



I. 7.10.2 Industry Sponsored Clinical Research Billing

Chapter 7 - Research and Sponsored Programs	Original Effective Date: November 2020
Section: 7.10 Research Administration	Date Last Reviewed:
Responsible Entity: Vice President for Research	Date Last Revised:

II. Purpose

The purpose of this policy is to outline the procedures and responsibilities for billing clinical research funded by pharmaceutical, device, or other for-profit companies (industry).

Faculty routinely participate in clinical research sponsored by industry (industry sponsored research). In general, the study plan (protocol) is developed by the industry sponsor. Occasionally, the study plan is developed locally by faculty, and the industry partner agrees to provide support for the research. The protocol defines the scope of work and research procedures that are used to determine actual costs and form the basis for the budget.

A contract (or clinical trial agreement) between the industry sponsor and the university (herein contract) defines the terms and conditions for sponsor payments to the university. The contract sets forth the payment schedule, allowance for conditional payments, withholding percentage, invoice submission method, timelines for invoicing and payments, and payment dispute procedures. The payment schedule is generally divided into the following: a) per patient costs based on defined milestones; b) individual procedure charges (i.e., unscheduled visits/procedures or expensive procedures); and c) startup or administrative costs.

Proper billing of industry sponsored clinical research requires knowledge of the budget and payment terms and conditions of the contract and awareness of the status of research activities as they relate to the invoicing triggers

III. Scope

This policy applies to all University of Texas Health Science Center at San Antonio (UT Health San Antonio) departments and Institutional Organized Research Units (IORU) involved in the approval, conduct, reporting, or billing of industry sponsored clinical research. Some of the procedures contained in this policy may not be applicable to

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industry sponsored clinical research started prior to the original effective date (above). However, these legacy studies are still expected to comply with the general principles of this policy.

IV. Policy

Contracts between the university and the industry clinical research sponsors are managed by the Office of Sponsored Programs (OSP).

The budget details and payment terms of each contract are negotiated by the Clinical Trials Office (CTO) in collaboration with the Principal Investigator (PI) and the Research Team. Budgets are approved by the PI and PI's Chair or Institutional Organized Research Unit (IORU) Director or designee.

The PI and Research Team is responsible for documenting study activity using the clinical trial management system (CTMS), specifically milestones that trigger budget payments.

The PI's department/IORU is responsible for billing and reconciling payments according to the terms and conditions of the contract. Each department must maintain a system of records documenting invoicing, payments, and other reconciliation activity.

All payments from sponsors must be processed for applicable Facilities and Administrative (F&A) costs by OSP.

A. Procedures

This process begins during the contract and budget review phase of study initiation. This process ends when the research study ends, and all sponsor payments have been received and reconciled.

1. Contract and Budget Approval

- a. Contracts will be managed by OSP using the Jaggaer application. OSP will document the contract negotiation progress. CTO will be provided access to Jaggaer reports for the purpose of status updates.
- b. With input from the PI and Research Team, the CTO will develop a draft budget based on the sponsor protocol, sponsor budget and an assessment of the actual costs (research coverage analysis). The CTO will negotiate with the sponsor and obtain approval of the negotiated budget from the Principal Investigator and the designated department/IORU official. Once approved, the final budget is provided to OSP for inclusion in the agreement.
- c. An OSP Certificate of Proposal (COP) must be signed by the PI and department Chair and provided to OSP.
- d. Prior to contract execution, OSP will generate a Project ID (PID) for the protocol, unless the department/IORU administrator informs OSP otherwise.

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- e. OSP will ensure that all contracts contain the PID assigned to the protocol and will include language in the contract that specifies all payments must reference the PID, payment by check must be mailed to the Vice President for Research's Clinical Trials Office (VPR CTO) or Mays Cancer Center's (MCC) Administration, and electronic payments must be transmitted to the university research bank account.
 - f. Executed contracts will be made accessible to the CTO, the Research Team and the department/IORU's designated administrator.
 - g. If the sponsor selects UT Health San Antonio as a study site, but later withdraws the study before the study is opened to enrollment, the CTO will attempt to recoup costs of work performed to-date as part of an early termination agreement with the sponsor.
2. Study Startup
 - a. Within 14 calendar days following contract execution and institutional review, the VPR CTO will invoice the sponsor for the initial "institutional review" fees. The CTO will track payments and ensure funds are deposited in the applicable reviewing office account(s).
 - b. Within 14 calendar days following contract execution and institutional approval, the department/IORU administration will invoice the sponsor for the start-up fees according to the terms of the contract. The CTO/IORU will track payments and ensure funds are deposited in the applicable research PID.
 - c. The CTO will build budget calendars in the Clinical Trials Management System (CTMS) based on the billing milestones and triggers contained in the contract.
 - d. The CTO will coordinate the creation of a study specific EPIC Research Account, as appropriate.
 3. Study Performance
 - a. The Research Team will register new participants to the study in the CTMS within one day of the date when the individual consents.
 - b. All subsequent study visits that are built into the CTMS project will be updated within three business days of performing the visit/procedure.
 - c. Any unscheduled visits will be documented in CTMS within three business days of performing the visit/procedure.
 4. Sponsor Billing
 - a. Each department/IORU will designate an administrator responsible for billing the industry sponsor according to the terms and conditions of the contract.
 - b. Research activity as it related to billing milestones and triggers will be assessed at least once every three months by the department/IORU's designated administrator.

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- c. Invoices should be generated by the CTMS. If not, invoices will include the PID, HSC IRB Number, and the PI name at a minimum.
 - d. Invoices will be generated by the department/IORU's designated administrator including payments covered by automatic sponsor payments.
 - e. Invoices for non-cancer clinical research will also be submitted to the VPR CTO for monitoring purposes.
 - f. Ongoing administrative fees charged by the institution (e.g. IRB review fee) will be invoiced by the VPR CTO. All other sponsor billing is the responsibility of the department/IORU.
5. Sponsor Payment Posting
- a. The Office of the Bursar will receive all electronic payments.
 - b. Payments via check will be received and managed centrally. VPR CTO for non- cancer studies or MMC Administration for cancer studies.
 - c. All payments will be reviewed against outstanding invoices, daily. Deposit instructions will be provided by the receiving office to OSP with CC to the department's designated administrator.
 - d. All study payments received will be credited to the applicable study PID by the OSP.
 - e. Department/IORU's designated administrator is responsible for reconciling payments to invoices which they have generated.
 - f. Final reconciliation of the study PID should be completed within 30 calendar days of site closure.
 - g. Following study closure, all study financial records will be maintained by the department's designated administrator, following the institutions archiving and disposition policy, HOP [2.2.1 Records Management](#).
 - h. For studies with a study specific PID, the OSP will close the study PID and transfer any residual balance to a non-grant 48001 fund group PID. Retention of any residual balances in excess of 25% of the total amount received shall require the prior approval of the Dean or Executive Committee (EC) Member as provided in HOP [7.1.9 Residual Funds on Fixed Fee Contracts/Agreements](#).
6. Compliance
- a. To assess compliance with data entry in the CTMS, the CTO will routinely monitor study records to identify late entries. Noncompliance will be reported to the PI for corrective action. Continuing noncompliance will be reported to the department Chair and EC member for corrective action.
 - b. To assess compliance with billing standards, department administrators designated by the Chair will monitor billing records to ensure timely invoicing to sponsor, reconciliation of payments and collections of delinquent payments.

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Noncompliance will be reported to the department Chair or delegate for corrective action.

- c. To assess status of payments for services rendered, administrators from departments/clinics providing a service to the research will routinely monitor billing records to ensure timely invoicing to the PI, reconciliation of payments and collections of delinquent payments.

7. Monitoring

The VPR (for non-cancer studies) and MCC (for cancer studies) will monitor compliance with this policy by performing a quarterly billing monitoring plan. The billing monitoring plan will review and confirm that the requirements of this policy are being performed by the department/IORU and Research Team. Each CTO will document the completed results and report the monitoring activities to the Office of Sponsored Programs and the Institutional Compliance and Privacy Office. Continuing noncompliance will be reported to the appropriate Dean/EC member.

V. Definitions

When used in this document with initial capital letter(s), the following words have the meaning set forth below unless a different meaning is required by context.

Clinical Trials Office (CTO) – indicates either the Mays Cancer Center's CTO (MCC CTO) for all cancer-related research, or the Vice President of Research's CTO (VPR CTO) for all other (non-cancer) research.

Institutional Organized Research Unit (IORU) – provide support for interdisciplinary research that complements the academic goals of departments of instruction and research. These units are typically referenced as institutes, laboratories, or centers (e.g. Mays Cancer Center or Glenn Biggs Institute for Alzheimer's & Neurodegenerative Diseases).

Research Team (RT) – the study staff responsible for the conduct of a specific research study (e.g., Principle Investigators, Associate Investigators, Research Coordinators, Data Manager, and anyone appointed by the PI).

VI. Related References

Handbook of Operating Policies (HOP)

[7.10.3 Clinical Research Service Provider Payments](#)

VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

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Effective Date	Action Taken	Approved By	Date Approved
11/2020	Policy Origination		