

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 (eg: 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 \geq \$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.

A decorative graphic on the left side of the slide, consisting of a light green vertical bar and a dark blue horizontal bar with rounded ends.

Recommended Reporting Tool For Taxable Payments

FAQ

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.

FAQ

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.

FAQ

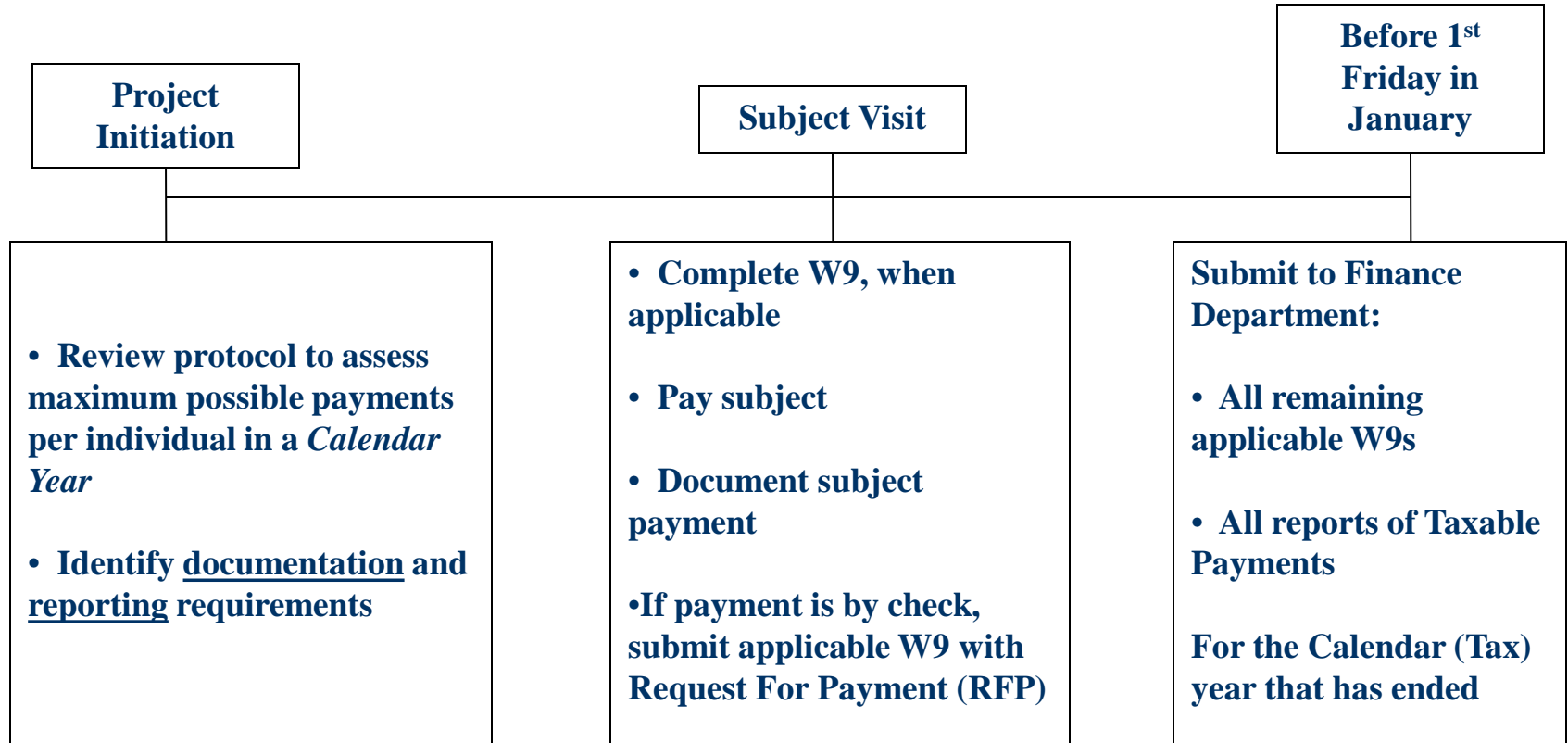
VII. What documentation for truly anonymous participation?

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*



A decorative graphic on the left side of the slide, consisting of a light green vertical bar and a dark blue horizontal bar with rounded ends.

Summary

Questions?

Marta Herman
mrta@Finance.Rochester.edu

Chris Butler
chris.w.butler@rochester.edu

Eric Rubinstein
eric_rubinstein@urmc.rochester.edu