Hartford HealthCare	**Subject:** **HARTFORD HOSPITAL POLICY ON:** **Clinical Research Billing**	
Policy Level: **Policy Number:**	**Original Date:** November 1, 2013 **Revision Date(s)**	**Approved By:** Lenworth Jacobs, M.D. VP, Academic Affairs & Chief Academic Officer

Purpose:

To ensure all clinical items and services provided during the course of a research project are billed to the appropriate individual, third party payer or sponsor in accordance with applicable contracts, and regulatory and institutional requirements.

Scope:

This policy applies to all research projects involving human subjects that may generate claims to an individual or third party payer for any items or services designated as part of a research project administered by Hartford Hospital (HH).

Policy:

All clinical items, services or procedures billed to research sponsors, individuals, and/or Medicare, Medicaid, or other third party payers must be:

1. Consistent with applicable federal and state billing rules of the third party payers.
2. In accordance with any grant provisions or contractual obligations.
3. Supported by all project related documents, including the protocol, grant/contract budget, Medicare Coverage Analysis (MCA) and informed consent form.

3. If a patient is involved in a research project, Medicare requires the following information be recorded in the beneficiary's medical record:

    - Trial Name
    - Sponsor's Name
    - Sponsor Assigned Protocol Number

    To ensure compliance with this requirement, Research staff must place a copy of the participant's informed consent form in the medical record at the time of enrollment, regardless of payer. If applicable, re-consents must also be placed in the participant's medical record.

4. Each visit associated with a research project must be clearly identified as such within the medical record by completing the electronic Research Study Notification document.

5. HIM coders will utilize the document to identify a patient participating in a research project and apply appropriate diagnosis codes to his/her claim.

6. Patients enrolled in a research project with clinical charges resulting in an individual or third party claim will be tracked, reviewed and billed within relevant systems in accordance with Patient Financial Services Policy 2.2 - *Research Studies/Grant Billing Policy and Procedures.*

7. Grants and Contracts will audit research account activity by conducting post - claim submission reviews of clinical charges resulting from a research project for compliance with the sponsor agreement.

Definitions:

Investigator - the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Medicare Coverage Analysis (MCA) - a systematic review tool of protocol-related documents (protocol, contract, budget, informed consent form) to determine if all the patient care costs in a project are covered by the sponsor, other funding sources, or qualify for reimbursement by third party payers.

Qualifying Clinical Trial - clinical research under which Medicare permits billing for routine costs of trial when the involved items and services are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision.)

Responsibilities:

Investigator

1. Accountability for compliance with laws, regulations and applicable HH policies pertaining to the identification and billing of clinical research related charges resides with the Investigator conducting the research project. This includes the identification and delineation of research specific charges and standard of care costs for each project before submission to the Institutional Review Board (IRB) for approval.

Research Institute - Clinical Research Center (CRC)

1. Assist Investigators with negotiation and development of research project budgets, including feasibility analysis, and preparation of MCA.
2. Monitor and track participant enrollment.
3. Assist Investigators with the review of participant claims for adherence with sponsor agreements and Medicare or other third party payer rules prior to billing.

Research Institute - Grants and Contracts

Monitor research project financial activities, including clinical services and items, for compliance with sponsor agreements.

Health Information Management (HIM)

Application of appropriate diagnosis codes to participant claims based on supporting documentation in relevant information systems.

Procedures:

1. For each research project which may result in a claim to an individual or third party payer, a Medicare Coverage Analysis (MCA) must be completed to determine if it is a qualifying clinical trial under Medicare rules, document clinical events and identify responsible payers.

2. As part of the research project application process, Investigators conducting research projects that include clinical items and services must complete and return a MCA and a budget to Grants and Contracts. The MCA is used to help determine if the project is considered a qualifying clinical trial according to Medicare and other third party payer billing rules. The budget identifies all clinical items, services, drugs, devices, treatments and tests that are considered part of the research project and delineates those that are standard of care versus sponsor provided.

Sponsor – an entity, such as a pharmaceutical or device company, private organization, academic institution, or government agency that initiates, manages, or finances a research project conducted at HH.

Related Policies:

Finance - Funds, Establishment, Maintenance and Disbursements Policy

Patient Financial Services Policy 2.2 - Research Studies/Grant Billing Policy and Procedures

Research Account Management Policy