1. **Purpose**
   This standard operating procedure (SOP) describes the use of three levels of PennChart research associations:
   a. Patient-Study Association: This association connects the patient to a research study.
   b. Encounter-Study Association: This association connects a visit or hospital stay to a research study.
   c. Procedure/Order-Study Association: This association connects an individual order or procedure to a research study.

2. **Scope**
   This SOP applies to all human subjects’ research that is conducted in, or sponsored by, Penn Medicine in which PennChart is utilized for data, records, tracking, and/or utilizes hospital services for clinical research assessments, such as x-rays, MRI’s, labs or where charges are generated via encounters in hospital space. This includes studies that have no billable activities except potential adverse events or severe adverse events.

3. **Instructions**
   PennChart study associations required of the research team include:
   a. Patient-Study Association: The trained, designated research staff will associate all research participants to the appropriate Research Study Record (RSH) in PennChart completing the following information
      i. Research Study
      ii. Enrollment status
      iii. Start and end dates used to assist in proper billing
      iv. Study coordinator
   b. Encounter-Study Association: The trained, designated research staff will associate all encounters that have any research related procedures, data, and/or charges related to research, to the appropriate RSH record in PennChart.
   c. Procedure/Order- Study Association: The trained, designated research staff will associate all procedures/orders that are related to research, to the appropriate RSH record in PennChart. This allows for differentiation in a visit between research and non-research procedures.
4. Specific Procedures
   a. Patient Association: Research teams will be responsible for creating patient-study associations through the Research Studies Activities. An enrollment status and start and projected end dates will be specified during patient association. The enrollment status and end date will be updated as study participation progresses from pre-consent, through active, to inactive (e.g. identified, consented/enrolled, completed) and as the participant’s study completion is clearly identified. A research participant must be associated to the appropriate RSH record with an active enrollment status for the following to occur:
      • Study-Encounter and Study-Procedure/Order associations to be completed
      • Research indicator to be visible in the patient header
      • Charges to be routed for research billing review
      • Research specific InBasket notifications:
        o ADT notifications for active participants that are admitted, discharged or transferred
        o Appointment change notifications for active research participants
        o Result results notifications when active participants have new research results
        o Deceased Patient notifications when an active participant is marked as deceased

   b. Encounter-Study Association: Research teams will be responsible for associating all encounters containing research related information/orders/procedures to the appropriate RSH record through the following processes:
      • Registration Specialty Billing Folder at visit scheduling
      • Appointment desk through right click linking
      • Active encounter using the Research:Active indicator
      • Reporting using the Find Patients Associated with My Studies or the ES Appt Search report

   c. Order- Study Association: Research teams will be responsible for associating orders to the appropriate RSH record through the Research Associate function in PennChart.

5. Roles and Responsibilities
   Research Team completes all levels of Research Associations as indicated.

   OCR Operations provides training and ongoing guidance regarding this SOP.