1. **Purpose**
This standard operating procedure (SOP) describes the research billing process in PennChart.

2. **Scope**
This SOP applies to all research studies that will utilize hospital services for clinical research assessments, such as x-rays, MRI's, or labs. This includes studies that have no billable activities except potential adverse events or severe adverse events. These assessments will generate charges that need Research Billing review to assure that they are charged to the appropriate billing account as outlined by the research protocol schedule of events. In order to expedite research billing review, all studies must associate research participants and research related encounters to the Research Study record (RSH) as defined in the PennChart Research Association SOP.

3. **Instructions**
The Principal Investigator, or designated staff, is responsible for completion of the Prospective Reimbursement Analysis (PRA) and Medicare Coverage Analysis (MCA), associating patients and encounters with RSH records, and reviewing charges for research patients. The Office of Clinical Research (OCR) Finance Unit will review study related charges and work with the UPHS Patient accounting to resolve billing errors.

4. **Specific Procedures**
   a. The PRA and MCA: The PRA is a review to determine what items and services pertaining to a research study can be billed to Medicare and other commercial payors, or can be paid by the study sponsor or other funding sources. The MCA is the documented list of tests, items and procedures with an indication of how those charges should be billed. It is the responsibility of the Principal Investigator (PI), the Sponsor, the Business Administrator (BA) and delegated study staff to complete the PRA and MCA. If needed, a Research Financial Specialist from the Office of Clinical Research (OCR) is available for consult. The PRA and MCA is filed in PennERA along with other pertinent study documents and financial information, (e.g. Budget, Informed Consent, Contract, Protocol) at the time of proposal submission.
   b. Charge routing for research procedures: Hospital Billing (HB) and Professional Billing (PB) charges generated from executed orders placed in PennChart must be routed to the appropriate billing
account. Based on the patient-study association and encounter-study association, there are four ways a charge will be routed and appear on the Patients Needing Research Billing Review report:
Study Related- Bill to Study, Study Related- Bill to Patient/Insurance, Non-Study Related and Related to Another Study. Each department will identify personnel responsible for reviewing and managing charges. This involves running the research billing review report and reviewing which one of the above categorization have been given to a charge. Corrections can be made before releasing charges if they have been classified incorrectly by the system.

c. Review of Study Related- Bill to Study charges: On a monthly basis, the OCR Finance Unit reviews all HB and PB charges routed as Study Related- Bill to Study to assure these charges are billed to their appropriate grant or departmental account as designated in the Central Account Management System (CAMS).

d. Billing Error: If a billing error is found by the research team as they are performing billing review, the research team will escalate the charge to the OCR Finance Unit who will work with UPHS Patient Accounting to have the charge corrected. These errors are tracked and qualify for a For-Cause Audit per the Research Compliance SOP.

5. Roles and Responsibilities
Research Team completes the PRA and MCA and reviews all charges for research patients.

OCR Finance Unit will review study related charges and work with the UPHS Patient Accounting to resolve billing errors

OCR Operations provides training and ongoing guidance regarding this SOP.