B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The survey for which we are requesting OMB clearance includes research faculty from medical schools in the 50 states, Washington D.C., and Puerto Rico. The frame from which we drew the stratified random sample of researchers included 115 of the 125 U.S medical schools recognized by the American Association of Medical Colleges (AAMC) that were listed by NIH as receiving 10 or more research project awards in 2005 and 2006. Institutions that receive PHS/NIH research project funding are required to have an approved research misconduct policy and procedures assurance document on file with ORI and to submit annual reports of research misconduct activity.

The primary units of analysis for this study are the medical school researchers listed in the position of PI on NIH awards made to U.S. medical schools. We requested and obtained a list of NIH research project awards in 2005 and 2006. There were 21,798 awards made to PIs listed at U.S. medical schools in 2005 and 2006. This reduced to 16,374 unduplicated PIs receiving at least one NIH award in either year. This list was used to identify medical schools with 10 or more unduplicated principal investigators (PIs) receiving at least one NIH research project award in 2005 or 2006. We decided to exclude PIs from the eight U.S. medical schools with 10 or fewer PIs because we felt that there would be too few PIs in each to reliably represent the research environment of a medical school. The secondary units of analysis in this study are the medical schools as characterized by their PIs knowledge of research misconduct policy and their perceptions of the medical school's efforts to control research misconduct.

The sampling design we employed for the selection of PIs for the samples was stratified by medical school. In an effort to keep the variances of the PI samples within medical schools reasonably close in size, a larger sampling fraction was used in selecting PIs from medical schools with fewer PIs. This resulted in our selecting every PI in medical schools with fewer than 110 PIs. The sampling fraction was reduced for medical schools with 111 or more PIs with the maximum number of PIs selected from any medical school being 168. The total selected sample size was 10,754.

We have developed a survey approach that is intended to achieve a 70 percent response rate for this Web-based survey. That will yield completed surveys of at least 7,528 researchers. In our experience, this will be a large enough number to obtain adequate quantitative information to conduct the planned analyses and prepare the desired report. We intend to use weighted data adjusted for non-response as well as by researcher and medical school characteristics in the analysis.

B2. Procedures for the Collection of Information

The project will utilize a Web-based survey. We will send an advance letter by e-mail to the 10,754 research PIs in the sample. The advance letter will provide an introduction to the study, explain the PIs selection, and review the survey procedures including how to log in to access the Web-based survey. This advance letter will be followed by an e-mail cover letter inviting the PI to participate in the survey. The cover letter will include a hyperlink that will take the PI to a secure survey site at RTI. Sample members will then have an opportunity to complete the survey.

The survey will be designed to take no longer than 20 minutes to complete and include approximately 60 survey items. Five follow-up e-mails will be sent to non-responders at two-week intervals. A week after the lead letter and each of the follow-up letters are sent, a thank you/reminder e-mail will be sent to persons receiving them. Each follow-up e-mail will include language that increases the importance of the study to them and urges their participation. The remaining non-responders following the fourth follow-up will receive one final follow-up. At the time of the fifth follow-up, the non-responders will be divided in half based on the participation rate of their respective institutions. Responsibility for contacting non-responders from institutions with low overall response will be given to the RTI Call Center to provide a telephone prompt. The remaining non-responders will be sent a final e-mail reminder stressing the importance of their participation in the study.

The split sample will help RTI to control costs by focusing resources on the most critical group of non-responders. Other RTI studies have been very successful in obtaining an increased response rate using a telephone prompt. It is expected that the telephone group will require several calls in order to actually reach the sample member.

After several calls, a voice-mail will be left for the sample member and be considered a successful prompt contact. RTI Call Center telephone interviewers will be trained in study procedures, protocol, and provided sufficient knowledge of the study to deliver the telephone prompt. Furthermore, they will be provided with a sheet with answers to frequently asked questions. Questions that cannot be answered by the telephone interviewer will be directed to the survey manager and a follow-up call will be made to the sample member.

In preparation for the telephone prompt component to this study, all telephone interviewers will be expected to complete a 4-hour training session prior to making telephone calls. RTI expects that some faculty may want to complete the interview by telephone during the telephone prompt. Telephone interviewers will be trained to conduct the survey by phone at the sample members' request. The telephone interviewer will be provided with scripts, consent information, and all of the necessary tools to conduct the interview with the respondent. Interviewers will enter the data into the Web-based instrument as they administer the questions. No additional programming will be necessary for an interviewer-assisted interview.

Data collection is expected to continue for up to two months. RTI is expecting to employ an aggressive follow-up in an effort to attain up to a 70 percent response rate using a combination of multiple reminders and telephone prompts. Assuming OMB clearance is received by early July 2008, we expect data collection to begin in September 2008 and run through October 2008.

B3. Methods to Maximize Response Rates and Deal with Non-response

As we indicated above, to maximize the response rate, sample member PIs will be e-mailed an advance letter explaining the purpose of the study and seeking the PIs' participation in the study. This will be e-mailed to all 10,754 PIs selected in the sample. The advance letter will provide an introduction to the study and provide a description of the login procedures in order to access the Web-based survey. Web-based surveys can be a great convenience for busy people who accept the importance of the survey, and we think that by reducing the burden for them, they are more likely to respond. Those who do not

respond after a reasonable time (one week) will be sent up to five reminder e-mails at one week intervals, and failing to respond to those reminders, non-respondents from medical schools with a below average response rate will be contacted by telephone by persons specially trained and experienced to solicit their participation in the study. In addition, the letters will indicate that the study is sponsored by ORI but stress only aggregated data will be reported to ORI and that any data that identifies individuals who were selected or responded, or identification of their medical school, will be kept confidential and not provided to ORI.

As for encouraging participation in the survey, we have tried to make the letters informative and the survey instrument as interesting as possible. Further, the survey will be conducted using a specially developed Web-based survey that RTI has created and tested. Again, we have developed a survey plan that experience has shown can achieve up to a 70 percent response rate. Research faculty who do not respond to the letters will be contacted by telephone and urged to complete the survey online. Further, RTI will have several trained and experienced interviewers available to conduct the telephone prompting of non-responders if necessary.

B4. Test of Procedures or Methods to Be Undertaken

We recently completed the process of pilot testing the solicitation by e-mail of research faculty for participation in the Web-based survey on researchers' knowledge of research misconduct and their perceptions of their institution's research misconduct educational efforts. The pilot test plans were reviewed and approved by the RTI IRB. The plan was to conduct follow-up activities until we receive up to nine responses. We solicited the participation of up to 15 randomly selected researchers who are similar to the sample members in the main study except that they were not selected to be in the main study sample. We asked the pilot study sample members to complete the questionnaire and to offer comments to us in writing (or orally by having us telephone them) on anything they found problematic in the letters they received, the instructions we gave, the items we asked, and response alternatives that they were given.

A total of nine persons responded to the pilot test. Overall, pilot test respondents had few comments on the letters, instructions, questionnaire items, and response options. However, two respondents were particularly helpful with suggested word selection and rewording of items in the instrument. All of their item modifications and wording suggestions were incorporated. Further review of the items and their responses by the survey team led to the reformulation of several complicated items into simpler ones, the addition of two new short items, and the elimination of three longer items. In addition to what seem to be useful alterations to the data collection instrument, the pilot test response rate suggested that it may be necessary to send at least five follow-up letters urging researcher participation to achieve the desired response rate

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing the Data

Sandra Titus, Ph.D. is the ORI staff person responsible for receiving the project deliverables, including the research plan, sampling design, and survey instrument.

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