Revised Subject Payment Policy

What are the changes?
How is compliance achieved and documented?
Why was the policy revised?

- Reconciliation of competing obligations
  - Proper financial documentation v. protection of privacy and “minimum necessary” use of Protected Health Information (PHI)
  - Highlighted by inquiries from investigators who were concerned that their practices were inherently non-compliant with existing policy
How were revisions developed?

- Initiated through PI discussions with Audit, Legal and Finance
- Brought to the Clinical Research Review Process Improvement Team (CRRPIT)
  - Discussed at three CRRPIT meetings
  - Collaborative revisions were created with stakeholder input (e.g., PIs who work with vulnerable populations and/or within the community)
- Adoption of a consensus-driven revision that:
  - accommodates compliance concerns from all perspectives
  - provides clear guidance on expectations
I. What Does this Policy Cover?

This policy pertains to compensation that is provided to individuals for their participation in a research study.
II. What Changes Have Been Made?

- A new threshold dollar amount that triggers the obligation to submit identifying information to the UR Finance Department -- $275

- A specific dollar amount for protocols that have been approved not to collect any subject-identifying information -- $75
  - establishes documentation requirements for this specific case (see section VII)
FAQ

III. What Does the $275 Threshold Mean?

This policy removes the obligation to report subject-identifying information to the Finance Department, if the maximum possible payments to a participant of a specific protocol cannot reach $275 in a calendar (tax) year.

- Per Participant
- Per Protocol
- Per Calendar Year
FAQ

IV. What Information is reported to Finance for $275 / Calendar Year?

Forward the following information to the Finance Department for each subject, typically with an IRS Form W-9 (http://www.irs.gov/pub/irs-pdf/fw9.pdf):

- Name
- Home address
- Social Security number
- Amount paid

Note that the Finance Department does not need to know study specific information such as study title or the principal investigator.
Recommended Reporting Tool
For Taxable Payments
V. What Does “Anonymous Participation” mean for this policy?

The protocol prohibits study personnel from collecting subject-identifying information

AND

The Institutional Review Board (IRB) has granted a waiver of the requirement for written documentation of consent or has exempted the protocol from IRB oversight

AND

Payments in a calendar year of less than $75.
VI. What must the research program document?

It is the responsibility of the department to maintain a record of all payments/disbursements made to research subjects.

Best practice is that this record would be reviewed periodically by another person with financial ledger accounting responsibilities.
It is essential that records sufficiently document the completion of participation by the research subject, and the payment of University funds for that participation, per protocol.
Recommended Documentation Tools For all Subject Payments
Recommended Steps For Applying the Finance Policy: Payments to Research Subjects for Incentives/Participation

**Project Initiation**
- Review protocol to assess maximum possible payments per individual in a Calendar Year
- Identify documentation and reporting requirements

**Subject Visit**
- Complete W9, when applicable
- Pay subject
- Document subject payment
- If payment is by check, submit applicable W9 with Request For Payment (RFP)

**Before 1st Friday in January**
- Submit to Finance Department:
  - All remaining applicable W9s
  - All reports of Taxable Payments
  For the Calendar (Tax) year that has ended
Questions?

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