POLICY AND PROCEDURE	
SUBJECT/TITLE:	Research and IRB (Institutional Review Board) Policy
APPLICABILITY:	All Canton City Public Health (CCPH) Personnel
CONTACT Title & DIVISION:	Epidemiologist, Administration
ORIGINAL DATE ADOPTED:	09/07/2016
LATEST EFFECTIVE DATE:	03/21/2024
REVIEW FREQUENCY:	Every 5 years
BOARD APPROVAL DATE:	N/A
REFERENCE NUMBER:	800-020-P

A. POLICY

Canton City Public Health (CCPH) upholds the highest ethical standards in the development, participation, and support of research involving human subjects. CCPH ensures that the health, safety and privacy of all human subjects is our priority and that all participants have provided their informed consent prior to conducting any research. To meet this standard the Research Committee at CCPH will process requests for research.

B. PURPOSE

The purpose of this policy is to ensure CCPH has the necessary protocols in place for the protection of human subjects in all research in which the agency is involved. This policy applies to all, including external and internal partners, who engage in the development, participation or support of research with human subjects at CCPH. Neither this policy nor CCPH provide an Institutional Review Board (IRB) process, which, if needed, must be done prior to submission of any research request. An example of the use of this policy would be for individuals wanting to complete research in partnership with CCPH and either do not require an IRB or one has already been completed. Note: Data requests are not considered research and would follow the public records request policy.

C. BACKGROUND

This policy supports the criteria established by the Public Health Accreditation Board (PHAB):

A. Measure 10.2.1 (PHAB version1.5): An adopted human subject research protection policy.

B. People who are subjects of research studies have certain protections under the Code of Federal Regulations, Title 45, Public Welfare: Part 46, Protection of Human Subjects. Federal law requires that all agencies that receive federal funds must have an Institutional Review Board (IRB) evaluate, approve and provide assurances regarding non-exempt research to protect the confidentiality and safety of research subjects.

Benefits of Research

- Access to important information about behaviors, risk factors and disease trends.
- Opportunity to demonstrate the outcomes and value of public health interventions.
- Drive innovation and continuous quality improvement in public health practices.
- Support the development and implementation of evidence-based services and programs.
- Lead to improved health for our community.

The Public Health Research Committee is comprised of CCPH employees with experience in fields of interest, a Health Insurance Portability and Accountability Act (HIPAA) coordinator and an epidemiologist.

The Research Committee will evaluate all research requests to determine whether to approve the request. The Research Committee serves to:

- Evaluate research requests for:
    - Alignment with CCPH's mission vision and values.
    - Compliance with patient confidentiality and conformity to the HIPAA regulations.
    - Compliance with Grant and Program -specific requirements.
- Assurance of protection of research participants according to the Code of Federal Regulations (45 CFR 46). Solicit CCPH research primary contact.
- Ensure ongoing communication with the Principal Investigator (PI) for each research project regarding the status of study approval and research progress.
- Approve or Disapprove research study and explain why.
- Notify requestor of approval/disapproval status.
- Share relevant research activities with senior Public Health leadership and the Health Commissioner.

Note: Research involving human subjects requires a separate IRB (if applicable) prior to a research committee's review.

D. GLOSSARY OF TERMS

Exempt: CCPH utilizes the definition of exempt provided by the Department of Health and Human Services (HHS). The definition can be found here: Exemptions (2018 Requirements) | HHS.gov

Expedited Review: Research activities that present no more than minimal risk to human subjects.

Full Board Review: Research that involves greater than minimal risk, prisoners, pregnant people/fetuses or people with intellectual disabilities requires a full IRB review from an entity other than CCPH.
HIPAA – Health Insurance Portability and Accountability Act of 1996 – a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

Institutional Review Board (IRB): A committee that performs ethical review of proposed research. (Note CCPH does not provide for an IRB process)

IRB Approval: The determination by an IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal Review (Exempt from Further Review): Research that involves commonly accepted educational settings, tests, surveys, or behavioral practices that does not have the possibility of revealing subject information or put subjects at civil, criminal, economic, or reputational risk.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Principle Investigator (PI): The person(s) overseeing, coordinating, and/or otherwise "in charge of" an experiment or research project.

Research: Under both the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Common Rule, "research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Research Committee: Members from CCPH, assembled for the purpose of assessing Research Requests and other responsibilities as noted in this policy.

Research Investigators: Research at a public health agency may be conducted by public health employees, researchers from other organizations, or in collaboration between public health employees and research investigators from other organizations.

E. PROCEDURES FOR RESEARCH AT CCPH

1. Complete and submit all required documentation as noted below:
    - Utilize Attachment A: 800-020-01-A_Canton City Researcher Application, for instructions to complete the incorporated request form for research at CCPH. An abbreviated version of the request form is available in a fillable PDF, Attachment B: 800-020-02-F_Research Application Form. These documents are available on the CCPH website.
    - A *CV or Resume* for each PI and Research Associate involved with the proposed research. (If researchers are not employees of CCPH).
    - *IRB materials* – if applicable, a copy of the complete research proposal as submitted to the Research Committee, with dated approval, exemption or denial.
    - Copies of *survey instruments, focus group and interview questions, and marketing material* for proposed research.
    - Copies of *documents for obtaining informed consent*.
    - Completed and signed documentation should be emailed to **communicabledisease@cantonhealth.org**.

2. The Research Committee will meet within 30 days of receiving a research request to review the proposal and make a recommendation of approval, exemption or denial to the Health Commissioner.

3. The Research Committee will communicate with the PI or designee to request additional information (if needed). Within 2 weeks of meeting, the Research Committee will notify the PI or designee of its decision to approve, exempt, or deny the research proposal.
4. A liaison from the Research Committee will be assigned to communicate with the PI and report research progress to the Research Committee.
5. When the research project has been completed or discontinued, the PI is requested to complete a Final Study Close-Out Report Form. This completed form can be found as a **fillable PDF** on the CCPH website and must be submitted to **communicabledisease@cantonhealth.org**.
6. Upon receipt of the Final Study Close-Out Report Form, the PI may be contacted to schedule a presentation of findings to CCPH staff.

EXEMPTIONS

- Research involving the collection of publicly available data.
- Study of existing data, documents or records.
- Information recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

F. CITATIONS & REFERENCES

[1] Code of Federal Regulations, Title 45, Public Welfare: Part 46, Protection of Human Subjects. 2009 Jan 15. U.S. Dept of Health & Human Services (HHS). Retrieved 8/16/2016 from http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#.
[2] Federal wide Assurances. HHS. Retrieved 08/16/2016 from www.hhs.gov/ohrp/assurances/assurances/index.html.
[3] Office for Human Research Protections (OHRP). HHS. Retrieved 08/16/2016 from www.hhs.gov/ohrp/assurances/index.html.
[4, 5] Code of Federal Regulations, Title 45, Public Welfare: Part 46, Protection of Human Subjects. 2009 Jan 15. HHS Retrieved 08/16/2016 from http://www.hhs.gov/ohrp/regulations-and- policy/regulations/45-cfr-46/index.html#46.102.
[6] Code of Federal Regulations, Title 45, Public Welfare: Part 46, Protection of Human Subjects. 2009 Jan 15. HHS Retrieved 08/16/2016 from www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101.
[7] Program Requirements for Title X Funded Family Planning Projects. Title X Program Requirements, Section 13.4, p. 19. 2001 January. USDHHS, Office of Family Planning, Bethesda, Maryland. http://www.hhs.gov/opa/program-guidelines/program-requirements#
[8] From "Research Committee," by Public Health – Dayton & Montgomery County, 2016-2024 (https://www.phdmc.org/programs-a-to-z/research-review-panel). In the public domain.
[9] From "Human Research Protection Policy (IRB)," by Toledo-Lucas County Health Department, 2018 (https://lucascountyhealth.com/wp-content/uploads/2018/10/Human-Research-Protection-Policy-IRB-8-13-18.pdf). In the public domain.

G. CONTRIBUTORS

The following staff contributed to the authorship of this document:

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H. APPENDICIES & ATTACHMENTS

Attachment A: 800-020-01-A_Canton City Researcher Application
Attachment B: 800-020-02-F_Research Application Form

I. REFERENCE FORMS

Not Applicable.

J. REVISION & REVIEW HISTORY

Revision Date	Review Date	Author(s)	Notes
09/07/16	09/07/16	C. Henning	Original Approval
		C. Henning K. Boyd N. Parry	Completed review and updated various sections to reflect current practices/responsibilities and planned practices for documents up for expiration review

K. APPROVAL

This document has been approved in accordance with the "800-001-P Standards for Writing and Approving PPSOGFs" procedure as of the effective date listed above.