Recruitment tools (advertisements, etc.) are required to have IRB review and approval prior to implementation. When reviewing recruitment tools the IRB must review the final mode of its communication, including the final copy of printed advertisements and the final audio or video advertisements.

Only IRB approved advertisements, considered fair, honest and appropriate by the IRB, may be used in the conduct of subject recruitment. Recruitment materials should be included with your initial application. If the material is not ready at the time of the initial application, investigators may submit the material as an amendment to an already approved project. Requests for approval of recruitment materials following initial IRB review of the protocol should allow sufficient time for any necessary revisions prior to publication. Advertisements, press releases, etc., may qualify for expedited review.

When recruiting subjects from another institution with an IRB, investigators are required to gain IRB approval from that institution. In institutions without an IRB, investigators are required to obtain a letter of agreement on the facility’s letterhead indicating the research can be conducted at the site and the agency or institution will review, abide by and comply with the procedures approved by the UofL IRB.

A recruitment tool informs potential subjects of a research activity and provides them with an opportunity to contact the researcher. A recruitment tool may include, but is not limited to, post-cards, flyers, advertisements, press releases, brochures, and postings on the Internet.

Investigators are required to use the following guidelines when developing recruitment tools:

1. name and address of the clinical investigator and/or research facility (letterhead is acceptable).
2. the condition under study and/or the purpose of the research.
3. in summary form, the criteria that will be used to determine eligibility for the study.
4. a brief list of the benefits of study participation, (if any) i.e. a free health examination.
5. time or other commitments required.
6. the location of the research and the person or office to contact for further information;
7. in drug or device studies, no claim should be made as to the superiority, safety or effectiveness of the drug or device. Proprietary names of study products may not be used.
8. do not provide excessive monetary or other incentives that could be interpreted as inappropriate or coercive.
9. tools are consistent with protocol.

The recruitment tool should not:

1. state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
2. include exculpatory language.
3. emphasize the payment or the amount to be paid, by such means as larger or bold type.
4. promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the investigation.
When following FDA regulations and guidance the recruitment tool should not:

1. make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
2. use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
3. allow 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 has been approved for marketing.

Due to contractual obligations, recruitment tools should not include any proprietary identifiers, contain therapeutic or outcome claims or mention the corporate sponsor by name.

An investigator may request assistance from the HSPPO in developing UofL Today submissions to ensure that their announcement meets the above guidelines as well as the 75 word limit impose by UofL Today.

IRB Review of Research Websites

When information posted on a research website goes beyond directory listings with basic descriptive information, such information is considered part of the informed consent process and therefore requires IRB review and approval.

Basic descriptive information includes:

1. study title
2. purpose of the study
3. protocol summary
4. basic eligibility criteria
5. study site location(s), and
6. how to contact the study site for further information.

Information exceeding such basic listing information includes descriptions of study risks and potential benefits, or solicitation of identifiable information. If you wish to use a website to recruit subjects for a study and more that the above basic information is included, you must have IRB approval of the website prior to making it available to the public.