	SOP: Subjects Selection Recruitment and Payments		
	NUMBER	DATE	PAGE
	HRP-094	5/1/2022	Page 1 of 1

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.
- 1.2 The SOP begins when a human research study is submitted to the Texas A&M University TAMU Institutional Review Board (IRB).
- 1.3 The SOP ends when the human research study's subject enrollment period ends.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from version 5/30/2017.

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 TAMU strictly prohibits researchers from accepting any offer from a sponsor to pay Investigators or study personnel an additional fee to encourage participant recruitment efforts and the timely or accelerated opening of research studies. It is impermissible to pay or accept "finder's fees."
- 3.3 It is impermissible to accept bonus payments for recruitment. TAMU employees cannot accept personal payments from sponsors or other Investigators or designees in exchange for accelerated recruitment or referrals of subjects.
- 3.4 Cash, cash-equivalent payment or payment in goods or services to TAMU personnel for referral of subjects or potential subjects is not permitted.

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 All recruitment methods must be described in the study application. All recruitment materials must be reviewed and approved by the IRB.
- 5.1.2 The following are examples of common recruitment methods for human research studies.
 - 5.1.2.1 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 ads, and radio and television advertisement.
 - 5.1.2.2 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 IRB initial application and will require IRB approval before use. See HRP-315 – WORKSHEET - Advertisements.

	SOP: Subjects Selection Recruitment and Payments		
	NUMBER	DATE	PAGE
	HRP-094	5/1/2022	Page 2 of 1

5.2.1.1 All approved recruitment materials must display the following items:

5.2.1.1.1 IRB Study ID Number

5.2.1.1.2 IRB Approval Date

5.2.2 Recruitment materials submitted to the IRB after the initial IRB approval must adhere to the same policy and guidance.

5.2.3 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 Payment to research participants for participation in studies is not considered a benefit. Rather, it should be considered compensation for time, travel and inconvenience. 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). See *WORKSHEET: Subject Payments (HRP-316)*

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 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.

5.3.4 Completion Payment - While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion may be acceptable, providing that such 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 Disclosure of Payments - All information concerning payment, including the amount and schedule of payment(s), should be described in the informed consent document.


5.3.6 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.

5.3.7 Payment Methods and IRS Reporting - Payments to research participants must be in accordance with TAMU SAP 21.01.99.M0.03 'Payments to Human Research Participants'.

6 MATERIALS

6.1 HRP-315 – WORKSHEET- Advertisements

6.2 HRP-316 – WORKSHEET - Subject Payments

	SOP: Subjects Selection Recruitment and Payments		
	NUMBER	DATE	PAGE
	HRP-094	5/1/2022	Page 3 of 1

7 REFERENCES

- 7.1 FDA 21 CFR 56.111
- 7.2 FDA: Recruiting Study Subjects Information Sheet (01/01/1998)
- 7.3 OHRP 45 CFR 46.111
- 7.4 AAHRPP II.3.C.1
- 7.5 TAMU SAP 21.01.99.M0.03 Payments to Human Research Participants