OMB No. 0990-0473
Approved for use through XXXXXXXX

U.S. Department of Health and Human Services (HHS)
Subpart C Certification Form

In compliance with 45 CFR 46.305(c), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2).

OHRP requires the electronic submission of Subpart C certification requests. Requests should be emailed to subpartc@hhs.gov. If an institution is unable to submit information electronically, please call 240-453-8141 to discuss an alternative submission process.

Do not print and scan the certification form for submission. Fill the form out electronically, and email a copy of the electronically filled-out form as an attachment.

To submit a subpart C certification request to OHRP, the institution must submit a completed copy of this certification form in conjunction with a copy of the research proposal in order to determine whether the appropriate findings have been made. The term "research proposal" includes:

- the IRB-approved protocol, including consent forms;
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review.

*Note: If an IRB considers the grant application during its review of the study, **only** submit the portions of the grant application relevant to subpart C review for the purposes of subpart C certification.*

Administrative Information

Name of the Institution that Operates the IRB of Record, or the Non-institutional IRB that Serves as the IRB of Record:	Click or tap here to enter text.
Address of the Institution that Operates the IRB of Record, or the Non-institutional	Click or tap here to enter text.

IRB that Serves as the IRB of Record:	
Name(s) of Institutions Relying on the IRB of Record:	
Contact Information for the Individual Submitting the Certification:	*Name:* Click or tap here to enter text. *Title:* Click or tap here to enter text. *Phone:* Click or tap here to enter text. *Email:* Click or tap here to enter text.
Relevant Grant Number(s):	Click or tap here to enter text.
Funding Agency:	Click or tap here to enter text.
Granting Institution's Program Officer:	Click or tap here to enter text.
Program Officer's Email Address:	
OHRP Assurance #:	Click or tap here to enter text.
IRB Registration # for Reviewing IRB:	Click or tap here to enter text.

Study Information

Study Title: Click or tap here to enter text.
Name of Principal Investigator(s): Click or tap here to enter text.
Brief Summary of Protocol: Click or tap here to enter text.
Date(s) of IRB meeting(s) in which protocol was considered, including the dates of initial IRB review and subpart C review: Click or tap here to enter text.

	What was the IRB's determination regarding the risk level of this study?:
☐	Greater than minimal risk
☐	Minimal risk

Permissible Categories of Research

This institution certifies that the IRB has determined that the research under review represents one of the categories of research permissible under §46.306(a)(2) or meets the criteria for use of the epidemiological waiver (45 CFR 46.305(a)(1) and 68 FR 36929):

Select One	Permissible Activity Description
☐	**45 CFR 46.306(a)(2)(i)**: *Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects*
☐	**45 CFR 46.306(a)(2)(ii):** *Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects*
☐	**45 CFR 46.306(a)(2)(iii):** *Research on 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) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.*
☐	**45 CFR 46.306(a)(2)(iv):** *Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. 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 has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.*

Select One	Permissible Activity Description
☐	**Epidemiological Waiver (68 FR 36929):** *Research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:* *(1) In which the sole purposes are:* *(i) To describe the prevalence or incidence of a disease by identifying all cases, or* *(ii) To study potential risk factor associations for a disease, and* *(2) Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that* *(i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and* *(ii) Prisoners are not a particular focus of the research.*

Certifications (both boxes must be selected before submitting this form)

The institution further certifies the following:

Select Both	Required Certifications
☐	That the research has been approved by an IRB that has adhered to all other responsibilities prescribed for Institutional Review Boards under subpart C (45 CFR 46.305(a)(1)).
☐	That an IRB has made the determinations required by 45 CFR 46.305(a)(2)-(7).