

<b>Payment of Research Participants</b>	Effective Date	08.22.2023
	Revision Date	

**1.0 Purpose:** The purpose of this standard operating practice (SOP) is to describe the University and Medical Center Institutional Review Board’s (UMCIRB) process for the review and approval of payments to human research participants and to provide guidance to Principal Investigators (PI) and designated research personnel in accordance with federal regulations. The UMCIRB must review and approve all payment schedules for incentives or reimbursement to ensure there is no coercion or undue influence on a participant’s decision to enroll in a research study.

**2.0 Persons Affected:**

- 2.1 Principal Investigators (PI) and designated research personnel
- 2.2 UMCIRB Chairpersons and members
- 2.3 UMCIRB Office staff members

**3.0 SOP:** The UMCIRB must review and approve all payment schedules contained in the recruitment documents and consent forms. For every study, the UMCIRB’s first responsibility is to determine whether the risks of harm and potential benefits are appropriately balanced for the study’s target population (i.e., those satisfying inclusion criteria and not meeting exclusion criteria). Payment to research participants for participation in studies is not considered a benefit that would be part of weighing of benefits or risks; it is a recruitment incentive. UMCIRB should consider whether payment is acceptable only after it is satisfied that the study is acceptable.

Participant payments should not be contingent upon completing the entire study and should be prorated when appropriate. In studies with very short participation windows and involving minor procedures/inconveniences, it may be appropriate to provide the compensation in one lump sum at the end of the study.

Payment for participation in research should be just and fair. The amount and schedule of all payments should be presented to the UMCIRB at the time of initial review. The UMCIRB must review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence. The UMCIRB must make sure that payments are not so high that they could compromise a prospective subject’s examination and evaluation of the risks or affect the voluntariness of his or her choices. In contrast to payment for participation, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence.

**4.0 Definitions:**

- 4.1 **Compensation or Incentive Payments:** A predetermined payment of cash or cash equivalent provided to research subjects for the time, effort, inconvenience, and general expense of participating in a research activity. Depending on the length of the study and number of research interactions, payment may be made on a one-time basis, or several payments may be made over a period of time. Compensation is considered taxable income.
- 4.2 **Reimbursement:** Money given to the research participant that reflects out of pocket

expenses associated with participating in a research study (e.g., transportation, parking, lodging, meals, childcare, etc.)

- 4.3 **Coercion:** Entails a threat to violate someone’s rights or fail to fulfill an obligation to him or her to obtain compliance, creating a circumstance in which the person has no reasonable alternative but to comply (OHRP).
- 4.4 **Undue Influence:** Potentially occurring “through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.” (OHRP).

## 5.0 Procedures/responsibilities

### 5.1 Investigators/study team members have the responsibility to:

- 5.1.1 Provide a detailed description of payment to UMCIRB including payment amount, method of payment, timing of payment, pro-rating schedule, and payment for participants who withdraw before study completion.
  - 5.1.1.1 Provide a payment amount to UMCIRB. Payment amount must not be so excessive as to increase the possibility of undue influence. Payment may be considered undue if it compromises a prospective subject’s examination and evaluation of the risks or affect the voluntariness of his or her choices.
  - 5.1.1.2 Describe the method of payment, including all odds of being selected for drawings. The Greenphire ClinCard System is the University’s payment method of choice to compensate and/or reimburse participants for participating in a research study. If the PI or study team member opts not to use it, he/she needs to get an exemption from Financial Services. Below is the Greenphire Exceptions SOP:  
<https://financialservices.ecu.edu/wp-content/uploads/sites/86/2018/05/Greenphire-Exception-SOP.pdf>
  - 5.1.1.3 Provide a payment schedule to UMCIRB. Payment should be prorated for the time of participation in the study rather than delayed until study completion, because the latter could unduly influence a subject’s decision to exercise his or her right to withdraw at any time.
  - 5.1.1.4 Provide a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (e.g., what will happen if he or she withdraws part way through the research, or the investigator removes a participant from the study for medical or noncompliance reasons).
  - 5.1.1.5 The IRB may approve the giving of course credit or extra credit to students who are expected to participate in research activities as part of a class curriculum only when alternative means of obtaining course credit or extra credit is made available to students who do not wish to volunteer as research participants. Students must be given other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit. For example, short papers, special projects, book reports, and brief quizzes on additional reading may be offered in lieu of research participation. Students must be told that they can withdraw from the study at any time and credit will be prorated.

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5.1.1.6 When research involves children (<18-year-old), incentives for participation should be appropriate to their ages and the nature of the study. Incentives (e.g., toys, coupons for food) should usually be given to the child participants, not the parents. Parents may be reimbursed or paid for expenses such as travel.

5.1.1.7 Payments to participants may be subject to taxation and there are institutional requirements for collecting Social Security Numbers. Information on these requirements is available through Financial Services.

5.1.2 Incorporate all information concerning payment into the designated section of the ePIRATE submission, protocol, advertisements, and consent documents.

5.1.3 Ensure that compensation is not listed as a benefit to participation in research and that it is not outlined as such in the ePIRATE submission or informed consent documents.

5.1.4 Ensure that research payments are not emphasized in any fashion within research advertisements (e.g., large/bold/font/exclamation points, etc.).

5.1.5 Ensure that payment is outlined in the parental permission form if a child participates in research.

5.1.6 Any alterations in research participant payment or liberalization of the payment schedule must be submitted to UMCIRB as an amendment and approved prior to implementation.

5.2 **UMCIRB Office staff members are responsible for:**

5.2.1 Reviewing the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence and to determine if the amount of payment is appropriate for the procedures, time, effort, and inconvenience involved.

5.2.2 Reviewing the proposed method of payment and ensure institutional policies are

satisfied.

This includes any requirements for Social Security Number disclosures.

5.2.3 Ensuring the entire payment is not contingent upon the participant completing the study unless the study is of short duration or only a one-time procedure. Payment should accrue as the study progresses.

5.2.4 Reviewing advertisements to assure that advertisements are not coercive or present undue influence and do not emphasize the payment or the amount to be paid, by such means as larger or bolded type.

5.2.5 Ensuring that compensation is not listed as a benefit and should not be outlined as such in the ePIRATE submission or the consent form.

5.2.6 Ensuring that any course or extra credit being offered as an incentive complies with section 5.1.1.5.

5.3 **UMCIRB Chairperson (or designee) will:**

5.3.1 Review the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence and to determine if the amount of payment is appropriate for the procedures, time, effort, and inconvenience involved.

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- 5.3.2 Ensure the entire payment is not contingent upon the participant completing the study unless the study is of short duration or only a one-time procedure. Payment should accrue as the study progresses.
- 5.3.3 If extra credit is available to student participants, ensure that students have other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit.
- 5.3.4 Ensure that incentive payments do not compromise the informed consent process.

**References**

[https://rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/457/2020/03/Recruiting-for-Human-Research-SOP\\_3-23-20\\_Clean.pdf](https://rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/457/2020/03/Recruiting-for-Human-Research-SOP_3-23-20_Clean.pdf)

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html>

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

<https://www.ecu.edu/pr/07/35/04>

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