

Clinical Research Budget Development and Billing Process

For assistance with establishing a study budget:

- Create a CRConnect cart with matching CRConnect study name listing all study services and procedures to be billed to a study PTAE0. The research price lookup function in CRConnect is based on CPT codes and provides Medical Center clinical prices, HB (hospital) research prices and PB (professional / UPG) research prices.
- Submit the cart in CRConnect once all study services and procedures have been identified.
- The research pricing cart is uploaded to CRConnect by SOM CTO.
- Research pricing information available from the CRConnect research price look up function is then used by the PI and study team to develop and negotiate a final study budget. The SOM CTO Budget and Billing coordinator will be available to provide assistance if CPT codes are not found in the CRConnect research price look up function. The negotiation of the clinical trial budget or contract is the responsibility of the PI and study team.
- When a study has completed IRB-HSR pre-review and the study documents – protocol, ICF, budget - have been uploaded into CRConnect by the study team, the SOM CTO will work with the PI and study team to develop a study Billing Coverage Analysis. A Billing Coverage Analysis is a document identifying all the services and procedures that are performed under the protocol with a designation as to whether each is to be billed the study or to patient/ insurance. This document will guide the CRC as to how charges associated with the clinical trial that are billed by Patient Financial Services and/or the University Physicians Group are to be designated for research billing review through Epic.

After the Clinical Trial Agreement is Fully Executed:

- When the Clinical Trial Agreement has been executed by the Office of Sponsored Programs (OSP) and a PTAE0 account has been established, this information is provided to OnCore. Once OnCore synchs the study to Epic, the SOM CTO Budget & Billing coordinator activates the study in Epic allowing subjects and orders to be associated and encounters to be linked to the IRB-HSR #.

When study subjects are seen in MC (Provider Based Clinic) space:

Note: Study visits, services, or procedures being billed to a study PTAE0 should not be scheduled in Medical Center space until the IRB-HSR # has been activated in Epic, the subject has been associated with the IRB-HSR # and the encounter having charges billed to the study has been linked to the IRB-HSR # in Epic.

- Scheduling and registration personnel may use the IRB-HSR # when performing their functions in Epic. CRCs should check their upcoming (14 day) report in Epic to be sure encounters are linked to IRB-HSR #s correctly. If an encounter was linked by someone other than a member of the study team, the CRC should review to confirm that it has not been linked in error. If no charges from an encounter are being billed to the study, the encounter can be un-linked from the IRB-HSR # in Epic.
- It is the PI/CRC's responsibility to link all encounter from **each location** where a study visit or procedure will take place, i.e., Clinical Lab, Radiology, in-patient hospital floor, 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 link a study encounter to an IRB-HSR # in Epic may result in all charges including those that should be covered by the study being to the patient or their insurance.**
- If there are services or procedures provided during an encounter that should be billed to a study that was not linked to the IRB-HSR # in Epic, CRCs should follow the instructions in the Epic Tip Sheet, "Research Linking after Encounter Closed".

Research imaging done by UVA Imaging at Fontaine, Northridge, Zions Cross Roads:

UVA Imaging bills at UVA's HB (hospital) research prices as a separate billing group from the UVA Medical Center. Their billing is done by invoice to departments, not through PTAE0 accounts.

If the study team responds affirmatively in CRConnect regarding research scans being done by UVA Imaging, the research pricing cart will be reviewed by the SOM CTO and a traditional Grant Pricing Request form is uploaded to CRConnect. This is sent to UVA Imaging for research pricing purposes.

Clinical Research Unit (CRU) studies / Billing Process

Both in-patient and outpatient industry sponsored or investigator initiated research can be conducted on the CRU. For example, this might occur if protocol specific PD/PK blood draws are being performed. Because the CRU is not provider based clinic space, subject registration through Patient Access is not required. The charges for using the CRU space are negotiated between the PI and the SOM CTO and could include certain procedures such as venipuncture, drug administration, and/or producing an ECG tracing. ECG interpretation is not provided by the CRU. Labs drawn on the CRU are billed directly to the study's PTAE0 through an internal lab account set up with Panwichit Tongvichit in Medical Labs. The CRConnect research price look up function can be used for any research services and procedures not provided by the CRU, but that will generate a Medical Center or University Physicians Group charge. A grant discounted room rate is available for inpatient CRU admissions for sponsored research.

Investigational Device studies

Studies using FDA IDE investigational devices require special consideration to ensure correct billing. Any PI or CRC involved with this type of protocol should contact the SOM CTO for assistance and guidance.

SOM CTO contacts for budget and billing information:

- CRConnect Support
- Jessica Morris, SOM CTO Budget and Billing coordinator
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- Kathy Richardson, SOM CTO Budget and Billing coordinator
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