1 PURPOSE

1.1 This procedure describes the process that principal investigators (PI) and study teams should follow to manage financial aspects of clinical research, ensuring accuracy, compliance, and transparency in all financial transactions through the study lifecycle.

1.2 The process begins when a PI receives a study for evaluation.

1.3 The process ends when the study is completed and all payments are received and reconciled.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 California Constitution Article XVI – Public Finance Section 6 prohibits "making of any gift, of any public money or thing of value to any individual, municipal or other corporation whatever."

3.2 UC Contracts and Grant Manual 5-100 cites the circumstances under which clinical research cost sharing may be permitted and describes the approval and documentation requirements associated with cost-sharing. Otherwise, the APM-020 policy statement "For all tests and investigations made for agencies outside the University, a charge shall be made sufficient to cover all expenses, both direct and indirect" applies.

3.3 UC Contracts and Grant Manual 5-300 describes the types of cost sharing and the requirements associated with each.

3.4 National Coverage Determination (NCD) 310.1 cites the applicable Medicare requirements for billing routine costs in a clinical trial.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring that all research activities comply with UC policies and all federal and state laws.

4.2 The PI or designee is responsible for tracking, managing, and reporting the financial status of the study.

4.3 The PI or designee is responsible for initiating the coverage analysis process by triggering the Office of Coverage Analysis Administration review at the time of initial submission in the electronic IRB system; studies with protocol services delivered in a UC San Diego health charge-capturing space require that the investigator or designee indicate that the research involves "events/procedures billable to sponsor/insurance/research participant" within the research characteristics of the electronic protocol application.

5 PROCEDURE

5.1 Pre-Award

5.1.1 The PI or designee should review each study protocol for financial feasibility and budget requirements.

5.1.1.1 The PI or designee will develop a budget for the study to recover all study-related costs, including start-up costs.

5.1.1.1.1 The budget should include UC San Diego faculty and staff salary and benefits costs, UC San Diego Health clinical

research charge master clinical care costs, and other applicable department-specific research charges (e.g., pharmacy, IRB, Center for Clinical Research).

5.1.1.1.2 Any study with protocol services delivered in a UC San Diego space that is capable of capturing clinical charges must undergo the coverage analysis process to determine prospectively whether clinical charges may be billed to the participant or their insurance or whether they must be recovered from the sponsor in the study budget.

5.1.1.1.3 Maintain documentation that supports budget calculations.

5.1.1.1.4 Review the sponsor's template budget or initial offer, if one is provided, and ensure that all costs identified in 5.1.1.1 are met by the sponsor's budget.

5.1.1.1.5 If the sponsor's budget does not meet the projected budget requirements, negotiate with the sponsor to arrive at a final budget that covers all costs.

5.1.1.2 The PI will sign the award or contract confirming budget compliance with the requirements of 5.1.1.1 above.

5.1.2 Post-award

5.1.2.1 The PI or designee will monitor research participant visits as they occur to ensure that costs and charges are aligned with the study budget; funding agency guidelines or study agreement; coverage analysis, if applicable; and UC San Diego policies.

5.1.2.1.1 Using OCR-110 Research Charge Adjudication Checklist, or equivalent, facilitate accurate billing and charge direction for each clinical item or service provided to research participants.

5.1.2.2 The PI or designee will utilize UC San Diego standardized systems, such as purchase orders, invoices, and receipts, to record study income and expenses.

5.1.2.3 The PI or designee will regularly review project expenditures against the approved budget, identifying potential cost overruns and taking timely corrective action, to include initiation of contract and/or budget amendments, if needed.

5.1.2.4 The PI or designee will ensure that appropriate and timely sponsor invoicing, if applicable, is carried out.

5.1.2.5 The PI or designee will comply with all funding agency/sponsor requirements for reporting and will ensure accuracy of financial report data.

5.1.3 Close-out

5.1.3.1 Prior to closing the study, the PI or designee will perform financial reconciliation and confirm that all payments, including payments for invoices, have been received from the sponsor.

5.1.3.2 The PI or designee will maintain the financial records for the study in accordance with the study agreement and/or funding agency/sponsor requirements; applicable UC San Diego policies; and relevant federal and state laws.

6 MATERIALS

6.1 OCR-110 Research Charge Adjudication Checklist

7 REFERENCES

7.1 California Constitution Article XVI – Public Finance Section 6

7.2 UC Contract and Grant Manual

7.3 General University Policy Regarding Academic Appointees APM-020

7.4 National Coverage Determination (NCD) 310.1