



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

Attachment E-2: Research Involving Prisoners as Subjects

Certain epidemiologic studies conducted or supported by the Department of Health and Human Services (DHHS) that focus on a particular condition or disease that might affect prisoners, as it would any other members of the population, may qualify for a waiver of certain requirements in Subpart C.

1. Does the research present no more than minimal risk and no more than inconvenience to prisoner-subjects?

- No Go to Question 3.
- Yes Explain your answer.

2a. Will the research describe the prevalence or incidence of a disease by identifying all cases?

- No Go to Question 2b.
- Yes Explain your answer.

2b. Will the research study potential risk factor associations for disease?

- No Go to Question 3.

Yes Explain your answer.

3. Are prisoners the focus of the research?

No

Yes Complete Item 4.

If the answers to 1 and 2a or 2b are “Yes” and the answer to 3 is “No,” the research may meet the requirements for an exemption. Otherwise, complete items 4 and 5.

DHHS-funded research that involves prisoners requires the investigator to comply with additional protections in 45 CFR 46, Subpart C. Subpart C specifies categories of permissible research with prisoners.

4. Check the category that applies to this research:

The research examines possible causes, effects, and processes of incarceration, and/or criminal behavior and the research presents no more than minimal risk and no more than inconvenience to the subjects ([45 CFR 46.306\(a\)\(2\)\(i\)](#)).

The research examines prisons as institutional structures or prisoners as incarcerated persons, and the research presents no more than minimal risk and no more than inconvenience to the subjects ([45 CFR 46.306\(a\)\(2\)\(ii\)](#)).

The research examines conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults.) ([45 CFR 46.306\(a\)\(2\)\(iii\)](#)).

Research falling into this category can be approved only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts, has published notice in the Federal Register of the Secretary's intent to approve such research.

The research examines practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects ([45 CFR 46.306\(a\)\(2\)\(iv\)](#)). *In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts, has published notice in the Federal Register of the Secretary's intent to approve such research.*

If the research falls into this category, explain how prisoners will be assigned to groups (if applicable).

5. Explain why the research falls into the category checked above.