Attachments for the Memo Request to OMB for Modification of Previous Clearance

Attachment 1: OMB clearance approved for RIO telephone interview; this document also directs us to submit an administrative request for changes with a copy of the web-based questionnaire and revised work plan.

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 01/09/2007

Department of Health and Human Services
Departmental Management
FOR CERTIFYING OFFICIAL: Charles Havekost
FOR CLEARANCE OFFICER: Seleda Perryman

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 08/30/2006

ACTION REQUESTED: New collection (Request for a new OMB Control Number)
TYPE OF REVIEW REQUESTED: Regular
ICR REFERENCE NUMBER: 200608-0990-004
TITLE: Research Integrity Officer (RIO) Study
LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved with change
OMB CONTROL NUMBER: 0990-0305
The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 01/31/2009 DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	0	0	0
New	2,556	647	0
Difference			
Change due to New Statute	0	0	0
Change due to Agency Discretion	0	0	0
Change due to Agency Adjustment	2,556	647	0
Change Due to Potential Violation of the PRA	0	0	0

TERMS OF CLEARANCE: Approved consistent with the following terms of clearance: OMB approves phase one of the survey, however, prior to initiating phase two HHS shall submit an administrative request change to OMB including the finalized phase two questionnaire and study plan. HHS shall not begin phase two prior to OMB approval of the requested change.

OMB Authorizing Official: John F. Morrall III
Acting Deputy Administrator,
Office Of Information And Regulatory Affairs

List of ICs			
IC Title	Form No.	Form Name	CFR Citation
Research Integrity Officer (RIO) Study	1	Semi-Structured Telephone Interview	42 CFR 93.300
Research Integrity Officer (RIO) Study	1	Semi-Structured Telephone Interview	42 CFR 93.300
Research Integrity Officer (RIO) Study	1	Semi-Structured Telephone Interview	42 CFR 93.300
Research Integrity Officer (RIO) Study	1	Semi-Structured Telephone Interview	42 CFR 93.300

Attachment 2: OMB approved RIO telephone interview.

Form Approved

OMB Control No.: 0990-0305
Expiration Date: 1/31/2009

Interviewer Name_____

Respondent Name_____

Institution Name_____

Phone Number_____

Date and Time_____

Identification Number_____

Final (Revision 7) Draft of the Semi-Structured Telephone Interview

Introduction

Hello (*respondent's name*), this is (*your name*) calling from RTI. As we told you in an earlier e-mail, RTI is a not-for-profit research organization headquartered in North Carolina. I want to thank you for agreeing to talk to us at this time about the things you do when there are allegations of research misconduct at your institution. Our questions will ask about your training, experience, and about what you do as the RIO in particular scenarios. 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 [RIO] to contact*.]

The purpose of this research is to understand how you and other RIOs carry out the responsibilities associated with these activities and to identify areas where the DHHS Office of Research Integrity or 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. Of course, your participation is voluntary and you may refuse to answer any question. Because your identity is protected we see little risk with participation and opportunities for RIO training as potential benefits that could result.

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. We will destroy the recording when the project is completed. 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 100 other institutions. [*Await response for a moment, re-ask if needed, and turn on recorder if affirmative*.]

START TIME_____ Identification Number_____

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

1. What is **<u>your</u>** usual title, office, or position in the organization when you are **<u>not performing</u>** 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 **<u>are not performing</u>** 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 **<u>are performing</u>** 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 **<u>are performing</u>** 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 a branch of 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 or fax me a copy of your written RIO job description after we finish the interview?

Yes…….1
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, OTHERWISE GO TO QUESTION 8.*]

7. Are you a tenured member of the faculty?

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

[*If responsible for all areas, Go To 4.*]

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

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

Yes…….1
No……..2

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

_____
_____
_____
_____

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 [*Go To SECTION III*.]
No……..2

7e. Does the person who is responsible for 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. In the past five years, are you aware of any cases in which your institution has mishandled an allegation of research misconduct in any way? Mishandled includes things such as allowing the person making the allegation to be discredited, not sequestering evidence quickly enough, or having the head of a department fail to pass 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 person making the allegation or whistleblower has a name beginning with "W", and the person being accused or respondent's name begins with "R".

Scenario 1

The RIO receives a phone call from a very upset third year graduate 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 reluctant 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 you were the RIO, what actions, if any, would you 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 Biostart 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 a 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 the allegations 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 your rationale for doing that.

Scenario 3

The RIO receives a telephone call from a person identifying herself only as a lab technician. She wants to know what the "rules" are for filing an allegation of research 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 was found "guilty" 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 institution 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 institution 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 institution's research 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 as the RIO in response to the chance encounter?

What would you do now in response to the second phone call 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 a terminally-ill woman had been enrolled in violation of protocol rules. She did not meet the inclusion criteria because she had recent non-protocol radiation therapy which in combination with the radiation therapy and drug that were part of the study 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.

If you were the RIO, what, if anything, would you 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' lab assistant 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 sends an e-mail to hundreds of colleagues attacking the RIO's integrity and competence. His lawyer writes a letter to the institute's general counsel threatening a law suit if the inquiry into the allegation continues, claiming it is untrue and has already injured his client.

How would you respond as the RIO in this situation?

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

IF RELEVANT: Please remember to e-mail (or FAX) me your RIO job description. [*Give your e-mail address/fax number to the respondent*]

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 AGAIN

END TIME _____

Attachment 3: Questionnaire for the proposed RIO web-based survey.

Form Approved

OMB Control No.: 0990-0305
Expiration Date: 1/31/2009

Web-Based Version of Revision 7 of the Semi-Structured Telephone Interview

Identification Number_____

Introduction

RTI is a not-for-profit research organization headquartered in North Carolina. The Department of Health and Human Services' (DHHS) Office of Research Integrity (ORI) has engaged RTI to conduct a study of what occurs when there are allegations of research misconduct at institutions performing federally-funded research. For this study, research misconduct refers to 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. We want to be sure you are the person doing that job at your institution?

Yes, I am the RIO……O [*Continue*.]
No, I am not the RIO…O [*Do Not Continue. Go to page to identify the correct person to contact*.]

The purpose of this research is to understand how you and other RIOs 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. This survey contains questions about your training, experience, and about what you do as the RIO, including some scenarios to address. This survey should take about 30 minutes to complete. Of course, your participation is voluntary and you may refuse to answer any question. We pledge to keep your identity and that of your institution confidential. Because your identity is protected, we see little risk with participation and opportunities for RIO training as potential benefits that could result.

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 240-453-8437). 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).

Instructions to respondents for completing information collection:

START TIME_____

I. 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, how involved would you say you are 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 different title or hold an identified office or position in the organizational structure when you **are performing** activities related to research misconduct issues?

Yes……....1
No…(Same title as in item 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

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. and Fill in 3d with 0*]
Other [*Specify title, office, or position* .] _____

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

Number of persons in structure between you (RIO) and the President/CEO _____

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

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 assigned to assist you in your RIO duties?

None……..0 [*Go To 4. and fill number with 0*]
Number of persons_____

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

Position/Role Description	% Time Committed
1._____	_____%
2._____	_____%
3._____	_____%
4._____	_____%

4. For how long have you been **involved in any way** with activities related to investigating and reporting on research misconduct at your institution?
_____ O Months…1 O Years…2

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)?
_____O Months…1 O Years…2

4b. Approximately what proportion of your time each year 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?
(1)_____
(2)_____
(3)_____
(4)_____
(5)_____

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?

_____ O Months…1 O Years…2

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

7. Are you a tenured member of the institution/faculty?

Yes……...…..1
No……..…2
No tenure available…3

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

9. What advanced degrees do you hold? **Check All That Apply**

(a) PhD…… 1
(b) MD …….2
(c) DDS/DMD/DVM…. 3
(d) MS/MA ……4
(e) MPH/MBA/MHA/MPA …….5
(f) BS/BA/AB ……6
(g) Other …7 [*Specify.*] _____
(h) 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 and Fill Number with 0*)
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. Responsibilities and Experiences

1. In addition to 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?

a. Financial conflicts of interest.	Yes..1	No..2	Shared..3
b. Protection of human research subjects.	Yes..1	No..2	Shared..3
c. Protection of animal research subjects.	Yes..1	No..2	Shared..3
d. Hazardous waste and radioactive materials.	Yes..1	No..2	Shared..3
e. Recombinant DNA.	Yes..1	No..2	Shared..3
f. Grants management issues.	Yes..1	No..2	Shared..3

g. Are there any other administrative or regulatory areas that you are **responsible** for?

Yes…….1 [*Specify area.*] _____

Shared..…..3 [*Specify area.*] _____

No…..……2

[*If responsible for all areas, (no "no"s to Question 1) Go To 4*. Otherwise, only show the items 1a – 1f answered "no" below in question 2.]

2. In which of the following areas do you participate in some 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.

a. Financial conflicts of interest.	Yes..1	No..2
b. Protection of human research subjects.	Yes..1	No..2
c. Protection of animal research subjects.	Yes..1	No..2
d. Hazardous waste and radioactive materials.	Yes..1	No..2
e. Recombinant DNA.	Yes..1	No..2
f. Grants management issues.	Yes..1	No..2

h. Are there any other administrative or regulatory areas in which you **participate,** but for which you are not responsible?

Yes…….1 [*Specify area*.] _____
No……..2

3. Do any of the persons responsible for the areas that **you are not responsible for** report to you?

Yes…….1
No……..2 [*Go To 3b*.]

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

Yes…….1
No……..2

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?

Number_____ [*If none, go to 5 and fill Number with 0*]

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

Number_____ [*If none, go to 5 and fill Number with 0*.]

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

Number_____ [*If none, go to 5 and fill Number with 0*.]

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

Number_____ [*If none, go to 5 and fill Number with 0*.]

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?

Number of Times_____[*If none or one, go to 6 and fill Number in 5a with 0 or 1*.]

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?

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?

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

Yes…….1
No……..2

7b. Please describe the key components of this RCR training and who implements it?

Key Components
(1)_____
(2)_____
(3)_____
(4)_____
(5)_____

(6)Who implements it? Specify (*Person's office, title, or position*)
_____

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 [*Go To SECTION III*.]
No……..2

7e. Does the person who is responsible for 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. Specific Responsibilities as RIO.

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 by office, title, or position to receive allegations of research misconduct?

(1)_____
(2)_____

1b. (Does/Do) the other person(s) designated to receive allegations **report to you** or to someone else in the institutional structure?

Yes, report to me…….1 [*Go To 2.*]
No, report to someone else……..2

1c. To 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 the allegations they receive to you?

Yes…….1
No……..2

2b. Through what process or means of communication do the allegations of misconduct get from those persons to you as the RIO?

(1)_____
(2)_____
(3)_____

2c. Normally, how soon after an allegation is made does notification of the allegation from them reach you? _____O Hours…1 O Days….2

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 (What is the *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?

1. Provide Orientation to New Members	Yes	No
2. Provide Handbook for Faculty, Staff, and Students	Yes	No
3. Website on Research Misconduct Policy	Yes	No
4. Publicize Institutional Policies and Guidelines	Yes	No
5. Announce in Newsletters	Yes	No
6. Give Presentations	Yes	No
7. Do On-Line Training	Yes	No
8. Hold Workshops	Yes	No
9. Organize Classes or Courses	Yes	No
10. Work through Advisors	Yes	No
11. Model through Mentors	Yes	No
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 <u>informing key institutional officials</u> 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 <u>deciding who deals with which parts of the allegation and in what order</u> they get handled?

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

7. Are you the person responsible for <u>sequestering evidence</u> 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 title, office, 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?

(1) Formulate_____

(2) 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 title, office, 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 office, title, 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?

Does it include 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 operating in your institution that direct allegations of research 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. In the past five years, are you aware of any cases in which your institution has mishandled an allegation of research misconduct in any way? (Mishandled includes things such as allowing the person making the allegation to be discredited, not sequestering evidence quickly enough, or having the head of a department fail to pass allegations on to the appropriate person**.)**

Yes……1
No…….2

Scenario 1

The RIO receives a phone call from a very upset third year graduate 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 reluctant 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 you were the RIO, what actions, if any, would you take in response to this second call?

1._____

2.

3.

4.

5.

6.

7.

8.

Scenario 2 *[Formerly3*]

The RIO receives a telephone call from a person identifying herself only as a lab technician. She wants to know what the "rules" are for filing an allegation of research 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 was found "guilty" 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 institution 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 institution 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 institution's research 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.

(a) If you were the RIO, what, if anything, would you have done in response to the chance encounter in the hallway?

1._____

2.

3.

4.

5.

6.

7.

8.

(b) What would you do now in response to the second phone call from Miss West?

1.

2.

3.

4.

5.

6.

7.

8.

Scenario 3 *[Formerly 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 a terminally-ill woman had been enrolled in violation of protocol rules. She did not meet the inclusion criteria because she had recent non-protocol radiation therapy which in combination with the radiation therapy and drug that were part of the study 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.

(a) If you were the RIO, what, if anything, would you do in response to the alarming audit report?

1._____

2.

3.

4.

5.

6.

7.

8.

(b) What, if anything, would you do in response to the allegations made by the medical resident?

1._____

2.

3.

4.

5.

6.

7.

8.

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

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 AGAIN

END TIME _____

Attachment 4: Revised e-mail letter to responsible institutional official

October 2, 2007

Dear Institutional Contact Person,

RTI International is a not-for-profit research organization located in North Carolina. The U.S. Department of Health and Human Services' (DHHS) Office of Research Integrity (ORI) has contracted with RTI to gather information on how ORI can assist institutions to deal with reports of research misconduct. We are contacting you because ORI has you listed as the person who signs the assurance document for your institution.

We want to identify the person responsible for implementing your institution's plan for addressing reported incidents of research misconduct - specifically fabrication, falsification, and plagiarism. By implementing we mean the person receives and assesses reports of research misconduct, organizes inquiries, and, if needed, oversees investigations. We want to identify this person to ask that he or she complete a brief self-administered questionnaire about what they do in that position. We realize that while you may be this person, many institutions have a separate research integrity officer (RIO) performing these activities who is not the person listed in the ORI registry.

Please click on the link below to be taken to a secure web site at RTI. Then, confirm your position as the current responsible institutional official (ORI contact person) or RIO and make any necessary changes or corrections to the contact information. Next, if you are the RIO, you will be asked to complete a questionnaire. If you are not the RIO, you will be asked to identify and provide contact information for the person you believe is your institution's RIO. That process should take less than five minutes. When you have finished, exit the site.

We expect to ask RIOs at approximately 1,300 institutions to complete the following questionnaire. Completing the questionnaire will take about twenty-five minutes and we pledge to keep the information collected confidential. Identifiers will be maintained separate from the data and destroyed as soon as it is practical. 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 will see the importance of knowing more about the roles RIOs perform and will respond as soon as possible.

Clicking on the following link will transport you to a secure site at RTI where you will be able to complete the questionnaire: http://rio-surveydev.rti.org

If you have any questions about this survey, 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 240-453-8437). If you have any questions about your rights as a study participant you may call RTI's Office of Research Protection toll-free at 1-866-214-2043. Thank you for your cooperation.

Sincerely,

Arthur J. Bonito, Ph.D.
Project Director

Attachment 5: Revised e-mail letter to research integrity officer

October 2, 2007

Dear Research Integrity Officer,

RTI International is a not-for-profit research organization located in North Carolina. The U.S. Department of Health and Human Services' (DHHS) Office of Research Integrity (ORI) has contracted with RTI to gather information on how ORI can assist institutions to deal with reports of research misconduct. We are contacting you because you were identified as your institution's research integrity officer or RIO by the person at your institution who signs the assurance document for ORI.

You were identified as the person responsible for implementing your institution's plan for addressing reported incidents of research misconduct - specifically fabrication, falsification, and plagiarism. By implementing we mean you receive and assess reports of research misconduct, organize inquiries, and, if needed, oversee investigations. We want to identify the RIO in order to ask that he or she complete a brief self-administered questionnaire about what is done in that role.

Please click on the link below to be taken to a secure web site at RTI. Then, confirm your position as the current RIO and make any necessary changes or corrections to the contact information. Next, if you are the RIO, you will be asked to complete a questionnaire. If you are not the RIO, you will be asked to identify and provide contact information for the person you believe is your institution's RIO. That process should take less than five minutes. When you have finished, exit the site.

We expect to ask RIOs at approximately 1,300 institutions to complete the following questionnaire. Completing the questionnaire will take about twenty-five minutes and we pledge to keep the information collected confidential. Identifiers will be maintained separate from the data and destroyed as soon as it is practical. 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 will see the importance of knowing more about the roles RIOs perform and will respond as soon as possible.

Clicking on the following link will transport you to a secure site at RTI where you will be able to complete the questionnaire: http://rio-surveydev.rti.org

If you have any questions about this survey, 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 240-453-8437). If you have any questions about your rights as a study participant you may call RTI's Office of Research Protection toll-free at 1-866-214-2043. Thank you for your cooperation.

Sincerely,

Arthur J. Bonito, Ph.D.
Project Director