

## GUIDANCE IRB014

### RECRUITMENT AND ADVERTISING

#### Recruitment of Study Subjects

Recruitment represents the start of the consent process. Direct advertising for research subjects, such as advertising intended to be seen or heard by prospective subjects to solicit their participation in the study, must be reviewed and approved by the IRB.

Materials should reflect that the project is research and explain the purpose, procedures, and time commitment. Materials must be clear, concise, and in language that does not place undue influence on a subject to participate. Materials may not include exculpatory language.

NOTE: FDA guidance states that the following are not considered direct recruitment of study subjects:

- Communications intended to be seen or heard by health professionals, such as doctor-to-doctor letters
- News stories not intended to target recruitment of study subjects
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors

#### Requirements

- All recruitment materials in their final form that directly target subjects must be approved by the IRB before implementation (e.g. oral scripts, newspaper, radio, TV, bulletin boards, posters, and flyers). IRB Review will be performed in accordance with federal regulations.
- The amount of compensation may be listed in recruitment materials so long as the amount is not overly emphasized
- Banner Health prohibits “finder’s fees” (payments to professionals in exchange for referrals of potential subjects). Any incentives, payments and/or bonuses (payments designed to accelerate recruitment that were tied to the rate or timing of enrollment) must be reviewed by the IRB for appropriateness and approved before the PI can accept payment.
- The IRB prohibits 'cold-calling' of research subjects for participation in studies. Examples of acceptable contact include:
  - Subjects can directly contact a researcher from contact information displayed on an advertisement
  - Subjects can be contacted via snowball method of recruitment. In this scenario, subjects agree to have their name forwarded to a researcher by someone they know (e.g. treating physician or friend forwards subject name to researcher after a subject has said it was OK).
  - Direct targeted recruitment of subjects can occur when the method and form are IRB approved (e.g. recruitment of students in a classroom)

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### Payments to Subjects

The IRB will review payments to subjects to determine that:

- Credit for payment accrues as the study progresses and not be contingent upon the subject completing the entire study.
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.
- All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

### Advertisements

Advertisements used to recruit study subjects should state only the information needed for prospective participants to determine their interest and eligibility. The following items may be included in the advertisements:

- The name and address of the investigator and/or research facility
- The condition under study and/or the purpose of the research
- A summary of the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any (e.g., a no-cost health examination)
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

<b>Do</b>
<ul style="list-style-type: none"><li>• Use the term 'research' or a synonym when describing the study</li><li>• Use the term 'investigational' or a synonym when describing the study</li><li>• Submit final scripts or recordings for IRB review and approval prior to use or broadcast</li></ul>
<b>Do Not</b>
<ul style="list-style-type: none"><li>• Use language or graphics that can be coercive or misleading, including making claims that are inconsistent with labeling of any FDA product</li><li>• State or imply a guarantee of benefits, cures, or favorable outcomes</li><li>• Use terms such as 'new treatment,' 'new medication,' or 'new drug' without explaining the test article is investigational</li><li>• Emphasize 'free' treatment or study products</li><li>• Claim the study product or procedure is safe, effective, equivalent, or superior to other options</li><li>• Place emphasis on payment, including offering a coupon good for a discount on the purchase of a product</li><li>• Advertise or place materials in a 'job section' of Craigslist or another similar website</li></ul>

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#### Recruitment and Research Site Authorizations

- Recruitment or research within Banner Health:
  - Permission from the department or unit where the recruitment or research will take place is required. Documentation of permission must be kept with the investigator's research files.
- Recruitment or research outside Banner Health:

When research procedures, including recruitment, occur outside of Banner Health, the first assessment to be made is whether the collaborating site is engaged in research.

Determination of engagement is made by the IRB. Investigators should consult with the IRB as soon as reasonably possible. If the other site is not engaged in research, then permission to access the location must be obtained from the site as described below.

- Written or verbal site authorization is required for posting of a flyer/brochure on a public bulletin board. Documentation must be kept with the investigator's research files.
- Written site authorization is required for posting of a flyer/brochure on a private bulletin board. Documentation of site authorization must be kept with the investigator's research files.
- Written site authorization is required for physically recruiting at any location.
  - Documentation of site authorization must be kept with the investigator's research files
- No additional site authorization is required if payment is made to post recruitment materials

#### ***Advertising for clinical trials over the internet***

Approval of clinical trials on the internet is NOT required in certain instances when the system format limits the information provided to basic trial information. Examples of such sites include: ClinicalTrials.gov, National Cancer Institute clinical trial listing, and government-sponsored AIDS clinical trials information services. The information posted must be limited to:

- Title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s)
- How to contact the site for further information.

Although approval of the language provided in the listing service may not be required, as with all recruitment methods, if the listing is intended for recruitment purposes, the use should be identified in the protocol/application as such.

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When the opportunity to add additional descriptive information is not precluded by the database system, IRB review and approval is required to assure that any additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the consent document. Similarly, any other type of recruiting completed via websites, web postings or the use of social media must be submitted for IRB review and approval.

### **Recruitment and Future Contact Databases**

Frequently researchers want to keep a list of contact information on potential subjects to contact about future research projects. These databases do NOT require IRB review if:

- The potential subject has freely given their contact information to the researcher for purposes of being put into a contact database about future research opportunities
- The database will be used only for contacting subjects about potential research opportunities, and
- No additional information will be obtained from the medical record of the potential subject to be included in the database

Databases that are considered repositories, or those that will be analyzed for research purposes (e.g. records reviews) require IRB approval.

### **Department-Specific Requirement Requirements**

Your individual department/unit may have additional requirements before posting materials or participating in a news interview. Please contact your communications director or press manager for further guidance.

### **References**

Element II.3.C.

Element III.1.E.