NOT OTHERWISE APPROVABLE RESEARCH

June 26, 2012

<This letter is to be sent to either DHHS or FDA, but not both. If subject to oversight by DHHS, send to OHRP. If subject to oversight by both DHHS and FDA, send to DHHS. If subject to oversight by FDA only, send to FDA. If subject to oversight by neither DHHS or FDA, send to organizational official.>

<If the research is DHHS-regulated or subject to DHHS oversight by virtue of a federalwide assurance (FWA), 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 only FDA-regulated:>[2]
Office of Pediatric Therapeutics
Office of the Commissioner
Food and Drug Administration
RM 13B-45, HFG-2
5600 Fishers Lane
Rockville, MD 20857
opt@fda.gov

<If the research is conducted or funded by the Department of Defense (DOD):>[3]
Director, Defense Research and Engineering
ddre@dtic.mil

<If the research is conducted or funded by the Department of the Navy (DOD):>[4]
Under Secretary of the Navy
1000 Navy Pentagon
Washington, D.C. 20350-1000

[1] See: http://www.hhs.gov/ohrp/policy/populations/guidance_407process.html
[2] See: http://www.fda.gov/cber/gdlns/childclininv.htm
[3] See: The Department of Defense Directive 3216.02, March 25, 2002.
[4] See: Secretary of the Navy Instruction 39000.39D, 6 November 2006.

Dear Sir or Madam:

<Select one of the following five paragraphs.>

<Name of organization> is requesting DHHS review of research that has been determined by our IRB to not meet the requirements of 45 CFR §46.404, §46.405, or §46.406, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

<Name of organization> is requesting FDA review of research that has been determined by our IRB to not meet the requirements of 21 CFR §50.51, §50.52, or §50.53, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

<Name of organization> is requesting the Department of Defense to review research that has been determined by our IRB to not meet the requirements of 45 CFR §46.204 or §46.205, but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

<Name of organization> is requesting organizational review of research that is not subject to regulatory oversight and that has been determined by our IRB to not meet the requirements for the categories of research involving children that can be approved by the IRB without additional approval, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

<Name of organization> is requesting organizational review of research that is not subject to DHHS oversight and that has been determined by our IRB to not meet the requirements for the categories of research involving pregnant women that can be approved by the IRB without additional approval, but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

The institution conducting the research is:

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

This request 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 Reviewed:	
IRB Review Date:	

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

<Choose one of the "a" items below.>

a. IRB minutes documenting required findings under 45 CFR §46.407 that the proposed research does not meet the requirements of §46.404, §46.405, or §46.406, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

a. IRB minutes documenting required findings under 21 CFR §50.54 that the proposed research does not meet the requirements of 21 CFR §50.51, §50.52, or §50.53, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

a. IRB minutes documenting required findings under 45 CFR §46.207 that the proposed research does not meet the requirements of §46.204 or §46.205, but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

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 parental permission/assent documents submitted to and reviewed by the IRB, and modified by the principal investigator if required by the IRB *(delete if not applicable)*

f. Most current version of parental permission/assent documents submitted to and reviewed by the IRB, and modified by the principal investigator if required by the IRB. *(delete if not applicable)*

g. Relevant DHHS grant application or proposal. *(delete if not applicable)*

h. Other relevant IRB minutes. *(delete if not applicable)*

i. Relevant IRB correspondence. *(delete if not applicable)*

Please let us know if you need additional information.

Sincerely,

IRB Manager

cc: <*Protocol Contact*>
<*Principal Investigator*>
<*Sponsored Projects Services (SPS)*>
<*Sponsor. Delete if none.*>
<*Contract Research Organization. Delete if none*>
<*Organizational Official*>