1. PURPOSE:

To standardize the UH Clinical Research Center's (UHCRC) process for research coverage analysis / clinical project budget development or approval.

2. SCOPE:

All research projects that involve clinical patient care and are conducted within the University Hospitals Health System, must follow stated policy requirements for coverage analysis (CA). Process variations to implementing CA and clinical budget development may occur dependent upon the situation. This SOP addresses all trials, excepting those trials administratively managed by the Seidman Cancer Center (SCC) Clinical Trials Unit (CTU).

3. RESPONSIBLE INDIVIDUALS: UHCRC Personnel; Departmental Research Personnel

4. DEFINITIONS:

CIRBI – Chesapeake IRB software for submission and routing of applications for human subject protection review.

Coverage Analysis (CA) – a uniform method of analyzing the items and services provided in a clinical trial to determine if that item or service can be appropriately billed to Medicare and other insurers. Such an analysis, when completed prior to study start and formally documented, can help provide a more accurate assessment of study costs for budgeting purposes; avoid submission of incorrect claims (protecting an institution from violations of the False Claims Act); identify non-covered study costs; and assist in the accurate coding of covered charges on billing claims.

iRIS – (integrated Research Information System) is a web-based application designed to process research studies for the Institutional Review Board (IRB). The IRB application and other research study documents are to be submitted, reviewed and stored electronically in iRIS™ in order to automate the IRB submission, review, and approval processes.

Local Coverage Determination (LCD) – specific payment decisions made by a regional Medicare Administrative Contractor (MAC) for their assigned states or a region of the country. Approval from the local MAC is required to bill for services related to the use of Category B devices.

Medicare Qualifying Status – the determination whether a clinical trial may have services covered (paid) by Medicare. To qualify, trials must evaluate an item or service that falls within a Medicare benefit category; must have a therapeutic intent; enroll patients with a diagnosed disease plus have seven desirable characteristics or meet deemed status. See National Coverage Determination (NCD) for Routine Costs in Clinical Trials, manual section number 310.1.

National Coverage Determination (NCD) – part of Center for Medicare and Medicaid Services Clinical Trial Policy; explains medical necessity, billing limitations and coding guidelines for services provided as part of a clinical trial. For approved clinical trials, defines the costs that Medicare will cover provided that the item or service is otherwise available to a Medicare beneficiary and specifies the claim format for billing such covered services.

The Sophia Knowledge Management System (Sophia) – Wellspring software product that is used by the UHCRC to manage the research contracting process. Allows assignment of a tracking number, housing of communication and documentation related to an agreement, and process metrics.

5. POLICY STATEMENT: Related to UH policies R-2, R-16, and R-39.

6. PROCEDURES:

1. In the event of multiple pending CA's, department submission to the IRB will trigger the Research Finance Specialist (RFS) prioritization of CA's / patient care budgets for clinical trials. The investigator and/or clinical department research staff will enter clinical trial application into iRIS or CIRBI.
    a. All the elements required for IRB submission are necessary in order for an application to be considered for IRB review.

2. IRB staff pre-review clinical trials submitted in the iRIS submission queue and an IRB coordinator is designated as being "assigned" to the project.

3. IRB Notification
    a. iRIS: for all applications indicated with a study type of "clinical" or "blood draw" the IRB coordinator will send email notification to ResearchFinance@UHhospitals.org (non-SCC trials) or CTUBusOps@UHhospitals.org (SCC trials).

    b. CIRBI: will send email notification for all new applications and amendments to ResearchFinance@UHhospitals.org (non-SCC trials) or CTUBusOps@UHhospitals.org (SCC trials).
    c. The RFS team will assess the ResearchFinance@UHhospitals.org inbox daily and distribute notifications to the team member assigned per department.
    d. Prior to departmental IRB submission, the RFS may also be notified of a new clinical trial directly from the department or from the Grants and Contracts Specialist (GCS) team.

i.

4. Upon notification, the RFS will add the clinical trial to the 'Coverage Analysis Tracking' spreadsheet located at S:\\Center for Clinical Research\Research Patient Billing.

5. The RFS & GCS will collaborate with the department in completing CA/budget development, negotiation, and contract execution.
    a. Industry sponsored clinical trials will be entered into Sophia by GCS and list themselves as the "First Agreement Manager" and the RFS as "Second Agreement Manager".
    b. Federally funded and internally funded clinical trials will be entered into Sophia by the RFS, listing themselves as "First Agreement Manager".
    c. All entries created as above will generate an automatic notification to the listed agreement managers.
    d. The GCS team will follow their standard process for contract review and negotiation.

6. The assigned RFS will email the clinical department contact identified in the IRB application to initiate dialogue regarding CA and patient care budget development.
    a. The assigned RFS will obtain the budget template and protocol (if not uploaded into IRB software) from either the clinical departmental or the GCS.
    b. The RFS will verify in the IRB application if Dahms Clinical Research Unit (DCRU) will be utilized. If so, DCRU Finance will be included in the budget discussions and associated correspondence.
    c. If the project is internally funded, an 'Internally Funded Research Project Request Form' will be provided to the clinical department contact.
        i. The clinical department contact will complete the 'Internally Funded Research Project Request Form' and obtain the necessary clinical departmental/division approvals and signatures before returning to their RFS.
        ii. The RFS will then complete the form by validating the balance in the identified account and obtain the clinical department finance director signature.

7. Working in conjunction with the departmental clinical team, the RFS will validate whether the project is a qualifying clinical trial.
    a. Documentation for qualifying status will occur on the "Qualifying Status" tab of the CA template.
    b. Per federal regulations, PI attestation of qualifying status is required.
    c. Clinical department personnel will obtain the PI signature on the "Qualifying Status" form.
    d. The RFS will save a .pdf signed copy or valid electronically signed forms in the department study specific CA folder in S:/Master Research/Research Billing.

8. For qualifying trials, the RFS will work with the clinical department to complete a CA and patient care budget which will include all of the required clinical care and billable items listed in the protocol.
    a. Personnel time calculations will be provided to the RFS by the department for input into the budget.
    b. The DCRU administrative team will provide any DCRU or coordinator core charges to the RFS for input into the budget.

c. CPT coding for "Patient care" charges will be identified by the RFS and current charge master pricing with approved research discounts will be applied.
d. Within the CA template, the RFS will document NCD, LCD or medical national standards that substantiate covered charges on the "Coverage Documentation" tab of the CA template.
e. The RFS will obtain PI (or designee) sign-off on the CA/budget final draft and save this approval in the in the department study specific CA folder in S:/Master Research/Research Billing.

9. For non-qualifying trials, the RFS will work with the clinical department and GCS to complete a patient care budget for negotiation with the Sponsor.

10. Once the CA/budget final draft has been approved, the RFS will notify the department contact, GCS, and document that the CA is complete via Study Correspondence in iRIS or by adding a note in CIRBI.
    a. The RFS will also enter this final draft completion date into the Coverage Analysis tracking spreadsheet and Sophia system:
        i. Update the "Coverage Analysis Complete" step in the 'Agreement Process' section of the agreement summary page:
            1. "Completed?" will be checked and the initial date of completion will be entered.
            2. The "End Date" will be populated as the date the CA & patient care budget is final / approved. This date may be overwritten / updated in the event of sponsor negotiations.
            3. The "Comments" section should list if the end date is an initial approval or result of renegotiation.
            4. List the CA fee to be invoiced.
    b. For federally or internally funded projects, the RFS will also enter all basic project detail for that project into Sophia, and update the "status" field from 'in process' to 'executed'.
    c. For industry funded projects that have not already been entered as in item 3a (E.g. industry projects from established sponsors, work orders, amendments), the CGS will complete entry of all additional project detail into the Sophia system.
    d. Documentation of a waiver of CA will also be documented in the IRB and Sophia systems, with comments to include that a CA is not needed & the rationale why.

11. The GCS will collaborate with the department and RFS as needed during negotiation of the contract budget, and payment terms.
    a. Once finalized, the GCS will generate a memo to the appropriate institutional official for sign-off of approval for the project.

12. Post Award communication
    a. Internally funded trials – upon IRB approval, the Grant Accountant will set-up a PTAEO account specific to the project once a completed 'Internally Funded Research Project Request Form', and an approved CA / clinical budget has been verified.
        i. The IRB will cc the RFS on the IRB approval letter.
        ii. The RFS will forward, via email, a copy of the completed & signed 'Internally Funded Research Project Request Form' to the assigned Grant Accountant.
        iii. The Grant Accountant will follow the award set-up procedure and upon set-up will send a 'Notice of Grant Award' to the RFS, DCRU and clinical departmental contact.
    b. Externally funded trials – upon IRB approval and contract execution, the GCS will send an email to the clinical department and the Grant Accounting team.
        i. The Grant Accountant will follow the award set-up procedure and upon set-up will send a 'Notice of Grant Award' to the RFS, DCRU and clinical departmental contact.
    c. Federally funded trials – the RFS will check for the project speed type from CWRU department administrators.
        i. Once the CWRU project speed type & a department N award is available, the RFS will create a new task to add the new speed type to the appropriate N award and enter the speed type number in the "description" field for the task. (Note: the grant award number will populate the "task name" field.)
        ii. RFS will add new information to "N Awards Res Pt Blg" spreadsheet located at path S:\\Center for Clinical Research\Research Patient Billing\N Award
        iii. If a department N award isn't set-up, the RFS will contact the Grant Accountant assigned to that department to request an award set-up.

13. Managing Amendments
    a. The department will notify their GCS when there is an amendment to existing clinical protocols.
    b. For amendments that include changes to clinical care, the department will also contact their RFS.
    c. The RFS will review the amendment and update the CA and clinical patient budget as needed, informing the GCS when complete.
        i. Coverage analysis updates will be completed in order of date of receipt of notification.
        ii. Data entry to the Sophia system will occur as above.

7. REFERENCES

National Coverage Determination for Routine Costs in Clinical Trials, section 310.1

Sophia Data Entry Standards document
CA Instructions document
UH Policies:
- R-2: Research Patient Billing
- R-16: Grants Accounting: Development of Clinical Trials Budgets
- R-39: Clinical Research Investigation
- R-41: Internally Funded Research Policy

8. FORMS OR ATTACHMENTS

a. Research Submission Process (Process Flow Chart)

APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– July 28, 2017
Approved by Kathy Hammerhofer, Director, Finance- July 26, 2017

RESEARCH FINANCE OFFICE COVERAGE ANALYSIS / PT CARE BUDGET REVIEW

Protocol Short Title:

IRB#: Wellspring#:

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

Protocol Short Title:

IRB#: Wellspring#:

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:

RESEARCH FINANCE OFFICE COVERAGE ANALYSIS / PT CARE BUDGET REVIEW

Protocol Short Title:

IRB#: Wellspring#:

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