1. **Purpose**

   This standard operating procedure (SOP) details the creation, revision and completion of the PennChart Research Study Record (RSH).

2. **Scope**

   Once funding is secured and all pertinent information gathered for a study needing Penn Medicine, including Chester County and Princeton hospital services, the study record is created in PennChart. This generates a Research Billing Number (RBN) which allows study teams to associate patients, place orders, run reports, track enrollment and perform Bill Review.

   The PennChart Research trained, designated coordinator must associate research participants, research related encounters and orders to the appropriate RSH Record per SOP.

3. **Instructions**

   RSH Record Creation: The Office of Clinical Research (OCR) Finance Unit is responsible for the creation of the RSH record in PennChart. Once the study information is entered in the appropriate tabs and saved, the RBN is automatically generated by PennChart and the Billing Status is set to Active. Once a study is set to Active, the study teams is able to begin associating patients and encounters, linking orders, and to perform research billing review.

   RSH Record Revision: Only staff that are listed on the RSH record have the ability to make patient-study, encounter-study and order-study associations, run reports and receive InBasket notifications. Changes to the study staff and any updates are made directly in the RSH record in the appropriate tab and can be requested by emailing OCR Finance. The OCR Finance Unit is responsible for the addition of the appropriate research staff to the RSH record.

   RSH Record Closeout: The OCR Finance Unit is responsible for updating the RSH record to close out the study. The RSH record can be marked completed when there are no additional tests or procedures.
required and/or funding has ended. When prompted that the study is closing, either by the study team or Business Administrators or notification or a Residual Balance closeout, the patients should be placed in a Completed patient enrollment status and their end date should be updated. The RSH Billing Status is then updated to Completed. This ensures that there will be no further billing implications and that associations can no longer be made to the study.

4. **Roles and Responsibilities**

Research Team will contact OCR Operations with any changes needed to the RSH record.

OCR Finance Unit and OCR Operations will update the RSH records and close out the study.

OCR Operations provides training and ongoing guidance regarding this SOP.