

Clinical Research Coordinator Handbook 2016



**Boston
Children's
Hospital**

Until every child is well™



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Acknowledgement:

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I. Introduction and Welcome

What is the role of a Clinical Research Coordinator?

The clinical research coordinator (RC) plays a vital role in the research study. Although the Principal Investigator (PI) is ultimately responsible for all aspects of the conduct of a research study, the PI can delegate various tasks to others on the research team, many of them to the RC. The RC carries forward the research goals thereby playing a significant role in the success of the study. Most importantly, RCs are often involved in essential duties that ensure compliance with the protocol and protection of human subjects. Although not exhaustive, some of the RC responsibilities include preparing the Institutional Review Board (IRB) submission, writing the informed consent document, recruiting and consenting participants, coordinating and conducting study visits, adverse event reporting, completing case report forms (CRF's), managing data and collecting biological specimens. Clinical research requires teamwork, which is crucial for its success. Ultimately, the clinical research at Boston Children's Hospital will likely play an important role in helping us better understand the causes of various diseases and finding therapies that can prevent and treat them, ultimately improving the health and well-being of children.

How do I use this handbook?

The hospital has many resources at your disposal that may be overwhelming to navigate at first. This handbook is intended as a resource to help you locate some of the important information needed in your role. It is organized alphabetically. If more information on a topic is needed, each section will include where to find it in the Children's system.

Values

Curiosity ▪ *Excellence* ▪ *Honesty* ▪ *Integrity* ▪
Accountability ▪ *Transparency* ▪ *Team Work* ▪ *Respect* ▪
Diligence ▪ *Flexibility* ▪ *Shared Learning*

II. Clinical and Translational Study Unit (CTSU)

The CTSU is the hospital's central location where clinical research visits are conducted. The CTSU website with contact and more detailed information about its policies and procedures can be found at <http://chbportal.tch.harvard.edu/ctsu/>. The CTSU also has a manual which can be found at <http://chbportal.tch.harvard.edu/ctsu/mainpageS2803P81.html>. Always check these sources to make sure the information you have is up to date as things changes frequently.

A. Outpatient study visit appointments

All CTSU clinic/outpatient appointments are scheduled through the Harvard Catalyst Scheduling System, the Scheduler. To get access to the Scheduler, contact Tina Kim at tina.kim@childrens.harvard.edu or a CTSU administrative coordinator. The Scheduler allows you to schedule your own appointments on the CTSU except for the following:

- DXA – contact [Kimberley Mitchell](#)
- CAT/CR – call ext. 5-6235
- Visits at Waltham – email [Michelle Gouthro](#)
- Inpatient stay requests – ctsubooking@childrens.harvard.edu (see p. 8 of CTSU manual for information.)

It is important to keep open lines of communication with the CTSU nurse assigned to the study to properly coordinate the study visit. Before a study visit can be scheduled for a patient on the CTSU, you must have:

- IRB approval for the protocol
- A CTSU implementation sheet that has been reviewed and signed off
- The study billing information added into EPIC based on the Study Tracking Sheet (STS) (the CTBO does this *See Research Finance Section, STS for more information*)
- Study orders that have been reviewed and approved by the CTSU study nurse and the study PI (*see Physician Orders section for more information*)

The CTSU days of operation are Monday through Friday and two Saturdays per month. The hours may change so please check their website for the most up to date information:

<http://chbportal.tch.harvard.edu/ctsu/mainpageS2803P59.html>

B. Overnight stay study visit booking (6 East)

For studies requiring overnight stays, the overnight visit can be book through the CTSU. The subject stays on 6 East but the booking happens through the CTSU.

To book an overnight stay, e-mail CTSU-booking with the following information:

- Patient MRN, Name, and DOB
- Visit #/Name
- EPIC Visit Type/#
- Protocol # (*IRB number*)
- PI/Attending Name
- Arrival Date/Time and Discharge Date/Time
- Scheduling Notes (Specific room/nursing time)
- Does the subject have any special needs?
- Does the subject require supplemental oxygen? If yes do they use it during the day?
- Does the subject have a tracheostomy tube (trach.)?
- Does the subject require the use of a ventilator or other assistive devices to breathe?
- Is the subject wheelchair bound?
- Does the subject have cystic fibrosis?
- Has the subject had any infections that would require special precautions?

C. Fast-track phlebotomy at CTSU

Phlebotomy is available at the CTSU in 15 minute increments and up to within 15 minutes of when the appointment is needed if this requires less than 24 hours notice. Appointments can be booked through CTSU booking processes. For appointment requests with greater than 24 hours notice, email CTSUbooking@childrens.harvard.edu. For appointment requests with less than 24 hours notice, please call ext. 57861 or (617) 355-7861 to book the appointment.

D. Clinical Lab Tests

Sometimes your study visit may coincide with a clinical visit for a patient. If the patient has clinical labs that were ordered by their provider and still active in Powerchart that they need drawn at the same time as the CTSU visit, the CTSU will draw those labs. To find out if a patient has clinical labs needed you can check PowerChart under "Lab Orders."

E. Physician Orders

Physician orders are required for any test, procedure or assessment performed on a patient in the CTSU. The writing of Physician Orders is a patient care activity that should be confined to licensed, credentialed healthcare providers. Please note that study coordinators are **not permitted to write or modify** physician orders. Orders for a study are created with the help of CTSU nursing during the study implementation process (refer to the CTSU manual at <http://chbportal.tch.harvard.edu/ctsu/mainpageS2803P81.html>). Orders specific to the visit should be completed and signed by the investigator and submitted to the CTSU a week before the study visit.

Tip Complete the name, MRN and study ID on the order form to identify the study subject for whom the order is intended. Leave the rest blank for the physician to complete.

Include copies of pertinent lab and other test results (copies of source documents) with the order for reference (e.g., if orders are dependent on results for an earlier visit, have them handy for PI review prior to signing orders).

F. Specimen Storage

The CTSU can only provide short-term storage for specimens for up to two weeks. Longer-term storage must be arranged by the study team. The BCH Biobank Core can provide long term storage at a cost. (See section XIII. Part E)



III. Clinical Research Informatics Technologies

The clinical research informatics team (CRIT) at BCH supports a variety of technologies for researchers described below. A request for support can be submitted at https://redcapi.tch.harvard.edu/redcap_edc/surveys/?s=I9H9JXHWyX . Training is also available for various tools such as REDCap and i2b2 and is highly recommended.

A. Patient 360

Patient 360 is a data warehouse that extracts information from PowerChart, EPIC and other hospital systems and makes it possible to do complex searches to answer specific research questions. Because it is patient information, access to Patient 360 has to adhere to the same HIPAA rules that safeguard Protected Health Information (PHI). Therefore, access to the data is restricted and managed by CRIT.

B. i2b2

i2b2 is a system through which researchers can query the data warehouse for exploratory purposes at the aggregate level without access to PHI. Through i2b2, researchers can run queries to explore questions such as the number of patients that meet their protocol's study inclusion and exclusion criteria to assess feasibility .

Note!

Once a protocol has IRB approval (proof required), some data may be directly extracted from the data warehouse and saved directly into an Excel file or into REDCap, eliminating the need to manually extract the information from patient's charts and saving time. Discuss this possibility with CRIT when planning your study.

C. REDCap and InForm Data Capture Tools

CRIT offers support for data capture and storage tools for your study data. InForm is used for studies that require compliance with FDA regulation Section 21 CFR, Part 11.

D. SharePoint and Open Atrium

An internal SharePoint site (only accessible within the BCH firewall) or "Open Atrium" (an external site that can be used for multi-site studies or when external collaborators need to access study related documents) are tools used to store, share, and manage study documents with research teams.

IV. Clinical Research Center

The Clinical Research Center actively supports one of the core missions of Boston Children’s Hospital, to be the leading source of research and discovery. The CRC directly contributes to the advancement of science and patient care and changes in clinical practice by focusing on support for clinical research methodology and providing assistance with research project design, implementation, conduct , and analyses as well as education on research methods and practices. At the CRC, there are biostatisticians, project managers, research specialists, clinical trials specialists, research coordinators and highly skilled nurses and nurse project managers who work every day to facilitate the many research needs of the BCH community.

Researchers can go to <http://www.childrenshospital.org/research-and-innovation/research/clinical/clinical-research-center> to submit a request on-line for services or a one hour consultation.

V. Clinical Research Map

The Clinical Research Map is designed to serve as a guide for investigators, study coordinators, and research nurses at Boston Children’s Hospital. The research map outlines the key steps in preparing to launch a research study and provides embedded links to institutional resources, tools, and documents.

You can view the map here:

[http://web2.tch.harvard.edu/nursing/Documents/Clinical%20Research%20Map%203_5_2012.pdf#search=%22clinical research map%22](http://web2.tch.harvard.edu/nursing/Documents/Clinical%20Research%20Map%203_5_2012.pdf#search=%22clinical%20research%20map%22)



VI. ClinicalTrials.gov

A. Registration Requirements

Some studies require registration through ClinicalTrials.gov. Most investigators are aware of this and should familiarize themselves with the requirements to register in order to meet FDA regulations and ICJME publishing requirements. However, it is important that you talk with your PI about it to make sure s/he has addressed it.

Note!

An overview of ClinicalTrials.gov registration requirements is available as a PowerPoint presentation on the IRB's website through the ClinicalTrials.gov: Review of Registration Requirements link at <http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation>

B. Registering a study

To register a study or make changes to the record, you have to have a ClinicalTrials.gov account. Accounts are obtained through Irine Breytberg at Irine.breytburg@childrens.harvard.edu.

Since the person who creates the initial registration record becomes the owner of the record, it is best that your PI initiate the registration and then grant you access to edit, complete and update the registration. Irine can help the PI complete these tasks if they don't know how. This record needs to be updated annually and closed out when the study ends.

For detailed information, go to the "Click here for more information" link on the BCH ClinicalTrials.gov Registration page at <http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/information-for-researchers/clinical-trials-registration>

Note!

The trial registration site is different from the informational site where a patient may go to look for a trial.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS). CMB NO: 9925-0246 EXPIRATION DATE: 10/31/2015 [Business Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

Registration site
<https://register.clinicaltrials.gov/>

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. [Learn more about clinical studies and about this site, including relevant history, policies, and laws.](#)

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

ClinicalTrials.gov currently lists 200,937 studies with locations in all 50 States and in 190 countries. Text Size

Search for Studies
Example: "Heart attack" AND "Los Angeles"

Advanced Search | See Studies by Topic | See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies

- Non-U.S. Only (64%)
- U.S. Only (41%)
- Both U.S. and Non-U.S. (8%)

Total: 38,883 studies (Data as of October 21, 2015)

- See more trends, charts, and maps

Learn More

- Tutorials for using ClinicalTrials.gov
- Glossary of common site terms
- For the Press
- Joining our RSS Feeds

For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more...

For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more...

Informational Site
<https://clinicaltrials.gov/>

VII. Financial Considerations

A. Study Participant Incentive and Reimbursement Methods

ClinCard is one type of payment method (incentive or remuneration) for patients participating in research. For information about its use, email RFHelp@childrens.harvard.edu. Other gift card methods are possible, but this offers safe and direct withdrawals from the BCH research fund.

Where can ClinCard be used?

- -In-store purchases (as a Credit or Debit card)
- -Online purchases
- -ATM withdrawals
- -Cash advances

What are the benefits for Research Sites/Study Coordinators?

- -Replace manual processes and eliminate paperwork
- -60% reduction in patient payment costs
- -90% reduction in payment administration for: Clinical Teams and Site Coordinators
- -Risk Reduction: Authorized Client Approvers release patient payments globally
- -Payment Execution Centralization: A single solution for diverse payment processes
- -Increase Patient Retention by 17%

What are the benefits to Research Subjects?

- -\$0 activation or user fees incurred when using the card
- -Real-time payments made from Research Sites to Subject's ClinCard
- -Use ClinCards worldwide, wherever MasterCard is accepted
- -Can be reloaded by research site at any time
- -24 Hour Customer Service is available
- -ClinCards can be replaced, at any time, if lost, stolen, or damaged



B. Parking Vouchers

Studies frequently pay for the patient's parking if they are coming in for a study visit. You will need to order parking vouchers from the parking office ahead of time. They are \$10 each and come as small yellow stickers that the patient's place on their parking ticket. When the patient leaves they must show the ticket and sticker to the cashier in the Patient Family Garage. To order parking vouchers for a study, e-mail parking@childrens.harvard.edu with the number of vouchers needed, the PI's name, the study name, and the study fund number. It typically takes a week for the parking office to get the vouchers ready. They will e-mail you when the vouchers are ready for pick up.

Tip: Parking vouchers are only available for the Patient Family Garage (the one directly across from the hospital) so it is a good idea to let your subjects know where to park.

C. Patient Billing Inquiries

Patients should not be billed for research visits or procedures. *See STS Forms below.* Sometimes mistakes happen, and it is best to take care of these immediately. For any questions, contact research finance at ResearchFinance-dl@childrens.harvard.edu. For FAQs on billing and research finance visit: <http://web2.tch.harvard.edu/finance/mainpageS2601P85.html#Q83>

D. Remuneration Logs

If you are giving cash or gift cards to subjects for participation in your study, you will need to complete a remuneration log and have the subject sign. For studies using cash payments to subjects, email a scanned copy of the log to the research finance office. For studies that provide subjects with gift cards or other forms of payment, retain the logs. Remuneration logs can be found at: <http://www.childrenshospital.org/research-and-innovation/research/research-administration/equip/remuneration-tracking>.

Tip: Due to confidentiality, subjects cannot see other subject's signatures. You will need to either cover up the previously filled lines of the log, or print a new log for each subject. You can have multiple logs per study.

E. Study Tracking Sheets (STS)

A STS is created to ensure research visits/components are billed to a study account and **not** billed to a patient's insurance. The billing is done in EPIC when, at the end of a CTSU visit, the CTSU staff enters the charges in EPIC and Patient Financial Services moves the charges to research, preventing them from being charged to the patient's account or medical insurance. The study team is responsible for working with Clinical Trial Business Office (CTBO) to develop an STS. An STS is created or used under the following scenarios:

- If a visit is "All Research"
- If a visit is "Mixed" (part research and clinical), a STS is created for **only** research components.

- If a visit has labs for research **and** the labs are being sent to the BCH lab, these should be put on the STS

An STS is **NOT** created if a visit is “Clinical” . If a visit has labs for research and the labs are being sent to Lab Corp (these labs are specific to the CTSU only), then they should **NOT** be put on the STS.

The CTBO is the keeper of all Study Tracking Sheets. The study coordinator needs to work with the PI and CTBO to develop and finalize the STS and needs to contact CTBO when any updates need to be made to the STS. After approval by the PI and the CTBO, the study coordinator should ensure that the the CTBO notifies the IRB and sends it to Patient Financial Services (PFS DL) so the study coordinator can put the protocol, PI, fund number, etc. into EPIC. The CTSU cannot schedule an appointment without this protocol information in EPIC. If changes are made to an STS, email the CTSU administrator with the most up-to-date approved version.

NOTE! If a STS is not accurate or not created, Patient Financial Services has no way of knowing that it is a research visit and the patient will inappropriately receive the bill.

VIII. Harvard Catalyst

Harvard Catalyst is funded by an NIH grant, which provides resources, funding, education and training to junior investigators and teams. It also is a major funding source for the CTSU. Some BCH investigators are eligible to receive Catalyst support for their studies (usually junior investigators and fellows).

Studies that intends to use any Catalyst supported service (e.g. CTSU, support of coordinator and/or project manager hours) must submit an application to Harvard Catalyst for review. If the PI had not submitted the protocol to Harvard Catalyst prior to IRB submission, when you select CTSU resources in the IRB submission Smart Form on CHERP, the IRB will alert you that Catalyst approval is needed prior to IRB approval.



For more information about eligibility for Catalyst funding and how to access it, see the CTSU manual at <http://chbportal.tch.harvard.edu/ctsu/mainpageS2803P81.html>.

For more information on the training and education offerings, visit the Harvard Catalyst website: <http://catalyst.harvard.edu>.

IX. Hospital Resources

A. Interpreter Services

When dealing with a patient or study participant who does not speak English, you must arrange for interpreter services. Boston Children's Hospital strongly discourages the use of untrained, ad hoc interpreters (e.g., family members, relatives, friends, bilingual strangers, other patients, or non-trained bilingual employees). Hospital staff must also refrain from encouraging the use of family members for interpreting, and are prohibited from using minor children as interpreters.



Advance notice is critical for ensuring an interpreter is available. To request interpreter services for Outpatient appointments, you can choose to:

- complete the Interpreter Request Form at http://chbportal.tch.harvard.edu/interpreter_svc/mainpageS2776P2.html
- email interpreters@childrens.harvard.edu or call 5-7198

For information on interpreter services visit: http://chbportal.tch.harvard.edu/interpreter_svc/

B. Library

The hospital library is located on Farley 1 and has a wealth of resources. It is open Monday-Thursday 8AM-6PM, and Friday 8AM-5:30PM and can be accessed with your Children's I.D. Meaghan Muir or Jessica LaBrie are the library contacts and can be reached at extension 57462. The library also offers courses on EndNote, PubMed, and Mendeley, has a monthly book club, and has archives of Medical and Management Grand Rounds.

Your Children's ID also allows you access to the Countway Library at Harvard Medical School. With your ID you can enter the library and use their print and electronic resources.

C. Mailroom and Postage Requests

The Mailroom is located in the Fegan basement, RM. FE-007. The mailroom only provides postage for funded projects. All mail that is dropped off must have postage, or a postage request form (with fund to charge listed). For a postage request, fill out a postage requisition form found at (<http://web2.tch.harvard.edu/finance/mainpageS2601P16.html>). Answers for entries 3, 4, and 5 should be confirmed with the Administrative team. Additional information can be found at <http://web2.tch.harvard.edu/supplychain/mainpageS2691P11.html>

or contact the mailroom by phone at 617-355-6591 (internally x 56591) or by email at MailRoomEmployees-dl@childrens.harvard.edu.

D. Outpatient Phlebotomy

Outpatient phlebotomy can be used to collect blood samples for research at no cost. The lab operates Monday through Friday in the main building and at 333 Longwood, as well as at the satellites. For hours of operation and locations visit <http://web2.tch.harvard.edu/labmed/mainpageS2644P42.html> For questions, you can contact phlebotomy at (617) 355-6355.

Any labs that are collected need to have an associated lab slip. If you are working with the CTSU, the lab technicians and nurses will help you set up the lab slips for the study.

If tubes are needed for blood draws either in outpatient phlebotomy or elsewhere in the hospital, the CTSU can provide tubes if these are available.

The lab slip will contain the project fund number and the client code. *See Section XII on Laboratories and Specimen Processing.*

E. Hospital Policies and Forms

The hospital has several policies and forms that are relevant to conducting clinical research and to your work here at BCH. These can be found at: <http://web2.tch.harvard.edu/policiesforms>

F. Shuttles

BCH and LMA run shuttles between hospital locations (Landmark, 1295 Boylston, Waltham) and transportation hubs (North Station, Ruggles Station, BCH parking garages) as well as Harvard Square. Up-to-date information can be found on the Parking and Commuter Services webpage:

<http://web2.tch.harvard.edu/parking/mainpageS2602P16.html>

Note!

A free shuttle runs from Brigham and Women's Hospital to Mass General Hospital all day.



X. Human Resources

Visit the [Human Resources Department](#) on Children's Intranet for all current forms and employee related information.

A. Effort Reports

Effort reports are required of all staff funded by government grants. Since most coordinators are partially funded by a grant, you will likely receive an Effort Report for your review and signature every month. Before you sign your effort report, it is important to look at it carefully and make sure it is accurate. If you have any questions about the report or if you find errors, talk with your supervisor.

For more information on effort reports visit:

<http://web2.tch.harvard.edu/osp/mainpageS2612P24.html>

B. Hospital Holidays

The hospital holidays can be found at:

<http://chbshare.chboston.org/elibrary/hr/tools/ref/refhr/refhr/Forms/Holidays.aspx>

C. Inclement Weather

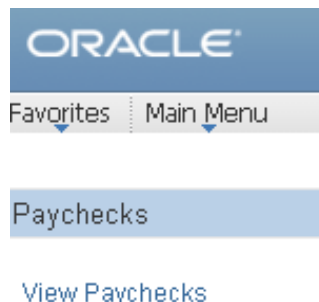
The hospital has an inclement weather policy and administrator on duty that will report on whether individuals are expected to be at work and clinics are open during major storms. Always check with your supervisor if you are unable to be at work due to weather and ensure clear communication with the patient and PI if a study visit is scheduled on that day as it may or may not be able to take place depending on staff availability and coverage.

D. People-Soft

[PeopleSoft](#) allows you to access your pay check stubs and view/change your benefits.

To view your paycheck stubs enter PeopleSoft:

- Choose Employee Self Service on the right hand side.
- Log in with your Children's log in.
- On the left hand side click View Paychecks.



E. Time Sheets

Timesheets are due every two weeks on the Friday preceeding payday and signed timesheets should be submitted to he appropriate administrative person for the Center. They can be turned in as hard copies or scanned and emailed to the administrative person. You will be sent reminder emails for timesheet due dates as a courtesy, but it is your responsibility to get your timesheet signed by your manager and turned in.

If you plan to take time off (vacation, personal, appointments, etc.), you will need to inform your manager in advance and your PI's in order to secure back-up for any study visits or meetings. In case of unexpected absences due to illness or other unforeseen events, notify your manager, study PI and other persons on a study team to ensure adequate back up for study visits or previously scheduled project meetings.

XI. Institutional Review Board (IRB)

The hospital has its own Institutional Review Board (IRB) that is managed by the Committee for Clinical Investigation and which functions to review human subjects protocols. All research done at the hospital must be approved by this board. Visit their website for detailed information for researchers and its policies and procedures at <http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation>

A. CHERP: Children’s Hospital eResearch Portal

CHERP is used to submit human subjects protocols to the IRB for review and track them through each step of the process.

- You will need to complete CHERP training, which can be found in NetLearning (also accessible through the Children’s Today homepage). This is a brief training but is necessary before you can edit the CHERP protocols.
- You will need to be added to any research protocols you will work on with a study staff amendment. This will need to be done by someone who is currently on the protocol. You can ask your PI to give you a list of protocols they are on, so you can ask to be added to them
- Once you log-in, you will see all of the protocols that you are currently on. You can go into each of these protocols and create amendments and continuing reviews, and access the history of the study (past approved protocol versions , amendments, and consent forms).

B. CITI (Collaborative Institutional Training Initiative)

CITI is a series of tutorials on the basics and ethics of human subject research. You must complete this training to be added to BCH protocols.

- Complete the human subjects training at <http://www.citiprogram.org/> . You can create an account using your personal email address, but you will need to enter Boston Children’s Hospital as the Institution and will be prompted to enter your employee ID.
- You will need to complete “CITI Biomedical” training and others as required by the study protocol that you are working on.

C. IRB Visiting Program

The Harvard Catalyst organizes a Visiting IRB program that allows study staff to observe area IRB meetings, including many in the Longwood Medical Area. For more information or to submit a request: <http://catalyst.harvard.edu/services/irb-visiting/>.

XII. Inpatient Units at BCH

Some research may take place on the hospital inpatient units during the patient's hospitalization. This research should always be coordinated with patient's clinical care team. The following is some helpful information when conducting research on the inpatient units.

A. Main Hospital Units

- B Lobby and Emergency Department (ED)
- 1 Pre-Op Clinic and Blood Donation Center
- 2 Outpatient Radiology
- 3 Surgical Suites
- 4 Maintenance/no regular access
- 6 Hematology and Oncology (Heme Onc) and CTSU (Farley/Pavilion Building)
- 7W General Medicine (Gen Peds)
- 7N Neonatal Intensive Care Unit (NICU)
- 7S Medical Surgical ICU (MSICU)
- 8S Cardiac ICU (CICU)
- 8E Cardiac (Cards)
- 9S/ 9W General Medicine (Gen Peds)
- 10 Surgical, Orthopedic, and Trauma
- 11 Medical ICU (MICU) and Intermediate Care Unit (ICP)
- Psychiatry inpatient unit is located on the 5th floor of the Bader Building. Accessing this unit requires special permission.

Generally, the team taking care of the patient will be present near the patient's room. There is a chart on every floor listing all patients' last names, room number, nurse, resident, and attending physician. You should always have permission from the patient's attending physician before enrolling a patient in a study, and from the assigned nurse before going into the room. Due to medical team rounding in the morning, it is better to wait until after 10 a.m. before trying to contact the team or the patient if your studies does not have special time constraints.

B. Precautions

Many patient rooms have a sign on their door detailing special precautions such as Contact, Droplet, Airborne, or Isolation. These precautions are taken when a patient is particularly contagious or has a very fragile immune system. Following precautions protects the patient, the staff, and other patients in the hospital. Specifics of the precaution level will be detailed on the sign (i.e. glove, gown, etc.) and supplies will be outside the door. Feel free to ask the nurse if anything is missing or unclear. Hand washing before and after entering a room is essential with every patient, regardless of whether they are on extra precautions or not.

C. Supplies

Supplies such as bio bags for transporting specimens and specimen cups for urine catch are available on the floors. Bio bags are usually out by the charting area. If a study requires tubes for research only labs, the study is responsible for supplying them. Work with your PI and team to make sure tubes are available and set up before the visit.

XIII. Laboratories and Specimen Storage

A. Hospital Core Lab (Lab Control)

The Core Lab is a division of Laboratory Medicine, a full-service clinical laboratory and transfusion medicine department. See <http://chbportal.tch.harvard.edu/labmed/> for information and documents you will need for research. The lab is located on Farley 7 (x56733). [Mark Kellogg](#) should be contacted to set up any unusual request or special consideration

Research samples can be sent to the core lab for tests that are available. Your PI will need to set up an account to have research only lab samples processed through the Core Lab.

A **Client Code** is needed when a study has labs that are being done at the BCH core lab and needs to be **billed** to a research account (fund number) and **not billed** to patient's insurance. Providing the client code with the order or at the time of the blood draw will prevent the lab costs from being billed to the patient's insurance.

To obtain a client code, you will need to obtain a Research Testing Check-off Sheet for 3000 series from the Department of Laboratory Medicine. For questions or to get started contact:

labmedadmin@childrens.harvard.edu or call x5-6347. Once the form is completed, it will need to be sent to Research Finance (follow instructions on the form). Research Finance will create an account for the lab and you will receive the **client code**. The client code will need to be provided at the time of the blood draw and included on the lab slip for each set of labs.

Reference ranges, CLIA documents and other clinical laboratory related information often required by sponsors can be found at <http://chbportal.tch.harvard.edu/labmed/>



B. LabCorp

The CTSU has a partnership with LabCorp, a lab that offers discounted pricing. The CTSU will send the samples to LabCorp for you. The samples will be sent same day, except for Saturdays, which are sent on Monday. Samples are picked up at the CTSU at 6:00PM.

Labs to be drawn at the CTSU during the visit will have to be included on your Research Orders for the study.

Labs drawn in Outpatient Phlebotomy can also be sent to LabCorp but you will need to provide a lab slip with the tubes to be used to the CTSU lab. You will also need to transport the tubes and samples to and from Phlebotomy and the CTSU.

For more information about using LabCorp through the CTSU, please see the CTSU manual at <http://chbportal.tch.harvard.edu/ctsu/mainpageS2803P81.html>

LabCorp Access: For non-industry studies, your PI will work with the CTSU to set up an account with a username and password. For industry studies, the sponsor will set up the LabCorp account and will give you access.

You can then go to LabCorp's website to access the results:

https://www4.labcorp.com/eResults/Navigation/er_Login.cfm.

Check Results! You have to have LabCorp access and go to their site to access the lab results. These results are not checked by the CTSU. It is the coordinator's responsibility to log into the LabCorp site, access the results, and have the reviewed by the PI in a timely manner.

C. TransLab

TransLab is a BCH lab that can run assays for research or can help with development of new assays. For more information go to <http://translabboston.org/>.

D. Shipping Biological Specimens/Samples

Some studies may require you to ship samples. The procedures for shipping will be study specific and should be outlined in the study manual of operations. Before shipping any specimens/samples, you must complete the Shipping Biological Substances & Dry Ice certification. The course can be found on NetLearning. Frozen samples you will need to ship with dry ice. Dry ice can be found in Lab Control on Farley 7. Their extension is 56351 and they are open Monday-Friday, 7AM-10PM.

E. Biorepository and Specimen Storage

The Biobank Core offers long-term sample storage. An account must be set up for the study to use the biorepository. There are also fees associated with the types and length of storage needed. For more information go to <http://web2.tch.harvard.edu/biobank/>

XIV. Learning Opportunities

A number of learning opportunities are available throughout the hospital. One way to stay informed is to get on the distribution list of research administration for announcements or to check the daily announcements scrolling on the BCH internal homepage <http://web2.tch.harvard.edu/>. In addition, outside agencies offer valuable certifications and the hospital offers potential reimbursement for outside courses.

A. Orientation for New Study Coordinators

A two part, half day course offered by the CRC developed with the purpose to introduce new clinical research coordinators and clinical research assistants to the IRB, consenting and patient interaction policies, and study implementation practices. This course is normally held on the third Thursday and Friday of each month. Check the CRC website for additional information and updated meeting times at <http://www.childrenshospital.org/research-and-innovation/research/clinical/clinical-research-center>

B. Coordinator Rounds:

Every month the CRC will host Coordinator Rounds. The exact day of the month varies, but they take place at noon and topics are research-related. You will receive e-mails advertising the rounds. All coordinators are required to attend unless they are running a study visit or in a study team meeting.

C. Department Grand Rounds:

Different departments across the hospital also host Grand Rounds. If you are interested in being involved, you can e-mail the department's administrator and ask to be put on the distribution list.

D. SOCRA/ACRP:

The Society of Clinical Research Associates (SOCRA) is a non-profit, charitable and educational membership organization committed to providing education, certification, and networking opportunities to all persons involved in clinical research activities.

SOCRA membership is available to all clinical research professionals who work with cooperative research groups, academic, government, and private institutions, pharmaceutical and biotechnology companies, device manufacturers, CROs, SMOs, independent research and development organizations, and those who are involved in the management of clinical trials.

For more information visit: <http://www.socra.org>.

The Association of Clinical Research Professionals (ACRP) supports clinical research professionals through membership, training and development, and certification. ACRP's vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world. ACRP's mission is to promote excellence in clinical research.

For more information visit: <http://www.acrpnet.org>.

E. Courses

Boston Children's Hospital has a generous tuition reimbursement program for employees. Before taking your course please make sure that it meets all criteria for tuition reimbursement. BCH will not reimburse for courses not meeting the eligibility requirements. All Tuition Assistance Application for Reimbursement Form within 90 days of the date of the official end of the class(es). Tuition assistance application can be submitted to [Kris Shigo](#) for supervisor signature and approval. After approval the application must be faxed (or mailed) to **Crosby Benefit Systems, Inc.**

You may visit

<http://www.crosbybenefits.com/Documents/Form/23/BCHApplicationforTuitionAssistanceandChecklist.pdf> for the full reimbursement application, instructions on how to submit the reimbursement application, and all qualifying course criteria.

To receive reimbursement via direct deposit, complete a **Direct Deposit Authorization Form** (<http://www.crosbybenefits.com/Documents/Form/17/DirectDepositAuthorizationForm.pdf>) and return it to Crosby Benefits.

XV. Professional Networking

A. BCHYP

Boston Children's Hospital Young Professional (BCHYP) is a group that is not exclusive to Research Assistants (RA's) and can give you a chance to meet and network with other people who work in similar roles in different areas of the hospital. They host monthly socials and are also involved in various community service projects. You can request to be added to the listserv and have access to their Sharepoint site by emailing John.Walters@childrens.harvard.edu

B. PRADA

PRADA stands for the Program for Research Assistant Development and Achievement, and is run by a group of BCH research assistants. They host different events for RAs, including mini grand rounds with guest lecturers, presentations on applying to Medical and Graduate schools, and they offer a variety of ways to volunteer. You can tutor inpatients in the hospital by being a member of SWAT (School Work Assistance Team), or mentor a high school student for the summer through Project Success. It is a great way to be involved in the hospital and surrounding community. They send emails about all of these groups and events and you can sign up to be on the listserv by emailing prada@childrens.harvard.edu.

XVI. Technologies

A. Adding a Printer

- Click Start tab at the bottom of the computer screen.
- Click on run and a text box will pop up. Type:
- [\\arctic\nameofprinter](#), then hit enter
- OR [\\timber\nameofprinter](#), then hit enter
- Call or email the help desk (see below) if you have difficulties

B. Adobe Connect and Screen Share

Adobe Connect 8 is the Hospital's web conferencing software. You can use Connect to create a desktop meeting space complete with audio/video, file sharing, whiteboard and screen sharing.

For directions and more information visit:

<http://web2.tch.harvard.edu/multimedia/mainpageS2748P2.html>

C. Conference Room Booking

There are many meeting rooms available throughout the Hospital. **Meet Me @ Boston Children's** is an online tool you can use to browse through an inventory of publicly available meeting rooms throughout the main campus, nearby offices and at the satellites. That master list will include information on capacity, available configurations and a list of the equipment available inside. You can also report problems with the room, like missing or broken equipment. You can access the site through the quick links section of Boston Children's Today or at

http://chbshare.chboston.org/elibrary/Pages/meeting_spaces.aspx.

Conference room booking is managed either through Conference Room Booking (CRB) or by individual room coordinators in each department.

Use this link to find out who manages booking for a particular room

http://chbshare.chboston.org/elibrary/recp/tools/ref/reffacility/Document%20Library/ref_re_conf_rm_s.doc

Tip: Room coordinator contact names change often and may not be current in the link below. The phone numbers remain the same.

CRB managed rooms can be booked directly through Outlook (prefaced with *crb* in the Outlook Global Address list). Add the room you want to the meeting request and CRB will accept or decline.

Directions to book a room can be found here:

http://chbshare.chboston.org/elibrary/isd/educate/mer/mer/erisd_outlook_crb_outlook_mtg_reques_ts.ppt

Plan ahead and check availability before you schedule a meeting. The rooms get booked well in advance and an opening may be difficult to find.

D. Conference Call Set Up

You can put in a request for a conference call line through the Hospital's CRB Meetingplace. To do this, send a meeting invite to CRBMeetingplace@childrens.harvard.edu through Outlook calendar for the date and time that you want. In the invite, ask for a call-in number and provide the 1) meeting name or study name, 2) PI name, and 3) expected number of people who will be calling in.

You will receive an acceptance notification from CRB with a conference call number and meeting ID provided in the body of the message.

Whoever signs onto the call first has control over the call (i.e., if they sign off, the call is terminated) so, you should be the first one to call in.

Note! Set the meeting time for 10 minutes longer at each end of the meeting so that you can sign on first and the number will not be disconnected before the meeting is over.

You can request to have the same meeting ID for similar meetings by including a request for the number in your meeting "invite" to CRB.

E. Videoconferencing

BCH has a video network in select conference rooms onsite. The network allows conferencing between two rooms (point-to-point) and conferencing among as many as seven rooms (point-to-multipoint.) The network also reaches outside the hospital's intranet allowing conferencing on a national and international level.

To set up a video conference, contact Audio Visual Services: 857-218-4479 or 4480 Pager: 0203 audiovisual@childrens.harvard.edu

F. Device Encryption

All devices that are used to access hospital related items (including e-mail) need to be encrypted. If you receive your BCH e-mail on your cell phone you will need to encrypt your phone before you can access it. The HelpDesk/IT team will help you with encryption and will encrypt your laptop for free!

Information on encryption can be found here:

<http://web2.tch.harvard.edu/ehelp/mainpageS2853P39.html>

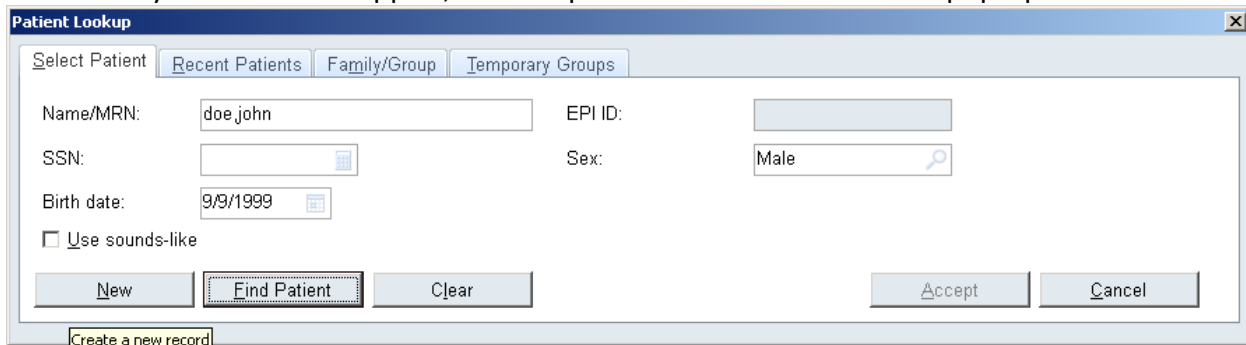
G. EPIC: The hospital's scheduling system

EPIC is the hospital's scheduling system, and all patients seen for research must also be booked in EPIC . Often your study visits may take place on the same day as a patient's clinical visit. There is a three

hour intro to EPIC class designed specifically for study coordinators. Please contact Cheryl.Lafochette@childrens.harvard.edu for the dates/times.

To create a new **medical record number** in EPIC you will need the following information from the patient: Name, Birthdate, Sex, Address/Phone Number, and Emergency Contact

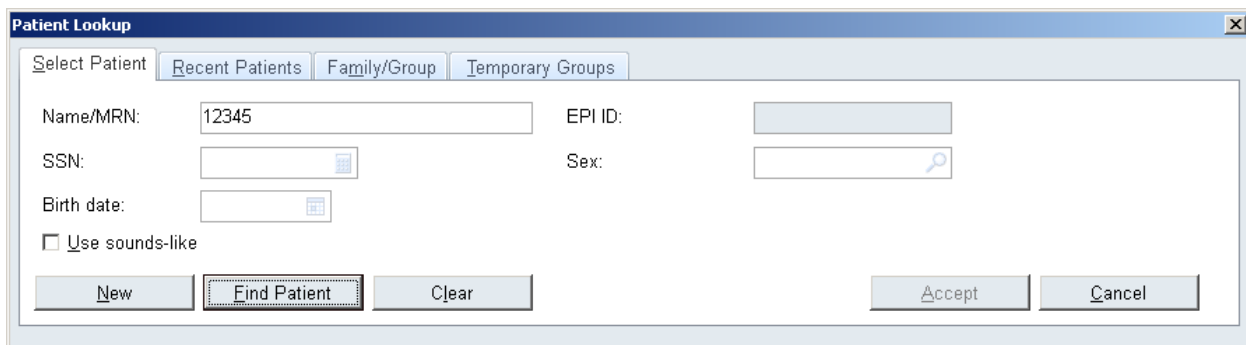
In EPIC you will select “Appts”, in the top left corner and will see the pop-up below:



The screenshot shows the 'Patient Lookup' dialog box with the 'Recent Patients' tab selected. The 'Name/MRN' field contains 'doe.john', 'EPI ID' is empty, 'SSN' is empty, 'Sex' is 'Male', and 'Birth date' is '9/9/1999'. The 'Use sounds-like' checkbox is unchecked. The 'Find Patient' button is highlighted with a dashed border. At the bottom left, there is a link that says 'Create a new record'.

You will then enter patient name (last,first), sex and birthdate and click ‘new’. You will then be prompted to enter the rest of the demographic information to complete the registration. You are not required to enter any insurance information.

Knowing when a patient has a clinic visit can be helpful when trying to schedule times for a research visit. In EPIC you will select “Appts”, in the top left corner and will see the pop-up below:



The screenshot shows the 'Patient Lookup' dialog box with the 'Recent Patients' tab selected. The 'Name/MRN' field contains '12345', 'EPI ID' is empty, 'SSN' is empty, 'Sex' is empty, and 'Birth date' is empty. The 'Use sounds-like' checkbox is unchecked. The 'Find Patient' button is highlighted with a dashed border.

To find a specific patient, you can either enter their MRN, or their name (last,first) and select “Find Patient”. You will then be able to see the selected patients upcoming appointment dates, times, and providers. If a patient has checked in to their appointment, you will see (Ar*), next to the appointment time (see image below).

EPIC Production - Production - CENTER FOR CLINICAL RESEARCH

Appointments View Sched Dept Appointments Work Lists Templates Unit Charge Entry Census ADT Patient

Appointment Desk for [Redacted]

MRN: [Redacted] Sex: Female
 DOB: [Redacted] Age: 6 yrs
 SSN: [Redacted] Lang: SPANISH
 Contact: [Redacted] MOTHER
 Home: [Redacted] Work:

Permanent Comments

Ovg Vc	Date	Time	Len	Dept	Provider	Visit Type	Notes	Hosp Acct
✓	9/17/2015 Thu	9:00 A(A*)	15	CHPCC [057]	[Redacted] [01003373]	WCC YOUNGER [05710]	Physical	67680296
✓	12/22/2015 Tue	5:15 P	15	CHPCC [057]	[Redacted] [01003373]	RETURN CHPCC [05705]	weight follow up	67910494

H. Hospital Staff Directory/Paging

To look up a hospital staff member's phone/extension or to page them you will navigate to Children's Intranet at: <http://web2.tch.harvard.edu/>

Navigate to the very top of the page, left hand side and click on "PHONE/PAGE SEARCH"

EXTERNAL SITE PHONE/PAGE SEARCH EMERGENCIES

Enter the last name or other information you know about the staff member and search.

Note!

When you are out of the office or otherwise not pageable, change your paging status to "not available" or "pager covered by" a team member.

I. Help Desk/STAT Ticket

The Help Desk is the IT team at Children's and can help with most requests. You can call the Help Desk at extension 5-4357 or e-mail them at help.desk@childrens.harvard.edu. If no one is available, you can submit a request through STAT by clicking the orange button in the toolbar at the bottom of your screen.

J. External Access to the BCH Network-VPN

VPN access allows you to log-in to the Children's systems from home or on a non-BCH computer. The employee needs to go to the help desk (1 Autumn Street Basement or Sub-Basement of Main Hospital, or Fegan 190, right next to outpatient phlebotomy) and ask for an Entrust grid card. The employee should then go to <https://accessmanager.chboston.org> to register this card. Once registered, their manager will receive an email letting them know that their employee now has remote access.

Note! To access email only, go to email.tch.harvard.edu and log in using your BCH username and password; you do not need VPN access for this.

K. Posting an Announcement on the BCH Internal Webpage

A scrolling list of hospital wide announcements can be found on the BCH internal webpage and may be used by any employee to post IRB- approved study recruitment materials as well as meeting announcements. In order to post an announcement, click the link below the scrolling announcements “Post/edit announcement”. From here you will be required to log in with your BCH credentials and provide details of your announcement. Once, complete, you will have the option to preview what the final posting will look like before you submit it, and assign the dates you would like your announcement to be displayed.

L. Mapping a Network Drive to your personal computer

1. Right click on My Computer on your computer’s desktop
2. Select Map Network Drive
3. Select name of drive, i.e. Y, J, etc.
4. Enter name of shared folder, i.e. “ [\\RC-FS.tch.harvard.edu\CRC](http://RC-FS.tch.harvard.edu\CRC)” etc.
5. Hit finish. Shared folder will appear in your list of shared folders when you select My Computer.

M. Bookmarks: My Links

My Links are bookmarks on your computer that follow you throughout the hospital. When you log-in to a BCH computer, your links will be accessible to you when you open the Children’s intranet (i.e. – Sharepoint sites, RedCap databases, e-mail, etc.). This way you can access everything you need no matter where you are in the hospital or when connecting through VPN.

To Access My Links:

Navigate to the Children’s Intranet: <http://web2.tch.harvard.edu/>

Enter your CHXXXXXX user name and password in the upper left hand corner.



Your links will appear in a new tab.

To Add/Edit My Links:

At the top of the page click on “CLICK HERE”

* Please [Click here](#) to Add/Edit New Links.

Enter the URL and the name for your link. It is helpful to name your links such as: External RedCap or Internal RedCap. You will most likely have multiple Sharepoint sites for your different studies and should name them accordingly.

[Take me back to MyLinks](#)
Add/Edit My Links

Link Name	<input type="text"/>	Example: Children's Hospital Boston
URL	<input type="text" value="http://"/>	Example: http://www.childrenshospital.org

N. NETLearning:

You will need to get access NetLearning to complete most of your hospital training requirements such as Powerchart , Epic or MYR's or to register for courses. The department administrator (tina.kim@childrens.harvard.edu or chelsea.tyler@childrens.harvard.edu) will need to submit an OAR Request to set you up in NetLearning.

- You will also need to complete the Mandatory Yearly Reviews (MYRs) through NetLearning. These tutorials and associated quizzes on the hospital's safety procedures will automatically appear in the “my courses/classes setion”

NetLearning can be found on the left hand side of the Children's Intranet homepage:

- [Infection Prevention & Control](#)
- [Meaningful Use](#)
- [MOLST](#)
- [NetLearning](#)

To log in to NetLearning enter your Children's user name WITHOUT the “CH” (just the digits).

O. Phone/ Voicemail Setup:

You will need to set-up your phone and voicemail when you arrive.

You can find useful guides to do this at: <http://web2.tch.harvard.edu/telecommunications/>

Long distance codes

To call patients outside of immediate Boston area codes from BCH phones you need a long-distance access code. Call the Help Desk (x54357) to request a code.

Voicemail through email:

Employees can submit a Help Desk ticket through Outlook at help.desk@childrens.harvard.edu to ask to get their voicemail via email. Provide your ID# and phone extension in the email.

P. PowerChart

PowerChart is the hospital's electrical medical record (EMR) system. Patients are searchable by their name or MRN. Training for PowerChart is highly recommended and can be found on NetLearning. Search for course listed "Powerchart Fundamentals" – it will be located on the second page of returned search results.

For some studies, the IRB approval letter specifies that a copy of the subject's signed informed consent must be scanned into their EMR. This can be done by bringing a COPY of the signed consent form to medical records in the Fegan Sub basement (room 0007) for scanning. The consent must have an EPIC label on it but not a study ID on it. This should generally be done within 48 hours of the subject signing the consent.

Q. Statistical Software

Most statistical software you may need can be found at <http://rcweb.tch.harvard.edu/Services/Applications.htm>. If you are looking for something not listed, contact the help desk.

Grant yourself administrative rights

- To install software on a BCH computer you must have temporary administrative rights. To do this:
 - Go to the intranet homepage (<http://web2.tch.harvard.edu/>).
 - Scroll down to the quick links on the left side and click "eHelp".
 - On the left side click on "Forms and Self Service".
 - On the right side click on "Administrative Rights Self-Service".
 - Click "Continue".
 - Follow the directions on the screen. You will need to log out and log back in for admin rights to take effect.

XVII. Directory of Research Offices

Research Administration

- [Clinical Trials Business Office \(CTBO\)](#)
- [IRB/Clinical Investigation](#)
- [Office of Sponsored Programs \(OSP\)](#)
- [Research Operations](#)
- [Technology & Innovation Development Office \(TIDO\)](#)

Other Research Related Offices

- [Clinical Research Center](#)
- [Compliance](#)
- [Harvard Catalyst](#)
- [Office of Faculty Development](#)
- [Office of Immigration Services](#)
- [Research Finance](#)
- [Translational Research Program](#)
- [Office of Fellowship Training](#)
- [Biorepository](#) (Biobank Core Lab)