

CERTIFICATION OF PRISONER RESEARCH

June 26, 2012

*<If the research is DHHS-regulated or subject to DHHS oversight by virtue of a federalwide assurance, send to:>*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

Director, Defense Research and Engineering
ddre@dtic.mil

*<If the research is conducted or funded by the Department of the Navy (DOD):>*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.

¹ See: <http://www.hhs.gov/ohrp/policy/prisoner.html>

² See: The Department of Defense (DOD) Directive 3216.02, March 25, 2002.

³ See: Secretary of the Navy Instruction 39000.39D, 6 November 2006.

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:

- a. IRB minutes documenting required findings under 45 CFR §46.305(a)(1)-(7).
- b. The IRB application form.
- c. Other information requested or required by the IRB to be considered during initial IRB review.
- d. 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.
- e. Most current version of consent documents submitted to and reviewed by the IRB and modified by the principal investigator if required by the IRB.
- f. Relevant DHHS grant application or proposal. *(delete if not applicable)*
- g. Other relevant IRB minutes. *(delete if not applicable)*

h. 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*>