<u>13560</u>

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, 2014August 28, 2014 (Revised Sentence 2, paragraph 4, page 9)

RTI Project/Proposal No.: <u>0212255.003.015.001</u>			
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 <i>or through identifiers linked to the subjects?</i> Yes No X 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 X NA If <u>yes</u> , explain:			

C2.	Fo	r research with existing data, documents, records, pathological or diagnostic specimens:
		Are the sources of the data publicly available?
		X Yes No NA
		If <u>no</u> , explain:
	2.	Is information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?
		Yes X No NA
		If <u>yes</u> , explain:
D.	De	scribe other categories of exempt research ¹ here:
		e: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt 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
Nan	ne o	f IRB Coordinator or Chair making exemption determination: Jamia Bachrach, JD
Plea	se	check appropriate answer(s):
		that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project er above. (Check applicable category below.)
	rese) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) arch on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among uctional techniques, curricula, or classroom management methods.
	or ob direc	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, stly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could onably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
	or ob publi) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, oservation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed ic officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally tifiable information will be maintained throughout the research and thereafter.
	thes) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if e sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, etly or through identifiers linked to the subjects.
	desi unde	Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are gned to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services er those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels ayment for benefits or services under those programs.
) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a 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.	

Jam / Bachel	
	08-28-2014
Signature of IRB Coordinator or Chair named above	Date

RESPONDENT INFORMATON (to be completed ahead of interview)	Name:
Title:	
Institution:	
Phone:	
Other Contact:	
	hank you
agreeing to participate in this interview. My name is I work for RTI International. We are help to learn more about how the peer review process is working, and today we are interested in hearing your tho about review service generally, your expectations for the level of commitment in review assignments, and the you use, or would use, to make decisions about accepting review assignments. Your insights will help us designed are planning to conduct of NIH reviewers later this year.	oughts e criteria
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 feel about these topics as well as how you think other people in your position might feel. There are no right or 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 conduct this research. You have been asked to participate because you have either served as a reviewer fithe 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 of to you personally for participating in this discussion.	or benefits

• 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

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

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.

not on who said it.

analyses of the interviews are completed.

• 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.

Do you have any questions before we begin?

GENERAL QUESTIONS	I would like
to first ask some general questions about you.	i would like
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 ONO ODON'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 f	or NIH?
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 <u>accept</u> an invitation to review?
- 5) Are there any other reasons why you think you, or [reviewers/investigators] like you, are likely to <u>decline</u> an invitation to review?

6)	Do the factor?	factors affecting these decisions vary according to the type of reviewer, the type of review, or a	ny other
	PR	OBES, 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?	
E	LIRDE	N / LEVEL OF EFFORT	Now I'd like
	ONDLI	V / LEVEL OF LITORI	to ask
abo	out the l	evel of effort required for review service.	
7)		EXPERIENCED REVIEWERS] Have you ever been offered a choice in the number of applications ed to review during a specific review cycle or period of time?	you are
	_	R REVIEWED] Do reviewers who accept review assignments have any choice in the number of apre assigned to review during a specific review cycle or period of time?	plications
	С	YES O NO O DON'T KNOW	
	7a) [IF	YES] What would you say are the most important factors influencing whether reviewers will accload of applications? PROBE:	cept a full
		Do these factors vary according to the type of reviewer, the type of review, or any other fa the person's field of study, their personal backgrounds or family circumstances, their geogr location, where they work (e.g., university-based versus a private research institute, or other	aphic
8)		EXPERIENCED REVIEWERS] Have you ever been offered a choice in in whether you attend the ring in person??	eview
	_	R REVIEWED] Do reviewers who accept review assignments have any choice in whether they attemeeting in person?	end the
	8a)	[IF YES] What would you say are the most <u>important</u> factors influencing whether reviewers wil	II attend a

meeting in person?

D	R	\cap	R	F	
	n	. ,	п	_	

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)

Thi	s has been very helpful. Thank you very much for your time and your insights.	
13)	Is there anything that I neglected to ask about that you think has an important impact on reviewers? O anything you would like to add to what has been said?	r is there
Tha	ank you. Those are all the questions I have.	
12)	Are there any additional topic areas that you feel should be added to the survey?	
11)	Are there any specific terms used that you think would be confusing to other investigators?	
for	your general impressions of the draft survey I sent you, if you've had a chance to look it over.	ine to ask
S	URVEY FEEDBACK	Finally, I'd like to ask
10)	What else does NIH need to know about reviewer burden and other potential barriers to participation?	
	9a) [IF YES] What do you think is the main reason they are feeling overburdened?	
9)	Do you think reviewers are being overburdened or fatigued by the review assignments they have been YES NO DON'T KNOW	given?

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 <u>randomly selected</u> 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, <u>your opinions</u> 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 **confidentialprivate 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!!!!!

1) In the past five years, have you led or worked on a research project supported by the National Institutes of Health (NIH)?
YES O 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 ○ N⑥ 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 O NO DON'T KNOW
40) IDDOCD AMMED. IE O1 - VESI Diago describe very role on the MILL organized research (Select all that emply)
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 leadc. 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]

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? O YES O NO DON'T KNOW
8) [PROGRAMMER: IF Q7 = YES]: Did you serve as a peer reviewer for a NIH Scientific Review Group:
○ YES ○ N♠ 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]

[PROGRAMMER: IF YES TO Q7]
13 What was the nature of your most recent service as a peer reviewer?
a Adhaa (Dafina in a nan un/humanlink)
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 O NO DON'T KNOW
15) FDD CCD AND FDD AFFECT COLLEGE AND A COL
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) IDDOCD AMMED: IE VES TO 017 1. In what way was the process burdensome?
18) [PROGRAMMER: IF YES TO Q17] In what way was the process burdensome?
[PROGRAMMER: ALLOW 250 characters]

19) What would be the main	reasons for you to accept	an invitation to review	for NIH? (Please	select the three mo	st
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*)
- 1. 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)

23) If you were t review? (Please s	o review for NIH in the future, which of the following types of grant activities would you prefer to elect 2)
up/hyperli Fellows Multipl Commo	R01-like Research project grant applications (U01, R21, R03, R15, R34, etc.) (Define in a pop-ink) ships/Career awards(Define in a pop-up/hyperlink) e project activities and Centers (P30, P50, U19) (Define in a pop-up/hyperlink) on fund/ Roadmap(Define in a pop-up/hyperlink) Business awards (Define in a pop-up/hyperlink) Please describe) [PROGRAMMER: ALLOW 20 SPACES]
	2: ACTIVITY TYPE 1 = FIRST RESPONSE SELECTED IN Q23; E 2 = SECOND RESPONSE SELECTED IN Q23]
24) For the next th	aree questions, please respond regarding reviews of [ACTIVITY TYPE 1].
How many review a. 0 b. 1- c. 3- d. ≥	4
critique. Others ar reasonable for a so	think about reviews of [ACTIVITY TYPE 1]. Some reviewers are assigned to prepare a written e assigned to read and discuss the applications. How many applications per meeting do you consider cientist like you to prepare written critiques ?
a. 1-b. 4-c. 7-d. 10e. 13	6 9 0-12
	plications per meeting do you consider reasonable for a scientist like you read and discuss as an during the meeting?
	6

[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

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]					

つ1)	T 1 11	1 4	4	C	professional	1 1	C CC 4	1 11	1	4	•	. 0
3 I I	Haealiv	what	nercentage	of vour	nroteccional	IEVEL	OT ATTORT	chailla	vou spend	on grant	review	Service?
$J \mathbf{I}$	i iucan y	, wilat	percentage	or your	proressional		or criort	SHOUIG	you spend	On grain	ICVICV	SCI VICC:

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

[PRO	GR	AMMER: IF Q1 = YES, ASK Q31]
		en did you submit your first research grant application to NIH as a PI for a single-PI or multiple-PI grant? 2012 to 2014
	_	having active research support from NIH make you more or less willing to review for NIH? More willing
(\mathcal{C}	Less willing
()	It has no effect on my willingness
33) WI		is your job title or position?
		Professor or equivalent rank
		Associate Professor or equivalent rank Assistant Professor or equivalent rank
		Other (Specify):
34) WI	e. f. g. h. i.	Hospital/medical center (including teaching hospitals) Independent research foundation or other non-profit institution
36) Ple		e indicate the degree(s) you have. Select all that apply.
	_	Ph.D. or other research doctorate
	ン つ	M.D.
	ノ つ	
	ノ	D.D.S.
() ~	D.V.M. or V.M.D.
()	Other (Specify):

37) What	is your age?		
\circ	Under 35	\circ	56 to 60
\circ	35 to 40	\circ	61 to 65
\circ	41 to 45	\circ	66 to 70
\circ	46 to 50	\circ	Over 70
0	51 to 55		
38) What	is your gender?		
\circ	Female		
0	Male		
39) What	is your ethnicity?		
\circ	Hispanic or Latino)	
0	Not Hispanic or La	atino	
COMME	NTS:		
	ace provided below, ral Research.	plea	se feel free to leave any comments, questions or suggestions for NIH's Office of
[PROGR	AMMER: ALLOW	200	SPACES]
THANK	YOU.		
•	•		evey is now complete. Your participation is critical for the NIH to have the most en making upcoming policy decisions, and we appreciate your contributions.
[DEDICA			ng this survey, please feel free to call either [RTI NAME] of RTI toll free at r ([EMAIL ADDRESS]@rti.org),or Dr. Luci Roberts in NIH's Office of Extramural
For more	information about t	he pe	eer review process at NIH, please visit:

http://grants.nih.gov/grants/peer review process.htm