

OHSU KNIGHT CANCER INSTITUTE Beacon Research Protocol Development

Purpose of procedure: The purpose of this procedure is to outline the process, parties responsible and turnaround time agreed to for the creation and compilation of all documents required to create a Beacon template for investigational protocol treatment in the Medical Oncology Division of the Knight Cancer Institute. In addition, this workflow will delineate the responsible parties for the individual steps necessary and the timelines by which steps are to be completed so that treatment commencement can coincide with IRB approval. The workflow and template documents are available at <http://www.ohsu.edu/xd/research/centers-institutes/octri/resources/policies-forms/beacon-procedures.cfm>.

Materials Required: Research Study protocol, Beacon research template (MS Word) Form, Lab manual, Pharmacy manual, Beacon Protocol Request Portal

Scope: Medical Oncology (excludes other departments eg: Radiation Oncology, Surgical Oncology)

Procedures:

Role Responsible	Task	Turnaround time, if defined
Beacon Template Author (study coordinator, research nurse)	<ol style="list-style-type: none"> Complete the Beacon Protocol Template Form (MS Word) with study details. The template may be found at: http://www.ohsu.edu/xd/research/centers-institutes/octri/resources/policies-forms/beacon-procedures.cfm Notify Research Pharmacy Services (RPS) of new build. 	
Research Pharmacy Services	<ol style="list-style-type: none"> Complete the EPIC Catalogue and return via email to Beacon Template Author 	≤10 business days (BD)
Beacon Template Author	<ol style="list-style-type: none"> Request Beacon Protocol Build through Portal and attach: <ol style="list-style-type: none"> Beacon Research Template EPIC Catalogue <p>The portal can be found on the OCTRI site at the address at the top of this document.</p> 	
Pharmacy Informatics	<ol style="list-style-type: none"> Review build documents and emails any questions to Beacon Template Author 	
Beacon Template Author	<ol style="list-style-type: none"> Answer Pharmacy Informatics questions via email 	
Pharmacy Informatics	<ol style="list-style-type: none"> Build plan in Proof of Concept (POC) environment Update Beacon Protocol Master Tracker Send email to Beacon Template Author requesting validation of the build 	≤15 BD

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Beacon Template Author	10. Request all reviewers (PIs, RPS, etc) to validate the build 11. Submit consolidated edits from all reviewers via email to Pharmacy Informatics. Indicate if revalidation is required. a. Updates provided by 4pm each Wednesday, will be available in Sandbox the next Monday (+ 5 days). Edits received after this time will be available the following Monday (+ 12 days).	
Pharmacy Informatics	12. Update tracker with validation date and reviewer names 13. Make edits in POC and migrate to Production (unreleased) a. If revalidation required, repeat steps 9 – 15 until plan is correct. 14. Release protocol in production and notify Beacon Template Author of released plan via email 15. Update tracker with release date	≤10 BD

Minor Changes to Template: Example: typographical error

- Email very minor changes to the build directly to Pharmacy Informatics.

Significant study modification or amendment to released plan required:

- The process for these changes must begin at step 4.

Beacon Protocol Master Tracker:

- Beacon Template Authors and other staff have view only access to the tracker through the entire process. The tracker is located at:
<https://bridge.ohsu.edu/health/pharmacy/beacon/SitePages/Home.aspx>