

PHDMC Research Review Panel Process for Website

The Research Review Panel serves to:

- Ensure that all research involving PHDMC data, staff, or clients supports the mission of PHDMC.
- Ensure that PHDMC staff are active collaborators on all proposals initiated by external researchers, where appropriate.
- Ensure that the Health Commissioner is aware of the findings from these endeavors and their public health implications.

Note: The Research Review Panel does not take the place of an Institutional Review Board (IRB). Research involving human subjects requires the review of the IRB.

Timeline and Procedures:

Generally, submissions to the Review Committee must be made at least two weeks prior to initiation of research. Application materials should be submitted electronically along with one paper copy. Please submit these to Mary Frost at MFrost@phdmc.org

Submissions should include:

1. Proposal application cover sheet complete with signatures
2. Summary of proposed research
3. Confidentiality agreement signed by the principal investigator
4. Any research tools such as a questionnaire or data collection tool
5. A copy of documents used to obtain informed consent
6. If the principal investigator is not an employee of PHDMC, a copy of a curriculum vitae
7. Copy of Request to Epidemiologist if request involves Vital Statistic Information
8. University IRB approval (if required) or Exemption Form

Resources:

1. Wright State University Research & Sponsored Programs (IRB)
2. Proposal application
3. Research Summary Template
4. Pledge of Confidentiality
5. Exemption Form

Members:

Michael Dohn, MD – Medical Director
Yvetta Hawley, MS, RN – Director of Nursing
Janine Howard, MS, RN – Director of Disease Prevention
Michael Matis – General Legal Counsel
Connie Freese, RS, MPH – PHDMC Staff with research experience
Sara Paton, PhD – Epidemiologist, Office of the Health Commissioner Liaison

Contact:

Mary Frost (937) 225-4479
MFrost@phdmc.org

Request for Approval of Research Involving Human Subjects or Protected Health Information

Please check type of review being requested:

- Exempt (attach Exemption Form)
 IRB-approved

Office Use Only
Protocol # _____ - _____ - _____
Date Received: ___ / ___ / ___

Title:

Principal Investigator:
Affiliation:
Address:
Phone:
Email:

PHDMC Collaborator:
Division:
Phone:
Email:

I request review and approval of the attached proposal by Public Health - Dayton & Montgomery County. I am aware of the federal regulations on the protection of human subjects and will obtain voluntary informed consent if required by the protocol. I will obtain approval of PHDMC prior to making any changes in the research protocol. I will advise PHDMC of any adverse events and submit progress reports as required and a completion report.

Signature of Principal Investigator

Date

Signature of PHDMC Collaborator

Date

The submission package for requests involving human subjects or Protected Health Information (PHI)* must include two (2) copies of the following documents:

1. Proposal application cover sheet complete with signatures
2. Summary of proposed research (see attached)
3. Confidentiality agreement signed by the principal investigator
4. Electronic Medical Record User Agreement signed by each investigator
5. Any research tools such as a questionnaire or data collection tool
6. A copy of documents used to obtain informed consent
7. If the principal investigator is not an employee of PHDMC, a copy of a curriculum vitae
8. Copy of Request to Local Registrar if request involves Vital Statistic Information
9. University IRB approval (if required)

* PHI refers to individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

Summary of Proposed Research Requirements

1. Title: should be succinct and descriptive
2. List of all investigators
 - a. Include academic degrees and affiliations
 - b. Include a statement if there are any vested interest in the research; if all of the investigators have no vested interest, state “Vested interest: none “
3. Background with review of current literature
4. Specific Aims or Objectives: What question(s) do you want to answer?
5. Methods
 - a. Design and Rationale
 - b. Selection of subjects, sample size needed
 - c. Data collection and statistical analysis planned
 - d. Time frame for study
6. If an IND or IDE has been filed, include #.
7. Possible Risks
8. Procedures for protecting confidentiality of subjects (e.g. responses kept in locked file, restricted access to information) or for assuring the anonymity of the subjects; (e.g. no personal identifiers on data collection tools). Please note that student investigators must store study records or data in a PHDMC or Wright State location (i.e. not at home).
9. Procedure for obtaining informed consent
10. Plans for reporting of results: conferences, meetings, journal publication
11. Source(s) of funding (if any)
12. References

Pledge of Confidentiality

1. I will use these data only for the project titled _____

2. I will not use these data in any way other than for statistical, scientific or medical research.
3. I will not release or allow access to these data in full or in part to any person without the written permission of PHDMC.
4. Unless it is part of my study or project, I will not attempt to learn the identity of any person or medical care provider beyond the information contained in these data.
5. I will not present or publish these data in a manner in which any individual can be identified.
6. I will not present or publish point maps showing residences of cases.
7. I will not release data for any sub-population of < 10 persons based on the relevant U.S. Census data.
8. I will not attempt to link, or permit others to link, these data to individually identified records in another database, file or other information source without the written permission of PHDMC.
9. In the event that the identity of any person is discovered or released inadvertently:
I will immediately notify PHDMC of the incident.
I will make no use of this knowledge.
I will inform no one else of any discovered identity.
10. I will include the following acknowledgment and disclaimer in any publication or presentation produced from these data: "Public Health - Dayton & Montgomery County data used in this study were obtained from the _____ (program name). Use of these data does not imply PHDMC agrees or disagrees with any presentations, analyses, interpretations or conclusions."
11. I will send a copy of any publication or presentation produced from these data to PHDMC program identified above in a timely manner.
12. I will destroy the data no later than 1 year after PHDMC approval, or an application to extend the date of required destruction of the data must be received by PHDMC no later than 5 working days prior to the 1 year.
13. I will make all reasonable efforts to maintain the confidentiality of these data.

Print Name

Signature

Date

EXEMPTION FORM

Projects that do not meet the definition of research and/or human subject, as well as certain categories of research involving human subjects, do not fall under the IRB purview or are exempt from IRB review. Please mark the relevant category or categories for which you are requesting an exemption determination. **Please attach this document to your Petition of Approval of Research Involving Human Subjects.**

Projects that do not meet the definition of research involving human subjects under 45 CFR 46.102:

<input type="checkbox"/>	IRB review of the project is not required because it does not meet the definition of research in 45 CFR 46.102(d) which defines 'research' as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Examples of projects that may not be research include quality improvement programs or required program evaluations that will not be published or disseminated formally.
<input type="checkbox"/>	IRB review of the project is not required because it does not involve human subjects as recognized by 45 CFR 46.102(f) which defines a 'human subject' as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

If you have checked either of the previous two boxes, your research does NOT have to be submitted for IRB approval. If your research does meet the definition of research involving human subjects and you feel it meets the criteria for exemption, please mark the appropriate category and submit this with your Petition of Approval.

Projects involving human subjects research activities in exemption categories allowed under 45 CFR 46.101:

<input type="checkbox"/>	(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices , such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
<input type="checkbox"/>	(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior , unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***Note: interview or survey research involving children does not qualify for exemption.***
<input type="checkbox"/>	(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
<input type="checkbox"/>	(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
<input type="checkbox"/>	(5) Research and demonstration projects which are conducted by or subject to the approval of [Federal] Department or Agency heads , and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (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.
<input type="checkbox"/>	(6) Taste and food quality evaluation and consumer acceptance studies , (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.