OMB No. XXX
Approved for use through XXXXX

Office for Human Research Protections Subpart C Certification Form

In compliance with 45 CFR 46.305(c), an institution responsible for the conduct of research conducted or supported by the U.S. Department of Health and Human Services (HHS) involving prisoners as subjects must certify to the Secretary, through the Office for Human Research Protections [OHRP], that the institutional review board (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).

To submit a subpart C certification to OHRP, the institution must submit a completed copy of this certification form with a copy of the research proposal and relevant materials, including: the IRB-approved protocol, including consent forms; any IRB application forms required by the IRB; and other pertinent 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. Do not submit the entire grant.*

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.

Name of Institution:	
Address of Institution:	
Contact Information:	*Name:* *Title:* *Phone:* *Email:*
Grant Number(s):	
Funding Agency:	
Funding Institution's Program Officer:	

OHRP Assurance #, if applicable:	
IRB Registration # for Reviewing IRB:	

Study Information	
Study Title:	
Name/Degree of Principal Investigator(s):	
Brief Summary of Protocol, and a study-specific rationale as to why the research represents the permissible category of prisoner research (below):	

Date of IRB Subpart C Approval:	
List of Institutions Relying on this IRB for Subpart C Review and Certification, and Assurance Numbers:	

Select One	Permissible Research Category
☐	**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 Research Category
☐	**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.*

Certification	
☐	**This research has been approved by an IRB that 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), or qualifies for the epidemiological waiver.**
Date:	