IRB ID Number: 12444

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: August 14, 2009 RTI Project/Proposal No.: 0212255 Project Title: NIH Constituent Surveys Project Manager: Kristina Peterson Sponsor: National Institutes of HealthDate Participation of Human Subjects Scheduled to Begin:

A. Brief Description of Study Procedures and Participant Population: RTI has received funding from the Office of the Director of NIH to conduct a series of surveys to help them assess their intramural and extramural peer review process. The first set of surveys are directed at the applicants and peer reviewers. Another survey will be directed at NIH staff. Questions in these surveys focus particularly on the impact that recent changes to the peer review process have had on the quality and efficiency of the process. Comparisons of the data will be made among various subgroups of interest (defined, for example, by race and ethnicity). The results of these assessments will not be published, and there are no plans to generalize the findings to the general population, only to the population of NIH's current pool of reviewers and applicants (i.e., those who fall into one or both of these categories as of 9/30/09). The Reviewer Questionnaire and Applicant Questionnaire are attached.

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 X No NA

These surveys are anonymous.

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 X 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 X 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 research[1] here:

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.

This project falls under the following category of exemption:

__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.

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Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: Wendy A. Visscher, Ph. D.

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.

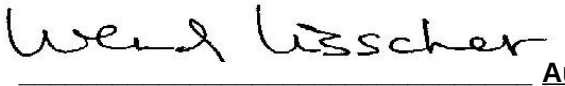
_**X**_(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through 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.



_____ **August 14, 2009 IRB Member or Chair Date**

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