SUBJECT: Payments to Research Participants

1. PURPOSE:

This SOP establishes the procedures for guidance for payments to human subjects research participants for studies approved under the Institutional Review Board and/or Research & Development Committee. The primary reference for this document is the 2019 report by the Department of Health and Human Services' Secretary's Advisory Committee on Human Research Protection (SACHRP) "*Addressing Ethical Concerns Regarding Offers of Payment to Research Participants*." Phrases in quotation marks are from this reference.

Note: *This policy only applies to studies enrolling decisionally-capable adults. It does not apply to payments that are part of the intervention being studied or to payments intended to reimburse or compensate for a study-related injury.*

2. DEFINITIONS:

IRB: Institutional Review Board
HHS: Department of Health and Human Services
OHRP: HHS Office of Human Research Protections
R&D: Research and Development
RDC: R&D Committee
SACHRP: HHS Secretary's Advisory Committee on Human Research Protection

3. OVERVIEW:

Participant payments are commonly used in human studies' research and "are often ethically important, assisting in recruitment and completion of trials, facilitating diverse participation, and acknowledging the value of participants' contributions to research". This SOP/guidance informs:

1. Investigators on how to categorize, describe and justify proposed participant payments in their IRB and RDC submission(s).
2. The IRB and RDC on how to evaluate the appropriateness of the proposed payment(s).

Broadly speaking, research participant payments may be categorized as either raising or not raising concerns about undue influence. OHRP FAQs define undue influence as potentially occurring "through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance." Undue influence may inhibit potential participants' "adequate consideration of and reflection about important study features such as risks, burdens, and discomforts" thus compromising the informed consent process.

Payments that do not raise concerns of undue influence: According to SACHRP, these include:

1. Reimbursement for costs related to study participation (e.g., travel and lodging expenses, meals outside the home, childcare)
2. Compensation for time and effort to compensate for income the participant may forego to participate in the study
3. Tokens of appreciation, i.e., small payments or gifts of minimal value offered to express appreciation

Incentive Payments: "In contrast to reimbursement and compensation, incentive payments go beyond what participants might be owed as a matter of fairness" and therefore "do have the

potential to compromise the informed consent process, raising concerns of undue influence." In such cases it is the responsibility of the IRB or RDC to ensure that the possibility of undue influence is minimized. The IRB or RDC should consider the following factors in its deliberations:

- Its responsibility to approve research only when risks are reasonable in relation to benefits
- The possibility that incentive payments will compromise the informed consent process and steps that can be taken to mitigate that outcome (see below)
- How restricting incentive payments might compromise recruitment success
- How similar payments might be viewed outside the research setting

Mitigating the effect of incentive payments on the Informed Consent process may be achieved by using a "cogent consent form and processes aimed at supporting and promoting informed decision-making" such as:

- Setting aside sufficient time for knowledgeable study staff to review the entire consent form with the potential participant;
- Incorporating waiting periods and including tests of comprehension to ensure full understanding of the study risks; or
- Explicitly discussing how current interests (payment now) may conflict with future harms from study participation.

Employees as Research Subjects: If they meet the study selection criteria,

1. Minneapolis VAHCS employees who are also Veterans may be enrolled in Minneapolis VAHCS research studies.
2. Non-Veteran MVAHCS employees may be enrolled in Minneapolis VAHCS research studies that have been approved by the RDC to enroll non-Veterans.
3. VA employees who are recruited to participate in a research study because of their role as an employee may participate during their work tour. When participating during their work tour, VA employees may not be additionally compensated.
4. VA employees who participate in research for which their role as an employee is not a criterion for inclusion must be in an approved leave status.

4. PROCEDURES:

a) The IRB or the RDC in the case of studies not requiring IRB approval, is empowered to approve or disapprove all protocol-based plans for payments to research participants.

b) If proposing any participant payments, it is the responsibility of the investigator, not the IRB or RDC, to adequately justify the dollar amounts proposed (see Appendix A). Investigators must specify in their IRB or RDC submission materials:

i) The purpose of the payment(s): reimbursement, compensation, appreciation or incentive;

ii) The dollar amount of the proposed payment(s); and

iii) The rationale for the amount(s) chosen.

c) If proposing incentive payments, investigators must also specify what steps they will take to mitigate the possibility of undue influence.

d) The IRB or RDC office staff will ensure that all IRB or RDC members are aware of the guidance in this SOP and have access to it during the review and discussion of studies that are offering subject payments.

5. REFERENCES:

HHS SACHRP "*Addressing Ethical Concerns Regarding Offers of Payment to Research Participants*" https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html (18 October 2019)

6. R&D COMMITTEE APPROVAL: 05 September 2023

7. RECISSIONS: Minneapolis Research Service SOP R&D-022 "Payments to Research Participants" (03 May 2022).

8. EXPIRATION DATE: N/A

9. FOLLOW-UP RESPONSIBILITY: Research and Development (R&D) Committee

<u>APPENDIX A.</u> Guidance from SACHRP for determining dollar amounts for "compensation for time and effort" payments

"IRBs need not determine dollar amounts in the abstract but should instead rely on investigators to justify the amounts they propose. Benchmarks that have been used include the average working wage and purchasing parity ratio in the community where the research is being done".