Tea with the IRB: Recruitment and Compensation

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HUMAN SUBJECTS PROTECTION PROGRAM

Participation in research is **VOLUNTARY**.

Guatemala victims of US syphilis study still haunted by the 'devil's experiment'

Survivors tell of damaged lives after being deliberately infected in secret 1940s experiment on 1,500 men, women and children

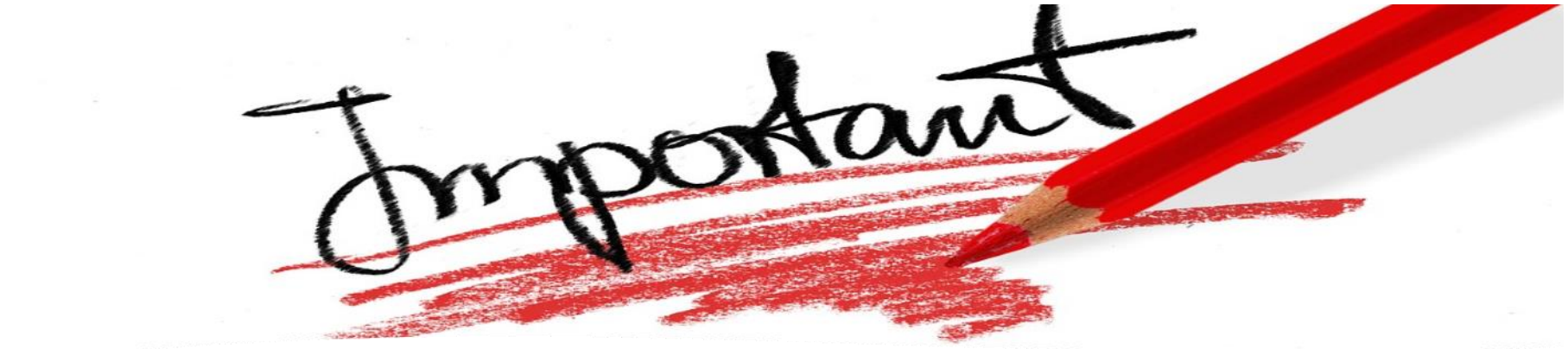
Marta Orellana, 74, a victim of the US syphilis trial when she was nine. 'They never gave me a chance to say no,' she says. Photograph: Rory Carroll for the Guardian

PURPOSE

This presentation will provide an overview about some of the ethical considerations investigators should think about when developing their recruitment plans and deciding on compensation for participation.

OVERVIEW

- IRB & PI Responsibilities
- What is recruitment, screening, and compensation?
- Ethical Considerations
- Protocol and Application Requirements
- Examples of Recruitment Tools: Bad and Good
- FAQs
- Resources



All recruitment methods, screening procedures and recruitment and screening materials for a study **MUST** be approved by the IRB ***prior*** to implementation.

IRB RESPONSIBILITES

- Authority to approve, require modifications in, or disapprove all research activities.

- Required to ensure that appropriate safeguards exist to protect the rights & welfare of research subjects.

- Review all research activities and documents that bear directly on the rights and welfare of the subjects of proposed research.

RECRUITMENT & ETHICAL CONSIDERATIONS

WHAT IS RECRUITMENT?

Any procedure intended to solicit participant enrollment in a research study.

Involves presenting potential subjects with information about the study, prior to their enrollment, to help establish interest and willingness to be a research subject.

The beginning of the informed consent process.

ETHICAL CONSIDERATIONS

- **Equitable Selection of Subjects**: Does the recruitment plan ensure that selection of subjects is equitable and appropriate for the study? Are you only enrolling English speaking populations because it is easier?

- **Respect for privacy**: Does the recruitment plan respect a potential subject's reasonable expectation for privacy? Will potential subjects be approached in a location where other people will not overhear the conversation?

- **Lack of pressure/undue influence**: Is the study being introduced in a way that allows potential subjects ample time to consider participation without pressure because of the timing of the invitation? ***Who*** is presenting the study (e.g., treating doctor, boss, teacher)? ***How*** is the invitation to participate being presented? What procedures are in place to avoid a lack of pressure or undue influence?

ETHICAL CONSIDERATIONS

- **Accurate & clear description of the study**: Is the information accurate and consistent with the protocol?

- **Unbiased presentation of the study**: Are the recruitment materials free of misleading information? Do the recruitment materials make the study excessively attractive?

- **Therapeutic Misconception**: Patients often think that participating in a clinical trial or any study proposed by a health care provider will benefit them even when they are told there is no assured benefit. Does the recruitment plan avoid therapeutic misconception?

PROTOCOL & APPLICATION REQUIREMENTS

PROTOCOL & APPLICATION REQUIREMENTS

1. Describe **HOW** potential subjects will be identified.

- ❑ **Review of private or public records (e.g., medical records, phone directories**): Identify the source records to be used

- ❑ **Personal Contacts (e.g., own patients):** Describe how potential subjects are known to the investigator.

- ❑ **Subject/Participant Pool (e.g., another research study)**: Describe how potential subjects previously gave permission/consent to be contacted about future studies. Identify the CHLA IRB #.

- ❑ **Referrals (e.g., colleagues):** Describe the process for obtaining referrals

- ❑ **Contacted by potential subject**: State that potential subjects will contact the study team in response to seeing advertisements about the study team.

PROTOCOL & APPLICATION REQUIREMENTS

2. Identify **WHO** is recruiting potential subjects.

- ❑ **No one:** Contact initiated by the potential subject

- ❑ **Recruiter initiates contact (e.g., in person approach, phone):** Member of the study team such as the PI, Co-PI, or research coordinator contacts potential subject directly

- ❑ **Recruiter initiating contact should be:**
  - Knowledgeable about the study
  - Able to answer questions
  - Appropriate person – depends on the type of research and/or study population (e.g., member of the study team, etc.).

PROTOCOL & APPLICATION REQUIREMENTS

3. Describe **WHEN & WHERE** potential subjects will be recruited.

- ❑ **Clinical Visit (COMMON)**: Describe when potential subjects/their families will be approached (e.g., clinical appointment, while sitting in the waiting room/exam room, during hospitalization, at discharge).

- ❑ **Day of surgery (UNCOMMON):** Provide the rationale(s) & describe how harm will be minimized.

- ❑ **Private room/area (e.g., exam room, private office)**

- ❑ **Public area (e.g., waiting room):** Provide the rationale as to why recruitment must be done in a public area & describe how subject privacy will be protected.

PROTOCOL & APPLICATION REQUIREMENTS

4. Describe **WHAT** recruitment methods will be used

METHODS	EXAMPLES
Advertisements	Flyers, brochures, information sheets, internet/social media postings
Direct Recruitment	Approach in person, call, email, presentation
Recruitment Letters	Letter mailed from healthcare provider or entity already known to the potential subject.
Patient Referrals	Dear Patient/Potential Study Participant letter from healthcare providers or others who are providing care for patients that may be eligible.
Subject/Participant Pools	Potential subjects have given permission to be contacted to participate in future research.

“Cold-calling” should be avoided. A “cold-call” is unsolicited contact by a person/group of which the patient/family is unfamiliar or does not have an existing relationship.

PROTOCOL & APPLICATION REQUIREMENTS

5. Describe **SCREENING** procedures

- **DEFINITION:** An activity/activities to determine whether a potential subject is eligible to participate in a research study based on the inclusion and exclusion criterion.

- **EXAMPLES:** Reviewing medical records, Interview, Questionnaire/Survey, Physical exam, imaging (e.g., MRI), laboratory tests, etc.)

- **INCLUDE:**
  - Identify & describe the screening procedures to be used
  - Describe the consent process
  - Identify what data will be collected, how the data will be stored, who will have access to the data, & when the data will be destroyed
  - **Screen failures**: Describe how & what data will be retained (if any), when the data will be destroyed, including whether identifiers are being retained from those who screen fail and whether contact information is being retained for future research
  - Submit copies of screening tools (e.g., scripts, surveys, consent forms)

PROTOCOL & APPLICATION REQUIREMENTS

- ❑ Consent not required per the Revised Common Rule (45 CFR 46.116 (g)]
  - **APPLIES TO**: Studies not FDA regulated & new studies approved after 1/21/2019
  - **UNDER THESE CONDITIONS**: Information obtained through oral/written communication (e.g., phone, email) OR obtaining identifiable private information/ biospecimens by accessing records (e.g., medical records) or stored biospecimens (e.g., biospecimens stored in a repository)

- ❑ Waiver of signed informed consent (waiver of documentation)
  - **APPLIES TO**: FDA regulated studies & studies approved before 1/21/2019
  - **UNDER THESE CONDITIONS**: Screening activities are minimal risk AND do not involve procedures for which written informed consent is normally required outside the research context.

- ❑ Written consent
  - **APPLIES TO**: FDA regulated studies & studies approved before/after 1/21/2019
  - **UNDER THESE CONDITIONS**: Screening procedures are greater than minimal risk OR involve procedures for which informed consent is normally required outside the research context.

- ❑ HIPAA Requirements
  - What information is being collected?
  - Is the information being retained?
  - IRB will determine does HIPAA apply, whether a HIPAA waiver is appropriate, or if HIPAA is required

ALL recruitment & screening materials require IRB review & approval ***prior*** to use and must be the final versions that subjects will see.

Any additions/changes to recruitment & screening materials **MUST** be submitted to the IRB via amendment applications in iStar for review & approval ***prior*** to use.

PROTOCOL & APPLICATION REQUIREMENTS

❑ Upload copies of **all** recruitment materials

- Include the following (as applicable):
  - ✓ Clear statement that study is research
  - ✓ Name of PI/institution
  - ✓ Contact information
  - ✓ Condition under study/purpose of study
  - ✓ Summary of eligibility criteria
  - ✓ List of benefits (if any)
  - ✓ Summary of study procedures

❑ Upload copies of **all** screening materials

PROTOCOL & APPLICATION REQUIREMENTS

- ❑ Use terms (e.g., new drug) without explaining that the test article is investigational
- ❑ Claims that an investigational test article is safe or effective
- ❑ Promise of cure or outcomes/benefits beyond the protocol & consent forms
- ❑ Promise of “free treatment”
- ❑ Language that appears to waive any rights
- ❑ Emphasis on payment/amount of payment
- ❑ Discount coupon for test article

PROTOCOL & APPLICATION REQUIREMENTS

Advertisement Scripts

Letters & Information Sheets

Flyers

Screening materials (e.g., scripts, surveys, ICFs)

Email Scripts

Brochures

In-person recruitment scripts

Telephone Scripts

RECRUITMENT TOOL EXAMPLES: BAD & GOOD

EXAMPLE #1: VOICEMAIL SCRIPT

"This is Caller's Name from the Division of [enter division/department] at Children's Hospital Los Angeles for Name of adult patient or parent/legal guardian of minor patient. This call is urgent. Please call me back at [enter phone number]. Thank you."

WHY ISN'T THIS ACCEPTABLE?

- Reflects an urgent call
- Doesn't inform person why they are being called
- Potential for mental/emotional harm

EXAMPLE #1: VOICEMAIL SCRIPT

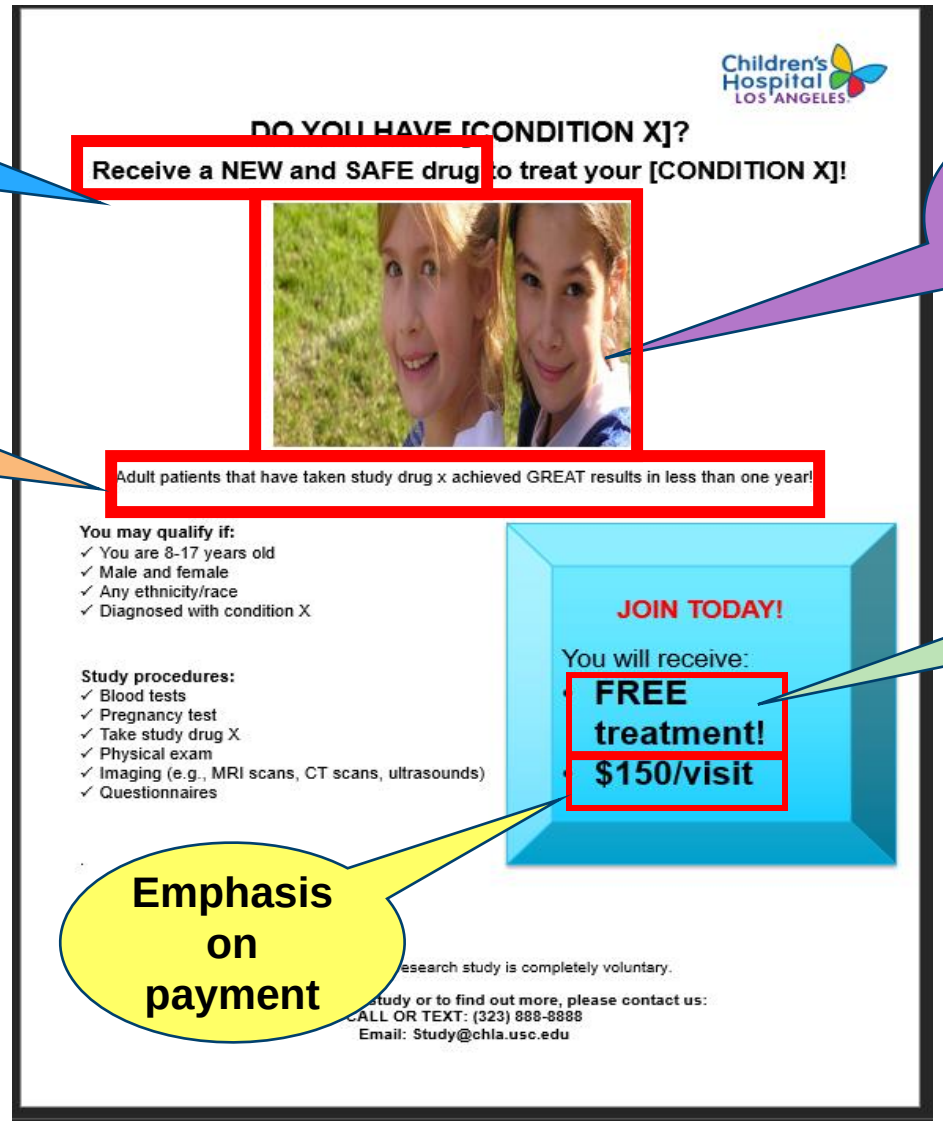
"This is Caller's Name from the Division of [enter division/department] at Children's Hospital Los Angeles for Name of adult patient or parent/legal guardian of minor patient. This call is not urgent.

[Enter name of PI] is conducting a voluntary research study that you may be eligible to participate in and I would like to discuss this with you. If you are interested in hearing more about this study, please call me back at [enter phone number]. Thank you."

WHY IS THIS ACCEPTABLE?

- Let's person know the call isn't urgent
- States why the person is being called/identifies PI
- Return call if interested

EXAMPLE #2: RECRUITMENT FLYER



Claim of safe new drug

Doesn't represent the study population

Claim of favorable outcome

Promise of free treatment

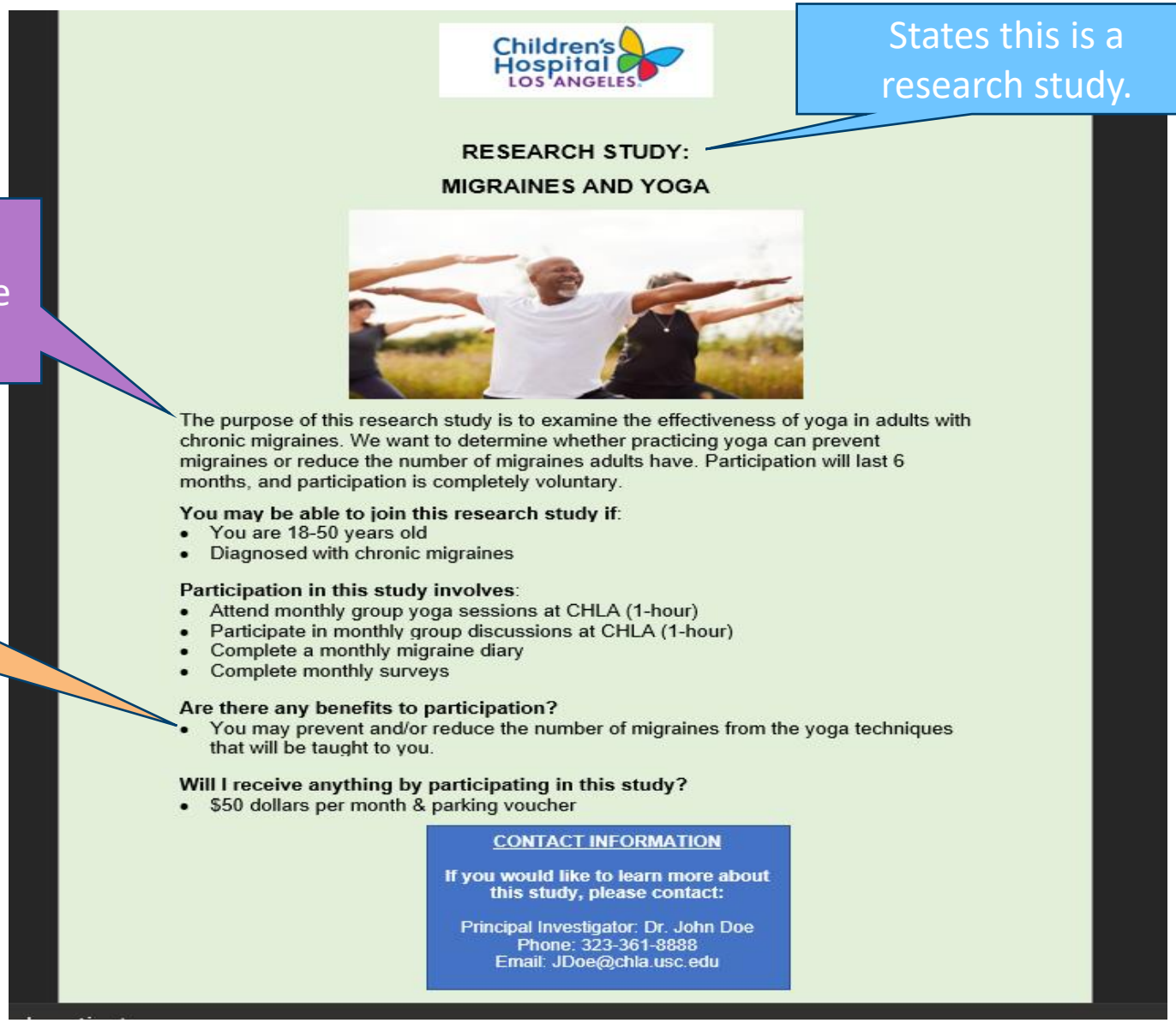
Emphasis on payment

EXAMPLE #3: RECRUITMENT FLYER

States this is a research study.

States the purpose of the study.

States potential benefit.



Children's Hospital LOS ANGELES

RESEARCH STUDY:

MIGRAINES AND YOGA

The purpose of this research study is to examine the effectiveness of yoga in adults with chronic migraines. We want to determine whether practicing yoga can prevent migraines or reduce the number of migraines adults have. Participation will last 6 months, and participation is completely voluntary.

You may be able to join this research study if:

- You are 18-50 years old
- Diagnosed with chronic migraines

Participation in this study involves:

- Attend monthly group yoga sessions at CHLA (1-hour)
- Participate in monthly group discussions at CHLA (1-hour)
- Complete a monthly migraine diary
- Complete monthly surveys

Are there any benefits to participation?

- You may prevent and/or reduce the number of migraines from the yoga techniques that will be taught to you.

Will I receive anything by participating in this study?

- $50 dollars per month & parking voucher

CONTACT INFORMATION

If you would like to learn more about this study, please contact:

Principal Investigator: Dr. John Doe
Phone: 323-361-8888
Email: JDoe@chla.usc.edu

COMPENSATION

WHAT IS COMPENSATION?

- **DEFINITION**: Money/item given to research subjects/legal guardians for time and inconvenience or a recruitment incentive
- **IS NOT** reimbursement. Reimbursement is money to subjects to cover out of pocket expenses associated with participating in a research study (such as parking, transportation costs, childcare costs, etc.).
- **IS NOT** a benefit for participation in research
- Currently, federal regulations **DO NOT** provide clear guidance on how research subjects should be paid & **DO NOT** set strict limits
- **FDA regulated research**: Must not include a coupon good for a discount on the purchase price of the product once it is approved for marketing.

ETHICAL CONSIDERATIONS

Undue Influence

Right to withdraw from participation

Vulnerable Populations

WHAT NEEDS TO BE INCLUDED IN MY PROTOCOL ABOUT COMPENSATION?

Amount of payment

Method of payment (e.g., Cash, gift card, check, ClinCard, toys, etc.)

Timing/schedule of payment (e.g., after survey, end of study visit, etc.)

Who receives the payment (e.g., minor subjects or their parent/guardian)

DON'T FORGET! Consent Documents & Recruitment Materials

Children's Hospital LOS ANGELES

WHAT ADDITIONAL INFORMATION NEEDS TO BE INCLUDED IN MY CONSENT FORM(S) ABOUT COMPENSATION?

- IRS Reporting Language (See the CHLA Consent Form Standards & Sample Language guidance)
  - ❑ Payments > $150 per visit or
  - ❑ Possibility the subject could receive ≥ $600 in a calendar year for all research and/or clinical programs

Identity of Participant Required for Payment:
Personal information about you, including your name, address, and social security number, will be released to the CHLA Patient Billing Office for the purpose of payment.

If the payments are greater than $150 per visit or if there is a possibility that you could receive $600 or more for your participation in any Children's Hospital Los Angeles studies, you will need to provide the name, address, date of birth, and social security number (or taxpayer ID number) of the person (family or friend) you'd like to receive the payments. If payments (for all research and/or clinical programs) in a calendar year equal $600 or more, the income will be reported to the IRS and a 1099 form will be issued. The person you designate to receive the payments can use this form with their income tax return, if appropriate.

LOTTERIES, RAFFLES, & DRAWINGS

- California Law **prohibits** conducting lotteries.

- The following information must be provided in the protocol:

  - ❑Use “drawing” rather than “lottery” or “raffle”
  - ❑Procedures to ensure that all people can participate in the drawing
  - ❑Procedures for choosing the winner & notifying them
  - ❑Procedures for protecting confidentiality and privacy Description of the prizes including the estimated value and the total # of prizes to be awarded
  - ❑Approximate chance of winning (if known) or an explanation as to why the approximate chance of winning can’t be stated

PI RESPONSILIBILITES, FAQs, & RESOURCES

PI RESPONSIBILITIES

- Describe the recruitment plan
- Describe screening procedures
- Describe the plan for payment for participation

- Submit the final versions of recruitment and screening tools to the IRB prior to use
- Submit amendments for any changes to recruitment & screening plans, recruitment & screening tools, and payment for participation
- Adhering to Hospital Policies & IRB Determinations

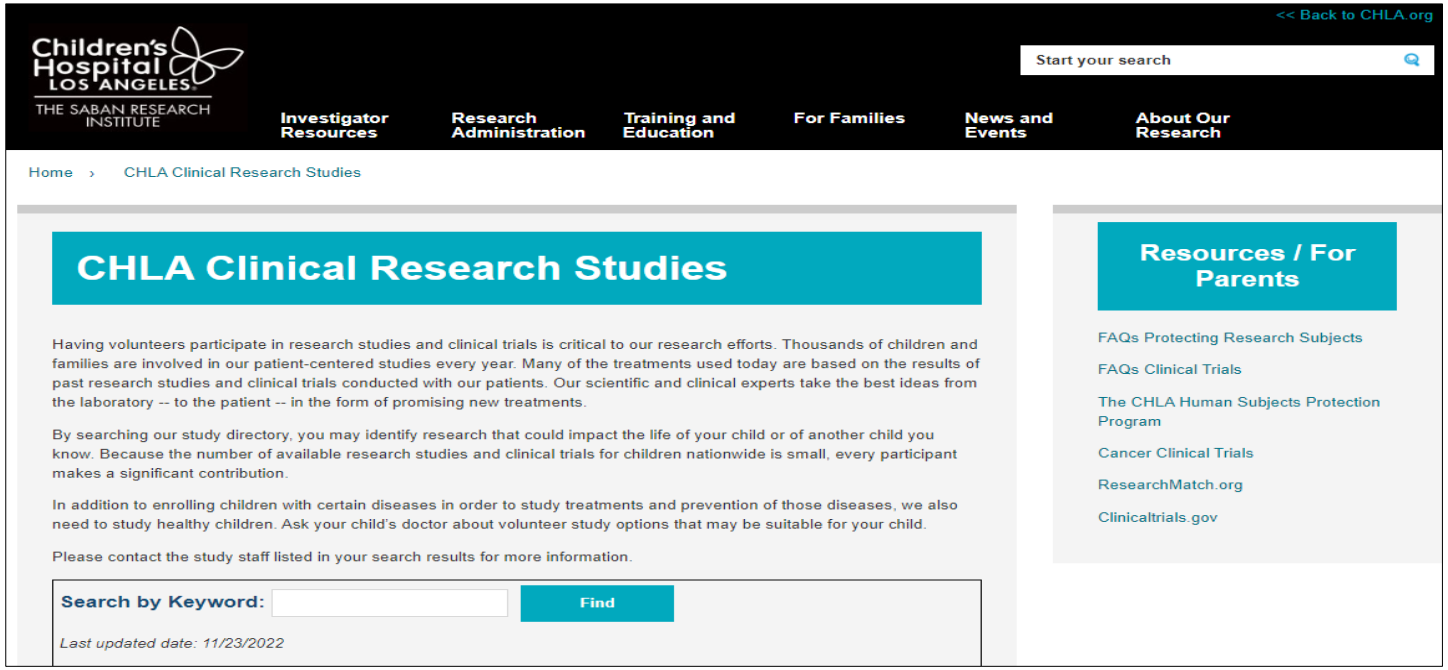
FAQS

1. Who can I contact if I need help developing recruitment strategies and/or recruitment materials?

- ❑ Contact CHLA Regulatory Affairs at RegulatoryAffairs@chla.usc.edu for assistance with recruitment strategies, tools, and templates.

2. Does CHLA have a directory of research studies where I can post information about my study?

- ❑ Yes. The CHLA Clinical Research Studies directory is available at https://www.chla.org/research/chla-clinical-research-studies. If you would like to have information about your study posted, contact CHLA Regulatory Affairs.



FAQS

3. Does the HSPP website have templates for recruitment materials?

- ❑ No. The HSPP website currently does not have templates for recruitment materials. Investigators should visit the Branding Site on inside CHLA for branded templates or contact CHLA Regulatory Affairs.

4. Do I need to submit translated versions of recruitment materials to the IRB?

- ❑ No. There is no requirement to submit translated versions of recruitment materials to the CHLA IRB (see "Amendments to CHLA IRB Approved Research" guidance document).

5. Do I need to request a partial waiver HIPAA authorization to screen, recruit, and contact potential subjects?

- ❑ No. When the person accessing CHLA medical records is part of the covered entity a partial waiver of HIPAA authorization does not need to be requested.

RESOURCES

- **CHLA HSPP website**: https://www.chla.org/research/hspp
- **Clinical Research Support Office**: https://www.chla.org/research/clinical-research-support-services
- **CHLA Education & Training Sessions**: https://www.chla.org/research/hspp-education-and-training-sessions
- **Guidance Document:** Identification and Recruitment of Research Participants
- HRP-315 – WORKSHEET: Advertisements
- HRP-316 – WORKSHEET: Payments
- **CHLA Branding website**: https://insidechla.org/page.php?pageid=351
- **FDA**: Recruiting Study Subjects
- **FDA**: Screening Tests Prior to Study Enrollment
- SACHRP Recommendations: Attachment A – Addressing Ethical Concerns Offers of Payment to Research Participants

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