



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Subject Recruitment: Advertisement and Incentives	POLICY # 5013
APPROVED:	EFFECTIVE DATE:
Richard J. Greene, M.D., Ph.D. IRB Chair 	September 1, 2005
John DeLuca, Ph.D. Senior Vice President for Research 	REVISED DATE: <u>April 10, 2014</u>

PURPOSE

To set guidelines for appropriate recruitment of research subjects through advertising and through the offer of incentives.

DEFINITIONS

An **advertisement** is a posted notice, such as a flyer posted on a bulletin board (either inside or outside of Kessler Foundation) and/or in a newspaper, magazine or on electronic media, that is used to recruit research subjects.

Notices directed to clinicians seeking study referrals include letters, electronic and other postings and notices in professional publications.

Incentives are dollar and non dollar inducements offered to encourage participation of research subjects.

PROCEDURE

- A.** All advertisements and notices seeking study referrals must be approved by the Institutional Review Board prior to their use and must be submitted annually as part of the application for continuation of project approval.

B. The Principal Investigator is responsible for ensuring that all advertisements on display and all notices seeking study referrals are the currently approved versions, bearing the IRB approval stamp. The PI must keep the most recent IRB-approved, stamped version of all advertisements and notices seeking study referrals in the project file.

C. Advertisements should include:

Name and location of the research facility

The word “research” in a prominent place in the advertisement

Name, degree, title and affiliation of the P.I.

Purpose of the research

Eligibility criteria (briefly stated)

Remuneration, if applicable

Contact person and phone number where interested persons may obtain more information

Information prospective subjects need to determine interest (e.g. study procedures, time commitment, and study duration).

D. Advertisements should:

Use simple lay language

Provide basic exclusion criteria whenever possible to reduce unnecessary calls

Specify the amount of monetary compensation (if the PI wishes) and use the word “up to” if prorated compensation is to be used

Use the words “at no cost” rather than “free” where relevant

E. Advertisement should NOT include:

Claims that the experimental intervention is safe or effective for the purposes under investigation or that the intervention is equivalent or superior to other interventions

References to “new treatment”, new medication” or “new device” without explaining that the treatment, medication or device is investigational.

Overly optimistic or effusive language implying benefit of the study intervention

Language that implies treatment benefit for chronic problems if the study involves a short term intervention

Emphasis on monetary remuneration

Do not feature monetary compensation as a lead, before describing the study purposes and procedures

Do not bold, italicize, underline or enlarge fonts describing monetary compensation

- F.** Notices written to clinicians seeking study referrals should include sufficient information about the study (including study design, placebo use, risks and possible benefits) to allow the clinician to reasonably present the study to his/her patients.
- G. Incentives** used to recruit study subjects (e.g. payments or non dollar benefits such as no cost care) will be reviewed by the Institutional Review Board for the appropriateness of both the amount and method of payment. The incentive should reflect the degree of risk, inconvenience or discomfort associated with participation in the study.

Acknowledgement: In the development of this Policy, Kessler Foundation acknowledges its reliance on the Guidelines for Advertisements for Recruiting Subjects of Partners Healthcare System, Boston, MA