This document applies to the following Participating Organizations:

- All Children's Health System, Inc.
- Johns Hopkins Bayview Medical Center, Inc.
- Johns Hopkins HealthCare LLC
- Johns Hopkins Medicine International
- Potomac Home Health Agency, Inc.
- The Johns Hopkins Hospital

Keywords: clinical, NCD, PRA, reimbursement, research

### I. POLICY

In response to the Centers for Medicare and Medicaid Services (CMS) September 2000 Clinical Research Policy National Coverage Decision (NCD 310.1), Johns Hopkins Medicine has determined that effective July 1, 2008, all new clinical research protocols that have the potential to generate a patient care charge at any Johns Hopkins Medicine facility are required to have a completed Prospective Reimbursement Analysis (PRA). Every protocol performed under the authority of an Institutional Review Board (IRB) will go through an initial review to determine if a PRA is required.

### II. PURPOSE

The PRA is a centralized, 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.

### III. DEFINITIONS

| Prospective Reimbursement Analysis (PRA) | The PRA is an internal JH document. It involves a systematic review of a clinical research study protocol, draft contract and sponsor budget, proposed Informed Consent Form (ICF) cost language and other study documents, such as Notice of Grant Award (NOGA), Investigator’s Brochure (IB) and information regarding the FDA status of the investigational item(s). This comprehensive review adjudicates billable patient charges as either standard of care or research based upon Medicare and clinical care guidelines. |
| National Coverage Decision (NCD)        | NCDs are national policy granting, limiting or excluding Medicare coverage for a specific medical item or service. These are developed and published by CMS and apply to all states. |
IV. RESPONSIBILITY
A. Every protocol performed under the authority of an Institutional Review Board (IRB) will go through an initial review, performed by Clinical Research Support Services (CRSS), to determine if a PRA is required.
B. A Clinical Research Coverage Analyst from Clinical Research Support Services will perform a PRA review documenting and supporting standard of care vs. research patient care services and costs performed as part of the clinical trial or clinical research.
C. It is the Principal Investigator’s (PI) responsibility to review and ensure the accuracy of the PRA when in draft form. Only the PI has the ability to approve or disapprove (with comment) the draft PRA.
D. The PRA and the Participant Financial Responsibility Sheet are finalized upon IRB approval and Contract execution/grant award (if applicable) by the Clinical Research Coverage Analyst.

V. PROCESS
A. Every protocol performed under the authority of an Institutional Review Board (IRB) will go through an initial review by Clinical Research Support Services to determine if a PRA is required. Generally speaking, all protocols involving human subjects and an investigational item or service will require a PRA. Typical exclusions from this process include retrospective chart reviews, observational studies, surveys, outcomes analyses of FDA-approved and marketed items/services, and head-to-head comparisons of FDA-approved and marketed items/services. However, some studies previously exempt from the PRA process may require an EPIC Billing Grid to ensure research services are directed to the study account. This includes trials that enroll healthy volunteers and studies that obtain research samples during a clinical visit. A full PRA will not be required for these types of studies.
B. If the study is determined to need a PRA, a Clinical Research Coverage Analyst from Clinical Research Support Services will perform a PRA review documenting and supporting standard of care vs. research patient care services. Study goals and payment structure will also be reviewed. Once the analysis is complete, a draft PRA document is uploaded to the eIRB system and sent to the Principal Investigator (PI) to accept or decline with comments. Only the PI has the ability to approve or disapprove the draft PRA. Questions or concerns related to the PRA or PRA process should be directed to the PRA analyst or CRSS@jhmi.edu mailbox. When the PI has accepted the draft PRA, it is sent to the IRB committee for use during their review of the study. The PRA process occurs concurrently with the IRB review process. The Clinical Research Analyst will continue to follow the trial through the IRB, CRSS 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. For studies requiring a PRA, the IRB will not approve a study without a completed PI approved draft PRA uploaded in the eIRB system.
C. 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 Research Billing Compliance Office. 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 Research Billing Compliance.
D. The PRA will be finalized upon IRB approval and Contract execution/grant award (if applicable). If changes to the protocol were made during this process, the PI must approve the revised draft PRA before it is marked as the Final PRA. When the PRA is finalized it is posted and available under “Stamped Documents” in the eIRB system, along with the Participant Financial Responsibility Sheet. The Participant Financial Responsibility Sheet is to be reviewed and given to research participants at the time of obtaining written consent.
VI. REVIEW CYCLE

Three (3) years