

**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), email to [ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov), 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)

**Protocol Title:** \_\_\_\_\_

**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?**

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**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 that you are proposing in this form 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](http://ohsr.od.nih.gov/New/mpafwa_docs.html)