eCRO-05-115 RESEARCH PARTICIPANT COMPENSATION

1 PURPOSE

To describe the process followed by ethica CRO Inc. for the development of the development of a research participant compensation plan in order to ensure a consistent approach and adherence to the Human Research Protection Program (HRPP).

2 SCOPE

This procedure applies to all research studies managed by ethica CRO Inc.

3 ADDITIONAL DEFINITIONS

Compensation: Payment or non-monetary reward given to research participants as remuneration for the time commitment and inconvenience of their participation. Compensation can include remuneration that is monetary (cash, gift cards, vouchers, etc.) and/or nonmonetary (gifts/promotional items, course credit, extra credit, services etc.). Compensation is not considered a benefit to research participation and should not taken into account when assessing the risks and benefits of the research.

Undue influence: An offer of compensation of excessive or inappropriate nature in order to secure participation or compliance against the research participant's better judgment.

Coercion: An explicit or implicit threat of harm or negative consequences that is intentionally presented to research participants in order to secure participation or compliance. Compensation for research is not coercive in and of itself, since it does not involve a threat of harm. However, compensation can create potentially coercive situations, as when a third party is paid for another subject's participation, and that third party can exert coercion over the subject in order to obtain payment. For example, payment to a parent for a child's participation could create coercion.

4 RESPONSIBILITY

4.1 It is the responsibility of the Associate Director of Clinical Research to oversee and confirm that all elements of this procedure are properly implemented and followed.

4.2 It is the responsibility of Clinical Project Managers (CPMs) and Clinical Research Associates (CRAs) to adhere to the elements of this procedure.

4.3 It is understood that roles and responsibilities outlined in this SOP, whether or not explicitly indicated, are to be carried out by the incumbent of the position mentioned herein or a trained delegate.

5 POLICY

5.1 This procedure shall be applied in order to ensure that the compensation of research participants is equitable.

5.2 See SOP on Regulatory Compliance (eCRO-05-003).

6 PROCEDURE

6.1 DOCUMENTATION OF THE RESEARCH PARTICIPANT COMPENSATION PLAN

6.1.1 The study protocol must fully describe the plan for compensation of research participants as well as the justification for the amount, method, and terms of compensation.

6.1.2 The informed consent form should disclose all information concerning payment, including the total amount, schedule/form of payment, and any plans for prorating payment if a research participant withdraws. Because compensation is not a benefit of research participation, this information should be stated separately from the discussion of benefits in informed consent form.

6.2 ETHICAL CONSIDERATIONS

6.2.1 Compensation Amount:

6.2.1.1 Compensation must be appropriate for the time and effort research participants devote to participation. The level of payment should not be high enough to cause research participants to accept risks that they would not otherwise accept or participate in activities to which they would otherwise strongly object based on personal values or beliefs. Excessive incentives may also be of concern since they could induce research participants to lie or conceal information that would disqualify them from the study in order to receive payment. This could in turn undermine the scientific integrity of the study or compromise the safety of the research participant.

6.2.1.2 The compensation amount can be based on the average wage in the location where the research is conducted or for the specific study population. When hourly payments are not suitable or feasible, compensation may be task- or procedure-specific (for example, some studies pay subjects per sample collection or survey).

6.2.1.3 Whenever possible, research participants must be reimbursed for costs incurred as a result of study participation (e.g., parking and transportation costs, meals, etc.). These payments should be differentiated from compensation in the study protocol and consent form(s).

6.2.2 Timing of Compensation

6.2.2.1 Consideration must be given to the timing of compensation in order to prevent that the timing represent an undue inducement.

6.2.2.2 For studies that require extended time or multiple visits/interventions, compensation must be prorated for the time of participation in the study rather than delayed until study completion.

6.2.2.3 While total compensation must not be contingent on completion of the entire study, it is acceptable to offer an additional incentive or completion bonus to research participants that remain for the duration of the study. If offered, these amounts must be reasonable so as not to unduly influence research participants to stay in the study when they otherwise would have withdrawn.

6.2.3 Form of Compensation

6.2.3.1 Alternative forms of compensation (such as gift cards, certificates, or other tangible gifts) are acceptable forms of payment and must be considered in the amount of their cash equivalent.

6.2.3.2 Efforts must be made to ensure that the proposed method of payment can be readily used by research participants (e.g., the store or outlet is easily accessible) and is appropriate to the study population.

6.2.3.3 Compensation in the form of coupons good for a discount on the purchase price of a test article (drug or device) once it has been approved for marketing is prohibited.

7 ATTACHMENTS

None

8 OTHER APPLICABLE SOPs AND REFERENCES

eCRO-05-003 Regulatory Compliance

9 HISTORY

05-015 Version 1 dated 19-Apr-2019 was converted to eCRO-05-115 Version 1 in electronic format. The electronic version of the SOP was reviewed and approved as per SOP eCRO-00-001.

10 EFFECTIVE DATE

eCRO-05-115 Version 1, 04-Nov-2021