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CCI Research Clinical Operations Team

center for clinical Investigation

Study Team Guide to Using CCI Clinical Research Resources in a Care Safe Research Environment

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Clinical Research Visits in the CCI

GUIDANCE TO RESEARCH TEAMS

JUNE 26, 2020

# Introduction

The CCI is fully re-opened in support of clinical research visits. As of June 22, all units are operational, staffed and supporting visits. In accordance with BWH COVID-19 recovery guidance, the CCI has adapted operational space, staffing, and processes. This guide is intended to advise and inform research teams of CCI operational approaches and expectations for research teams, CCI staff and subjects working in or using CCI facilities.

# Shared Responsibility for a Safe Research Environment

We are committed to offering research teams, subjects and our staff a COVID-19-safe environment for conducting clinical research activities. That commitment requires a collective effort from both study team members and CCI staff. Research teams using CCI facilities will assume shared responsibility to ensure a safe work and research environment, which includes requirements to screen subjects, ensure social distancing and clean spaces and equipment used in a visit. CCI staff will also conduct front desk screening, remind everyone to abide by social distancing guidelines and on an hourly schedule, clean outpatient clinic common areas, frequently touched surfaces, and exam rooms.

# Clinic and Exam Room Cleaning

Based on BWH policies, the CCI has adopted cleaning protocols for common use areas of the clinic, the lab and exam rooms.

* Per existing policy, study teams remain responsible for cleaning rooms and resources used in a visit at the conclusion of the visit.
* CCI staff will clean the clinic common areas and exam rooms on an hourly basis.



Exam room cleaning checklist

(Click to open)

By using the room, study team members agree to clean the facilities used and sign off on the room cleaning log at the conclusion of each visit. Cleaning checklists have been posted in each exam room. Cleaning supplies are provided in each exam room. **At the end of each visit, the study coordinator should use the checklist as a guide to thoroughly clean the exam room and equipment used and sign the cleaning attestation log posted in the exam room.** If you need time added to your templates for cleaning, please submit the request to CCI@bwh.harvard.edu. If CCI staff observe that a room was not cleaned, or the cleaning was not logged, the CCI staff member will clean the room and adjust visit check out times to account for CCI staff room cleaning time.

CCI staff have a checklist for the common areas and labs that will be used for hourly cleaning at each clinic.

These stringent cleaning protocols are critical to maintain a safe care environment for your research team, CCI staff and research participants.

# PPE

CCI will provide standard supplies for research visits as we have in the past. Research subjects should receive masks when entering BWH building. Research study teams are expected to bring their own supplies including any required PPE. The BWH ordering process is being adjusted, but study teams can access PPE supplies via the BWH research ordering process, described here:

**New PPE Ordering Process for Research**

June 24, 2020

BWH Research Community,

Due to the continued instability of the PPE supply lines, we are using a temporary online order form to fulfill PPE requests. These requests are for weekly PPE needs including procedure masks, surgical masks, gloves, hand sanitizer, disinfecting materials, flu swabs, viral media and gowns. This process will also cover requests for N95s and face shields however, please be aware of the following limitations as related to these items:

* N95s:warranted if working with confirmed COVID person or for research involving an aerosolizing procedure (OHS to review and approve requests)
* Face Shields: warranted for the following three scenarios: (1) a large splash risk is expected; (2) during AGPs (aerosol generating procedures); or, (3) if both eye and mask protection are needed and goggles don’t suffice

**The Process:**

* Complete the [link survey](http://r20.rs6.net/tn.jsp?f=001nZeQAsvrSRygF2xIWnThsItR5S8neGjjgU-5qQqjZROX7a43m13i2elXluQWhSmf7I3htCn4L96bX2tufO7gUAcHosJNuPwSm-y5W14DrgFQBnc4RRWW5r0gUd6rMXOvkYG03MBlk6dQhOtDXkxvFl9LEauuI0u9HpzKsspaqdDjTI4OAzGkMvlb1oemMl_Ppq4LqmvEBOAYoJHzXuWIjIph3VxYirSAoDoIzLspcBjBeyDZdts4ptBxPk7sED4TiVx2HA8gQQ3K3bIZ3gfNgi3ycS0XljRoO8tghSDdqiDnlQYzKmxbiQ==&c=tbwq-Nlq9QzAMLRSEq0XWz1uNFsH6rP-35Hd1FenEAxE9mDBNedofg==&ch=hGfovP1y64NmEUrHQ9SYTeeX_cb6GDRfjlV7xE4BKimgNFG0-LxUBA==) each week before Tuesday @ 11AM (reminders will be sent out each MON)
* The order will then be sent to Research Operations for review
* Should there be questions on the order as related to size/scope, Research Ops will reach out
* Research Operations will then send orders to Materials Mgt for delivery later the same week to the address identified by you in the link survey

# BWH and CCI visitor policy

CCI will follow the BWH visitor policy.

## <https://hospitalpolicies.ellucid.com/documents/view/2498/active>

Recent updates (June 10, 2020) to the policy can be viewed here:

## <https://www.bwhpikenotes.org/news/memos/documents/VisitorPolicyUpdates.pdf>

Inpatients will now be allowed one healthy adult visitor between the hours of 1 - 8 p.m.

* All visitors will be screened. Screening must be complete by 7 p.m., one hour prior to the close of visitor hours.
* We encourage visits to be less than 2 hours in duration.
* Exceptions can be made for end of life circumstances, pediatric patients or at the discretion of nursing/clinical leadership.
* All visitors are required to wear masks at all times.
* To minimize the risk of spread of infection, COVID positive patients cannot have visitors.
* PeriOp patients may have one visitor who can drop them off, wait with them until they are ready to enter the procedural area, and pick them up post-procedure.
* PeriOp visitors are not allowed in the pre-op or PACU areas.
* All visitors will be screened and are required to wear masks at all times.
* We are working on a pass system to make it easy for these visitors to return for patient pick-up.

ED and Ambulatory patients cannot have visitors to ensure we can meet our Safe Care Commitment standards of physical distancing in areas with space limitations.

Local leadership will review exception requests using the existing process. Anyone with an approved exception should tell screeners at front door that they were approved to have a visitor. All visitors will be screened. If visitors that are not included in the exceptions arrive without prior approval, they will be asked to leave the clinic.

Mother and Infant studies will be allowed with both participants. Subject should notify staff at hospital entrance that visitor was approved.

# Subject Infectious Disease (COVID-19) Screening

All outpatient subjects should be screened for infectious disease 24 hours prior to the visit. BWH Ambulatory’s most recent Infectious Disease Screening Guide should be used for screening. Inpatient subjects should also be screened and will be required to have a negative COVID-19 test. (See section on Testing.)

Study teams should advise subjects that screening will occur several times prior to the visit and the day of the visit. Study teams should follow screening requirements set by the study for recruitment and BWH for all in-person visits. All outpatient visits are required to screen subjects for COVID-19 within 24 hours prior to visits at BWH. Subjects will then be screened upon entrance to BWH buildings per current guidelines and again at the check-in desk of CCI clinics. Any visitors will also be screened. Although multiple instances may seem inconvenient, this BWH policy must be adhered to for the safety of all persons in the clinic space.

Please refer to the most recent BWH Ambulatory Infectious Disease Screening guide.

## [BH Ambulatory Infectious Disease Screening Worksheet](http://sharepoint.partners.org/bwh/practicemanagersgroup/Shared%20Documents/Ambulatory%20Recover%20Links/BH%20Amb%20Infectious%20Disease%20Screening%205_15_20.pdf)

# Research Subject COVID-19 Testing

All inpatient subjects will need to be COVID-19 tested with negative results prior to their admission. Study teams are responsible for ensuring subjects have been tested and negative results can be reviewed in EPIC prior to admission.

1. **Test within 72 hours and prior to admission**

COVID-19 RT-PCR test orders should be entered within 72 hours prior to admission.

When submitting the order in EPIC, you MUST include:

* The indication for patient to be tested (eg, Planned admission to / approved procedure at Partners facility)
* The date of the admission
* An ordered test will then be referred to the Access Center who can schedule the patient for ambulatory testing at one of several sites
* It should be associated to the study protocol
* Study team staff are responsible for ordering, reviewing the results of the patient
1. **Test day of admission**

If tests are not conducted within 72 hrs in advance, and the subject has been screened with negative results, BWH policy may allow for a test to be ordered and conducted the day of admission. It is the responsibility of the study team to ensure this option is viable and to order the test. This will potentially result in several hours of waiting time for the subject. For tests conducted the day of admission, all intervention procedures will not begin until the negative result can be reviewed in EPIC.

The same process (from previous paragraph) should be followed for ordering COVID-19 RT-PCR in EPIC.

1. **Test outside of BWH**

COVID-19 tests should be conducted within 72 hours prior to the patient’s admission to ensure timely scheduling, testing, and resulting. External tests should be validated assays and standard training testing samples, nasopharyngeal swabs.



(CLICK ON THE PDF TO OPEN)

EPIC Tip Sheet “Entering External COVID-19 Results”

Study teams are responsible for entering the test results in EPIC so they can be reviewed in EPIC prior to subject admission or procedures.

EPIC Tip Sheet “Entering External COVID-19 Results” defines this process.

If a patient test positive, the study team is responsible for cancelling the visit or rescheduling a new subject. Please work with our Nurse Manager to adjust visit times if you need to change subjects/dates/times.

**Brigham Health Testing Locations**

<https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/testing_locations_and_respiratory_illness_clinics>

**Testing Center Changes Effective Monday, June 15**

Some BWH testing capabilities have been moved to new locations. Starting Monday, June 15, the BWH Ambulance Bay and BWFH drive-in testing locations will be closed, and a new drive-through testing site will open at 1245 Centre St. in West Roxbury near BWFH. Patients can also be tested by appointment at Partners Urgent Care locations in Natick and Brookline. No walk-in testing is available. Providers who are approving tests will continue to use the existing workflow to enter an order, and the scheduling team will contact the patient. Testing will be available seven days a week at all three locations.

# Visit Scheduling

## Outpatient and Inpatient

Please use the traditional CCI scheduling process to schedule either outpatient or inpatient visits.

<https://hccrc-bwh.partners.org/scheduler/>

If you have difficulty scheduling, please submit an overbook.

<http://cci-webservices.dipr.partners.org/Scheduling_Support/Scheduling_Support.html>

Some inpatient CCI staff are training offsite through mid-July, which may affect availability during that time. Scheduling capacity will be in accordance with distancing requirements in each clinic. If you have any questions, please reach out to us at BWHschedulingcci@bwh.harvard.edu.

## Aerosol Generating Procedures

If your visit will include aerosol-generating procedures, please contact us at 617-732-8750 or CCI@bwh.harvard.edu prior to scheduling. Per BWH policy, all patients receiving aerosol-generating procedures will need to be tested for **COVID-19 tested 72 hours in advance.**

Partners has posted information governing aerosol procedures:

## <https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/use_of_aiirs_or_standard_rooms_for_agp>

# Outpatient Visit Orders Electronic Signature

To reduce personal interactions in the check-in and waiting areas of the clinics, CCI is encouraging use of electronically signed orders for outpatient visits. This does not apply to inpatient visits. Once study orders are approved by the CCI, each subject’s visit orders may electronically signed and submitted via email.

* Study orders must be signed by the study investigator for each visit.
	+ The investigator signing the Lab orders should be either a PI or co-investigator on the study.
	+ Study MD or licensed independent practitioner (LIP) is required to sign on the research study orders.
	+ All study orders should include a responsible physician who is available to answer questions about the study or the study participant during the study visit.
* Study orders can be signed either electronically or using wet-ink signature.
	+ For electronic signatures, platform such as Adobe is preferred.
	+ All signatures, including electronic signatures should only be performed by the licensed study staff member.
* Authentication can be verified through (per Electronic Signature/Authentication Policy PH 144)
	+ electronic signature (whereby the author must click a button to affirmatively accept, verify or electronically sign the entry) (used for electronic notes, operative reports, discharge summaries, and information entered through dictation),
	+ written signature or initials, or
	+ the network/system logon process whereby one’s identity is authenticated upon entering his/her unique user ID and password, that identity is captured, recorded and attributed to entries made for the duration of the session.

## Submit electronically signed orders

Orders should be submitted via email and then the study team should open the visit in Scheduler and add a visit comment that states that orders were electronically signed and submitted.

* Lab orders can be submitted to: bwhccioutptlab@partners.org.
* Inpatient orders can be submitted to: CCI9ABorders@partners.org.
* Visit orders for RN, NP or PA can be submitted to: cciadvancedoutptservices@partners.org.
* Nutrition orders can be submitted to: ccidietary@partners.org

# Visit Day

CCI will follow BWH clinical ambulatory and inpatient policies as they apply to research.

Mask Policy

Everyone in CCI clinic spaces is required to wear a mask. For outpatient visits, all staff, research participants and study staff are required to wear BWH provided face masks for the duration of the visit. For inpatient, all BWH, CCI and study team staff must wear BWH mandated masks and participants must wear masks when staff are in the room.

<https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/universal_mask_policy>

## Visit Day Guidance

Prior to visits, study teams should advise subjects on the most current BWH guidance for in-person visits.

* Subjects should bring minimal personal items to clinical visits to limit exposure.
* BWH’s current visitor policy does not allow for visitors to accompany outpatient subjects, with exceptions for special conditions. Anyone with an approved exception should tell screeners at front door that they were approved to have a visitor.
* Study coordinators and subjects should arrive on-time for visits. Anyone arriving too early may be asked to leave the clinic and return at the scheduled appointment time.
* Food that is not part of the visit should not be consumed in the clinic.

## Maximum Clinic Capacity

Clinic maximum capacity is anchored on waiting area/exam room capacity (one research visit per exam room at max capacity). Research visits are gradually returning to normal operational levels. As visit load grows, CCI will iterate capacity planning to ensure distancing requirements.

## Check-In and Check-Out

CCI front desk staff will screen participants and direct each to the exam room as soon as possible to reduce personal interactions.

Exam rooms, waiting rooms, elevators, and other spaces will be marked with social distancing recommendations (maximum capacity, foot traffic flow, “do-not-use” equipment). Please observe and follow all recommended social distance practices in the clinic. CCI staff are expected to observe anyone in CCI space and remind and encourage compliance with guidance.

Study team members should clean the exam room according to the checklist and attest to the cleaning by signing the cleaning log.

Please follow CCI check-out procedures to let the front desk know that the room has been cleaned and the subject is departing the clinic.

# Working Together

Our goal through re-opening and beyond is to help research move forward in a safe care research environment. Inconvenient processes and unexpected challenges will undoubtably emerge as we implement new guidance and safety measures. We look forward to working together to tackle the challenges and enable new approaches to research in these uncertain times.

Thank you for your patience and partnership in providing a safe care research environment.

Please let us know if you have any questions:

Phone: 617-732-8057

Email: cci@bwh.harvard.edu

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# CCI CLEANING CHECKLIST

|  |  |
| --- | --- |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Room #: \_\_\_\_\_\_  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SURFACES[[1]](#endnote-1)** | **CLEANED** | **NOT CLEANED / NOT USED** | **NOTES** |
| **Chairs**[chair arms, desk chair, exam chair, stool, etc.] |  |  |  |
| **Door Handles**[both sides] |  |  |  |
| **Cabinet Area**[counter tops, cabinet and drawer handles, sink] |  |  |  |
| **Tabletops**[desk, exam table, any table surface] |  |  |  |
| **Computer**[keyboard, mouse, printer etc.]  |  |  |  |
| **Hand Sanitizer**[bottle or dispenser] |  |  |  |
| **Light switch** |  |  |  |
| **Call button** |  |  |  |
| **Phones**[headset, keypad, cord, etc.] |  |  |  |
| **Pens**[any writing implement]  |  |  |  |
| **Clipboards** [any surfaces used for writing]  |  |  |  |
| **Bed** (if used)[replace sheet, replace pillow case, drawer) |  |  |  |
| **Reusable Medical Equipment**[[2]](#endnote-2)[Dinamap and blood pressure cuffs, exam tables, phlebotomy chairs, EKG Machine, etc.] |  |  |  |

1. Use Virex wipes instead of a Purple Top Wipe [↑](#endnote-ref-1)
2. Any Medical equipment that directly encounters a patient/subject skin needs to be cleaned with purple top wipes [↑](#endnote-ref-2)