Supporting Statement
For The

Research Mentoring Dyad Study:

Comparing the Views of Faculty Advisors/Mentors and Their Ph.D. Students on Training/Learning to be a Responsible Researcher

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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Research Mentoring Dyad: Comparing the Views of Faculty Advisors/Mentors and Their Ph.D. Students on Training/Learning to Be a Responsible Researcher

A. JUSTIFICATION

Overview of the study: The Office of Research Integrity (ORI) recognizes the importance of mentoring students in Ph.D. and Ph.D./M.D. programs. This study will use in-depth personal interviews to find out how faculty and their doctoral students who have graduated in the last five years view the doctoral training process with particular focus on how they teach/learn skills in conducting responsible research. Interviews with matched faculty/doctoral student pairs will provide a unique opportunity to compare these two perspectives. To the best of our knowledge, research that includes matched faculty and doctoral student perspectives on doctoral training and education has not previously been conducted.

The prior research that this is related to is:

ICR Reference Number 200804-0990-004
Approved August 18, 2008

Training Ph.D.s: Faculty Views on Their Role and Their Institution's Role to Promote the Development of Responsible Researchers (0990-0327) which was completed in 2009.

1. Circumstances Making the Collection of Information Necessary

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. (Appendix A) Subsequently, 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]) (Appendix B**)**.

2. Purpose and Use of Information Collection

The **purpose of the study** is (1) to describe the development of the faculty/doctoral student relationships in terms of the methods and experiences that the faculty member provides or does not provide for their trainee. In addition, the dyad study strengthens the ORI Faculty Survey[1]results by (2) getting more detailed descriptions on how Responsible Conduct of Research (RCR) training on issues such as maintaining data integrity, working on collaborative research efforts, and publishing research results is implemented and (3) identifying challenges to research integrity training and mentoring brought on by technology, financial pressures, and diversified research teams. Because the dyad study is unique, we will have both the faculty member and the matched doctoral student perceptions and learn how well the educational effort enables doctoral students to publish and work collaboratively.

The **information collected will be used** in several ways. The results of the study will provide valuable information that can be used to engage the educational community in a dialogue about training the future generation of researchers. It appears to be widely assumed and taken for granted that advisors and mentors know what their role is in relation to training students to be successful and conscientious researchers. We want to encourage a dialogue about the faculty role and how to strengthen it. In particular, as noted above, the dyad study will add the student perspective to this discussion. Faculty have enormous time constraints and cutting corners is common. Hence, it also seems likely that institutions must become more involved and foster the climate that leads to the development of sound scientific practices. We want to engage mentors, advisors, students, and institutions in a conversation about the processes used to educate doctoral students. The population of doctoral students is dynamic and changes as new students arrive and others graduate. Therefore it is particularly important that institutions and faculty members are

[1] The ORI Faculty Survey is the prior research conducted with ICR Reference Number 200804-0990-004.

vigilant in making sure there is ongoing attention to the professional development of doctoral students.

The dyad study has been designed to gather information for ORI to use to facilitate discussion in the scientific community on the role that institutions can have to promote and support faculty activities that contribute to the development of responsible researchers. This information will be used for conferences, workshops, and publications, and in the development of training materials. The specific findings will also be used to facilitate the improvement and promotion of best practices for doctoral student research training, such as case studies that can be used for RCR instruction. Complementing the data collected in the ORI Faculty Survey, this will provide the most comprehensive account thus far of faculty activities related to the development of doctoral students.

3. Use of Improved Information Technology and Burden Reduction

The recruitment process for both faculty and their doctoral students will begin with email invitations and will include telephone contacts as needed, to facilitate ease of response to the request for an interview appointment. Other communication such as confirmation of interview date, time, and location will also begin with email, with telephone contact used as needed. The mode of data collection is primarily in-person interviews. In-person interviews are recommended because the goal of the research is to obtain in-depth information about faculty/doctoral student relationships. Telephone interviews will be used only when an in-person meeting is not possible because of geographic or scheduling difficulties. All of the interviews will be audio-recorded to reduce respondent burden of having to repeat answers for a written record. Audio recording transcriptions will provide the data file for electronic analysis using ATLAS.ti[2]—a computer program that can be used as a tool to systematically review qualitative information.

[2] More information about ATLAS.ti can be found at http://www.atlasti.com.

4. Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, the proposed data collection effort has never been done before and there is no similar set of data. A literature review was conducted to identify research on faculty roles to promote the training and education of doctoral students. We found no reports on faculty roles that were directly relevant to this study or used the dyad methodology to conduct research to learn more about the faculty/doctoral student relationship. To the best of our knowledge, there is only one other study that looked at the differences in outcomes between mentored and non-mentored students using matched faculty/student information (Campbell and Campbell 1997). However, that research focused on academic achievement as measured by the student grade point average—not on RCR—so it is not relevant to the research questions that will be addressed by this project.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The information collection is only planned for one time and has never been collected before.

If we do not collect this information we will not learn details about the faculty members' interactions with graduate students and their role in training the next generation of researchers. This study is both unique and important for several reasons: (1) having matched faculty/doctoral student information and using multiple research methods will improve our understanding of the complex faculty/doctoral student relationship and whether and how RCR training and education is introduced and reinforced and (2) in-depth interviews about the process of learning to be a responsible researcher will give ORI a comprehensive understanding and ways to describe successful strategies and best practices used by faculty. In addition, we will also get both faculty

and doctoral student perspectives on the institution's role and contribution to the scientific training of doctoral students.

At present there are not any plans for faculty and doctoral students to participate in any other studies. There are no legal obstacles to reduce the burden.

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

There are no special circumstances involved with this data collection.

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

A 60-day Federal Register Notice was published in the *Federal Register* on October 19, 2009, vol.74, No. 200 pp. 53504-53505 (see Appendix D). There were not any public comments.

Nationally recognized experts in data collection and interview protocol design from Mathematica Policy Research worked with Sandra Titus, Director of Intramural Research at ORI to develop both the faculty and doctoral student interview protocols and study design. The development of the dyad project began in April 2009 based on research from the ORI Faculty Survey which began in October 2006. Mathematica's main contact was Janice Ballou (a senior fellow and nationally recognized survey research expert who has more than 30 years of experience conducting in-person, mail, telephone, and web-based surveys). She has extensive experience with qualitative interviews and has conducted prior research on mentoring. Mathematica developed the criteria for faculty selection, drafted the materials to use for faculty and doctoral student recruitment, Gail Baxter, a Mathematica senior survey researcher, conducted a quality assurance review. Francis L. Macrina (Virginia Commonwealth University), a recognized author and expert on the Responsible Conduct of Research, advised the development of the ORI Faculty Survey which is the foundation for the dyad study. A pilot study was conducted from July to September 2009 with nine faculty members and nine doctoral students to obtain information about the research design and the topics covered in the interview

protocol. The primarily in-person pilot interviews[3] provided an opportunity for both faculty and doctoral students to comment on the dyad process and protocol. Faculty members, in particular those who have taught RCR or have developed mentoring guidelines for their departments and/or institutions, provided comments on coverage of the topic based on their experiences.

The following is the contact information for the key contributors to the project:

- Sandra Titus, Ph.D., Director Intramural Research, Office of Research Integrity; 240-453-8437;Sandra.titus@hhs.gov
- Janice Ballou, Senior Fellow, Mathematica Policy Research, 609-750-4049, jballou@mathematica-mpr.com
- Gail Baxter, Ph.D.,Senior Survey Researcher, Mathematica Policy Research, 609-936-2787, gbaxter@mathematica-mpr.com
- Francis L. Macrina, Ph.D., Vice President for Research, Virginia Commonwealth University, 804-827-2262,macrina@vcu.edu

9. Explanation of any Payment/Gift to Respondents

Faculty and doctoral students will receive $50 as compensation for the interview, which will last 1.5 to 2 hours. Based on the level of effort expected from faculty members and the doctoral students who have graduated and now have full-time employment, $50 is a fair amount to compensate them for their time to participate in this research and is comparable to remuneration for similar research. Methodological work on the optimum amount for an incentive with owners of new businesses used this amount (DesRoches et al. 2007).

10. Assurance of Confidentiality Provided to Respondents

The study will be conducted in accordance with all relevant regulations and requirements, including the Privacy Act of 1974 (5 USC 552a), the Privacy Act Regulations (34 CFR Part 5b), and the Freedom of Information Act (5 CFR 552) and related regulations (41 CFR Part 1-1, 45

[3] One faculty and two doctoral student interviews were conducted by telephone because their geographic locations were beyond the travel area budgeted for the pilot study.

CFR Part 5b, and 40 CFR 44502). In addition, the project will adhere to the guidelines outlined in the Mathematica Security Manual. Procedures will be in place to protect the privacy of dyad interview participants to the extent the law allows. Faculty members and doctoral students will be assigned unique identification numbers that will be used to match faculty/doctoral student pairs and to manage interview tracking. Mathematica has rigorous requirements in place to protect the security of the electronic and paper information from the interviews. The project data file will only be accessible to the research team and any transfer of electronic information will be secure and within Mathematica's firewalls. All paper documents will be kept in secure file cabinets and the information will use only identification numbers so no names will be attached to any responses to ensure the privacy of the subject to the extent allowed by law. Dyad interview participants will sign a consent form that describes how the interview will be carefully protected so that others will not know what is said. The Institutional Review Board (IRB) submission to Public/Private Ventures included information about data security. Specifically the consent form states that responses will be carefully protected so that others will not know what is said. It then goes on to explain that we secure all records during the length of the project, omit information that can be attributed to an individual, and destroy recordings at the end of the project. Individual quotes will be used to highlight important points only if there is no way to track them back to an individual or an institution. In addition, all of the data reported or available for public use will be only key themes. The IRB panel approved the ORI Faculty survey and data collection in May 2007 and an amended request to involve students in the data collection process was approved in October 2009.

11. Justification for Sensitive Questions

Overall, none of the questions included in the interview protocol are commonly considered to be sensitive (Appendix C). The protocol does not request personal data that are not generally

available to the public. Faculty members typically make information about their professional activities available on university websites. However, faculty may perceive questions about activities related to responsibilities for doctoral student training to be sensitive. Doctoral student information for both those who are completing their Ph.D. or Ph.D./M.D. and graduates is also generally available on departmental or program websites. Doctoral students may perceive questions about the role faculty had in their training and educational experiences as sensitive.

The study will ask for gender and race of participants because we know from previous research that both of these can have a strong impact on how well one does in graduate school. Specifically the literature suggest that gender gender and race/ethnicity may influence mentoring relationships (Nettles and Millet 2006). There are numerous other studies that also indicate that people of different races receive different treatment. It is important to learn whether gender or race influences learning the responsible conduct of research. For instance, teams of the same gender or race may be the most successful teams, while teams that are composed of different races or genders may have more difficulty connecting and talking about the necessary research tools and methods to become a strong researcher. While we can certainly record gender by observation, it is much harder for us to visually determine race and ethnicity and the study would be diminished significantly without this information.

12. Estimates of Annualized Hour and Cost Burden

Burden will result from the proposed data collection for the 100 faculty and 100 doctoral student respondents who are invited to participate one time in these interviews. From the initial group of 1,686 faculty members who agreed to be re-contacted following the ORI Faculty Survey, 100 will be selected to participate in the dyad study. An equal number of doctoral students who have graduated in the last five years, matched with and identified by faculty members, will be recruited to be interviewed.

Average burden per respondent will not vary because, while there are two interview protocols that focus specifically on either faculty or student experiences, they are of similar length. The average completion time is expected to be 90 to 120 minutes per interview, including time to respond to email invitations to participate in the study. These estimates are based on pilot testing with nine faculty members and nine doctoral students, using protocols similar in length and complexity to those proposed for the dyad study. The pilot testing suggested that some faculty members and doctoral students may take longer if they have complex research projects and report on laboratory experiences. Some may take less time if the research described does not include laboratory experiences. But overall, we anticipate that 90 to 120 minutes is a reasonable estimate of time burden (Table 12A). During the pilot testing, we asked about the content of the protocols and the interview experience. We received no negative comments about the topics covered by the protocols or the amount of interview time.

12a.Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Faculty who oversee doctoral students*	Faculty Interview and Email Request	100	1	120/60	200
Doctoral student graduates**	Doctoral Student Graduates Interview and Email Request	100	1	120/ 60	200
Total					**400**

*Of the 1,686 faculty members who participated in the ORI Faculty Survey and agreed to be re-contacted, 340 are in the geographic area targeted for the dyad study.

**Each of the 100 recruited faculty members is expected to provide an average of five names of doctoral students who graduated in the last five years. We estimate getting the names of 500 doctoral student graduates to use for recruitment of the matched dyad pair.

12b. Estimated Annualized Burden Costs

Based on hourly wages for each faculty member the cost of two hours is $142.00 ($71.00 x 2 hours) and for each doctoral student who graduated in the last five years the cost is $62.00 ($31.00 x 2 hours) (Table 12B).

TABLE 12B.

ESTIMATED ANNUALIZED BURDEN COSTS

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Faculty	200	$71.00	$14,200
Doctoral Student Graduates	200	$31.00	$ 6,200
Total	**400**		**$20,400**

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

There are not any capital or maintenance costs to the respondents.

14. Annualized Cost to Federal Government

The estimated annualized cost of administering the "Research Mentoring Dyad: Comparing the Views of Faculty Advisors/Mentors and their Ph.D. Students on Training/Learning to Be a Responsible Researcher" is $440,000 (12 months). In addition, the cost of the ORI project officer is $30,000 for two years, which is 15 percent of an annual average salary of $100,000. The total annualized cost to the Federal Government is $470,000.

15. Explanation for Program Changes or Adjustments

This is a new, one-time data collection plan with a burden of an estimated 400 hours. We are not requesting any changes to programs based on this study.

16. Plans for Tabulations and Publication and Project Time Schedule

This is a qualitative study and there will not be any quantitative tabulations. The study data will be the text of the interviews and these data will be reviewed to identify key themes and descriptions of best practices. Tools such as ATLAS.ti will be used to organize the interview information. The publication plans include dissemination of information from the analysis of the interviews, which can be used to promote doctoral student RCR training and education.

The full timeline for the project is presented in Table 16. The protocol and interview recruitment materials were developed during the 2009 dyad pilot study, and were found to work well. While these will be reviewed, there will be minimal time prior to the recruitment of faculty and doctoral students needed for this step in the process. Assuming OMB approval by April 2010, the interviews will begin in July 2010. To carefully manage and ensure matched pairs of

faculty and doctoral students, we plan to focus on 25 pairs (50 total interviews) each two months for eight months starting in July 2010; we plan to complete the interviews by February 2011. The data analysis and report writing will occur from approximately February 2011 and on. A subsequent draft of the paper based on report will be done during the remaining time on the two year contract.

TABLE 16

PROJECT SCHEDULE

Activity	Completed	Schedule
1. OMB and IRB Submission		
IRB submission and approval	September 2009	
OMB submission	November 2009	
OMB approval	April 2010	
2. Dyad Sample Development		
Finalize faculty selection		May 2010
Develop doctoral student list		May – July 2010
3. Data Collection-Dyad Interviews		6 months – 1 year
4. Data Analysis		3 months
5. Reporting Results		3 months
6. Journal Article		Part of reporting results

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

Approval not to display the expiration date for OMB approval is not requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions taken to Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-1.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Overview of the study: The Office of Research Integrity (ORI) recognizes the importance of mentoring students in Ph.D. and Ph.D./M.D. programs. This study will use in-depth personal interviews to find out how faculty and their doctoral students who have graduated in the last five years view the doctoral training process to teach responsible research skills. Interviews with matched faculty/doctoral student pairs will provide a unique opportunity to compare these two perspectives. To the best of our knowledge, research that includes matched faculty and doctoral student perspectives on doctoral training and education has not previously been conducted.

1. Respondent Universe and Sampling Methods

This dyad study does not use statistical means to select the sample and there will not be any quantitative data for analysis. There are two kinds of sample members in the dyad study—the faculty member and the matched doctoral student[4] who has graduated in the last five years or, as needed, may also include "all but dissertation" students to increase the number of candidates for interviews. The faculty sample will be purposively selected. However, the selection will be based on information from the ORI Faculty Survey,[5] which used a representative sample of 2005 and 2006 NIH grant recipients. The matched sample of graduated doctoral students will be developed based on information primarily collected from faculty. Using the information from the ORI Faculty Survey two types of information will be used to guide faculty selection: the term faculty reported they prefer to be called by their doctoral students—advisor or mentor—and faculty perception of the institutional resources for the training and education of doctoral students. Based on the data from the ORI Faculty Survey, Table B.1 has the expected number of the 100 faculty

[4] The doctoral students matched with faculty members have graduated in the last five years. Since the research focuses on the training and educational experience while they were students, they are referenced as doctoral students. Students' doctoral experiences are cumulative over the time they are working on their degrees. Graduates will have a complete set of research training and educational experiences.

[5] For the ORI Faculty Survey, a national random sample of 10,000 2005 and 2006 NIH grant recipients was selected from publicly available information. The 1,686 faculty members who agreed to be re-contacted are a sub-set of the original ORI Faculty Survey sample.

TABLE B.1

Institution/Program	Faculty Role Description*	
	Advisor	Mentor
Has guidelines**	36	30
Does not have or does not know if it has guidelines	21	13

*The ORI Faculty Survey results among all faculty, not just those who agreed to be re-contacted, have estimates of those who prefer advisor (54 percent), mentor (38 percent), supervisor (2 percent), and some other name (6 percent).

** Includes faculty who report guidelines for both their institution and graduate program (46%), only for their graduate program (15%), and only for their institution (5%).

members that will be included in the study to represent these two different experiences that can influence a doctoral student's training experience.

Using these guidelines, we will begin the faculty selection process by listing the names of faculty who answered "yes" to the question "Someone from the study team may contact you in the future as a follow up to this survey. Are you willing to be contacted?"

Among the 1,686 faculty who agreed to be re-contacted, we will focus on faculty at schools located in the northeast corridor to reduce project travel costs. Using this criterion, there are 340 faculty (20 percent of the 1,686) at 28 academic institutions who agreed to be re-contacted.

a. Doctoral Student Graduates

The graduated doctoral students for the dyad study have to be matched with the selected faculty described in the prior section. Unlike faculty, we do not have a list of the names and background information of the students who have graduated to use for recruitment. The goal is to select and interview faculty who reported they have had at least five students receive their doctoral degrees in the past five years. There are two reasons for this criterion: (1) the possibility

of obtaining a student match with a faculty referral increases with more student names and (2) including more names maximizes the privacy of the student reporting on his or her experiences with the faculty member.

The primary method will be to ask selected faculty to provide a list of doctoral students who have graduated in the last five years and, if needed, students they have had in the last five years —even if they have not graduated. This approach will protect the privacy of students who will be interviewed because those who participate will be one among many. With one request we will obtain a sufficient number of names to identify one matched student without having to re-contact the faculty member for additional names. This approach was used successfully for all of the student recruitment in the pilot study. Although the level of information varies, department and faculty websites typically have lists of current doctoral students and alumni. In some cases, this information includes doctoral students' contact information, which could be used for recruitment.

b. Institutional and Graduate Program Resources

Based on faculty reports in the ORI Faculty Survey, about 6 in 10 graduate programs and about half of the academic institutions have written policies or guidelines that describe responsibilities of faculty members who work with doctoral students and, as described above, this information will be used to guide faculty selection. The faculty reports about an academic institution's guidelines can be compared with information on the institution's websites. In addition, the survey results provide other information about faculty perceptions of institutional and graduate program resources that we can learn more about during the dyad interview. For example, one in five or fewer report the availability of faculty training in advising and mentoring students or developing students' research skills. Plus, we will have the student's perspective on this training, or lack of it. When we have recruited the faculty/student dyad for an interview, we

will review available information about the institution to have a context for the interview responses related to this topic.

2. Procedures for the Collection of Information

a. Statistical Methodology for Stratification and Sample Selection

As described in Section B.1, this qualitative study will use a purposive sample. The purposive sample will be selected using representative data from the ORI Faculty Survey. Using two methods—quantitative and qualitative—will increase confidence in the information ORI has about a complex set of relationships among faculty, students, and institutions that they can use to promote the development of responsible researchers.

b. Estimation Procedure

Estimation procedures will not be used for the qualitative results.

c. Degree of Accuracy for the Purpose Described in the Justification

Degree of accuracy is not applicable to qualitative information.

d. Data Collection Procedures

The data collection process described below was successfully tested in a pilot study. Following faculty and student selection as described in Section B.1, the data collection process will be as follows:

Recruit faculty

Selected faculty will be sent an email message (Appendix C.1.a) inviting them to participate in the study. Because we used these email addresses for the recently completed ORI Faculty Survey, we expect them to be valid. The email invitation will (1) thank faculty for their participation in the ORI Faculty Survey; (2) describe the dyad study and ask them to participate; (3) notify them that they will receive $50 as a token of our appreciation; and (4) provide an email address and toll-free telephone number for them to schedule the interview or to learn more about the study. For faculty who do not respond to the email invitation, as needed, we will make follow-up telephone contact using the script in Appendix C.2.a. Faculty who would like more

information will be sent (via email, fax, or U.S. Postal Service) Frequently Asked Questions (Appendix C.5.a).

Develop doctoral student list

When the faculty member agrees to an interview, he or she will be asked to provide eligible students' names (doctoral students who have graduated in the last five years) and contact information. We expect to get a minimum of five students' names per faculty member. Although the preference is for doctoral students who have graduated, we will also obtain names of current students who are close to completing their doctoral programs to expand the number of potential students to achieve a match. Getting a complete list of graduates in the past five years will minimize possible bias of having faculty exclude problem students. Appendix C.1.b includes the email message that will be used to obtain students' names. As with the initial contact, faculty who do not respond to the email request will be contacted by telephone to provide students' names.

Contact students

Similar to the faculty recruitment, each student whose name we receive from a selected faculty member will be sent an email invitation to participate in the study (Appendix C.1.c). The email invitation will (1) describe the study and invite students to participate; (2) inform students how we obtained their names and contact information; (3) notify them that they will receive $50 as a token of our appreciation; and (4) provide an email address and toll-free telephone number for them to schedule the interviews or to learn more about the study. For students who do not respond to the email invitation, as needed, we will make follow-up telephone contact using the script in Appendix B.2.b. If more than one student expresses interest in participating, they will be prioritized based on criteria such as gender, type of degree (Ph.D. or Ph.D./M.D.), current geographic location, and availability during the scheduled interview period.

Schedule and confirm interview

We will make sure that we have a matched pair—with both a faculty member and one of his or her students agreeing to an interview—and then we will schedule the date, time, and location for each interview. Faculty and students will be interviewed separately. In addition, although faculty and students may inform each other that they are participating in the study, we will not communicate this information. A confirmation message will be sent by email, fax, or U.S. Postal Service (Appendix C.4) and the day prior to the interview a confirmation email or call will also be made. If either member of the pair—faculty or student—is not interested or is not available, we will select a replacement faculty member and begin the process again.

Conduct interviews

Faculty and student interviews will be conducted in person. As needed, telephone interviews will be considered if there are high-priority students whose geographic location prevents an in-person interview. Faculty interviews will be scheduled prior to student interviews to provide a core set of information about the graduate student experience. Interviews will be conducted by trained, full-time Mathematica professional staff including the three who conducted the pilot

interviews. Up to four additional staff will be trained to use the interview protocols and will listen to pilot interviews to prepare for their assignments. Interviews will be conducted using faculty and student protocols. Faculty and student interview protocols (Appendixes C.3.a and B.3.b, respectively) have been designed to standardize questions about the topics of interest for the study, to follow up on information from the ORI Faculty Survey, and to address the attributes of faculty/student relationships identified in the conceptual framework.

The interviews will take approximately 1.5 to 2 hours and will be audio-recorded to facilitate analysis. Faculty and student consent forms (Appendices B.6.a and B.6.b, respectively) will be reviewed and signed prior to beginning the interview. Participants will sign a receipt form and receive their $50 after the interview is completed. Following the first interview by each interviewer, there will be a debriefing among all interviewers to discuss the protocol and any other aspect of the interview logistics. Periodic debriefings will be conducted with the team, at weekly meetings or as needed, to inform the interview process.

e. Use of Periodic Data Collection Cycles to Reduce Burden

This survey has a single data collection cycle.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The list of faculty for the dyad study previously agreed to be re-contacted for additional research. For their convenience, faculty can select the date, time, and location for the interview. For selected faculty who do not respond to the initial email invitation, we will make telephone calls and up to two additional email attempts. Professional, highly trained interviewers will make the telephone contacts. These will be the same interviewers who will meet with faculty members to conduct in-person interviews so they will have comprehensive information about the study to use in converting reluctant participants. Since we will have profiles of the selected faculty members based on their responses to the ORI Faculty Survey, we will be able to identify any systematic differences between those who do and those who do not participate in the survey. We expect that doctoral students will be interested in participating and, since they will know their names were provided by a faculty member, will find the study credible. The follow-up telephone calls and email procedures used for faculty will also be used for the doctoral students.

4. Tests of Procedures or Methods to Be Undertaken

Nine interviews were conducted with faculty and nine with doctoral students to pilot test the data collection process and interview protocols. The selection and recruitment procedures described above achieved the variation in faculty profiles and academic institutions that we targeted. We were able to obtain matched pairs of faculty and students with less effort than expected. Faculty were not hesitant about providing the names and contact information of doctoral students who graduated in the last five years. Since this student information is typically available on public-access websites, potential concerns about privacy were minimal. Protocol instruments were carefully assessed for terminology, clarity, sensitivity, and relevance. Faculty and students who participated in the pilot responded positively to the process and the topics covered during the interview. The testing was used to provide an estimate of respondent burden for completing the interview.

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

The following people were consulted on the technical aspects of the study design:

- Sandra Titus, Office of Research Integrity, 240-453-8437
- Janice Ballou, Mathematica Policy Research, 609-750-4049
- Gail Baxter, Mathematica Policy Research, 609-936-2787
- Eric Grau, Mathematica Policy Research, 609-945-3330
- Frank Macrina, Virginia Commonwealth University, 804-827-2262
- Frank Potter, Mathematica Policy Research, 609-936-2799
- Brian Roff, Mathematica Policy Research, 609-750-4041

This group consists of survey methodologists and statisticians who have extensive experience in the design and implementation of both qualitative and quantitative data collection. Frank Macrina is the subject matter expert on the team.

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APPENDIX A

42 U.S.C. § 289b : US Code - Notes

SUBTITLE C – RESEARCH INTEGRITY

Secs. 161, 163, June 10, 1993, 107 Stat. 140, 142.)
CODIFICATION
June 10, 1993, referred to in subsec. (a)(1), was in the original "the date of enactment of this section" which was translated as meaning the date of enactment of Pub. L. 103-43, which amended this section generally, to reflect the probable intent of Congress.
AMENDMENTS
1993 - Pub. L. 103-43, Sec. 161, amended section generally. Prior to amendment, section read as follows:
"(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity -
"(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and
"(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.
"(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such fraud."
Subsec. (e). Pub. L. 103-43, Sec. 163, added subsec. (e).
REGULATIONS
Section 165 of Pub. L. 103-43 provided that:
"(a) Issuance of Final Rules. -
"(1) In general. - Not later than 180 days after the date of

the enactment of this Act [June 10, 1993], the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act [this section and section 289b-1 of this title].

"(2) Definition of research misconduct. - Not later than 90 days after the date on which the report required in section 162(e) [107 Stat. 142] is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term 'research misconduct'.

"(b) Applicability to Ongoing Investigations. - The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act [this section] does not apply to investigations commenced before the date of the enactment of this Act [June 10, 1993] under authority of such section as in effect before such date.

"(c) Definitions. - For purposes of this section:

"(1) The term 'section 493 of the Public Health Service Act' means such section as amended by sections 161 and 163 of this Act [this section], except as indicated otherwise in subsection (b).

"(2) The term 'section 493A of the Public Health Service Act' means such section as added by section 164 of this Act [section 289b-1 of this title].

"(3) The term 'Secretary' means the Secretary of Health and Human Services."

APPENDIX B

FEDERAL REGISTER MAY 12, 2000 NOTICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary; Office of Public Health and Science

Statement of Organization, Functions, and Delegations of Authority

Part A, (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AC, Office of Public Health and Science (OPHS), paragraph ACA, Immediate Office, as last amended at 62 FR 5009–10, 2/3/97; and paragraph ACF, Office of Research Integrity (ORI), as last amended at 60 FR 56606–06, dated November 9, 1995, are being amended to make policy changes approved by the Secretary. Specifically, the Notice is to reflect that the Assistant Secretary for Health (ASH) will make proposed findings of research misconduct and administrative actions in response to allegations of research misconduct involving research conducted or supported by components of the Public Health Service (PHS); that direct investigations, previously conducted by ORI, will be conducted by components of the PHS for intramural research and by the Office of Inspector General for extramural research; and that role and structure of ORI will be changed to focus more on preventing misconduct and promoting research integrity through expanded education programs. The changes are as follows:

I. Amend Chapter AC.20 Functions, paragraph A. ''Office of Public Health and Science,'' paragraph titled, ''The Immediate Office (ACA)'' by adding the following new clause:

(1) Proposes findings of research misconduct and administrative actions in response to allegations of research misconduct involving research conducted or supported by the Public Health Service (PHS) OPDIVs, including reversal of an institution's no misconduct finding or opening of a new investigation.

II. Under Section AC.20 Function, delete, paragraph E. ''Office of Research Integrity (ACF)'' in its entirety, and replace with the following:

E. Office of Research Integrity (ACF)—The Director reports to the Secretary and will: (1) Oversee and direct Public Health Service (PHs) research integrity activities on behalf of the Secretary with the exception of the regulatory research integrity activities of the Food and Drug Administration; (2) recommend to the Assistant Secretary for Health for decision, findings of research misconduct and administrative actions in connection with research conducted or supported by the PHS; (3) coordinate the development of research integrity policies designed to ensure that subjects of investigations and whistleblowers are treated fairly, including clear specification of what constitutes misconduct, a fair hearing process, appropriate time limits on pursuing allegations, and specific whistleblower protections; (4) manage the financial resources and provide overall administrative guidance in carrying out the activities; and (5) oversee and direct the research misconduct and integrity activities of the office, including the oversight of research misconduct inquiries and investigations, education and training in the responsible conduct of research, activities designed to promote research integrity and prevent misconduct, and research and evaluation programs.

1. Division of Education and Integrity (ACF2)—The Director and staff: (1) develop and implement, in consultation with the PHS OPDIVs, activities and programs for PHS intramural and extramural research to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and to enable the extramural institutions and PHS OPDIVs to respond effectively to allegations of research misconduct; (2) coordinate the dissemination of research integrity policies, procedures, and regulations; (3) conduct policy analyses, evaluations, and research to improve DHHS research integrity policies and procedures and build the knowledge base in research misconduct, research integrity, and prevention; (4) develop (in consultation with the PHS OPDIVs) policies, procedures, and regulations for review by the Director, Office of Research Integrity, and recommendations to the Secretary; (5) administer programs for: approval of institutional assurances; response to Freedom of Information Act and Privacy Act requests; review and approval of intramural and extramural policies and procedures; and response to allegations of whistleblower retaliation.

2. Division of Investigative Oversight (ACF3)—The Director and staff: (1) review and monitor investigations conducted by applicant and awardee institutions and intramural research programs; (2) evaluate investigations and investigatory findings of awardee and applicant institutions, intramural research programs, and the Office of Inspector General and develop and recommend to the ORI Director, findings of research misconduct and proposal administrative actions against those who committed misconduct; (3) assist the Office of the General Counsel (OGC) in preparing and presenting cases in hearings before the Research Integrity Adjudications Panel of the DHHS Department Appeals Board; (4) provide information on DHHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct; and (5) establish and implement a program of advice and technical assistance to entities that conduct inquiries and investigations, or otherwise respond to allegations of research misconduct.

III. Under Chapter AC, Section ACF–30, Delegations of Authority—All delegations and redelegations of authority to the Assistant Secretary for

Health and officials of the Office of Research Integrity that were in effect prior to the effective date of this reorganization shall continue in effect pending further redelegation.

Dated: April 14, 2000. **Betsy D'Jamos,**
Acting Assistant Secretary for Management and Budget.

[FR Doc. 00–11958 Filed 5–11–00; 8:45 am]
BILLING CODE 4150–04–M

APPENDIX D

FEDERAL REGISTER NOTICE