



ADM SOP 0.015 – Observers and Visitors to the CCI Research Units

Document Controls

Version: 4
Authors: Sheila Driscoll
Approved by: Yemi Talabi-Oates, CCI Administrative Director

Signature: 

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Version History

Version	Effective Date	Description
1	July 28 2008	Created SOP to establish a process for approving professional and/or educational observers and visitors to the CCI research units that ensures confidentiality and safety of subjects and data, and a process for CCI staff to request in limited situations visits for family or friends in the public areas of the CCI research units.
2	November 27 2015	Converted SOP to a new format.
3	June 9 2016	Content and format was updated based on Operations Manager's review.
4	July 25 2018	Updated to include BWH Office of Sponsored Programs Onboarding process for observers touring CCI units for more than 2 weeks.

Access Date: Wednesday, August 01, 2018

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Purpose

The purpose of this SOP is to establish a process for approving professional and/or educational observers and visitors to the CCI research units that ensures confidentiality and safety of subjects and data, and a process for CCI staff to request in limited situations visits for family or friends in the public areas of the CCI research units.

Scope

This SOP applies to all units and personnel within the Center of Clinical Investigations (CCI).

Responsible Personnel

CCI Leadership and Sponsors– Responsible for ensuring that the confidentiality and safety of the research subject, staff, and data are maintained while supporting Observers and Visitors experience on the research unit

CCI Staff – Responsible for requesting permission and a sponsor for any family or friend visits to restricted public areas of the CCI research units where subject and/or staff information is protected

References

1. Admin Policy 6.1.2 Hospital Safety
2. Admin Policy 9.1-2 HIPPA and Patient Rights
3. INPT SOP 1.041 - Visitors for Subjects in Non DSM Protocols on the 9B/IPM Unit
4. BWH Office of Sponsored Staff and Volunteer Office:
<https://www.brighamandwomens.org/about-bwh/volunteer/sponsored-staff-on-boarding-process>
5. BWH Sponsored Staff and Volunteer forms: <https://www.brighamandwomens.org/about-bwh/volunteer/volunteer-forms>

Definitions

Sponsor – A CCI administrator or supervisor and/or BWH investigator with affiliation to the CCI research units.

Visitor – Guest of the sponsor who tours the CCI unit for a single visit of less than one day.

Observer – Guest of the sponsor who is approved to watch research procedures on the unit for a day or more



Equipment & Materials

1. Schedule Program Calendar
2. Observer Agreement Form
3. BWH Visitor Pass
4. BWH Temporary ID badge
5. Visitor Confidentiality and Non-Discourse Agreement (Attachment A01)
6. Observer Agreement (Attachment A02)

Standard Operating Procedure

1. All visitors and observers must have a Sponsor who will escort and conduct tour on unit.
2. Sponsor must obtain approval of visit dates, times, duration and location from the Nurse Director (or covering manager) at least 24 hours prior to visit.
 - a. Sponsor must follow up with a booking request to add to Catalyst Schedule program.
3. Sponsor is responsible for securing completion of Observer Agreement forms and arrangements for Temporary ID badge (obtained from BWH Security) or Visitor pass (obtained at Security desk at 75 Francis Street entrance), if applicable.
4. Observers and Visitors who remain on a CCI research unit for more than 2 hours must wear Visitor Pass visibly.
 - a. BWH Temporary ID is required by BWH for observers/visitors with extended stay at institution of 1- 3 months.
5. Visitors: Must complete Visitor Confidentiality Agreement
6. Observers: Must complete Observer Agreement
7. Sponsor is responsible for reviewing and instructing the Visitor/Observer on confidentiality, environmental safety, and hand hygiene prior to entering unit.
8. Sponsor must check with staff member at start of tour to ensure that research staff has been able to complete procedures to ensure confidentiality and safety.
9. Visitors: Must be escorted by the Sponsor on the unit at all times.
10. Observers: With prior approval of subject and investigator/Project Leader may stay on unit to watch procedures without Sponsor's presence.
11. The Nurse Director and/or CCI leadership reserve the right to revoke Observer/Visitor privileges at any time due to operations of unit, and safety of subject, or staff or for data reasons.
12. Observers touring CCI units for more than 2 weeks must be onboarded by the BWH Office of Sponsored Staff and Volunteer Offices (see OSSVS link above)
 - a. Schedule a New Sponsored Staff Orientation by sending the following to bwhoss@partners.org
 - i. POI form
 - ii. Copy of a government issued photo ID (passport, Driver's license, school ID w/ Birth certificate for minors)
 - iii. Quick Registration form
 - iv. Confidentiality agreement

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- v. Immunization records
- b. Complete assigned HealthStream modules and attend NSS Orientation
- c. Be cleared by Occupational Health
- d. If the Observer getting onboarded is a minor (age 16/17), s/he will also need to submit the following:
 - i. A complete and signed work permit
 - ii. Medical Screening Minor Consent Form
 - iii. Consent to Evaluate and Treat Minor Form
 - iv. Laboratory Minor Consent Form
 - v. CORI Parental Consent Form

Special Notes

N/A

Allowable Exceptions

N/A

Attachments

A01 – Visitor Confidentiality and Non-Discourse Agreement

A02 – Observer Agreement



BRIGHAM AND WOMEN'S HOSPITAL

Center for Clinical Investigation
in partnership with Harvard Catalyst

VISITOR CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

This Visitor Confidentiality and Nondisclosure Agreement is made by the individual whose name and address is set forth below. This Agreement applies to any information obtained by Visitor while at the Brigham and Women's Hospital Center for Clinical Investigation.

Confidential Information includes, but is not limited to: (a) clinical medical records; (b) doctors' study orders; and (c) private communication between investigator/study team and study subject

The visitor shall hold all confidential Information in confidence, and shall not disclose any Confidential Information to any other party or person with a "need to know" during his or her time at the Brigham and Women's Hospital Center for Clinical Investigation. *

If there is any question about information that is obtained or inferred during the visit, the Visitor will address a Center for Clinical Investigation staff personnel.

Visitor Name: _____

Signature: _____ Date: _____

Study Team Contact: _____ Number: _____

Study Team Group: _____

Please provide a copy of this form to Sheila Driscoll, Nurse Director and Yemi Talabi-Oates, Administrative Director

* Unless required by law.



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BRIGHAM & WOMEN'S HOSPITAL, INC.

OBSERVER AGREEMENT

The Brigham & Women's Hospital ("BWH") has a legal and ethical responsibility to safeguard the privacy of all patients and to protect the confidentiality and security of its health information. Outside persons requesting access to patient care interactions at BWH must agree to certain obligations with respect to information disclosed to them while at BWH, including but not limited to patient health information disclosed in the course of patient care.

Understanding the above, by signing this document, I agree to the following:

1. I agree not to access any information other than that which I am specifically permitted to access.
2. I will not disclose to any third parties any patient or other proprietary information I learn during the course of patient care to which I will have access, or which I otherwise learn at BWH, and will not discuss such information with anyone except in connection with discussions that I may have with BWH individuals involved in the care.
3. To the extent I am permitted to access written information, I will return all such information at the conclusion of the observership and will not make any copies or otherwise remove the information from the premises.
4. I will comply with all applicable policies of BWH, including infection control, safety, confidentiality and security policies.
5. I further understand that BWH may in its sole discretion deny or revoke permission granted to me to access health information.

Signature

Date: _____

Print Name

BWH Sponsor/Supervisor/Contact

Title

Name of Company/Hospital/ Institution

Department Contact Phone with which affiliated