**Research with Boston Health Net Community Health Centers (BHN CHCs)**

**If you are planning to collaborate with Boston Healthnet Community Health Centers (BHN CHCs) on** **a study, then follow the six steps below and check the applicable boxes.**

# First, determine if your initial submission is time-sensitive (for example, grant deadlines). If so, then consider getting the initial application approved by the IRB first, and then submitting an amendment later to add the BHN CHCs – see Step 6. Then, determine what research activities will take place involving the BHN CHCs; and whether the BHN CHCs will be “engaged in research.” Check the following boxes that apply. If you have any questions, send an email to [medirb@bu.edu](mailto:medirb@bu.edu).

# I will submit an amendment later to add the CHCs.

# CHCs are NOT “engaged in research” if:

**I will just post flyers at the CHCs; no further involvement will be required by the CHCs.**

**The CHCs will inform prospective subjects about the availability of the research; or will provide prospective subjects with contact information for enrolling in the study and may provide prospective subjects with information about the research (for example, a copy of the informed consent document and other IRB-approved materials) but will not answer questions about the study; will not be obtaining subjects’ consent; and will not be administering any study interventions; flyers may be posted at the CHCs.**

**The CHCs will seek or obtain the prospective subjects’ permission for study investigators to contact them.**

**The CHCs will release identifiable private information or identifiable biological specimens pertaining to the subjects of the research (such as a chart review) to you.**

**The CHC physicians, staff, and/or patients are the targeted subjects for your research study; and none of the CHC staff will be involved with administering the study interventions or obtaining consent.**

# CHCs are “engaged in research” if:

**Specific CHC staff members will be actively involved with interacting directly with subjects for the purpose of collecting research data; obtaining individually identifiable data for research purposes; consenting subjects; or administering the study intervention.**

Please note: **INSPIR cede applications \*cannot\* add CHCs that are “engaged in research” because the BMC/BU Medical Campus IRB will be ceding review to another institution as the IRB of Record. The CHC(s) will need to cede review directly to the Reviewing IRB.**

**Go to Step 2.**

# Boston HealthNet has implemented a mandatory new pre-screening process required for all Principal Investigators wishing to collaborate with the BHN Community Health Centers on a study. This new BHN pre-screening process should be followed before adding the BHN Community Health Centers to the INSPIR application. If you have already submitted an INSPIR initial application or amendment adding the BHN CHCs, then the IRB will return your submission with a request to submit the BHN Qualtrics pre-screening form.

# Refer to the instructions at this updated BHN website under *“Guide for Partnering with BHN CHCs*”: [Boston HealthNet (BHN) | Clinical & Translational Science Institute (bu.edu)](https://www.bu.edu/ctsi/community-engagement/boston-healthnet-bhn/). Then, submit the BHN Qualtrics pre-screening form, which replaces the “CHC Project Summary Form” Word template: [Qualtrics Survey | Qualtrics Experience Management](https://bostonu.qualtrics.com/jfe/form/SV_0lEmefvoiohm9xk). Your selected BHN CHCs will receive and review your completed pre-screening form. Each CHC will provide you with a signed “Boston HealthNet Letter of Approval” if your activities at the CHC for the study are approved. It is acceptable if a CHC requests a modification to the recruitment procedures on their signed “Boston HealthNet Letter of Approval,” but the CHC-specific modification must be added to the application for IRB approval. If you have any questions about the new BHN pre-screening process, please reach out to [Allyson Richmond](mailto:Allyson.Richmond@bmc.org), BHN Program Manager or [Dema Hakim](mailto:dkhakim@bu.edu), Program Manager of the BU CTSI Community Engagement Program.

**Go to Step 3.**

# Collect the signed ”Boston HealthNet Letter of Approval” from each CHC, then prepare your INSPIR initial submission or amendment to add the CHCs to the application. If several BHN CHCs are involved, then amendments can be submitted for “batches” of signed ”Boston HealthNet Letters of Approval” as they are received.

# Save the signed “Boston HealthNet Letters of Approval” to the INSPIR application under “Other Study Documents – Letter.”; and then add them as attachments to the initial or amendment submission.

**Go to Step 4.**

# If the BHN CHCs will NOT be “engaged in research”: Populate the following INSPIR application sections with the specific names of the BHN CHCs for which you have attached their signed ”Boston HealthNet Letters of Approval.” The order of the sections, section numbers and section titles will vary depending on the type of INSPIR application you are submitting. If you had previously added the BHN CHCs to the application prior to the implementation of this new process, but you do not yet have their signed ”Boston HealthNet Letters of Approval,” then reconfirm that you have populated all the applicable INSPIR sections.

# AMENDMENT DESCRIPTION: Explain that you *“have updated the INSPIR application to add the following BHN CHCs (list them); and have attached their signed ”Boston HealthNet Letters of Approval.”* OR, state that you *“have submitted the BHN Qualtrics pre-screening form, and have added the BHN CHCs to the appropriate sections of the application.”* Please note that this 2nd option is only available for studies that started making these changes prior to this new process being implemented. In the future, you will not be able to add BHN CHCs unless you have the applicable signed BHN Letter of Approval.

# STUDY SUMMARY

# EXPLANATION OF STUDY PROCEDURES / DESIGN AND PROCEDURE

# QUESTIONS SPECIFICALLY ASKING ABOUT BHN CHCS / RECRUITMENT PROCEDURES / CONSENT PROCEDURES: Answer YES and list specific BHN CHCs where text box is provided. Explain your CHC recruitment and/or consent process; and any recruitment/consent modifications specific to a CHC as documented in the signed ”Boston HealthNet Letter of Approval.” The information you enter in the application must match the information in the signed ”Boston HealthNet Letter of Approval.”

# SAMPLE SIZE/SPECIMENS/DATA ANALYSIS: Provide estimated numbers and explanation of sample size for all listed CHCs

# SUBJECT INCLUSION CRITERIA

# HIPAA COMPLIANCE and SELECTION CRITERIA: Answer YES if obtaining medical record data from CHCs prior to obtaining signed consent/authorization from subjects; then list the specific CHCs in the Selection Criteria.

**Go to Step 5.**

# If the BHN CHCs WILL be “engaged in research”: This will require a reliance agreement with each BHN CHC “engaged in research.” Reliance agreements must be pre-screened and pre-approved by the IRB before completing the reliance agreement sections of the INSPIR application. BHN CHC External Investigators must also comply with [Medical Campus CITI training](https://www.bumc.bu.edu/ohra/required-training/).

# Send an email to IRB Reliance Specialist Roz Schomer at [roz@bu.edu](mailto:roz@bu.edu) for assistance, and for further instructions to revise the application, if needed. OR

# This step is not applicable since the BHN CHCs will not be engaged in research.

**Go to Step 6.**

# Submit your initial application or amendment in INSPIR.

# IF TIME-SENSITIVE: Send an email to [medirb@bu.edu](mailto:medirb@bu.edu) with your INSPIR study H-# and an explanation of your time-sensitive deadlines (for example, grant deadlines) for the IRB’s review priority consideration.

**IRB Contact:**

**“Roz”**

**Rosana B. Schomer**

**IRB Reliance Specialist**

**Institutional Review Board for**

**Boston Medical Center &**

**Boston University  Medical Campus**

**Email:** [**roz@bu.edu**](mailto:roz@bu.edu)