TITLE: Guide to Creating and Submitting Advertisements/Recruitment Materials to the CHS CIRB		POLICY/PROCEDURE NUMBER: IRB 14	
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Supersedes:		Issued By:	CHS CIRB
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

The use of direct advertisements to recruit potential research subjects is the beginning of the process of subject selection and informed consent. The Community Healthcare System Central IRB (CHS CIRB) must review the methods and content of the material that investigators propose to use to recruit potential research subjects to ensure adequate subject protection. The goal of the review is to ensure that recruitment procedures are informative, but not coercive or misleading, and do not imply an outcome or benefit for participants unless it is also described in the study protocol and consent document. Additionally, the advertisement should not falsely imply or suggest that research is treatment. Overall, the advertisement should be limited to the information that prospective subjects need in order to determine their eligibility and whether they may be interested in participating in the research.

All clinical trial advertisements/recruitment materials that have been developed by a local investigator must be approved by Marketing and Public Relations prior to submission to the CHS CIRB.

Clinical trial advertisements/recruitment materials that have been developed by a sponsor must be reviewed by the CHS CIRB prior to use.

The wording of all advertisements/recruitment materials must be exactly as approved by the CHS CIRB.

DEFINITIONS:

Direct advertisements/recruitment materials are those materials intended to be seen or heard by prospective subjects in order to solicit their participation in a study. They may include, but are not limited to:

- Written scripts,
- Mailings,
- Printed flyers,
- Posters,
- Newspaper advertisements,
- Press releases,
- Television and radio spots,
- Videotapes,
- Web pages and
- Electronic mailings

The following types of advertising are not within the FDA definition of direct advertising and should not be submitted to the CHS CIRB for review:

- Communications intended to be seen or heard by health professions, such as “dear Doctor” letter and doctor-to-doctor letters (even when soliciting for study subject)
- News stories and publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

INTERNET POSTINGS

In keeping with DHHS and FDA Guidance, the CHS CIRB has determined that review and approval of listings of clinical trials on the internet is not required when the system format limits the information to the following:

- The Title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s)
- How to contact the site and/or the person for further information

Examples of clinical trial listing services that do not require prospective CHS CIRB approval are:

- National Cancer Institute’s Cancer Clinical Trial Listing (PDQ)
- Government sponsored AIDS Clinical Trials Information Service (ACTIS)
- National Institutes of Health (NIH) ClinicalTrials.gov

When information posted on a clinical trial website goes beyond directory lists with the basic descriptive information listed above, such information is considered part of the consent process and therefore requires CHS CIRB review and approval. Information exceeding the basic descriptive information includes description of trial risks and potential benefits, or solicitation of identifiable information from potential research subjects.

GUIDANCE ON DEVELOPMENT OF MATERIALS

The content of advertisements should be limited to:

- The name and address of the Principal Investigator
- A statement about where the study is being conducted
- A statement about who is sponsoring the study
- The purpose of the study clearly stating that the project is research and includes the use of an investigational drug or device, if applicable
- A brief description of the eligibility requirements
- A straightforward description of any benefits to study participation. These should not be overstated.
- A brief list of procedures involved
- The time or other commitments required of participants; number of visits, duration of study, etc.
- Any compensation or reimbursement. May state that subjects will receive compensation but should not use bold or enlarged print or other means to emphasize payment or the amount to be paid. Do not refer to payment in the header. Alternatively, the advertisement may simply state; “Compensation will be provided”
- The person to contact for further information

The advertisement should avoid:

- Claims that imply that the safety or effectiveness of an investigational drug, biological or device has been determined or is equivalent, or in any way superior, to any other drug or device
- Use of the term “new” in reference to a drug or device without explaining that the test article is investigational
- Promises of “free treatment”, when the intent is to say that subjects will not be charged for taking part in the investigation
- A statement or an implication of CHS CIRB or Community Healthcare System’s endorsement of the study.

- Statements that may be considered exculpatory or coercive
- The use of any inappropriate pictures or images that would be inconsistent with equitable subject recruitment
- Statements that may imply certainty of a favorable outcome or other therapeutic benefits beyond what is outlined in the consent document or protocol
- Overemphasis on payment as an enticement to enroll, e.g., indicating the amount for payment in a larger font than other text or in bold type.
- Offers of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it had been approved for marketing
- Exhibition of the ad in inappropriate venue; hallways, restrooms, stairwells, elevator, etc.

References:
21 CFR 56.109
21 CFR 56.107 and 56.111
21 CFR 56.110
21 CFR 812.7 and 312.7
45 CFR 46.111

ACCEPTED BY:

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DATE REVISED: 7/2010, 11/2017

REVIEWED BY: CHS CIRB 4/12/05, 6/2009, 9/2010, 8/2013, 3/8/2016, 11/2017, 4/2020

Date	Initials
6/2009	JL
9/2010	JL
3/2013	JL
2/2016	JL
11/2017	JL
4/2020	JL