

DHMH and the BCHD

The JHSPH IRB and the Baltimore City Health Department (BCHD) have in place an [IRB Authorization Agreement](#) allowing the JHSPH IRB to serve as the IRB of record for collaborative human subjects research using BCHD sites or facilities, or for which BCHD personnel serve a research role. BCHD explains it this way:

“If your study does not involve our:

- Clients
- Staff
- Facilities
- Funds
- Activities or events
- Data

then you do not need our review and approval.” *Email from Paul Overly, 4Aug2014.*

Research applications that involve BCHD from the start of a study, or that are revised to include BCHD after study initiation, should clearly identify the BCHD site(s), facilities, or personnel involved. The JHSPH IRB will review the application, and internal BCHD review will follow IRB approval. At the completion of the IRB review process, the IRB may issue approval for all sites except BCHD and will notify BCHD about the action taken. If BCHD sites are the only locations for the conduct of the study, the IRB will approve the study, but not the BCHD involvement, until the BCHD review is completed.

Once the JHSPH IRB approves the study, the PI must complete the [BCHD Public Health Review Form](#), and send it, with the research protocol and IRB approval letter, to Paul Overly at Paul.Overly@baltimorecity.gov. The form specifies that the research protocol and IRB approval letter are submitted to BCHD automatically, and that is true for the SOM eIRB applications, but for JHSPH applications, the PI should submit the whole package together.

The BCHD will conduct a review to determine if the study is consistent with the public health mission of the health department. The review decision may result in either BCHD permission to proceed or a decision not to approve a study. The JHSPH IRB staff and the principal investigator will be notified when BCHD review is complete. The PI may then submit the BCHD approval to the IRB for review by an expedited review process.

Amendments to studies already approved by BCHD may be reviewed and approved for all sites by the JHSPH IRB. BCHD reserves the right to review these changes after JHSPH IRB approval and notify the investigator if they do not approve the changes. In such cases, the investigator must revise the application submitted to the IRB to remove BCHD.

Note: Collaborative human subjects research studies between JHSPH and BCHD that are funded by or through the Maryland State Department of Health and Mental Hygiene (DHMH), use patients or clients of DHMH, or use data held or compiled by the DHMH must go through the DHMH IRB. Collaborative human subjects research studies between JHSPH and other County Health Departments must go through the DHMH IRB. The DHMH IRB policy is found here: <http://dhmh.maryland.gov/oig/irb/Documents/IRB%20Policy%20effective%2009-25-2012.pdf>.

The contact person for BCHD is:

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Grants and Policy Development Officer

BCHD

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