

IRB Use Only
Protocol No. _____
Program(s) Review: _____
Date of Review: _____

**Application for Protocol Review
OHIO DEPARTMENT OF HEALTH (ODH)
Institutional Review Board (IRB)**

Instructions: Fill out the form below and include all of the additional materials as required for your request. If you will be requesting ODH data, contact the relevant ODH program to determine the guidelines for data release. Some ODH programs may offer guidelines to use in applying for data. The IRB requires the ODH program involved review requests prior to submission.

The IRB meets on the fourth Tuesday of each month except for November and December. The meeting for those two months is combined and held on the first Tuesday of December. To be considered for review, protocol must be received by the chair 14 calendar days prior to the scheduled meeting.

- (1) Provide the following materials (*mandatory*):
 - a. Completed application for protocol review
 - b. A formal study proposal
 - c. Completed Curriculum Vitae form for all persons who will have access to the data as part of the study
 - d. Signed confidentiality agreements for all persons who will have access to data as part of the study

- (2) Provide the following materials (*if applicable*):
 - a. Your institution's IRB approval
 - b. Consent forms
 - c. Expedited Review – Initial Review form

All items are to be sent electronically to: odhirb@odh.ohio.gov

Questions may be directed to Pam Leimbach – pam.leimbach@odh.ohio.gov or Lisa Heinbach – lisa.heinbach@odh.ohio.gov

1. PROJECT TITLE
CDC or HHS Federal Project Number (if any):

2. PRINCIPAL INVESTIGATOR (PI)	
Name (Last, First):	Degree(s):
Title:	
Agency/Institution:	
If ODH, Bureau & Div.:	
Mailing Address:	

E-mail:	Fax:
Phone:	Emergency phone:

3. ADDITIONAL CONTACT(S)	
Specify the additional contact person(s) (e.g., study or regulatory coordinator, research assistant, etc.) in case the PI is not available. If more than three, attach additional page with their information.	<input type="checkbox"/> N/A
Name (Last, First):	Phone:
E-mail:	Fax:
Name (Last, First):	Phone:
E-mail:	Fax:
Name (Last, First):	Phone:
E-mail:	Fax:

4. CO-INVESTIGATORS & KEY PERSONNEL	
List any other staff who will be participating in this research. You will need to provide signed confidentiality agreements and CVs for each member of the team. Attach additional page if necessary.	<input type="checkbox"/> N/A
Name (Last, First):	

5. ODH CONTACT(S)	
Please list any ODH staff members you are working with on this protocol.	<input type="checkbox"/> N/A
Name (Last, First):	Phone:
E-mail:	Fax:
Signature:	
Name (Last, First):	Phone:
E-mail:	Fax:
Signature:	

6. OTHER INSTITUTIONAL REVIEW BOARD APPROVALS	
Check all that apply and provide applicable documentation. Attach additional page if necessary.	
<input type="checkbox"/> Centers for Disease Control and Prevention	
<input type="checkbox"/> Univ./Institution	Name: _____ Status: _____

<input type="checkbox"/>	State IRB	Name:	Status:
<input type="checkbox"/>	Other	Name:	Status:
<input type="checkbox"/>	Other	Name:	Status:

7. EXPEDITED REVIEW

Are you requesting **Expedited Review**?

The Federal Regulations establish two main criteria for an expedited review:

1. The research may not involve more than "minimal risk." "Minimal risk" means that "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" ([45 CFR 46.102\(i\)](#) and [21 CFR 56.102\(i\)](#)).
2. The entire research project must be consistent with one or more of the federally defined categories (see Expedited Review Form for complete list).

Yes → Complete Expedited Review Form

No

8. SUMMARY OF THE RESEARCH

Summarize the proposed research using *non-technical* language that can be readily understood by someone outside the discipline. Explain briefly the background, research design, years of data being examined and procedures to be used.

9. RESEARCH OBJECTIVES

List the specific objectives of the research study.

10. RESEARCH METHODS

- a. Briefly describe the methods to be used in the research study. What is the nature of the measures or observations that will be made? Please provide a copy and a brief description of any questionnaires, tests or other instruments.

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b. Check all research activities that apply:

<input type="checkbox"/> Invasive Procedures	<input type="checkbox"/> Investigational Device or Apparatus	<input type="checkbox"/> New Drug, Vaccine or Diagnostic Test	<input checked="" type="checkbox"/> Existing Data
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11. DURATION

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

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12. SUBJECTS

Who will be the subjects of this study? How will they be solicited or contacted?

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13. OHIO DEPARTMENT OF HEALTH DATA

- a. Are any data from ODH being requested? Yes
 No

IF YES → Specify variables (i.e. identifying information, years, fields, etc.)

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- b. How long will the data be kept and when will it be returned to ODH or destroyed? (Note: data must be returned to ODH, or certified that it has been appropriately destroyed, no later than a year after date of IRB approval. Requests to keep the data longer than one year will require that an extension be requested from the IRB.)

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14. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

- | | |
|---|--|
| a. Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval. | |
| b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.). | |
| c. Will your work with the participants take place at multiple locations?
<input type="checkbox"/> Yes → Indicate the total number of participants to be enrolled across all locations:
<input type="checkbox"/> No | |

15. PARTICIPANT POPULATION

- | | |
|--|--|
| a. If applicable, specify the age range of the individuals who are being included in the research/data request:
Age(s): | |
| b. Specify the participant population(s) or subject category/ (categories). Check all that apply:
<input type="checkbox"/> Adults
<input type="checkbox"/> Minors (< 12 years of age)
<input type="checkbox"/> Adolescents (12-17 years of age)
<input type="checkbox"/> Pregnant women
<input type="checkbox"/> Fetuses – Live or Dead
<input type="checkbox"/> Abortion
<input type="checkbox"/> Human In Vitro Fertilization
<input type="checkbox"/> Tissues
<input type="checkbox"/> Wards of the State or other Agency, Institution or Entity
<input type="checkbox"/> Prisoners
<input type="checkbox"/> Mentally Disabled Individuals
<input type="checkbox"/> Mentally Retarded Individuals | |
| c. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion. | |
| d. Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status?
<input type="checkbox"/> Yes
<input type="checkbox"/> No

If Yes → Explain the criteria and reason(s) for each exclusion. <i>Consider the study’s scientific or scholarly aims and risks.</i> | |

The remaining question is for research involving direct contact with the participants. If you are using data only, please skip to Question 20.

- e. Are any of the participants likely to be vulnerable to coercion or undue influence? *Consider students, employees, terminally ill persons, or others who may have limited resources and/or autonomy.* Yes No

If Yes → Describe additional safeguards to protect participants' rights and welfare. *Consider strategies to ensure voluntary participation.*

16. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

- a. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.
- b. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.
- c. List the names of investigator(s) and/or key personnel who will recruit participants and their qualifications.
- d. Describe the process that will be used to determine participant eligibility.
- e. Describe the recruitment process; including the setting in which recruitment will take place. *Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).*
- f. Explain how the process respects potential participants' privacy.

17. INCENTIVES TO PARTICIPATE

- Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? Yes No
- Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable.*

If Yes → Describe the incentive, including the amount and timing of all payments.

18. INFORMED CONSENT PROCESS

Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. ***Provide copies of documents.***

- | | | |
|--|--|------------------------------|
| <input type="checkbox"/> Informed Consent – Form | <input type="checkbox"/> Assent – Form | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Informed Consent – Verbal | <input type="checkbox"/> Assent – Verbal Script | |
| <input type="checkbox"/> Informed Consent – Addendum | <input type="checkbox"/> Parental Permission – Form | |
| <input type="checkbox"/> Translated Consent/Assent – Form(s) | <input type="checkbox"/> Parental Permission – Verbal Script | |

b. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives. N/A

c. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)? N/A

d. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. N/A

e. Explain how the possibility of coercion or undue influence will be minimized in the consent process. N/A

f. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? Yes → ***Provide copies of these tools***
 No

g. Will any other consent forms be used (e.g., for third parties being questioned, marketing of products or services, etc.)? Yes → ***Provide copies of these forms***
 No

19. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants. ***Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.***

b. Does the research require access to personally identifiable private information? Yes
 No

If Yes → Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

20. CONFIDENTIALITY OF DATA

a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. ***Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with Federal, State and Ohio Department of Health policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure location, or if electronically transmitted.***

b. Will any aspect of the data be made part of any permanent record that can be identified with the subject? Yes
 No

If Yes →Please describe

c. Will any data from files or archival data be used? Yes
 No

If Yes →Please describe

d. If no aspect of the data is to be made part of any permanent record, how will the data be destroyed?

e. Describe how issues of small cell size will be addressed so that confidentiality is maintained. (Reference ODH small cell policy. See [Disclosure Limitation Standard](#) for full details.)

f. Will a subject's participation (or lack of) in the study be made a part of any permanent record available to supervisors, teachers or employers? Yes
 No

If Yes →Please describe

g. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. N/A

h. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality (i.e. as per Ohio's mandatory reporting requirements). N/A

21. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable data (Protected Health Information [PHI]) subject to the HIPAA Privacy Rule be accessed, used, or disclosed in the research study? Yes
 No

If Yes → Please describe

22. REASONABLY ANTICIPATED BENEFITS

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.***

b. List the potential benefits that society and/or others may expect as a result of this research study.

23. RISKS, HARMS, & DISCOMFORTS

a. Describe all reasonably expected or anticipated risks, harms, and/or discomforts that may apply to or result from the research. Discuss severity and likelihood of occurrence. ***Consider the range of risks, including physical, psychological, social, legal, and economic. All research carries some risk. "No Risk" is not an acceptable answer.***

b. Describe how risks, harms, and/or discomforts will be minimized. ***If testing will be performed that might***

identify individuals with a previously unknown medical condition, address timing and method of testing; include how positive test results will be handled.

24. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described above beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? Yes No

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

25. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

26. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

b. List any costs to participants that will be covered by the research study.

27. ASSURANCE - PRINCIPAL INVESTIGATOR

I agree to follow all applicable federal regulations, guidance, state and local laws, and ODH policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Initial Review of Human Subjects Research application is accurate and complete. I will initiate this research only after having received notification of final IRB approval.

Signature of Principal Investigator (Electronic Signatures are acceptable)

Date

Printed name of Principal Investigator

29. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes. **Bold = Mandatory**

- Initial Review of Human Subjects Research Application**
- Research Protocol**
- Signed Confidentiality Forms for all Persons Handling Data**
- Curriculum Vitae form for all Persons Handling Data**

May also be required depending on your specific protocol

- Expedited Review – Initial Review Request
- Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question)
- Data Collection Form(s) for Investigator-Initiated Studies (question)
- Data Collection Form(s) involving protected health information
- Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question)
- Script(s) or Information Sheet(s), including Debriefing Materials (question)
- Instruments (e.g., questionnaires or surveys to be completed by participants) (question)
- Other Committee Approvals/Letters of Support (questions)
- Other supporting documentation and/or materials