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.

Finder's Fees and Bonus Payments

The University of Arizona prohibits "finder's fees" and "bonus payments" as these payments may create coercion, undue influence, or a conflict of interest. These types of payments could cause investigators or administrators to stretch enrollment criteria, distort information provided to potential participants, or pressure subjects to participate.

- Finder's fees are payments, which include 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 research participants.

- Bonus payments are payments, which include extra credit for students, designed to accelerate recruitment that are tied to the rate of enrollment.

However, payments are usually considered appropriate to compensate for the time and effort research teams spend on the referral process. For example, research teams may be paid a reasonable amount (not to exceed fair market value) for any services (e.g., obtaining a medical history, performing screening examinations, conducting medical record reviews) they perform in support of a research study.

It is important to remember that compensation to support staff would be paid regardless of whether any of the referred potential participants end up enrolled in the study, or even whether they screen for the study. Financial support for staff performing recruitment and screening related activities must be time-based (not based on referrals or enrollment numbers), and there must be no other direct or indirect incentives related to enrollment which could create a conflict of interest.

The IRB may approve these types of requests on a case-by-case basis when negotiation is done via a formal contract with the sponsor, payment is to the institution, and abides by the above guidance.

Cold-contacting

The IRB prohibits 'cold-calling' research subjects (i.e., solicitating potential participants who have had no prior interaction with the research team) 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 sampling methods of recruitment. In this scenario, subjects agree to have their name forwarded to a researcher by someone they know (e.g., a treating physician or friend forwards the potential subject's name to a 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 and Advertising

Recruiting Dyads

Within the context of research, a dyad consists of the participant and a person with whom they have a partnership or relationship with. For example, parent-child pairs, patient-caregiver interactions, spouses, siblings, or friends. The following are acceptable practices for recruiting dyads:

- The original participant directly informs the proposed dyad participant that an investigator will be contacting them about a research study. There should also be a process in place where the proposed dyad participant can opt out (e.g., notifying the investigator via email).

- Any communication from the researcher to the dyad should reference the original enrolled participant that shared the potential dyad participant's contact information. For example: [Name of original participant] *is participating in* [title] *study and shared your name as a potential dyad participant. If you are interested, your participation will involve* [describe research procedures]. *Please respond to this email if you would like to opt out of receiving further communications.*

Recruitment methods must ensure that participation is entirely voluntary. Participants should not feel coerced by their relationship with the other member of the dyad (e.g., feeling obligated to participate because their partner or friend has agreed). All recruitment materials should also clearly describe the nature of the study and the dyadic participation requirement.

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
• Use the term 'research' or a synonym when describing the study • Use the term 'investigational' or a synonym when describing the study • Submit final scripts or recordings for IRB review and approval prior to use or broadcast

Unacceptable Requirement Material Content
• Use language or graphics that can be coercive or misleading, including making claims that are inconsistent with labeling of any FDA product. • State or imply a guarantee of benefits, cures, or favorable outcomes • Use terms such as 'new treatment,' 'new medication,' or 'new drug' without explaining the test article is investigational • Emphasize 'free' treatment or study products • Claim the study product or procedure is safe, effective, equivalent, or superior to other options • Place emphasis on payment, including offering a coupon good for a discount on the purchase of a product. • Advertise or place materials in a 'job section' of Craigslist or other similar websites

Recruitment and Research Site Authorizations

1. Recruitment or research <u>within</u> 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 <u>outside</u> 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.
- 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.

Acceptable Social Media Recruitment
• Include basic study information, such as name of the study and the required characteristics for potential participants • Mention or tag organizations related to the research • Following general recruitment requirements as outlined above
Unacceptable Social Media Recruitment
• Tagging or mentioning individuals by their handles or profiles • Sharing posts made by others who have mentioned or tagged individuals • Messaging individuals, even privately, unless you are answering a direct question about the research • Friending/following individuals for the purpose of alerting them to the research • Any other behavior that associates an individual (by name or social media identity) with a message about a research study • Tag or link to an individual study investigator/research staffer's handle or social media profile in a post related to a research study

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.

Best Practices to Avoid Fraudulent Participants

All research has the potential to attract bad-faith actors, but the nature of social media makes it much easier for these individuals to find, share, and exploit opportunities for compensation. Consider the following strategies to mitigate the risk of attracting fraudulent responders, bots, and scammers to the study:

- Use targeted advertising on closed or moderated specific topic groups or professional accounts instead of public-facing platforms like X, Reddit, Instagram, etc.
- Avoid listing compensation amounts on social media recruitment materials.
- Incorporate screening that involves contact with the study team or providing additional documentation to verify identity or eligibility. For example:
    - Provide each study participant (in person or by U.S. Postal Service mail) with a

Personal Identification Number (PIN) to be used for authentication in subsequent computer- and internet-based data collection. In this example, the PIN used must not be one that could be used by others to identify the individual (e.g., social security number, phone number, birth date, etc.).
    - Collect IP addresses to screen out repeat responders and ensure residency in the U.S. Ensure the informed consent states the collection of IP addresses will occur and develop a process to discard IP addresses as soon as possible.
    - Use bot-targeting screening mechanisms (such as CAPCHA)
    - Structure the screening survey to separate out unusual, repetitive, or inconsistent responses.
- Add language in advertisements and consent forms warning participants that compensation may be withheld if verification checks are not passed, and that additional follow-up may be needed to verify identity.

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.

Researchers are permitted to request limited self-reported information from participants to refine recruitment efforts for studies. This information, along with contact details, is strictly to be used for the purpose of narrowing down potential study candidates. Under no circumstances should this self-reported information be used for research purposes.

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.