Pennsylvania Department of Education (PDE)
Institutional Review Board (IRB)
Application for Full PDE IRB Review

PDE IRB USE ONLY

# Project Identification

* 1. Project Title Click or tap here to enter text.
	2. Principal Investigator

|  |  |
| --- | --- |
| NAMEClick here to enter text. | HIGHEST DEGREE(S) EARNEDClick here to enter text. |
| AGENCY OR ORGANIZATION NAME (AGENCY, UNIVERSITY, PROFESSIONAL ORGANIZATION, COMMERCIAL RESEARCH FIRM, ETC.) Click here to enter text. |
| COMPLETE MAILING ADDRESSClick here to enter text. |
| CITY, STATE, ZIP CODEClick here to enter text. |
| OFFICE PHONE NUMBERClick here to enter text. | ALTERNATE PHONE NUMBERClick here to enter text. | EMAIL ADDRESSClick here to enter text. |

* 1. Research Abstract. Provide a brief summary of the research purpose and methods. Please limit to this page. Attach a protocol, if one exists, for your study in Attachment B.

Click here to enter text.

* 1. Alignment with PDE Strategic Priority

Does your proposed research project align with PDE Strategic Priorities?

[ ]  No
[ ]  Yes; If yes, which PDE Strategic Priority or Research Agenda question(s) will be supported by the results of this request?. Click here to enter text.

* 1. Project Time Line

Anticipated Start Date: Click here to enter a date. Anticipated End Date: Click here to enter a date.

Provide a detailed timeline of the entire research project using Attachment C.

* 1. Training

Principal investigators, co-investigators, and all research staff who will have contact with human subjects and/or access to identifiable personal records must complete training in human subject protections. A certificate of completion should be attached to each Curriculum Vitae (CV). HIPAA, Good Clinical Practice, or Responsible Conduct of Research training is *not* accepted in lieu of human subject protections training.

Name of most recent human subjects protection training: Click or tap here to enter text.

Date completed: Click here to enter a date.

As Principal Investigator, I acknowledge that I am responsible for the submission of this application. I have fully reviewed the application forms and instructions and believe this application is complete and accurate. I affirm that, if approved, this research will be conducted in compliance with PDE IRB-approved procedures and requirements.

| SIGNATURE: | DATE: Click or tap to enter a date. |
| --- | --- |

* 1. Supervisor of Principal Investigator:

|  |  |
| --- | --- |
| NAMEClick here to enter text. | TITLEClick here to enter text. |
| AGENCY OR ORGANIZATION NAME (AGENCY, UNIVERSITY, PROFESSIONAL ORGANIZATION, COMMERCIAL RESEARCH FIRM, ETC.) Click here to enter text. |
| SIGNATURE DATE | EMAIL ADDRESSClick here to enter text. |

* 1. Other Research Staff: List all other research staff who will have contact with human subjects or access to identifiable personal records in Attachment A. Attach Curriculum Vitae’s (CVs) or resumes for all research staff, including the PI and Co-PI, along with a certificate of completion of human subjects training and financial conflicts of interest training, as applicable, to Attachment A. CVs or resumes should not exceed five (5) pages per person.
	2. Student Research. Applications submitted by students must also be approved by their academic advisor or chair of their committee.

|  |  |
| --- | --- |
| NAME OF CHAIR OR ACADEMIC ADVISORClick here to enter text. | HIGHEST DEGREE(S) EARNEDClick here to enter text. |
| COLLEGE OR UNIVERSITYClick here to enter text. |
| COMPLETE MAILING ADDRESSClick here to enter text. |
| Click or tap here to enter text. |
| CITY STATE ZIP CODEClick here to enter text. |
| OFFICE PHONE NUMBERClick here to enter text. | ALTERNATE PHONE NUMBERClick here to enter text. | EMAIL ADDRESSClick here to enter text. |
| As Academic Advisor/Committee Chair to the Student Investigator, I will provide oversight for this research. I have read and approved the research design and methods. |
| SIGNATURE DATE |

* 1. IRB Approval

You are obligated to obtain an IRB review and approval for your study, prior to applying for research data from PDE.

Are you obligated to use your organization’s IRB for this project? [ ]  Yes [ ]  No

Has another IRB reviewed this study? [ ]  Yes [ ]  No
Include a detailed explanation of the previous (review(s)) by other IRB(s) in Attachment L.

Has another IRB declined to review, tabled, deferred, disapproved, suspended, or terminated this study? If yes, please include a brief explanation:
Click here to enter text.

* 1. Research Status

Working as an “Authorized Representative” of The Pennsylvania Department of Education.

[ ]  No
[ ]  Yes: Complete Attachment D

# Funding

* 1. Is this research funded by a grant, contract, cooperative agreement, or other award?

[ ]  No. Explain how costs of the proposed research will be supported:
Click or tap here to enter text.

[ ]  Yes. Identify the agency or organization that received the award:
Click or tap here to enter text.

Type of Funding Sources

|  |
| --- |
| [ ] FEDERAL [ ] STATE/LOCAL GOVERNMENT [ ] PRIVATE FOUNDATION[ ] OTHER - EXPLAIN: Click here to enter text. |
| FUNDING AGENCY(S) NAMEClick here to enter text. | CONTACT NAMEClick here to enter text. |
| COMPLETE MAILING ADDRESSClick here to enter text. |
| CITY, STATE, ZIP CODEClick here to enter text. |
| PHONE NUMBERClick here to enter text. | EMAIL ADDRESSClick here to enter text. |

If this project is funded by a federal agency, attach an electronic copy of the entire application or proposal (exclusive of appendices/attachments) with Attachment M.

* 1. Research budget total: $ Click here to enter text.

Start Date: Click here to enter a date. End Date: Click here to enter a date.

Provide proposed research project budget. See Attachment M: Project Budget.

# Conflict of Interest

Conflicts of interest can include financial and non-financial interests. All individuals involved in the research who have responsibilities in the design, conduct, or reporting of the research (including consultants and student research staff) must complete and submit a copy of Attachment N: Conflict of Interest Reporting.

# Requests for State Agency Records Information and/or Staff Resources

If the research requires record information (data), the researcher shall complete and submit Attachment G: Data Element Crosswalk, providing a specific listing of the items of data being requested and a rationale for each data element.

If the research requires resource contributions from PDE, the researcher shall complete and submit Attachment H, providing a list of non-data information request such as but not limited to letters of support or subject matter expertise. If identifiable PDE records will be used or disclosed in electronic form, complete and submit Attachment J with your application.

* 1. Does the research require use and/or disclosure of identifiable records?

[ ]  No; if no, skip to item 4.3.

[ ]  Yes; complete Attachment G: Requests for Use or Disclosure of Records. However, if the research is funded or conducted by the agency from which records are requested, Attachment G is not necessary.

* 1. Will the identifiable records be accessed or disclosed in electronic form?

[ ]  No

[ ]  Yes; complete Attachment J: Electronic Data Security Plan only if any of the research will be conducted outside of the State agency secure network.

# Study Description/Research Methodology

Provide a description of the Research methods that will be employed in this study and demonstrate how the data and methods are suitable to answer the research question.

Use lay language that can be understood by a person who is not familiar with your area of expertise. Do not refer to, or copy and paste from, a grant application or from the Research Abstract in Section 1.3 of this application.

* 1. Purpose and Conceptual Rationale

Describe the background and significance of this research.
Click or tap here to enter text.

Specify the questions this research will attempt to address.
Click or tap here to enter text.

Include a brief summary of the pertinent literature with full citations, if applicable.
Click here to enter text.

If this is evaluation research, briefly describe the program or intervention being evaluated.
Click here to enter text.

* 1. Study Design

State the primary hypotheses or objectives of this research.
Click here to enter text.

Indicate whether the design will involve randomization, and/or whether comparison or control groups will be used.
Click here to enter text.

Describe the sampling plan, the size of the sample or study group(s), and the power of the planned statistical tests, if applicable.
Click here to enter text.

Specify the major independent, dependent, and extraneous variables, and discuss possible threats to internal and/or external validity.
Click here to enter text.

Describe the statistical tests or analyses that will be used and explain how the expected results will address the hypotheses or research objectives.
Click here to enter text.

* 1. Data Collection Procedures
		1. Does the research involve contact with human subjects?

[ ]  No, Go to item 5.3b.
[ ]  Yes, Explain all of the following:

* what subjects will be asked to do: Click here to enter text.
* who will perform the data collection procedures: Click here to enter text.
* where data collection procedures will be performed: Click here to enter text.
* when or how often data collection procedures will be conducted: Click here to enter text.
	+ 1. Does the research involve use of identifiable records?

[ ]  No, Go to item 5.3c.
[ ]  Yes, Explain all of the following:

* the agency holding each source of identifiable records or PPI: Click here to enter text.
* how each source of records will be obtained: Click here to enter text.
* plans to link records from multiple sources and the sequence of linkage, if applicable: Click here to enter text.
* the identifiers to be used to link multiple records sources, if applicable: Click here to enter text.
	+ 1. Does the research involve multiple data collection periods?

[ ]  No, Go to item 5.3d.
[ ]  Yes, Explain the following:

* the number of data collection intervals: Click here to enter text.
* the time period between data collection intervals: Click here to enter text.
* the data collection methods to be used at each interval: Click here to enter text.
	+ 1. Will the study take place in clinics, hospitals, welfare offices, jails, or other facilities?

[ ]  No, Go to item 5.4.
[ ]  Yes, Attach a copy of letters of cooperation from each facility to Attachment L.

* 1. Data Collection Instruments

List all data collection instruments, including questionnaires, interview guides, assessments or tests, focus group guides, record review forms, etc. Attach copies of all data collection instruments to Attachment K. If none, skip to Section 6.

Click here to enter text.

# Study Subjects

* 1. Expected number of subjects over the course of the research: Click here to enter text.
	2. Specify inclusion criteria for subjects. Click here to enter text.
	3. Specify exclusion criteria for subjects. Click here to enter text.
	4. Will individuals of either gender be excluded?

[ ]  No

[ ]  Yes, Explain why the research focuses on one gender:
Click here to enter text.

* 1. Is the research limited to specific age group(s)?

[ ]  No

[ ]  Yes, Specify the age group(s) and explain why the research focuses on them:
Click here to enter text.

* 1. Vulnerable subject groups

Vulnerable subjects may be the focus of the research or may be recruited incidentally. For example, if women of reproductive age would be eligible for the research, Attachment E-1 should be completed.

Check all that apply:

[ ]  Pregnant women/human fetuses/neonates (complete Attachment E-1)

[ ]  Prisoners (complete Attachment E-2)

[ ]  Children (complete Attachment E-3)

[ ]  Developmentally disabled

[ ]  Dementia/Cognitively impaired

[ ]  Mentally/behaviorally/emotionally impaired

[ ]  Socially/economically disadvantaged

[ ]  Low literacy/educationally disadvantaged

[ ]  Seniors, over 65

[ ]  Seriously/chronically ill

[ ]  Substance users/abusers

[ ]  Undocumented immigrants

[ ]  Other (describe): Click here to enter text.

# Risks and Benefits

This Section must be completed for all research.

The federal definition of “minimal risk” states 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.

* 1. This research is (check one box):

[ ]  Minimal risk
[ ]  More than minimal risk

Explain why this research is minimal risk *or* more than minimal risk in relation to the above definition of minimal risk. Provide examples of how research procedures are consistent with the level of risk checked above.
Click here to enter text.

* 1. Does the research involve any of these possible harms and/or discomforts to subjects?

Check **all** that apply.

[ ]  Invasion of privacy or breach of confidentiality

[ ]  Psychological/emotional discomfort or distress

[ ]  Social stigmatization

[ ]  Legal repercussions

[ ]  Economic (e.g., employment, insurability)

[ ]  Physical harm or discomfort

[ ]  Withholding standard care or procedures

[ ]  Significant time or inconvenience

[ ]  Other (describe): Click here to enter text.

* 1. Describe what steps will be taken to minimize each of the possible harms and/or discomforts to subjects.

Click here to enter text.

* 1. If this research involves interactions or interventions with human subjects, describe what steps will be taken if subjects experience serious distress, discomfort, or decompensation during study participation. Indicate whether a resource list or referrals will be available to give to subjects routinely or as needed, and attach the list to Attachment L. (If this is records research only, indicate “NA.”) [ ]  N/A
	2. Describe any anticipated benefits of this study including the potential for improving instructional and educational outcomes, etc?
	Click here to enter text.
	3. Describe how the results of this study will be used, for example how can PDE use the research in its final form?
	Click here to enter text.
	4. Describe any anticipated benefits for individual subjects who are participating or whose records are being used in this research. If none, indicate “None.”
	Click here to enter text.
	5. Describe how this research will benefit this cla ss of subjects or how it will contribute to general knowledge.
	Click here to enter text.
	6. Explain how the anticipated benefits of this research outweigh the harms and/or discomforts.
	Click here to enter text.

# Use and/or Disclosure of Identifiable Records

* 1. Does this research involve use or disclosure of State Agency records?

[ ]  No
[ ]  Yes, If identifiable records are requested from PDE, complete Attachment G.

* 1. Does this research involve use or disclosure of identifiable records?

[ ]  No, Go to Section 9.
[ ]  Yes

* 1. Will signed authorization be obtained from study subjects and/or their parents/guardians for the use or disclosure of their identifiable records?

[ ]  No

[ ]  Yes Explain how, when, and where signed authorization will be obtained and complete Attachment F.

* 1. Are you requesting a waiver of authorization for use or disclosure of existing identifiable records?

[ ]  No

[ ]  Yes Complete Attachment I, Section 4 (a ll items).

# Confidentiality

Direct identifiers include name, address, phone, email address, gender, race, ethnicity, school, PASecureID, etc.

* 1. Will names and other direct identifiers of study subjects be accessed or obtained for any purpose (e.g., screening, recruitment, analyses)?

[ ]  No, Go to item 9.5.

[ ]  Yes, List the direct identifiers to be collected and explain why they are needed for the research.

* 1. Will names and all direct identifiers be removed or segregated from research records and replaced with study codes as early in the process as possible?

[ ]  N/A: All records are non-identified.
[ ]  Yes
[ ]  No Explain your answer. Click here to enter text.

* 1. Will a link between direct identifiers and study code numbers be retained until the research is completed?

[ ]  Yes - Explain why it is necessary to retain the link between study codes and direct identifiers.

[ ]  No - Specify when the link between identifiers and code numbers will permanently destroyed.

[ ]  N/A - All records are non-identified.

 Explain: Click here to enter text.

* 1. Specify when all direct identifiers will be permanently separated from study records and destroyed. (See Definitions on pg. 2 of the application.) If all records are non-identified, indicate “NA.”

Click here to enter text.

* 1. Will identifiable research records be disclosed to anyone who is not involved with this research?

[ ]  No

[ ]  Yes – Describe the data to be disclosed, to whom, and the purpose of each disclosure.
Click here to enter text.

* 1. Will identifiable research records be used for a future study?

[ ]  No

[ ]  Yes – Explain
Click here to enter text.

* 1. Will a public-use/de-identified dataset be made available at the completion of the research? (See Application Definitions.)

[ ]  No

[ ]  Yes - Note: a file layout of all data elements must be submitted for PDE IRB review prior to release.

* 1. Will any identifiable research data or the study consent form be placed in a subject’s medical record or case file?

[ ]  No

[ ]  Yes – Explain
Click here to enter text.

* 1. Will a federal Certificate of Confidentiality be requested?

[ ]  No

[ ]  Yes – Agency name:
Click here to enter text.

**For records-only research, skip Sections 10 and 11.**

**Go to item 12.1 and complete all relevant Attachments.**

# Mandatory Reporting

*Pennsylvania Agency Policy* requires reporting of all suspected abuse/neglect of children and vulnerable adults, and reporting of threats of harm to self (suicidal ideation) or others. Some research involves diagnostic testing or clinical care, such that reporting of health conditions is required. Mandatory reporting requirements must be described in study consent/assent forms as exceptions to confidentiality.

* 1. Could interventions or interactions with subjects produce information that may lead to suspicion of abuse/neglect of a child?

[ ]  No

[ ]  Yes - Describe plans for reporting such incidents to Child Protective Services.
Click here to enter text.

* 1. Could interventions or interactions with subjects produce information that may lead to suspicion of abuse/neglect of a vulnerable adult?

[ ]  No

[ ]  Yes - Describe plans for reporting such incidents to Adult Protective Services or, in the case of state hospital patients, to hospital staff.
Click here to enter text.

* 1. Could interventions or interactions with subjects produce information that may lead to concern about threats of suicide or harm to other persons?

[ ]  No

[ ]  Yes - Describe plans for reporting such incidents and plans to be implemented in the event of imminent threat of harm.

* 1. Will study procedures involve testing or diagnosis of any disease or condition that is reportable under [PA Code, Title 28, Chapter 27](http://www.pacode.com/secure/data/028/chapter27/028_0027.pdf) (Such as notifiable diseases, blood lead levels, etc.)

[ ]  No

[ ]  Yes - Include a statement in the study consent form that the subject’s condition will be reported to the state or local health department, as applicable.

# Subject Recruitment

* 1. Explain how potential subjects will be identified. Explain each method to be used to identify them (e.g., agency records, databases, referrals, advertisements, etc.).
	Click or tap here to enter text.
	2. Does this research involve recruiting subjects who are minors or dependent adults?

[ ]  No

[ ]  Yes, Explain how, when, and where a parent or legal guardian will be contacted and asked for permission to recruit the minor or dependent adult. (If a waiver of parental/guardian permission will be requested, complete Attachment I, Section 3.)

* 1. Explain how subjects will be recruited.
	Click here to enter text.
	2. Explain when recruitment will occur.
	Click or tap here to enter text.
	3. Explain w here potential subjects will be recruited.
	Click here to enter text.
	4. Explain who will make initial research contact with potential subjects. (If confidential state agency records will be used to identify potential subjects, the state agency must make initial contact.)
	Click here to enter text.
	5. Explain how privacy will be respected during the recruitment process**.**Click or tap here to enter text.
	6. Explain what steps will be taken to minimize undue influence to participate.
	Click here to enter text.
	7. Will potential subjects be offered gifts, payments, services without charge, or other incentives to participate?

[ ]  No

[ ]  Yes, Specify the type of incentive, the monetary value, and when incentive(s) will be given.
Click or tap here to enter text.

# Informed Consent/Assent Process

Unless specific requirements are met and the PDE IRB approves a waiver, signed consent/assent and signed parent/guardian permission for the participation of a child are required for studies that involve interventions or interactions with human subjects.

* 1. Are you requesting:
* A waiver of documentation of consent/assent for study participation?

[ ]  No [ ]  Yes (Complete Section 1.1 or Section 1.2 of Attachment I).
* A waiver of consent/assent?

[ ]  No [ ]  Yes (Complete Section 2 of Attachment I).
* A waiver of parent / guardian permission for study participation of a child?

[ ]  No [ ]  Yes (Complete Section 3 of Attachment I).
* A waiver of authorization for use/disclosure of identifiable records?

[ ]  No [ ]  Yes (Complete *all* items in Section 4 of Attachment I).

**If you are not contacting subjects, skip the remainder of Section 12.**

* 1. Identify who will obtain consent, assent, or parent/guardian permission. Provide job titles/credentials, and a description of consent training for all individuals responsible for obtaining consent:
	Click here to enter text.
	2. Describe how, when, and where consent, assent, and/or parent/guardian permission will be obtained.
	Click here to enter text.
	3. Explain how subjects’ understanding of the research procedures and the risks and benefits of study participation will be assessed.
	Click or tap here to enter text.
	4. Will an impartial witness be present during the consent/assent session?
	[ ]  No [ ]  Yes - Identify the individual who will serve as a witness and describe his/her qualifications.
	Click here to enter text.
	5. Complete Attachment F: Recruitment, Consent/Assent, and Authorization Documents. Put the document title in a footer on each document. List all documents and readability scores in Attachment F and attach them to the Attachment. Names of electronic documents should match the document titles listed in this Attachment.

# Application Checklist

The following documents must be submitted with the application, when applicable.

[ ]  Attachment A: Research Information

[ ]  Attachment B: Project Information

[ ]  Attachment C: Project Timeline

[ ]  Attachment D: Evidence that the Researcher is working as an “Authorized Representative”

[ ]  Attachment E-1: Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects

[ ]  Attachment E-2: Research Involving Prisoners as Subjects

[ ]  Attachment E-3: Research Involving Children as Subjects

[ ]  Attachment F: Recruitment, Consent/Assent, and Authorization Documents

[ ]  Attachment G: Requests for Use or Disclosure of Records

[ ]  Attachment H: Resource Requests

[ ]  Attachment I: Consent/Authorization Waivers

[ ]  Attachment J: Data Element Crosswalk

[ ]  Attachment K: Data Collection Instruments

[ ]  Attachment L: Miscellaneous Study Documents

[ ]  Attachment M: Project Budget

[ ]  Attachment N: Conflict of Interest Reporting – Required for all applications.

Submission of an incomplete application is a common cause for delay in the review of proposals.