

Advertising and Recruitment Materials

Why do advertising and recruitment materials require prospective IRB approval?

Because recruitment is the initial step of the informed consent process, prospective IRB approval is required for any advertising or recruitment materials used for subject recruitment into a study. This includes:

- Letters of invitation
- Scripts for telephone or other personal contact
- Flyers, posters, newspaper ads, press releases
- TV and/or radio spots
- Websites/internet ads
- Electronic mailings

The IRB Chair or designee will review these materials as part of the initial review or as amendments/changes to the protocol. If an ad will be posted on the Internet, the Internet address (URL) and/or print-out of the webpages/internet ad must be provided with the submission so that the IRB can verify the website content.

Any changes to the initial approved method of recruitment or materials used for recruitment must be submitted to the IRB for review and approval prior to use. As advertising and recruitment materials are subject to ongoing review, they should be submitted along with other submission documents and materials at the time of continuing review.

What are the content requirements for advertising and recruitment materials?

Advertising and recruitment materials must clearly state that the purpose for recruitment is “research.”

In addition, the materials should generally contain the following elements:

- The name of the investigator or research facility (letterhead is acceptable)
- The condition under study and/or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- The location where the research will be conducted
- Time or other commitments required by the study
- Indication of whether subjects will be reimbursement for time and expenses (do not include the amount)
- The person or office to contact for further information

Additional requirements:

- Information in the advertising or recruitment materials must be consistent with the protocol and consent document
- Use of language that may pose undue influence, such as: “Want to earn some easy money?” or use of dollar signs - “\$\$\$\$\$\$” - as a header, may not be used
- Information in the recruitment material must not be misleading to the subjects
- If the target population involves children or the cognitively impaired, the information should address parents or legally authorized representatives, as appropriate.

- Special requirements for drug, device, or biologic studies:
 - The advertisement may not claim the superiority, safety or effectiveness of the investigational drug or device
 - The terms “new treatment,” “new medication,” or “new drug” may not be used because it inappropriately implies that safety and effectiveness have been determined. It must be clear that the drug or biologic is investigational, meaning non-FDA approved. Proprietary names of study products may not be used
 - Advertisements or recruitment materials must not contain the promise of “free medical treatment” when the intent is only to say the participants will not be charged for taking part in the research

What about finder’s fees - are they permitted?

Finder’s fees and other financial incentives paid by a sponsor or by an investigator to individuals in return for the recruitment of research subjects are prohibited. No one may receive any incentive for the purpose of encouraging individuals to participate in research.

Can you provide an example of an acceptable recruitment flyer?

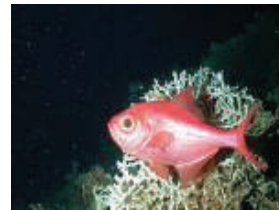
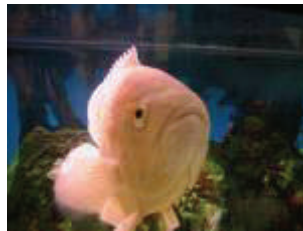
An example of an acceptable recruitment flyer is provided on page 3.



Sample of an acceptable recruitment flyer

VOLUNTEERS NEEDED
for a research study

“Improving Image Database Search Strategies”



The study is open to adults 18 and older.

The purpose of the study is to better understand how people organize pictures in order to improve image database search strategies.

Participation involves sorting 250 selected images into categories.

Time commitment: One visit that lasts approximately 2 hours.
You will be reimbursed for your time and travel expenses.

The research will be conducted at the University at Buffalo, North Campus
For additional information, contact Harriet Pxxxxx: at 888-8888
or email Harriet at: hpxxxx@xxxxxxx

Principal Investigator: Dr. Samantha Dxxx, PhD
University at Buffalo, Psychology Department