

SOP: Participant Selection Recruitment and Payments

Section III: IRB Protocols

Number	Date
IRB III-009	9/13/2025

1. PURPOSE

- 1.1. This SOP describes the process of subject selection, recruiting, advertising, and payment to participants involved with human research at Texas A&M University-Kingsville.
- 1.2. The SOP begins when a human research study is submitted to the TAMUK Institutional Review Board (IRB).
- 1.3. The SOP concludes when the human research study's subject enrollment period ends.
- 1.4. All recruitment methods must be described in the study application. All recruitment materials must be reviewed and approved by the IRB.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP 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 on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. The benefits and burdens of research must be fairly distributed.
- 3.2. TAMUK IRB strictly prohibits investigators and study personnel from accepting any form of payment, incentive, or bonus—whether cash, cash-equivalent, goods, or services—from sponsors, other investigators, or their designees in exchange for participant recruitment, subject referrals, or the expedited initiation of research studies. This includes, but is not limited to, finder's fees, recruitment bonuses, and any personal payments intended to accelerate or influence enrollment efforts.

4. RESPONSIBILITIES

4.1. The investigator is responsible for ensuring that all study personnel and designees adhere to policy and 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.
 - 5.1.1.1. Use of advertisements, notices, and/or media to recruit subjects, including email, video, audio and telephone scripts, social media, text messages, flyers posted in public settings, newspaper, radio, and television advertisements.
 - 5.1.1.2. Providing basic study information and investigator contact information to other sources that may inform subjects of available studies.

- 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, email, social media, text messages, or solicitations from outside sources) are considered an extension of the informed consent and subject selection processes. Accordingly, they need to be included as part of the initial IRB application and will require IRB approval before use.
 - 5.2.1.1. All approved recruitment materials must display the following items:
 - 5.2.1.1.1. TAMUK Boilerplate statement (located on the IRB webpage)
 - 5.2.2. Any subsequent changes to IRB approved recruitment materials must be submitted for IRB review and approval prior to use.

5.3. Payments to Participants

- 5.3.1. All compensation to participants must be described in the IRB protocol and approved by the IRB. 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 ensure that neither are coercive or presents undue influence. Payment to research participants for participation in studies is not considered a benefit. Rather, it should be considered compensation for time, travel, and inconvenience. Procedures for prorating payment, should the participant withdraw should be included in the IRB application and informed consent document(s).
- 5.3.2. The amount and schedule of payments described in the study application and/or protocol are to be consistent with any contract or agreement.
- 5.3.3. <u>Timing of Payments</u> 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.
- 5.3.4. <u>Completion Payment</u> While the entire payment should not be contingent upon study completion, payment of a small proportion as an incentive for completion may be acceptable, provided that such an incentive is not coercive. The IRB will determine whether the amount paid for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- 5.3.5. <u>Disclosure of Payments</u> All information concerning payment, including the amount and schedule of payment(s), should be described in the informed consent document.

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

6. REFERENCES

6.1. 21 CFR 56.111

6.2. 45 CFR 46.111

Approved by: Sai Kupezznodi

Lori Kupczynski, EdD

Special Assistant to the Vice President,

Office of Research and Innovation

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