UNIVERSITY OF ROCHESTER
CLINICAL RESEARCH STANDARD OPERATING PROCEDURES
REGARDING FINANCIAL OVERSIGHT AND BILLING COMPLIANCE

I. PURPOSE

The purpose of these standard operating procedures is to outline the mandatory processes to follow and templates to utilize in order to comply with the University of Rochester Clinical Research Billing Policy.

NOTE: As appropriate, the words "division" or "unit" should replace the word "department" within the document for those departments whose organization structure includes divisions or units, respectively.

II. STANDARD OPERATING PROCEDURES (SOP)

SOP 1 BUDGET DEVELOPMENT

1.1 Prospective Reimbursement Analysis

A Prospective Reimbursement Analysis (PRA) is the process of determining and documenting what procedures, items and tests in a protocol are standard of care or strictly related to research. This information is then used to determine the appropriate payer of such activities.

A PRA is mandatory for each clinical trial unless it is determined that the trial is exempt. The criteria for exemption are included on the Clinical Trial Proposal Sign Off Form. If the sponsor is agreeing to pay for all costs of a proposed trial, the PRA does not need to be completed. Also, the PRA is not completed for investigational device studies since the requirements tested by the PRA do not relate to device studies.

When a trial is not exempt, the determination of whether the trial is a qualifying trial is documented on the "PRA Template" contained within the Budgeting Workbook. The PRA must be signed by the Principal Investigator and submitted to ORPA with the sign off form. A copy of the PRA Template must be retained in the trial files within the department.

1.2 Participant-Related Costs

All procedures, items and tests to be paid by the trial sponsor as per the PRA are to be included on a grid which is created using the protocol narrative and schedule of events contained within the trial agreement. The grid is the "Participant Grid" located within the Budgeting Workbook. Department administrators, study coordinators and Principal Investigators obtain assistance with estimating the costs of procedures and tests (including determination of CPT codes) from their Billing staff. This often involves obtaining clarification from the sponsor regarding procedures to be performed in the study.

For hospital-related costs to be paid by the sponsor, the charge master amount is used and a factor applied based upon the identity of the sponsor. The factors for federal sponsored clinical trials are obtained from the annual Research Patient Care Rate Agreement (Agreement) between the Department of Health and Human Services and Strong Memorial Hospital. The factor for industry sponsored trials is derived from third party payer recovery rate data and is currently 58.5 percent.

For professional service fees, the faculty practice group fee schedule is used. For federal sponsored trials, the amount payable by Medicare (as per the faculty practice group fee schedule) is used to value the professional fees. For professional fees incurred on industry sponsored trials, use the faculty practice group fee schedule as a reference to negotiate an acceptable amount of reimbursement. It is preferred that the amount per the fee schedule be accepted by the potential sponsor. If a discount to the fee schedule is needed, the discount should not be greater than 40% (i.e., the professional fee should never be less than 60% of the fee schedule amount). If the professional service to be discounted is to be provided by another department, that department's approval of the discounted rate is needed.

Clinical trial team members estimate time required to complete the participant-specific protocol activities on the Participant Grid that are not a component of the hospital or professional fees. The time is valued using computed hourly rates of pay (using an assumption of average hours worked per week) including a fringe benefit factor.

The combination of the procedure costs and other clinical trial team member time is used to derive a per participant total cost for reimbursement.

A copy of the Participant Grid is provided to Office of Research and Project Administration (ORPA) with the Clinical Trial Proposal Sign Off Form.

1.3 Non-Participant-Specific Costs

Activities and costs associated with a clinical trial (but which are not participant-specific procedure costs) are documented on the "Non-Participant Grid" worksheet in the

Budgeting Workbook. There are both variable cost and fixed cost components on the worksheet.

For personnel costs, clinical trial team members estimate the time involved with these various activities and enter the estimates on the worksheet. The time is then valued using the hourly rates of pay (including fringe benefit factors) from SOP 1.2.

Non-payroll cost estimates are based upon quotes derived from internal and external sources, as appropriate.

Documentation of cost estimates are to be maintained by the department.

1.4 Budget Negotiation

An inflation factor of 3 percent per year (compounded) is applied to all costs if the trial is anticipated to extend beyond 12 months.

The "Total Budget Comparison" worksheet in the Budgeting Workbook allows the computed per patient reimbursement amount and non-participant-specific costs to be compared against the amount proposed by the sponsor. The areas of greatest disparity are negotiated. The Participant Grid and Non-Participant Grid (and the documentation obtained for their preparation) provide the necessary information to effectively negotiate with the sponsor.

Except for extenuating circumstances, it is expected that a clinical trial agreement be executed only if the budget reflects an expectation of at least a break even financial position. (Footnote 1, page 18) Additionally, the indirect cost rate is to be at least 30 percent for industry funded trials, unless a waiver is obtained from the Dean's Office.

If the final budget reflects a surplus of at least $20,000 and 20% of the trial's budgeted revenue, Dean's Office approval is required to address the risks of underlying conflicts of interest and unrelated business income.

The University of Rochester always prepares a budget for a clinical trial independently of the budget provided by the sponsor. In order for the negotiation process to be complete, ultimately there must be a mutual understanding regarding which protocol procedures (if any) are payable by insurance versus payable by the sponsor. This step is also important since the visits to be billed to insurance (if any) will involve participant co-payments and deductibles.

Prior to executing the contract, verification of the consistency between the informed consent form, the clinical trial agreement and the study budget (as regards responsible payer of each procedure, item and test) occurs.

A copy of the "Total Budget Comparison" worksheet is provided to ORPA with the Clinical Trial Proposal Sign Off Form.

1.5 Notifications

When a clinical trial agreement is finalized, communication of the existence of the study (including the study name, ten digit ledger number 5-XXXXX-XXXX and the person to whom the bills should be sent) is to be made from the clinical trial team (likely the study coordinator) to Pharmacy (if applicable), Operations Manager for Patient Scheduling and Registration, Patient Accounts Office Inpatient Billing Manager and Patient Accounts Office Outpatient Billing Manager.

1.6 Approvals Required for Device Studies

When a company sponsors a device study, the company files an Investigational Device Exemption (IDE) application with the Food and Drug Administration (FDA). For investigator-initiated device studies, a formal application to the FDA may not be required for a non-significant risk study; rather, the University of Rochester Research Subjects Review Board may be able to serve as a surrogate overseer. If the non-significant risk criteria are not met, the investigator files an IDE application with the FDA.

The FDA responds within 30 days with a coverage determination and IDE number (if approved), including whether the investigational device is regarded as a Category A device or a Category B device. Category A devices are not billable to third party insurance. Category B devices are potentially billable to third party insurance, pursuant to certain restrictions.

The FDA might issue a conditional approval letter in response to an IDE application. There are various reasons for conditional approval.

If a sponsor files the IDE application, it is best to obtain the full FDA letter to understand the FDA's concerns. The sponsor should share the letter since UR is being requested to enter into a contractual relationship, thus has a vested interest in the FDA's comments. If the sponsor has concerns regarding confidentiality, UR can suggest signing a confidentiality agreement (CDA), if one has not already been signed.

IRB approval is not possible without an unconditional FDA letter, thus an IRB-approved consent form will be delayed until the letter is obtained, and UR will not be able to enroll participants. If there is a concern that the sponsor might end negotiations if UR does not execute a contract prior to receipt of an unconditional letter, ORPA can add language to the clinical trial agreement to indicate the agreement will be terminated if the FDA does not provide an unconditional letter with a Category B device classification and/or the IRB does not approve the final version of the consent form.

Thus, a contract is executed to demonstrate the UR's intent to participate, but eliminates UR's exposure to the current uncertainty. If a contract is prepared with the termination clause as described, the budget should be prepared assuming insurance coverage of the device and associated reasonable/necessary costs associated with the device (though there is always chance some insurers will not agree to do so).

For industry sponsored studies, if the sponsor is not going to pay for the cost of the device, the sponsor typically provides an estimate of the cost of the device. For investigator-initiated studies, the investigator must compute an estimated cost for the device. The device description and estimated cost is provided to Corporate Purchasing. Corporate Purchasing performs an analysis to verify that the cost is reasonable.

For industry sponsored studies where the sponsor does not pay for the device, and for investigator-initiated studies, the hospital is exposed to financial risk—specifically, third party insurance might not reimburse for the device, participants might not have the financial resources to pay for the device, and the hospital might be required to maintain an inventory of the device which could be subject to obsolescence.

As a result of these financial risks, the New Technologies Committee must review and approve all potential new device studies where device costs will be at least $2,500 per patient or that might involve hospital resources of $25,000 or greater in the aggregate. If the New Technologies Committee does not approve the device study, the study cannot proceed.

If the New Technologies Committee approves the device study, a submission is made to the Institutional Review Board (IRB). If the IRB does not approve the device study, the study cannot proceed.

If the IRB approves the device study, the department files an application with the Medicare Administrative Contractor (MAC). Non-Medicare insurance carriers typically do not approve reimbursement of device study costs unless the MAC approves such trials.

If the MAC approves the device, Hospital Finance contacts non-Medicare insurance carriers to get approval for an add-on to the Diagnosis Related Group (DRG) codes associated with the device study's procedures. The DRG code add-on approval is the authorization for non-Medicare insurance carriers to be billed for the costs of the device study.

SOP 2 PARTICIPANT REGISTRATION

2.1. Enrollment in Device Studies

Enrollment in a device study can only begin once MAC approval is obtained. All potential registration/encounter points and the billing department must be informed of the existence of the device study (refer to SOP 1.5). Invoices for device studies often require additional, supplementary information to be submitted (for example, the IDE number and device cost documentation). Invoices submitted to Medicare require certain modifiers to be included.

As participants enroll, visits are scheduled, and visits are completed, it is important to ensure communication of a patient's participation in a device study to the registration/encounter points and the billing department (refer to SOP 2.2).

2.2 Scheduling Inpatient and Outpatient Visits

When a new participant enters a trial and the sponsor is paying for the cost of some of the procedures, items or tests, a Study Grant Group (SGG) case needs to be established in FLOWCAST. SGG case fields need to be completed to indicate to whom the invoices should be sent (including PO Box and phone number), the trial's general ledger account number and department/unit name.

Dates of participant visits/appointments are tracked in a workbook as described in **SOP 3.1.2. Participant Grid in the Post-Award Workbook**.

When a study participant goes to a visit or appointment whereby the study sponsor is to pay the associated fee, the study coordinator notifies the registration desk and the registration desk will attach the SGG case to the visit/appointment record. (Footnote 2, page 18).

When a patient has one outpatient encounter whereby some costs are being borne by the sponsor and some costs are being borne by insurance, two separate registrations are entered for that same date. One registration is to bill the sponsor account (thus an SGG case will be attached) and the second registration is to bill insurance. The encounter form is used to indicate which procedures/items are to be billed to each respective party. Alternatively, two separate requisition forms can be completed.

When a patient admitted to the hospital is registered as a grant study inpatient (thus, a SGG case is attached) but is going to have procedures/charges not related to that study while admitted, ambulatory administration will create an outpatient visit record in FLOWCAST for that same date in order to invoice insurance appropriately for the non-trial procedures/charges.

When a patient admitted to the hospital is registered under primary insurance but is going to have procedures/charges related to a study while admitted, ambulatory administration will create an outpatient visit record in FLOWCAST (and attach a SGG case) for that same date in order to generate an invoice for the trial charges to be borne by the study sponsor.

Patients admitted to the hospital might also incur attending fees billable by Medical Faculty Group Office (i.e. in addition to the hospital charges). The study coordinator notifies the point-of-service contact of the payer of the professional fee (i.e. sponsor or insurance).

When Adverse Events occur and result in hospitalization, the reason for admittance to the hospital needs to be determined, with subsequent reference to the clinical trial agreement and informed consent document to determine the proper payer.

If a trial's general ledger account changes, the SGG case with the outdated general ledger account must be closed and a new SGG case is created with the new general ledger account.

2.3 Scheduling Ancillary Services

Dates of participant visits/appointments are tracked in a workbook as described in **SOP 3.1.2. Participant Grid in the Post-Award Workbook**.

For tests and procedures to be charged to a sponsor, a study specific requisition that includes the trial's general ledger account number and department contact information is requested from the ancillary center. The study coordinator provides the study specific requisition to a participant to take to their visit/appointment as opposed to a standard of care requisition.

If some tests/procedures from a visit/appointment are to be charged to a sponsor and some are to be charged to insurance, two separate requisitions—one study specific and the other standard of care, each containing the respective tests/procedures—are provided to a participant to take to their visit/appointment.

If it is known that a participant is going to have tests at a non-UR lab, the non-UR lab needs to be informed in advance regarding the appropriate payer of the tests/procedures.

SOP 3 SERVICES PROVIDED

3.1 Coding and Billing

3.1.1. Documentation of the Service

If insurance reimbursement is to be requested for certain protocol procedures, the patient's medical record must contain the trial name, the trial sponsor and the protocol number. A copy of the participant's informed consent must be available if requested.

3.1.2. Participant Grid in the Post-Award Workbook (PAW)

A PAW Participant Grid is created from the Budgeting Workbook Participant Grid. The PAW Participant Grid includes the procedures to be paid by the sponsor.

The PAW Participant Grid contains participant-level detail. Each participant is assigned a row on the grid and the study coordinator enters the dates of the participant's visits throughout the study. The PAW Participant Grid is updated with dates of service at least weekly.

3.1.3. Ancillary Services – URMC Labs

For all URMC Labs services performed for which a study specific requisition is used, a monthly summary is printed by the lab and sent to the department contact identified when the specific requisition was initially requested. The monthly summary must be reviewed and approved within 30 days of receipt to ensure (i) all lab charges that should be billed to clinical trials are included therein and (ii) no unanticipated charges appear.

3.1.4. Ancillary Services - Radiology

Insurance companies require pre-authorization for most imaging exams. When a standard of care requisition is used, radiology staff ensures that this authorization has been obtained by the scheduling office prior to performing the service—otherwise, insurance will likely not pay for the exam. For exams ordered using the study specific requisition, a review for prior authorization is not performed as the intent is to bill the study ledger and not insurance.

When Radiology service is performed at Strong Memorial Hospital, the associated hospital technical fee bill is sent without review of the requesting department. A department must request a UB-04 form from Patient Accounts Office to ensure the patient and service aligns with the PAW Participant Grid. For professional fees, a HCFA insurance form is sent to the department. If the information aligns with the PAW Participant Grid, the department prepares a Form 312 requisition containing the trial's

general ledger account number and sends it to Radiology to process the expense. Copies of the UB-04 form and HCFA insurance form are retained in the department's file.

When Radiology service is performed at Science Park, a global fee (technical and professional fees inclusive) is charged and a HCFA insurance form is sent to the department. If the information aligns with the PAW Participant Grid, the department prepares a Form 312 requisition containing the trial's general ledger account number and sends it to Radiology to process the expense. A copy of the HCFA insurance form is retained in the department's file.

Radiology staff reviews all HCFA insurance forms against information in FLOWCAST prior to department ledgers being charged for the cost of procedures. If an SGG case is attached to the record, the visit is allowed to be charged to the sponsor. Radiology staff also verifies the patient is enrolled in the trial, the appropriateness of the ledger account to be charged and the recovery factor applied to the charge master fee.

When HCFA insurance forms and the monthly University ledger are received in the department and indicate Radiology charges have been processed, timely comparison to the PAW Participant Grid is essential to ensure (i) all Radiology fees that should be billed to the clinical trial are included therein and (ii) no unanticipated charges appear.

3.1.5. Ancillary Services - Pharmacy

Pharmacy prepares a monthly report for departments to review for billing accuracy. The report includes a cover letter and details of the following fees: start-up, dispensing, monthly maintenance and close-out. Departments compare the monthly report against their copies of correspondence with the Pharmacy and ensure timely communication of questions and exceptions.

3.1.6. Inpatient and Outpatient Visits

Patient Accounts Office provides a UB-04 form and University Medical Faculty Group provides a HCFA insurance form for fees charged directly to sponsor accounts. These documents are used for comparison against the PAW Participant Grid and the general ledger and are the basis for timely communication of questions with Patient Accounts Office and Medical Faculty Group Office.

3.1.7. Update the PAW Participant Grid (all services)

The respective PAW Participant Grid is accessed and the format of the date associated with a service is modified to indicate receipt of documentation of the associated charge to be made to the sponsor account (for example, the date could be highlighted in purple).

The “Insert Comment” EXCEL feature is used for notations and to ensure follow through when the services provided (as per the documentation) do not agree completely with the services scheduled. Until the exception is resolved, the date is not modified as would otherwise happen (as per the previous paragraph).

At least every two months the PAW Participant Grids for active trials are reviewed to determine if certain patients’ services that were scheduled did not appear on subsequent reports or documentation. The date associated with a service requiring investigation (because it was not included on a billing report or supporting documentation) is modified to ensure follow through occurs (for example, the date could be highlighted in pink).

The associated procedure, item and test fee amounts will rarely agree with the Participant Grid, since fees will likely change during the life of a trial. If the overall cost is reasonable (within 5 percent of the budgeted cost) no follow through is deemed necessary.

3.2 Allocation of Effort of Clinical Trial Team Members

All clinical trials receive direct allocations of payroll for clinical trial team members. The percents of effort are initially computed based on data entered on the Participant Grid and Non-Participant Grid in the Budgeting Workbook.

Completion of the “Computation of Percent Effort” worksheet in the Budgeting Workbook provides an initial estimate of the average percent of effort to be allocated to the clinical trial account throughout the life of the trial for each clinical trial team member. The actual percent of effort to be allocated during various periods of the trial will vary based upon several factors (such as enrollment levels and the weighting of procedures among various periods during the life of the trial).

During the life of the trial, clinical trial team members (other than the Principal Investigator) periodically complete time entry worksheets referred to as “My Activities” worksheets.

The resulting information is compared to that person’s current effort allocation percentage in the payroll system. If there is a significant variance (10% or greater), the reason needs to be determined, including a determination of whether or not the person’s effort allocation needs to be modified.

Regarding Principal Investigators, the “My Activities” worksheet is not maintained; rather, their effort allocations are based on initial estimates (as per the Participant Grid and Non-Participant Grid in the Budgeting Workbook), with periodic reviews for potential modification based upon consideration of changes in coordinator effort on the same trial (which might indicate a similar change in Principal Investigator effort has occurred) and periodic meetings with the Principal Investigator during which effort levels are discussed.

3.3 Ongoing Oversight, Review and Reconciliation

The PAW Non-Participant Grid is created from the Non-Participant Grid in the Budgeting Workbook and includes non-participant-specific costs. Any non-payroll charges reflected on the Budgeting Workbook Non-Participant Grid that are to be separately invoiced to the sponsor should be reflected on the Post-Award Workbook Non-Participant Grid. Only time-related tasks on the Budgeting Workbook Non-Participant Grid which are to be invoiced to the sponsor should be reflected on the Post-Award Workbook Non-Participant Grid. The cost of these transactions is entered onto the worksheet as they are incurred.

Comparison of the expenses entered on the worksheet against the University's monthly ledger reports is done periodically (at least quarterly, preferably monthly) to ensure the trial has been charged for all related activity, and only its activity. [NOTE: If a department uses the UR General Encumbrance Management Software (URGEMS) application to manage its accounts, URGEMS will be the data source for both updating the Non-Participant Grid and reconciling the monthly ledgers.]

As unforeseen costs are incurred, they are entered at the bottom of the PAW Non-Participant Grid. The worksheet is reviewed monthly for such activity, with determination of cause and potential opportunities for contract re-negotiation (i.e. for additional reimbursement).

SOP 4 PAYMENT RECONCILIATION

For industry sponsored trials, the University requires that sponsor payment of participant procedures and tests be based on submission of University prepared case report forms, without payment being contingent on a monitor's visit, review and query resolution. If the University is required to create invoices, the invoices can be composed timely and efficiently using the PAW. The PAW identifies when milestones are achieved, thus when invoices are due to the sponsor.

Other non-participant-specific costs are negotiated as separately invoice-able items. The PAW Non-Participant Grid facilitates preparation of such invoices.

[Note: At times the sponsor includes some non-participant-specific costs in the per patient reimbursement amount, which then requires more careful review and analysis.]

The Non-Participant Grid has a section to indicate when invoices are sent to a sponsor and the dates the sponsor pays each invoice. This data is updated continuously. Unpaid invoices are closely monitored and are actively followed through if they become past due. If an invoice becomes 30 days past due (as per the contractual terms), the originator of the invoice contacts the sponsor and arranges for expedited payment. If an invoice remains unpaid and is 60 days past due, the originator of the invoice contacts the sponsor, warns of the contractual violation, and arranges for expedited payment. If an invoice remains unpaid and is 90 days past due, the originator of the invoice notifies ORACS and ORACS (in consultation with the Principal Investigator and department administrator) notifies the sponsor of the contractual term violation, the possibility of terminating the trial, and arranges for expedited payment of the past due amount.

A detail of each remittance must be obtained from the sponsor, with comparison to the patients and dates on the respective PAW Participant Grid for verification that all participant visits are paid.

SOP 5 STUDY CLOSE OUT

5.1 Notifications

When a study is complete, the ancillary service areas (e.g. URMC Labs, Radiology, Pharmacy as applicable), Operations Manager for Patient Scheduling and Registration, Patient Accounts Office Inpatient Billing Manager, Patient Accounts Office Outpatient Billing Manager, ORPA and ORACS are notified by the clinical trial team (likely the study coordinator).

5.2 Final Review and Reconciliation

The Close Out Checklist is used to document the completeness of all charges (including effort of clinical trial team members and clinical fees) and revenues (receipts from sponsor) appearing in the general ledger for a clinical trial that is ready for close out.

The Report of Expenditures is prepared and is submitted to ORACS with the Close Out Checklist. A copy of the checklist is maintained in the department files for the respective trial.

Trials are closed within 90 days of termination. Specifically, within 90 days after all expenses and adjustments have been posted and all revenue is received, ORACS must be given all required information/documentation from the department and will make the final entries to close the account.

5.3 Deficits

The Report of Expenditures submitted to ORACS must include an unrestricted account to fund the deficit.

A detailed variation analysis should be performed based upon a comparison of the Budgeting Workbook against the PAW Workbook. Variation explanations will likely provide insight for future negotiations. If the deficit is at least $20,000 and 20 percent of the trial's final revenue, the Department Chair's approval is needed.

5.4 Residuals

The Dean's Office must approve clinical trial accounts that are ready to close out and reflect a residual of an amount equal to at least $20,000 and 20 percent of the trial's final revenue.

The Dean's Office must be provided a detailed variance analysis based upon a comparison the Budgeting Workbook and the PAW. The Dean's Office approval is documented on the Close Out Checklist.

5.5 Record Retention

Scientific and administrative records related to a clinical trial need to be retained for specified periods of time after close out. The University's record retention policy is located at http://www.rochester.edu/adminfinance/records.html. The records are subject to audit at any time during the record retention period.

III. ROLES AND RESPONSIBILITIES MATRIX

Certain tasks and internal controls are required in order for clinical research teams and other University departments to fulfill their responsibilities effectively. These are presented in the following table:

Key (see note on p. 16)

PI	Principal Investigator	AD	Ancillary Department	P = Primary Responsibility
S	Sponsor	B	Billing	S = Supporting Responsibility
SC	Study Coordinator	CO	Compliance Office	J = Joint Responsibility
DA	Department Administrator	Acct	Staff Accountant	

	PI	S	SC	DA	AD	B	CO	Acct
BUDGET DEVELOPMENT								
Perform Prospective Reimbursement Analysis (PRA) to determine if the trial is a qualifying trial or else complete Section C of the Clinical Trial Proposal Sign Off Form to indicate why the trial is exempt from PRA	J	S	J	J	S	S		
For qualifying trials, determine which procedures, items and tests represent standard of care (thus billable to insurance)	P		S	S				
Obtain/provide cost quotes for study procedures, items and tests to be paid by sponsor			S	P	S	S		
Populate a Participant Grid using the protocol, schedule of events, determination of standard of care procedures and cost information	S		J	J		S		
Prepare a budget and include procedures, items and tests for which the sponsor is assuming financial responsibility	S		S	P			S	
Ensure consistency between the informed consent form, the clinical trial agreement and study budget as regards sponsor funding of procedures, items and tests	S	S	J	J				
Obtain time estimates from all clinical trial team members for participant-specific and non-participant specific activities based upon the protocol and schedule of events	J		J	J				
Negotiate acceptable reimbursement from the sponsor	S	S	S	P				

	PI	S	SC	DA	AD	B	CO	Acct
PARTICIPANT REGISTRATION								
Obtain a study specific requisition from URMC Labs and Radiology (if applicable)			P	S	S			
Notify Pharmacy the clinical trial is about to commence (if applicable)			P	S	S			
Notify Patient Scheduling Operations Manager and Patient Accounts Outpatient and Inpatient Billing Managers of the study's name, 10-digit account number and end date			P	S		S		
As each new patient is enrolled into the study, establish a SGG case in FLOWCAST if there will be inpatient or outpatient visits billable to the sponsor			P	S	S	S		
SERVICES PROVIDED								
Prepare a patient-level Participant Grid using the Budgeting Grid			J	J				
Update the Participant Grid in the Post-Award Workbook showing participant activity for procedures, items and tests to be paid by sponsor (insert a date on the participant's row and the respective column)	S		J	J				
Obtain and review/approve the monthly billing reports from URMC Labs and modify the respective cells (e.g. highlight in purple)			J	J	S			
Obtain and review/approve the HCFA Insurance forms for Radiology services and modify the respective cells (e.g. highlight in purple)			J	J	S			
Obtain and review/approve the reports of dispensing fees from Pharmacy and modify the respective cells (e.g. highlight in purple)			J	J	S			
Obtain and review/approve the UB-04 Forms from the Patient Accounts Office for the hospital-based charges coded to clinical trial ledger accounts and modify the respective cells (e.g. highlight in purple)	S		J	J	S	S		
Obtain and review/approve the HCFA Insurance Form from URMFG for the professional charges coded to clinical trial accounts and modify the respective cells (e.g. highlight in purple)	S		J	J		S		
Follow through with ancillary providers for expected fees that are not reflected on the ledger and fees on the ledger that are not expected			S	P	S			S

	PI	S	SC	DA	AD	B	CO	Acct
SERVICES PROVIDED (continued)								
Follow through with Patient Accounts Office for expected billings that are not reflected on the ledger and for billings on the ledger that are not expected			S	P		S		S
Follow through with URMFG for expected billings that are not reflected on the ledger and for billings on the ledger that are not expected			S	P				S
If insurance reimbursement is to be requested, ensure the following appears in the patient's medical record: trial name, sponsor name, protocol number	S		P	S				
Update the Non-Participant Grid for cost activity that can be invoiced to the sponsor according to the clinical trial agreement			S	P				

PAYMENT RECONCILIATION								
Send an invoice to the sponsor for non-refundable start-up costs upon receipt of signed agreement				P				S
Monitor timely sponsor payment of invoices submitted				P				
Monitor timely sponsor payment of participant visits and procedures			S	P				
Obtain details of each sponsor remittance and modify the respective participant cells (e.g. change highlight from purple to green)			S	P				
STUDY CLOSE-OUT								
Resolve all outstanding questions from prior month comparisons of the general ledger to the Post-Award Workbook			S	P	S	S		S
Ensure all participant visit cells on the Participant Grid have been modified to reflect receipt of payment from the sponsor			J	J				S
Ensure all separately invoiced items have been billed to, and paid by, the sponsor			S	P				S

	PI	S	SC	DA	AD	B	CO	Acct
STUDY CLOSE-OUT (continued)								
Provide notifications to internal departments (Patient Accounts Office, URMFG, RSRB, Pharmacy, ORPA and ORACS) that the trial is no longer active	S		J	J				
For variances of +/- $20,000 and +/- 20% of the trial revenue, explain the variance and obtain Department Chair approval	S		S	P				
For variances of +$20,000 and + 20% of the trial revenue, obtain Dean's Office approval	S		S	P				

Note: This matrix presents a suggested assignment of roles and responsibilities. Depending on a department's/division's organizational structure, the assignment of certain tasks in the above matrix might vary among departments. For example, it is possible that a department does not have an accountant other than the Department Administrator.

IV. INTERNAL CONTACTS AND RESOURCES

University of Rochester Medical Center Compliance Office
Corporate Compliance Officer
Compliance Program Medical Director
http://www.urmc.rochester.edu/urmc/compliance/

University of Rochester Office of University Audit
Director of University Audit
http://www.rochester.edu/adminfinance/audit/people.html

Office of Research and Project Administration
Associate Vice President for Research Administration
Research Compliance Officer
http://www.rochester.edu/ORPA/

Clinical and Translational Science Institute/Office of Regulatory Support
Executive Director for Research Services
Director, Office of Regulatory Support
http://www.urmc.rochester.edu/ctsi/research/regulatory-support/index.cfm

University of Rochester Research Subjects Review Board (RSRB)
Executive Director, RSRB
http://www.rochester.edu/rsrb/indexs.html

Footnotes

(1) Illustrative examples of extenuating circumstances: (i) the ability to access the latest technology to best serve a particular patient base; (ii) UR's participation as a subawardee of a peer institution's trial allows for collaboration with other prestigious peers that is otherwise not possible

(2) The study coordinator uses the following script:

"I want to schedule patient X for an appointment. A study case should be attached. Can you see if one is already built? If not, I can provide the information to build one—study name, ten digit general ledger number, PO Box to which the bill should be sent, and the billing coordinator's name."