

**Public Health Research Review Program**

**New Project Application**

***Instructions and Overview***

**Baltimore City Health Department (BCHD) Public Health Research Review (PHRR) is required for all research projects involving BCHD. Please review the *Baltimore City Health Department Public Health Research Review Program Policies, Procedures*, *and Guidelines* for additional information. PHRR is based on the proposed projects’ impact on BCHD’s clients, operations, resources and staff, the potential benefit to the health of Baltimore residents, and consistency with the philosophy of the department.**

**BCHD has a long history of supporting and participating in health and public health research. The promotion of health research is consistent with the mission of BCHD to protect and preserve the health of its residents, and BCHD intends to continue its support and encouragement of research.**

**The purpose of PHRR is to facilitate the conduct of health research, and to ensure that research activities do not interfere with or diminish BCHD services or priorities. PHRR is the mechanism for examining research proposals at the executive level to determine whether to permit the proposed research to be conducted utilizing BCHD staff, resources, facilities, data, activities, operations, funds, or access to clients/patients.**

**PHRR does not have authority to approve contracts or Memoranda of Understanding (MOU) or Agreement (MOA) pursuant to providing or sharing resources. If these are needed, standard avenues of initiation and execution are required. PHRR permission to conduct research does not guarantee subsequent approval of contracts, MOUs, or MOAs, and likewise approvals of contracts, MOUs, or MOAs do not guarantee subsequent PHRR approval.**

**BCHD requires all research projects to have received a determination (either approval or exemption) from an institutional review board (IRB) that is affiliated with BCHD. This determination must be made before submitting a PHRR application.**

**Internal research projects that are initiated and conducted under the leadership of a BCHD staff member as part of their work at BCHD must receive an IRB determination. All other projects (including those by staff conducting research that is not part of their work at BCHD) must follow the PHRR process.**

**All research projects require a BCHD collaborator who serves as the BCHD point of contact for the project. This person does not necessarily need to be a co-author or co-investigator. Please see *PHRR Policies, Procedures, and Guidelines* for more details.**

**Steps for PHRR approval are listed below. Projects requiring PHRR approval may also involve a request for data or data sharing. In these cases, a *Data Request Form*, which is distinct from the PHRR Application, is also necessary. Please refer to the BCHD *Data Request Form* for additional information. If the data request includes protected health information, a *Data Use Agreement* may also be required.**

**BCHD may charge a clinic use fee to projects, depending on the resources required from the clinic.**

**BCHD is happy to discuss your project with you before you submit your application to help determine which among (1) a PHRR Application, (2) a *Data Request Form*, and 3) a *Data Use Agreement* are necessary. If an investigator submits a PHRR Application and BCHD subsequently determines that a data request or data sharing is necessary, BCHD will ask the investigator to complete those forms as well.**

**BCHD** is not only interested in the result of the studies; it also requests updates on the progress of their work in a brief research project update every six months. The report should include a status report on project enrollment (accrual) if appropriate, as well as progress to date. **Learning the results is a vital component of improving our work, informing our communities, and educating BCHD staff. It is the responsibility of the investigator team to update BCHD semi-annually for updates on the progress of their work. BCHD also requests that upon completion of research, investigators present their findings to BCHD staff, and also be prepared to present findings at BCHD-sponsored community events.**

***Steps for PHRR Approval***

* **Read *Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***
* **Determine whether project is under BCHD’s jurisdiction.**
* **Contact the BCHD program, clinic, or office with which they will propose to be associated with their project. Meet any preliminary requirements of that BCHD program.**
* **Acquire a determination from an IRB that is affiliated with BCHD. The determination must either approve the proposed research or exempt it. The list of affiliated IRBs can be found in the *PHRR Policies, Procedures, and Guidelines*.**
* **If passive recruitment only is requested (such as hanging up posters or fliers), complete *PHRR Application—Brief Review*.**
* **If more than passive recruitment is requested, complete *PHRR Application—Full Review*.**
* **Determine if a data request is needed. If so, read the Baltimore City Health Department *Data Request Form* and submit with the PHRR Application.**
* **Determine if the project requires protected health information. If so, a *Data Use Agreement* is required.**



**Public Health Research Review Program**

**New Project Application**

***Full Review***

The Public Health Research Review Program includes review of research projects and the impact on Baltimore City Health Department (BCHD) clients, staff, and city residents.

If your project includes passive recruitment only at BCHD (such as hanging up fliers) you can complete the PHRR Application— Brief Review instead of the full review. All other projects should be submitted on this application, the PHRR Application—Full Review.

 If your project includes a request for data owned or collected by BCHD, complete a *Data Request Form*. If the data request includes a request for protected health information, also complete a *Data Use Agreement*.

Complete this form and submit it to paul.overly@baltimorecity.gov. We will complete review within four weeks.

Please also include with your application:

[ ] The full research protocol that was submitted to your IRB

[ ] Proof of IRB approval

[ ] Fliers, pamphlets, and other materials used for recruitment

[ ] Questionnaires/surveys

[ ] Consent forms

[ ] Data Request Form (if needed)

[ ] Data Use Agreement (if needed)

Name of PI: Click or tap here to enter text.

Institution Name Click or tap here to enter text.

Address 1Click or tap here to enter text.

Address 2Click or tap here to enter text.

Address 3Click or tap here to enter text.

City, State, Zip Code Click or tap here to enter text.

E-mail address: Click or tap here to enter text.

Telephone number: Click or tap here to enter text.

Title of research project: Click or tap here to enter text.

Name of IRB from which you obtained approval: Click or tap here to enter text.

IRB approval date: Click or tap here to enter text.

IRB protocol number: Click or tap here to enter text.

BCHD collaborator: Click or tap here to enter text.

1. Briefly describe the research study plan and goals. Provide a summary of how research operations will occur with BCHD clients and staff. Click or tap here to enter text.
2. BCHD and Client Involvement

Participant Recruitment

* + 1. Number of participants to be recruited through BCHD: Click or tap here to enter text.
		2. Will recruitment be passive only? Choose an item.
		3. Will recruitment be active? Choose an item.
			1. By BCHD staff? Choose an item.
				1. Time spent Click or tap here to enter text.
				2. Plan for compensation for BCHD staff Click or tap here to enter text.
			2. By research staff? Choose an item.
			3. Office/desk required? Choose an item.
			4. BCHD recruitment site(s): Choose an item.

If “Other” or “Multiple Sites,” identify them: Click or tap here to enter text.

* + - 1. Anticipated duration of recruitment: Click or tap here to enter text.

Clinic use needed, other than for recruitment? Yes

* + 1. If yes, please indicate which areas
1. Waiting area: Choose an item.
2. Office space for privacy Choose an item.
3. Clinical space for exam/treatment/tests Choose an item.
4. Other: Choose an item.

If “Yes” identify the area: Click or tap here to enter text.

* + 1. What site for research activities: Choose an item.
		2. Anticipated duration and frequency of use: Click or tap here to enter text.

Staff time

* + 1. Will research activities require BCHD staff to arrange appointments or perform other clerical work? Choose an item. If yes, please describe the tasks needed from BCHD staff, expected staff time needed per participant, expected number of participants, and plan for BCHD staff compensation:Click or tap here to enter text.
		2. Will research activities require BCHD staff to raise awareness of recruitment for the research study? Choose an item. If yes, please describe the planned process for raising awareness of the study. Click or tap here to enter text.

Other clinic resources

* + 1. Will research activities require use of other resources (telephones, computers, expendable supplies)? Choose an item. If yes, identify them: Click or tap here to enter text.

Plan for compensation

* + 1. If active recruitment, clinic space, or other clerical work will be asked of BCHD, please describe the plan for compensation: Click or tap here to enter text.
1. Data use
	1. Will research activities require use of data that already exists? Choose an item.
	2. Will research activities require use of data that is prospectively collected? Choose an item.
	3. Is a *Data Request Form* necessary? Choose an item.

If YES, complete a *Data Request Form*.

* 1. Is Protected Health Information included? Choose an item.

If YES, complete a *Data Use Agreement*.

1. Describe the benefits to Baltimore residents that will accrue through this study

Click or tap here to enter text.

1. Estimated recruitment completion date

Click or tap here to enter text.

1. Estimated study completion date

Click or tap here to enter text.

1. Describe the plan for dissemination of knowledge from this research project (abstract, manuscript, report, other deliverables). Has authorship, and the role of BCHD staff if appropriate, on the manuscript been discussed?

Click or tap here to enter text.

1. Has the investigator been apprised of his/her reporting responsibilities? Choose an item.
2. Describe the plan for dissemination of results to the BCHD: to which programs, staff, and in what setting? Click or tap here to enter text.

Check the following:

[ ] I have read and understand the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ]  **I understand that PHRR approval may come with special conditions**

[ ]  **I understand that post-PHRR approval, I will submit any changes in protocol, contact information, and key personnel to the BCHD PHRR Administrator**

[ ]  **I understand that I will inform BCHD of adverse events, unexpected harm to participants, research misconduct investigations, or other information that may influence BCHD’s desire to associate with the study.**

[ ]  **I understand that I will submit a Research Conclusion Form informing BCHD that the portion of the project involving BCHD is complete.**

[ ]  **I understand that BCHD staff who are among the study authors must submit to BCHD advance copies of any manuscripts, abstracts, or presentations of study findings for review and comment.**

[ ]  **I understand that when BCHD staff are not involved in authorship, BCHD requests but does not require advance copies of manuscripts and presentations as a courtesy**

[ ]  **I understand that BCHD requests all investigators provide final copies of any publications, abstracts, or presentations of the study findings**

[ ] **I have reviewed and understand the BCHD Dissemination Product Review Policy in** the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ]  **I understand the failure to comply policies in** the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ]  **I understand that BCHD may impose a clinic use fee.**

[ ]  **I understand that I may be asked to present my findings to BCHD staff and/or participate in community events to inform them of the findings of this research**



**Public Health Research Review Program**

**New Project Application**

***Brief Review***

The Public Health Research Review Program includes review of research projects and the impact on Baltimore City Health Department (BCHD) clients, staff, and city residents.

If you seek permission only to conduct passive recruitment at BCHD (such as hanging up fliers or posters) complete this application and submit it to paul.overly@baltimorecity.gov. We will complete review within two weeks.

Include with your application:

[ ] The full research protocol that was submitted to IRB

[ ] Proof of IRB approval

[ ] Fliers, pamphlets and other materials used for recruitment

[ ] Questionnaires/surveys

[ ] Consent forms

Name of PI: Click or tap here to enter text.

Institution Name fun

Address 1Click or tap here to enter text.

Address 2Click or tap here to enter text.

Address 3Click or tap here to enter text.

City, State, Zip Code Click or tap here to enter text.

E-mail address: Click or tap here to enter text.

Telephone number: Click or tap here to enter text.

Title of research project: Click or tap here to enter text.

Name of IRB from which you obtained approval: Click or tap here to enter text.

IRB approval date: Click or tap here to enter text.

IRB protocol number: Click or tap here to enter text.

1. Briefly describe the research study plan and goals. Click or tap here to enter text.
2. Describe the benefits to Baltimore residents that will accrue through this study: Click or tap here to enter text.
3. Estimated study completion date: Click or tap here to enter text.
4. Describe the plan for dissemination of knowledge from this research project (abstract, manuscript, report, other deliverables): Click or tap here to enter text.
5. Describe the plan for BCHD review before dissemination: Click or tap here to enter text.
6. Describe the plan for dissemination of results to the BCHD: to which programs, staff, and in what setting: Click or tap here to enter text.

Check the following:

[ ] I have read and understand the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ] **I understand that post-PHRR approval, I will submit any changes in protocol, contact information, and key personnel to the BCHD PHRR Administrator**

[x] **I understand that I will inform BCHD of adverse events, unexpected harm to participants, research misconduct investigations, or other information that may influence BCHD’s desire to associate with the study.**

[ ] **I understand that I will submit a Research Conclusion Form informing BCHD that the portion of the project involving BCHD is complete.**

[ ]  **I understand that BCHD staff who are among the study authors must submit to BCHD advance copies of any manuscripts, abstracts, or presentations of study findings for review and comment.**

[ ] **I understand that BCHD requests all investigators provide final copies of any publications, abstracts, or presentations of the study findings**

[ ] **I have reviewed and understand the BCHD Dissemination Product Review Policy in** the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ]  **I reviewed and understand the“failure to comply” policies in** the ***Baltimore City Health Department Public Health Research Review Program Policies, Procedures, and Guidelines***

[ ] **I understand that I may be asked to present my findings to BCHD staff and/or participate in community events to inform them of the findings of this research**