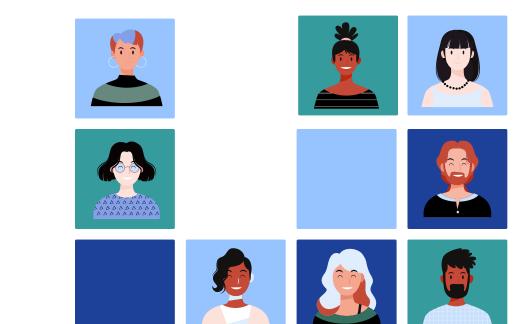




Clinical & Translational Science Institute

#### A Guide for Partnering with BHN Community Health Centers to Support Research Engagement



Updated: Jan. 2022

### Boston HealthNet is an integrated delivery network of 11 Community Health Centers which are affiliated with Boston Medical Center Health System

#### Overall

Over **20 years of working together** to provide quality care to the communities served<sup>1</sup>

275,000 patients served at these health centers

Provided 1.34 million patient visits in 2019

#### **BMC/BU School of Medicine Partnership**

- A notable share of BMC patient volume comes from the health center network:
  - 25% of outpatient visits
  - 30% of inpatient admissions
  - 32% of day surgeries
- Majority of these CHCs participate in Boston Accountable Care Organization (BACO)
- Partnership extends into clinician training and joint hiring<sup>2</sup>:
  - ~240 BUSM students use health center education programs (pre-COVID)
  - 78 residents have longitudinal ambulatory experience at CHCs
  - 38 individuals jointly hired by health centers and BU Family Medicine across 6 health centers

1. Geography spans Boston's neighborhoods and Winthrop, Quincy, Taunton, and Attleboro 2. Annual figures



Bringing Together the Best

# Established the BHN Research Collaborative and Health Center Liaison role to streamline communication with the Research Community

#### BHN Research Collaborative

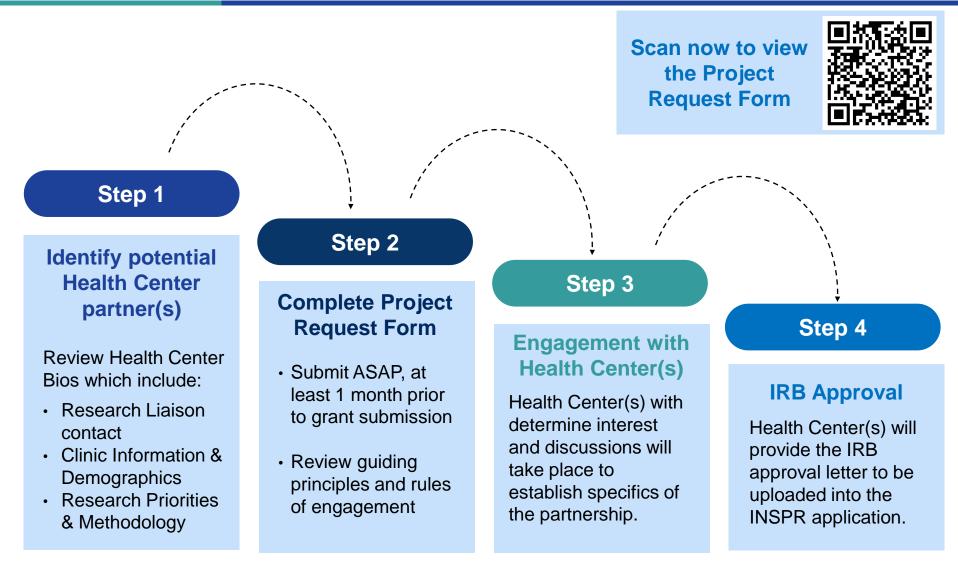
- Partnership between Boston HealthNet, CTSI CE Program and 8 participating CHCs
- Each Health Center is an independent FWA-assured institution and can be added to INSPIR studies with BMC or BU Medical Campus Principal Investigators

Health Center Research Liaisons

- Embedded staff at each CHC to serve as local process expert and liaison to the larger research community
- Respond to initial inquiries by researchers
- Meet regularly with peers in the BHN Research Forum
- Be involved in research design to help represent the community and CHC perspective in the grant planning process



#### Steps at a Glance for Partnering with Health Centers in Research Projects





#### **Greater Roslindale Medical & Dental Center Research Bio**



Contact Info		
Research Liaison	Arielle Albert (Arielle.albert@bmc.org)	
СМО	Jennifer Trieu, MD	
CEO	Courtney Urick	

	Clinic I	nfo	
Service Area	Roslindale, Hyde Park, West Roxbury		
Number of Sites	1		
Primary Care Patients	6,123	FWA# 00023612	
Annual Clinic Visits	12,374	Expiration: 6/4/2025	

Research	<b>Priority</b>	Tonice
Research	THOMY	TOPICS

- **Operations**: treatment cost analysis, wait-time reduction, medical equipment utilization analysis
- **Population Health**: diabetes (A1c), health equity (health access/affordability), needs assessment, cancer prevention, chronic conditions, hypertension, pediatric immunization, COVID-19
- Behavioral Health

Patient Demographics			
Male	41%	Asian/Pacific Islander	2.4%
Female	59%	Black/African American	26.1%
Medicaid	30%	White	36.9%
Primary Language not English	20%	Hispanic/Latino	16.6%
Most Common Languages Spoken	Albanian, English, Greek, Portuguese, French-Creole, Spanish		

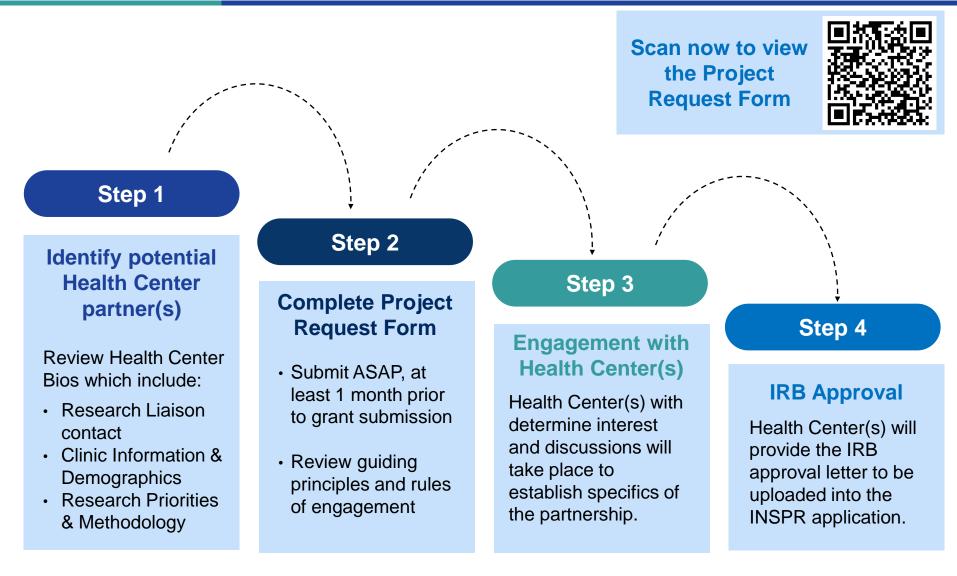
https://www.roslindale.org/

#### Best Practices: Research Methodology

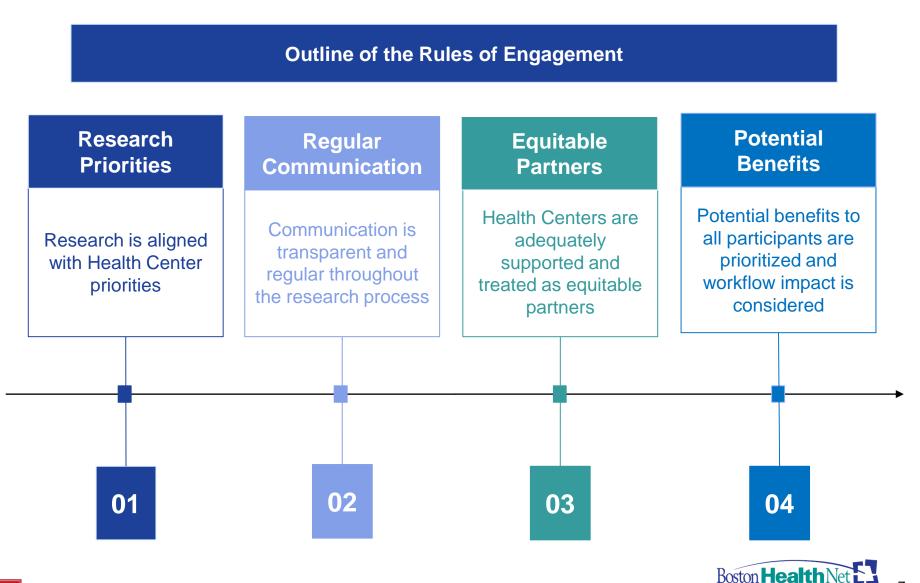
- **Study methodologies:** qualitative surveys, focus groups, 1:1 interviews, secondary data analysis (contracted out)
- Workflow considerations: integrating SDOH into clinical practice, flowcharts, written-workflows (step-by-step/ if-then statements)



#### Steps at a Glance for Partnering with Health Centers in Research Projects

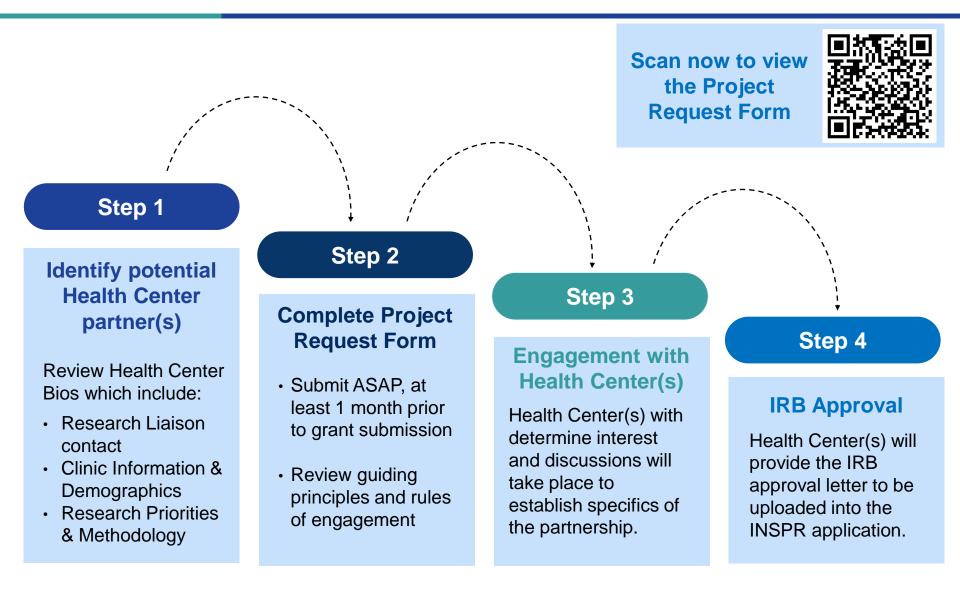






Bringing Together the Best

#### Steps at a Glance for Partnering with Health Centers in Research Projects





News About Us Training & Mentoring Support for Research Community Engagement COVID-Action Program Evaluation

Q

#### Need Assistance? Contact CTSI Services

Submit a request here.

#### Community Engagement $\rightarrow$

	Capacity Building v	vith Partners
	Disseminating Best	Practices
Resources	Dur Team	
	Resources	

# Boston HealthNet (BHN)

BHN is an integrated health care system consisting of Boston Medical Center and 11 Community Health Centers dedicated to improving the health of Boston's low-income and minority populations. Boston University and Boston Medical Center researchers collaborate with the Community Health Centers of the BHN

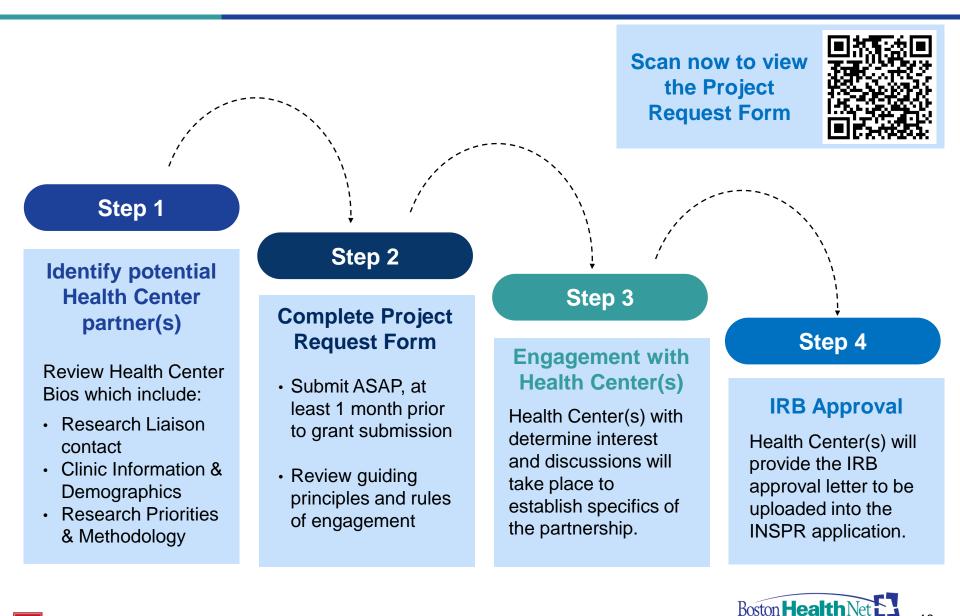
BHN Patient Population Snapshot	+
Boston HealthNet Community Health Centers (BHN CHCs) Bios	+
Steps for Partnering with Health Centers in Research Projects	×
Step 1: Review the <u>Health Center Bios</u> to identify potential partners	
Health Center Bios include patient demographics of the CHC, the CHC's research best practices of research methodology	arch priorities, and
Step 2: Complete the BHN Project Request Form 🗅	
<ol> <li>Use the BHN Project Request Form to outline your proposed project as soo project in mind, ideally 1 month before grant submission.</li> </ol>	on as you have a







#### Steps at a Glance for Partnering with Health Centers in Research Projects



#### How to Navigate the IRB Process for Partnering with CHCs

- The electronic INSPIR application has been updated to reflect the changes in the BHN CHC research process:
  - Linking to the IRB "Guidance for Adding Community Health Centers (CHCs) to INSPIR Studies"
  - Collecting information in the INSPIR application about the involved CHCs and the research activities that will occur at each

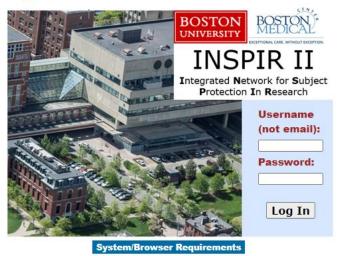
#### **Research with Community Health Centers (CHCs)**

If you are collaborating with Boston Healthnet Community Health Centers (CHCs) or non-Healthnet CHCs on human subjects research, there are special processes that you need to follow. Please review the following guidance for instructions on how to conduct research with CHCs:

Guidance for Adding Community Health Centers (CHCs) to INSPIR Studies

More information about research with CHCs may be found by <u>contacting us</u>.

Log In





Clinical & Translational Science Institute

### Step One:

1) 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.

2) Then, determine what recruitment activities will take place at the BHN CHCs; and whether the BHN CHCs will be "engaged in research." Check off the boxes that apply. If you have any questions, send an email to <u>medirb@bu.edu</u>.



 $\Box$  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.\*

\*If the CHCs are engaged, a reliance agreement will be needed to cover their IRB oversight. See Step 5.

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.



# Step Two:

- 1) Refer to the instructions at the updated BHN website under *"Guide for Partnering with BHN CHCs*": <u>Boston HealthNet (BHN) | Clinical & Translational Science Institute</u> (bu.edu).
- 2) Submit the BHN Qualtrics pre-screening form, which replaces the "CHC Project Summary Form" Word template: <u>Qualtrics Survey | Qualtrics Experience Management</u>.

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.



### **Step Three:**

- 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.



## **Step Four:**

If the BHN CHCs will NOT be "engaged in research":

- Populate the applicable 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.



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."

□ 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." <u>The information you enter in the application must match the information in the signed "Boston HealthNet Letter of</u> <u>Approval."</u>

□ 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.



### **Step Five:**

- 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.

□ Send an email to IRB Reliance Specialist Roz Schomer at 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.



### **Step Six:**

Submit your initial application or amendment in INSPIR.

□ IF TIME-SENSITIVE: Send an email to <u>medirb@bu.edu</u> 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: <u>"Roz"</u> Rosana B. Schomer IRB Reliance Specialist Institutional Review Board for Boston Medical Center & Boston University Medical Campus Email: roz@bu.edu



## **INSPIR** Application

17.4 Will you be recruiting or using data from one or more Boston HealthNet Community Health Centers (CHC)?

$\cap$	N	
$\cup$	/ 13	

Yes\*

\* Please refer to updated instructions at <u>IRB CHC Website</u> before adding BHN CHCs to this application. If you do not yet have CHC approval, check No. Research activities at CHC(s) may only be added after obtaining their approval.

<u>Provide details below about which Boston HealthNet CHC(s) will be involved and the activities that will occur at the CHC(s).</u>

Click here to access the text editor.

List of CHC centers and corresponding activities



# Thank You!!

What Questions Do You Have?

