Subject Recruitment Materials

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Objectives

- Review regulations and guidance for advertisements
- Discuss institutional practices regarding review
Common rule

- Nothing explicit in 45CFR46
- In practice
  - IRB reviews and approves all study materials
  - Recruitment materials are earliest part of consent process
Explicit guidance:

- Guidance for Institutional Review Boards and Clinical Investigators
  1998 Update –”Recruiting Study Subjects”
Direct Advertising

- Newspaper
- TV
- Radio
- Bulletin boards
- Posters
- Flyers
not direct advertising

- Communications intended for health professionals
- News stories
- Publicity for other audiences
  - e.g., financial page advertisements towards potential investors
- Clinical trial website registration
“FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process.”
When to review

- At initial review
- Can be submitted as an amendment (expedited procedures OK)
- At continuing review
FDA Criteria

- Not unduly coercive
- Does not state or imply
  - Certainty of favorable outcome
  - Benefits - beyond what is stated in the ICF or protocol
Procedural guidelines

- Review final printed form
- Review final tape/audio
  - PI should submit transcript prior to taping in case changes are required
No-No’s

Claims of:

- Safety or effectiveness for purpose under investigation
- Claims of superiority to other drug, biologic, or device
No-no’s

Must explain “investigational” CANNOT use:

- “New”
- “Treatment”
- “New treatment”
- “New drug”
- “Receive new treatment”
- “Free medical treatment”
Payment

- OK to say subjects will be paid, NOT “earn” money
- Do not emphasize payment or amount by means of larger or bold type
FDA General Info to Include:

1. Name and address of investigator/facility
2. Purpose of research
3. Summary of eligibility criteria
4. Brief list of participation benefits
5. Time or other commitment
6. Location and contact info
Are You Taking Atenolol or Metoprolol To Manage High Blood Pressure?

You may be eligible to participate in a research study to see if melatonin can help lower your blood pressure.

Earn up to $2,000.

if you are:
  • 35-65 years old
  • otherwise healthy

Contact Erin for more information
(617) 278-0924
or highbp@rics.bwh.harvard.edu
Do you have IBS?

Boston University School of Medicine is seeking volunteers, ages 18-65, with irritable bowel syndrome for a patient education research study. The study involves one visit and completing questionnaires packets. The compensation for participating in the study is $35-$55.

For more information, please call 617-638-6579 or email ibs.study@bmc.org.
Concerned About High Blood Pressure? Earn $500.00

Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University is now recruiting.

<table>
<thead>
<tr>
<th>Whom</th>
<th>Non-smoking men and women aged 30-70 with blood pressure 120-150/95 or less. No personal history of diabetes or heart disease. Not taking blood pressure medication.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>To participate in an 8 week blood pressure research study investigating the health effects of drinking a hibiscus beverage.</td>
</tr>
<tr>
<td>When</td>
<td>LAST screenings Fri, 8/24 &amp; 9/7, 11am-3pm</td>
</tr>
<tr>
<td>Where</td>
<td>711 Washington St, downtown Boston Close to New England Medical Center T station Refreshments and nutrition info provided</td>
</tr>
</tbody>
</table>

Please call Helen P. at (617) 427-3100 to schedule an appointment. Walk-ins are also welcome!
Consult the IRB office and/or federal guidance:

- Guidance for Institutional Review Boards and Clinical Investigators
  1998 Update – “Recruiting Study Subjects”