

RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: ~~May 7, 2014~~ August 28, 2014 (Revised Sentence 2, paragraph 4, page 9)

RTI Project/Proposal No.: 0212255.003.015.001

Project Title: NIH Peer Review Evaluation Study:

Key Informant Interviewers and Surveys for Peer Reviewers

Project Manager: Kristina Peterson & David Roe Sponsor: National Institutes of Health (NIH)

Date Participation of Human Subjects Scheduled to Begin: 4/28/14 (Key Informant Interviews Only)

A. Brief Description of Study Procedures and Participant Population: This survey of NIH peer reviewers is to help the National Institutes of Health (NIH) understand reviewers' expectations for the level of commitment in review assignments, and the criteria they use, or would use, to make decisions about accepting review assignments. Activities will begin with 9 key informant interviews conducted to refine the draft questionnaire before it is used in a survey later this year.

Following the May interviews, a voluntary web survey of additional peer reviewers will take place. Because both the activities involve gathering data about institutions and their processes, and not the human subjects themselves, we are requesting exemption from further IRB review.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: None.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?

Yes No NA

If yes, explain: _____

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

Yes No NA

If yes, explain: _____

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

Yes No NA

If no, explain: _____

2. Is information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?

Yes No NA

If yes, explain: _____

D. Describe other categories of exempt research¹ here:

¹ Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

-----Space below this line for IRB use only.-----

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: Jamia Bachrach, JD

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.


(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or

environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



Signature of IRB Coordinator or Chair named above

08-28-2014

Date

NIH Peer Review Evaluation Study Peer Reviewers Web Survey

RESPONDENT INFORMATION (to be completed ahead of interview)

Name:

Title:

Institution:

Phone:

Other Contact:

INTRODUCTION

Thank you
again for

agreeing to participate in this interview. My name is _____. I work for RTI International. We are helping NIH to learn more about how the peer review process is working, and today we are interested in hearing your thoughts about review service generally, your expectations for the level of commitment in review assignments, and the criteria you use, or would use, to make decisions about accepting review assignments. Your insights will help us design a survey we are planning to conduct of NIH reviewers later this year.

We really appreciate you taking time today to help us with this research.

I have a set of questions that I will use to guide us through the interview. We are interested both in how you personally feel about these topics as well as how you think other people in your position might feel. There are no right or wrong answers to any of these questions.

I have a few things I need to tell you about your rights as a human subject before we begin:

- This research is sponsored by the National Institutes of Health (NIH). NIH has contracted with RTI International to conduct this research. You have been asked to participate because you have either served as a reviewer for NIH in the past and/or received funding from NIH. You are one of nine people we are interviewing.
- Your participation will involve an interview that lasts approximately 30 to 45 minutes. There are no risks or benefits to you personally for participating in this discussion.
- Your participation today is voluntary. You don't have to answer any specific question and you can ask to end the interview at any time.
- This discussion will be recorded so that we can check our notes to be certain we have heard your comments correctly. These recordings are for our internal purposes only. These recordings will be destroyed as soon as the analyses of the interviews are completed.
- The information you provide today will be kept confidential by RTI. In the reports we submit to NIH, your name will never be associated with your statements or with the information you provide. We will report on what is said but not on who said it.
- If you have any questions or concerns about your rights as a human subject, or if you want more information about this study, you may direct questions to the RTI study director, Dr. Kristina Peterson, 919-485-7722 or kpeterson@rti.org or to Dr. Luci Roberts in NIH's Office of Extramural Research at (301) 594-1841.

**NIH Peer Review Evaluation Study
Peer Reviewers Web Survey**

Do you have any questions before we begin?

NIH Peer Review Evaluation Study Peer Reviewers Web Survey

GENERAL QUESTIONS

I would like

to first ask some general questions about you.

1) In the past five years, have you led or worked on a research project supported by

the National Institutes of Health (NIH)? YES NO DON'T KNOW

the National Science Foundation (NSF)? YES NO DON'T KNOW

the Canadian Institutes of Health Research (CIHR)? YES NO DON'T KNOW

2) Have you ever served as a peer reviewer for

a NIH Scientific Review Group? YES NO DON'T KNOW

the National Science Foundation (NSF)? YES NO DON'T KNOW

the Canadian Institutes of Health Research (CIHR)? YES NO DON'T KNOW

2A) IF YES TO NIH: About how many years' experience would you say you have as a peer reviewer for NIH?

≤ 2 years [=new reviewers]

More than 2 years [=experienced]

2B) Which NIH study section did you (do you usually) serve? _____

THE DECISION TO REVIEW

Now I'd like to ask you about how investigators decide whether to accept a review assignment.

3) [NEW / EXPERIENCED REVIEWERS] What kinds of issues do you, and [reviewers/investigators] like you, take into account when you decide whether to accept or decline an invitation to review for NIH?

[NEVER REVIEWED] If you were asked to review for NIH, what kinds of factors do you think would influence your decision?

4) Are there any other reasons why you think you, or [reviewers/investigators] like you, are likely to accept an invitation to review?

5) Are there any other reasons why you think you, or [reviewers/investigators] like you, are likely to decline an invitation to review?

NIH Peer Review Evaluation Study Peer Reviewers Web Survey

- 6) Do the factors affecting these decisions vary according to the type of reviewer, the type of review, or any other factor?

PROBES, IF NEEDED:

- a. Are there any differences based on the person's field of study?
- b. Their personal backgrounds or family circumstances?
- c. Their geographic location?
- d. Where they work (e.g., university-based versus a private research institute)?
- e. Other factors?

BURDEN / LEVEL OF EFFORT

Now I'd like to ask

about the level of effort required for review service.

- 7) [NEW / EXPERIENCED REVIEWERS] Have you ever been offered a choice in the number of applications you are assigned to review during a specific review cycle or period of time?

[NEVER REVIEWED] Do reviewers who accept review assignments have any choice in the number of applications they are assigned to review during a specific review cycle or period of time?

YES NO DON'T KNOW

- 7a) [IF YES] What would you say are the most important factors influencing whether reviewers will accept a full load of applications?

PROBE:

Do these factors vary according to the type of reviewer, the type of review, or any other factor? (e.g., the person's field of study, their personal backgrounds or family circumstances, their geographic location, where they work (e.g., university-based versus a private research institute, or other factors)

- 8) [NEW / EXPERIENCED REVIEWERS] Have you ever been offered a choice in whether you attend the review meeting in person??

[NEVER REVIEWED] Do reviewers who accept review assignments have any choice in whether they attend the review meeting in person?

YES NO DON'T KNOW

- 8a) [IF YES] What would you say are the most important factors influencing whether reviewers will attend a meeting in person?

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PROBE:

Do these factors vary according to the type of reviewer, the type of review, or any other factor? (e.g., the person's field of study, their personal backgrounds or family circumstances, their geographic location, where they work (e.g., university-based versus a private research institute, or other factors))

- 9) Do you think reviewers are being overburdened or fatigued by the review assignments they have been given?
 YES NO DON'T KNOW

9a) [IF YES] What do you think is the main reason they are feeling overburdened?

- 10) What else does NIH need to know about reviewer burden and other potential barriers to participation?

SURVEY FEEDBACK

Finally, I'd like to ask

for your general impressions of the draft survey I sent you, if you've had a chance to look it over.

- 11) Are there any specific terms used that you think would be confusing to other investigators?

- 12) Are there any additional topic areas that you feel should be added to the survey?

Thank you. Those are all the questions I have.

- 13) Is there anything that I neglected to ask about that you think has an important impact on reviewers? Or is there anything you would like to add to what has been said?

This has been very helpful. Thank you very much for your time and your insights.

NIH Peer Review Evaluation Study

Peer Reviewers Web Survey

Introduction

This survey of scientists is to help the National Institutes of Health (NIH) examine the preferences of prospective reviewers in relation to the peer review of NIH grant applications. The objectives of this survey are to better understand reviewers' incentives and optimize our efforts to identify highly qualified scientists to serve as reviewers. The information you provide will also be used to help define appropriate expectations for reviewer commitments.

You were **randomly selected** to participate in this survey from a pool of scientists who have applied for research grant funding in the past five years. We are interested in the opinions of potential reviewers with different levels of research and peer review experience. Even if you have limited experience reviewing research grant applications, **your opinions are very important to us.**

The survey should take approximately 15 minutes to complete. You can stop at any point and continue at another time. There are no right or wrong answers, so please give the answers that best describe your opinion. While we would like you to answer all the questions in this survey, you may skip any questions that you do not wish to answer.

Your participation is entirely voluntary. If you choose to complete the survey, your responses will remain **confidential/private under the Privacy Act.** Your responses will **not** be made known to NIH staff or grant applicants. They will not be used to assess the performance of individual NIH Institutes, Centers, Scientific Review Groups, or NIH staff, and will not affect whether you will be invited to serve as a reviewer in the future. Aggregate responses will be used to guide NIH management in refining our peer review process.

For more information about the peer review process at NIH, please visit:

For more information about the NIH Peer Review Process, please visit:

http://grants.nih.gov/grants/peer_review_process.htm

Your participation is greatly appreciated!!!!

**NIH Peer Review Evaluation Study
Peer Reviewers Web Survey**

1) In the past five years, have you led or worked on a research project supported by the National Institutes of Health (NIH)?

YES NO DON'T KNOW

2) In the past five years, have you led or worked on a research project supported by the National Science Foundation (NSF)?

YES NO DON'T KNOW

3) In the past five years, have you led or worked on a research project supported by the Canadian Institutes of Health Research (CIHR)?

YES NO DON'T KNOW

4a) [PROGRAMMER: IF Q1 = YES] Please describe your role on the NIH-supported research (Select all that apply)

- a. Principal Investigator/Project Director/Project Manager
- b. Subproject/Core lead
- c. Subcontract/Consortium lead
- d. Training Program Director/Principal Investigator
- e. Fellow/Trainee/Research Assistant on NIH grant
- f. Other (Please specify): _____ [PROGRAMMER: ALLOW 20 SPACES]

4b). Did your role on any of these NIH-supported research projects involve the conduct of clinical research, defined by NIH as research involving human subjects?

YES NO DON'T KNOW

5) [PROGRAMMER: IF Q1 = NO AND Q2 = YES] Please describe your role on the NSF-supported research (Select all that apply)

- a. Principal Investigator/Project Director/Project Manager
- b. Subproject/Core lead
- c. Subcontract/Consortium lead
- d. Training Program Director/Principal Investigator
- e. Fellow/Trainee/Research Assistant on an NSF grant
- f. Other (Please specify): _____ [PROGRAMMER: ALLOW 20 SPACES]

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6) [PROGRAMMER: IF Q1 = NO AND Q2 = NO AND Q3 = YES] Please describe your role on the CIHR supported research (Select all that apply)

- a. Principal Investigator/Project Director/Project Manager
- b. Subproject/Core lead
- c. Subcontract/Consortium lead
- d. Training Program Director/Principal Investigator
- e. Fellow/Trainee/Research Assistant on a CIHR grant
- f. Other (Please specify): _____ [PROGRAMMER: ALLOW 20 SPACES]

7) In the past 12 months, have you been asked serve as a peer reviewer on a NIH Scientific Review Group?
 YES NO DON'T KNOW

8) [PROGRAMMER: IF Q7 = YES]: Did you serve as a peer reviewer for a NIH Scientific Review Group:

- YES NO DON'T KNOW

(Include definition/clarification of review to distinguish Peer Review from Council Review or Board of Scientific Counselors Review)

9) [PROGRAMMER: IF NO TO Q7] In the past 12 months, were you invited to serve as a peer reviewer for NSF?

- YES NO DON'T KNOW

10) [PROGRAMMER: IF Q9 = YES]: Did you serve as a peer reviewer for a NSF:

- YES NO

11) [PROGRAMMER: IF NO TO Q9] In the past 12 months, were you invited to serve as a peer reviewer for CIHR?

- YES NO DON'T KNOW

12) [PROGRAMMER: IF Q11 = YES]: Did you serve as a peer reviewer for CIHR?

- YES NO

[PROGRAMMER: IF NO to Q7 skip to Q19]

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[PROGRAMMER: IF YES TO Q7]

13 What was the nature of your most recent service as a peer reviewer?

- a. *Ad hoc (Define in a pop-up/hyperlink)*
- b. *Chartered member (Define in a pop-up/hyperlink)*
- c. *Mail (Define in a pop-up/hyperlink)*

14) During the last round you served as a NIH peer reviewer, was the NIH review process more burdensome than it could be? YES NO DON'T KNOW

15) [PROGRAMMER: IF YES TO Q14] In what way was the process burdensome?

[PROGRAMMER: ALLOW 250 characters]

[PROGRAMMER: IF NO TO Q7]

16 Prior to 12 months ago, did you serve as a peer reviewer on a NIH Scientific Review Group?

- YES NO

[PROGRAMMER: IF YES TO Q16]

17 During the last round you served as a NIH peer reviewer, was the NIH review process more burdensome than it could be? YES NO

18) [PROGRAMMER: IF YES TO Q17] In what way was the process burdensome?

[PROGRAMMER: ALLOW 250 characters]

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19) What would be the main **reasons** for you to accept an invitation to review for NIH? (Please select the three most important to you):

- a. Opportunity to travel
- b. Networking with other scientists
- c. Honoraria
- d. Grantsmanship experience
- e. Intellectual stimulation
- f. Learning the latest news about the funding agency
- g. Release from personal/departmental responsibilities
- h. Increased opportunity for Tenure/Promotion
- i. Opportunity to contribute to my scientific field
- j. Feel a sense of responsibility to serve as a reviewer
- k. Flexible terms of service for chartered reviewers (*Define in a pop-up/hyperlink*)
- l. Continuous submission (*Define in a pop-up/hyperlink*)
- m. Other (please specify): _____ [PROGRAMMER ALLOW 20 SPACES]

20) What would be the main **reasons** for you to decline an invitation to review for NIH? (Please select the 3 most relevant to you.)

- a. Requirement to travel from home
- b. Time required to prepare the interviews
- c. Competing responsibilities: Personal (family, social, civic, etc.)
- d. Competing responsibilities: grantsmanship/research related
- e. Competing responsibilities: within own institution (administration, teaching, etc.)
- f. Quality of travel, hotel and meeting room accommodations
- g. Complexity of technology used in the review process
- h. Complexity of NIH's review policy
- i. Previous review service ("I've done my time")
- j. Disillusionment with government generally
- k. Other (please specify): _____ [PROGRAMMER ALLOW 20 SPACES]

21) If you were to serve as a peer reviewer for NIH in the future, which type of review service would you prefer?

- a. Ad hoc (*Define in a pop-up/hyperlink*)
- b. Chartered (*Define in a pop-up/hyperlink*)
- c. "Mail" review (*Define in a pop-up/hyperlink*)

[PROGRAMMER: IF Q8 or Q16 = YES go to 6; IF Q8 and Q16 = NO skip to Q30]

22) If you were to review for NIH in the future, which of the following review formats would you prefer?

- a. Traditional/In-person study section meeting
- b. Teleconference
- c. Video conference
- d. Editorial Board(*Define in a pop-up/hyperlink*)
- e. Internet Assisted Meeting (IAM) (*Define in a pop-up/hyperlink*)

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23) If you were to review for NIH in the future, which of the following types of grant activities would you prefer to review? (Please select 2)

- R01 or R01-like Research project grant applications (U01, R21, R03, R15, R34, etc.) (Define in a pop-up/hyperlink)
- Fellowships/Career awards(Define in a pop-up/hyperlink)
- Multiple project activities and Centers (P30, P50, U19) (Define in a pop-up/hyperlink)
- Common fund/ Roadmap(Define in a pop-up/hyperlink)
- Small Business awards (Define in a pop-up/hyperlink)
- Other (Please describe)_____ [PROGRAMMER: ALLOW 20 SPACES]

[PROGRAMMER: ACTIVITY TYPE 1 = FIRST RESPONSE SELECTED IN Q23;
ACTIVITY TYPE 2 = SECOND RESPONSE SELECTED IN Q23]

24) For the next three questions, please respond regarding reviews of [ACTIVITY TYPE 1].

How many review meetings per year for [ACTIVITY TYPE 1] would you consider reasonable for a scientist like you?

- a. 0
- b. 1-2
- c. 3-4
- d. ≥ 5

25) Again, please think about reviews of [ACTIVITY TYPE 1]. Some reviewers are assigned to prepare a written critique. Others are assigned to read and discuss the applications. How many applications per meeting do you consider reasonable for a scientist like you to **prepare written critiques**?

- a. 1-3
- b. 4-6
- c. 7-9
- d. 10-12
- e. 13-16

26) How many applications per meeting do you consider reasonable for a scientist like you **read and discuss** as an assigned reviewer during the meeting?

- a. 1-3
- b. 4-6
- c. 7-9
- d. 10-12
- e. 13-16

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[PROGRAMMER: SKIP TO Q9 IF ACTIVITY TYPE 2 = BLANK]

27) For the next three questions, please respond regarding reviews of [ACTIVITY TYPE 2].

How many review meetings per year for [ACTIVITY TYPE 2] would you consider reasonable for a scientist like you? Please assume that participation requires travel and a hotel stay 1-3 days in duration.

- a. 0
- b. 1-2
- c. 3-4
- d. ≥ 5

28) Again, please think about reviews of [ACTIVITY TYPE 2]. How many applications per meeting do you consider reasonable for a scientist like you to prepare written critiques?

- a. 1-3
- b. 4-6
- c. 7-9
- d. 10-12
- e. 13-16

29) How many applications per meeting do you consider reasonable for a scientist like you read and discuss as an assigned reviewer during the meeting?

- a. 1-3
- b. 4-6
- c. 7-9
- d. 10-12
- e. 13-16

NIH Peer Review Evaluation Study Peer Reviewers Web Survey

30) Please estimate the percentage of your professional effort you currently allocate to each of the following responsibilities?

	Less than 5%	5 - 10%	11- 20%	21- 30%	Greater than 30%
Conducting research (e.g., , data collection and analysis, preparation of scientific manuscripts based on research, presentations at scientific conferences/meetings)					
Laboratory management/ Revenue oversight (e.g., development of IRB protocols, managing research staff/students, regulatory compliance, etc.)					
Institutional administrative and teaching responsibilities (e.g. teaching, , service on departmental committees, service on IRB committee, required training, etc.)					
Preparing grant applications/Progress reports					
Service to science (journal review, editorial boards, professional societies, etc.)					
Clinical/surgical/patient care					
Grant peer review service (for NIH and other funding agencies, organizations)					
Other (please describe) [PROGRAMMER: ALLOW 50 SPACES]					

31) Ideally, what percentage of your professional level of effort should you spend on grant review service?

- a. Less than 5%
- b. 5 - 10%
- c. 11- 20%
- d. 21- 30%
- e. Greater than 30%

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[PROGRAMMER: IF Q1 = YES, ASK Q31]

31b) When did you submit your first research grant application to NIH as a PI for a single-PI or multiple-PI grant?

- | | |
|------------------------------------|-------------------------------------|
| <input type="radio"/> 2012 to 2014 | <input type="radio"/> 1997 to 1999 |
| <input type="radio"/> 2009 to 2011 | <input type="radio"/> 1994 to 1996 |
| <input type="radio"/> 2006 to 2008 | <input type="radio"/> 1991 to 1993 |
| <input type="radio"/> 2003 to 2005 | <input type="radio"/> 1990 to 1992 |
| <input type="radio"/> 2000 to 2002 | <input type="radio"/> Prior to 1990 |

32) Does having active research support from NIH make you more or less willing to review for NIH?

- More willing
- Less willing
- It has no effect on my willingness

33) What is your job title or position?

- a. Professor or equivalent rank
- b. Associate Professor or equivalent rank
- c. Assistant Professor or equivalent rank
- d. Other (Specify): _____

34) What type of organization do you work for? **Select all that apply.**

- e. Institution of higher education (including a university foundation)
- f. Hospital/medical center (including teaching hospitals)
- g. Independent research foundation or other non-profit institution
- h. Private sector/for-profit organization (including small businesses)
- i. Federal, state, or local government agency
- j. Other (Specify): _____

36) Please indicate the degree(s) you have. **Select all that apply.**

- Ph.D. or other research doctorate
- M.D.
- D.D.S.
- D.V.M. or V.M.D.
- Other (Specify): _____

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37) What is your age?

- | | |
|--------------------------------|--------------------------------|
| <input type="radio"/> Under 35 | <input type="radio"/> 56 to 60 |
| <input type="radio"/> 35 to 40 | <input type="radio"/> 61 to 65 |
| <input type="radio"/> 41 to 45 | <input type="radio"/> 66 to 70 |
| <input type="radio"/> 46 to 50 | <input type="radio"/> Over 70 |
| <input type="radio"/> 51 to 55 | |

38) What is your gender?

- Female
 Male

39) What is your ethnicity?

- Hispanic or Latino
 Not Hispanic or Latino

COMMENTS:

In the space provided below, please feel free to leave any comments, questions or suggestions for NIH's Office of Extramural Research.

[PROGRAMMER: ALLOW 200 SPACES]

THANK YOU.

Thank you for your time. The survey is now complete. Your participation is critical for the NIH to have the most accurate information possible when making upcoming policy decisions, and we appreciate your contributions.

If you have any questions regarding this survey, please feel free to call either [RTI NAME] of RTI toll free at [DEDICATED 800 NUMBER] or ([EMAIL ADDRESS]@rti.org), or Dr. Luci Roberts in NIH's Office of Extramural Research at (301) 594-1841.

For more information about the peer review process at NIH, please visit:

http://grants.nih.gov/grants/peer_review_process.htm