Toledo-Lucas County Health Department Policy

Human Research Protection Policy (IRB)

Original Effective Date:	Review / Revision Date:	Board of Health Resolution:
July 29, 2014	August 13, 2018	BOH 2017.07.097

Maintenance Steward: Health Commissioner **History:** ☐ New ☒ Revised ☐ Archived

Organizational Scope:

☒ Full Agency ☐ Administration ☐ Community Services ☐ Environmental Health ☐ Health Services

Frequency of Review:

☐ Annually ☒ Biennially ☐ 5 Years ☐ As Needed ☐ Other:

Location:

G-Drive: G: → Users → Common → Policies & Procedures

Website: www.lucascountyhealth.com/employee-login/

Hardcopy: Policies and Procedures Manual, HR Office

Archived Version(s): G: → Users → Common → Policies & Procedures

Requisite Signatures

☒	Board of Health President	Date: 7/29/2017
☒	Health Commissioner	Date: 07-28-17
☒	Director of Administrative Services	Date
☒	Director of Environmental Health & Community Services	Date: 7-28-2017
☒	Director of Health Promotion & Policy Integration	Date: 7/27/17
☒	Director of Health Services	Date: 7-31-17
☒	Director of Human Resources	Date: 7-31-17

Human Research Protection Policy (IRB)

I. Policy

The Toledo-Lucas County Health Department upholds the highest ethical standards in the development, participation, and support of research involving human subjects. The Department ensures that the health, safety, and privacy of all human subjects is our first priority and that all participants have provided their informed consent prior to the conduction of any research.

II. Scope

This policy applies to all employees of the Toledo-Lucas County Health Department (TLCHD) who engage in the development, participation, or support of research with human subjects.

III. Purpose

TLCHD does not have an internal Institutional Review Board to approve research protocols. The purpose of this policy is to ensure TLCHD has the necessary protocols in place for the protection of human subjects in all research in which the agency is involved.

IV. Background

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

A. Measure 10.2.1: An adopted human subjects research protection policy.

B. 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.

V. Human Research Protocols

A. TLCHD does not have an internal Institutional Review Board to approve research protocols.

1. There are three types of IRB Review, see section *VIII. Glossary* for more information.

    a. Minimal Review (Exempt from Further Review)
    b. Expedited Review
    c. Full Board Review

B. All research protocols are to be reviewed and approved by the IRB of the Health Department's collaborating research partner(s).

1. Before collaborating in any research involving human subjects, the Health Department requires proof of IRB approval from the institution where an IRB review was completed.

2. In cases where research protocols cannot be reviewed by a collaborating partner's IRB, the Health Department may submit an application for protocol review to an independent Institutional Review Board or Independent Review Board.

3. The IRB must provide assurance they are in compliance with, and follow, the rules of the United States Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

4. Research activities that involve the use of data from external organizations will require the submission of an Application for Protocol Review to the collaborating partner(s) IRB if the qualifications are met for Expedited or Full Board Reviews.

C. Research collaborations may be pursued with hospitals, universities, state departments, and/or federal agencies.

D. Research proposals and IRB approval must be submitted to the Principle Investigator, the appropriate TLCHD Division Director, and the Health Commissioner.

1. The Health Commissioner will make a formal recommendation to the Board of Health for final approval prior to the implementation of any experimental research.

VI. Information Confidentiality

A. No staff member shall publicly distribute research materials or information without the express, written permission from the Principle Investigator(s).

B. No staff member shall be granted access to research materials or information without first signing and submitting a confidentiality agreement to the Principle Investigator(s).

C. Any TLCHD policy or procedure governing 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 review and involvement. Failure to adhere to the provisions of any policy or procedure concerned with confidentiality, or with the *Human Research Protection Policy (IRB)* may result in discipline up to and including termination.

VII. Maintenance

A. Review

1. The *Human Research Protection Policy (IRB)* is to be reviewed biennially to ensure compliance with both agency and accreditation standards.

B. Revision

1. All changes made to this policy are to be noted on the **Record of Change**. Substantial changes will require renewed signatures from all applicable parties. This includes changes to the intent, scope, procedures, or policy statement.

2. Changes in style, format, grammar or minor error correction will not require renewed signatures but must be indicated on the Record of Change.

VIII. Glossary

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

B. Full Board Review: research that involves greater than minimal risk, prisoners, pregnant women/fetuses, or mentally disabled persons requires a full IRB review.

C. Institutional Review Board (IRB): a committee that performs ethical review of proposed research.

D. 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.

E. 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.

F. 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.

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

Record of Change

(Required for all policies)

Date of Change	Changes Made By	Changes Made/Notes	Approved By
8/13/2018	BP	During review by TLCHD staff the Personnel Committee on 8-13-18, this policy's content was found to be accurate, sufficient, and current.	Personnel Committee