National Marrow Donor Program
POLICY

Advertisements for Recruiting Subjects to Research Studies

Business Section / Department: Center for International Blood and Marrow Transplant Research (CIBMTR)
Effective Date: _____

Policy Owner Approval:	**Quality Systems Review:**	**Final Approval:**
_____ *Name/Title*	_____ *QS Director*	_____ *CEO/Officer Designee*

Review Cycle:	**Policy Type:**	**Board Approval** (Governance Policy only)
□ 1 year □ 2 year □ Other: _____	□Operations □Governance***** **requires BoD approval →*	_____ *NMDP Board Officer*

Policy

It is National Marrow Donor Program (NMDP) policy that advertising materials for the purpose of recruiting subjects to NMDP/CIBMTR studies shall not adversely affect the equitable selection of participants or an appropriate consent process.

Purpose

The purpose of this policy is to issue guidelines for the creation of research study recruitment advertisement materials, so that such advertisement materials fulfill the requirements for consent and do not affect the equitable selection of subjects.

The federal regulations [45 CFR 46.111(a)(3) and 21 CFR 56.111(a)(3)] state that the selection of human subjects to research studies must be equitable. This is assessed by taking into account the purpose and setting of the research and being particularly aware of special problems of research involving vulnerable populations.

The federal regulations [45 CFR 46.116 and 21 CFR 50.20] also outline the general requirements for informed consent. This includes a consent process that minimizes the possibility of coercion or undue influence and materials that exclude any exculpatory language.

Recruitment methods, including advertisements and participant payment arrangements, may affect the equitable selection of participants and an appropriate consent process. For example, recruitment methods, advertisements, or payment arrangements that target economically disadvantaged subjects can lead to unfair selection of subjects despite reasonable selection criteria. In addition, recruitment methods, advertisements, or payment arrangements that are misleading, inaccurate, exculpatory, coercive, or unduly influential violate the regulatory requirements for consent.

Scope

This policy applies to NMDP and CIBMTR personnel involved in the creation of research study recruitment advertisement materials.

Definitions

Coercion: Overt threat of harm intentionally presented in order to obtain compliance.

Exculpatory language: Any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights.

Undue influence: Offer of excessive or improper reward in order to obtain compliance.

Vulnerable to coercion or undue influence: Children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, or NMDP unrelated donors.

Procedure

Advertisement materials for the purposes of recruiting subjects to research studies shall not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the research protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise "free treatment" when the intent is only to say subjects will not be charged for taking part in the investigation.
- Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
- Use terms such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
- 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.

Advertisement materials shall be limited to the information prospective subjects need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.

- A brief list of benefits to subjects, if any.
- The time or other commitment required of the subjects.
- The location of the research and the person or office to contact for further information.

Responsibilities

This policy shall be managed by Research Administration. All NMDP and CIBMTR personnel involved in the creation of research study recruitment advertisement materials shall be responsible for following this policy. The NMDP Institutional Review Board (IRB) shall be responsible for reviewing advertisement materials submitted to the IRB in accordance with this policy and federal regulations.

References / Related Documents

Not applicable