# BALTIMORE CITY HEALTH DEPARTMENT

## Public Health Review Program

### POLICIES, PROCEDURES, AND GUIDANCE

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## PUBLIC HEALTH REVIEW POLICY

All investigators proposing to conduct research involving BCHD employees, facilities, clients, data, funding, events, or activities must receive Public Health Review approval from the Baltimore City Health Department in order to conduct the research. Reviews are based on the proposed projects' impact on BCHD's clients, operations, staff, resources, and philosophies, and the potential benefit to the health of Baltimore residents.

Research projects may only be considered after an affiliated Institutional Review Board has reviewed and approved or exempted the proposed research. Once approved, investigators must meet post-approval responsibilities, including abiding by the Baltimore City Health Department Dissemination Product Policy and submitting changes to protocols, adverse events, and other information that might influence BCHD's interest in supporting the research.

## ESTABLISHMENT AND PURPOSE OF THE BALTIMORE CITY HEALTH DEPARTMENT PUBLIC HEALTH REVIEW PROGRAM

The Baltimore City Health Department (BCHD) has a long history of supporting and participating in health research. The promotion of health research is consistent with BCHD's mission to protect and preserve the health of its residents, and BCHD intends to continue its support and encouragement of research.

The Commissioner of Health established the Baltimore City Health Department Public Health Review in January 2006. The Public Health Review's purpose is to facilitate the conduct of health research by both external and internal investigators, and to ensure that research activities do not interrupt or diminish BCHD services or priorities. Public Health Review is the mechanism for examining research proposals at the BCHD executive level to determine whether to permit the proposed research to be conducted using BCHD staff, resources, facilities, activities/events, data, or access to clients/patients.

Public Health Review provides:

- A necessary avenue for communication between investigators and BCHD's administrative and executive authorities
- A procedure to permit investigators to have access to BCHD patients/clients and the use of BCHD facilities, data, and staff time and expertise
- Opportunities to create new partnerships and strengthen established relationships
- Promotion of health and biomedical research
- Avenues for dissemination of research findings

## JURISDICTION AND AUTHORITY

The BCHD Public Health Review Program has jurisdiction over research under one or a combination of the following conditions:

- The study uses clients of the Baltimore City Health Department
- The study is conducted or assisted by Baltimore City Health Department staff (employee, volunteer, or intern) as part of his/her employment or training
- The study is conducted in whole or in part at BCHD facilities, premises, events, or activities
- The study seeks to utilize data held or compiled by or for BCHD
- The Baltimore City Health Department provides funding support for the study

The BCHD defines research as an activity whose primary intent is to generate generalizable knowledge (i.e., knowledge that could be applied to populations outside Baltimore City). If the primary intent is to prevent or control disease or injury in Baltimore City or to improve a Baltimore City Health Department program, then the project is non-research. Refer to the Research Determination section for more details.

The BCHD Public Health Review has the authority to:

- Grant or deny permission for an investigator to conduct research using BCHD staff, resources, or clients based upon consideration of BCHD's mission, philosophy, operations, priorities, resource limitations, and community concerns

- Place restrictions on research studies

- Provide oversight of the research

- Suspend or terminate the permission, and thus the research activities associated with BCHD

- Conduct inquiries, investigations, or otherwise undertake activities to ascertain information that promotes accurate, informed decisions and actions

- Review, comment on, and approve of drafts of publications and presentations of research findings when BCHD is involved in authorship, prior to publishing or presentation

The BCHD Public Health Review does not have the authority to approve contracts or Memoranda of Understanding or Agreement pursuant to the provision or sharing of resources as part of a research-project relationship. If the investigator or BCHD requires such instruments, they must follow Baltimore City's standard avenues of initiation and approval for them. PHR permission to conduct research does not guarantee subsequent approval of contracts, MOUs or MOAs; likewise, approvals of contracts, MOUs, and MOAs do not guarantee subsequent PHR permission to conduct research.

## FEDERAL REGISTRATION; COMPLIANCE WITH LAWS AND REGULATIONS

The Baltimore City Health Department complies with the *Terms of the Federal Wide Assurance For Institutions Within the United States*. BCHD's Federal-Wide Assurance

Number is FWA00002106. As part of this Federal Wide Assurance, BCHD has established and maintains Policies and Procedures Regarding Research Misconduct, and any research conducted under BCHD's authority is subject to its provisions. Those policies and procedures are Appendix 1.

The Baltimore City Health Department observes and adheres to all applicable federal, state, and local laws and regulations relevant to the conducting of biomedical research. BCHD intends to supply all investigators with a research environment that is compliant with these laws and regulations.

BCHD cooperates with all federal and state regulatory agencies having jurisdiction over the conduct of human subject biomedical research.

## PUBLIC HEALTH REVIEW APPLICATION PROCEDURE

## INTERNAL INVESTIGATOR

An internal investigator is a BCHD employee, intern, or volunteer.

- An investigator internal to the Baltimore City Health Department must first determine if the proposed project constitutes research, or if it is non-research. Guidance for this determination appears elsewhere in this manual under the heading **RESEARCH DETERMINATION** (page 11).

- The investigator must then determine, if the project is research, whether it constitutes human subject research that must be reviewed and approved by an Institutional Review Board. (Again refer to **RESEARCH DETERMINATION**, page 11.)

- If the project is human subject research, the investigator must then acquire approval from an IRB that is affiliated with the Baltimore City Health Department (See **IRB Affiliation** section, Page 7). If it is not human subject research, the investigator should proceed directly to Step 4.

- The investigator must acquire a Public Health Review Application form (available online or through the Public Health Review Administrator), complete it, and submit it to PHR Administrator. The investigator must also submit as part of the application either a complete protocol or an abstract of the proposed project. The application may be e-mailed to the PHR Administrator. After submitting the application, the investigator should provide answers to questions that may arise in the review process. These questions may come from the PHR Administrator, an Assistant Commissioner, Deputy Commissioner, or the Commissioner.

- Once permission is granted, the investigator must follow the terms of permission and the requirements listed in the Post Approval Responsibilities section.

## EXTERNAL INVESTIGATOR

An external investigator is any person who is not an employee, intern, or volunteer of BCHD who proposes to conduct a study under BCHD's jurisdiction, whether it is research or non-research. All projects originating from investigators external to BCHD are subject to Public Health Review.

- An external investigator must determine whether a proposed project is under BCHD's jurisdiction. Jurisdiction subsists if a project would involve BCHD clients or patients; would be conducted using BCHD staff, facilities, or resources; would use BCHD data; would be conducted during BCHD activities or events; or would be funded in whole or in part by or through BCHD. Even in the rare instances in which a proposed project is considered non-research, the project is subject to Public Health Review.

- External investigators must contact the BCHD program, clinic, or office with which they will propose to be associated with their project. The programs, clinics, and offices may have preliminary requirements, and external investigators must meet them.

- If the proposed project constitutes human subject research, the investigator must first acquire IRB approval from an IRB that is affiliated with the Baltimore City Health Department (See **IRB Affiliation** section, Page 8) before submitting to BCHD Public Health Review.

- The investigator must submit a completed Public Health Review Application form (available online or through the Public Health Review Administrator to PHR Administrator. Once the application is submitted, the investigator should provide answers to questions that may arise in the review process. These questions may come from the PHR Administrator, an Assistant Commissioner, Deputy Commissioner, or the Commissioner.

- Permission and approvals are granted contingent on the availability and capacity of BCHD resources. It is possible that BCHD will require an approved project to delay commencement of activities associated with BCHD until a specified date because of resource limitations.

- Once permission is granted, the investigator must follow the terms of permission and the requirements listed in the Post Approval Responsibilities section.

*Individuals carrying out work at the request of the Baltimore City Health Department are not considered investigators.*

## RESEARCH DETERMINATION

*What Constitutes Research*

Use the following guidelines to determine if a project is research:

- If the primary intent is to generate generalizable knowledge (i.e., knowledge that could be applied to populations outside Baltimore City) the project is research.
- If the primary intent is to prevent or control disease or injury in Baltimore City or to improve a Baltimore City Health Department program, then the project is non-research.
- If the primary intent changes to generating generalizable knowledge, then the project becomes research.

For an in-depth explanation of guidelines, the following guidance from the Centers of Disease Control and Prevention provides more context:

> "The regulations [45CFR46] state that 'research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.' Obtaining and analyzing data are essential to the usual practice of public health. For many public health activities, data are systematically collected and analyzed, blurring the distinction between research and non-research. Scientific methodology is used both in non-research and research activities that comprise the practice of public health. Because scientific principles and methodology are applied to both non-research and research activities, knowledge is generated in both cases. Furthermore, at times the extent to which that knowledge is generalizable may not differ greatly in research and non-research. Thus, non-research and research activities cannot be easily defined by the methods they employ…
>
> "The major difference between research and non-research lies in the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge may be gained in any public health endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered…
>
> "The ultimate decision regarding classification lies in the intent of the project. If the primary intent is to generate generalizable knowledge, the project is research. If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research. If the primary

intent changes to generating generalizable knowledge, then the project becomes research."

*Human Subjects Research Determination*

Human subjects research is research that involves:

- Data that is obtained through interaction with living individuals
- Activity using existing data relating to living persons where the identity of the persons could be determined

If the research involves the following data, it is not human subjects research:

- None of the subjects are living
- The identity of the persons cannot be determined from the data collected and used

Investigators may use the **RESEARCH DETERMINATION WORKSHEET** (Appendix) to help them determine if their project is research, and then if the project constitutes human subject research.

## IRB AFFILIATIONS

All proposed research must be reviewed by an external IRB that has signed an IRB affiliation agreement with the Health Department before applying for Public Health Review permission. The Baltimore City Health Department accepts the reviews and decisions of its affiliated Institutional Review Boards as the authorities for the protection of the health, safety, and dignity of human subjects in biomedical research. The Public Health Review Program does not duplicate IRB review; rather, it considers research proposals in the context of BCHD's own public health mission, philosophy, priorities, and available resources.

Institutions that have signed IRB affiliation agreements are:

- Johns Hopkins Medical Institutions
- Johns Hopkins School of Public Health
- Johns Hopkins University Homewood
- University of Maryland School of Medicine
- Maryland Department of Health and Mental Hygiene
- Morgan State University
- Towson University
- Adelphi University

If the proposing investigator is an employee of the Baltimore City Health Department and does not have a relationship with any of the affiliated institutions listed above, he/she should locate an interested co-investigator affiliated with one of those institutions and enter into a research partnership. The Baltimore City Health Department may consider affiliating with a commercial IRB as an alternative to partnering; however, any fees that a

commercial IRB charges would be the responsibility of the investigator and/or study sponsor.

If the proposing investigator is affiliated with an institution with which BCHD does not have an IRB affiliation, BCHD will consider entering into an affiliation agreement.

## AMENDED APPLICATIONS/REJECTED APPLICATIONS

If an Assistant Commissioner or Deputy Commissioner perceives or foresees significant difficulties accommodating a proposed project, he/she will communicate concerns to the investigator, either directly or through the PHR Administrator. The investigator may amend the proposal to satisfy concerns or conditions. If the concerns cannot be resolved through amendment of the proposal, the AC or DC will reject the project as unsuitable for association with BCHD. The reasons for rejection will be explained in the letter sent to the investigator.

An investigator may resubmit a rejected proposal in the future with previously-noted concerns addressed and conditions satisfied.

## POST-APPROVAL RESPONSIBILITIES

The **Investigator** must:

- Submit changes to protocol, contact information, and key personnel
- Inform of adverse events, unexpected harm to participants, research misconduct investigations, or other information that may influence BCHD's desire to associate with the study
- Submit a **Research Conclusion Form**, which is a simple notice informing BCHD that the portion of the project involving BCHD is complete (see Appendix 5)
- Abide by the BCHD's **Dissemination Product Review Policy**:
    - Internal investigators who are the primary authors must submit to BCHD advance copies of any manuscripts or presentations of the study findings for review and comment
    - External investigators who are the primary authors but who also credit BCHD staff with authorship for secondary contributions must submit to BCHD advance copies of any manuscripts or presentations of the study findings for review and comment
    - When BCHD and its staff are not involved in authorship, BCHD also requests, but does not require, advance copies of manuscripts and presentations from external investigators as a collaborative courtesy
    - BCHD requests that all investigators provide final copies of any publications or presentations of the study findings
    - For further information, please refer to the **Dissemination Product Review Policy** (Appendix 6)

If needed to effect the research association with BCHD, the investigator must initiate any contractual, MOU, or MOA negotiations.

The **PHR Administrator** will maintain the project file, and will input updates, changes, adverse events, IRB communications, and the receipt of the Research Conclusion Form.

The PHR Administrator will initiate responses to issues (adverse events, misconduct, unanticipated disruption of BCHD operations) should they arise, via advice to BCHD executives. If action is warranted, the PHR Administrator will draft correspondence as desired, and/or will coordinate with executive staff as directed.

The PHR Administrator will coordinate publication/presentation review by transmitting advance copies to the interested executive(s) (Assistant Commissioner, Deputy Commissioner, and Commissioner of Health).

**Assistant Commissioners**, **Deputy Commissioners, and Commissioner of Health** will monitor conduct of the study regarding its impact on BCHD operations and activities. If issues of a significant nature arise, any may initiate changes in permission requirements, or suspension or termination action. Any may also apply sanctions against investigators who do not comply with the policies and procedures contained in this manual. They also will review advance copies of publications and presentations of the study findings for review and comment.

## FAILURE TO COMPLY

Investigators failing to comply with the provisions and requirements of the BALTIMORE CITY HEALTH DEPARTMENT PUBLIC HEALTH REVIEW POLICY AND PROCEDURES will be notified of the compliance issue and provided an opportunity to achieve compliance without sanction. However, if the failure results in harm to BCHD, its clients, staff, resources, or reputation, and/or if the failure appears to be due to negligence or willful disregard, the investigator may be sanctioned. The nature and extent of the sanction will be proportionate to the compliance failure, and could include any, or any combination of, the following:

- Suspension of activities associated with BCHD until compliance is effected
- Termination of activities associated with BCHD
- Rejection of application
- Moratorium on future PHR applications from the noncompliant investigator

Either the Assistant Commissioner, the Deputy Commissioner, or Commissioner of Health may determine whether to apply sanctions and which to apply.

Baltimore City Health Department employees/investigators who are responsible for PHR compliance may also face disciplinary action.

## DISCLAIMER REGARDING LETTERS OF SUPPORT

The Baltimore City Health Department commonly issues letters of support for grant applications for research studies. These letters are supplied as a sincere courtesy and encouragement to investigators to help them acquire funding assistance; the Commissioner considers only the general principles of the proposed research project when contemplating writing a letter of support. Such a letter of support is not to be employed for any other purpose associated with the research proposal. It is not a guarantee of subsequent Public Health Review permission and is not intended for use as evidence to an IRB that BCHD has submitted the proposed research to a rigorous scientific or policy review and found it to be acceptable.

## PROCEDURE RESPONSIBILITIES

**Public Health Review Administrator**
The Public Health Review Administrator is the contact point for all PHR activities. He/she is responsible for intake functions, assigning applications to Assistant Commissioners for review, tracking application and project progress, generating correspondence, and interacting with affiliated IRBs. In the PHR process, the Administrator will be the person with whom the investigators interact the most.

- The PHR Administrator receives and logs in applications, and acknowledges receipt of the application to the investigator.
- The Administrator then reviews the application to ensure it is complete. If it is not complete, the Administrator contacts the investigator to get completing information.
- The Administrator transmits the application and a PHR Review Form to the Assistant Commissioner having authority over the area of BCHD in which the investigator proposes to conduct the project.
- The Administrator receives the completed review form from the AC.
- The Administrator forwards the application and the AC's completed review form to the Deputy Commissioner.
- The Administrator drafts the permission (or denial) letter, and consults with either the AC or the DC to include in the letter any special provisions that they require.
- The Administrator receives the signed letter from Deputy Commissioner and sends it to the investigator.
- If the Deputy Commissioner wishes to defer to the Commissioner, the Administrator will direct his efforts to the Commissioner.

**Assistant Commissioner/Proposal Reviewer**
Assistant Commissioners perform the reviews of proposed research. Their participation ensures that they have knowledge of, and approve of, research activities conducted within their divisions. They recommend actions to the Deputy Commissioners.

- The Assistant Commissioner receives the project application form and review form from PHR Administrator.
- The Assistant Commissioner reads and considers the application.
- The Assistant Commissioner may consult with program managers or others.
- If the AC has questions, he/she may contact the investigator, or may ask the PHR Administrator to present the questions to the investigator.
- If the conducting of the proposed research would carry significant implications for a community or population group, the AC may consult an advisory board with knowledge/expertise related to that community or population group.
- The AC completes the review/findings form and sends it to the PHR Administrator.

**Deputy Commissioner of Health or Commissioner of Health**
Deputy Commissioners or the Commissioner of Health approve or disapprove applications, based on the recommendations of the Assistant Commissioners, and employing their own knowledge and perspectives.

- The Deputy Commissioner or Commissioner receives the application, completed review form, and draft permission letter.
- The DC/C reads and considers the material.
- The DC/C may consult with the AC, program managers, the City Law Department, the Commissioner, or others, if desired.
- If the DC/C has questions, he/she may contact investigator, or may ask the PHR Administrator to present the questions to the investigator.
- The DC/C gives final approval or disapproval of permission, and approves and signs the letter sent to the investigator.

**Commissioner of Health**
The BCHD Public Health Review Program is accountable to the Commissioner of Health, who is the ultimate responsible authority of the Baltimore City Health Department.

The Commissioner of Health may initiate research misconduct investigations, if information indicates this is appropriate. The Commissioner may change, suspend, or halt research or terminate PHR permission. He also will review advance copies of publications and presentations of the study findings for review and comment.

## APPENDICES

**1: POLICIES AND PROCEDURES REGARDING RESEARCH MISCONDUCT**
**2: RESEARCH DETERMINATION WORKSHEET**
**3: PUBLIC HEALTH REVIEW APPLICATION FORM**
**4: PUBLIC HEALTH REVIEW FINDINGS FORM**
**5: RESEARCH COMPLETION FORM**
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# APPENDIX 1 - POLICY AND PROCEDURES REGARDING RESEARCH MISCONDUCT

BALTIMORE CITY HEALTH DEPARTMENT
Effective February 25, 2006

The Baltimore City Health Department has established the following policy and procedures for handling allegations of research misconduct. For the purpose of this policy and procedures, research includes all basic, applied, and demonstration research. These policies and procedures are pursuant to federal regulations of the U.S. Department of Health and Human Services (HHS) at 42 CFR Part 93.

## I. Definition of Research Misconduct

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record [i.e. the record of data or results that embody the facts emerging from the research, and includes, but is not limited to, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books].
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

## II. Findings of Research Misconduct

A finding of research misconduct requires that:

- there be a significant departure from accepted practices of the relevant research community (i.e. the humanities, social sciences, or scientific research community);
- the misconduct be committed intentionally, or knowingly, or recklessly; and
- the allegation be proven by a preponderance of evidence.

## III. Phases of the Response to an Allegation of Research Misconduct

A response to an allegation of research misconduct will consist of several phases, including:

1. an inquiry--the assessment of whether the allegation has substance and if an investigation is warranted;

2. an investigation--the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies;

3. adjudication--during which recommendations are reviewed and appropriate corrective actions determined.

**IV. Procedures for Inquiry and Investigation**

1. Upon receiving an allegation of research misconduct, a Health Department employee immediately should notify the Commissioner. The Commissioner shall designate a Research Integrity Officer who is responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Commissioner shall designate a Deciding Official to adjudicate the allegation of research misconduct.

2. If the allegation of research misconduct involves an outside institution that has signed an IRB affiliation agreement with the Health Department, the Commissioner may choose to defer to that affiliated institution to designate a Research Integrity Officer to conduct the research misconduct proceedings and a Deciding Official to adjudicate the allegation of research misconduct. At anytime, however, the Health Department may proceed with its own inquiry and investigation.

3. Inquiry, Investigation, and Adjudication

   a. *Inquiry, investigation, and adjudication conducted by the affiliated institution*

   - The affiliated institution shall provide the Health Department with a copy of its policy and procedures (which shall comply with 42 CFR Part 93) under which it will conduct the inquiry and investigation, and the curriculum vitae of the Research Integrity Officer who is conducting the inquiry and/or investigation. The curricula vitae should be reviewed in consultation with the City Solicitor for indicators of possible conflicts of interest (personal, professional or financial).

   - At the time of or before beginning the inquiry, an affiliated institution must make a good faith effort to notify in writing the presumed respondent, if any. Further, the affiliated institution shall promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

   - At any time during an inquiry or investigation, the affiliated institution will immediately notify the Commissioner if (a) health or safety of the public is at risk, including an immediate need to protect human or animal subjects, (b) HHS resources or interests are threatened, (c) research activities should be suspended, (d) there is reasonable indication of possible violations of civil or criminal law, (e) federal action is required to

protect the interests of those involved in the research misconduct proceeding, (f) the research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved, or (g) the research community or public should be informed.. The affiliated institution also must notify the Office of Research Integrity (ORI) of HHS immediately if any of the above conditions exist.

- The affiliated institution shall conduct the inquiry pursuant to 42 CFR §§ 93.307 through 93.309. Upon completion of the inquiry, the affiliated institution shall provide a copy of the inquiry report and the comments of the respondent to the inquiry report (if any) to the Commissioner.
- If an investigation is warranted, the affiliated institution shall conduct the investigation pursuant to 42 CFR §§ 93.310 through 93.313.
- When the investigation is complete, the affiliated institution shall forward to the Commissioner a copy of the affiliated institution's investigative report.
- When the affiliated institution completes the adjudication phase, it will forward the Deciding Official's decision to the Commissioner. If, as a result of the investigation's findings, the affiliated institution takes action against anyone, it should provide the name and title of the person(s) who imposed the action and copies of documents detailing how the action was implemented.
- After reviewing the record of the inquiry, the investigation report and any adjudicative actions taken by the affiliated institution, the Commissioner will take additional actions if necessary.

b. *Inquiry, investigation, and adjudication conducted by the Health Department*

- The designated Research Integrity Officer of the Health Department shall conduct the inquiry pursuant to 42 CFR §§ 93.307 through 93.309. Upon completion of the inquiry, the Research Integrity Officer shall decide if an investigation is warranted.
- If an investigation is warranted, the Research Integrity Officer shall conduct the investigation pursuant to 42 CFR §§ 93.310 through 93.313.
- When the investigation is complete, the Research Integrity Officer shall forward to the designated Deciding Official a copy of the investigative report.
- When the Deciding Official completes the adjudication phase, he/she will forward the Deciding Official's decision to the respondent.

**V. Notification of the respondent of the allegation**

Before the Deciding Official of the Health Department or the affiliated institution makes any finding of misconduct or takes any action on such a finding, the Research Integrity Officer will, in timely fashion, notify the respondent in writing regarding substantive allegations made against him/her; provide a description of all such allegations; provide reasonable access to the data and other evidence supporting the allegations; and provide the respondent the opportunity to respond to the allegations, the supporting evidence and the proposed findings of research misconduct (if any)..

## VI. Procedures for Adjudication and Appeal

1. If there is a recommendation for a finding of misconduct, the Deciding Official of the Health Department (in consultation with the City Solicitor) or the Deciding Official of the affiliated institution (in consultation with its Law Department), will review the recommendations of the Research Integrity Officer and determine the appropriate administrative actions in accordance with applicable laws, regulations, or policies.

2. In deciding what administrative actions are appropriate, the Deciding Official should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct was knowing, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.

3. Administrative actions available include, but are not limited to: appropriate steps to correct the research record, letters of reprimand and other personnel actions. With respect to administrative actions imposed upon Health Department employees, the Deciding Official must comply with all relevant City policies and laws.

4. When the Deciding Official has made a decision, the Deciding Official will notify the respondent of the final institutional action.

5. The respondent has no appeal of the final action of the Deciding Official of the Health Department. The respondent may have an appeal of the final action of the Deciding Official of an affiliated institution depending on its policies and procedures for research misconduct.

## VII. Retention and Custody of Research Misconduct Proceeding Record

The Health Department and the affiliated institution shall keep retention and custody of the research misconduct proceeding record pursuant to CFR § 93.317. The research misconduct proceeding record must be maintained in a secure manner for 7 years after completion of the research misconduct proceeding.

## VIII. Timeliness

The inquiry, investigation, adjudication, and appeal phases (if any) should be conducted within 330 days of the initial receipt of the allegation, with allowances for extensions where appropriate. See attached Timeline Chart.

## IX. Safeguards for Complainants and Witnesses

Safeguards for complainants and witnesses give individuals the confidence that they can bring allegations of research misconduct made in good faith to the attention of appropriate authorities or serve as witnesses to an inquiry or an investigation without suffering retribution. Safeguards include: protection against retaliation for complainants and witnesses who make good faith allegations or testimony, fair and objective procedures for the examination and resolution of allegations of research misconduct, and diligence in protecting the positions and reputations of those persons who make allegations of research misconduct in good faith.

## X. Safeguards for Respondents of Allegations

Safeguards for respondents give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research or Health Department review of a research proposal to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Such safeguards include the right to prompt written notification to the individual or institution to be investigated, unless notification would prejudice the investigation or unless a criminal investigation is underway or under active consideration. If notice is delayed, it must be given as soon as it will no longer prejudice the investigation or contravene requirements of law enforcement policies. If a proposal by a respondent of an allegation is pending, to avoid influencing reviews, reviewers or panelists will not be informed of allegations or of ongoing inquiries or investigations.

## XI. Confidentiality During the Inquiry, Investigation, and Adjudication Process

To the extent possible being consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of respondents, complainants, and witnesses is limited to those who need to know. Records maintained or created by the Health Department or an affiliated institution during the course of responding to an allegation of research misconduct are kept confidential to the extent permitted by law and regulation.

## APPENDIX 2 - RESEARCH DETERMINATION WORKSHEET

This worksheet is a guide to help the investigator determine if the activity is human subject research and regulated by the Department of Health and Human Services (DHHS) and/ or Food and Drug Administration (FDA). Activities that meet the definition of human subject research will require submission to an IRB, as well as Public Health Review by the Baltimore City Health Department.
If you are still uncertain after completing this worksheet contact the Public Health Review administrator (paul.overly@baltimorecity.gov)

Human subjects research must be *research* and must involve *human subjects* as described in the tables below:

| IS IT RESEARCH? | | |
|---|---|---|
| IF: | the project is a systematic investigation designed to contribute to generalizable knowledge, for example if there is intent to publish or otherwise disseminate the results outside BCHD | THEN IT **IS** RESEARCH |
| IF: | the project is NOT a systematic investigation, eg. it involves very few cases,<br>or<br>its primary intent is to prevent or control disease or injury in Baltimore City or to improve a Baltimore City Health Department Program and there is no intention to publish and disseminate the results | THEN IT **IS NOT** RESEARCH |

| DOES IT INVOLVE HUMAN SUBJECTS? | | |
|---|---|---|
| IF | Data is obtained through interaction with living individuals<br>OR<br>Activity uses existing identifiable data relating to living persons (ie. where the identity of the subject can be known) | THEN IT **DOES** INVOLVE HUMAN SUBJECTS |
| IF | None of the subjects are living<br>OR<br>Data are all anonymized/deidentified (the subjects can not be identified) | THEN IT **DOES NOT** INVOLVES HUMAN SUBJECTS |

If the project is research and involves human subjects as defined above, both IRB review by an external IRB and public health review by BCHD are required.

## APPENDIX 3 – PUBLIC HEALTH REVIEW APPLICATION SAMPLE

Note: This is only a ***sample*** of the form. The form itself is a Microsoft Word form document that is designed to be filled out on computer. Contact Paul.overly@baltimorecity.gov to acquire one.

**BALTIMORE CITY HEALTH DEPARTMENT**
**PUBLIC HEALTH REVIEW FORM**

Once you have obtained IRB approval, please fill out this form and submit, along with the research protocol and proof of IRB approval, to paul.overly@baltimorecity.gov . We will complete the public health review within two weeks. If you received approval from a JHMI IRB, all you need to do is submit this form; your protocol and proof of approval are submitted to us automatically.

**Name of PI:**
**Title of research project:**
**Name of IRB from which obtained approval:**
**IRB approval date (enter as mm/dd/yyyy):**
**IRB protocol number:**

1. **Briefly describe the goals and methods of the research study.**

2. **BCHD and Client Involvement**
   Please complete all applicable sections

   **Participant Recruitment**
   **Number of participants to be recruited through BCHD:**
   **Active recruiting:**
   **By BCHD staff? ☐ Yes ☐ No Time required per prospect: minutes**
   **By Research staff? ☐ Yes ☐ No Office/desk required? ☐ Yes ☐ No**
   **Passive recruiting (i.e., posters, pamphlets)? ☐ Yes ☐ No**

**CONTENT OF RECRUITMENT MATERIALS SUBJECT TO APPROVAL BY ASSISTANT COMMISSIONER**

**Location of recruiting site: Eastern**
**Specify (if Other, Combination, or SBHC):**
**Anticipated duration of recruitment: Days**

**Clinic Use** (other than for recruitment)
**☐ Yes ☐ No**
If yes, please check area(s) you seek to use:
☐ **Patient Waiting Area (complete forms, surveys, etc.)**
☐ **Office space providing privacy/confidentiality**
☐ **Clinical space for treatment, examinations, tests**
☐ **Other**
**Clinic site(s): Eastern**
**Specify (if Other, Combination, or SBHC):**

**Anticipated duration:** **Days**

**Staff Time**

☐ **Participant/Patient Appointment Management**
**Number of participants:**
**Expected number of appointments/participant:**
**Plan for compensation**

☐ **Other Staff Time**
**Total staff time required per day:** **Hours**
**Anticipated duration:** **Days**
**Plan for compensation**

**Other Clinic Resources**

(Telephones, computers, expendable supplies, etc.)
☐ **Yes** ☐ **No**
**Describe:**
**Anticipated duration:** **Days**
**Plan for compensation**

**Data Use**

☐ **Yes** ☐ **No**
**Describe data required:**
**Is this readily available?** ☐ **Yes** ☐ **No** ☐ **Do not know**
If BCHD must data compile, process, analyze, or otherwise prepare data for your use:
**Plan for compensation for staff time:**

**Other BCHD Involvement**

If your research requires BCHD involvement not covered by any of the above, please specify:

3. **Describe the benefits to Baltimore residents that will accrue through the study.**

## APPENDIX 4 - PUBLIC HEALTH REVIEW FINDINGS

**Baltimore City Health Department**
**Public Health Review**

To be filled out by the relevant Assistant Commissioner.

**Project PI:**
**Project Title:**
**IRB protocol number:**
**Date of review:**

**Resources required from BCHD**
Are the resources required from BCHD readily available? Will this project displace other essential activities? If so, is adequate compensation planned?

**Research relevancy**
*What is the relevance of the project to BCHD's programs and goals?*

**Potential community concerns**
*Are there any community concerns that might arise because of this project?*

**Other concerns**

**RECOMMENDATION**
☐ approve as is
☐ reject
☐ approve with conditions:
☐ consider community input before proceeding:
☐ other:

## APPENDIX 5 - RESEARCH COMPLETION

**Baltimore City Health Department**
**Public Health Review**

Investigators: complete this form when you complete the portion of your study that involves the Baltimore City Health Department. Submit via e-mail to: paul.overly@baltimorecity.gov

**Project PI:**
**Project Title:**
**IRB protocol number:**
**Date:**
**Date of conclusion of activities involving BCHD:**
**Estimated date of conclusion of study:**

## DISSEMINATION PRODUCT REVIEW POLICY

**Purpose**
This policy provides BCHD the opportunity to comment on publications or other dissemination products with which it is associated, and to ensure that research findings are incorporated in practice.

***Applicability:*** This policy applies to any research, analysis, evaluation, or non-research study in which Baltimore City Health Department staff are involved in authorship.

***Prior to*** submission of any dissemination products based on research or analyses conducted in association with the Baltimore City Health Department, the Assistant Commissioner must review the product. The review is to ensure that BCHD programs are accurately presented and data is accurately used, and to assess scientific quality.

Assistant Commissioners may seek the advice of Deputy Commissioners or the Commissioner. In addition, the Chief Epidemiologist may be asked to help review if there is need for a technical evaluation of analytic methods.

**Definition**
*Dissemination products* include manuscripts, presentations (either live or electronic, including displays on Internet or intranet sites), conference abstracts, and workshops that include study data, analysis, and findings.

**Procedure**

*Investigator/Author Responsibilities*

- Submit all dissemination products to the Assistant Commissioner *prior to submission to the disseminating entity (i.e., journal, conference, web site)*
- Respond to questions that arise during the review
- Once approval is obtained, inform the Assistant Commissioner about acceptance and publication of dissemination products

*Assistant Commissioner Responsibilities*

- Review product for dissemination within 1-2 weeks of submission by the investigator/author
- Share and discuss findings with other BCHD staff

For studies associated with the Baltimore City Health Department but in which BCHD has no authorship participation or interest, the courtesy of an advance copy of dissemination products for review and comment is requested.