Title: RECRUITMENT INCENTIVES **Version No.:** 1.0

SOP No.: RR-413 **Effective Date:** January 21, 2025

1. Purpose

This policy describes MSK IRB recruitment incentive requirements for exempt and non-exempt human research studies.

2. Policy

The informed consent process begins when a potential research participant first learns of a study, which is usually accomplished through recruitment efforts. The IRB is required to review all documents and activities related to recruitment that affect the rights and welfare of human participants.

Recruitment incentives include payment, reimbursement, gifts (*e.g.*, article of clothing, cooler bag, etc.), or any other financial incentive offered to prospective research participants to take part in the research study. If payment and/or reimbursement is offered by the sponsor, MSK PIs cannot opt out.

There is no minimum or maximum amount of incentive that can be provided to participants. All recruitment incentives must be reviewed and approved by the IRB to ensure the incentive is appropriate. Incentives may be provided by either an external entity (*e.g.*, pharmaceutical company) or MSK.

Payments for participation in research may have tax implications for research participants. Therefore, this must be an opt-in/out component of the informed consent/research authorization.

Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of a product once it has been approved for marketing is not allowed.

3. Specific Procedures

3.1 IRB Review and Approval

3.1.1 The IRB will review the information contained in the recruitment incentive documents to determine that the procedure is not unduly coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. These documents include but are not limited to the MSK travel form, external entity informational brochures, consents with the company, and/or payment/reimbursement method details (*e.g.*, reloadable credit/debit card). The amount and schedule of all payments must be included.

3.1.2. The IRB will review the informed consent language to ensure participant may opt-in/out of receiving research payments. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document and/or ancillary form.

3.1.3. Participant-facing documents (*e.g.*, consent, advertisements, etc.) may not overly emphasize payment for participation or the amount to be paid. For example, making this information larger or bolded compared to other information on the document, not being the first statement that a participant would read, etc.

3.2 Incorporating incentives after MSK IRB Approval of a Study

When an investigator decides to incorporate recruitment incentives after the initial approval of a research study by the IRB, the proposed changes, ancillary documents, updated consent form and recruitment plan shall be considered by the MSK IRB as an amendment to the ongoing research study.

3.3 Payment to Participants

3.3.1 The amount of payment and the proposed method and timing of disbursement should not be coercive nor present undue influence.

3.3.2 Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.

3.3.3. Any amount paid for completion of part or all of the study is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

3.3.4. If MSK is providing stipends, the PI is responsible for providing the research participant, regardless of amount, the required documents for the Center to track amount of potential tax reporting and requirements as per MSK CR SOP 108.

3.4 Payments from Sponsors to Investigators

3.4.1 Investigators may not receive payments from sponsors that are designed to accelerate recruitment or that are tied to the rate or timing of enrollment (“bonus payments”).

3.4.2 Investigators (or Sponsors) may not provide payments to MSK physicians in exchange for referrals of prospective participants (“finders fees” or “referral fees”).

3.4.3 MSK does not allow compensation for participation in a trial offered by a Sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. Applicable Regulations and References

- 45 CFR 46.111(a)(3)
- 21 CFR 56.111(a)(3)
- MSK CR SOP 108

Revision History

Revision	Effective Date	Reason for Change
1.0	1/21/25	NEW