



**Human Subject Protection Program
Investigator Guidance
June 22, 2020**

IDENTIFICATION AND RECRUITMENT OF RESEARCH SUBJECTS

Identification, initial contact, screening and recruitment of potential subjects is the beginning of the research informed consent process. All recruitment and screening procedures for a study must be approved by the CHLA IRB.

Acceptable Recruitment Methods

- In preparing recruitment materials, Investigators should consider the purpose of the research, the setting in which the research will be conducted, and be aware of the additional protections necessary for vulnerable populations, such as children and individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- The following methods of recruiting subjects are common and generally acceptable, keeping in mind some methods might not be appropriate for a particular study. All recruitment methods must be described in the research protocol and approved by the CHLA IRB.

Advertisements, Flyers, Information Sheets, Notices, Internet Postings and/or Media

- The text of these documents needs to be submitted to the CHLA IRB. Upload attachment(s) in the iStar application. Potential subjects who respond to these materials will contact the study investigators.

Direct Recruitment of Potential Subjects

- Examples of this strategy include physicians talking with their own patients about participation in a study; contact between the study team and potential subjects in person, by the phone or via the internet. With this method care must be taken to assure the person contacted does not feel pressured to participate. In addition, "cold-calling" should be avoided. A "cold-call" is unsolicited contact by a

person/group of which the patient/family is unfamiliar or do not have an existing relationship. Lastly, when recruiting by telephone, a voicemail/message script should be created to help maintain privacy and inform the potential participant that the call is not urgent.

Recruitment Letters

- Ideally, the recruitment letter would come from a physician or entity (e.g., clinic) that is already known to the potential subjects. Preferably, the letter would ask the person to call the study team for additional information if they are interested in participating in the study. There may be situations where it might be acceptable to ask the person to opt out if not interested in being contacted by the study team.
- A recruitment letter can be brief, but it should include information about how the person was identified to be sent the letter, who is doing the study and why, and an overview of study participation, including main risk and benefits. It should also let the person know how to inform someone if he or she wants to participate, not to participate, or where to get answers to additional questions.

Patient Referrals

- These are referrals from healthcare providers and others who are providing care for patients who may be eligible for study participation. Investigators may provide colleagues with a “Dear Patient” letter or a “Dear Potential Study Participant” letter describing the study, or study Information Sheets to colleagues or associates.

Subject Pools/ Recruitment Databases

- These are subject pools or databases for which potential subjects have given permission to be contacted to participate in future research. For recruitment databases, in most cases subjects have already provided consent to be contacted through another research study or other mechanism. The details of how potential subjects gave permission to be contacted for study participation must be described in the research protocol.

Review of publicly available records or other records

Use of Medical Records

- It is fairly common to use medical records for the purpose of identifying, contacting, and recruiting participants. Investigators wishing to review medical records to identify

and/or screen potential subjects for research purposes must obtain approval from the CHLA IRB. Access to medical records and protected health information by people not directly involved in CHLA patient care is highly restricted, and in most cases, not approved by the CHLA IRB.

- **NOTE: HIPAA regulations apply** to the screening process if it involves review of medical records. Investigators must obtain prospective HIPAA authorization or apply for a partial waiver of HIPAA authorization and informed consent.

Bonus Payments and Finder Fees for Recruitment of Potential Subjects

- CHLA prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments.”) Lump-sum payments not tied to the number of patients referred or enrolled is allowed for studies when it is approved as part of the CHLA contract with a study sponsor.

Recruitment of CHLA Employees or Students

- If Investigators wish to enroll their employees or students they directly supervise into one of their research studies, there are special provisions that need to be considered and implemented so that the employees or students do not feel obliged or pressured to participate in the study. Investigators should carefully consider the appropriateness of enrolling individuals they directly supervise or instruct. A plan to avoid circumstances that place undue influence or pressure on employees and students to participate must be described in the protocol (e.g., use of flyers or information sheets that allow volunteers to initiate contact about the study).

Recruitment Materials

All recruitment materials require IRB review and approval prior to their use. The following are examples of the types of recruitment documents that must be submitted for IRB review. Any information that is provided or made available to potential subjects requires IRB review. The IRB application should describe how the materials will be used. Any additions or changes to these documents must be submitted as iStar amendments to the study.

- **Letters and Information Sheets for Subjects:** All letters and information sheets provided to subjects or their representatives.

- **Advertisements:** The text of all advertisements in all media, including flyers, posters, newspaper ads, radio or television announcements, and informational videos. However, investigators are not required to submit to the IRB the final version of an advertisement as long as the template, actual text or script has been approved and does not modify what was approved. Investigators are responsible for maintaining copies of the final product in their research files.

- **Scripts:** All scripts or guides that will be used for in-person or telephone recruitment interviews.
 - If screening activities will take place prior to the subject providing informed consent for participation in the research, the researcher may request a waiver of informed consent or signed informed consent for screening activities in accordance.
 - If screening activities will take place only after the subject has provided informed consent for participation in the research, then the waivers described above are unnecessary.

- **Web Postings or Web Pages:** Submit printouts of postings or pages used for direct recruitment. However, web site postings that are limited to basic study information, such as title, purpose of the study, basic eligibility criteria and study site location, intended for informational purposes and not solely for recruitment may not require IRB review and approval.

Advertisement Content

- Advertisements to recruit subjects include the following information to determine eligibility and interest. The following elements are suggested but not required, although CHLA should be referenced whenever appropriate (for example, exceptions may be made for national campaigns). The information should be worded to be informative but not overly enticing or promise benefit from participation. See HRP-315 - WORKSHEET: Advertisements for details on IRB approval of Advertisements.
 - Indicate that the recruitment is for a “CHLA Research Study”
 - Provide the name and address of investigator/location of the research
 - Identify disease/condition under study, or the purpose of the research
 - Any key criteria used to determine eligibility (in summary form)

- Identify any significant risks or inconveniences, as applicable
- Identify any direct benefits of participation, as applicable
- Identify any payments
- Provide the time or other commitments required
- Person or office to contact for further information
- A statement that participation is voluntary

For Clinical Trials

- Whether the drug or device is investigational or FDA-approved for use in the study
- Whether the study involves use of a placebo or sham procedure
- Investigators and the IRB must ensure that all materials used for recruitment **do not**:
 - Characterize payment as a benefit, be the focus of the material, emphasize payment by using a larger font or bold type, or promise a bonus for completion of the study.
 - State or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the consent documents.
 - Include any exculpatory language that appears to waive any rights of the prospective participants.
- **For clinical trials, recruitment materials should not:**
 - Make any claims, either explicitly or implicitly, that investigational drug or device is known to be safe or effective, or equivalent or superior to any currently available treatment or other drugs, biologics or devices.
 - Promise a certainty of cure or of other favorable outcomes or benefits beyond what is outlined in the consent and the protocol.
 - Use terms such as “new treatment,” “new medication” or “new drug” without explaining the test article is “investigational or “experimental”.
 - Promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the study
 - Offer a coupon good for a discount on the purchase price of the investigational product once it has been approved for marketing.

CHLA Branding Web Site

- Visit the [Branding Site](#) on Inside CHLA for branded templates (PPT, fliers, posters, etc), photos and more.