POLICY AND PROCEDURE	
SUBJECT/TITLE:	Research: Protection of CCHD Clients, Staff and Individuals Stored in Datasets Accessible by CCHD
APPLICABILITY:	All Canton City Health District (CCHD) Personnel
CONTACT PERSON & DIVISION:	Christina R Henning, Laboratory
ORIGINAL DATE ADOPTED:	09/07/16
LATEST EFFECTIVE DATE:	09/07/16
REVIEW FREQUENCY:	Every 5 Years
BOARD APPROVAL DATE:	N/A
REFERENCE NUMBER:	800-020-P

A. PURPOSE

This document is intended to:

1. Provide optimal protections to CCHD clients and individuals stored in datasets accessible by CCHD who are subjects of research that CCHD conducts or collaborates in;
2. Delineate optimal protections for CCHD staff and CCHD research partners who conduct or collaborate in research that involves CCHD clients and individuals stored in datasets accessible by CCHD; and
3. Participate in and contribute to research when appropriate.

B. POLICY

CCHD staff and partners shall adhere to the procedures in this document when engaged in research involving CCHD clients and individuals stored in datasets accessible by CCHD.

C. BACKGROUND

People who are subjects of research studies have certain protections under Federal law (the *Code of Federal Regulations, Title 45, Public Welfare: Part 46, Protection of Human Subjects*). Federal law requires that all agencies who receive funds from any federal agency must have an *Institutional Review Board* (IRB) review, approve, and provide assurance regarding non-exempt research in regards to protecting the confidentiality and safety of research subjects[1].

D. GLOSSARY OF TERMS

Federalwide Assurance (FWA): A document on file with the U.S. Department of Health & Human Services (HHS) Office for Human Research Protections (OHRP) by which an institution commits that it will comply with the requirements of Federal law for the protection of human subjects[2]. Nearly all research undertaken with federal funds, even indirectly, requires an FWA.

Institutional Review Board (IRB): A committee that performs ethical review of proposed research[3].

IRB Approval: The determination by the 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[4].

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

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities[5].

E. PROCEDURES & STANDARD OPERATING GUIDELINES

1. **Research Exempt from IRB Review:** The following types of research are exempt from IRB federal laws[6]**:**
    a. Research about instructional techniques, curricula, or classroom management methods.
    b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
        i. The human subject's personal information can be identified, directly or through identifiers linked to the subject.
        ii. Any disclosure of the subject's responses could place him/her at risk of criminal or civil liability, or be damaging to his/her financial standing, employability, or reputation.
    c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if the subject is an elected or appointed public official or candidate for public office; or when federal law indefinitely requires the confidentiality of the personally identifiable information to be maintained.
    d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:
        i. These sources are publicly available; or
        ii. The information is recorded by the investigator in such a manner that the subject cannot be identified directly or through identifiers linked to him/her.
    e. Research and demonstration projects which are conducted or designed to study, evaluate, or examine:
        i. A public benefit or service program;
        ii. Procedures for obtaining benefits or services under those programs;

iii. Possible changes in or alternatives to those programs or procedures; or
iv. Possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies if:
   i. Wholesome foods without additives are consumed;
   ii. A food is consumed that contains a food ingredient, agricultural chemical or environmental contaminant at or below a level found to be safe by the Food and Drug Administration, Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2. Submitting a Request for Research which Involves CCHD Staff, Clients and/or Individuals Stored in Datasets Accessible by CCHD

a. The PI shall complete the CCHD *Research Request Form (see Attachment A).* The CCHD Request Form includes:
   i. The title of the research study or project.
   ii. The name and contact information of the PI(s). A PI for any research done at CCHD must have documented experience conducting research or for new researchers with no or little experience, contact information for an experienced advisor must be included.
   iii. Qualifications of the PI(s). Describe the qualifications and previous research experience of the PI(s).
   iv. Names, contact information, and roles of all other persons who will be involved in conducting the research project.
   v. Whether the proposed research study is deemed *Exempt* or *Non-exempt*. If Non-exempt:
   vi. Indicate whether the study was submitted to another agency's IRB. If the study was submitted to another agency's IRB, include a copy of the full research proposal as submitted.
   vii. Indicate whether the IRB request was approved or denied. If approved, attached a dated copy of the written IRB approval.
   viii. Dates. State the dates of the research project period that involves CCHD.
   ix. Goal(s) or Significance of the Research Proposal. Explain the purpose for the research proposal.
   x. Need. Identify the need for this research project. Include references if applicable.
   xi. Study Population. Indicate inclusion/exclusion criteria for the study population. Justifications for inclusion/exclusion based solely on gender, race, or ethnicity, according to USDHHS guidelines, must be explicit. Indicate the number of intended research subjects.

xii. Sites of Interaction with Study Participants. Document all locations where CCHD clients and/or individuals stored in datasets accessible by CCHD will be encountered for the study.

xiii. Method of Data Analysis. Outline the major steps and methodologies to be used. Include the methodology for determination of the sample size. Identify the variables to be measured and how they will be statistically evaluated.

xiv. Risks. Identify potential risks. Include risks to patient confidentiality and the researcher's inability to maintain research records. (Researchers must maintain proposal records and IRB correspondence for three years after completion of the project.)

xv. Risk Minimization. Describe procedures for protection against or minimizing potential risks.

xvi. Benefits. Describe the potential benefits that will be gained from the study. Rate the overall importance of this research.

xvii. Publication of Results. Indicate how research results will be disseminated and to whom (i.e. who is the target audience for what is learned?).

xviii. All actual and in-kind internal and external resources dedicated to the study. Also disclose any financial compensation information (dollar amount and payer/ organization) if any that will be received for undertaking the study.

b. The PI shall submit the completed CCHD Research Request Form electronically to the Division Director of the program most closely associated with the research.
   i. If the PI is a CCHD staff person, the Research Request Form is submitted to their supervisor who shall follow their chain-of-command and ultimately submit it to the division director.
   ii. If the PI is external to CCHD, the Research Request Form may be submitted to the division director most closely associated with the research. The program manager shall follow chain-of-command and submit the request to his/her division director.

3. For Non-Exempt Research (i.e. Research that Requires IRB Review)

a. All non-exempt research must have IRB approval in order to be done at CCHD and/or with CCHD staff, clients and/or individuals stored in datasets accessible by CCHD.

i. Non-exempt research shall utilize the IRB and IRB processes of the respective hospital or non-profit wanting to conduct the research project at and/or with CCHD.

ii. In the event that the requesting agency does not have its own IRB process consistent with the *Code of Federal Regulations, Title 45, Public Welfare; Part 46, Protection of Human Subjects (2009)*, an IRB from The Ohio State University (OSU) or the Ohio Department of Health (ODH) must be used for approval.

iii. An IRB Authorization Agreement shall be implemented between CCHD and the outside collaborators for the research project(s) being done.
iv. CCHD staff must abide by decisions of the respective IRB in terms of the research at hand.
v. CCHD shall maintain an FWA on file with HHS that references the respective research project's collaborator-IRB FWA Assurance number.

4. Title X Grant-Funded Programs

a. The Ohio Department of Health (ODH) requires that all programs receiving Title X funds notify ODH in writing of any research involving clients in receipt of Title X services[7]. The written notice shall be prior to the initiation of the respective research.
    i. CCHD's currently does NOT receive Title X funding. Prior to initiating any research, this should be verified as it can change at any time.

5. CCHD Research Review Committee

a. The Division Director who is in receipt of a completed Research Request Form shall notify and forward the documentation to the Research Review Committee Chairman.
b. The Research Review Committee shall be co-chaired or chaired by the CCHD Medical Director and the Health Insurance and Portable Accountability Act Officer/Privacy Officer.
    i. Other standing members of the Research Review Committee can include:
        1. The Nursing Director and
        2. The Epidemiology Program Manager.
    ii. Ad hoc members will be added to the CCHD Research Review Committee at the discretion of either Chair, given the nature of the research at hand.
    iii. The respective program manager and/or division director will be ad hoc members of the Review Committee.
c. The CCHD Research Committee will complete the review within 30 days of receipt of the research proposal.
d. The research request will be reviewed for but not limited to:
    i. Relevancy to the CCHD Mission Statement and department goals;
    ii. Compliance with other existing CCHD policies and procedures;
    iii. Patient confidentiality and conformity with HIPAA standards.
e. The CCHD Research Committee will provide the applicant-researcher with a written response to the request within two weeks of the Committee's meeting.
f. Decisions of the Research Review Committee about whether the research project is tenable for CCHD are binding.
g. Potential researchers who disagree with a decision of the Research Review Committee can appeal it to the Health Commissioner. If the Health Commissioner was a member on

the IRB Board that denied the request, an appeal can be made to the Board of Health President.

6. **Confidentiality**
    a. All existing CCHD policies and procedures relating to client confidentiality and Health Insurance Portability and Accountability Act (HIPAA) laws must be adhered to regardless of whether the research is exempt or non-exempt from IRB involvement.
    b. Researcher and other research-related staff may be required to sign a CCHD confidentiality statement and/or *Research Data Use Confidentiality Form* (Attachment B).
7. **Research Findings**
    a. Researcher shall acknowledge CCHD in all respective research project documentation, including but not limited to poster presentations, news articles, journal articles and PowerPoint-like publications.
    b. CCHD may elect to be a co-author in articles submitted for publication, with up to two CCHD staff contributing to the article and being listed as co-authors.
    c. The researcher and/or research associates may be asked to present related research findings to CCHD staff in a presentation format. Failure to do so within a timely manner of the request may result in future requests for research at CCHD to be denied.

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] Federalwide 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#

G. CONTRIBUTORS

The following staff contributed to the authorship of this document:

1. Laurie Dietsch, Performance Improvement and Accreditation Coordinator, Columbus Public

Health Department

2. Christina R Henning, Laboratory Director CCHD
3. Tammy Stolicny
4. Janet Frank
5. David Hampton

H. APPENDICIES & ATTACHMENTS

Attachment A: 800-020-01-A_Canton_City_Researcher_Applic_Form

Attachment B: 808-020-02-A_Research_Data_Use_Confidentiality_Agreement

I. REFERENCE FORMS

Not Applicable

J. REVISION & REVIEW HISTORY

Revision Date	Review Date	Author	Notes
09/07/16	09/07/16	C. Henning	Original Approval

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.