



SOP for Non-Beacon Research (Investigational) Medications in PennChart

Purpose of this document: This document outlines the standard operating procedures, which must be followed, for the request and maintenance of research medications utilized in PennChart. Research (investigational) medications may refer to any novel therapies or commercially available medications ordered or administered as part of a research protocol.

Scope: This SOP applies to all Non-Beacon Research (Investigational) medications and associated builds (Order Panels, Order Sets, smart Sets) including commercially available medications used for investigational purposes, where the subject is treated at a Penn Medicine location(s).

For Research Studies requiring Beacon Protocol/Treatment Plan build in PennChart, please refer to PennChart Beacon Team Policies/Guidelines available via the following link [UPHS Information Services - New Protocol Build Request \(upenn.edu\)](https://www.upenn.edu/uphs-information-services-new-protocol-build-request).

Instructions: All Clinical Investigators and Clinical Research Staff are required to follow the Procedures outlined below. All research (investigational) medications for research participants being seen at Penn Medicine locations are to be electronically ordered via PennChart. All research (investigational) medications being administered to research participants at Penn Medicine locations are to be documented in PennChart.

Research teams who determine they have a compelling privacy concern related to research (Investigational) medication information appearing in PennChart should petition the Pharmacy and Therapeutics Committee (P&T) prior to submitting to the IRB for initial review. The P&T Committee will determine, when requested based on privacy concerns, considering any safety or other clinical concerns, whether a waiver of this requirement will be granted. Documentation of the waiver, if approved, must be included in submission to the IRB.

Procedures:

1. Non-Beacon Research Medication Build Request

- i. **Pharmacist** submits a medication build request form to PennChart Research Team using the following link [Beacon or Research Medication Build Request](#)
- ii. The applicable request form (Investigational Medication Build Request) is included in the Athena ticket using the hyperlink above.
- iii. Pharmacists should use the medication request form in the Athena ticket to ensure they are using the most current version.
- iv. Pharmacy and PI Approval required prior to activation of the medication build(s)
 - a. Investigational Medication build(s) not submitted by Investigational Drug Services Pharmacy also require IDS approval.
- v. Missing or incomplete information, or delays in approvals may result in delays in build.



2. Non-Beacon Research Order Set or Smart Set Build Request(s)

- i. Study team submits a Research Order Set build request with the completed build request form to PennChart Research Team using the following link [IS Self Service Portal \(upenn.edu\)](https://www.upenn.edu/is-self-service-portal)
- ii. The applicable request form (Non- Beacon Research Order Set or Smart Set Build Request) can be accessed via CHPS website. <https://www.itmat.upenn.edu/chps/epic-beacon.html>
- iii. IDS Pharmacy submits a separate ticket for Investigational Medication build per instructions listed in **section 1** if the order set/smart set includes investigational medication build(s).
- iv. For Standard of Care (SOC) medication(s), only medication(s) that are P&T approved for formulary, available on the Hospital Pharmacy Preference list, and applicable to the research study protocol can be requested to be added to an Order Set.
- v. Research Order Set(s) or Smart Set(s) with Investigational Medication(s) require approval from study PI and other reviewers listed in the request form (The requester, Pharmacist, Research study coordinator/nurse, Clinical Practice Lead) prior to activation.
 - i. IDS Pharmacist approval required for the Investigational med build(s) section in the order set or smart set.
- vi. Research Order Set(s) or Smart Set(s) without Investigational Medication(s) require approval from the requester and study PI prior to activation.
- vii. Missing or incomplete information, or delays in approvals may result in delays in build.

Note: The research order set(s) or smart set(s) do not replace SOC workflow and are to be used in conjunction with clinical workflow as applicable to the specialty.

3. PennChart Ordering

- i. All investigational medications to be electronically ordered in PennChart
- ii. Select prebuilt and approved investigational medication(s) in PennChart
- iii. Complete required fields
- iv. Confirm appropriate pharmacy or dispense location
- v. Separate orders for investigational medications based on dispense (e.g. If order for 60 tablets, with patient taking on site at Penn Medicine location, should be two orders: one for administration on site, one for take home from pharmacy)

4. PennChart Medication Administration

- i. All investigational medication being given to patient at Penn Medicine location to be documented in PennChart
- ii. Select ordered investigational medication in PennChart
- iii. Complete require administration fields



5. Amendments to Non-Beacon Research (Investigational) Medication(s):

- i. Pharmacist submits a ticket to PennChart Research Team using the following link [Beacon or Research Medication Build Request](#)
- ii. PennChart Research team to complete the update
- iii. Pharmacy and study PI Approval required prior to activation of the update to the Investigational medications.
- iv. Missing or incomplete information, or delays in approvals may result in delays in completing the update.
- v. Requests for updates to active study meds in PennChart are prioritized over new med build requests for studies not yet active and based on impact to patient safety/quality of care.

6. Amendments to Non-Beacon Research Inpatient Order Set(s) or Outpatient Smart Set(s):

- i. Study team submits a ticket to PennChart Research Team using the following link [IS Self Service Portal](#)
- ii. For updates to the Investigational medication(s) section of the order set, IDS Pharmacy submits the ticket per instructions listed in **section 3**.
- iii. PennChart Research team to complete the update
- iv. PI and other reviewers listed in the update request (The requester, Pharmacist, Research study coordinator/nurse, Clinical Practice Lead) approval required prior to activation of the update to the Order Set(s)/Smart Set(s).
 - a. IDS Pharmacist approval required for updates to the Investigational med build(s) section in the order set/smart set.
- v. Updates to Research Order Set(s)/Smart Set(s) without Investigational Medication(s) require approval from the requester and study PI prior to activation.
- vi. Missing or incomplete information, or delays in approvals may result in delays in completing the update.
- vii. Requests for updates to active Order Set(s)/Smart Set(s) in PennChart are prioritized over new build requests for research studies not yet active and based on impact to patient safety/quality of care.

7. Study Completion/Request to Inactivate Non-Beacon Research (Investigational) Medications and Order Sets or Smart Sets

- i. IDS Pharmacists submit a ticket to IS Service Desk via [IS Self Service Portal](#) to the PennChart Research Team to inactivate Investigational medication(s) and order set(s)/smart set(s) with Investigational medication(s) in PennChart.
- ii. For Order Set(s) without Investigational Medication(s): Research study team submit a ticket to IS Service Desk via [IS Self Service Portal](#) to



Penn Medicine

PennChart Research Team to inactivate the order set(s)/smart set(s) in PennChart.

- iii. PennChart Research team to inactivate Investigational medication(s)/order set(s)/smart set(s) records.

Roles and Responsibilities:

Clinical Investigators and Clinical Research Staff:

Comply with the procedures outlined in this SOP. If utilizing Investigational Drug Services, compliance with IDS policies and procedures is required.

Corporate Information Services (PennChart Team):

Provide the services specified above in accordance with all other PennChart SOPs and practices.

a) PennChart Research Team:

- a. Responsible for building Research medication records (NOT ordered part of a Beacon Protocol) and for patients receiving treatment in non-oncology departments as follow:
 - i. **Inpatient units** - patient receives research medication while admitted in the hospital in a non-oncology unit.
 - ii. **Outpatient clinics** – patient receives research medication in the clinic setting and medication is ordered through Clinic Administered Med workflow.
 - iii. **Outpatient/e-Fax prescription** - Research medication(s) is dispensed by Investigational Drug Services Pharmacy (IDS) for home administration.

b) PennChart Beacon Team:

- a. Responsible for building protocols and research medication records for patients receiving treatment in any outpatient infusion departments which includes Center for Human Phonemic Science (CHPS) Departments or inpatient oncology units.

Institutional Review Board:

Review compliance with this SOP by Clinical Investigators and Clinical Research Staff for all protocols including the use of an investigational or research medication.

Pharmacy and Therapeutics Committee:

The P&T Committee is tasked with balancing patient privacy concerns with the need to minimize risks to research participants and will serve as a decision-making body for teams who determine, for their research protocol, there is a compelling enough privacy concern and therefore, the investigational medication should not be in PennChart.