PURPOSE
This policy is to describe and establish processes to manage proper and timely closure of study financial accounts related to all human subject research studies. A specific close-out procedure ensures that the process is carried out in a planned and authorized manner, which involves all key stakeholders related to the process.

The processes should include:
- Completion of a final account reconciliation prior to closure
- Receipt of proper documentation to authorize account closure
- Identification and notification to the specific departments or positions on closing of accounts
- Verification that the account close-outs have occurred

DEFINITIONS
- OSP: Office of Sponsored Programs
- UT Medicine
- CTRC-CTO: Cancer Therapy & Research Center – Clinical Trials Office
- VPR-CTO: Vice President of Research – Clinical Trials Office
- CTMS: Clinical Trial Management System (Velos eResearch)

RESPONSIBILITY

Office of Sponsored Programs – Designated OSP Staff are responsible for the activation and closure of Research Study related Project/Grant financial accounts.

UT Medicine – The UT Medicine Research Billing team is responsible for the establishment, review, invoicing, verification and closure of EPIC Research accounts.

Clinical Trials Office – Designated CTO staff are responsible for the financial oversight and closure of all human subject study research accounts, to mitigate the risk associated with the failure to close and reconcile study financial accounts in a timely manner:
- CTRC-CTO – Oversight over Cancer related research trials
- VPR-CTO – Oversight over all research studies

Principal Investigator or Research Team –
- Studies not managed by a central office – The PI and Research team are responsible for all financial oversight and closure for their study specific accounts.
- VPR-CTO Managed Research Studies – For studies managed by the central VPR-CTO, the research team should provide study related communication of activity to central offices upon request. Additionally study related activity must be entered into the CTMS to accurately reflect and communicate all study related activity to central office.
Study Financial Management – Closing Out Study Accounts

RELEVANT DOCUMENTS, as applicable

Appendix A: OSP – Closing Study Accounts
Appendix B: UT Medicine – Closing Study Accounts
Appendix C: CTRC – Closing Study Accounts
Appendix D: VPR-CTO – Closing Study Accounts (Future State)

REFERENCES, as applicable
Appendix A:

**OSP Closing Study Accounts**

Required Information and notices:
- Notice of IRB Completion/Termination
  - OIRB emails Quarterly Reports detailing the IRB Completed or Terminated Studies
- Study Team Notice of Completion/Termination
- Study Team Acceptance/Verification at 1 year post IRB Completion/Termination

Email notifications should be sent to the following address:

EMAIL: grants@uthscsa.edu

Processing of Closure:
- OSP designated staff will review Quarterly IRB Completed/Terminated Studies report
- When notice is received that the IRB Status of: IRB Complete/Terminated has been reached
  - OSP will use 1 year from the Recorded date of IRB Complete/Terminated Status
- At the 1 year anniversary of IRB Complete/Terminated Status
  - OSP to send notice to Study Team that Project Account will be closed to activity within 30 days.
    - Study Team to send Acceptance of request for account closure.
    - Study Team Provides Justification:
      - Must provide detailed Justification of why the account is to remain active, additionally the Study team needs to provide tentative date of expected closure of account to activity.
    - No Response by Study Team
      - After 60-days of no response, lack of response will be considered omission and account will be closed to activity.
Appendix B:

UT-Medicine Closing EPIC Research Accounts

Required Information:
- Epic Account Number
- Epic Account Name
- Reason For Closure

Processing of Closure:
- Email all of the required information above to:
  UTMSARESEARCHBILLING@UTHSCSA.edu
- Verification of authorization to request account closure.
  - This is completed by ensuring that the requestor is either the PI (Principal Investigator), the Clinical Nurse/Coordinator or the designated Clinical Trials Office identified in the documentation provided to create the account.
- The account is reviewed for a $0.00 balance in the Epic System.
  - If the account does not have a $0.00 balance the account cannot be closed and will need to be reconciled.
- The account is deactivated

Special Account Team Responsibilities:
- Deactivate the patients from the Guarantor’s Account for the closed research study

Research Team Responsibilities:
- Remove the patient “Research Flag” if the patient is not active on a research study.
Appendix C:

**Process for Clinical Trial Contract Billing (CTRC)- Contracts Outside of VELOS**

1. Maintain record of Sponsor Invoicing required per Study.
2. Request research account to be set up in EPIC per Study.
3. Routinely verify and complete Sponsor Invoicing based on completed patient services. This is done per Study until all study patients are off study and all invoicing has been sent to Sponsor.
4. Payments are received from Sponsor by the CTRC Accounting Associate and posted into Peachtree against the invoice.
5. Accounts Receivable aging schedule is reviewed for invoices that are more than 30, 60 or 90+ days overdue. Monthly communications are sent to Sponsors with invoices older than 45 days.
6. Studies that are closed to accrual are notated and reviewed on a monthly basis for final invoicing to Sponsor of any remaining patient study visit activity and/or contracted payments with Sponsor.
7. Maintain contact with study Sponsor and Study Nurse for Sponsor Close Out visit schedule.
8. Ensure that all invoices have been paid prior to Sponsor Close Out visit.
9. Verify that Final payment of any Hold Back amounts is received from Sponsor following the Sponsor Close Out visit.
10. Request closure of research account in EPIC per Study.

**Process for Clinical Trial Contract Billing (CTRC)- Contracts in VELOS**

1. Set up milestones in VELOS for Visits, Events, Study Status & Patient Status per Study.
2. Request research account to be set up in EPIC per Study.
3. Set up Administrative Calendar in Velos to create email notifications for quarterly invoicing time points per Study. This Calendar is deactivated from the Study once all milestones have been achieved and invoiced.
4. Send Invoices to Sponsor based on milestones achieved as indicated in Velos.
5. Accounting Associate receives payment from Sponsor and posts the payments into VELOS against the invoice.
6. Accounts Receivable aging schedule is reviewed for invoices that are more than 30, 60 or 90+ days overdue. Monthly communications are sent to Sponsors with invoices older than 45 days.
7. Studies that are closed to accrual are notated and reviewed on a monthly basis for final invoicing to Sponsor of any remaining patient study visit activity and/or contracted payments with Sponsor.
8. Maintain contact with study Sponsor and Study Nurse for Sponsor Close Out visit schedule.
9. Ensure that all invoices have been paid prior to Sponsor Close Out visit.
10. Verify that Final payment of any Hold Back amounts is received from Sponsor following the Sponsor Close Out visit.

11. Request closure of research account in Epic per Study.
Appendix D:

VPR-CTO Closing Study Accounts

PURPOSE:
The purpose of this document is to outline the process for the close out of Study Financial Accounts when a study is using the financial services of The Vice President of Research - Clinical Trials Office (VPR-CTO). The VPR-CTO takes no financial responsibility or liability for studies of which oversight is provided.

RESPONSIBILITY:
The VPR-CTO requires all research studies that meet the requirements for entry into the institutional Clinical Trial Management System, Velos eResearch (herein referred to as eResearch), provide financial oversight of the activities pursuant to the information entered into eResearch by the Study Research Team, Clinical Research Unit or other Clinical Staff. Additional documentation may be requested from the Study Research Team, Clinical Research Unit or other Clinical Staff to help ensure the validity and accuracy of the data within eResearch.

PROCESS:
The Vice President of Research - Clinical Trials Office (VPR-CTO) establishes Studies in eResearch in a manner that will facilitate financial oversight on the behalf of the Principal Investigator and research teams.

Responsibilities of the Principal Investigator or Research Team
Financial evaluations and reconciliations should occur in a timely manner pursuant to the level of activity on a clinical trial but no less than quarterly. Any discrepancies identified in the activity should be notated and presented to the Principal Investigator and/or designated Department Official within 30 days of the completion of evaluation or reconciliation.

In addition to the regularly scheduled financial evaluations and reconciliations of study activity, payment reconciliations are to occur no later than 30 days after receipt of a payment, pending receipt of proper documentation of payment breakdown. All reconciliations inclusive of any discrepancies in payment should be notated and presented to the Principal Investigator and/or designated Department Official within 30 days of the completion of payment reconciliations.

Final evaluations and reconciliations are to occur no later than 30 days after notice of final payment or termination of the study is received.

Final reconciliation should result in a $0.00 balance. Any discrepancies in the final reconciliation should be communicated to the Sponsor within 30 days after the notice of final payment or termination of the study is received with copy to Principal Investigator and/or designated Department Official.
In order to close a Study Account the following actions must be completed:

1) Account balance must be $0.00, confirmed through completion of “Final Reconciliation,” reviewed and approved by the Principal Investigator and/or designated Department Official.
   
   A. If there is an outstanding balance post notifications to Sponsor or applicable funding agent, the Principal Investigator and/or designated Department Official should be notified to sign off on the closing of the account.

2) Proof of IRB Study Closure:
   
   i. Disapproved
   
   ii. Inactivated
   
   iii. Withdrawn

3) Notification of intent to close study research accounts should be sent to the Principal Investigator and/or designated Department Official, with copies to the following:
   
   A. Office of Sponsored Programs
   
   B. UT – Medicine