



Clinical Research News You Can Use

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DII Review and Approval Process

Radiology is a specialty that is at the crossroads of every aspect of clinical diagnosis, treatment, and care. Radiology research must comply with CPHS (Committee for the Protection of Human Subjects) and HIPAA (Health Insurance Portability and Accountability Act) regulations, as well as follow all related federal, institutional, and ethical guidelines.

It is important for the Department of Diagnostic And Interventional Imaging (DII) to be aware of imaging being performed for research, as well as to ensure that imaging resources are available and billing occurs appropriately. The [DII Approval Form](#) is required for all research projects that utilize diagnostic imaging procedures, whether the research is initiated by a DII faculty member or is being conducted by members of other departments, schools, or institutions.

Please obtain approval for all studies involving the use of Radiology and Medical Physics services (e.g., interpretation, reporting, processing, establishing imaging equipment performance/compliance etc.) that are NOT required for patient care and are performed for research purposes only. Any studies that involve the non-routine use of Radiology (e.g., in the assessment of a new implant or device), non-routine imaging methods, or new/improved contrast methods also need departmental approval. As with standard of care imaging, all research imaging performed on MHHS imaging equipment needs to be read by a UTHealth radiologist. Please obtain

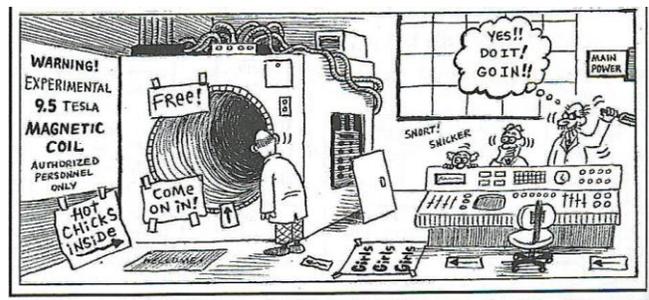
research pricing for professional read fees by emailing Radiology.Research@uth.tmc.edu.

A Radiology start-up fee of **\$750** will be assessed on all studies that involve research-only (non-standard of care) imaging. This fee will be waived for investigator-initiated unfunded studies and studies that involve the services of our radiologists in the role of Co-Investigator or Consultant. This fee will also not be charged on studies that are conducted on the UTHealth 3T MRI scanner.

Investigators from other departments who wish to utilize the capabilities of DII are advised to discuss potential projects with a Radiologist during the planning phase of a project, in parallel with the CPHS approval process.

Attach a completed DII Approval form for all applicable studies with the IRB initial application. The IRB coordinators will send the initial application back for corrections if this form is not attached.

To learn more about the DII Review and Approval process, contact Usha Menon, PhD, Program Manager, Radiology at Usha.N.Menon@uth.tmc.edu. Also, **attend the July 24, 2019 Coordinator Forum (11:30 am-1:00 pm, MSB B.645) on the topic of the billing process for radiology services.**



Central Invoicing for Administrative Start Up Fees

Kristin Parks, Director, Clinical Research Finance and Administration

EFFECTIVE JULY 1, 2019:

- 1. Administrative start up fees will be invoiced centrally for all industry-initiated clinical studies** (see process chart at [this link](#)). The PI and/or Department is responsible for ensuring terms related to administrative startup costs are clearly incorporated within the Clinical Trial Agreement as well as the budget. Note: If the administrative startup fees are not clearly defined within the contract, they cannot be invoiced. Each Clinical Trial Agreement will generate an IRB fee invoice and an Administrative Startup invoice. It is the department's responsibility to provide SPA with the names of the financial staff whom they would like to be cc'd when the invoices are sent to sponsor. The most efficient approach would be to simply include applicable financial staff on cc upon initial submission of the contract to SPA. *Info on central invoicing is found on the SPA website at: <https://www.uth.edu/sponsored-projects-administration/manage/clinical-trialsresearch/central-invoicing>*
- 2. The IRB will no longer perform collection activities for unpaid invoices.** CPHS will continue to invoice the sponsor directly for IRB fees; however, CPHS will no longer be responsible for following up with sponsors if payment is not received. Departments are now responsible for monitoring applicable financial project accounts for payment receipt and for performing collection activities if necessary. IRB fees will be automatically debited from study project FMS account 120 days after invoice has been sent to the sponsor. SPA will provide assistance to departments experiencing payment issues. Please contact SPA with any payments >120 days past due to request assistance with collection activities.

CENTRAL INVOICING FAQs

If I forget to include start up fees in the contract, will they be invoiced anyway?

No, we will not invoice for these services if they are not clearly defined in the contract. It is the department's responsibility to assess the costs to conduct the study and to ensure these costs are covered in the contracted budget. If you find that some of your costs are not covered, immediately contact the sponsor and request a contract amendment to amend the budget.

How should I contact someone if I have questions or concerns about the IRB and/or start up invoice?

Send an email to centralinvoicing@Uth.tmc.edu

Does CPHS include the IRB fees and the startup fees in one invoice?

No, CPHS will send two invoices within one email. One invoice for the IRB fees and one invoice for the startup fees.

After the invoices for IRB fees and Startup fees have been sent to Sponsor, how long should I wait to follow up with sponsor?

Typically departments follow up monthly on invoices. However, each department has their own processes for follow up. Please check with your DMO or direct supervisor to learn departmental procedures. Payments usually arrive within 30-45 days from receipt of invoice.

What items are included in the "Administrative Startup Fee" invoice?

Any tasks performed to prepare/make ready for conducting the study at UTHealth as outlined in the contract/budget.

Some examples of items that would be included are:

- Administrative Startup fees: This is a fee charged to cover administrative preparation to conduct the study. This fees covers time and effort expended on items such as (but not limited to) reviewing the protocol, completing feasibility assessment, negotiating contract and budget, completing coverage analysis, completing all regulatory

documents, completing IRB submission forms, attending investigator meetings, creating source documents, in-service training sessions, etc.

- Investigational Drug Pharmacy set up/start up fees:
- Clinical Research Unit set up/start up fees
- Radiology Start up fees

Note that in some contracts various administrative start up items are listed out separately rather than included in one 'Administrative startup fee'

Will record archiving and storage fees be included in the "Administrative Startup Fee" invoice?

Yes, it is best practice to collect these fees upfront. You may forget to invoice for these services later.

Contracts vary in the way they are written. In some contracts all of the administrative start up activities may be listed out separately, but in other contracts they may be combined together in one sum. How will the central office note this on the invoice?

Example contract lists out all of the below items in the "One time Invoicable" section of the contract:

- Administrative Startup fee \$6000.00
- IRB submission preparation fee \$1000.00
- Attend investigator meeting fee \$2000.00
- EDC Training activities fee \$1000.00
- IDS Pharmacy set up fee \$2000.00
- Archiving and Storage fee \$1500.00

All of the above will be listed as separate lined items within the Administrative Start up Invoice. Each lined item will be added together to create a grand total.

I understand the IRB fee will be debited from the project account 120 days after invoice is sent to sponsor. If there are not enough funds in the account to cover the IRB fee, will this create a negative balance?

Yes, although this is an unlikely scenario, the account associated with the study will be debited 120 days after the invoice was sent to sponsor. If there are not funds in the account, this will cause a negative balance. Sponsors normally pay for services provided, however if a case arises in which you have not received payment for an invoice, please contact SPA/CRF at crf@uth.tmc.edu. SPA/ CRF will help you to communicate with sponsor to uncover what underlying issues are causing the delayed payment(s).

How do I make sure the person responsible for financial aspects of this study is included on the cc when the startup invoice is sent to sponsor?

All department personnel listed on the cc within the "PAF Notification for Account Setup" email chain will be included on the cc when the IRB & Start up invoices are sent to sponsor. You should let your SPA Contract Analyst know the name(s) of the person (s) to be included on the cc in the "PAF Notification for Account Setup" email string.

(The "*PAF Notification for Account Setup*" email chain is in reference to the email sting in which SPA/ Preaward sends the contract and all associated documents to SPA/Post Award Finance (PAF) via email and requests a new account set up. PAF builds the study- specific financial account in UTHealth's financial management system (PeopleSoft FMS) and replies with the new account number.)

Let's Welcome Mary Rangel to Pulmonary/Critical Care!



Mary Rangel, CCRP is the newest member of the Department of Internal Medicine's Pulmonary/Critical Care Division, serving as its Study Coordinator. Prior to joining UTHealth, Mary worked at an Internal Medicine private practice for 23 years. She is a Certified Clinical Research Professional and has more than 15 years of experience working in the clinical research field. Happily married, she has 2 children—a son who's a recent graduate of Texas A&M University and who's proudly serving as a 2nd Lieutenant in the US Army, and a daughter who's entering her sophomore year at Texas A&M. Congratulations and good luck on your new position within our institution!

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHHealth's CPHS and AWC.

Date and Time: 7/10/19 (9:30am – Noon); 8/1/19 and 8/27/19 (1:30am – 4:00pm)

Location: UCT 1155 (parking will be validated)

Registration is required. [Register here.](#)

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information [here.](#)

Date: July 24, 2019

Topic: Billing Process for Radiology Services

Time: 11:30 am – 1:00 pm

Location: MSB B.645

Lunch will be provided for the first 40 participants.

Registration is not required.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals from TMC member institutions.

Date: August 7, 2019

Time: 3:30 pm – 4:30 pm

Topic: FDA GCP and ICH GCP

Speaker: Dalal Murai, COO, GXP Quality Systems

Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue

Registration is required. [Register here.](#)

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.

MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640

SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room)

An appointment is not necessary

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT suite 1840. Please visit <https://www.uth.edu/ctrc/> for more information.

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We would love to hear from you.

Please send your comments, suggestions and feedback to clinicaltrials@uth.tmc.edu