recruitment And Informed Consent Process?

Yes. Announcements and/or advertisements may not be utilized until the study, and the individual announcements and/or advertisements have written HAC approval.

Do We Have To Say Where The Advertisements May Be Posted, Shown, Broadcast, Printed, Etc.?

Yes. The DRP must indicate where the advertisements will be used or placed.

What Can Be Included In The Advertisement?

The announcement or advertisement should be limited to:

- Investigator's (PI) name, address and telephone number Principal
- study and eligibility criteria Purpose of the
- description of the benefits (e.g., payments, free treatment, *etc.*) A truthful
- research and contact person Location of
- HAC file number

What Cannot Be Included in the Advertisement?

The announcement or advertisement cannot include the following:

HAC Policies and Procedures

- A statement or implication of a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Exculpatory language
- Emphasis of the payment or the amount to be paid, by such means as larger or bold type
- Promise of “free treatment” when the intent was only to say subjects would not be charged for taking part in the investigation.
- For FDA-regulated research:
 - Claims, either explicitly or implicitly, about the drug, biologic or device under investigation that were inconsistent with FDA labeling.
 - Use of terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational.
 - Allowance of 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 had been approved for marketing.

Are There Any Special Requirements For MCG Advertisements?

Yes. The Medical College of Georgia (MCG) printed announcements or advertisements must include the official MCG seal in compliance with the trademark and size. The Clinical Trials templates or the Clinical Research templates for advertisements, brochures, and/or fliers provided by the Office of Strategic Communications must be used. Refer to the Recruitment Templates

Who Reviews the Advertisement?

The Human Assurance Committee will review the advertisement for accuracy and compliance with federal regulations. The HAC Administrative Office staff will send the advertisement/brochure/flier to the MCG Graphics Standards Committee for their review and approval. Do not send the advertisement/brochure/flier directly to the MCG Graphics Standards Committee. According to MCG policies, the Graphics Standards Committee in addition to the HAC must approve all announcements and advertisements involving MCG personnel or facilities.

Will Revisions Be Required?

Revisions to the advertisement/brochure/flier may be required by the Graphics Standards Committee and/or the HAC. The HAC Administrative Office staff will notify the investigator or designee of the required revisions. Once the revisions are made and re-submitted to the HAC, the HAC Administrative Office forwards the corrected document to the Graphics Standards Committee for their final approval. Please remember that a letter of HAC approval will not be sent to the investigator until the HAC receives approval from the Graphics Standards Committee.

Does The HAC Have An Approval Stamp For Printed Recruitment Materials (e.g., Advertisements/Brochures/Fliers)?

HAC Policies and Procedures

Approved announcements or advertisements will bear a stamp of approval from the HAC. Any bulletin board notices must use the HAC stamped approved copy of the advertisement or state that the stamped approval is on file in the regulatory documents.

What About The Large Ad Campaigns Of The Sponsor? Do We Have To Submit Those to the HAC?

Yes.

What Do We Do If We Need To Revise A Previously Approved Ad?

Revisions to previously approved ads must be submitted to the HAC as an amendment using the HAC Form 113, Amendment Submission Form, for approval prior to placement.

What About TV Or Radio Ads?

Written scripts for television, 800 referral lines or radio ads must be submitted to the HAC prior to the placement of such ads. The HAC must approve these types of recruitment methods as well. The Graphics Standards Committee may also have to review these items.

Are There Any Hints For Advertisement?

Hints for advertisements:

- Use proper grammar.
- Be certain that the advertisement is written so that the target audience can understand it.
- Be certain that the advertisement is not coercive.
- Use the advertisement/brochure/flier templates.
- If the ad was previously approved by the HAC and/or Graphics Standards Committee for another study, please include that information with the ad.

Do Letters To Referring Researchers or Clinicians Constitute Advertising?

Yes. Letters to fellow physicians providing notification of the study do require prospective HAC approval.

What About Direct Mail Letters To Prospective Subjects?

Direct mail letters to potential subjects do require prospective HAC approval.

HAC Policies and Procedures

If HAC Approved Ads Will Be Posted On Bulletin Boards On And Off Campus, Should The Copy With The HAC Approval Stamp Be Posted?

Yes. The only exception would be the large ad campaigns from external sponsors. In these instances, the site should maintain an original stamped version of the ad in their regulatory documents. The posted announcements may be posted without the HAC approval stamp.

Can An Ad Approved For A Previous Study Be Re-Used For Another Study Without Re-Approval From The HAC?

No. Each ad has to be submitted to the HAC for approval prior to its use for a specific study.

This Is A National Ad Campaign That Can't Be Changed. Does It Still Need HAC Approval?

Yes.