CERTIFICATION OF PRISONER RESEARCH

July 1, 2019

*<If the research is DHHS-regulated or subject to DHHS oversight by virtue of a federalwide assurance, send to:>* [[1]](#footnote-1)

Division of Policy and Assurances

Office for Human Research Protections

The Department of Health and Human Services

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

(866) 447-4777

(301) 496-7005

ohrp@osophs.dhhs.gov

*<If the research is conducted or funded by the Department of Defense (DOD):>[[2]](#footnote-2)*

Director, Defense Research and Engineering

ddre@dtic.mil

*<If the research is conducted or funded by the Department of the Navy (DOD):>[[3]](#footnote-3)*

Under Secretary of the Navy

1000 Navy Pentagon

Washington, D.C. 20350-1000

Dear Sir or Madam:

*<Select one or more of the following three paragraphs.>*

*<Name of organization>* is requesting *<DHHS/The Department of Defense>* certification of research involving prisoners as subjects.

*(Include when appropriate.)* We also seek *<DHHS/The Department of Defense>* approval for this research as it involves research on conditions particularly affecting prisoners as a class.

*(Include when appropriate.)* We also seek *<DHHS/The Department of Defense>* approval for this research as it involves assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups, which may not benefit from the research.

The institution conducting the research is:

|  |  |
| --- | --- |
| Organization: |  |
| FWA: |  |
| IRB Registration: |  |
| Address: |  |
| Contact Name: |  |
| Contact Title: |  |
| Contact Phone: |  |
| Contact Fax: |  |
| Contact Email: |  |

This certification is in regard to:

|  |  |
| --- | --- |
| Type of Review: | *<Indicate Initial, Continuing, or Modification>* |
| Title: |  |
| Investigator: |  |
| IRB ID: |  |
| Funding: | *<Indicate “None” if there is none.>* |
| Grant Title: | *<Indicate “None” if there is none.>* |
| Grant ID: | *<Indicate “None” if there is none.>* |
| IND, IDE or HDE: | *<Indicate “None” if there is none.>* |
| Documents Review: |  |
| IRB Approval Date: |  |
| Subpart C Review Date: |  |

Attached are the following documents in hard copy and on the enclosed CD-ROM in PDF format:

1. IRB minutes documenting required findings under 45 CFR §46.305(a)(1)-(7).
2. The IRB application form.
3. Other information requested or required by the IRB to be considered during initial IRB review.
4. Most current version of protocol and grant application submitted to and reviewed by the IRB and modified by the principal investigator if required by the IRB.
5. Most current version of consent documents submitted to and reviewed by the IRB and modified by the principal investigator if required by the IRB.
6. Relevant DHHS grant application or proposal. *(delete if not applicable)*
7. Other relevant IRB minutes. *(delete if not applicable)*
8. Relevant IRB correspondence. *(delete if not applicable)*

Please let us know if you need additional information.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*

*<Principal Investigator>*

*<Sponsor. Delete if none.>*

*<Contract Research Organization. Delete if none>*

*<Organizational Official>*

1. See: <http://www.hhs.gov/ohrp/policy/prisoner.html> [↑](#footnote-ref-1)
2. See: The Department of Defense (DOD) Directive 3216.02, March 25, 2002. [↑](#footnote-ref-2)
3. See: Secretary of the Navy Instruction 39000.39D, 6 November 2006. [↑](#footnote-ref-3)