

Report on Research Compliance Volume 15, Number 4. April 30, 2018 Framework for Designing, Evaluating Payments to Research Subjects

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Investigators and institutional review boards (IRBs) often wrestle with the propriety and type of payments to be offered to research subjects. Published in The New England Journal of Medicine, “A Framework for Ethical Payment to Research Participants” addresses issues specific to investigators and to IRBs.

Considerations for Investigators Proposing Payment Offers

- Clearly communicate the rationale for payment amounts to the IRB by itemizing payments according to the following categories: reimbursement for out-of-pocket expenses, compensation for time and burdens, or recruitment incentive. Include justification for specific amounts proposed.
- Focus first on treating participants fairly by reimbursing and compensating them for participation before assessing whether incentive payments are needed.
- Plan to reimburse participants for out-of-pocket expenses unless there are strong countervailing reasons against doing so.
- Consult with the IRB on what types of expenses and amounts the IRB considers reasonable for reimbursement.
- Consider compensating participants for their time commitment and the burdens they assume.
- Provide justification for why the compensation rate proposed should be considered fair, drawing analogies to nonresearch contexts such as employment.
- Propose payment as a recruitment incentive only when proposing to offer more than would be justified for reimbursement and compensation.
- When possible, offer options for insurance coverage for participants (or other mechanisms of financial protection) in order to compensate for reasonable expenses arising from research-related injury.
- When compensation or recruitment incentive is offered, consider increasing safeguards around participant comprehension and informed consent, particularly as payment amounts increase. Include measures to assess comprehension (e.g., having participants explain key aspects of research in their own words) as appropriate.

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