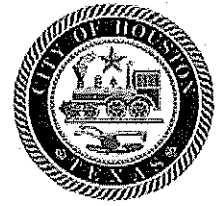


HOUSTON HEALTH DEPARTMENT



POLICY TITLE:
INVESTIGATIVE REVIEW GUIDANCE

EFFECTIVE DATE:

TYPE OF POLICY (PLEASE INDICATE)

- ADMINISTRATIVE
- PROGRAM/SERVICE

- CLINICAL
- STANDING MEDICAL ORDER
- STANDING DELEGATION ORDER

1. POLICY STATEMENT

1.1. This policy establishes principal guidelines for all Houston Health Employees regarding the review, approval and coordination of human subject's research conducted with and by the Houston Health Department.

2. SCOPE

- 2.1 This policy applies to all full-time, part-time, contract and temporary employees.
- 2.2 This policy supersedes all other policies regarding research.
- 2.3 This policy applies to all areas, programs and divisions.
- 2.4 This policy establishes the authority of the Investigative Review Committee.
- 2.5 The Investigative Review Committee is a subcommittee of the Quality Council.

3. AUTHORITY:

3.1. There are six (6) types of policy instruments which guide employee performance. The Administrative and Regulatory Affairs Department has oversight over the five (5) different policy instruments in use by the City governing City-wide employee behavior, 1) The City of Houston Charter, 2) the City of Houston Code of Ordinances, 3) Executive Orders, 4) Mayor's Policies, and 5) Administrative Policies and Procedures. The sixth policy instrument is department policy. In addition, all employees are expected to comply with all applicable federal and state laws, rules and regulations during the conduct of their daily duties. Houston Health Department employees are expected to comply with all City of Houston policies and procedures and all department policies.

3.2. Houston Health Department (HHD) will adhere to all City of Houston Policies and Procedures; we shall create department policies only where there are department or division or program specific circumstances. Please note that the Investigative Review Committee (IRC) is unique to the Houston Health Department.

4. PURPOSE:

- 4.1. This policy shall shape, guide, optimize, and protect performance by ensuring that all programs are aware of human subject's research requests that impact their program. The Investigative Research Committee will coordinate appropriately with the program manager, bureau chief or assistant director as appropriate.

4.0 DEFINITIONS: key terms and words.

- 4.1 *Policy* is the fundamental principle, the general guideline, the administrative action, doctrine. Within the context of public health, policy development includes the advancement and implementation of public health law. Policies should be aligned with the strategic plan and objectives of the organization. Policy development is an essential public health function.
- 4.2 *Purpose* reason for the creation of the policy, is this policy because of new requirement, new guidance, explanation provides a brief statement of the expectations.
- 4.3 *Resources* provides links, identify materials, academic materials or guidance such as Public Health Accreditation Board guidance, standards, materials that provide greater clarity
- 4.4 *Quality Council* is part of the Quality Assurance infrastructure of the department. This body includes as chairman the Public Health Authority and includes all department Chief Physicians, the Women Infant and Children (WIC) Director, the Laboratory Services Director, the Chief Pharmacist, the Chief Technology Officer, the Chief Program Officer, the Environmental Health Assistant Director and the department director.
- 4.5 *Administrative policies* predominately address financial or employee related subjects such as dress code, attendance, and more. An administrative policy is unique to department but does not replace or conflict with any City of Houston policy.
- 4.6 *Human Subject* means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private health information.
- 4.7 *Interaction* means communication or interpersonal contact.
- 4.8 *Intervention* means physical procedure by which data is gathered and manipulations of the of the subject or the subject's environment that are performed for research purposes.
- 4.9 *Institutional Review Board (IRB)* means a group of individuals formally assigned in accordance with federal regulations to review and monitor research involving human subjects. The Houston Health Department does not have an IRB.
- 4.10 *Investigative Review Committee* means a group of HHD employees that reviews, approves and coordinates research requests with appropriate programs. This committee has the authority to make decisions regarding human subject research on behalf of the Houston Health Department.

4.11 *Research* means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalized knowledge. This may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis, demographic and epidemiological research, program evaluation, oral histories, documents and records and other methods associated with biomedical, behavioral and social sciences.

5.0 ROLES AND RESPONSIBILITIES:

- 5.1 The Chairman of the Investigate Review Committee is the Deputy Public Health Authority.
- 5.2 The Chairman determines the membership of the IRC, they shall appoint at a minimum five (5) committee members. Appointment to the Committee is based on expertise required, familiarity with applicable laws and regulations.
- 5.3 The IRC has the authority to approve or disapprove all human subjects research projects in consultation with the program manager, program leadership.
- 5.4 The Chairman determines the meeting dates, the IRC shall meet on a quarterly basis or as needed.
- 5.5 All documentation including action items and correspondence shall be maintained in the Quality Council SharePoint site with restricted access.
- 5.6 The IRC can request additional information or additional documents before granting approval.
- 5.7 The IRC is not an IRB, HHD employees must obtain prior IRB approval before there is an IRC review. And a copy of the IRB (if applicable) shall be provided to the Committee.
- 5.8 Researcher completes a written request that explains the research request with sufficient details for the IRC to consider the request. Researcher shall clearly articulate the purpose of the human subject's research, provide the context and purpose and identify all the data sources.
- 5.9 Researcher conducts the research project upon the approval of the IRC. The Researcher submits a progress report to the IRC and requests an extension to the IRC if the approved timeframe needs to be extended.
- 5.10 Researcher shall forward to the IRC a copy of all final reports and publications and the Houston Health Department shall be appropriately identified in all publications.

6.0 COMPLIANCE:

- 6.1 Activities contained in this policy are subject to Department Quality Assurance review and auditing. And the Quality Council may request a periodic report on the IRC reviews.
- 6.2 The Health Insurance Portability and Accountability Act (HIPAA) carries an associated Privacy Rule that can significantly affect the way research can be obtained, use and disclosure of protected health information (PHI) must meet the minimum standard. Only the minimum amount of information needed for any specific purpose can be disclosed. HIPAA compliance is in addition to the IRC policy, both sets of requirements apply. This is usually addressed in the IRB process.
- 6.3 Federal Wide Assurance (FWA) for the Protection of Human Subjects. All Human Subjects research must be quidded by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. This statement of principles may include (a) an appropriate existing code, declaration (such as the World Medical Association's Declaration of Helsinki), or statement of ethical principles (such as the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research), or (b) a statement formulated by the institution itself.
- 6.4 The Houston Health Department shall renew or update their FWA's on-line in a timely manner, the department shall update the FWA within 90 days after changes, such as change of leadership of the committee. <http://ohrp.cit.nih.gov/efile/FwaRenew.aspx>

7.0 REFERENCES:

Protection of Human Subjects: The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the US. Department of Health and Human Services (HHS).

Office for Human Research Protections/ www.HHS.gov/ohrp/

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>
Common Rule

<https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm113818.htm>
Federal Policy for the protection of Human Subjects (Common Rule)

<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwass/update-renew-fwa/index.html>
Federal Wide Assurance


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5/30/2019
Date


Dr. David Persse, Public Health Authority

6/3/2019
Date: