REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443) or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: _____

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: _____
(Signature)

Through: _____
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Principal Investigator(s):_____
_____
IC _____ Laboratory/Branch _____
Building & Room No. _____ Tel. No. _____ FAX No. _____

Is the Principal investigator an NIH employee? _____Yes _____No

If no, please explain:_____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms): _____
_____
_____
_____
_____
_____

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #
_____
_____
_____
_____

3. Proposed start date of your research _____
Proposed completion date _____

4. Will you be _____these samples or data?

Collecting Yes/No
Receiving Yes/No
Sending Yes/No

5. Do the samples or data:
(a) Already exist?___Yes ____No

(b) Or are they being collected for the express purpose of this study? ___Yes ____No
If "yes," please describe:_____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

___ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.
_____

_____Other (If necessary, use this space to describe your role in this research).
_____
_____

7. Where are the subjects of this research activity located?
_____
_____

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes ____No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?

_____

_____

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source ___Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) ___ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) ___ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?

_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for **each** IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

_____Yes _____No

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html