



# Recruitment and Advertising

## ***Recruitment of study subjects***

Recruitment is considered the start of the informed 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; and
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

## ***General 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).
- Recruitment material must also include the IRB required recruitment blurb. It may be shortened, but the main concept must remain: *An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.*
  - Spanish translation: *Una Junta de Revisión Institucional responsable de la investigación con seres humanos en la Universidad de Arizona examinó este proyecto de investigación y encontró que era aceptable, de acuerdo con las disposiciones estatales y federales, así como las políticas universitarias destinadas a proteger los derechos y el bienestar de los participantes en la investigación.*
- The amount of compensation may be listed in recruitment materials so long as the amount is not overly emphasized.
- The University of Arizona prohibits “finder’s fees” and “bonus payments.”
  - Finder’s fees are payments, which includes extra credit for students, to any individual or company, including but not limited to, professionals, students, staff, and faculty, in exchange for referrals of potential subjects.
  - Bonus payments are payments, which includes extra credit for



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students, designed to accelerate recruitment that were tied to the rate or timing of enrollment.

- The IRB prohibits 'cold-calling' (i.e., the solicitation of a potential participants who had no prior interaction with the research team). 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 the potential subject's name to researcher after a subject has authorized this). "Permission to Contact" cards are often utilized in these cases.
  - Direct targeted recruitment of subjects can occur when the method and form are IRB approved (e.g., recruitment of students in a classroom).
  - The clinical care team can mail a letter to potential subjects, on behalf of the research study, inviting participants to take part in the research.

Please reach out to the HSPP if you have questions about your specific recruitment method.

### ***Recruitment Material***

Material 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 material:

- 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

Acceptable Recruitment Material Content
<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>



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Unacceptable Requirement Material Content
<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 other similar websites</li></ul>

## ***Recruitment and Research Site Authorizations***

1. Recruitment or research within the University of Arizona:

- Permission from the department or unit where the recruitment or research will take place is required. For example, use of UA Centers or student subject pools require permission from the head of that unit before any research or recruitment may take place.
- Written site authorization is required for posting flyers on any bulletin board at the University of Arizona. Documentation of permission to post the flyer must be obtained by the UA unit that owns the bulletin board (e.g., Student Affairs must give permission to post a research flyer in a dorm). The UA IRB requires that permission be obtained for research outside of the home unit of the Investigator. A copy of this document must be kept with the investigator's research files but does not need to be submitted to the HSPP.

2. Recruitment or research outside the University of Arizona:

When research procedures, including recruitment, occur outside of the University of Arizona, the first assessment to be made is whether the collaborating site is engaged in research. Determination of engagement is made by the HSPP. Investigators should consult with the HSPP as soon as reasonably possible. In addition, researchers should review OHRP's [Guidance on Engagement in Research](#). 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.



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- 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, University of Arizona 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.

When the opportunity to add additional descriptive information is not precluded by the database system, HSPP 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 HSPP review and approval.

### ***Social Media Recruitment***

Recruitment of potential research participants on social media (i.e., Facebook, Twitter, Instagram, etc.) is generally acceptable. Special consideration must be made when identifying how one will recruit on social media. Consider whether the method is 'private' or 'public' social media recruitment. For example, if there is a private Facebook group and the investigator wants to post in that private group, the investigator MUST get permission from the owner of the private group to get the recruitment material pre-approved for posting in the private group. The investigator cannot simply join the group under the guise of being a member of the private group and then post secondarily to that.

If an investigator wishes to use publicly available information to contact subjects, that is generally acceptable; however, the researcher cannot use contact information on a **private** page without permission from the owner of the page first, as outlined above.



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Acceptable Social Media Recruitment
<ul style="list-style-type: none"><li>• Include basic study information, such as name of the study and the required characteristics for potential participants</li><li>• Mention or tag organizations related to the research</li><li>• Following general recruitment requirements as outlined above</li></ul>
Unacceptable Social Media Recruitment
<ul style="list-style-type: none"><li>• Tagging or mentioning individuals by their handles or profiles</li><li>• Sharing posts made by others who have mentioned or tagged individuals</li><li>• Messaging individuals, even privately, unless you are answering a direct question about the research</li><li>• Friending/following individuals for the purpose of alerting them to the research</li><li>• Any other behavior that associates an individual (by name or social media identity) with a message about a research study</li><li>• Tag or link to an individual study investigator/research staffer's handle or social media profile in a post related to a research study</li></ul>

### Examples of Acceptable Social Media Recruitment Posts:

Twitter: May is National Asthma & Allergy Awareness Month. If you have #asthma, you may be eligible for this study: [insert link]. This research has been approved by the UArizona IRB.

Facebook: If you suffer from rheumatoid arthritis, you may be interested in a new research opportunity through The University of Arizona entitled [insert title]. Please click this link for more information [insert link]. An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

### **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 include in the database.

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



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### ***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.