PURPOSE
This document describes the procedure for creating an EPIC order set for clinical research studies conducted at Johns Hopkins Medical Institutions (JHMI). All studies conducted in both inpatient and outpatient settings at JHMI require an EPIC order set.

RESPONSIBILITY
The PI, with the assistance of the study team, is responsible for ensuring that the EPIC order set is created using the procedure below.

STAKEHOLDERS & RESPONSIBILITIES

- **PI and/or Study Team**
  - Submit request for order set
  - Respond to queries related to build
  - Approve final build
  - Attend Order Set Review Committee Meeting

- **Clinical Research Epic Application Coordinator ("Epic Research Team")**
  - Receive original request for order set build
  - Provide direction and Excel template
  - Provide organization of content
  - Provide screen shots to PI/Team for review during build
  - Facilitate and attend Order Set Review Committee Meeting
  - Submit order set to Quality Control.

- **IDS Pharmacist and Medication Builder**
  - Review order sets for investigational drug studies
  - Provide direction
  - Attend Order Set Review Committee Meeting

- **Nursing Informatics Specialists**
  - Review order sets
  - Provide direction regarding nursing content and workflow
PROCEDURE

1. STUDY TEAM REQUEST: IRB approval, the PI or study team member must place an initial request to build the order set by emailing epicresearch@jhmi.edu.
   • Subject of email: “Request for Study Order Set”
   • Body of email must include:
     ▪ IRB # of study
     ▪ Confirmation of prospective reimbursement analysis (PRA)
     ▪ Email should state “PRA done.”

2. EPIC TEAM RESPONSE: The Epic Research Team will respond to the initial request via email with the following:
   • “Tips for Developing Research Order Sets” document to guide PI or study team through writing an order set in EPIC
   • Request Research Order Set Consent Form
   • Order Set Specifications Document with example

3. STUDY TEAM SPECS: The PI or study team member must complete the request form and specifications and return to the Epic Research Team via email.

3. EPIC TEAM REVIEW: The Epic Research Team will review the completed request form and specifications.
   ▪ The request form will be prioritized by the Epic Research Team and an approximate start date will be assigned accordingly

4. EPIC TEAM BUILD: When the Epic Research Team starts the Epic build (on assigned start date), they will notify the study team.
   • Building the order set is an iterative process with queries to the study team
   • The Epic Research Team will provide screen shots for review. Requires study team endorsement to move forward.
   • Study team can expedite process by responding to build team queries ASAP

5. EPIC TEAM PHARMACY COORDINATION: The Epic Research Team will contact IDS Pharmacy to coordinate their involvement in the order set (if the study includes an investigational drug)
   • IDS Pharmacy assigns a specific pharmacist to participate in the order set review and attend the Order Set Review Committee (OSRC) meeting

6. STAKEHOLDER REVIEW & APPROVAL: Once a “first draft” of the order set is complete, the Epic Research Team will provide screen shots for review.
   • Screen shots will be sent to the PI/study team, IDS Pharmacist, Nursing Informatics Specialist, and any additional stakeholders.
   • All parties must approve the set of screen shots before the process can move forward.
     ▪ Parties indicate their approval by replying “Approved” to the email chain containing the final screen shots.
7. ORDER SET REVIEW COMMITTEE MEETING: When finalized, the Epic Research Team will facilitate meeting with OSRC.
   • The Epic Research Team forwards via email with link to scheduling interface
   • PI will receive a meeting invite with a Zoom link for the review.

8. COMMITTEE APPROVAL/REVISIONS: The PI will attend the OSRC meeting and receive one of three decisions: approval, approval with minor changes (i.e. spelling, grammar, etc.), or disapproval with comments.
   • If the order set is approved with minor changes, then the Clinical Research Application Coordinator will make these changes, and the process will continue.
   • If the order set is disapproved with comments and requires major changes, the Epic Research Team will collaborate with the PI to make these changes, and the new order set will be re-submitted to the OSRC.
     ▪ Once the new order set is re-submitted to the OSRC, another meeting will be scheduled using the same process as above.

9. FINAL REVIEW: If significant changes are not required by the OSRC, the Clinical Research Application Coordinator will send out another set of screen shots for final review.
   • Again, all parties must approve the set of screen shots before the study can move forward.
     ▪ Parties indicate their approval by replying “Approved” to the email chain containing the final screen shots.

10. PRODUCTION & USE: After Quality Control (QC), OSRC, and all stakeholders approve the final order set, it will go into production. At this time, the Epic Research Team will send an email to the PI to notify them that the order is in production and provide additional information about how to use it.
    • QC can approve the order set at any time during this process prior to production.
      ▪ The Epic Research Team submits the order set to Quality Control.
    • If PIs have additional questions regarding utilizing the order set, please contact the Epic Research Team via email.
ORDER SET PROCESS DIAGRAM

1. **Submit initial request for order set**
   (PI/study team)

2. **Complete request form and specifications**
   (PI/study team)

3. **Epic Research Team reviews and prioritizes request**
   (IT)

4. **Epic Research Team notifies PI when order set build is initiated**
   (IT)

5. **Epic Research Team contacts IDS Pharmacy, Nurse Informatics, and other relevant stakeholders for input**
   (IT)

6. **Epic Research Team circulates first draft screen shots**
   (IT)

7. **All stakeholders approve first draft screen shots**
   (PT/study team and other stakeholders)

8. **Epic Research Team submits order set to the OSRC* (IT)**

9. **PI/Study Team schedules OSRC meeting**
   (PI/study team)

10. **PI/Study Team attends OSRC meeting**
    (PI/study team/IDS Pharmacy)

11. **If necessary, make changes mandated by OSRC* (IT)**
    (PI/study team & IT)

12. **EPIC Research Team circulates final screen shots**
    (IT)

13. **All stakeholders approve final screen shots**
    (PT/study team and other stakeholders)

14. **Verify Quality Control review completed**
    (IT)

15. **Order set production in EPIC (IT)**

16. **Order set is live and ready to use**

*ORSC: Order Set Review Committee