

# KESSLER FOUNDATION

## *Policies and Procedures Manual* *IRB*

<b>SUBJECT: Participant Recruitment: Advertisements and Incentives</b>	<b>POLICY # 5013</b>
<b>APPROVED:</b>	<b>EFFECTIVE DATE:</b>
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### **PURPOSE**

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

### **DEFINITIONS**

An **advertisement\*** is a notice that is shared either internally or outside Kessler Foundation for the purpose of recruiting research participants. Advertisements may include (but are not limited to) flyers, social media posts, newsletter articles, “e-blasts,” newspaper or magazine advertisements, videos, website listings, or other electronic or printed media.

**Referral notices** refer to messages directed to clinicians seeking study referrals and include letters, electronic and other postings and notices in professional publications or other venues.

**Incentives** are monetary and non-monetary inducements offered to encourage participation of research subjects. Compensation provided for time and effort is considered an incentive, as are payments offered to offset potential costs (such as travel expenses).

\*The following types of materials are **NOT** considered advertisements for purposes of this policy, based on guidance from the Food and Drug Administration:

- Communications (such as referral notices) intended to be seen or heard by health professionals, unless the study is recruiting health professionals as participants. This includes “dear doctor” letters intended to inform doctors of a study to which they may wish to refer patients. (Note: letters intended to be sent to patients themselves are considered advertisements.)
- Publicity or other materials created for audiences other than potential research participants, such as donors or investors.
- News stories (as featured in newsletters, press releases, etc.)

## **POLICY / PROCEDURE**

### **A. IRB Approval and Documentation Requirements**

- (a) All advertisements and referral notices must be approved by the Institutional Review Board prior to their use. This includes advertisements being shared through Kessler Foundation's communication channels as well as advertisements being shared via third party recruitment entities (such as ResearchMatch, CliniContact). Study listings on the Kessler Foundation website that include content derived entirely from IRB-approved materials do not require separate IRB review.
- (b) Advertisements must be submitted annually as part of the application for continuation of project approval for those studies that undergo annual review.
- (c) The Principal Investigator is responsible for ensuring that all advertisements on display and all referral notices are the currently approved versions. Formatted pieces intended for distribution to potential participants (such as flyers, brochures, postcards, etc.) should include the IRB approval stamp\*\* on the advertisement being shared. Recruitment letters and short form advertisements (such as social media post text, classified ads, etc.) do not require a stamp to be displayed in the versions provided to potential study candidates. Please consult with the IRB staff with questions you may have about requirements for stamping.

\*\*Flyers produced by Kessler Foundation's recruitment team that list multiple studies will include text indicating the date of IRB approval of the flyer (since the studies listed will have various expiration dates). This text will be included in lieu of a stamp to facilitate formatting.

- (d) The PI must keep the most recent IRB-approved and stamped (where applicable) version of all advertisements and notices seeking study referrals in the project file.

### **B. Appropriate Content**

- (a) Advertisements should include information that prospective participants need to determine interest and to connect with the research team or project.
- (b) Advertisements should use plain language (also referred to as "lay language"). Such language avoids scientific or clinical terms and uses simple vocabulary and shorter sentences or phrases. Guides for plain language writing are referenced below.
- (c) Advertisements should include the following information:
  - The word "research" in a prominent place in the advertisement
  - Name of the research facility (stated in text or via a logo with alternative text to ensure accessibility)
  - Street address of the research facility. For remote studies, please use the PI's professional address.

- Name and credentials (such as PhD, MD) of the principal investigator with a lay-friendly label indicating they are principal investigator (“Lead Investigator: Sally Smith, PhD”)
- Purpose of the research
- Eligibility criteria (briefly stated)
- A brief description of the types of procedures that the study involves (such as surveys, MRI, blood tests), time commitment, study duration, and whether procedures will take place in-person or remotely
- The phrase “at no cost” rather than “free” where relevant
- Potential benefits of the study, stated in a manner that does not imply a guarantee of direct benefit, even when direct benefit is possible
- Whether payment will be provided to participants. The specific payment amount may be stated, but is not required. Use the phrase “up to” if prorated compensation is to be used.
- Contact person and phone number and email where interested persons may obtain more information
- A box for the IRB stamp, except as specified in section A(c) above
- Whenever possible, formatted advertisements should include a QR code linking to a form that allows prospective participants to provide contact information or a webpage that provides additional information. Any forms that gather contact information should be created and implemented in collaboration with Kessler Foundation’s Recruitment team to ensure they conform to expectations for branding and security. Similarly, any webpage to which an advertisement links should only contain content that has undergone IRB review.

### **C. Inappropriate Content**

Advertisements 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. If using the term “new,” it must be clear in the advertisement that the benefits of the intervention are not yet known and are presently being studied
- Overly optimistic or effusive language implying benefit of the study intervention. The advertising should not promise a certainty of benefit beyond what is outlined in the consent and the protocol.

- Emphasis on compensation
  - 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
  - Do not include pictures of dollar signs, currency, or anything implying financial benefit
  
- D. Referral notices** written to clinicians 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.
  
- E. 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. Whenever feasible, the payment schedule should allow for partial payments if a participant completes some (but not all) of the study procedures.
  
- F. Flyers** should be created using templates provided by Kessler Foundation. (This requirement is effective January 6, 2025). The use of these templates is intended to assist investigators in preparing flyers that include required content, meet guidelines for accessibility, have visual appeal, and are consistent with Kessler Foundation branding and style guidelines for published materials. Information about how to access and use these templates is available from individual Center administrators/coordinators or the Foundation research recruitment manager.
  
- G. Audio or video advertisements** should be provided to the IRB in their final form to allow a full assessment of the presentation of content. It is recommended that a script for the spoken or text content of the audio or video piece be presented and approved before production to minimize the need for re-recording or additional edits. The final audio or video advertisement prepared from text that was previously IRB-approved may be reviewed through expedited procedures at the discretion of the IRB.

Acknowledgements:

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

References:

Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators. Food and Drug Administration. Accessed December 11, 2023. Accessible from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects>.

Writing and Testing Plain Language. Model Systems Knowledge Translation Center. Accessed February 12, 2025. Accessible from [https://msktc.org/sites/default/files/2022-06/MSKTC\\_Plain\\_Lang\\_Tool\\_508.pdf](https://msktc.org/sites/default/files/2022-06/MSKTC_Plain_Lang_Tool_508.pdf).