Patient-Study Association: Patients are associated to research studies using patient research statuses. These statuses indicate an individual patient's relationship to a research study. Research patient status can be in one of three categories; Pre-consent, Active or Inactive.

These are NOT IRB terms. These categories are used for billing purposes.

There are multiple different statuses to choose from in PennChart. Each enrollment status falls into 1 of 3 buckets: Pre-consent, Active or Inactive.
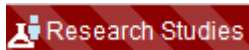
A patient must be in an Active status in order to link encounters and/or orders or have charges associated to the study.
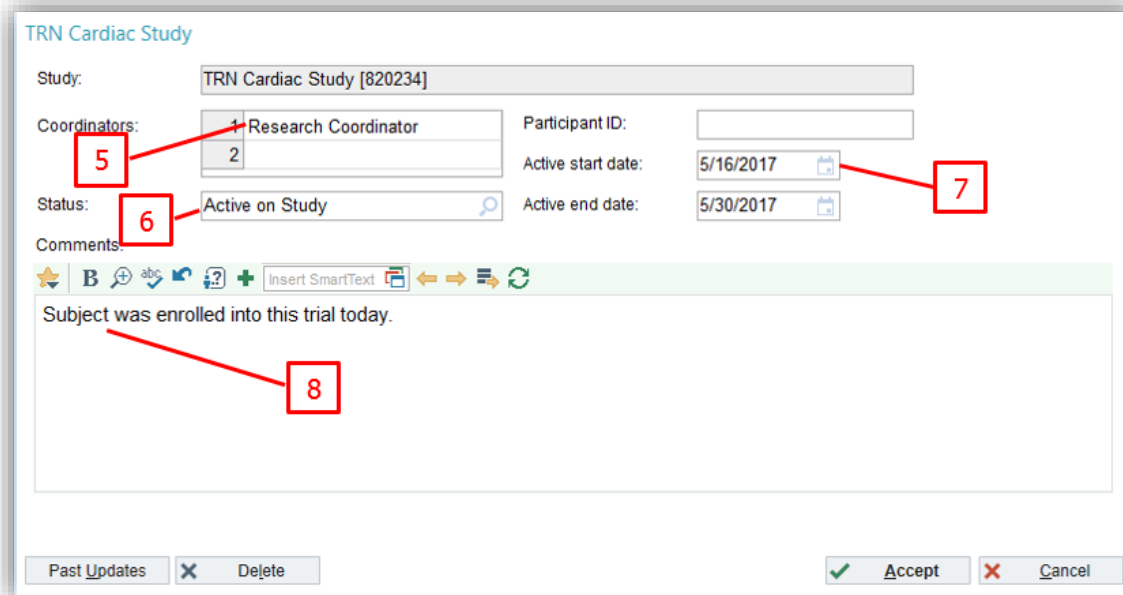
There have been updates to the patient enrollment status list within PennChart. These new statuses will provide granularity to the patient-study association.

PRE-CONSENT

- Identified
- Interested

ACTIVE

- Active follow –up
- Active on Study
- Consented/Enrolled
- Off Treatment: Disease Progression
- Off Treatment: Failed Post-Consent Screening
- Off Treatment: PI Decision
- Off Treatment: SAE/AE
- Off Treatment: Subject Decision
- Off Treatment: Subject Relocated
- On Treatment
- Post-Consent Screening
- Pre-Consent Screening

INACTIVE

- Declined
- Ineligible – Did not meet full criteria
- Long-term Follow-Up
- Off Study/Withdrawn: Completed Protocol
- Off Study/Withdrawn: Disease Progression
- Off Study/Withdrawn: Failed Post-Consent Screening
- Off Study/Withdrawn: Lost to Follow-Up
- Off Study/Withdrawn: Never treated
- Off Study/Withdrawn: PI Decision
- Off Study/Withdrawn: SAE/AE
- Off Study/Withdrawn: Subject Decision
- Off Study/Withdrawn: Transferred to another Institution

Updated 12/2018

Patient-Study Association Workflow:

To associate a patient with a research study:

1. Click on your main [Research Studies] toolbar.

2. Look up your patient and click Accept. The Research Studies activity opens.
3. Click ✚ **Add**. The record select window appears with a list of available studies.
4. Select the appropriate study and click Accept. A details form opens for the study.
5. Enter the Coordinator's name into the Coordinators Field.
6. In the Status field, enter the appropriate status for the patient, such as Interested.
7. Enter the Active start date: The start date drives billing logic. Enter a 't' Note: T is an Epic shortcut used to default today's date. There are several date and time shortcuts that can be used in Epic. T=today, Y=year, M=month, W=week
8. Enter any additional information or comments