General Guidelines

1. **Study Coordinators will be specific in detailing information for study-related treatments and procedures. Language used in the template should be written in layman terms and should not include abbreviations. Protocols that specifically state "Use Institutional Standards/Guidelines" for medications will be populated by Pharmacy Informatics (Beacon builder(s)). Protocols allowing "Investigator Discretion" require principal investigator input – this may be consistent with Institutional Standards/Guidelines and therefore referred to Pharmacy Informatics with input from an Oncology Pharmacist for completion.**

2. **Please indicate which medications will be supplied by Research Pharmacy and which will be supplied as standard of care.**

3. **Research Pharmacy will complete an Epic Catalog Template form for each study medication as well as a Research Pharmacy Supplement. Three build forms should be submitted to the Epic Support Desk for each new build request:**
    a. **Beacon Research Template Form**
    b. **Epic Catalog Template**
    c. **Research Pharmacy Supplement**

PLAN OVERVIEW

1. **Treatment Plan Name:**
   Convention for naming research treatment plans:
   (Department) INV (eIRB number) (Template descriptor)
   Example: ***HEM INV 6256 Paclitaxel / MK2206***
   Departments include:
   - HEM – Hematology Oncology
   - CHM – Center for Hematologic Malignancies
   - CHO – Community Hematology Oncology
   - PHO – Pediatric Hematology Oncology
   - NEU – Neurologic Oncology
   - GYN – Gynecologic Oncology

   If more than one department is conducting the same study, a distinct plan must be submitted for each of the departments. Please reference any other Beacon template that is similar to the plan that you are submitting, including if another department already has the same Beacon plan available.

2. **Template summary:**
   This is to be used as an overall guide to help Pharmacy Informatics understand the template(s) associated with the protocol. Include disease site, stage, study phase, general treatment plan including drugs, order of treatment:

   Example: "*Treatment arm of I-SPY, multi arm study of neoadjuvant chemotherapy in primary breast cancer. This arm treats with weekly trastuzumab and paclitaxel x 12 weeks and oral investigational agent MK2206 once weekly for 12 doses"*

3. **Synonyms:**
   -Brand or other name of drug(s)
   -Sponsor protocol number
   -Disease site

4. **Principal Investigator:**
   Name/Title:
   Phone/Pager:

5. **Study Coordinator:**
   Name/Title:
   Phone/Pager:

6. **Type of Plan:** Where will treatment be given?
   - Inpatient only
   -Outpatient only
   -Combination of both an inpatient stay and outpatient visits
   -Are both inpatient and outpatient only versions needed?

   Build plan based on the location where the majority of subjects will be treated.

7. **Number of Cycles:**
   Define optimum number of cycles to be used for baseline template. "Optimum" will vary from template to template – if there are a fixed number of cycles in the protocol, that number will be used. If the number of cycles is open-ended, as in many metastatic treatments, it is suggested you choose a number of cycles that will cover treatment for 6-12 months. Plans should not be built for more than 1 year without discussion with Pharmacy Informatics.

8. **Number of Days per Cycle:**
   Do not include range. Only provide a single number.

9. **Plan properties:**
   Weight/BSA criteria for dose recalculations. Unless otherwise specified, the Beacon plan will default to the actual weight of the patient at the time the plan is assigned.

Weight/BSA warning criteria (a warning will display in Beacon if weight or BSA differs by greater than or equal to 5%)

PRE-CYCLE

10. Pre-Cycle Procedures/Medications:

Research Procedures/Medications - List any protocol specific outpatient medications or ordering guidelines that need to be initiated or completed before Cycle 1, Day 1.

Standard of Care Procedures/Medications – See General Guidelines for medications.

TREATMENT

11. Standard of Care Labs: List any labs that need to be done in clinic before infusion

12. Research labs:
Labs to be reimbursed by study sponsor (Downtime Forms): Due to the significant effort needed to maintain an accurate list of specific research labs for each study along with the inability to associate the industrial account number with research labs in Beacon, specific research labs will not be listed in the Beacon template.

If research labs are to be drawn, please specify which days they will be drawn and a general research communication order will be added to the template instructing the nurse to see the downtime form for study labs.

If PKs are involved summarize time points for draws on each day, segregated by Cycle and Cycle Day.

13. Treatment parameters:
List relevant criteria for holding treatment or dose modification, OR default to "Hold chemo and notify MD or study coordinator for any abnormal labs or vital signs"

14. Nursing communications:
List any items that the nursing staff should be aware of for treatment; Examples may include: patient specific instructions regarding the study medication, or patient reminders.

15. Pre-Medications:

Research Pre-Medications: List any protocol specific medications the patient should receive before chemo in the order they are to be received. Follow General Guideline #2.

Standard of Care Pre-Medications: Follow General Guidelines #1 and #2.

16. Ordering guidelines:

List any instructions necessary for principal investigator completion of treatment orders. Include dose modification levels/doses. This may include escalation dosing.

Starting dose (or dose 0):

- **Drug name, strength, amount to be dispensed. Instructions for dosing**

Dose Level -1, Dose Level -2 etc:

- **Drug name, strength, amount to be dispensed. Instructions for dosing**

17. Oral Chemotherapy

List protocol specified oral chemotherapy *in order they are to be received*, regardless of whether research or standard of care**,** numbering therapies in order of administration. Be specific about when oral chemo is to be given (i.e., give dose just prior to Infusion #1).

For each treatment, note where medications will be prepared (research vs. standard of care pharmacy) and on which cycle(s) each medication is dispensed, i.e. (**TO BE DISPENSED EVERY CYCLE, or TO BE DISPENSED ON CYCLES 1, 4 and 7**)

18. Parenteral Chemotherapy

List protocol specified parenteral chemotherapy *in order they are to be received*, regardless of whether research or standard of care**,** numbering therapies in order of administration. For each treatment, note if where medications will be prepared (research vs. standard of care pharmacy) and on which cycle(s) each medication is dispensed, i.e. (**TO BE DISPENSED EVERY CYCLE, or TO BE DISPENSED ON CYCLES 1, 4 and 7**)

19. Hypersensitivity Medications

List any medications that should be given if hypersensitivity or infusion related events develop during the infusion.

DISCHARGE MEDICATIONS

20. Take Home Chemotherapy:

Use the following convention for each drug and dose level:

Starting dose (or Dose 0):

- **Drug name, strength, amount to be dispensed. Repeat if multiple strengths are used to complete dose.**
- **Instructions for dosing**

Dose Level -1, Dose Level -2 etc:

Drug name, strength, amount to be dispensed. Repeat if multiple strengths are used to complete dose.

- **Instructions for dosing**

Clarify on which cycle(s) these medications are dispensed

21. Take Home Palliative Medications:

List any protocol specific outpatient prescriptions the patient should receive. If there are no protocol specified medications, or if protocol dictates "use institutional guidelines", write "standard of care only". These will be completed by Pharmacy Informatics. Note where medications will be prepared (research vs. standard of care pharmacy) and on which cycle(s) each medication is dispensed, (i.e. TO BE DISPENSED EVERY CYCLE, or TO BE DISPENSED ON CYCLES 1, 4 and 7). List protocol specified outpatient prescriptions, following General Guidelines #1 and #2.