

RESEARCH FINANCE OFFICE COVERAGE ANALYSIS / PT CARE BUDGET REVIEW

Protocol Short Title:

IRB#:

Wellspring#:

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CA / budget completed by: \_\_\_\_\_

CA Version Date: \_\_\_\_\_

UHCRC reviewer: \_\_\_\_\_

Review Completed Date: \_\_\_\_\_

**Validate that each of the following have been completed. Please place a “✓” mark in the box for those items completed correctly, and an “x” in the box for those items that need correction.**

There are appropriately signed copies of the Qualifying Status, Device/Drug, and Pre-award tabs (CA template) saved with the correct path name & date and located in the correct departmental coverage analysis folder in S:\Master Research\Research Billing

If IDS or DCRU services will be utilized on this trial, there are completed and signed copies of either the BioSpecimen Core form, DCRU Resources Request form, or Investigational Pharmacy Request form (as appropriate) saved in the correct departmental coverage analysis folder in S:\Master Research\Research Billing

If the study is internally funded, a completed Internally Funded Research Project form has been submitted & signed off; designating how financial study support will be provided. Verify that Finance has validated adequate funding exists in the designated source.

Verify the result of the qualifying status assessment. Any trial that does not meet qualifying criteria should have all study required services paid by the Sponsor.

Review the Device/Drug form responses and assure that the appropriate steps have been initiated dependent upon the answer. Any Category A or B device trial will need a submission to CGS to determine coverage parameters. Any trial involving investigational drugs or devices will require that drug or device added to the charge master with revenue codes 256 (drug) or 624 (device).

On the actual coverage analysis / budget template, assess that the following is in place:

Items are categorized correctly as “patient care” versus “personnel” time (A comment is present to explain when personnel is used for a typically patient care charge)

There are appropriate dollars allocated for all personnel line items in the “contracted charge rate” column

There are professional and technical components listed separately for procedural items

CPT codes have been used for all patient care items

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Actual coverage analysis / budget template assessment (continued from page 1):

- The approved discounts have been used & documentation exists to support discounts greater than standard (e.g. email approval from KAH or RFS)
- Pharmacy and DCRU charges have been transcribed into budget as per documentation from respective service area; including per patient charges on the CA template and start-up charges on the "Invoiceables" tab
- CA contains line for drug or device and the appropriate charge for the item if UH must purchase. Validate the purchase terms (or provision as free) in the contract
- Assure that the proposed Sponsor payments are accurately reflected in the CA
- Assure that the "contracted charge rate" and "sponsor payment" totals are correctly summed at the bottom of the CA template and that 40% indirect line item is added to UH total

**Outstanding issues to be addressed in order to finalize CA/patient care budget approval:**

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When the CA/patient care budget is complete and approved, the RFS will complete the following:

- iRIS email notification that the CA is completed and approved (include the department contact & Pre-award contact on this email)
- Enter the date "CA completed" and checkbox in Wellspring
- If federally or internally funded trial, change status from "in process" to "executed" in Wellspring
- Update the "COVERAGE ANALYSIS tracking" spreadsheet in S:\CCRT\Research Patient Billing folder
- Sign and scan this document to the appropriate departmental CA folder in S:\Master Research\Research Billing