 JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTH SYSTEM	The Johns Hopkins Health System Policy & Procedure	<i>Policy Number</i> FIN132
	<i>Subject</i>	<i>Effective Date</i> 10/1/08
	CLINICAL RESEARCH PROSPECTIVE REIMBURSEMENT ANALYSIS	<i>Page</i> 1 of 2
		<i>Supersedes</i>

POLICY

This policy applies to The Johns Hopkins Health System Corporation (JHHS) and the following affiliated entities: The Johns Hopkins Hospital (JHH), Johns Hopkins Bayview Medical Center, Inc. (JHBMC), Johns Hopkins Community Physicians (JHCP) and Howard County General Hospital (HCGH).

Purpose

The Prospective Reimbursement Analysis (PRA) is a systematic review that identifies what patient care services are to be billed as standard of care vs. research in regards to clinical research studies. This document defines what a PRA is, its creation, its use, and describes the process in which differences regarding coverage determinations are resolved.

Policy and Process – Prospective Reimbursement Analysis


In response to the Centers for Medicare and Medicaid Services (CMS) September 2000 Clinical Research Policy National Coverage Decision (NCD), Johns Hopkins Medicine has determined that effective July 1, 2008, all new clinical research protocols are required to have a completed Prospective Reimbursement Analysis (PRA). The PRA is a systematic review of the protocol, consent form, budget and contract (if applicable) to ensure that these documents are consistent and provide appropriate support and justification for the billing of hospital and professional fee patient care services. The PRA is a comprehensive analysis to identify standard of care and research patient care services and incorporates Medicare coverage principles.

A Clinical Research Coverage Analyst from the Office of Research Administration - Clinical Research Support Services will perform a PRA on all new protocols submitted to the IRB to document and support standard of care vs. research patient care services and costs. Study goals and payment structure will also be reviewed. A Draft PRA will be submitted for the Principal Investigator's (PI) approval.

A Clinical Research Analyst may attend a "start up" meeting with research staff to review the Draft Prospective Reimbursement Analysis and budget. The Clinical Research Analyst will continue to follow the trial through the IRB and ORA (if applicable) process and will be available to assist research staff with any clinical research patient care billing concerns prior to the start of the study, or budgeting issues and amendments related to the study budget at the start and throughout the life of the study. The IRB will not approve a study without a completed PI approved draft PRA uploaded in the eIRB. The PRA will be finalized upon IRB approval and Contract execution (if applicable). If changes to the protocol were made during this process, the PI must approve the revised PRA before it is marked as the Final PRA.

A department may request assistance in protocol planning or budget development at any time during the process. The ORA Clinical Research Support Services office will also negotiate budgets with commercial sponsors for departments upon request.

Every effort will be made to ensure adequate reimbursement for patient care services through a reasonable, thoughtful and comprehensive process. Clinical Research Support Services will research and confirm all standard of care resources suggested by the PI or department chair/designee in making the final decision regarding clinical standards of care. If necessary, the PI may be asked to supply justification based on his/her own or divisional/departmental clinical practice. If any differences remain unresolved, the PI and CRSS will work to reach consensus.

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A difference of opinion regarding Medicare coverage determinations will be addressed with the PI. Every effort will be made to ensure adequate reimbursement for services including direct communication with the local or national Medicare Program. All such communication must be coordinated through the Johns Hopkins Health System's Compliance Office and/or the Johns Hopkins University's Clinical Practice Association's Office of Billing and Quality Assurance. The final determination of whether services will be billed to federal payers will be made by the Johns Hopkins Health System's Compliance Office and the Johns Hopkins University's Clinical Practice Association's Office of Billing and Quality Assurance.

REFERENCE

This policy can also be found on the Office of Research Administration website at <http://www.hopkinsmedicine.org/Research/ora/>

RESPONSIBILITIES

SPONSOR

Deputy Chief Compliance Officer and Director of Billing Compliance (JHHS)

REVIEW CYCLE

Three (3) years

APPROVAL


 Vice President of Finance/CFO and Treasurer, JHHS

7-9-09
 Date