Clinical Research Budget Development and Billing Process

For assistance with establishing a study budget:

- Clinical Research Coordinator (CRC)/ Principal Investigator (PI) will submit a protocol with schedule of activities and any available budget information to the School of Medicine Clinical Trials Office (SOM CTO) Budget and Billing coordinator.

- The CRC/PI will identify all study services and procedures that will generate a billable charge to the Medical Center (MC) and/or Health Services Foundation (HSF).

- A Grant Pricing Request Form (copy attached) listing all services to be covered by the grant with their associated CPT codes will be completed by the CRC/PI, with assistance as necessary from the SOM CTO Budget and Billing coordinator. Coding assistance may be obtained from coders in specific departments or billing offices when necessary. Coding and/or pricing assistance for unlisted codes will be obtained from MC Finance and/or HSF, as necessary, by the SOM CTO Budget and Billing coordinator. When all study services and procedures are listed with CPT and/or SMS codes, the Grant Pricing Request Form is sent to the SOM CTO Budget & Billing coordinator for prices.

- Referencing the Grant Fee Schedule spreadsheet of grant pricing set by Medical Center Finance, the SOM CTO Budget and Billing coordinator will provide the Medical Center's standard and grant discounted prices for the study services/procedures required by the protocol. Grant pricing from HSF and the HSF special payer account # will also be obtained by the SOM CTO Budget and Billing coordinator.

- Pricing information will be emailed by the SOM CTO Budget and Billing coordinator to the requester (CRC, PI, grant administrator, etc.) within 72 hours of receipt of a correctly completed request.

- PI/CRC will use the pricing information to develop and negotiate a final budget. The SOM CTO Budget and Billing coordinator will be available to assist in the development of the study budget, as needed, but not with the negotiation of the budget or the contract.

Development of a Billing Coverage Analysis:

- Utilizing information from the protocol, informed consent and contract (study agreement), the SOM CTO Budget and Billing coordinator will collaborate with the CRC and/or PI to identify the source of payment (study or subject/subject's insurance) for each of the services/procedures that will generate a Medical Center and/or Health Services Foundation charge. (Note: If the study budget provides payment for any service/procedure, that service/procedure cannot be billed to the subject/subject's insurance, even if the service/procedure is considered standard of care.)

- The SOM CTO Budget and Billing coordinator and the CRC/PI will complete the Billing Coverage Analysis grid/template detailing the source of payment for each protocol-required service/procedure.

- The PI will sign the completed Billing Coverage Analysis, documenting the accuracy of the source of payment for each service/procedure.

- The SOM CTO Budget and Billing coordinator will review the Billing Coverage Analysis to ensure that it is consistent with the supporting documentation (contract, informed consent, and protocol).

- For all industry-sponsored trials, the SOM CTO Budget and Billing coordinator will submit a completed Billing Coverage Analysis to SOM Grants and Contracts Office. The final contract will not be executed until the Billing Coverage Analysis is on file with the remainder of the required documents.

After Clinical Trial Agreement Fully Executed:

- The CRC/PI will e-mail the Grant Pricing Request form to the SOM CTO Budget and Billing coordinator after the clinical study agreement has been fully executed and a PTAEO account has been established by the Office of Sponsored Programs. Both the PTAEO and the study's IRB-HSR approval numbers are added to the Grant Pricing Request form so that the study can be added to the Clinical Trials Billing Profile in the SOM CTO.

- The CRC/PI and the Grant Administrator will be provided with a completed Grant Encounter form. The Grant Encounter form is used to schedule and register subjects for study visits and procedures in provider based clinic space at the Medical Center. This form is printed by the study coordinator and completed with encounter specific information for individual subjects for study visits and the services/procedures required by the study.

SOM CTO contact for budget and billing information:

- Kathy Richardson
  SOM CTO Budget and Billing coordinator
  Phone: 982-4383 Fax: 243-5999 E-mail: kr3m@virginia.edu

- Jennifer Crosby
  SOM CTO Budget and Billing coordinator
  Phone: 243-5350 Fax: 243-5999 E-mail: jac8tr@virginia.edu

<u>Study Subjects Seen in MC (Provider Based Clinic) Space:</u>

Note: Study services/procedures being charged to a PTAEO should not be scheduled in Medical Center space unless the study is entered into the Clinical Trial Billing Profile in the SOM CTO.

- The PI and/or CRC should be sure that the study IRB # is entered with the subject's pre-registration information when a study visit is scheduled. Scheduling personnel will prioritize the grant code as a '1' on the scheduling insurance screen. Also, the scheduler can be asked to "flag" the study subject by entering "grant visit" in the comments field.

- When the IRB # is entered with a scheduled study subject, an auto pre-registration will be established the next day or as soon as the appointment is only 22 days out. The Insurance Verification Unit will prioritize the grant as a '1' on the account. Insurance priority should not be zeroed out.

- When the IRB # is provided to the registration staff, it is entered into the A2K3 registration system for all study related visits. **Please contact Kathy Richardson, the SOM CTO Budget and Billing coordinator, if you suspect or are aware of a grant related billing problem, i.e., a subject notifies you that a bill for a study procedure has gone to their insurance.**

- It is the PI/CRC's responsibility to provide the Grant Encounter form to **each** department registration staff where a study visit or procedure will take place, i.e., Clinical Lab, Radiology, etc. Depending on the location, this may be done the day before the scheduled visit, the morning of the visit, or at the time of the visit as a walk-in.

- **Failure to register study subjects with the Grant Encounter form may result in erroneous billing of the study's procedures to the subject or their insurance carrier** because the visit will not be prioritized first on the subject's account.

- The care unit rendering services to the study subject will bill the study procedures/ services performed to the IRB # on the Grant Encounter form. Billing will flag the visit by assigning a generic Grant Plan Code. These are R96, R97, R98 or R99.

- If services are provided at the visit that are considered conventional care not related to the study and are to be billed to a third party payer, those services may be ordered on a standard clinic encounter form.

- If services are provided at the visit that are study-related but were unanticipated at the time the study was entered into the Clinical Trials Billing Profile (ex., services to treat a study-related adverse event), record those services on the Grant Encounter form for that subject, and contact the SOM CTO Budget and Billing coordinator to have those services added to the Grant Pricing Request and Encounter forms and to the Patient Financial Services (PFS) billing spreadsheet.

MC Patient Financial Services Billing:

- Sue Ruddock in Patient Financial Services (PFS) will send a monthly account statement spreadsheet to the study coordinator and to the Department Grant Administrator listed on the Grant Pricing Request form. The account statement will include all charges generated, and will identify the following:

    - Account #
    - Patient Name
    - Date of Service
    - Generic grant billing plan code
    - Medical insurance code – Medicare, private insurance, etc
    - SMS procedure code
    - CPT code
    - Medicare modifier, if applicable
    - Service description
    - Hospital Price
    - Grant discount
    - Grant price
    - Billing direction (PTAEO # being debited; "standard of care, bill patient")

  The study coordinator should review and reconcile the charges on the statement. If an error in billing is noted, such as a duplicate or erroneous billing, the study coordinator should note this in the Billing direction column (Column M) of the account statement.

- A ten day period is provided for the account review. A billing direction for each charge should be listed for each line item on the account statement with a designation of the appropriate payer, either the grant PTAEO, other 3rd party/self pay or query regarding the accuracy of the charge. Reconciled account statements are returned to Sue Ruddock in PFS.

- After ten days, unless a question about the statement is raised, a bill is put through to Oracle to debit the identified PTAEO number for the grant and to credit the patient account within Patient Financial Services.

HSF Professional Services Billing

- The department billing staff for each clinical department is responsible for entering study charges through Transaction Editing System (TES), the charge entry system. The grant encounter should be keyed using the HSF Special Payor Account number assigned to each IRB # instead of the medical record number (MRN) of the patient. This ensures that the professional component of the study service/procedure will be billed to the department instead of the subject.

- Monthly account statements are sent to the Department Grant Administrators for reconciliation. These should be forwarded on to study coordinators for verification of the charges.

- All clinical standard of care services should be billed to 3rd party insurance through the normal HSF charge entry process using the patient's medical record number.

For assistance:

All questions related to clinical trials billing, for either a Medical Center technical charge or a HSF professional charge, may be directed to:

Kathy Richardson
SOM CTO Budget and Billing coordinator
Phone: 982-4383 Fax: 243-5999 E-mail: kr3m@virginia.edu

Jennifer Crosby
SOM CTO Budget and Billing coordinator
Phone: 243-5350 Fax: 243-5999 E-mail: jac8tr@virginia.edu