

Updates and Reminders “Present”-ation

RARA Meeting

December 2015





UNIVERSITY *of* ROCHESTER

VA Appointments

- If a faculty member has an appointment at the VA and the UR, a Memo of Understanding (MOU) must be written and signed by both parties.
- A standard MOU template must be used (contact Mike Ritz).
- The MOU must be updated whenever there is a change to either the VA appointment or the UR appointment.
- ORPA will request an MOU whenever a sponsored project is to be submitted to a sponsor with an investigator who has a joint VA and UR appointment.





Updated Nepotism Policy 121

- No employee involved in employment decisions may make, participate in, or attempt to influence employment or evaluative decisions involving a relative or closely related person.
- The policy is intended to prohibit employees who are related from working in direct reporting or supervisory relationships.



Updated Nepotism Policy 121

- Where employment would be in conflict with this policy...the problem may be avoided by adjustment of the duties assigned to one or both of the individuals or by modification of the administrative relationships of their positions, or both, through the development and implementation of a management plan which will ensure that all employment decisions are made by others.



Updated Nepotism Policy 121

- As a general rule, a Principal Investigator shall not permit a person with whom he/she is related to be paid from funds of a grant or contract supervised by the Principal Investigator unless disclosure has been made to...the department chair and an appropriate management plan has been put in place to ensure that the work of the relative is being supervised by another individual on the grant who is not related to the Principal Investigator.



Updated Nepotism Policy 121

- All related persons are expected to disclose their relationship in advance of any employment decisions being made involving the other. Employees must self-report to the head of their organizational unit before they make, participate in or attempt to influence employment decisions covered by this policy.
- Individuals who become “related”...are expected promptly to disclose the relationship...



Updated Nepotism Policy 121

- In the case of employees who are aware of relationships that may be in conflict with this policy, reports about possible violations of this policy may be submitted to the University's AVP for Human Resources for further evaluation and investigation.
- All such reports/complaints will be treated as confidentially as feasible. Retaliation against a person who reports a possible violation of this policy is prohibited.





Clinical Trials - Close out Process

- As per the UR Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance (specifically SOP 5.2), a Close Out Checklist is to be provided to ORACS (and possibly the Dean's Office) at the time any clinical trial account is closed out.
- The Close Out Checklist is to be completed when closing out a trial that was budgeted using the UR Budgeting Workbook and whose transactions were then monitored through use of a UR *Post Award Workbook* (“PAW”).
- If you are unsure whether an account needs a Close Out Checklist, you may contact Mike Ritz or Terese Mason.



Clinical Trials

Greenphire and Similar Vendors

- Sponsor might want subjects to be paid by a third party vendor debit card.
- Concerns: HIPAA, Tax Reporting, and administrative burden without overhead recovery
- Sponsor needs to indemnify UR for breaches of PHI that might occur by such third party and to acknowledge that sponsor is delegating tax reporting to the third party.



Clinical Trials

Unfunded Studies with Billing Risk

- Certain PI-initiated, unfunded studies have inherent billing risk, similar to industry-sponsored studies.
- If so, a budget/billing plan needs to be prepared and post-award transaction monitoring will be needed, similar to industry-sponsored studies.
- If insurance is to pay for some costs, a PRA Template might also need to be prepared.
- Should you need assistance in determining the applicability of these items, please contact Mike Ritz.



Clinical Trials

Phase 1 Studies

- Third party insurance generally can be billed for routine costs of a clinical trial if it meets the four criteria of a Qualifying Clinical Trial.
- Once characteristic of a QCT is that the study has therapeutic intent.
- Therapeutic intent must be stated a primary or secondary objective in the protocol or PI provide memo to Research Compliance Officer citations/quotes from the protocol that discuss therapeutic intent.



Clinical Trials

Phase 1 Studies

- Therapeutic intent exists when a major objective of the study is the diagnosis or treatment of disease, including the observation of benefit of the intervention under study. There must be the possibility that the subject will benefit.



Clinical Trials

Payments to Participants

- If participants are to be paid for participation, specify the amount, schedule of payment, conditions for payment and the taxability of those payments.
- If participants are to be reimbursed for travel expenses, specify the need for actual receipts and that such reimbursements are not taxable.



Questions

