UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:017 Page 1 of 3
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SOP TITLE: FINANCIAL COVERAGE ANALYSIS		

1 PURPOSE

1.1 This procedure establishes the process for principal investigators (PI) and study personnel under the PI's supervision to follow in determining whether a coverage analysis is applicable for a study, and if so, for requesting, reviewing and approving financial coverage analyses for applicable sponsored or investigator-initiated clinical trials, observational studies, or other research activities.

1.2 The process begins when a clinical study is being considered by a clinical investigator.

1.3 The process ends when a determination is made that a coverage analysis is not needed, or if a coverage analysis is required, all study participant visit activities have been completed and any associated charges have been billed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 UC San Diego Health Policy 342.2 defines compliant clinical research billing practices and specifies studies to which coverage analysis requirements apply.

3.2 UC San Diego Health Policy 342.2 applies to any clinical research study, regardless of funding source, in which clinical services are provided.

3.3 Research billing must conform to UC San Diego policy, applicable state and federal laws, federal regulations, and Centers for Medicare and Medicaid Services (CMS) requirements.

3.4 CMS National Coverage Determination (NCD) 310.1 describes Medicare coverage of Routine Costs in Clinical Trials.

3.5 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.

3.6 Coverage analysis is a process in which a trained coverage analyst prospectively examines each protocol item and service to render a determination about whether the item or service will be billed to the study guarantor account (PI's research account), the patient account (patient or third-party payor), or is not billable.

3.7 The coverage analysis process requires a comprehensive review of the study protocol, the approved informed consent form, and the study financial agreement in order to align final billing determinations with available payment sources, including items and services for which the sponsor has agreed to pay in the study financial agreement and items that have been promised to the study participant for free in the informed consent form.

4 RESPONSIBILITIES

4.1 The PI is responsible for complying with, and ensuring that all study personnel to whom coverage analysis and billing tasks are delegated comply with, all UC San Diego, state, and federal requirements for research billing compliance.

4.2 Study personnel who have delegated responsibilities for charge adjudication and billing verification tasks are responsible for timely communications with the Office of Coverage

Analysis Administration (OCAA) and for prompt research participant charge review and adjudication.

5 PROCEDURE

5.1 For new studies, the PI or designee will prepare the IRB electronic submission, responding to the research characteristics section of the new study application to indicate whether the research involves: "services/procedures billed to the sponsor/insurance/research participant (e.g., labs, imaging, and tests that are performed at a UCSD Health facility)".

- 5.1.1.1 Not selecting this option in the IRB application results in OCAA **not** reviewing the study. If there are billable services conducted in a UC San Diego Health facility, improperly selecting this option may result in non-compliant billing for items and services provided to research participants.
- 5.1.1.2 There may be instances where OCAA is notified of potentially billable procedures by another research oversight entity, in which case, OCAA may reach out directly to the PI for information.
  - 5.1.1.2.1 If coverage analysis review is not triggered, this process stops.
- 5.1.1.3 Selecting this option in the IRB application initiates a coverage analysis review from the OCAA.

5.2 For modifications to existing studies, the PI or designee will prepare the IRB electronic submission, responding to the study classification question to indicate whether the amendment affects the OCAA coverage analysis, which will trigger OCAA review of the amendment for coverage analysis revisions, if necessary.

5.3 If coverage analysis review is triggered, the OCAA team will review the IRB submission, and create the initial coverage analysis or amend the current coverage analysis, as applicable.

- 5.3.1 The coverage analyst assigned to the study will forward a copy of the draft coverage analysis to the PI and will include the project manager and the study coordinator, as applicable.

5.4 The PI or designee will review the draft coverage analysis to verify the following:

- 5.4.1 All items and services required to conduct the study are reflected in the initial or amended coverage analysis.
- 5.4.2 The billing determinations noted in the coverage analysis are congruent with the study budget development or amended budget, if applicable, such that costs of items and services will be recovered in the study budget.

5.5 The PI or designee will respond to the coverage analyst within 7 calendar days of receiving the coverage analysis draft, confirming agreement with the billing determinations or providing comments or justification in support of suggested revisions.

- 5.5.1 If the PI or designee do not respond to the OCAA within 21 calendar days, the study may be placed on administrative hold and the study will not be initiated, or no further enrollment will be permitted, until the coverage analysis is completed.

5.5.2 The coverage analyst assigned to the study will review the revisions, if any, and submit a revised coverage analysis to the PI, who will repeat steps 5.4 and 5.5 above until the coverage analysis is complete.

5.6 If no further changes to the coverage analysis are required, the PI or designee will notify the coverage analyst that the coverage analysis is approved.

5.6.1 The final coverage analysis grid is submitted to the clinical trial management system (CTMS) team to build the study participant calendar.

5.7 The PI or designee will update the participant calendar in the CMTS as participant visits occur.

5.8 The PI or designee will perform regular research account reconciliation of the charges that are expected to be billed to the research account and the research account statements in the electronic medical record.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 Centers for Medicare and Medicaid Services National Coverage Determination 310.1

7.2 UC San Diego Health Policy (UCSDHP) 342.2

7.3 Memo: Velos – UCSD's Clinical Trial Management System