



INPT SOP 1.052 – Licensed Independent Practitioner’s responsibilities for the research participant and study activities on the CCI 9AB inpatient unit

Document Controls

Version: 1
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Version History

Version	Effective Date	Description
1	February 25, 2019	Created SOP to outline the expectations of the Licensed Independent Practitioner responsible for a research study participant and study activity on CCI inpatient unit.



Purpose

The purpose of this SOP is to outline the requirements of the Licensed Independent Practitioner (LIP) responsible for a research study participant and the study activities on CCI inpatient units.

Scope

This SOP applies to those LIPs designated in study orders as accountable for the participant in a research study on the CCI Inpatient Unit.

Responsible Personnel

1. Licensed Independent Practitioner (LIP) is responsible for a research study participant and study activities on the CCI
2. LIP delegate is assigned by LIP to provide services during times when LIP unavailable (hereafter referred to as covering LIP)

References

1. BWH Administrative and Medical Staff Manual: 5.3.3 BWHC Medical Record Documentation Policy- <https://hospitalpolicies.ellucid.com/documents/view/2636/15599/>
2. BWH Pharmacy Policy and Procedures: section. Investigational Drug Services Policy- <https://hospitalpolicies.ellucid.com/documents/view/12408/39938/>

Definitions

N/A

Equipment & Materials

N/A

Standard Operating Procedure

1. BWH Medical staff policies and procedures related to patient care, safety, compliance and documentation are standard expectations for the Licensed Independent Practitioner (LIP) accountable for a research participant on the CCI.
2. The LIP must have appropriate BWH hospital privileges. For Inpatient admissions, there must be a LIP with BWH Clinical admitting privileges. For outpatient encounters, the LIP must have appropriate clinical licensure and BWH approvals for research activities.

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3. The LIP is accountable and responsible for these procedures:
 - a. Documentation requirements:
 - i. Submit the LIP signed **protocol orders** with **completed consent form at least 72 hours prior** to visit to CCI9ABorders@partners.org
 - ii. Enter **Epic encounter orders** for investigational medications and labs to BWH Clinical laboratory **at least 48 hours prior** to the visit utilizing study specific or generic research template.
 1. Enter required study medications in Epic
 2. Confirms accuracy of PAML (Pre-Admission Med List) for admissions including current non-study medications on subject's record
 3. Enters all non-study medications that will be administered during inpatient study. Reviews with IDS Pharmacy if subject's home medications are not available in formulary or if instructions should indicate that subject "may take own medication".
 4. Order ancillary tests and/or clinical lab tests for BWH clinical services (i.e. Lab Control, MRI).
 - iii. Complete **History and Physical** exam for admissions and for outpatients with research infusions.
 1. Research subject's History and Physical exam documentation may be **scanned to CCI9ABorders@partners.org** with study orders and consent form prior to MD entry of data into Epic.
 2. History and Physical exam and documentation may be completed **onsite for inpatients at time of admission or for outpatients prior to infusion OR within 7 calendar days** prior to either type of visit. Below are the categories for studies that qualify for completing history and physicals within 7 days prior to the visit:
 - a. Inpatient studies and outpatient studies requesting LIP visit prior to drug administration at 9A.
 - b. At CCI implementation, study is deemed to be low risk. (For example, studies with healthy human volunteers or well-established, and familiar study procedures that are already active.)
 - c. If Study team proposes the request of History and Physical exams to be done 7 days prior to visit during implementation meeting, then CCI will make the determination on case by case basis.
 3. Study protocols or subjects not qualifying with the above conditions will require completion of history and physical on admission or at visit per BWH policy.
 - iv. Discharge:
 1. For inpatient visits, LIP should complete Epic documentation for legal discharge order prior to research participant's discharge. Follow the Discharge Navigator steps, reviews listed medications and include any



- specific instructions for "After Visit Summary" document given to participant to take home.
2. For outpatient visits at Tower 9, study orders should contain any specific requirements/ research participant instructions that needs to be completed prior to providing clearance to discharge research subject for the visit.
 - b. Additional Inpatient encounter Process requirements:
 - i. Submit the CCI Booking form for BWH Admissions to CCI9ABorders@partners.org email as soon as the visit is scheduled in the scheduling system.
 - ii. LIP visits the research participant daily and a progress note is documented in Epic. Communicates any deviations/deletions of the protocol for individual subjects to appropriate service (i.e. dietary/nursing/imaging) and documents in Epic.
 4. The Attending LIP may delegate the tasks related to admission process, study records, Epic documentation, subject clinical and/or research issues and discharge process to another qualified LIP. The Attending LIP must be identified on the research participant's CCI admission form for BWH inpatient study encounters.
 - a. LIP and covering LIP names and licensure are listed with identified Primary and Back up person and contact information (Beeper # and/or cell phones) on each research participant's study orders.
 - b. The LIP must be available by beeper or cell phone during entire hospital visit/stay of research participant.
 - c. There should be local medical coverage for research subjects.
 - i. Throughout the subject's admission or outpatient visit, the LIP must always be available in person or via contact number/phone to discuss with nurse any potential issues
 - ii. If both primary and delegate LIPs are not available, CCI Tower 9 Nursing may contact CCI Inpatient Medical Research Officer as back up medical contact.
 1. A discussion between CCI Admin/MRO and study PI may ensue to ensure CCI policy is followed by all study teams.
 - d. Changes in coverage:
 - i. Changes of LIP coverage prior to research participant arrival must be communicated in a revised order set and emailed as "ALERT" to the BWH CCI9AB order email with explanation "change in LIP coverage".
 - ii. Changes after participant arrival must be communicated directly to the Charge Nurse and in writing through the Epic Order in the Nurse Communication option
 - iii. Last minute changes in LIP coverage made during off shift/weekend/holidays should be called in directly to 9AB staff and followed with documentation as directed above for pre/post participant arrival.

5. Emergency



- a. For any research participant requiring immediate emergency assistance, the CCI 9A/B staff will activate medical assistance through the BWH CODE System. (732-6555).
- b. For any research participant requiring urgent evaluation for clinical safety, the CCI 9A/B staff will activate the Emergency Assistance Algorithm for Tower 9AB.

Special Notes

N/A

Allowable Exceptions

N/A

Attachments

N/A