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

Attachment I: Consent/Authorization Waivers

Are you requesting a waiver of:

Documentation of consent/assent for study participation? ☐No ☐Yes (Complete Section 1.1 or Section 1.2).

Some or all required elements of consent/assent? ☐No ☐Yes (Complete Section 2).

Parent/guardian permission for study participation of a child? ☐ No ☐Yes (Complete Section 3).

Waiver of authorization for use/disclosure of identifiable records or protected health information? ☐No ☐Yes (Complete <u>all</u> items in Section 4).

Section 1: Waiver of Signed Consent/Assent for Study Participation

PDE IRB may waive the requirement for written documentation (but still require that consent be obtained) if either of the following conditions exist. Indicate which condition applies and provide protocol-specific language to explain.

1.1 The only record linking the subject and the research would be the consent form and the primary risk of the research would be the potential harm from a breach of confidentiality. Subjects must be given the option of whether they want to provide signed consent, and the subject's wishes will govern.

Explain how or why the study meets this requirement:

OR

1.2 The research involves minimal risk to subjects and includes no procedure for which written consent is normally required outside the research context.

Explain how or why the study meets these requirements:

Note: In either case, the PDE IRB may require the researcher to provide the participant with a written statement about the research.

Section 2: Waiver of Some or All Required Elements of Informed Consent/Assent for Study Participation

Required Elements of Informed Consent / Assent may be found at 45 CFR 46.116(a)(1)-(8) and (b)(1)-(6) as made applicable. Explain which of the required elements at 45 CFR 46.116(a) you propose *not* to disclose to study subjects:

PDE IRB may waive the requirements for informed consent/assent in accordance with 45 CFR 46.116(d) if all of the following conditions are met. Use protocol-specific language to explain how the proposed research meets the following conditions.

2.1 This research involves no more than minimal risk to subjects.

Explain how or why the study meets this requirement:

2.2 The waiver will not adversely affect the rights and welfare of the subjects participating in the research.

Explain how or why the study meets this requirement:

2.3 This research could not practicably be carried out without a waiver or alteration.

Explain how or why the study meets this requirement:

2.4 When appropriate, subjects will be provided with pertinent information after participation.

Explain how or why the study meets this requirement:

Section 3: Waiver of Parent/Guardian Permission for Study Participation of a Child

PDE IRB may grant a waiver of parent/guardian permission for participation of a child in research if all of the following conditions are met. Use protocol-specific language to explain.

3.1 This research involves no more than minimal risk to the child.

Explain how or why the study meets this requirement:

3.2 The waiver will not adversely affect the rights and welfare of the child participating in the research.

Explain how or why the study meets this requirement:

3.3 This research could not practicably be carried out without a waiver of parent/guardian permission.

Explain how or why the study meets this requirement:

3.4 This research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect children.

Explain how or why the study meets this requirement:

3.5 An appropriate mechanism for protecting the children who will participate in this research will be substituted for parent/guardian permission.

Explain how or why the study meets this requirement:

3.6 When appropriate, parents/guardians will be provided with pertinent information after their child's participation.

Explain how or why the study meets this requirement:

Section 4: Waiver of Authorization for Use or Disclosure of Identifiable Records or Personally Identifiable Information (PII).

Please read the last page of this Appendix before completing this Section.

PDE IRB may grant a waiver(s) of authorization for use or disclosure of identifiable records or PHI if the following conditions are met. Use protocol-specific language to explain, and then sign the assurance below. The research must meet <u>all</u> the criteria below for a waiver of authorization.

Briefly describe the identifiable personal records or protected health information for which the waiver is requested:

4.1 The research involves no more than minimal risk to subjects.

Explain how or why the study meets this requirement:

4.2 The waiver of authorization will not adversely affect the rights and welfare of the subjects participating in the research.

Explain how or why the study meets this requirement:

4.3 It is not practicable to obtain signed authorization for this disclosure.

Explain how or why the study meets this requirement:

4.4 It is not possible to conduct this research without use or disclosure of identifiable records or PHI.

Explain how or why the study meets this requirement:

4.5 Identifiable information used or disclosed for this research will be protected from improper uses or disclosure.

Explain how or why the study meets this requirement:

4.6 This research is of sufficient importance to outweigh the intrusion into the privacy of subjects that will result from the use or disclosure of his/her identifiable records and/or protected health information. Explain how or why the study meets this requirement:

4.7 When appropriate, the subjects will be provided with additional pertinent information after participation. Explain how or why the study meets this requirement:

4.8 Explain when and how identifiable information used or disclosed for this research will be destroyed.

If you are requesting a waiver of authorization, provide your signed assurance:

As Principal Investigator, I assure that identifiable personal records and/or protected health information used or disclosed for this research without written authorization will not be reused for other purposes, or disclosed to any other person or entity, except as specifically required or permitted by law and approved by the PDE IRB. I further assure that no individual whose personal records or protected health information is used in this research will be identified in any written report resulting from this research. I understand that, as the principal investigator of this research, I am also responsible for ensuring that all members of this research team will abide by these restrictions.

PRINICIPAL INVESTIGATOR'S SIGNATURE	DATE