Subject Payments for Studies Involving Minors
Policy and Procedure

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I. Policy

A. In 45 CFR part 46 the IRB is charged with ensuring that all research subjects or their legally authorized representatives consent to the subject’s participation in the research under circumstances that minimize the possibility of coercion or undue influence. Providing payments to minors participating in research or to their parents raises additional issues compared to providing payments to adult research subjects because the individuals giving permission for the child to participate in the research (the parents) may not be personally subject to the risks of the research. In addition, depending on the maturity of the minors involved, the research participants may have a different understanding of the meaning and value of a payment compared to an adult participant. Any payments offered must be of an amount that is not so excessive that it compromises the examination and evaluation of risks by the parent or child, or causes the parent to exert pressure on the child to participate, negatively impacting the rights and/or welfare of the child. However, not providing appropriate payment may unfairly discourage or prevent some subjects (particularly those of lower socioeconomic status) from participating in research studies they would otherwise join, due to the financial burden; this also impacts the rights and/or welfare of the child.

B. The IRB will evaluate each study separately, as the suitability of a particular payment plan is protocol-specific and situation-specific. The IRB will evaluate whether the proposed payment(s), either separately or as a whole, constitute an undue influence on the decision of the parents or the child to participate in the study.

C. The IRB recognizes four categories of payments to participants in studies involving children (Wendler et al. 2002):

1. Reimbursement payments compensate parents and children for their direct research-related expenses and should be based on the actual costs (e.g., transportation, meals, lodging) that families incur. These are intended to ensure that research participation is “revenue neutral” and may be different amounts for each family based on receipts presented.

2. Compensation payments compensate parents and children for the time and inconvenience of research participation. Levels of compensation payments should be a function of the demands (e.g. clinic visits, hospital stays, research procedures) that research places on families. Each
family in the study would typically receive the same compensation payments for an equivalent level of study participation.

3. **Appreciation payments** are bonuses given after children’s participation to thank them for their efforts. These are usually of no more than token value and may include non-cash items such as toys, event tickets, or gift certificates.

4. Incentive or **inducement** payments are payments beyond the family’s expenses intended to encourage children’s research enrollment. Other types of payments may unintentionally become incentive payments if they exceed the family’s cost of participation.

II. Procedure

A. The principal investigator should describe the purpose of each payment, including payments of both cash and non-cash items such as toys, books, gift certificates, tickets, etc.

B. General guidelines for types of payments:

1. Reimbursement payments

   Reimbursement of costs associated with research participation is not generally considered to raise issues regarding undue influence, and may allow families of limited means access to studies they could not otherwise afford to participate in. Reimbursements are generally allowable and encouraged.

2. Compensation payments

   Compensation payments should go to the person who bears the burden of research participation, usually the child, although it may also be appropriate to provide compensation to a parent who must take time off from work to allow the child to participate. A "wage-payment" model may be the most appropriate for cash payments to adolescents and parents, with payments for the time spent participating in the study based on either the legal minimum wage or typical wages that could be earned by the child for tasks such as baby-sitting or lawn mowing. Use of the minimum wage as the payment standard helps to prevent compensation payments from becoming inadvertent inducements for the least well-off families.

   Investigators should keep in mind the age and maturity of the study subjects when planning payments to children. Research has suggested that children below the age of nine do not have an understanding of appropriate wages and payment; for these younger subjects, even a nominal cash payment may be perceived as a large sum, so a non-monetary gift of appreciation such as a toy may be more appropriate. Older children and adolescents tend to have a more well-formed conception of the value of money, and are more capable of assessing whether a payment is of appropriate value to compensate for their participation. However, the investigator should also consider whether possession of cash could put the child at risk of harm.

3. Appreciation payments

   Age-appropriate appreciation payments in the form of cash or gifts of no more than nominal monetary value are generally permissible, although they may not be necessary if both reimbursement and compensation are provided.

4. Incentive payments

   While incentive payments are discouraged, the IRB recognizes that in some cases they may be necessary to recruit enough patients to complete important research. Incentive payments may be
allowed in cases where the proposed payment plan minimizes both the likelihood of distorted decision making and the magnitude of potential harms (i.e. both the proposed payments and the risks of the study are low). Investigators must provide adequate explicit justification for paying subjects/parents in excess of expenses.

In cases where there is concern that planned compensation or incentive payments may represent an undue inducement to enroll in research that poses more than minor risks, the IRB may require that an independent child advocate assess the appropriateness of the payment and families’ decision to enroll. One individual may serve as the advocate for more than one child. The advocate must have the background and experience to act in, and agree to act in, the best interests of the child, and not be associated in any way (except in the role as advocate or member of the IRB) with the research or the investigator(s).

C. Withdrawal of subjects from research

The subject payment plan should include reimbursement of any incurred covered expenses, compensation for the visits completed, and payment of promised incentives to any study subject who becomes ineligible to participate after enrolling in the study, to minimize undue influence to keep the child participating in the research.

III. References

A. Definitions (see Glossary)

