1 PURPOSE

1.1 This guidance describes the process of subject selection, recruiting, advertising, and payment to participants involved with human research at Sharp HealthCare (SHC).

1.2 The guidance begins when an application for a human research study is submitted to SHC Institutional Review Board (IRB).

1.3 The guidance ends when a human research study subject enrollment period ends.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 Recruitment and selection of participants must be equitable (fair or just) within the confines of the study. Investigators or designees may not exclude participants based on gender, race, national origin, religion, creed, education, or socioeconomic status. The benefits and burdens of research must be fairly distributed.

3.2 In instances where the investigator is also the potential participant's treating physician there may be a conflict between increasing enrollment and patient benefit. Conflicts should be decided in the best interest of the patient.

3.3 Payments from research sponsors and/or their collaborators to Investigators or study personnel, such as an additional fee to encourage participant recruitment efforts and the timely or accelerated opening of research studies are not permitted. These payments are strictly prohibited per California Health and Safety Code Section 445.

3.4 It is impermissible to pay or accept "finder's fees" or "referral fees."

3.5 It is impermissible to accept "bonus payments." SHC employees cannot accept personal payments from sponsors or other Investigators or designees in exchange for accelerated recruitment or referrals of patients.

3.6 Cash or cash-equivalent payment to health care providers for referral of subjects or potential subjects is not permitted.

3.7 Other types of compensation to health care provider or Investigators or designees (e.g., books, other non-cash gifts) are also prohibited.

4 RESPONSIBILITIES

4.1 The IRB is responsible for ensuring that Investigators or designees adhere to guidance on participant selection, recruitment, and payment.

5 PROCEDURE

5.1 Recruitment Methods

5.1.1 The following are examples of common recruitment methods for human research studies. All recruitment methods must be described in the narrative of the IRB protocol and recruitment materials reviewed and approved by the IRB. (*WORKSHEET: Advertisements [HRP-315]*)

5.1.1.1 Use of advertisements, notices, and/or media to recruit subjects. Examples include flyers posted in public settings, newspaper ads, social media, and radio and television advertisement. All advertisements and recruitment materials (e.g., video, audio, telephone scripts, and recruitment forms) require prior IRB approval.

5.1.1.2 Direct recruitment of participants unknown to the Investigators or designees. Examples include random digit dialing, approaching people in public settings, snowball sampling, use of social networks.

5.1.2 Request a Waiver of Consent/Health Insurance Portability and Accountability Act (HIPAA) Authorization, if potential subjects' Protected Health Information (PHI) are to be accessed by study personnel for the purpose of identifying potential participants through review of medical records. Waivers must be justified in *FORM: Initial IRB Review Application (HRP-211)* and in *TEMPLATE: Research Protocol (HRP-500)*. Waivers may be documented by an IRB Chair or designated IRB member via

CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410) and/or *CHECKLIST: HIPAA Waiver of Authorization (HRP-441)*.

5.2 Advertisements and Recruitment Materials Requirements

5.2.1 Advertisements and recruitment materials for human research subjects (posters, flyers, newspaper/magazine ads, scripts for radio/TV, electronic mail, social media, or solicitations from outside sources) are considered an extension of the informed consent and subject selection processes and require IRB approval before use. Accordingly, they need to be submitted with *FORM: Initial IRB Review Application (HRP-211)*.

5.2.2 When recruitment materials are submitted to the IRB after the initial IRB approval, the submitter includes a completed *FORM: Update Recruitment Materials Request (HRP-222)*.

5.2.3 Changes to Recruitment Materials

5.2.3.1 Any subsequent changes in the content of an approved advertisement must also be submitted for IRB review and approval prior to use with a completed *FORM: Update Recruitment Materials Request (HRP-222)*.

5.2.3.2 Occasionally, newspapers or magazines may alter copy to fit available space. Therefore, when submitting an advertisement to a newspaper or magazine, the cover letter should state that the advertisement has undergone institutional approval and cannot be altered.

5.2.4 The designated IRB reviewer uses *WORKSHEET: Advertisements (HRP-315)* to assess proposed recruitment materials.

5.3 Payments to Participants

5.3.1 Payment - Payment to research participants for participation in studies is not considered a benefit. Rather, it should be considered compensation for time and inconvenience or a recruitment incentive. The amount and schedule of all payments should be described in the study protocol at the time of initial IRB review, including a summary of both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. Procedures for prorating payment, should the participant withdraw, should be included in the IRB application and informed consent document(s). (*WORKSHEET: Subject Payments [HRP-316*])

5.3.2 Timing of Payments - Credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time the study would have been completed had they not withdrawn. For example, in a study lasting only a few days, it would be permissible to allow a single payment date at the end of the study, even to participants who withdraw before completion. However, for a study lasting several months, it would not be permissible to allow a single payment date. Participants who withdraw before completion of the study should receive accrued compensation in a timely manner.

5.3.3 Completion Bonus - While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion is acceptable, providing that such incentive is not coercive. The IRB will determine whether the amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

5.3.4 Disclosure of Payments - All information concerning payment, including the amount and schedule of payment(s), should be described in the informed consent document.

5.3.5 Alterations in Payments - Any changes in participant compensation or flexibility of the payment schedule must be reported to the IRB as a modification prior to implementation.

5.3.6 Payment Methods, Fund Management, and Internal Revenue Service (IRS) Reporting - Payments to research participants must be in accordance with SHC accounting policy and procedures for payments to research subjects.

5.4 Subject Selection - The IRB primary reviewer confirms selection of subjects is equitable by completing *WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)*, signing and maintaining in the study file.

6 MATERIALS

6.1 FORM: Initial IRB Review Application (HRP-211)
6.2 FORM: Update Recruitment Materials Request (HRP-222)
6.3 CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)
6.4 CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
6.5 WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)
6.6 WORKSHEET: Advertisements (HRP-315)
6.7 WORKSHEET: Subject Payments (HRP-316)
6.8 TEMPLATE: Research Protocol (HRP-500)

7 REFERENCES

7.1 California Health and Safety Code Section 445

This document is available on IRBANA or by contacting research@sharp.com.