Supporting Statement
For The
Research Integrity Officer (RIO) Study

Submitted by:
Office of Research Integrity (ORI)
Office of Public Health and Science (OPHS)
Office of the Secretary of Health and Human Services (OS)
U.S. Department of Health and Human Services (HHS)
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A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Office of Research Integrity (ORI) is conducting this study of Research Integrity Officers (RIOs) because RIOs are the institutional representatives responsible for implementing the Office of Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93). ORI reviews of institutional research misconduct policies and research misconduct investigation reports, institutional requests for technical assistance in handling research misconduct allegations, and analyses of institutional filings of the Annual Report on Possible Research Misconduct (PHS 6349) have raised concerns about the capabilities, knowledge, and experience of individuals occupying RIO positions.

Receipt of a research misconduct allegation is a low probability event at most institutions. From 1992-2001, only 248 institutions reported receipt of an allegation and more than half of these institutions reported receiving only a single allegation. Although concentrated in the top 150 National Institutes of Health (NIH) funded institutions, allegations are received by institutions located much further down the funding ladder as well. Consequently, many allegations are processed by RIOs who have no experience handling such allegations. In addition, anecdotal data compiled by ORI suggests that there is a high turnover rate among RIOs.

To address this situation, ORI believes it is desirable and necessary to establish a training program for RIOs, developing educational materials and holding conferences and workshops to assure that they are capable of appropriately discharging the responsibilities assigned to RIOs. ORI, however, has no systematically collected information on the knowledge, experience, or qualifications of individuals holding RIO positions. In addition, ORI has no information on the authority or responsibilities assigned to RIOs, the training or resources provided to them, or their position in their organization. Without this information, ORI cannot properly establish the parameters of a training program. Nor can it begin to evaluate how well institutions are implementing the PHS Policies on Research Misconduct.

The ability of ORI to directly communicate with RIOs is limited because the ORI database of institutional officials is limited to the officials who sign the "face page" on PHS grant applications and the Annual Report on Possible Research Misconduct. Frequently, this individual is not the RIO. The groundwork necessary to identify the RIOs for this study will enable ORI to develop an e-mail network of RIOs that will permit ORI to directly communicate with them and permit them to communicate with each other. Authorization for ORI to collect this information is provided for in the founding legislation, a copy of which is in **Attachment 1**.

A2. Purpose and Use of Information Collection

This study has been designed to gather information for ORI to use in the development of conferences, workshops, and other training materials for RIOs. It is needed to identify the areas of responsibility and specify the activities that RIOs have responsibility to perform in the process of handling allegations of scientific misconduct at their institutions, but for which their training, experience, and knowledge may be inadequate. Without the information on what RIOs know and do, and how they have been trained or otherwise prepared to perform their required roles, ORI will be left with no basis for determining what is needed for upgrading the training of RIOs, improving the performance of their role, and assuring that ORI's research integrity charge is being properly implemented.

The planned study will consist of two phases with surveys of different groups of RIOs. This supporting statement is requesting clearance for both the Phase I. and Phase II surveys. The Phase I survey will employ a semi-structured telephone interview methodology with a stratified random sample of 120 RIOs. RIOs in this survey will be interviewed by trained persons with advanced degrees. The Phase II survey will employ a truncated, less in-depth, web-based, self-administered questionnaire (created from a subset of the questions from the Phase I instrument) to be used with the RIOs from the remaining 1,300 institutions. We are ready to start Phase I immediately after OMB clearance is completed, whereas we expect to start Phase II approximately 9 months later.

Senior and mid-level professional staff of RTI International, the contractor for this project, will be trained to conduct the Phase I interviews with the RIOs. A copy of the Phase I interview schedule that emerged from the pilot testing is in **Attachment 2**. The Phase II instrument will be considerably shorter, more closed-ended, and formatted to be self-administered and completed on the internet (and on paper as an option). We plan to submit an amendment to OMB that contains the instrument before we begin the Phase II data collection. We want to conduct Phase I first in order to carefully select the most useful items for inclusion in the self-administered Phase II survey instrument.

It should be noted that Phase I has been preceded by two small pilot studies with a random sample of RIOs not included in the Phase I or II samples. The first pilot used a draft interview schedule to conduct interviews with eight RIOs. The second used an expanded and more refined instrument to interview five RIOs, for a combined total of thirteen RIO pilot study interviews. It is our intention to use the actual Phase I interview experience to refine and reduce the size of the data collection instrument for use in Phase II.

A3. Use of Improved Information Technology and Burden Reduction

As indicated above, data collection for this study will be completed in two phases. We are employing available information technology in both phases to reduce the burden on respondents and thereby increase the ease with which they can participate.

Phase I involves completion of up to 120 semi-structured telephone interviews. In this phase, letters will be e-mailed to the responsible institutional official whose name was on file with ORI and supplied to RTI as an initial institutional contact. This e-mail to the responsible institutional official will explain the purpose of the study and ask that he/she confirm his/her position as the responsible institutional official. Then it will ask him/her to identify the individual who is responsible for implementing the institution's

research misconduct policies and procedures (the person we refer to as the RIO) because we want to interview him/her, and to respond to us by e-mail. (It is possible that the responsible institutional official will be the RIO as well, but most often that position is delegated to another person.) To handle the e-mail responses, RTI has developed a web-based recruitment application that will allow individuals to respond securely over the Internet. In an effort to obtain the identities and contact information for all of the RIOs, the RTI data collection manager will make telephone follow-up calls to responsible institutional officials who do not respond to the original or reminder e-mails.

Once identified, the 120 RIOs will also be e-mailed a letter explaining the purpose of the study. This letter will ask them to consent to an interview about what they do as their institution's RIO, and what training and experience they had for filling that position. The letter will explain that the interview is voluntary, will take approximately one hour, and that their responses to the questions will be combined with those of other RIOs. They also will be given assurance that their identity and that of their institution will not be apparent from the report prepared for ORI at the conclusion of the survey. RIOs will be asked to respond to the letter with their contact information and potential dates of availability for an interview by return e-mail. Again, RTI will use the web-based recruitment application to allow RIOs to respond to the solicitation securely over the Internet. As before, the RTI data collection manager will make telephone follow-up calls to RIOs who do not respond to the original or reminder e-mails. The actual date and time of the scheduled interviews will be sent by e-mail (or telephone if preferred by the RIO) as soon as RIOs respond to the original solicitation letter or reminder.

The sample for Phase II will consist of those RIOs at institutions not selected for participation in Phase I. We will identify the RIOs using the same process that was employed in the first phase, i.e. by contacting through e-mail the responsible institutional official whose name is on file with ORI. During Phase II, we expect to contact the approximately 1,300 RIOs who were identified by the responsible institutional officials. The RIOs will be contacted by e-mail and their participation in the study through the completion of a questionnaire solicited. In Phase II, RIOs will have the option of completing the questionnaire securely on the Internet or request the materials to be able

to complete a traditional paper and pencil questionnaire and mail it back to RTI. Respondents will also have access to a toll-free number to use in the case of questions regarding the study and/or questionnaire. Similar to Phase I, the RTI data collection manager will conduct telephone follow-up calls to responsible institutional officials and RIOs who do not respond to their respective e-mail requests. RIOs who do not return a completed questionnaire will also be contacted by the RTI data collection manager.

A4. Efforts to Identify Duplication and Use of Similar Information

This proposed data collection effort has never been done before, thus, there are no similar data available. The RTI project staff conducted an automated search of the literature to identify potentially similar data and reviewed prior data collections, published documents, and available reports seemingly relevant to this study to ensure that this planned data collection is not duplicative of others already performed. No published assessments of the background, training, organizational position, and role performance of RIOs were identified. RTI staff also spoke at length with ORI with the intent of identifying previous studies of RIOs that might serve as models for this one, and there were none. We also spoke with other investigators working in the area of research misconduct, but they were not able to identify anyone who collected data similar to what are planned for collection in this study.

We are satisfied from these efforts that this study will collect important new information that will allow ORI to develop conferences, workshops, and other training opportunities for improving the performance of RIOs to handle allegations of research misconduct in their institutions and therewith carry out its mission. Such training will help to ensure a higher level of RIO performance and greater comparability of performance among RIOs in different institutions, therein addressing ORI's mission to ensure that research misconduct is identified and sanctioned, and to foster research integrity.

A5. Impact on Small Businesses or Other Small Entities

Not applicable. We do not anticipate that small businesses will be included in this study. The collection of information under consideration in this supporting statement

does not include small businesses or other small entities as part of the organizational respondent universe. The entities from which RIOs will be contacted are universities, medical centers, research institutes, and hospitals conducting PHS funded research. If a small business were to be included in these entities it would not be treated any differently than larger institutions.

A6. Consequences of Collecting the Information Less Frequently

This information collection is only planned for one time and has never been collected before. In Phase I, respondents will be asked to participate in the semi-structured telephone interview one time. Those who participate in Phase I will not be contacted for participation in Phase II. Likewise, the Phase II respondents will be asked to complete the self-administered questionnaire only one time. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection activity fully complies with the Guidelines of 5 CFR 1320.5.

A8A. Comments in Response to the Federal Register Notice

Federal Register notice published on May 31, 2006, Vol. 71, No. 104, pg. 3092. There were no public comments. A copy of the Federal Register notice is located in **Attachment 3**.

A8B. Efforts to Consult Outside the Agency

Dr. David Wright, a former RIO at Michigan State University, has been used by ORI as a consultant for this project. He has helped with the development of the proposed survey, in particular with the scenarios that are included in Phase I to assess how RIOs handle or would handle specific aspects of hypothetical misconduct investigations. He has been involved since October 2004. Dr. Wright can be contacted by telephone (517-353-1916) or e-mail (dewrite@msu.edu).

Drs. Kenneth Wilson (wilsonk@mail.ecu.edu, phone 252-328-4897) and Alan Schreier (schreiera@mail.ecu.edu, phone 252-328-9470), of East Carolina University, and David Resnik (resnikd@niehs.nih.gov, phone 919-541-5658) of NIEHS, were also

contacted with regard to their study of research record keeping which included interviews with 96 RIOs. Through our discussions, we determined that their study did not address the same topics that we are addressing in the proposed study. Their study focused on the issue of research record keeping and how RIOs found it affected inquiries and investigations into allegations of research misconduct.

A9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be given to respondents in either phase of the study. We have found great interest in the study and willingness to participate. We do not believe that incentives are needed.

A10. Assurance of Confidentiality Provided to Respondents

Concern for data confidentiality and protection of respondents' rights has always played a central part in RTI's studies and will again for the current project. Our e-mail to the responsible institutional official whose name was supplied by ORI only will be used to locate the individual who implements the institution's misconduct policy (the RIO). We will communicate this clearly in order to maximize every respondent's understanding of RTI's commitment to maintaining confidentiality to the extent legally possible. The letter will explain that their responses will be kept as secure as possible, being available only to the survey staff and analysts in an identifiable form. A copy of the letter to the responsible institutional official for Phase I is in **Attachment 4**. For both phases, the letter requests that the responsible institutional official respond with the RIO contact information including his/her name, phone number, address, and e-mail address for future contact concerning an important study being conducted by ORI. The Phase I letter will be revised slightly for Phase II. It will be submitted to OMB with the Phase II data collection instrument. This process of contacting the responsible institutional officer and the information obtained from it will be used to identify the samples of RIOs for both phases of this study.

All RIOs identified through this process will then be contacted with a letter by e-mail in both phases of the study. A copy of this letter to RIOs for Phase I is in **Attachment 5**. For Phase I, this letter will describe the study, explain that participants'

data will be kept as secure as legally possible, and request that RIOs select a convenient date to participate in an hour-long telephone interview about the training they received to fill the RIO position and what they do as a RIO. To support response from the responsible institutional officials and each of the identified RIOs, RTI has developed a secure web-based recruiting application that will allow individuals to respond safely over the Internet. RTI will also make telephone response available through the RTI data collection manager in case Internet access is limited or inconvenient for the RIO, and for non-respondent follow-up.

RIOs will be contacted via e-mail for Phase II as well. A copy of the letter will be submitted with the Phase II data collection instrument. This letter will serve as an introduction to the study, explain that participants' data will be kept as secure as legally possible, request that they complete a self-administered web-based questionnaire, and inform RIOs of the paper and pencil option for completion of the questionnaire.

Approval for both phases of this study will be obtained from RTI's standing IRB. RTI conducts all research involving human subjects in accordance with federal regulations (45 CFR 46 and 21 CFR 50 and 56). RTI prepared all of the documents necessary for completing this process, submitted all relevant research protocols and study materials, and ensured that IRB approval was obtained before piloting the structured interview. A copy of the IRB approval for Phase I is in **Attachment 6**. RTI will revise those IRB materials as needed to obtain IRB approval to conduct the web-based survey with the Phase II sample when the questionnaire is more nearly final and certainly before that surveys begin.

RTI's IRB will review the research plan to ensure that:

- risks and burden to subjects are minimized and are reasonable in relation to anticipated benefits to subjects (if any) and to the importance of the scientific knowledge resulting from the research,
- selection of the subjects is equitable,
- research subjects are fully informed of the risks and benefits of participation and are informed that legally effective, informed consent is obtained from

subjects prior to their participation and documented in accordance with applicable regulations, and

- privacy of subjects and confidentiality of data are ensured.

RTI is accustomed to handling information of an extremely confidential nature. For both the semi-structured telephone interviews and the self-administered questionnaire, the information collected will be treated securely despite its obvious lack of sensitivity. RTI's normal survey procedures for securing data will be followed. They are as follows:

- Security awareness training for project staff: Topics include careful selection and changing of passwords, use of screen saver passwords when leaving a computer unattended, leaving confidential records and media in locked facilities, file encryption techniques, and Internet security issues.
- System security measures include underground location in a masonry building, fire protection via halon systems, Liebert heating and air-conditioning systems, temperature and humidity controls with alarms, alarm to detect water under the raised floor, controlled access with logs, and automatic backup of data files on a regular schedule.
- Emergency, backup, and contingency planning.
- An active IRB, which reviews all aspects of the project plan to determine whether any potential exists for physical, psychological, or social risk to study participants.

A11. Justification for Sensitive Questions

There are no questions of a sensitive nature included in the interview.

A12A. Estimates of Hour Burden

Two small pilot studies already have been conducted involving a combined total of 13 interviews to test the Phase I interview. In these pilot studies, cognitive testing was conducted with the two versions of the interview instrument. The pilot testing has been completed and the respondent burden for the Phase I study is based on the pilot study and included in the table below. ORI provided RTI with the names, telephone numbers, and e-mail addresses of responsible institutional officials for approximately 4,000 institutions worldwide. RTI drew a random stratified sample of 10 institutions in the US whose responsible institutional officials were requested to provide the name of their RIO to participate in the first pilot test round of the semi-structured telephone interviews. Five RIOs, of which four participated, were e-mailed an invitation to be involved in the

development of the interview by participating in a thinking out loud interview (cognitive testing), and called a few days later to make an appointment for the interview. Another five RIOs were e-mailed an invitation to pilot test the interview without the cognitive testing component and four of these RIOs participated in the interview. The first round of the pilot interview process required approximately one hour of RIO time. The questionnaire was modified slightly after the first round to clarify questions and reduce response burden based upon the cognitive testing results. The second round was designed similarly to the first round, but RTI only included a random stratified sample of six institutions. Three of the six RIOs from these institutions participated in the cognitive testing interview and two RIOs participated in the interview without the cognitive testing component. One RIO was not available. The interviews for the pilot studies were completed from September to November, 2005.

Based on the pilot studies, it is estimated that the average time per respondent needed to complete the survey interview in Phase I will be one hour. The solicitation of the RIOs' identity from the responsible institutional officials should take approximately five minutes per person. Respondent burden is presented below in **Tables 1 and 2**. Based on an 80% response rate the # of completed questionnaires will be 96.

Table 1. Estimated Annualized Respondent Burden for Phase I

Type of Respondent	**No. of Respondents**	**No. Responses per Respondent**	**Hrs/Response (in hours)**	**Total Annual Burden Hours**
E-mail to Identify RIOs (Responsible Institutional Officials)	120	1	5/60	10
Telephone survey (RIOs)	96	1	1	96
TOTAL				106

The questionnaire that will be developed for Phase II is estimated to take approximately 25 minutes. The instrument will include 20-25 close-ended multiple choice type questions and up to 5 open-ended questions. We will include the RIOs from the remainder of U.S.-based institutions still considered active by ORI that were not

already included in the Phase I or pilot studies as the sample for Phase II. This is estimated to be approximately 1,300. Based on an 80% response rate the # of completed questionnaires will be 1,040.

Table 2. Estimated Annualized Respondent Burden for Phase II

Type of Respondent	No. of Respondents	No. Responses per Respondent	Hrs/Response	Total Annual Burden Hours
E-mail to Identify RIOs (Responsible Institutional Officials)	1,300	1	5/60	108
Questionnaire (RIOs)	1,040	1	25/60	433
TOTAL				541

A12B. Estimate of Annualized Cost Burden to Respondents

We have estimated the cost burden to respondents based on the expected response burden for each phase and an estimated hourly wage for RIOs and responsible institutional officials. These are contained in **Tables 3 and 4**.

Table 3. Estimated Annualized Cost to Respondents for Phase I

Type of Respondent	Total Hours	Hourly Wage Rate	Total Respondent Costs
E-mail to Identify RIOs (Responsible Institutional Officials)	10	$100	$1,000
Telephone survey (RIOs)	96	$75	$7,200
TOTAL			$8,200

Table 4. Estimated Annualized Cost to Respondents for Phase II

Type of Respondent	Annual Burden Hours	Hourly Wage Rate	Respondent Costs
E-mail to Identify RIOs (Responsible Institutional Officials)	108	$100	$10,800
Questionnaire (RIOs)	433	$75	$32,475

TOTAL			$43,275

A13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no capital or maintenance costs to the respondents.

A14. Estimate of Annualized Cost to the Federal Government

The total cost to the Government for collecting the data in Phases I and II is estimated to be the portion of the evaluation contractor and Government staff time that is devoted to the data collection and analysis effort for each separate phase of this study. This is presented in **Tables 5 and 6**. The estimated cost of the Government staff time represents the pro rated share of the project monitor's time expected to be spent monitoring contract activities during each phase of the study.

Table 5. Estimated Annual Cost to the Federal Government for Phase I

Type of Costs	Source	Amount
Salaries	RTI	$66,979
Other Direct Costs	RTI	$4,211
Indirect Costs	RTI	$55,555
Fee	RTI	$8,876
Total Contractor	RTI	$135,673
Total Fed. Govt. Salary	ORI	$10,000
ORI Consultant	ORI	$7,000
Total Combined of Contractor and Government		$152,673

Table 6. Estimated Annual Cost to the Federal Government for Phase II

Type of Costs	Source	Amount
Salaries	RTI	$91,237
Other Direct Costs	RTI	$5,276
Indirect Costs	RTI	$74,008
Fee	RTI	$12,556
Total Contractor	RTI	$191,943
Total Fed. Govt. Salary	ORI	$10,000
ORI Consultant	ORI	$7,000
Total Combined of Contractor and Government		$208,943

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

The time schedule for the data collection, analysis, and reporting for Phase I is presented in **Table 7**.

Table 7. Phase I Project Time Schedule

Task	Time Schedule
Training of high level telephone interviewers	Approximately 1 month before OMB approval
E-mails sent to respondents to identify RIOs and schedule interviews	1-2 months after OMB approval
Conduct follow-up telephone calls to e-mail non-respondents	2 months after OMB approval
Conduct semi-structured telephone interviews with up to 120 RIOs (at least 80 percent response rate expected)	2 to 4 months after OMB approval
Begin analysis of semi-structured interview data in Phase I	4 to 5 months after OMB approval
Conduct small pilot test of Phase II questionnaire and letters	4.5 months after OMB approval
Provide initial draft of Phase analysis to ORI	6 months after OMB approval
Provide complete draft of Phase I report to ORI	7 months after OMB approval
ORI provides comments on draft Phase I report to RTI	8 months after OMB approval
RTI revises and submits final Phase I report to ORI	9 months after OMB approval
RTI submits Phase II instrument to OMB with amendment to prior approval	9 months after OMB approval of Phase I

During the collection of data for Phase I, RTI will conduct a small pilot study to test the draft instrument for Phase II. After revising the questionnaire based on results of the pilot study, RTI will submit a memo to OMB to update and complete this clearance document which will include the final Phase II contact letters and instrument for OMB

approval. **Table 8** presents the timeline for Phase II based on OMB approval of the final draft of the questionnaire following the pilot study. It is worth noting that there will be some amount of overlap between the two Phases of this study such that analysis of Phase I and data collection for Phase II are occurring at the same time.

Table 8. Phase II Project Time Schedule

Task	Time Schedule
E-mails sent to responsible institutional officials to identify RIOs	0.5 month after OMB approval of memo amending the OMB clearance document
Conduct follow-up telephone calls to e-mail non-respondent responsible institutional officials	1 months after OMB approval of memo amending the OMB clearance document
E-mails sent to RIOs inviting them to complete web-based questionnaire or to request paper and pencil version of questionnaire.	1.5 months after OMB approval of memo amending the OMB clearance document
Conduct follow-up telephone calls to e-mail non-respondent RIOs	2 months after OMB approval of memo amending the OMB clearance document
Time allow for completion of web-based or paper and pencil questionnaire	2 to 4 months after OMB approval of memo amending the OMB clearance document
Begin analysis of Phase II	4 to 5 months after OMB approval of memo amending the OMB clearance document
Provide initial draft of analysis of Phase II data to ORI	6 months after OMB approval of memo amending the OMB clearance document
Provide complete draft of Phase II analysis report to ORI	7 months after OMB approval of memo amending the OMB clearance document
ORI provides comments on draft Phase II report to RTI	8 months after OMB approval of memo amending the OMB clearance document
RTI revises and submits final Phase II report to ORI	9 months after OMB approval of memo amending the OMB clearance document

A17. Display of OMB Expiration Date

The collection of information for Phase I will be done through semi-structured telephone interviews. With the exception of the recruitment letter (which respondents will receive by e-mail but can print), participants will not receive any other "written" material. Since the respondents will not receive a questionnaire or interview schedule in this phase, there is not another item on which to display the OMB expiration date where the respondent will see it except on the recruitment letter.

The collection of information for Phase II will be done utilizing either a web-based version or a printed paper version of the self-administered questionnaire. The number and expiration date of OMB approval for the data collection in Phase II will be displayed as required on the questionnaire.

A18. Exceptions to Certification

This collection of information for Phases I and II involves no exceptions to the Certification for Paperwork Act Submissions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The surveys for which we are requesting OMB clearance only includes RIOs from non-government operated institutions in the 50 states, Washington D.C., and Puerto Rico. The frame from which we drew the random stratified sample for Phase I included the universe of 1,427 institutions with approved research misconduct policies and procedures on file with ORI. The sample for Phase II consists of the RIOs in the remaining institutions.

The data collection effort for both phases of this study will entail surveys of RIOs from the following types of PHS-funded institutions: (1) research institutes, (2) institutions of higher education, and (3) independent hospitals. ORI had already classified institutions in these three strata. The unit of analysis for this study is the position of research integrity officer. While turnover of individuals in the RIO position does occur, we expect that replacements will be named reasonably quickly to assure continuity in the institution's monitoring of research misconduct.

For Phase I, we used the list of the NIH awards to identify the top 100 awardees by dollar amount, thereby creating a fourth stratum. The vast majority of the institutions in this stratum were institutions of higher learning, but some research institutes and independent hospitals were included. Of those top 100, we selected a random sample of 60 awardees. For the remaining sample, we randomly selected 20 RIOs each from the remaining research institutes, institutions of higher education, and independent hospitals. The total sample size for Phase I is 120. For Phase II, we will survey the approximately 1,300 RIOs remaining from the population not included in the pilot test sample or surveyed in Phase I.

Based on the response to our two rounds of pilot study interviews for Phase I, where we completed interviews with 13 of 16 RIOs solicited, we expect to achieve at least an 80 percent response rate in the Phase I survey. That will yield completed interviews with at least 96 RIOs. In our experience, this will be a large enough number to obtain adequate qualitative information to incorporate in the report and to test whether

our expectations for the Phase II survey (which will solicit the participation of the remaining RIOs) with regard to question types, content areas, and response categories are reasonably correct. A response rate of 80 percent is expected for Phase II, which will yield approximately 1,040 usable responses. We intend to use weighted data adjusted for non-response in the Phase II analysis.

B2. Procedures for the Collection of Information

The Phase I study will utilize a semi-structured telephone interview. Letters will be e-mailed to responsible institutional officials to identify RIOs. Then, a letter will be e-mailed to the RIOs to solicit their participation in the study. The letter will tell them they were selected for a telephone interview, explain the purpose of the study, and request their participation in the study. RIOs will be asked to respond by e-mail and to sign up for an appointment to be interviewed. Those who do not respond will be contacted by telephone to solicit their participation in the study and to arrange a time to conduct the interview. While the persons conducting the interviews will record answers on the interview schedule, to save time and assure accuracy, we plan to tape record the interviews as well. In the introduction to the interview, we will request the RIOs' permission for the taping. We plan to produce transcripts from the taped interviews so the interview data can be easily checked and supplemented with direct but anonymous quotes in the Phase I analysis report to illustrate our major findings. We find that using the respondents' own words can be a more effective and powerful way of communicating study results than numbers and tables alone.

Near the conclusion of data collection for Phase I, a small pilot study will be conducted to test the instrument developed for use in Phase II. Ten RIOs not contacted for Phase I (and not included in Phase II) will be asked to participate in the study by completing a questionnaire. Participants will be given the opportunity to complete the questionnaire on the Internet or by paper and pencil, just as they would in the actual

survey. Based on our Phase I pilot test experience, we do not expect all solicited RIOs to complete the pilot test interviews.

Following the completion of the pilot study for Phase II, necessary changes in the instrument will be made. Then, a sample of approximately 1,300 RIOs will be contacted by e-mail and asked to complete a questionnaire. Since up to two months could have passed from when we solicited the information on the identity of the RIOs from the responsible institutional officials and the start of the Phase II survey, we may find that some persons we contact as the RIO are no longer in that position or at the institution. This will require repeating the process of ascertaining the name of the replacement RIOs from the responsible institutional official, so we do not suffer a lower response rate and smaller RIO sample.

RIOs in Phase II will receive a letter via e-mail which will serve to introduce the study, ask them to confirm their identity as the RIO, and ask them to participate in a web-based survey about what they do as RIOs. They will also be given an opportunity to complete the self administered questionnaire on paper if they prefer that. The letter sent to RIOs will include the credentials they need to logon to the secure web version of the questionnaire (i.e., personal username and password), and a project-specific toll-free number to call for questions regarding the study or the instrument. Thank you/Reminder e-mails will be sent to RIOs approximately two weeks after the initial e-mail to them. A second Thank you/Reminder e-mail will be sent approximately two weeks following the first one, but only to non-respondents. RIOs who have not completed questionnaires after the second round of Thank you/Reminder e-mails will receive telephone follow-up calls. The telephone follow-up will encourage participants to respond via the web. If during any telephone follow-up call a RIO requests a paper version of the questionnaire to complete, it will be mailed out to him/her.

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

To maximize response rates in Phases I and II, sample members will be e-mailed a letter explaining the purpose of the study and seeking participation in the study. Participants in Phase I will be asked to respond by e-mail

and to sign up for an appointment to be interviewed. Phase II respondents will be given the opportunity to complete the questionnaire on the Internet. This can be a great convenience for busy people, 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 will be sent reminder e-mails, and failing to respond to those reminders will be contacted by telephone by persons specially trained and experienced to solicit their participation in both phases of the study. In addition, the letters will indicate that the study is sponsored by ORI. We found in the pilot studies for Phase I that institutions were eager to participate, and we expect that will be the case again. Based on our pilot study experience, we anticipate close to100 percent response to our letters requesting information on the identity of the institution's RIO.

As for the participation in the survey, we have tried to make the instruments as interesting as possible. In our pilot test of the interview, RIOs reported that they found it interesting and challenging, and a useful experience. Further, RTI will have several trained and experienced executive level interviewers available to conduct the interviews in Phase I. Finally, scheduling of interviews will be done through a special computerized system RTI is creating to schedule the interviews at the times RIOs request with interviewers who are available at those times. By requesting and receiving the days and times RIOs are available for an interview by e-mail in response to our solicitation, we will demonstrate the flexibility and consideration that will lead to a greater willingness to respond. RIOs who fail to respond to our initial e-mails will be telephoned until we contact someone who is or can speak for the institution's RIO. This was successful in the Phase I pilot studies. Again, based on the Phase I pilot studies experience, we expect to achieve at least an 80 percent response rate in Phase I. RIOs who do not respond to the letters sent in Phase II will be contacted by telephone and urged to complete the questionnaire online. For Phase II, we also expect to achieve an 80 percent response rate.

B4. Test of Procedures or Methods to Be Undertaken

The system of solicitation by e-mail of RIOs for participation in a survey for Phase I was tested in two rounds of pilots. Both rounds of the pilot testing were reviewed and approved by the IRB. The survey instrument was also piloted in two rounds of testing. A total of 13 RIOs were interviewed of the 16 initially sought. Approximately half of the pilot test interviews employed cognitive testing techniques, asking respondents to give their understanding of questions or the responses available. The first round of the pilot testing, half of which used the cognitive testing method, resulted in revisions to the wording of the instrument and the addition of several new questions. A second round of pilot testing was conducted using the revised instrument. Three of the five interviews in the second round employed cognitive testing.

One round of pilot testing will be completed before the administration of the Phase II questionnaire. We will contact ten institutions that have not participated in Phase I to request that their RIO complete the questionnaire. Based on Phase I experience, we anticipate completing fewer than all ten of the questionnaires in the pilot test. Before the pilot testing is conducted, the RTI IRB will review and approve the questionnaire and introductory letters. What we expect will be minor revisions will be made to the questionnaire and letters based on the results of the pilot study. The final version of the questionnaire and letters will be attached to a memo to be sent to OMB for approval prior to contacting the sample and initiation of the web-based survey.

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

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C. ATTACHMENTS

1. Authorizing Legislation: 42 U.S.C. § 289b

2. Semi-Structured Telephone Interview

3. Federal Register Notice

4. Letter to the Responsible Institutional Officer (Phase I)

5. Letter to the Research Integrity Officer (Phase I)

6. IRB Approval (Phase I)

Attachment 1: Authorizing Legislation

Attachment 2: Semi-Structured Telephone Interview (Phase I)

Form Approved
OMB #0990-xxxx
Expiration Date

Final Draft of Questions for the Semi-Structured Telephone Interview

Introduction

Hello (*respondent's name*), this is (*your name*) calling from RTI. I want to thank you for agreeing to talk to us about the things you do when there are allegations of research misconduct at your institution. For this discussion, research misconduct includes falsification, fabrication, and plagiarism of research. You were identified as the person with responsibility for carrying out the policies and procedures for handling research misconduct allegations at your institution. Persons in this role are often referred to as the Research Integrity Officer or RIO. I just want to be sure. Are you the person doing that job at your institution?

Yes…… [*Continue*.]
No…….. [*Do Not Continue. Identify the correct person to contact*.]

The purpose of this discussion is to understand how you carry out the responsibilities associated with these activities and to identify areas where ORI may be able to provide additional training or support to make this job easier. As we indicated in our earlier letter, this interview should take about an hour to complete.

Before we begin, I would like your permission to record our interview so we can have an accurate record that is more complete than the notes I could take as we talk. I want to assure you that the information from the interview that we use to prepare our report to ORI will not contain material that can be used to identify you or your institution. Information from this interview will be reported aggregated with the responses of RIOs from other institutions.

I. First, I would like to ask you some questions about your Current Organizational Position and Professional Background

1. What is **your** usual title, office, or position in the organization when you are **not performing** activities related to allegations of research misconduct?

1a. When functioning in your usual position, would you say that you are very involved, somewhat involved, only slightly involved, or not at all involved in seeking opportunities to financially support research at your institution?

Very Involved……..…1
Somewhat Involved…..…2
Only Slightly Involved....3
Not at All Involved…..….4

2. What is the title, office, or position of the person to whom you ordinarily report when you **are not performing** activities related to research misconduct?

_____

3. Do you have a special title or hold an identified position or office in the organizational structure when you **are performing** activities related to research misconduct issues?

Yes……....1
No…(Same title as in 2)……..2 [*Go To 3b.*]

3a. What is the title, office, or position you hold when you are performing activities related to research misconduct?

_____

3b. Do your institution's written policies and procedures identify the title, office, or position of the person responsible for handling allegations of research misconduct?

Yes……....1
No…….2
No Written Policies/Procedures…3

3c. What is the title, office, or position of the person to whom you report in the institutional structure when you **are performing** activities related to research misconduct?

President/CEO….1 [*Go To 3e.*]
Other [*Specify.*] _____

3d. How far removed is that person from the Office of the President/CEO; in other words, how many people are there in the organizational structure between your supervisor and the President's office?

[*Enumerate/List the Titles/Offices/Positions between PRESIDENT/CEO and the RIO. Make notes as needed to create an organization chart.]*

PRESIDENT/CEO

1_____ _____ _____
2_____ _____ _____
3_____ _____ _____

4_____ _____ _____
5_____ _____ _____

RESEARCH INTEGRITY OFFICER

3e. Do you have a written job description of what you are expected to do as the RIO (person handling allegations of research misconduct) at your institution?

Yes…….1
No……..2 [*Go To 3g*]

3f. Would you be willing to e-mail me a copy of your written RIO job description after we finish the interview?

Yes…….1 [*Give your e-mail address to the respondent*]
No……..2

3g. In your position as RIO, do you have a **separate** budget to pay for activities related to investigation of alleged research misconduct?

Yes…….1
No……..2

3h. How many persons do you have assisting you in your RIO duties?

None……..0 [*Go To 4*.]
Number of persons_____

3i. How would you describe their positions/roles, including their percentage time commitment?

_____
_____

4. For how long have you been **involved in any way** with activities related to investigating and reporting on research misconduct at your institution?

_____

4a. For how much of that time have you been the RIO (person **responsible for** carrying out your institution's policies and procedures for investigating and reporting on research misconduct)? _____

4b. Approximately what proportion of your time do you commit to carrying out responsibilities related to research misconduct?

_____

4c. What special training, conferences, workshops, or job experiences have you had that helped to prepare you to discharge your research misconduct responsibilities?

_____
_____

4d. Prior to joining your current institution, were you involved in any activities related to investigating and reporting on allegations of research misconduct at some other institution?
Yes…….1
No……..2

5. For how long have you been employed at your current institution?_____

6. How did you come to be the person responsible for investigating and reporting on research misconduct there?

_____
_____
_____
_____

[*ONLY ASK QUESTION 7 OF PERSONS IN ACADEMIC INSTITUTIONS*]

7. Are you a tenured member of the faculty/staff?
Yes…….1
No……..2

8. In what field(s) did you receive your professional training? (a)_____
(b)_____(c)_____

9. What advanced degrees do you hold? (a)_____(b)_____(c)_____
(d) None……..99

10. Do you consider yourself primarily a researcher?
Yes…….1 [*Go To 10b*.]
No……..2

10a. Did you ever consider yourself to be primarily a researcher?
Yes…….1
No……..2 [*Go To SECTION II*.]

10b. On **approximately** how many **research** grants have you been a Principal Investigator (PI)?
None……0 [*Go To SECTION II*.]
Number of Grants _____

10c. **Approximately** how much was the total dollar funding from those **research** grants? _____

10d. Of the **research** grants on which you were a PI, **approximately** how much was the total dollar funding from PHS/NIH? _____

II. Next, I would like to learn more about your <u>Responsibilities and Experiences</u> in the RIO Position. When I ask about being responsible, I mean that according to your job description, either as it is written or from your supervisor's directives, you are identified as the person with the authority and independence to do whatever is necessary to carry out the specified functions.

1. In addition to your responsibility for carrying out your institution's policies and procedures for handling research misconduct, are you responsible for any of the following areas as well? (*Read list a-f.*)

2. In which of those areas do you participate in any way, even though you are not responsible for the area? By participate, I mean that you are involved in some way, but not in charge of the area. (*Read list of a-f for which the response to item 1. Responsible is No, and code response for whether participates under 2. Participate.*)

	1. Responsible			2. Participate	
a. Financial conflicts of interest.	Y..1	N..2	Shared..3	Y..1	N..2
b. Protection of human research subjects.	Y..1	N..2	Shared..3	Y..1	N..2
c. Protection of animal research subjects.	Y..1	N..2	Shared..3	Y..1	N..2
d. Hazardous waste and radioactive materials.	Y..1	N..2	Shared..3	Y..1	N..2
e. Recombinant DNA.	Y..1	N..2	Shared..3	Y..1	N..2
f. Grants management issues.	Y..1	N..2	Shared..3	Y..1	N..2

g. Are there any other administrative or regulatory areas that you are **<u>responsible</u>** for?
Yes…….1 [*Specify.*] _____
Shared..…..2
No…..……3

h. Are there any other administrative or regulatory areas in which you **<u>participate</u>** but for which you are not responsible?
Yes…….1 [*Specify.*] _____
No……..2 [*If responsible for all areas, Go To 4.*]

3. Does the person who is responsible for the areas that **you are not responsible for** report to you? (*Refer if needed to areas in 2a -2f that are both marked no*)
Yes…….1
No……..2 [*Go To 3b.*]

3a. Which area(s)?
None……..0 [*Go To 4.*]
Specify Letter(s)_____

3b. Do any of the persons responsible for these areas, who **do not report to you**, report directly to the same person you report to?

Yes…….1
No……..2 [*Go To 4*.]

3c. Which area(s)?

None……..0
Specify Letter(s)_____

4. Since you began in the RIO position, about how many **allegations** of research misconduct would you estimate have been received concerning **externally** sponsored research projects?

None……..0 [*Go To 5*.]
Number_____

4a. How many of those allegations would you say actually had an initial **inquiry** conducted?

None……..0 [*Go To 5*.]
Number_____

4b. About how many of those initial inquiries led to formal **investigations**?

None……..0 [*Go To 5*.]
Number_____

4c. How many of the allegations investigated would you say involved **PHS/NIH-funded research** projects?

None……..0 [*Go To 5*.]
Number_____

5. Since you became a RIO, approximately **how many times** would you say that you have conferred with RIOs at other institutions about difficulties you faced/might face in handling cases?

None……..0 [*Go To 6*.]
Number of Times_____[*If only once, Go To 6*.]

5a. With approximately **how many** different RIOs have you conferred over difficulties you faced or thought you might face in handling cases since becoming a RIO?

One……..1
Number of RIOs_____

6. Since you became a RIO, about **how often** would you say that you have conferred about "hypothetical cases" or spoken off the record with someone at a Federal oversight agency, like the Office of Research Integrity, about how to handle difficult cases?

None……..0
Number of Times_____

7. Does your institution have a policy, educational program, or other mechanism for promoting the Responsible Conduct of Research?

Yes…….1
No……..2 [*Go To SECTION III*.]

7a. Please describe what it is and how it is implemented (What are its key components, and who implements it)?

_____
_____
_____
_____

7b. Does your institution **require** all persons conducting research to receive training in the Responsible Conduct of Research?

Yes…….1
No……..2

7c. Is administering that policy or program part of your responsibility as the RIO?

Yes…….1
No……..2

7d. Are you involved in its implementation in any way?

Yes…….1
No……..2

7e. Does the person who is implementing it report to you?

Yes…….1 [*Go To SECTION III*.]
No……..2

7f. Does the person who implements it report to the same person you report to?

Yes…….1
No……..2

III. We know that the scope of RIO's responsibilities differ from institution to institution. Now I want to try to better understand your specific responsibilities and how you carry them out.

1. Are you the primary person identified by your institution to **receive allegations** of research misconduct directly from members of your institution?

Yes…….1 [*Go To 2*.]
No……..2

1a. Who (is/are) the primary person(s) identified to receive allegations of research misconduct (What Office, Title, or Position)?_____

1b. (Does/Do) the other person(s) designated to receive allegations **report to you** or to someone else in the institutional structure?
Yes, to me…….1 [*Go To 2*.]
No, to someone else……..2

1c. To whom (what Office, Title, or Position) do they report?_____

2. Are there other persons at your institution who are also authorized to receive allegations of research misconduct?
Yes…….1
No……..2 [*Go To 3*.]

2a. Are these persons who receive allegations of misconduct required to report **all** of them to you?
Yes…….1
No……..2

2b. Through what process do allegations of misconduct get from those persons to you as the RIO? (*Probe for means of communication*.)
_____

2c. Normally, how soon after an allegation is made does notification of the allegation from them reach you? (*Probe for number of hours*.)
_____

3. Are you the person responsible for informing persons who conduct research about the institution's research misconduct policy and explaining what constitutes falsification, fabrication, and plagiarism, including the procedures for reporting them?
Yes…….1 [*Go To 3b*.]
Done with someone else…2 (*Specify person's Title, Office, or Position*)
_____[*Go To 3b*.]
No……..3

3a. Does the person who is responsible report to you?
Yes…….1
No……..2 [*Go To 4*.]

3b. By what means or mechanisms do you do that? (***Do not read list***)

1. Provide Orientation to New Members Y
2. Provide Handbook for Faculty, Staff, and Students Y
3. Website on Research Misconduct Policy Y
4. Publicize Institutional Policies and Guidelines Y
5. Announce in Newsletters Y
6. Give Presentations Y
7. Do On-Line Training Y
8. Hold Workshops Y
9. Organize Classes or Courses Y
10. Work through Advisors Y
11. Model through Mentors Y
12. Other (*Specify*)_____

3c. Does your institution require researchers to sign something saying that they are aware of your institution's research misconduct policy?

Yes…….1
No……..2

4. In the process of handling a typical allegation of research misconduct, with whom (what positions, titles, or offices) at your institution do/would you normally interact? (*Specify*)

_____

5. Are you responsible for informing key institutional officials when an allegation of research misconduct has been received?

Yes…….1
No……..2

6. If an allegation involves more wrongdoing than just research misconduct, are you responsible for deciding who deals with which parts of the allegation and in what order they get handled?

Yes…….…...…….1
Done in collaboration with the others involved….2
No……..…….3

7. Are you the person responsible for sequestering evidence when an allegation of research misconduct has been filed?

Yes…….1
No……..2 [Go To 8.]

7a. About how many times have you actually done it?

Never……0
Number of Times_____

8. Are you responsible for reminding potential whistleblowers/persons making allegations of their vulnerability and informing them of the institution's responsibility to protect them from retaliation?

Yes……....1 [*Go To 8b*.]
Done with someone else…2 (*Specify person's Office, Title, or Position*)
_____ [*Go To 8b*.]
No……....3

8a. Does the person who is responsible for informing them report to you?

Yes…….1
No……..2 [*Go To 8c*.]

8b. (Are you/Is the person who reports to you) responsible for telling whistleblowers **specifically what measures will be used** to protect them if they file an allegation?

Yes…….1
Done with someone else…2 (*Specify Person's Office, Title, or Position*)
_____
No……..3

8c. Whose responsibility (what Title, Office, or Position) is it to formulate and implement the specific measures to protect the whistleblower from retaliation?
Formulate_____

Implement_____

9. Do you conduct the assessment of allegations to decide if there should be an inquiry?

Yes…….1
Done with someone else…2 (*Specify person's Title, Office, or Position*)
_____
No……..3 [*Go To 10*.]

9a. Do you interview the person making the allegation in that assessment process?

Yes…….1
Done with someone else…2 (*Specify Person's Office, Title, or Position*)
_____
No……..3

9b. Do you interview any witnesses in that assessment process?

Yes…….1
No……..2

10. Is it your responsibility to select the persons who will serve on the inquiry panel?

Yes…….1 [*Go To 11*.]
Done with someone else…2 (*Specify person's Title, Office, or Position*)
_____[*Go To 11*.]
No……..3

10a. How are the members of the inquiry panel selected?

_____

_____

11. If the inquiry panel recommends a formal investigation, is it your responsibility to select the persons who will serve on the investigation committee?

Yes…….1 [*Go To 12*.]
Done with someone else…2 (*Specify person's Title, Office, or Position*)
_____[*Go To 12*.]
No……..3

11a. How are the members of the investigation committee selected?

_____

_____

12. Are you responsible for training or briefing the panel and committee members on how to conduct a proper inquiry or investigation?

Yes…….1
Done with someone else…2 (*Specify person's Title, Office, or Position*)
_____
No……..3 [*Go To 13*.]

12a. What do you train/brief them to be able to do?

(***Do not read list***)	Mentioned
How to:	
1. Develop an investigation strategy	Yes 1 No 2
2. Interview witnesses as well as the accused and accuser	Yes 1 No 2
3. Identify needed technical expertise	Yes 1 No 2
4. Identify available forensic techniques	Yes 1 No 2
5. Work with legal counsel	Yes 1 No 2
6. Handle exigencies	Yes 1 No 2
7. Draft the panel/committee report	Yes 1 No 2
8. Other (*Specify*)_____	

13. Would you say that you are extremely satisfied, very satisfied, satisfied, or not satisfied with the amount of authority and independence you have to carry out your duties as RIO?

Extremely Satisfied……1
Very Satisfied…….2
Satisfied……..3
Not Satisfied……...4

14. Since becoming the RIO in your institution, have you ever had concerns that research misconduct has not come to your attention because it was being handled by other persons through different mechanisms?

Yes…….1
No……..2 [*Go To 15.*]

14a. Are there policies or unofficial norms at play in your institution that direct allegations of scientific misconduct to alternative ways of resolution that do not involve you in your role as RIO?

Yes…….1
No……..2 [*Go To 15.*]

14b. Please describe these alternative ways of resolving alleged research misconduct. _____

_____

15. That you know about in the past five years, has your institution in any way mishandled an allegation of research misconduct? By mishandled I mean to include things such as where the whistleblower was discredited, evidence was not sequestered quickly enough, or the head of a department did not pass on allegations to the appropriate person**.**

Yes……1
No…….2 [*Go To Section IV.*]

15a. In what way (or at what point in the process) was it mishandled (the most recent time). Please just give a general description and do not mention names?

_____
_____

IV. In this next section of the interview I am going to read you several scenarios involving situations in which RIOs sometimes find themselves. Such scenarios can be helpful in pointing out areas for further RIO development through workshops or conferences. Because we know that RIOs in different institutions may act differently in similar situations, we would like you to comment on these fictitious cases. To make it easier for you, the RIO is always unnamed, the accuser or whistleblower has a name beginning with "W", and the accused or respondent's name begins with "R".

Scenario 1

The RIO receives a phone call from a very upset third year grad student. As best the RIO can understand through the student's accent, she is upset that her thesis advisor is attempting to publish some of her data without naming her an author or giving her adequate credit, and in addition, he is misrepresenting her data. She also complained that he is assigning her work to do in the lab that is unrelated to her dissertation, thereby impeding progress on her degree. The RIO invites the student to come by her office to discuss these allegations, but the student declines.

During that initial call, the RIO advises the student to call the assistant dean of the graduate school who deals with mentor-trainee problems to discuss progress toward her degree. She then asks the student for more details on the alleged misrepresentation of her data. The student alleges that her advisor is making claims in proposals and manuscripts that her data do not support and that he is selectively using bits of her data that make it appear like the data do support his claims. She tells the RIO that she and a post doc in the lab have argued with the advisor over this, but that the post doc is afraid to join her in this complaint because he needs a letter of reference from the advisor. The RIO encourages the student to come see her and to bring her lab books so she can better understand the situation. The student says she will think about it.

Two days later, the student calls the RIO again, very agitated. She says that the post doc had an argument with the advisor over the integrity of the data, and that he wants her to join him in writing to a journal editor about it. She notes that the advisor is in the lab at that time shredding films and printouts.

If this scenario unfolded at your institution, what actions, if any, would you as the RIO take in response to this second call?

Scenario 2

Dr. Rivers is a renowned professor emeritus at a university. He discovered a drug that made millions of dollars for him and the university. Upon retiring from the university, Dr. Rivers founded a pharmaceutical research company called Biostart, and he has the company developing a promising new drug. Dr. Rivers entered into a research agreement with the university under which Biostart received partial funding and the collaboration of some scientists from the university. The agreement stated that in return the university would have partial ownership of any intellectual property that its funds or staff helped to develop. The agreement stipulates that the university's research regulations and procedures have jurisdiction over any work at Biostart involving university funds or staff.

A claim of misconduct has been brought against Dr. Rivers by a university scientist, Dr. Wheeler, who has been working with Biostart on the new drug. He alleges that the Biostart scientists did not do the work it claimed, but had rather "stolen" university scientists' data and falsified data to mask the theft. In addition, Dr. Wheeler claims that Dr. Rivers is retaliating against him for making the allegation by refusing to renew his "guest" appointment at Biostart.

Upon receiving the allegations from Dr Wheeler, the RIO, as required by university procedures, informed the university's General Counsel, President, Provost, and Vice President for Research of the allegations and prepared to visit Biostart to sequester data and inform the Biostart scientists and Dr. Rivers of the allegations against them. Before the RIO could contact Dr. Rivers and Biostart about the allegations, however, the university's General Counsel came to the RIO's office. The General Counsel told the RIO that he had just spoken with the President and they both agreed that the RIO should not pursue the allegations because the university had no effective way to sanction the Biostart scientists or Dr. Rivers if they were confirmed. The RIO reminded the General Counsel of the agreement in which Biostart agreed that the university's regulatory policies and procedures would apply to all research at Biostart in which the university was involved. The General Counsel said that he had considered that. Then the RIO asked the General Counsel whether he and the President might not have a conflict of interest in making that decision because they wanted to preserve their partnership with Biostart in anticipation of another financial bonanza for the university from the new drug. The General Counsel declined to respond.

What would you do now if you were the RIO? Please explain why.

Scenario 3

The RIO receives a telephone call from a person identifying herself only as a lab technician on campus. She wants to know what the "rules" are for filing an allegation of misconduct. Specifically, she wants to know whether she would be identified as the person making the allegation and what would happen to her job if the head of the lab learned that she had accused him of fabricating data. She also asked what would happen to her job if the head of her lab were "convicted" of misconduct.

The RIO explains that she can remain officially anonymous unless or until her testimony is needed in a proceeding reviewing the allegation. The RIO adds that if she declines to testify, while the university would not compel her, it might not be able to continue to investigate the allegation. As to what would happen to her if the head of the lab learned that she had made the allegation, the RIO tells her that, in the small world of a laboratory, it is very likely that the head of the lab will guess who made the allegation, even if everyone maintains confidentiality. However, the RIO tells her that as long as she is acting in good faith, the University will take steps to protect her.

The caller eventually identifies herself as Wendy West and she decides to make a formal allegation, but asks for anonymity. The RIO goes to the laboratory to inform the head of the lab, Dr. Ralston, of the allegation and to sequester the pertinent data.

The next week Ms. West is invited to come to the RIO's office to provide more details on the allegation. As she is leaving, Dr. Ralston happens to come into the RIO's office, he says, to ask about his rights under the University's misconduct procedures. There is an awkward moment in the hallway as Ms. West leaves and Dr. Ralston enters. The next week, Ms. West calls the RIO to report that Dr. Ralston accused her of making the allegation and upset her so much that she had to go home "sick." But, even as she tried to leave work, Dr. Ralston followed her down the hall screaming at her.

What, if anything, would you have done differently as the RIO ?

What would you do next if you were the RIO?

Scenario 4

The University's RIO receives a telephone call from the chair of the Medical School's IRB who requests an immediate meeting. On arriving at the RIO's office, the IRB chair explains that IRB staff had been concerned for some time about a Phase 1 clinical trial operating at an affiliated Cancer Center. The protocol involves a new oncology drug, developed by the investigators, in combination with experimental radiation therapy. The University's Medical School IRB is the IRB of record.

The IRB chair explains that IRB staff had noted for some time that the project submitted tardy adverse event reports and incomplete annual reports accompanying their requests for renewed approval of the protocol. Consequently, IRB staff had decided to conduct an audit of the project over the past two days. They found that where patient records appeared to be complete, there were numerous protocol violations, including some involving inclusion and exclusion criteria. In addition, many of the patient records had incomplete enrollment information and were missing consent forms.

On learning of these initial audit results, the IRB chair went to the Cancer Center to examine the records. While there, a medical resident who had worked briefly on the project asked to speak to him in private. The resident told the IRB chair that some of the consent forms had been completed and back-dated only when the project staff learned of the impending IRB audit, some many months after the patient had been enrolled. Further, the resident alleged that one patient, a terminally-ill woman who did not meet the inclusion criteria because she had had recent non-protocol radiation therapy, had been enrolled in violation of protocol rules because recent radiation plus the radiation therapy that was part of the project in combination with the study drug was potentially cardio-toxic. The patient died after protocol radiation therapy, but the death was not reported to the IRB. Further, the resident alleged, the record of her having been enrolled in the project had been destroyed.

What, if anything, should the RIO do in response to the alarming audit report and the allegations made by the medical resident?

Scenario 5

The institute's RIO receives an allegation of research misconduct —falsification of data —against Dr. Rogers. The RIO, an assistant, and the general counsel immediately visit Dr. Rogers' office to inform him of the allegation, and to sequester data that could constitute evidence in any eventual investigation of the allegation. Dr. Rogers reacts angrily to being informed of the allegation, and states he's being unfairly accused. He further claims that by pursuing this allegation the institute is "persecuting" him. He refuses to cooperate with the sequestration of the data in question. Accordingly, the RIO, the assistant, and a member of the security force consult Dr. Rogers' post-doc and senior graduate student as discreetly as possible to identify and sequester the pertinent data, all the while making every effort to not disrupt Dr. Rogers' lab. Nevertheless, the next day, Dr. Rogers sends a letter to the institute's president accusing the RIO of abusing him, disrupting his work, and interfering with his academic freedom.

Meanwhile, as part of the initial assessment of the allegation, the RIO invites Dr. Rogers to meet. However, Dr. Rogers does not respond to the RIO's telephone messages, e-mails, or registered letter. Unable to talk with Dr. Rogers and get his explanation of the alleged data falsification, the RIO confers with general counsel and decides that a formal inquiry is needed to assess the allegation.

Upon being informed that the allegation has resulted in a formal inquiry, Dr. Rogers files a grievance against the RIO. The grievance claims that the RIO has taken the side of the whistleblower, is therefore not impartial, and should be removed from any involvement with the case.

While the grievance is pending, the inquiry begins. When invited to an interview by the inquiry committee, Dr. Rogers responds that he will only attend if his lawyer can speak for him and cross-examine witnesses. In response, the RIO sends a letter to Dr. Rogers explaining that under institute policy he may be accompanied by counsel, but that counsel may not speak for him. In addition, the letter explains that inquiries are conducted through sequential, confidential interviews as opposed to in an open hearing where cross-examination might be appropriate. Dr. Rogers does not respond to the RIO's letter or to subsequent invitations from the inquiry committee for an interview. However, Dr. Rogers does send an e-mail to hundreds of colleagues attacking the RIO's integrity and competence, and his lawyer writes a letter to the institute's general counsel threatening a law suit if the inquiry into the allegation, claiming it is untrue and has already injured his client, continues.

How should the RIO respond in this situation?

Thank you very much for the time you took to answer our questions.

IF RELEVANT: Please remember to e-mail me your RIO job description.

Now that we are done, are there any questions that you think we should have asked that we did not?
Yes…….1 [*Specify*] _____
No……..2

Were there any questions that we asked that you thought we should not have asked?
Yes…….1 [*Specify*] _____
No……..2

Thank you very much for your help.

Attachment 3: Federal Register Notice

Attachment 4: Letter to Responsible Institutional Officer (Phase I)

Dear Dr/Mr./Ms. Surname,

The Office of Research Integrity (ORI) has contracted with RTI International to gather information on how ORI can better assist institutions to deal with reports of research misconduct. Because you sign the annual assurance document, you are listed in the ORI registry as the institution's contact person. That is why we are contacting you.

We want to identify and schedule an interview with the person responsible for implementing your institution's plan for addressing reported allegations of research misconduct - specifically fabrication, falsification, and plagiarism. By implementation we mean the person who receives and assesses allegations of research misconduct, organizes inquiries, and, if needed, oversees investigations. We realize that while you may be this person, many institutions have a research integrity officer (RIO) performing these activities who is not the contact person listed in the ORI registry.

Please click on the link below to be taken to a secure web site at RTI where you will be asked for a User ID. The User ID is the e-mail address to which this message was sent (**Surname@institution.edu**). Then, confirm your position as the current responsible institutional official or contact person and make any necessary changes or corrections to the contact information. Next, you will be asked if you are the research integrity officer (RIO) for your institution. If you are not, you will then be asked to identify and provide contact information for the person who is your institution's research integrity officer (RIO). This whole process should take less than five minutes. When you have finished, exit the site. The information you supply will be used to contact your institution’s RIO.

We expect to conduct telephone interviews with RIOs at approximately 120 institutions. The interviews will last about an hour and the information collected will be kept confidential. The analysis will present results tabulated so that no individual RIO or institution will be identifiable. While participation in this project is voluntary, we hope you see the importance of knowing more about the roles RIOs perform and will respond to this request as soon as possible.

Clicking on this link will transport you to a secure site at RTI http://localhost/rio/index.cfm.

If you have any questions, you may e-mail or call Dr. Arthur J. Bonito at RTI (ajb@rti.org or 919-541-6377) or Dr. Sandra Titus at ORI (stitus@osophs.dhhs.gov or 301-443-5300).

Thank you for your cooperation.

Sincerely,

Arthur J. Bonito, Ph.D.
Project Director

Attachment 5: Letter to Research Integrity Officer (Phase I)

Dear Dr/Mr./Ms. Surname,

The Office of Research Integrity (ORI) has contracted with RTI International to gather information on the activities research integrity officers (RIOs) perform, where RIOs are located in their institution's administrative structure, and how they respond to difficult situations presented as scenarios. A goal of this study is to suggest how ORI might help RIOs to be better prepared to deal with troublesome situations arising from alleged research misconduct.

We want to schedule an interview with you because you have been identified by the responsible institutional official as your institution's RIO – the person responsible for implementing your institution's plan for addressing reported incidents of research misconduct - specifically fabrication, falsification, and plagiarism. By implementation we include receiving and assessing reports of research misconduct, organizing inquiries, and, if needed, overseeing investigations.

We expect to conduct telephone interviews with a random sample of RIOs at approximately 120 institutions. The interviews will last about an hour and the information collected will be kept confidential. The analysis will present results tabulated so that no individual RIO or institution will be identifiable. While participation in this project is voluntary and you may choose to skip any question, we hope you can see the importance of knowing more about the roles RIOs perform and where they are situated administratively in their institutions. Please sign up for an interview as soon as possible.

Click on the link below to be taken to a secure web site at RTI where you will be asked for a User ID. The User ID is the e-mail address to which this message was sent **(Surname@institution.edu**). Then, confirm your position as the current RIO, and make any necessary changes or corrections to the contact information. Next, you will be asked to select a day and time that you will be available to talk with an RTI research professional about what you do as the research integrity officer (RIO) for your institution. This whole appointment process should take less than five minutes. When you have finished, exit the site. The information you supply will be used to contact you for an interview.

Clicking on this link will transport you to a secure site at RTI http://localhost/rio/index.cfm.

If you have any questions about the interview, you may e-mail or call Dr. Arthur J. Bonito at RTI (ajb@rti.org or 919-541-6377) or Dr. Sandra Titus at ORI (stitus@osophs.dhhs.gov or 301-443-5300). If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

Thank you for your cooperation.

Sincerely,

Arthur J. Bonito, Ph.D.
Project Director

Attachment 6: RTI Institutional Review Board Approval Letter (Phase I)

Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709-2194
Federal-wide Assurance No. 3331

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

PROJECT LEADER: Arthur Bonito

TITLE: Research Integrity Officer (RIO) Study

SPONSOR AGENCY: NIH

SUBMISSION DOCUMENT DATE: June 10, 2005

NUMBER: 8490.014 **or PROPOSAL NUMBER: _____**

NATURE OF REVIEW:
(check one) **FULL___ EXPEDITED_X_ ___**

MEETING DATE: N/A

TYPE OF APPROVAL:

- **___ PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS.**
- **_X_ PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION.**
- **___ FULL IMPLEMENTATION**
- **___ RENEWAL.**
- **___ AMENDMENT:**

Please note the following requirements:

PROBLEMS OR ADVERSE REACTIONS: If problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately.

CHANGES IN PROTOCOL: If there are significant changes in procedures or study protocol, you must notify the IRB Chairperson before they are implemented.

RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active.
Approval for this project expires and your next review date should be before June 15, 2006.

_____ **June 15, 2005**
IRB Member or Chair **Date**

Lori Ebert, Ph.D.
Print or Type Name

Signed Approval Notice in IRB File