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Advertising and Recruitment Letter Guidelines

Advertising Guidelines

Recruitment Letter Guidelines and Sample Letter

Advertising Guidelines

These guidelines follow FDA guidance ^[1]. Review the recruitment guidelines ^[2] for more info about recruiting patients via advertising.

The content of any advertisements, notices and/or media materials must be limited to the following information

- Name and address of the investigator or research facility.
- Condition under study and/or purpose of the research.
- Summary of the eligibility criteria.
- Brief list of participation benefits, if any (e.g., a no-cost health examination).
- Time or other commitment required.
- Location of the research.
- Contact info for the person or office to reach for further information.
- Include a reference to UCSF. An exception may be made for national recruitment campaigns but these will be reviewed on a case-by-case basis.

Ensure that the advertisements, notices and/or media do NOT include the following

- State or imply or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol.
- Make claims, either explicitly or implicitly, that the research procedures are safe or effective for the purposes under investigation.
- Make claims, either explicitly or implicitly, that the research procedures are known to be equivalent or superior to other drugs, biologics or devices.
- Use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.
- Promise "free medical treatment" when the intent was only to say participants would not be charged for taking part in the investigation.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Characterize payment for participation as a benefit of the research. (The amount and method of payment can be stated, but should not be included in the benefits section.)
- Include any language that announces the investigator cannot be held liable or at fault for any research related event.
- Allow for compensation towards the investigational agent once FDA approved.

The IRB must approve all advertisements before they are used to ensure that the mode of communication and content of the ads include accurate information and are not coercive. See the Recruitment Methods ^[3] page for a list of materials that need IRB review.

The IRB should review the final copy of printed ads to evaluate the relative font size used and other visual effects. When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording.

Note: The UCSF IRB does NOT have to review a study sponsor's national recruitment campaign materials if these materials will be reviewed and approved by a central IRB or commercial IRB.

Recruitment Letter Guidelines and Sample Letter

Review the recruitment guidelines ^[2] for more info about recruiting patients by letter. Submit the recruitment letter for IRB review and approval.

Recruitment letters should include the following information

- Name the PI.
- Describe basic study purpose, procedures and time commitment.
- Provide the name and phone number to call for questions and enrollment.
- Clarify that participation is voluntary.
- Print the letter on the PI's departmental letterhead.

We have written a sample recruitment letter with guidance from the UCSF Participant Recruitment Program ^[4], which you can view below or download as a Word doc ^[5]. Adjust the

content for your particular study.

Sample recruitment letter

Date

Patient Name

Address 1

Re: Research Study at UCSF

Dear Patient,

We are writing to see if you would like to participate in a new research study being conducted at UCSF. Research plays an important role in advancing our understanding of clinical care and helps lead to improvements in health. UCSF recruits patients to participate in these research studies.

The following information summarizes the study and what it involves:

[Study Title]or [Study Topic]or [Study nickname]:

[Note: please be sensitive to a recipient?s perspective upon receiving. Try not to use the NIH study title or use keywords that could be alarming to the recipient. Define all acronyms and do not include any information that would refer to a diagnosis.]

Study Purpose: *1-2 sentences describing the study in lay terms*

Example: This study is evaluating whether a mobile app can help people pay closer attention to eating habits and eat in a healthier way.

Participation Requirements: *Bullets or concise description*

Example: The study lasts approximately five (5) weeks. You will have two (2) in-person visits.

Compensation: *Only if the study involves compensation*

Example: Upon completion of the study, you will be paid [INSERT AMOUNT] for your time.

Contact Information:

Example: If you are interested in participating in this study or learning more about it, you can learn more at MyStudyExample.org. For questions about this study, contact (name of PI and, if applicable, the Study Coordinator who will field these calls) at (415) 123-4567.

Participating in research is voluntary. It won?t affect your treatment at [site at which patient is being treated] if you decide not to call about the study or decide not to participate.

Sincerely,

[Name of Principal Investigator]

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Source URL: <http://irb.ucsf.edu/advertising-and-recruitment-letter-guidelines>

Links

- [1] <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>
- [2] <http://irb.ucsf.edu/recruitment>
- [3] <http://irb.ucsf.edu/recruitment#materials>
- [4] <https://recruit.ucsf.edu/participant-recruitment-program>
- [5] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/sample-recruitment-letter.doc>