

Guidance for Working with Boston HealthNet Community Health Centers (CHCs) on INSPIR Studies

Boston Medical Center is a founder of Boston HealthNet, a network affiliation of the Medical Center, Boston University School of Medicine, and fourteen Community Health Centers.

Each CHC is an independent FWA-assured institution and can collaborate in research studies with other institutions, but they do not have their own IRB (except for Dimock Community Health Center, Inc.). CHCs can be added to INSPIR studies with BMC or BU Medical Campus Principal Investigators (except for ceded studies if the CHC is engaged in research); or when CHC Principal Investigators wish to initiate their own INSPIR studies when there is no other outside institution IRB involved.

- See the 1/9/19 [Boston HealthNet CHC Contact Information](#) for a complete list, and any special notes regarding a specific CHC. See also <https://www.bmc.org/about-us/affiliates/boston-healthnet-community-health-centers>.
- Posting Flyers: If you wish to simply post IRB-approved flyers at a CHC for self-recruitment without needing additional involvement by the CHC staff, then contact the CHC's Chief Medical Officer for permission. You will not need any additional approvals from Boston HealthNet or Boston Health Care for the Homeless Program. Flyers must be IRB-approved, and the posting of flyers must be described as a recruitment activity in the INSPIR application.
- Obtain Boston HealthNet approval: Any INSPIR study requiring a CHC's involvement (such as adding a CHC as a recruitment site, performing a CHC medical record review, or requesting the CHC staff to also be engaged in research, but does not include just posting flyers), will require review and approval by the Boston HealthNet Research Subcommittee. Contact Boston HealthNet Associate Director Judi Henderson (judy.henderson@bmc.org; 617-638-6903) to obtain a Project Summary Form for completion, listing all the involved CHCs and describing their research activities. This completed Project Summary Form will enable Judi to initiate the administrative review process by the Boston HealthNet Research Subcommittee. When the Boston HealthNet administrative approval process is complete, Judi will then instruct the investigator to print out a copy of the Project Summary form for each CHC and obtain each CHC CEO's signature. The investigator returns the CHC-signed Project Summary form(s) to Judi. Judi will then obtain the Boston HealthNet signature on each Project Summary form, and forward these fully signed forms to IRB Coordinator Roz Schomer (roz@bu.edu; 617-358-5329) to attach to the investigator's INSPIR study and to send the investigator a receipt confirmation (or to acknowledge receipt in the IRB approval letter). Research activities can begin at a CHC when the signed Project Summary form(s) is/are attached to the investigator's approved INSPIR study in which the CHCs have been added (either by a new INSPIR initial submission or by an amendment to an approved INSPIR study).
- Boston Health Care for the Homeless Program (BHCHP): All investigators (including BHCHP investigators) are required to submit their research studies to the internal BHCHP Review Committee for approval prior to obtaining Boston HealthNet approval OR listing BHCHP on the INSPIR application. Contact Melanie Racine, BHCHP Director of Special Projects

(mracine@bhchp.org; 857-654-1933) to obtain a BHCHP Research Proposal Form for completion to initiate the internal BHCHP review process. Upon approval, the investigator will receive a BHCHP project approval letter. The investigator can then obtain Boston HealthNet approval by providing Judi Henderson with the BHCHP project approval letter, and completing just Page 1 of the Project Summary form without needing to obtain the BHCHP CEO's signature. Judi will then obtain the Boston HealthNet signature on the BHCHP Project Summary form; and then forward both the BHCHP project approval letter and the fully signed BHCHP Project Summary form to IRB Coordinator Roz Schomer for attaching to the investigator's INSPIR application and sending a receipt confirmation. At that time, the investigator can add BHCHP to either a new initial INSPIR application, or by an amendment to an approved INSPIR study.

- Dimock Community Health Center, Inc.: Dimock has its own IRB. Contact them directly for a letter of approval to participate in INSPIR studies.
- Update the INSPIR Application:
Investigators should list the specific CHCs to be involved in the research study in appropriate sections of the INSPIR application (sections and section numbers may vary depending on the type of application in Section 4.1 such as Exempt, Chart Review, Expedited, Full Board). Appropriate sections would include:
 - Study Summary
 - Subjects inclusion criteria
 - Recruitment Procedures/Materials
 - Look for the question, *"Will you be recruiting using one or more Community Health Center (CHC)?"* with a textbox to provide details.
- If/When the CHCs are "Engaged in Research":

When a CHC is added as a recruitment site, it is NOT considered engaged in research when it:

- Informs prospective subjects about the availability of the research
- Provides prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB-approved materials) but not obtaining subjects' consent for research or acting as representatives of the investigators
- Provides prospective subjects with information about contacting investigators for information or enrollment
- Seeks or obtains the prospective subjects' permission for investigators to contact them
- Does not administer any study intervention being tested or evaluated under the protocol
- Releases to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research (such as a chart review)

If specific CHC staff members will be "engaged in research" (interacting with subjects for the purpose of collecting research data; obtaining identifiable data for research purposes; consenting subjects; administering the study intervention), then they must be individually listed

in the INSPIR application as CHC “external” investigators requiring an IRB Authorization Agreement. INSPIR application sections to be updated included:

- Study Site Information
 - Answer YES to the question, “*Does this study have or require an Authorization Agreement for External (non-BMC/BU Medical Campus) investigators who will rely on BMC/BU Medical Campus IRB review?*” This will create a new section.
- New Section: IRB Authorization Agreement – BUMC is the Reviewing Institution
 - Refer to the CHC Contact List for FWA Numbers. However, CHCs that have expired FWA Numbers cannot be engaged in research (consult with Judi Henderson for questions regarding a specific CHC’s availability to be engaged in research.
 - List Judi Henderson as the IRB Contact for the Authorization Agreement (judy.henderson@bmc.org; 617-638-6903).

The engaged CHC staff members must also meet the Medical Campus CITI human subjects protection training requirements for the study (see <http://www.bumc.bu.edu/ohra/required-training/>). Since the BMC/BU Medical Campus IRB is required to track the Medical Campus CITI human subjects protection training for engaged CHC staff members, the CHC staff members must complete INSPIR profiles naming their CHC as their department so that their CITI certificates can be uploaded. They also need to be added as internal study personnel in the following section:

- Section 3.0 Key Personnel
 - When adding CHC personnel to Section 3.2B as Research Support Staff, select the role “CHC Personnel”.
- Questions? Contact IRB Coordinator Roz Schomer (roz@bu.edu; 617-358-5329).