TITLE Clinical Research Charging and Billing			**IDENTIFICATION NUMBER** A07-150
ORGANIZATION(S) University of Kentucky / UK HealthCare	**SITES AFFECTED** ☒ Enterprise ☐ Chandler ☐ Good Samaritan ☐ KCH ☐ Ambulatory	**CATEGORY** ☒ Enterprise ☐ Nursing ☐ Department ☐ Guideline ☐ Protocol	**REPLACES:** A07-055, A07-060
REVIEW CYCLE ☐ 1 year ☒ 3 years **REVIEW DATES:** 8/1/2022; 1/15/2024		**EFFECTIVE DATE:** 2/15/2024	

POLICY STATEMENT

UK HealthCare (UKHC) adheres to 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. All clinical research trials involving human subjects conducted at any UKHC facility or by its personnel, must comply with the institutional requirements set forth by the University of Kentucky (UK), including Institutional Review Board (IRB) processes, training, financial management and other fiscal and ethical considerations.

UKHC policies and procedures for patient management, including but not limited to registration, medical record documentation, and billing, require that all patients and charges for all services rendered are documented in the UKHC electronic health record (EHR).

The process of ensuring clinical research patient care expenses are charged and billed appropriately involves a coordinated effort among the Principal Investigator (PI), research study team members, department administrators, the Office of Sponsored Projects Administration (OSPA), Research Financial Services (RFS), the Clinical Research Support Office (CRSO), and UKHC teams. All clinical items or services must be: 1) billed in accordance with all applicable federal, state, and third-party payor regulations; 2) billed in accordance with the grant or contract funding guidelines; 3) consistent with all research study related material including research informed consent; and 4) in compliance with all applicable UKHC institutional policies and procedures.

PURPOSE

To provide standards that ensure compliance with federal and state rules and regulations, as well as national best practices with billing integrity in clinical research. This includes ensuring that all costs associated with the clinical services associated with 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 clinical research studies involving human subjects that utilize UKHC, including the use of any UKHC facilities, equipment, hospital and/or professional services rendered by UKHC clinicians. Any researchers or research study personnel within UK who require services from UKHC are subject to this policy and compliance with all EHR system processes and workflows.

DEFINITIONS

Clinical Trials Management System (CTMS): UK's CTMS is the central repository and source of truth for clinical research study data including but not limited to research participant/patient data and demographics, research billing integrity review, coverage analysis, National Clinical Trial Identifier (NCT#), study team members, certain research protocol documentation, informed consent form template. The CTMS is supported by the CRSO and UKHC IT.

Electronic Health Record (EHR): UKHC's electronic health/medical record system.

Human Subject Research: According to 45 CFR 46, a human subject is a living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Institutional Review Board (IRB): The UK IRB is responsible for the protection of human subjects. All human subjects research, funded and unfunded, must be reviewed according to the UK Office of Research Integrity policies and processes.

National Clinical Trial Identifier (NCT#): a unique number assigned by the National Library of Medicine (NLM) when the study is registered in the NLM Clinical Trials database at clinicaltrials.gov. The format is the letters "NCT" followed by an 8-digit number (for example, NCT00000999). Required by CMS on certain claims for tracking and identification purposes.

National Coverage Determination (NCD): Nationwide determination by the Centers for Medicare and Medicaid Services (CMS) of whether original Medicare will pay for an item or service. Medicare coverage is limited to items and services that are considered "reasonable and necessary" for the diagnosis or treatment of an illness or injury and are within the scope of a Medicare benefit category.

Research services: services provided to a participant in a clinical trial that are performed for research purposes and are billed to and paid for by the study (regardless of funding source).

Routine cost or conventional care services: services that are provided to an individual for a diagnosed disease regardless of whether he or she is participating in a clinical research trial.

OPERATIONAL RESPONSIBILITIES

It is the responsibility of the PI to ensure that the clinical research billing of his or her studies is compliant with all laws and regulations and adheres to UK and UKHC policies. The PI, his or her study team members, department administrators, the CRSO, OSPA, RFS, and UKHC teams must work together to ensure the components of compliant billing are in place (refer also to PROCEDURES).

- The CRSO must review all clinical research study submissions to identify studies that include clinical patient care to evaluate for potential billing risk.
- The CRSO must ensure all coverage analyses are recorded and uploaded in the CTMS and that all applicable clinical research studies with UKHC billable services are entered into the EHR, supported by UKHC IT.
- The PI and study team members must comply with the research billing integrity reviews outlined by the CRSO Standard Operating Procedures (SOP's).
- The PI and study team members must ensure that the services for human subjects enrolled to qualifying clinical research protocols are billed in accordance with the coverage analysis

(or the billing grid for those that are not qualifying per CMS definitions or Non-NIH defined protocols), and that the bills are based on actual services rendered and consistent with the IRB-approved protocol documents.

- The PI and study team members must ensure that research study patients are linked/associated to the appropriate clinical research study within the EHR.
- The PI and study team members must ensure, where necessary, that research visits/encounters are linked/associated to the clinical research study within the EHR.
- After clinical items or services are provided, PI and study team members must ensure that applicable research patient and research protocol required visit data is entered into the CTMS, the source of truth for clinical research study data and certain clinical research study participant data.
- After visit/encounter charges are entered into the EHR, the PI or designated study team members must review all items or services and corresponding charges to ensure proper information is present. Each department/clinic and enterprise revenue cycle team must follow all applicable documentation, coding, charging, and billing procedures to ensure that clinical research billing is conducted appropriately and accurately.
- The PI and/or delegated study team members must conduct periodic reconciliation of clinical research charges billed, per UK policies. Through the review and reconciliation period, if any discrepancies are noted, the PI and/or study team members must report promptly to support timely review and response. If any corrections are necessary, these must be properly documented and performed per UK and UKHC policies and procedures.

PROCEDURES

Research Billing Integrity Review Procedure (Including Coverage Analysis)

UK and UKHC require that all clinical research studies involving the provision of clinical procedures and services at UKHC facilities or by UKHC personnel, must undergo a billing integrity review and obtain a coverage analysis (CA) as applicable. The billing integrity review is conducted by the CRSO as documented in the CRSO standard operating procedure CRB-SOP-5001. Research billing integrity review documentation is located in the CTMS, which is supported by the CRSO and UKHC IT.

The billing integrity review includes the determination of qualifying status, the coverage analysis (CA), and the billing calendar/grid. The CRSO analyzes financial responsibility as a predictive model that indicates if coverage by third-party payors is likely to occur. Likewise, the CRSO team will determine the initial financial risk as a tool for PI/study team members 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") processes will be subject to a billing integrity review (including CA as applicable).

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 research study. The CA is based on the rules and regulations pertaining to Medicare coverage decisions in clinical trials. CMS oversees the NCDs and the Local Coverage Determinations (LCDs) and defines the coverage of routine costs in clinical research trials.

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.

Drugs, Biologicals, and Devices Procedures

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

All investigational device trials must follow the CMS and the U.S. Food and Drug Association (FDA) requirements and may require additional review and/or approvals from UKHC device review committee(s), including the Value Analysis team. Any investigational devices that are part of a qualifying trial, must meet the criteria and receive notification response from the regional Medicare Administrative Contractor for Kentucky, and CMS as applicable.

Registration, Documentation, Coding, and Billing Procedures

Research study enrollment is the responsibility of the PI/study team. Clinical research study data and patient demographic information is entered by PI/study team member in the CTMS and, where appropriate, linked to the corresponding research study record in the EHR. Patient visits/encounters may occur in the inpatient or outpatient setting at any UKHC facility and with any UKHC clinician.

UKHC patient access representatives are responsible for scheduling and arriving/registering UKHC visits/encounters in the EHR at all UKHC facilities. When clinical care items or services are provided, and documented in the EHR, the items or services will be coded and charges will be generated.

The UKHC charge description master (CDM) is maintained by UKHC and shared periodically with study team members. Based on the CA, charges for certain items or services may be performed for research purposes only and will be billed to the research study (see the Two-Tier Research Billing Review Procedure).

Following charge segregation, UKHC Enterprise Revenue Cycle (ERC) is responsible for submitting claims and performing collections for routine and conventional patient services to the proper third-party payor or patient. Billing for research services for hospital and professional services is initiated by UKHC ERC based on a research study being associated with the visit/encounter, including applicable discounted rates. Research discounts for hospital and professional services are reviewed periodically and approved by the UKHC Pricing Committee.

Billing for all hospital and professional items or services to the associated research study occurs via internal automated process of journal voucher (JV) transactions from the EHR to UK's accounting system. The automated JV process correspondingly applies transactions from the research study cost object to the designated hospital ledger account.

Hospital and professional services billed as research responsibility shall be available for the PI and applicable study team member, including summary and line item details for each research study.

ERC shall receive notification from the PI/study team member no less than 30 calendar days before the closure of a cost object (i.e., WBS element or cost center assigned in UK's accounting system) associated with a research record in the EHR to verify that any outstanding hospital and/or professional billing for patient care items or services has been resolved.

Two-Tier Research Billing Review Procedures

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 EHR, including a review of all standard/routine care and research related charges prior to the submission of a claim.

Note: Certain de-identified/blinded lab services may be excepted from this procedure and may follow procedures related to institutional accounts with client billing, subject to prior documented research billing integrity review. See also UKHC Policy A07-080.

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 services and 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 and may be delegated to designated study team members within the applicable/responsible department and must be performed within 5 calendar days after posted on the EHR dashboard reporting.

Second Tier: responsibility of UKHC and performed by the UKHC ERC Patient Financial Services (PFS) team members and must be conducted within the standard set forth in any and all applicable procedures following the first-tier review.

Once any required segregation corrections have been made and all charges have been marked as reviewed, the account in the EHR will be released in a timely manner and billed compliantly.

First-Tier Research Billing Review Central Monitoring Procedure
The CRSO is responsible for centrally monitoring the First-Tier Research Billing Review process. The CRSO will monitor daily select work queues generated by the EHR via the billing dashboard and reports. The CRSO will notify study teams of any pending or delinquent first-tier reviews.

First-Tier Research Billing Review Escalation Hierarchy Grid

Reminder	Timeline	Recipients
First	3 calendar days from initial charge posting to the queue	study team (i.e., clinical research coordinator and/or research financial manager)
Second	5 calendar days from initial charge posting to the queue	study team, PI, and UKHC Enterprise Specialty Billing leadership
Third	7 calendar days from initial charge posting to the queue	study team, PI, department administrator; UKHC Enterprise Specialty Billing leadership
Fourth	10 calendar days from initial charge posting to the queue	study team, PI, department administrator, department chair; UKHC Enterprise Revenue Cycle (ERC) leadership
Fifth	14 calendar days from initial charge posting to the queue	study team, PI, department chair, UKHC ERC leadership, UKHC CFO, UKHC COO
Sixth	30 calendar days from initial charge posting to the queue	study team, PI, department chair, UKHC ERC leadership, UKHC CFO, UKHC COO, UKHC EVPHA

REFERENCES

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) Routine Costs in Clinical Trials NCD 310.1
- Uniform Guidance 2 CFR Part 200
- False Claims Act: 31 USC § 3729
- Investigational New Drug Application 21 CFR Part 312

- Investigational Device Exemptions 21 CFR Part 812
- UK Administrative Regulations:
    - AR 7:3 Policies and Procedures for Soliciting, Receiving, Recording, and Administering Grants and Contracts for Sponsored Projects
    - AR 7:4 Human Research Protection and Institutional Review Boards
- UK Business Procedural Manual:
    - E-13 Fiscal Roles and Responsibilities
    - E-17-6 Reconciliation and Review of Financial Transactions
    - E-1-4 Internal Controls
- UK Office of Research Integrity, Institutional Review Board (IRB)
- UK HealthCare Policies:
    - A06-000 Consent to Treatment
    - A14-020 Drug Research
    - A07-080 Charges for Services Not Billable to Patients
    - A05-045 Medical Record Documentation and Completion
    - Corporate Compliance Policy Manual
- UK CRSO Standard Operating Procedures Coverage Analysis CRB-SOP-5001

APPROVAL

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