

Supporting Statement

For the

Whistleblower Study

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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Supporting Statement for the Whistleblower Study:

A Descriptive Study to Assess the Information Needs of Those Who Report Potential Research Misconduct

A. Justification

1. Circumstances Making the Collection of Information Necessary

- The Office of Public Health and Science (OPHS) and specifically the Office of Research Integrity (ORI), requests approval for a new collection to examine issues related to whistleblowers who report research misconduct.
- The Department of Health and Human Services (DHHS) through the Public Health Service Act section 493 directed the Secretary to create a regulation to protect against biomedical and behavior research fraud. (See Appendix A). In response, the Office of Research Integrity (ORI) was created (42 USC 289 - Sec. 289b. Office of Research Integrity) and the Secretary issued 42 CFR part 50 and 93 which created regulations requiring institutions to report their investigations of research misconduct. (See Appendix B) In addition, 42 U.S.C. § 289b: specifically directed the protection of whistleblowers against retaliation for reporting research misconduct. (See Appendix C).
- In 2000, the Division of Education and Integrity (DEI) at ORI was directed to “focus more on preventing misconduct and promoting research integrity through expanded education programs.” Specifically, DEI was directed to “conduct policy analyses, evaluations, and research to improve DHHS research integrity and build the knowledge base in research misconduct, research integrity and prevention” (Federal Register: May 12, 2000, Volume 65, Number 93, pages 30600-30601) (See Appendix C).
- This research effort is focused on providing educational information on how whistleblowers are handling reporting research misconduct and whether they experience retaliation for doing so. We believe this information will help institutions become better able to anticipate whistleblower issues and be more supportive of those individuals who are trying to report possible research misconduct.
- The system of uncovering research misconduct is dependent on the voluntary reporting of allegations of research misconduct by fellow researchers, often referred to as “whistleblowers” or complainants. Institutions that receive PHS funding for research are required to educate their research staff regarding what constitutes research misconduct as well as their responsibility to report it if they suspect it.
- ORI has research which suggests that suspected misconduct is often not reported. Failure to report suspected misconduct threatens continued research funding. Among the reasons offered for the reluctance of complainants to come forth with their allegation is that they do not understand the resolution process

or know what to expect from their institution. Responsibility for educating research staff and informing complainants in particular often falls to the institution's Research Integrity Officer (RIO).

- In pursuit of its legislative responsibility, ORI needs to develop responsive educational materials and training opportunities for RIOs so they can be well prepared to handle the challenge of informing and assuring complainants and potential complainants. To do that requires that ORI gather information on what questions and concerns complainants express at various points in the allegation resolution process so that materials and training can be developed to prepare RIOs to more appropriately deal with them.
- ORI has contracted with RTI International to conduct personal interviews with up to 100 RIO's by telephone to learn what kind of information complainants and potential complainants seek and receive from Research Integrity Officers (RIOs) at various stages of the allegation resolution process. The stages include when they initiate the process of making an allegation, while they are in the midst of the resolution process, and following completion of the process.
- Admittedly, the ideal study of complainants would involve talking with former complainants. However, because of the confidentiality protections provided to research misconduct complainants, ORI cannot release the names of former complainants. RTI has been unable to identify, recruit, and directly contact complainants to obtain the desired information. Consequently, we plan to interview RIOs who have had contact with whistleblowers to examine the kinds of questions and issues complainants and potential complainants raised with them, as well as to ascertain the kinds of information the RIOs provide. The interviews will give us an observational perspective on the degree to which complainants report fear of making allegations of research misconduct and/or report retaliation for having made the allegation before, during and after the investigation is over.

2. Purpose and Use of Information Collection

- ORI wants complainants and potential complainants to be fully informed and comfortable about the need to report suspected research misconduct and to be fully aware of the process for resolving allegations of misconduct that are made. In order to develop information targeted to complainants and potential complainants it is important to know what questions and concerns previous complainants have had during the course of their involvement in a case that he/she initiated by making an allegation.
- The information to be collected will be used by ORI to gain a fuller understanding of the questions and concerns expressed by complainants and potential complainants at various stages of the allegation resolution process. (See Appendix D for a copy of the draft data collection instrument.)

- The information will be used to develop educational materials and training opportunities for RIOs so they are better able to attend to the information and assurance needs of complainants and potential complainants.

3. Use of Improved Information Technology and Burden Reduction

- We have done several things to reduce the burden of the study on RIOs. These include asking questions almost exclusively about what complainants and potential complainants ask the RIOs as they proceed through the resolution process. By building into the interview form pre-coded answers to the extent possible, it will make noting the answers of RIOs easier and quicker, thus allowing the interview calls to be shorter. Also, by allowing RIOs to make their own appointments by logging on to the RTI appointment scheduler can save RIOs time and get them their choice of time slots. Finally, by recording the interviews, it saves interviewers time in writing down responses verbatim or calling respondents back to clarify cryptic notes because they can go back and listen to what was said in the interview and thereby not burden the RIO further.
- We have considered alternative modes of data collection for this study including use of a web-based self-administered questionnaire. RTI has conducted a web-based survey of RIOs for ORI. However, in our opinion, for the type of information we are soliciting from the RIOs, the response rate would suffer greatly, and data quality and quantity would be diminished as well. It will help to have a trained interviewer be able to listen to the responses and probe to clarify them when they are vague, incomplete, or miss the point of the question.

4. Efforts to Identify Duplication and Use of Similar Information

- ORI is the primary source of funding for research on research misconduct and the issues associated with whistleblowers in the context of PHS-sponsored research conducted in institutions of higher education. For that reason ORI staff members are the most knowledgeable about the availability of existing databases that would satisfy the needs of this study. ORI staff members have no knowledge of any existing databases or recent studies addressing the problems and concerns of complainants or potential complainants over the course of the allegation resolution process.
- There was an earlier study of “whistleblowers” sponsored by ORI and conducted nearly two decades ago by RTI. Our automated search for studies of research misconduct complainants/whistleblowers did not turn up any more current studies comparable to what this current one is intended to investigate. ORI funded the current study in order to determine whether there are new or different questions and concerns since the earlier RTI study was conducted, and to examine whether the questions and concerns that complainants and potential complainants have currently change or differ over the course of the allegation resolution process, something the earlier RTI study did not investigate.

5. **Impact on Small Businesses or Other Small Entities**

- No small businesses will be involved in this study.

6. **Consequences of Less Frequent Collection of the Information**

- This is a one-time data collection activity. Failure to collect the needed information will mean that the full range of questions and concerns of complainants and potential complainants will likely not be available to ORI to guide it in the development of planned educational materials and training opportunities for RIOs to better prepare them to receive and assess allegations of research misconduct.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

- The request fully complies with the Guidelines of 5 CFR 1320.5.

8. **Comments in Response to the Federal Register Notice/Outside Consultation**

- A 60-day Federal Register Notice was published in the *Federal Register* on March 19, 2010, Vol. 75, No. 53; pp. 33287-33288 (See Appendix D for a copy of the published notice.). No public comments were received.

9. **Explanation of any Payment/Gift to Respondents.**

- No payments or gifts will be provided to the respondents.

10. **Assurance of Confidentiality Provided to Respondents**

- Data will be kept private to the extent allowed by law. RTI will give respondents its assurance that the interview information will be reported in such a way that it will not be possible to identify the respondents or their institution. In addition, interviewers and other project staff with access to identifying information will be required to sign RTI data privacy pledges. RTI will maintain identifying and interview information in separate files on a share drive that will have access limited to persons working on the project. During data collection and cleaning, the identification and interview files will have a numeric link between them. That link will be removed when the data have been edited and a final data set is produced. No information that will allow identification of respondents/non-respondents will be provided to ORI.

11. **Justification for Sensitive Questions**

- RTI will not ask questions of a sensitive nature during the data collection effort.

12. **Estimates of Annualized Hour and Cost Burden**

12A. **Estimated Annualized Burden Hours**

Type of	Form	No. of	No.	Average	Total
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Respondent	Name	Respondents	Responses per Respondent	Burden per Response (in hours)	Burden Hours
RIOs	Interview Form	100	1	45/60	75

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
RIOs	75	\$100.00	\$7,500

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

- Respondents will not incur capital costs or capital maintenance costs as a result of participating in this information collection effort.

14. Annualized Cost to Federal Government

- ORI has contracted with RTI, International to conduct the data collection and analysis, and to prepare a report. The contract will cover a four year period at a total cost of \$400,000 to the government. Annualized contractor costs are estimated to be \$100,000 per year.
- It is expected that the ORI project officer (Sandra Titus, Ph.D.) will spend a total of 10 percent of her time on the project (200 hours of involvement per year over the four years of the project). At the average rate of \$100 per hour, we estimate it will cost the government \$80,000. Annualized the cost to the government for the ORI staff time is estimated to be \$20,000.
- It is anticipated that the ORI consultant (David Wright, Ph.D.) assisting on this project will spend a total of 10 days participating over the four years. At the daily rate of \$400, the total cost to the government is expected to be \$4000. Annualized the cost to the government for the ORI consultant time is estimated to be \$1,000.
- The total cost to the government would be \$484,000; annualized it would cost the government \$121,000.

15. Explanation for Program Changes or Adjustments

- This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

- There is a plan to prepare a manuscript for possible journal publication that describes the types of questions that complainants and potential complainants in institutions of higher education come to the RIOs with at various points in the allegation resolution process. It will be a descriptive presentation in which tabulations will involve percentages and numeric counts. No statistical analysis is planned beyond the tabulations.
- It is important to note that the critical nature of obtaining OMB clearance to proceed with the study by the start of July 2010 so that the study can be completed before the expiration of the contract, as we have been informed that it cannot be extended. The schedule for preparation of the manuscript follows:

Activity or Task	Time by Which to Be Achieved/Completed
1. Prepare and submit supporting statement materials (including data collection forms and letters) for OMB review	March 2010
2. Obtain IRB approval or exemption	March 2010
3. Conduct pilot study	March – April 2010
4. Notify OMB of changes resulting from pilot study results	May 2010
5. Finalize data collection instrument, advance letter, and survey procedures	April – May 2010
6. Obtain OMB clearance	July 2010
7. Train interviewers and conduct interviews with RIOs	August – November 2010
8. Key, code, and analyze interview data	December 2010 – March 2011
9. Prepare report from interview data to describe questions and concerns of complainants and potential complainants	April – July 2011
10. Prepare manuscript for possible publication on the questions and concerns of complainants and potential complainants	August – September 2011

17. Reason(s) Display of OMB Expiration Date is Inappropriate

- RTI is not seeking approval to not display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

- There are no exceptions to the certification.