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Owner	Dawn Benson: SVP, General Counsel
Area	Institutional Review Board (IRB)
Applicability	Phoebe Putney Memorial Hospital
Reference Tags	Policy

Subject Recruitment and Review of Advertisements

Scope:

This policy applies to Phoebe Putney Health System, Inc., and its affiliates, including Phoebe Putney Memorial Hospital, Inc., Phoebe Physician Group, Inc., Phoebe Sumter Medical Center, Inc., and Phoebe Worth Medical Center, Inc.

Purpose:

This policy describes the Institutional Review Board's procedures for review of study advertisements and/or subject recruitment materials submitted to the Phoebe Putney Memorial Hospital, Inc. Institutional Review Board ("IRB").

Definitions:

Policy:

Research projects often involve recruiting potential participants using a variety of methods. Some of the more commonly used recruitment methods include flyers, posters, brochures, media advertisements, recruitment letters and word-of-mouth recruiting.

Recruitment of study subjects is part of the informed consent process; therefore, the recruitment and

advertising methods must be reviewed by the IRB prior to their use by an investigator. The review is done to ensure that the information is not misleading to subjects.

It is also the responsibility of the IRB to determine that the procedure for recruitment is not coercive and that it accurately describes the likely risks and benefits of study participation. In addition, Federal Regulations states that selection of subjects must be equitable.

Procedure:

The following procedures are for researchers whose studies involve advertising and recruiting participants for their studies. These are consistent with requirements published by the U.S. Department of Health and Human Services.

1. Advertisements and recruitment materials should be limited to the information prospective participants need to determine their eligibility and interest such as:

- The name and address of the Principal Investigator or the research site.
- The purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any, should be included but not guaranteed.
- The time or other commitment required of the participants.
- The IRB requires that advertisements and recruitment materials include:
  • A statement that the information provided pertains to a research study/clinical trial/clinical study (or equivalent).
  • A definition of the word “placebo”, if applicable.
- An explanation of any compensation given to the patient.

2. In addition, the IRB requires that advertisements and recruitment materials do NOT:

- State or imply a certainty of favorable outcome beyond what is outlined in the consent document and the protocol.
- Emphasize (e.g., by such means as larger or bold type) compensation.
- Allow compensation for participation in a trial to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing (FDA- regulated research).
- Include testimonials (defined as a statement in support of a particular truth, fact, or claim). Recruitment materials cannot contain statements that explicitly or implicitly make effectiveness claims about the investigational product or procedure. Testimonials, in general, advertise the product or procedure that they discuss in the words of a “satisfied user,” and so, by their very nature, are claiming success, improvement, and/or effectiveness. Should not use misleading mottos or the terms: “state of the art,” “cutting edge,” “breaking technology,” or “improved.”
- Make claims, explicitly or implicitly, that the test article is known to be equivalent/superior to any other drug, biologic, or device.
- Make claims, explicitly or implicitly, that the test article is safe/effective for the purpose under

investigation.

- Use the word “free” when referring to procedures and medications that may be received as a part of participation in the research study. Acceptable language would be, “at no cost,” or “at no charge”.
- Contain the word “new” or “treatment” when referencing the test article, unless qualified as “investigational treatment” or “possible treatment”.
- Contain the word “experimental” when referencing the test article.
- Contain the word “earn”.
- Include coercive language, tone, or exculpatory language.
- Refer to the FDA or IRB in any other capacity than what is stated in the consent.

3. For print advertisements, a copy of the print ad should be submitted in the format that it will appear so that the IRB can review the layout of the advertisement as well as the text. If advertisement recruitment materials are being submitted with a reference or link to a website, any research-related content, including any information which pertains to a study under the review of the IRB, must be submitted to the IRB for review and approval prior to use. It is the Principal Investigator’s responsibility to ensure that the submission includes any web content which requires IRB review.Print advertisements that are approved by the IRB may be used as website recruitment advertisements without IRB approval, as long as they are not modified in any way.

4. The IRB does not require the submission of, but will review upon request, website recruitment content where the system format limits the material presented to basic trial information, such as the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and information on how to contact the site for further information. Examples of such listings include content posted to government-sponsored sites, such as the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute’s cancer clinical trials listing (PDQ), and the AIDS Clinical Trials Information Service (ACTIS). However, the IRB does require the submission of web content where the opportunity to add additional descriptive information is not prevented by the system format, for review and approval prior to use..

5.If participating in a large, multi-site study, the Sponsor may prepare a package of recruitment materials/advertisements for the site to use once approved by the IRB. Each site choosing to use these recruitment materials should include their site-specific information, such as the clinic name, telephone/ contact information and compensation information (if already approved by the IRB), taking care not to alter the layout, type font or size of the approved advertisement. These recruitment materials/ advertisements are considered approved, and do not need to be re-submitted to the IRB.6.

6. Radio and television advertisement scripts must be submitted to the IRB for approval. It is recommended that scripts are reviewed and approved prior to production. All recruitment media must be approved before advertising begins. In accordance with 45 CFR 46.115 and 21 CFR 56.115, the IRB must retain copies of materials that have been reviewed. Recruitment media should be provided to the IRB in an electronic format that can be saved, as hyperlinks.

7. Recruitment materials/advertisements provided with the original submission will be reviewed with initial review. The IRB will notify the Principal Investigator or designee if any revisions are required before

approval can be granted. Approved recruitment materials/advertisements will be provided in the initial approval documents and will be marked with an "Approved" stamp.

8. Recruitment materials/advertisements submitted after the Investigator's initial review must be accompanied by a completed Amendment/Modification Form. The IRB will notify the Principal Investigator or designee if any revisions are required before approval can be granted. Approval documents and the recruitment materials/advertisements that have been stamped "Approved" will be sent to the site.

9. The IRB must review any revision made to previously approved recruitment materials/ advertisements. These include text changes, and other image changes such as pictures, font type or size. Please contact the IRB if there are any questions regarding changes to participant recruitment materials/advertisements.

References:

- 21 CFR 56.111(a)(3)
- 45 CFR 46.115
- FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators, Recruiting Study Subjects, January 1998.
- OHRP, Clinical Trial Websites: When is IRB Review Required and What Should IRBs Consider with Reviewing (OHRP Guidance, 2005).

Approval Signatures

Step Description	Approver	Date
CEO Final Approval	Deborah Angerami: CEO	3/27/2025
CMO Approval	Jason Smith: CMO, PPMH	3/10/2025
Chief Operating Officer	Jane Gray: PPMH Chief Operating Officer	3/7/2025
Owner/Legal Approval	Janine Sarti: Deputy General Counsel	1/30/2025

Applicability

Phoebe Putney Memorial Hospital

History

Edited by Pardue, Sharon: Paralegal on 1/20/2025, 10:04AM EST

> In reference Section - changed 45 CFR 46.111 to 45 CFR 46.115

Sent for re-approval by Pardue, Sharon: Paralegal on 1/30/2025, 12:27PM EST

> As stated in the previous comment a change was made in the reference Section - changed 45 CFR 46.111 to 45 CFR 46.115. This policy was approved by the IRB Committee on January 29, 2025.

Last Approved by Sarti, Janine: Associate General Counsel on 1/30/2025, 2:05PM EST

Last Approved by Gray, Jane: PPMH Chief Operating Officer on 3/7/2025, 4:19PM EST

Last Approved by Smith, Jason: CMO, PPMH on 3/10/2025, 10:09AM EDT

Administrator override by Williams, Mary: Paralegal on 3/12/2025, 5:33PM EDT

> Owner changed from Janine Sarti to Dawn Benson.

Last Approved by Angerami, Deborah: President/CEO PPMH on 3/27/2025, 3:18PM EDT

Activated on 3/27/2025, 3:18PM EDT