Clinical Research Support Office

Clinical Research Support Office ("CRSO")
STANDARD OPERATING PROCEDURE

SOP NUMBER **CRB-SOP-5001**	**TITLE** **Research Billing Integrity Process including Coverage Analysis**
EFFECTIVE DATE 8/21/2024	**WRITTEN BY** **Adriana Jenkins, Director of Clinical Trial Administration and Billing Integrity**
APPROVAL Jessica Heskel Digitally signed by Jessica Heskel Date: 2024.08.21 16:23:15 -04'00' **SIGNATURE**	**DATE**

1. POLICY STATEMENT

The University of Kentucky ("UK") through the Clinical Research Support Office ("CRSO") conducts a formal review of all prospective clinical protocols/studies to ensure compliance with clinical research billing rules and regulations. The billing integrity process is inclusive of the Coverage Analysis (CA).

The research billing review process is required for all clinical research protocols involving human subjects. However, the CA (device, treatment and drug) is only applicable to qualifying studies that meet the clinical trial's criteria as set forth by the National Institutes of Health ("NIH"). Studies that meet the NIH's criteria of a clinical trial are henceforth referred to as "clinical trials." Clinical studies that do not meet these criteria are henceforth referred to as "clinical research."

The formal CA review is an itemized and systematic review of clinical trial documents to determine the qualifying status and the potential coverage by insurances or the study sponsor for items and services that will be performed during the study. The CA is based on the rules and regulations pertaining to Medicare coverage decisions in clinical trials.

The Centers for Medicare & Medicaid Services ("CMS") oversees the National Coverage Determinations ("NCDs") and the Local Coverage Determinations ("LCDs") and defines the coverage of Routine Costs in Clinical Trials. The national policy governing the fiscal coverage of clinical trials is documented under NCD 310.1.

The billing review follows the same rules as the CA which also includes the review of national clinical guidelines for all specialties to determine conventional care/routine care such as UpToDate®, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and Lexicomp. The goal of the billing review and the CA is to provide a tool (billing grid) that facilitates compliant clinical research budgeting and billing by identifying the financial responsible party for study-related items and services.

2. PURPOSE

The purpose of this policy is to outline the UK research billing process for clinical trials and clinical research providing patient care services at UK Health care facilities or by its personnel.

CONSIDERATIONS

All UK clinical trials are required to utilize the Clinical Trial Management System ("CTMS"). All other clinical research studies are required to be managed in the CTMS only if they contain patient services rendered at any UK Health Care facility or by UK Health Care providers. However, all studies/protocols managed by the Markey Cancer Center have a separate guideline that can be more restrictive or extensive for OnCore inclusion. Protocol builds and data entry in the CTMS for clinical research that does not contain billable activity is available at a study team's request for subject management and/or tracking/budgeting purposes.

The CRSO will only process studies that have been funded and are soon to be submitted to the IRB for review or already have been submitted to the IRB, and it does not perform pre-coverage analysis or billing reviews for early stage projects.

3. SCOPE

This policy is applicable to all UK clinical research studies with UKHC billing activity and to all clinical trials that meet the NIH definition of a clinical trial.

4. RESPONSIBILITIES

Principal Investigator or designee

- Prepare and submit all documentation including but not limited to the protocol, IRB submission, informed consent (ICF), investigator's brochure, draft budget, clinical trial agreement, funding sheet, investigational drug approval/exemption (IND), FDA device approval/ exemption (IDE, 510k, PMA), CMS letter of approval for devices and the CGS notification for devices – as applicable;
- Notify CRSO proactively when the status of the study has changed (i.e., IRB not approved, substantial changes in the protocol while performing the CA, and hold status) as soon as it is known;
- Ensure that there is clear and consistent language in the approved protocol, ICF, clinical trial agreement, budget or funding memo, regarding research related services and patient services (routine costs);
- Ensure through clear documentation that study participants will be informed of the procedures and services occurring at each visit, which procedures and services will be covered by the research study and under what circumstances the participant and/or their insurer may have a potential financial obligation;
- Provide timely information about study personnel, including finance staff who may be able to resolve billing questions, to the CRSO, obtain an account prior

opening the study to accrual, and to comply with the UK Health Care policy A07-150 Clinical Research Charging and Billing;
- If applicable, include clear information about where all study procedures will take place (i.e. CCTS outpatient or UK Health Care space);
- Once the billing review has been finalized, ensure that first tier billing review is conducted throughout the study's duration in a timely manner and observe data management according to CTM-SOP-2001 V4 Subject Data Lifecycle Management;
- Continues to notify CRSO for any changes to the protocol/amendments for review until IRB closure.

CRSO Clinical Trials Administrative Services and Billing Integrity Team (CTASBI):
- Triage and review the documents submitted to determine if the study needs inclusion in the CTMS
- Identify the required initial data entry in the CTMS system (excluding oncology), following the CTMS guidance on data inclusion;
- Create a comprehensive calendar detailing all services and procedures to be rendered in accordance with the protocol and other study documents;
- Communicate with the study teams to gather additional information to complete the billing grid;
- Consult the national specialty guidelines including UK conventional care guidelines (UpToDate® and Lexicomp), NCDs, LCDs, claims processing and manuals issued by CMS related to the provision of health care services and other nationally recognized resources as applicable;
- Develop an initial billing grid with detailed justifications on the CTMS for all studies regardless of funding source, identify items and services considered routine costs by CMS, and items and services that must be covered by research;
- Provide clarification as needed and timely resolve issues so that the study teams can proceed with the next steps in the process;
- Once approved by the study team (PI or designee), complete the billing grid in the CTMS (if changes were needed), and perform the system required sign off;
- Prepare the official response to the study team in a timely manner to ensure they can proceed with the next steps in the process;
- Escalate to the CRSO Executive Director any potential financial and non-compliance risks uncovered during the billing review process that cannot be solved or addressed without escalation;
- Maintain all the communication and documents in the CRSO folders for future reference;
- Monitor upcoming PI separations for roles that any impact in Epic billing and the compliance billing requirements for the PI under the CMS guidance. Verify study teams know of the departure and remind them to add replacement(s) to OnCore;

- Identify unsegregated first tier charges in Epic HB and PB reports that are at least 3 days old. Remind/assist study teams to prevent delinquent study accounts;

5. PROCEDURES

Coverage Analysis/Billing Review:

1. The following documents are required (as applicable) to initiate a billing review:
    a. Final protocol (not the IRB submission) to be submitted to IRB for approval (study must be funded)
    b. Informed Consent
    c. Clinical Trial Agreement
    d. Draft budget or funding memo
    e. FDA IND approval
    f. FDA IDE/510k/PMA approval*
    g. CMS IDE approval*
    h. CGS notification for devices only (the billing grid/CA may be completed but the study cannot be active in Epic for billing unless the CGS approval has been obtained)

*Regardless of IDE promise to pay by sponsor, all IDE studies must have CMS and local contractor approval (CGS) in order for a clinical trial to meet qualifying status. However, if a sponsor does not want the CMS/Medicare coverage, they can opt out from obtaining the approval and conduct the study as non-qualifying by covering all of the items and services delineated on the protocol.

Note: Per CMS Medicare claims for routine care items and services related to Category A or B IDE studies and Category B IDE devices should be submitted to MACs (CGS) that will identify routine costs for which Medicare payment is made for each related claim. CGS Administrators, LLC (CGS) is the Local Medicare Administrative Contractor (MAC) for Kentucky.

2. The analyst identifies and documents whether a study is clinical research or a clinical trial and if so, the analyst will determine if the clinical trial is qualifying
3. The analyst thoroughly reviews the final protocol, ICF and other documents and ensures:
    a. That the documents are consistent, including the place of service, frequency and providers;
    b. That the ICF does not promise financial payments not supported by the protocol;
    c. That the ICF offers payment of items promised by sponsors in the protocol;
    d. That the IRB submission, when available, is accurate and includes patient care services;
    e. That the protocol language aligns with all other documents.

4. The analyst determines and documents billing designations for all procedures and services documented in the protocol. Billing designations for protocol related items/services may either be:
    a. Routine Costs that may be billed to a study participant and/or their insurer(s); or
    b. Study Costs for items/services that are primarily required for research purposes that should be paid for by research funding including time and effort.
5. The analyst contacts the study teams once the billing grid is in draft form for review and approval. A meeting will be recommended for new teams and those that may need additional clarification before the billing grid is finalized. For experienced study teams, billing grids will be sent for approval via e-mail, and the PI/study team designee will have 5 business days to respond with questions or change requests. If no response is received after 5 business days, the billing grid will be finalized.
6. The CRSO has 15 calendar days from the initial submission to present a draft grid and to resolve issues as applicable to finalize the billing grid in the CTMS.
7. After the study team has approved the billing grid, the analyst will send a notification with the grid and formal letter of notification attached to assist with the budget development. The analyst will also upload these documents to the CTMS system, and will perform the CTMS sign off.

Amendments:

1. The following documents are required (as applicable) for amendment review:
    a. Redlined study protocol
    b. Redlined informed consent form
    c. Any other relevant documents
2. The analyst reviews the amended documents to determine whether there are changes that necessitate updating the calendar or coverage analysis and updates billing designations or justifications accordingly.
3. The analyst prepares a new draft billing grid and communicates any changes with the study team.
4. Once the new billing grid is approved, the analyst will send a notification with the final billing grid and a formal letter of notification. The analyst will also upload these documents to the CTMS system and will perform the CTMS sign off.

6. <u>ESCALATION PROCESS AND PROBLEM RESOLUTION FOR CA/BILLING REVIEW ISSUES:</u>

The escalation process should be utilized when the PI disagrees with the billing designations that indicate that no patient/insurance coverage is recommended.

First step for additional review:

a. The study team must reach out to the CRSO Executive Director and Faculty Director with the petition for escalation.

b. The CTASBI director will provide a statement to the CRSO Executive Director summarizing the billing justification, the risks for the patient, and the risks for the institution.
c. The CRSO Faculty Director will assemble a review panel that includes a representative for the department, UK Health Care revenue and Compliance teams and other faculty and staff members to discuss the issues and the impact.
d. The PI will be given the opportunity to provide additional information that will support insurance coverage, to this panel.
e. Once the panel has discussed the information available, it will issue a formal notification to either change or maintain the designations.

7. REFERENCES

UK Health Care A07-150 Clinical Research Charging and Billing
UK Clinical Research Subject Management Guidelines
CTM-SOP-2001 Subject Data Lifecycle Management