

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

Date: \_\_\_\_\_

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 1C-116

From: \_\_\_\_\_

Through: \_\_\_\_\_  
(Official appropriate for ICD, e.g., Lab./Branch Chief)

Name of NIH Research Investigator(s):

\_\_\_\_\_

ICD \_\_\_\_\_ Laboratory/Branch \_\_\_\_\_

Building & Room No. \_\_\_\_\_ - \_\_\_\_\_ Tel. No. \_\_\_\_\_ FAX No. \_\_\_\_\_

Nature of Research Activity:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Associate or Collaborating Investigator(s):

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

Proposed Starting Date of Research Activity: \_\_\_\_\_

Expected Duration of Research Activity: \_\_\_\_\_

PLEASE ANSWER ALL THE FOLLOWING QUESTIONS REGARDING THIS RESEARCH ACTIVITY

- (a) Are you contributing to the design or conduct of the study? \_\_\_\_\_ Yes/No
- (b) Do you expect your name to appear on a publication resulting from this study? \_\_\_\_\_ Yes/No

Please describe your role in this research activity:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. Where are the subjects of this research activity located?

\_\_\_\_\_  
\_\_\_\_\_

3. If the research activity is taking place elsewhere (not at NIH), will you have direct contact or intervention with the human subjects? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subjects?) \_\_\_\_\_ Yes/No

Has the activity been reviewed and approved by an Institutional Review Board (IRB) elsewhere? \_\_\_\_\_ Yes/No

If "Yes", specify which IRB and when reviewed

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

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Will you be:

collecting	_____	Yes/No
receiving	_____	Yes/No
sending	_____	Yes/No

these samples or data?

5. Do the samples or data:

(1) Already exist?	_____	Yes/No
(2) Or are they being collected for the express purpose of this study?	_____	Yes/No
(3) Or a combination of (1) and (2)?	_____	Yes/No

If "Yes", please describe:

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6. Do the samples or data come from individuals who may need special safeguards (e.g., individuals under 18 years of age, pregnant women, or prisoners)? \_\_\_\_\_ Yes/No  
If "Yes", please specify \_\_\_\_\_

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7. Do the samples or data you expect to collect, receive or send have

(a) Subjects' names or other personal identifiers?	_____	Yes/No
(b) Codes (i.e., numbers or initials)?	_____	Yes/No

8. If the samples or data are coded, do you or your collaborators intend to seek the identity of the subjects or collect additional samples or data from them during the course of the study? \_\_\_\_\_ Yes/No

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Please attach separate sheet if there is anything else you wish to add or any answer you wish to amplify. (For further information on exemptions, see the attached "[Guidelines for Research Involving Human Subjects](#)")

