INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 01/14/2014
Revision No.: 4
Effective Date 12/01/2016

TITLE: Institutional Review Board Review of Research
RR 409 Review of Research Advertisements and Research Recruitment Materials

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects (21 CFR 56.107 (a) and 56.111). In fulfilling these responsibilities, an IRB is expected to review all research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The IRB should also review the methods or materials used to recruit subjects. This policy describes the expectations for submission and review of recruitment methods and materials.

GENERAL PROVISIONS: The IRB must review advertising that is to be seen or heard by prospective participants to solicit their participation in a study. This allows the IRB 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 protocol. Any advertising may be considered a part of the informed consent process. Mercy Health Regional IRB will review all advertisements, patient information documents and scripts to be used to ensure that the information provided to potential subjects is accurate, non-coercive and the content does not violate any regulations concerning claims made.

Submission of recruitment materials to Mercy Health Regional IRB must be done through the IRBManager electronic submission portal.

Types of Advertisements and Recruitment Materials:

Print Advertisements (brochures, posters, ads)
For print advertisements, a copy of the print ad must be submitted in the format it will appear in order for the reviewer to review the layout of the advertisement as well as the content.

For large multi-site studies, the sponsor may provide a package of recruitment material for the sites to utilize. Each site must submit the package to the IRB for review and approval prior to the use of any of the materials. Each site choosing to use the recruitment materials should update the materials to include their site specific information such as clinic name, location, telephone/contact information, compensation information and any other specific information pertaining to the site, taking care not to alter the layout or the size of the sponsor's pre-designed advertisement.

Recruitment Scripts:

Radio and television advertisement scripts: must be first submitted to Mercy Health Regional IRB for approval. After the script has been approved, a final copy can be produced. A copy of the final product (CD's for radio and DVD's for television ads) should be submitted to Mercy Health Regional IRB (when available) for approval before the use of the advertising or recruitment begins. The investigator or sponsor must submit with the copies of the advertisement or recruitment materials a written statement of where the copies of the materials will be posted, shared and stored and who has access to the copies and any plans for future broadcasts other than those approved by the Mercy Health Regional IRB.
Institutional Policy & Procedure

All advertisements and recruitment materials must be submitted before they are used, and all advertisements and recruitment materials cannot be used until they are approved by Mercy Health Regional IRB.

Advertisements and recruitment materials provided in the original submission will be reviewed with the initial study submission. Mercy Health Regional IRB will notify the investigator or sponsor in writing of any revisions before approval can be granted. Reference to the approved advertisements and recruitment materials will be provided in the initial approval letter and signed by the IRB chairperson.

Advertisements and recruitment materials submitted after the initial review will be reviewed within 5 business days, and Mercy Health Regional IRB will notify the investigator or sponsor in writing of any revisions required before approval can be provided. When submitted materials are found to be acceptable the Mercy Health Regional IRB will issue an approval letter and will reference the specific approved recruitment materials and advertisement(s).

Mercy Health Regional IRB must review any revision(s) made to a previously approved advertisement or recruitment materials that could affect its impact as required in 21 CFR 56.108(a)4. These include test changes, other image changes such as pictures, font or size.

Patient educational materials, study posters or pamphlets are considered recruitment materials and must be reviewed and approved by Mercy Health Regional IRB prior to use.

A copy of all advertising or recruitment materials along with the IRB, investigator, and sponsor correspondence will be kept in the IRB files for the study.

The initial application will collect detailed information regarding the plan to use any recruitment materials/advertisements/tools and the methods to be used for recruitment.

REFERENCES:
- 45 CFR 46
- 21 CFR 56.108(a)4

ATTACHMENTS:
RR 409-A Checklist for Review of Advertisements and Recruitment Materials

PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
</table>
| IRB Specialist/IRB Coordinator | 1. Review all incoming recruitment and advertisement submissions and ensure the submission package is complete and ready for review.  
2. Provide review package to IRB Chairperson or their designee for review along with the RR 409-A checklist. |
| IRB Chairperson or their designee | 1. Review incoming recruitment and advertisement materials and methods and issue approvals or denials, as appropriate. |

CONCURRENT CONSENTS:
Institutional Official [Signature]

Version Date 11/04/2016