Policy for Subject Recruitment Materials and Advertising
implemented March 25, 2015

Outreach to the general public for subject recruitment efforts is considered to be the first point of contact in the informed consent process. Actively advertising for research studies for the sole purpose of soliciting subject participation is not, in and of itself, an objectionable practice. When done correctly and under the guidance of an institutional review board, it can be a successful mechanism for study recruitment efforts.

Because recruitment is considered part of the informed consent process, the Weill Cornell Medical College Institutional Review Board (WCMC IRB) must review and approve all recruitment methods, as well as the content of the recruitment materials. Recruitment activities cannot be initiated until approval is received from the IRB. In addition, any changes to an approved recruitment tool must be submitted to the IRB for review as an amendment prior to implementing the changes.

The Joint Clinical Trials Office (JCTO) has established the following policies for utilizing advertising in seeking subjects to participate in research studies at WCMC/NYP.

Materials for advertising (paid and free) **might** include, but are not limited to:

- Flyers
- Posters
- Brochure
- Newspaper
- Table tents
- Postcards
- Websites
- Social Media
- Online banners
- Video blogs
- Podcasts

Investigators **are required to** prospectively provide the IRB with recruitment materials to be used in identifying potential subjects including:

- Content, including online sites
- Avenue of communication activities
- Final copy / audio / video of materials

Advertisements **must** include:

- Simple to understand lay language
- Words ‘research study’ to appear at or immediately near the top / beginning
- Main purpose of the research
- Basic eligibility criteria
- Tests / procedures spelled out (no acronyms)

http://irb.duhs.duke.edu/wysiwyg/downloads/Advertisement_Guidelines_93.pdf accessed March 6, 2015
http://www.hhs.gov/ohrp/policy/clinicaltrials.html accessed March 9, 2015
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm accessed March 9, 2015
updated 11/17/15, 7/12/16

- Study contact details (PI and/or research nurse or study coordinator) – name, phone, e-mail (if using a study e-mail address it must be @med.cornell.edu; Gmail, Yahoo, Hotmail, AOL, etc. are **not** allow)
- IRB protocol number and approval beginning / end date

Advertisements **may** include:

- Experimental / investigational drug (not approved by the FDA) – if applicable
- Placebo controlled study (i.e. inactive drug) – if applicable
- Brief list of potential benefits utilizing conservative language (not overpromising)
- Timeframe of commitment (e.g. one visit, once a week for 12 weeks, etc.)
- Compensation (no bolding or text larger than other content) – if applicable
- Study-related and/or all medical care included – if appropriate

Advertisements may **not** include:

- Language implying a favorable outcome or other benefits other than as approved in the informed consent form and protocol
- Claims that the drug or device is safe or effective for the purposes under investigation
- Claims that the test article is known to be equivalent or superior to any other drug or device
- Language such as "new treatment, drug or medication" without explaining test article is investigational
- "Free medical treatment" when the intent is only to say subjects would not be charged for taking part in the study

In accordance with the OHRP and FDA guidelines, the IRB **does not** require review or approval for brief Internet advertisements / postings when information is limited to the following information:

- Study title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s) and how to contact the site for further information

This practice is consistent with the current guidance on posting to the JCTO clinical trials website. It is important to note that informed consent and IRB approval must be obtained if any individually identifiable information will be used or obtained as part of the recruitment activities.

Recruitment materials are submitted for review and approval via the WCMC eIRB system (requires network or VPN access). We highly encourage you to include all documents in the initial submission in order to avoid potential delays in recruitment efforts during the study.

Upon receiving IRB approval, advertisements may be posted off campus, as appropriate, as well as on the WCMC & NYP campus in the following designated areas and publications:

http://irb.duhs.duke.edu/wysiwyg/downloads/Advertisement_Guidelines_93.pdf accessed March 6, 2015
http://www.hhs.gov/ohrp/policy/clinicaltrials.html accessed March 9, 2015
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm accessed March 9, 2015
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- WCMC – News & Community listservs, JCTO website via Clinical Trials Summary Template, physician / clinic offices (with permission)
- NYP – Emergency Room (with permission, predetermined locations), display frames near most elevators (must include date posted, limited to two week intervals and can be reposted), bulletin board outside cafeteria, staffed table in cafeteria or Starr lobby

Please remember to retrieve or replace your materials after an amendment, continuing review or study termination.

Of note: Materials are **prohibited** from being posted or placed on walls, and in lobbies, restrooms, stairwells, hallways, and elevators except in display frames / locations designated for such announcements. In particular, flyers may **not** be taped to walls or elevators. Investigators and their research staff are required to adhere to these policies, non-compliance may result in the IRB / JCTO taking action to suspend subject recruitment for a study or an investigator.

For more information about recruitment guidelines and policies please visit the WCMC Office for Research Integrity, Office for Human Research Protections and the Food and Drug Administration.

For information about IRB approval for recruitment materials, please contact:	For information about posting recruitment materials, please contact:
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http://irb.duhs.duke.edu/wysiwyg/downloads/Advertisement_Guidelines_93.pdf accessed March 6, 2015
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