

UVA SOM Recommended Steps for Successful Institutional Recovery from Industry Sponsored Clinical Trials

1) Contract/Budget Negotiations

- a. Whether you are new to the clinical trials process or a seasoned veteran, please check with the budget coordinator in the SOM Clinical Trials Office for guidance and updates on current best practices relative to appropriate budget development prior to entering into any financial agreement with industry.
- b. Take the time necessary to make sure that all costs associated with the trial (Medical Center, Physician, Department, etc.) are fully identified and included in the proposed budget. Underestimating costs leads to financial stress within your unit and inappropriate subsidization of industry. Overestimating costs can not only damage your reputation with sponsors, but in some cases could expose the institution to significant liability.
- c. The first step towards a successful revenue recovery process is the negotiation of reasonable and consistent payment terms as part of the contract with industry
- d. Set enrollment targets as part of the budget negotiations but also negotiate payment terms that will cover your incurred costs whether or not you meet the target.
- e. Avoid holdback clauses in any agreements if possible. They make payment reconciliation extremely difficult.
- f. Ideally payments should be made on a monthly basis if at all possible. The more you can standardize payment methods and schedules across sponsors, the easier it will be to follow-up, track, and reconcile payments from industry.
- g. If monthly payments are not possible, quarterly would be the second preference, with purely milestone based being the third preference unless the milestone based allow for more timely collection in a particular study.
- h. The contract should state that the sponsor must provide payment detail with each payment to facilitate reconciliation.

- i. Review sample payment terms from other successful contracts. SOM Grants and Contracts Office can provide these upon request.
- j. Sample responsibility matrix for Contract/Budget Negotiations is under development.

2) Coordinator and Administrator Communication

- a. Coordinator and administrator MUST both have access to the trial invoicing/payment tracking data. This is a key contributor to the success of the institutional recovery process.
- b. To accomplish this, the SOM recommends that you store all tracking data on a shared drive that both the administrator and the coordinator can access.
- c. All invested parties must agree on the file structure for the shared data.
- d. Data files should either be organized by:
 - 1. Sponsor
 - 2. PI
 - 3. Protocolor by
 - 1. PI
 - 2. Sponsor
 - 3. Protocol
- e. If your department does not have the capability to provide a shared drive, the SOM Dean's Office can provide the service. Please contact the SOM Office of Grants and Contracts for more information.
- f. Sample responsibility matrix for Coordinator and Administrator Communication is under development.

3) Invoicing vs Clinical Research Form (CRF) based payments

- a. Ultimately some contracts will rely on invoicing and some will rely on CRF submission to the sponsor and some will rely on both.
- b. It is critical for coordinator and administrator to have clear lines of communication

- c. Until such time as an institutionally based tracking system is in place, coordinator and administrator should rely on a software package, like Excel, that can act as a tracking system for study and related payments. A recommended spreadsheet format is attached. Some people prefer to organize the spreadsheet with patients in the rows and other data in columns while some prefer patients in columns with other info in rows. While the content of the attached spreadsheet example is critical, the format can be modified to meet your personal preferences.
- d. There must be clear responsibility defined regarding who is responsible for issuance of invoices – sample invoice attached - content required but format may be modified to fit your needs.
- e. Sample responsibility matrix for Invoicing vs Clinical Research Form (CRF) based payments is under development.

4) Reconciliation

- a. Administrator and coordinator review spreadsheets monthly to make sure appropriate invoices have been issued and appropriate payments received.
- b. If no payment, make sure there is appropriate follow-up by the responsible party.
- c. Use SP23 forms as appropriate to correct incorrect deposits.
- d. Sample responsibility matrix for Reconciliation is under development.

5) Accountability

- a. Each department must have clearly defined responsibility matrices that outline who is responsible for all steps of trial tracking, timely payment collection, and account reconciliation.
- b. Responsibility matrices should be reviewed and updated as necessary but always annually at a minimum.

Agreement Title

INVOICE#

PO # xxxxx
Vendor # xxxxx

To: Sponsor name.... contact

Please accept this invoice for the fully executed agreement between SPONSOR and the University of Virginia for the TITLE Agreement.

PI - <name of PI>
Protocol # - <protocol number>

Payment is due no later than <date> and shall be made payable to the Rector and Visitors of the University of Virginia, Tax ID # 54-6001796, and mailed to:

Office of Grants and Contracts Administration
University of Virginia
101 Hospital Drive
Davis 5 Room 5293
PO Box 800793
Charlottesville, VA 22908-0793
Attn: Director, Grants and Contracts

To ensure appropriate credit of your payment, please include the PI and Protocol number as reference information on the check stub.

Item	Amount
Initial IRB submission and review fees	\$
	\$
	\$
(insert more rows as needed)	\$
Total Due	\$

TOTAL amount due for this invoice at this time: <\$amount due>

If you have any questions regarding this invoice, please contact <study coordinator/administrator> in <department/center> at <phone number>.