A07

| TITLE<br>Clinical Research Billing Integrity Policy | | | IDENTIFICATION NUMBER<br>A07-150 |
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| ORGANIZATION(S)<br>University of Kentucky / UK HealthCare | SITES AFFECTED<br>X Enterprise<br>☐ Chandler<br>☐ Good Samaritan<br>☐ KCH<br>☐ Ambulatory | CATEGORY<br>X Enterprise<br>☐ Nursing<br>☐ Department<br>☐ Guideline<br>☐ Protocol | REPLACES:<br>A07-055, A07-060 |
| REVIEW CYCLE ☐ 1 year X 3 years<br>REVIEW DATES: 8/1/2022 | | EFFECTIVE DATE: 10/15/2022 | |

## POLICY STATEMENT

UK HealthCare complies with all applicable federal and state laws, rules, and regulations, as well as patient safety considerations, in the use and conduct of clinical research involving human subjects. The performance of clinical research with UK HealthCare patients require coordination among all University of Kentucky (UK) colleges and departments and UK HealthCare (UKHC) departments participating in and/or impacted by clinical research programs.

UKHC policies and procedures for patient management, including registration, medical documentation, and patient care billing, requires that all patients and charges for all services rendered are documented in the UKHC electronic health record (EHR). Clinical researchers within the university who require services from UKHC are subject to this policy and compliance with the EHR system processes and workflows.

All clinical research trials involving human subjects adhere to this policy, and must be approved by the UK Institutional Review Board (IRB) and/or central IRB of record prior to initiation. In order for research teams to utilize the UKHC EHR to enroll, order and render patient care services they must follow UK processes to ensure compliance with regulations and internal compliance policies, including the UK Clinical Research Support Office (CRSO) billing integrity review and utilization of the UK Clinical Trial Management System (CTMS).

## PURPOSE

To provide standards for ensuring compliance with federal and state guidance and best practices with billing integrity in clinical research by ensuring that all clinical research trials that require patient care services at UKHC undergo a billing integrity review, including determination of qualifying status, and coverage analysis (CA) process as applicable. Additionally, ensures that all costs associated with the clinical research are billed accurately and in a timely manner to the appropriate payor whether it is the research account cost object, a third-party payor, or the patient.

## SCOPE

This policy is applicable to all UK human subject clinical research trials that receive patient care services from the UK HealthCare system, including hospital services and/or professional services.

## PROCEDURES

### *Billing Integrity Review Process Including the Coverage Analysis*

UKHC requires that all clinical research studies involving the provision of clinical procedures and services at UKHC or by UKHC personnel, must undergo a billing integrity review and to obtain a CA as

applicable. The billing integrity review is conducted by the Clinical Trials Administrative Support and Billing Integrity team (CTASBI) within the CRSO as documented in the CRSO standard operating procedure CRB-SOP-5001.

The billing integrity review includes: the determination of qualifying status, the coverage analysis (CA), and the billing calendar for those that do not meet the CA criteria for coverage, The CTASBI team analyzes financial responsibility as a predictive model that indicates if coverage by third-party payors is likely to occur. Likewise, the CTASBI team will determine the initial financial risk as a tool for principal investigators researchers to negotiate budgets and appropriately coordinate coverage. Any clinical research involving human subjects as defined by the National Institutes of Health ("NIH") that needs to follow the Institutional Review Board ("IRB") process will be subject to a CA.

The formal CA is a systematic review of clinical trial documents to determine the billing designation for those 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.

All investigational device trials must follow the CMS and the U.S. Food and Drug Association (FDA) requirements and may require additional approvals from the UK HealthCare Technology Assessment Committee. Any devices that are part of a qualifying clinical trial, must meet the criteria and receive notification response from the regional Medicare Administrative Contractor for Kentucky (CGS), and CMS as applicable.

Clinical research studies involving investigational drugs and/or FDA-approved drugs for non-approved indications may also be subject to the UKHC Policy on Drug Research A14-020.

Documentation of the billing integrity review, the CA and study data, including National Clinical Trial Identifier (NCT Identifier) from clinicaltrials.gov, study team information, certain study protocol details, and certain study participant data is located in the UK Clinical Trial Management System (CTMS) and is supported by the CRSO and UKHC IT.

Modification of the study protocol, informed consent form, clinical trial agreement, and/or budget must be submitted to the CRSO for review and any necessary amendments to the CA, study calendar and/or other data in the CTMS.

*Two-Tier Research Billing Review Process*

All hospital and professional charges generated by a patient during active participation in a research study with UKHC billable services require Two-Tier Research Billing Review in the UKHC electronic health record platform (EHR), including a review of all standard/routine care and research related charges prior to the submission of a claim.

To ensure that all charges are properly segregated to be allocated to a research study account or to a third-party payor and that the payor is correctly billed in a timely manner, it is necessary that all patient care charges are reviewed in the EHR daily. The Two-Tier Research Billing Review process is carried out as follows:

**First Tier:** responsibility of the Principal Investigator (may be delegated to designated study team members) and performed by the clinical research coordinator or other designated study team personnel within the applicable/responsible department and must be conducted within 5 calendar days after posted on the EHR dashboard reporting.

**Second Tier:** responsibility of UKHC and performed by the UKHC Patient Financial Services (PFS) team members and must be conducted within the standard set forth in the UKHC claims processing manual following the first-tier review.

Once all charges have been reviewed and any required corrections made via the Two-Tier Billing Review process, the account in the EHR will be marked as reviewed to ensure that all applicable charges are released in a timely manner and billed compliantly.

*First-Tier Research Billing Review Central Monitoring Process*

The CRSO is responsible for centrally monitoring the First-Tier Research Billing Review process. The Clinical Trials Administrative Support and Billing Integrity team (CTASBI) within the CRSO will monitor select work queues generated by Epic via the billing dashboard. The billing dashboard including the individual charges, as well as calculation of the aging report of charges, will be monitored daily. The CTASBI team will notify study teams of any pending or delinquent first-tier reviews.

The CTASBI team will send a daily reminder and offer to assist the study team with questions regarding the first-tier review. If first-tier review is not performed by the study team or no response is received from the study team after 5 calendar days, a notification is sent to the Principal Investigator (PI).

After the PI is notified, and if the CTASBI team has not received a response within the same day, the CTASBI team will notify UKHC PFS Specialty Billing Leadership that the account has surpassed the allotted time for processing, or will communicate the reason for the delay (i.e., access issues or technical difficulties).

If the review or release of charges is not processed following the second notification, a third notification will be sent at 7 calendar days to also include the department administrator.

If the review or release of charges is not processed following the third notification, a fourth notification will be sent at 10 calendar days to also include the department chair, UKHC Revenue Cycle leadership, and the Office of Corporate Compliance.

*First-Tier Research Billing Review Escalation Hierarchy Grid*

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| **First** | 3 calendar days after the charges are posted to the queue | study team (i.e., clinical research coordinator and/or research financial manager) |
| **Second** | 5 calendar days after the charges are posted to the queue | study team (i.e., clinical research coordinator and/or research financial manager), PI, and UKHC PFS Specialty leadership |
| **Third** | 7 calendar days after charges are posted to the queue | study team, PI, department administrator; UKHC PFS Specialty leadership |
| **Fourth** | 10 calendar days after charges are posted to the queue | study team, PI, department administrator, department chair; Corporate Compliance; UKHC Revenue Cycle leadership |

## REFERENCES

Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) Routine Costs in Clinical Trials NCD 310.1.

University of Kentucky Clinical Research Support Office Coverage Analysis Standard Operating Procedure CRB-SOP-5001.

UK HealthCare Policy on Drug Research A14-020.

UK Office of Research Integrity, Institutional Review Board (IRB)

## APPROVAL

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| **NAME AND CREDENTIALS:**<br>Paula White<br><br>**TITLE:**<br>Chief Revenue Officer | **NAME AND CREDENTIALS:**<br>Anne Wray<br><br>**TITLE:**<br>Compliance Operations Officer |
| **SIGNATURE** | **DATE** |
| **SIGNATURE** | **DATE** |