# 3.8 Research Subject Compensation and Reimbursement

## 1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements and limitations regarding compensation and reimbursement of research subjects.

## 2.0 Policy

It is the policy of the Organization that:

- **2.1.** Compensation for research subjects may be acceptable if 1) the possibility of undue influence is minimized, and 2) the compensation is considered reasonable payment for time spent, or, if minimal risk research, a reasonable incentive for participation.
- **2.2.** Compensation in any form is not considered a benefit to be weighed against risks in the IRB's assessment of the risk/benefit relationship of the research, and that compensation not be presented to the potential subject as a benefit in either the process of consent, or the potential benefits section of the consent form.
- **2.3.** Reimbursement for study-related travel and out of pocket expenses is acceptable.
- **2.4.** Investigators should attempt to minimize financial sacrifice on the part of subjects and, as possible and appropriate, offer equitable reimbursement for costs.

## 3.0 Definitions

- **3.1. Compensation** refers to monetary or other payment to the subject primarily intended to compensate for time spent in participating in the research activities, but also, in limited circumstances, as incentive to participate.
- **3.2 Reimbursement** refers to monetary payment to offset expenses incurred as a direct result of participating in research activities. This includes travel expenses, lodging, meals, daycare, and may also include specific costs associated with research interventions (for example, costs of medications or therapies).

## 4.0 General Principles

- **4.1.** Compensation for participation in research is not a requirement.
- **4.2.** The amount or type of compensation should not serve as undue inducement to potential subjects.
- **4.3.** For research posing greater than minimal risk to subjects, the amount of compensation should reflect the amount of time required of the subject. The amount of compensation should not be tied to the degree of risk or discomfort associated with the study.
- **4.4.** For research posing minimal risk to subjects, since the risks associated do not exceed those of daily life or routine physical or psychological examination, compensation is not an inducement to offset risk. Therefore, compensation for minimal risk research may represent a reasonable incentive for participation.
- **4.5.** Reimbursement for expenses is not a requirement; however, participation in research should, if possible, not require any financial sacrifice on the part of the subject. Investigators must provide adequate justification for failure to reimburse reasonable expenses.
- **4.6.** The IRB will consider financial burden imposed on subjects as a consequence of participating in the research when evaluating whether risks are minimized and whether the risk-benefit relationship of the research is acceptable.

## 5.0 Specific Requirements for Compensation

- **5.1.** Compensation for research which involves greater than minimal risk should be based on a reasonable hourly wage for time spent in preparation for, participation in, and recovery from, research interventions. A reasonable hourly rate is $20.00 per hour.
- **5.2.** The IRB has the authority to review the level of compensation and, in appropriate circumstances, limit the total value.
- **5.3.** Research interventions include procedures performed, visits to a clinic or research setting, phone interviews, or surveys completed. If appropriate, such hourly compensation should include all parties involved. For example, if a family member is required to be present to drive a

research subject home after a procedure, his/her time may be included in determining appropriate compensation.

- **5.4.** Compensation above these levels must be specifically justified by the investigator, and must comply with the general principles described Section 3.0 of this policy.
- **5.5.** The terms of the compensation must be disclosed in the IRB application and ICF, and discussed during the informed consent process, but the total amount of compensation should not be emphasized.
- **5.6.** Compensation to subjects must be prorated based upon the duration of participation of the subject in the research. Any credit for payment should accrue as the study progresses and may not be contingent upon the subject completing the study. If a subject does not complete the study, prorated payments should be made regardless of whether withdrawal was voluntary (subject decided to withdraw from the study) or involuntary (based on withdrawal criteria of the research protocol.). Prorated compensation should be provided, if possible, to subjects at defined intervals as opposed to at the end of a study.
- **5.7.** The preferred form of compensation to subjects is a Cash Debit Card; however, subjects may be paid in any manner consistent with Business & Finance policies of the relevant component of the Organization (UNMC, UNO, CHMC, NM, BMC) with adequate justification and IRB or ORA approval.
- **5.8.** The IRB does not allow bonuses to be paid for completion of a study, as it may offer undue influence to a subject to continue in a study when he/she would otherwise have chosen to withdraw.
- **5.9.** Compensation for participation in research may not include free sample(s) or coupon(s) good for a discount on the purchase price of the test product upon conclusion of the study. The IRB views this form of compensation to be an inappropriate marketing tool when associated with research participation.
- **5.10.** For studies where compensation is likely to total more than $600, the consent form must include a statement that an IRS form 1099 will be issued if the total compensation from participation in research reaches $600 in any given year.
- **5.11.** Records should be maintained at the department or other level that tracks all forms of compensation and their distributions. The amount and type of compensation must be able to be tracked to a corresponding recipient. If the accounting and/or payment office required the subject to provide their Social Security Number, this must be both justified and disclosed in the consent form.
- **5.12.** Monetary payments for involvement of young children <7 years of age in research should not be made directly to the minor (though parents may still be compensated as per 5.3 above). It may be appropriate to offer young children an age appropriate token for their participation, such as a small toy. Direct payment to older children (7-12 years) may be made with appropriate justification. Adolescents (>13 years) may be directly compensated.
- **5.13.** Due to the concerns relating to the potential subject's overestimating the value of compensation the UNMC IRB will not allow the use of a lottery (or raffle) as a mechanism to provide compensation to subjects for participation in greater than minimal risk research.
- **5.14.** The IRB may allow use of a lottery (or raffle) as a mechanism to provide compensation to subjects for participation in minimal risk research on a case-by-case basis. This method of compensation must be approved by the IRB Executive Chair/designee.

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## 6.0 Requirements for Reimbursement

- **6.1.** Any costs to the subject that may result from participation in the research must be justified and disclosed in the consent form.
- **6.2.** The terms of the reimbursement must be disclosed in the IRB application and ICF, and discussed during the informed consent process.
- **6.3.** Any reimbursement for costs incurred by subjects must be equitable, based on actual or reasonably estimated costs.
- **6.4.** Eligibility for reimbursement for travel associated expenses may not be contingent on distance (that is, investigators may not offer reimbursement only for subjects who travel more than X miles).
- **6.5.** The preferred form of reimbursement to subjects is a Cash Debit Card; however, subjects may be reimbursed in any manner consistent with Business & Finance policies of the relevant component of the Organization (UNMC, UNO, CHMC, NM, BMC), or with the terms of a Clinical Trial Agreement as applicable.

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ADMINISTRATIVE APPROVAL:

- **BRUCE G. GORDON, MD**; IRB EXECUTIVE CHAIR & ASSISTANT VICE CHANCELLOR FOR REGULATORY AFFAIRS
- **CHRISTOPHER KRATOCHVIL, MD**; INSTITUTIONAL OFFICIAL

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POLICY AMENDED:

- REVISED — **AUGUST 31, 2021**: Separated policies and requirements for compensation (payment) from reimbursement, and reorganized policy accordingly; included definitions of above; explicitly stated that investigators should attempt to minimize financial sacrifice on the part of subjects and, as possible and appropriate, offer equitable reimbursement for costs;

explicitly stated that compensation for minimal risk research may represent a reasonable incentive for participation (previously implied since no restriction placed on payment for minimal risk research); added prohibition that reimbursement for travel associated expenses may not be contingent on distance; specified preferred mechanism for compensation and reimbursement; allowed for direct payment to adolescents (and older children with justification).
- REVISED — MARCH 8, 2019
- REVISED — JANUARY 26, 2018
- REVISED — MAY 10, 2017
- INITIAL — DECEMBER 28, 2015

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