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Survey of Medical School Researchers Regarding their Institution's Research Misconduct Policy and Procedures (3/26/09)

Section I. In this section we ask some questions about your educational background and training as well as your demographic characteristics.

1. What advanced degrees (post bachelor's) have you received? Degree
2. Have you ever completed a residency or a post-doctoral training appointment? No, neither Yes, a residency appointment Yes, a post-doctoral appointment (3) Yes, both (4)
3. For how many years have you been conducting biomedical research? Under 5 years (1) Between 5 and 14 years (2) Between 15 and 24 years (3) Between 25 and 34 years (4) 35 years or more (5)
3a. How would you characterize your current research activity? Would you say it's: Basic Science, or (1) Clinical Research? (2)
3b. Does your research activity typically require submitting a request for review to your Institutional Review Board (IRB)? No (1) Yes (2)
4. In the past 10 years, on how many NIH research project grants have you been named the Principal Investigator (PI)? Fewer than 5 grants (1) From 5 to 9 grants (2) From 10 to 19 grants (3) 20 or more grants (4)

project grants o	n which you were the Less	e named PI? s than \$1,000,000	(1)	e of all the NIH research
	om \$1,000,000 to less m \$5,000,000 to less \$10,		(2) (3) (4)	
6. Is your <i>primo</i>	ary appointment in thi	is medical school?	Yes (1) No (2)	
7. For how man	y years have you bee Under 5 years Between 5 and 9 yea Between 10 and 14 y Between 15 and 24 y 25 years or more	(1) ars (2) years (3) years (4)	is institution?	
8. What is your	current institutional t Research Associate Assistant Professor Associate Professor Full Professor Emeritus Professor Other:	(1) (2) (3) (4)		
9. How depended research grant f		-	-	continuing to obtain
	Dependent for less the Dependent for half of Fully dependent on of	han half of my salar or more of my salary	y y	(2) (3) (4)
10. What is you	r age group? Under 35 years of ag Between 35 and 44 y Between 45 and 54 y Between 55 and 64 y 65 years of age or ol	years of age (2) years of age (3) years of age (4)	• •	
11. What is you	r gender? Male (1) Female (2)			

Section II. Every institution that receives research project funding from the US Public Health Service (PHS) is required to have an assurance document that states its policy and procedures for complying with Federal regulations involving research misconduct on PHSfunded projects. In this section, the questions focus on your awareness of your institution's policy and procedures with respect to how it says it handles allegations of research

misconduct.
1. Have you ever read your institution's research misconduct policy and procedures? Yes, I have read them fully (1) Yes, I have read them in part (2) No, I have not read them at all (3)
2. On a scale that runs from 0 to 10, how would you describe your knowledge of your institution's research misconduct policy and procedures? [CIRCLE A NUMBER]
[Know Nothing] <u>0 1 2 3 4 5 6 7 8 9 10</u> [Know Everything]
(0 indicates that you know nothing about your institution's research misconduct policy and procedures, while 10 indicates that you know everything.)
3. How familiar are you with what your institution's policy says about:
a. The Federal regulation's definition of activities that constitute research misconduct? 1 Very Familiar 2 Somewhat Familiar 3 Not Very Familiar 4 Not At All Familiar
 b. To whom allegations of this kind of research misconduct should be officially reported? 1 Very Familiar 2 Somewhat Familiar 3 Not Very Familiar 4 Not At All Familiar
c. What information should be included in an allegation of this kind of research misconduct? 1 Very Familiar 2 Somewhat Familiar 3 Not Very Familiar 4 Not At All Familiar
d. The process by which allegations of this kind of research misconduct are examined? 1 Very Familiar 2 Somewhat Familiar 3 Not Very Familiar 4 Not At All Familiar
e. Procedures for protecting "complainants" ("whistleblowers") of this kind of research misconduct from retaliation?1 Very Familiar 2 Somewhat Familiar 3 Not Very Familiar 4 Not At All Familiar
4. Indicate which of the following activities the Federal regulations specifically define as research misconduct? [CHECK ALL THAT APPLY] a. Financial conflict of interest (1) b. Falsification (2) c. Fraudulent use of research funds (3) d. Plagiarism (4) e. Not maintaining confidentiality (5)
f. Ignoring IRB requirements g. Immoral behavior h. Violating research protocol i. Embezzlement j. Fabrication (3) (6) (7) (8) (9) (10)

5. Does your institution's research misconduct policy and procedures state:
a. Whether allegations of research misconduct can be made anonymously or not? No (1) Yes (2) Don't Know (3)
b. Whether allegations of research misconduct can be reported orally or not? No (1) Yes, (2) Don't Know (3)
6. Does your institution's research misconduct policy and procedures describe the process by which a determination will be made whether research misconduct actually occurred? No (1) Yes (2) Don't Know (3)
7. Does it say that the institution will protect persons from retaliation if they make an allegation of research misconduct in good faith? No (1) $_$ Yes (2) $_$ Don't Know (3) $_$
8. Does it indicate that the institution will take action against persons who knowingly make false allegations of research misconduct? No (1) $_$ Yes (2) $_$ Don't Know (3) $_$
9. Does it say that assessments, inquiries, and investigations into allegations of research misconduct must be treated confidentially by <i>everyone</i> involved. No (1) Yes (2) Don't Know (3)

Section III. Now we have some questions about when and how research faculty and staff learn about your institution's research misconduct policy and procedures?

1. How long after new research faculty and staff are hired by your current institution are they typically exposed to its research misconduct policy and procedures? In the first few days of employment (1) Within the first month of employment (2) Before completing one year of employment (3) They are never formally exposed to them (4) [GO TO 4] Other (5) [Specify]
2. In what context are these policies and procedures typically first presented to new research faculty and staff? [CHECK ALL THAT APPLY] As part of new employee group orientation. (1) To meet new grant award requirements. (2) As part of the IRB's continuing educational activities. (3) In a Responsible Conduct or Research (RCR) program. (4) In an "all hands meeting on the topic. (5) By means of a general distribution of the document (printed or electronic).(6) Through an e-mail notice and referral to a web site. (7) Other (8) [Specify]
3. In what format are they first typically presented? As part of a printed faculty manual (1) As an electronic version of a faculty manual (2) As an on-line course (3) In a live group/workshop setting (4) [GO TO 5] In a one on one discussion (5) [GO TO 5] Don't Know (6) Other (7) [Specify]
4. Do research faculty and staff have an opportunity to attend a workshop, class, or other live presentation to get clarification or answers to questions about the institution's research misconduct policy and procedures? No (1) Yes (2) Don't Know (3)
5. Are the institution's research misconduct policy and procedures included in a <u>printed</u> handbook that is readily available to research faculty and staff in a library or some other <u>public</u> location? No (1) Yes (2) Don't Know (3)
6. Are the institution's research misconduct policy and procedures readily available to research faculty and staff on the institution's internal or external web site? No (1) Yes, internal (2) Yes, external (3) Yes, both internal and external (4) Don't Know (5)

7. Does your institution require that research faculty and staff periodically certify that they have reviewed its research misconduct policy and procedures? No (1)
Yes, annually (2) Yes, when awarded new research grants (3) Don't Know (4) Other (5) [Specify]
8. Have you ever been required to review your institution's research misconduct policy and procedures? No (1) Yes (2) Don't Know (3)
9. Does your institution have a responsible conduct of research (RCR) training program? No (1) Yes (2) Don't Know (3)
10. Have you participated in any of the responsible conduct of research (RCR) training? No (1) Yes (2) Don't Know (3)
[IF YES:] Did the RCR training specifically discuss research misconduct? No (4) Yes (5)
11. Do you have responsibility for overseeing the research of one or more doctoral degree students, post doctoral fellows, or otherwise mentoring new investigators in your current institution?
No (1) [GO TO SECTION IV] Yes, one (2) Yes, two to five (3) Yes, six to ten (4) Yes, more than 10 (5)
12. How often do you talk with your doctoral student(s), post doctoral fellow(s), or "mentee(s)" about issues related to research misconduct? Never (1) _ [GO TO 15] Rarely (2) _ Sometimes (3) _ Often (4) _

13. What aspects of research misconduct have you discussed?
[CHECK ALL THAT APPLY]
Maintaining proper records and documentation. (1)
Responsibility to report alleged misconduct. (2)
Possible repercussions on your career of making a misconduct allegation. (3)
To whom a report of misconduct should be made. (4)
The process by which allegations of misconduct are resolved. (5)
The kinds of evidence needed to support a misconduct allegation. (6)
Potential response of colleagues to your making a report. (7)
The amount of time and energy reporting misconduct can consume. (8)
How to make a report of research misconduct. (9)
What activities constitute research misconduct. (10)
What it means that every report of a research finding is expected to be honest (11)
How some allegations of misconduct made in good faith may be erroneous. (12)
14. In what context(s) do these discussions arise? [CHECK ALL THAT APPLY] During a seminar on the topic. (1) In a discussion of research methods. (2) During report, proposal, or manuscript preparation. (3) With the appearance of misconduct articles in scientific journals. (4) When stories about misconduct appear in the popular press. (5) Other [Specify]
15. What advice would you give doctoral student(s), post-doctoral fellow(s), or "mentee(s)" who believe they have witnessed research misconduct and are considering making a report?
Section IV: Next we are interested in researchers' perceptions of efforts made by their

Section IV: Next we are interested in researchers' perceptions of efforts made by their institutions to support the responsible conduct of research and seek to resolve allegations of research misconduct. The following statements represent different perceptions of an institution's commitment to identifying and handling cases of research misconduct. Please indicate whether you strongly agree, agree, disagree, or strongly disagree with each statement as it applies to your current institution.

- 1. I think this institution does all it can to assure that members of the research faculty and staff are familiar with the policy and procedures governing research misconduct.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 2. I believe that this institution has made a concerted effort to educate research faculty and staff about what constitutes research misconduct.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 3. I feel that the climate at this institution makes research faculty and staff feel comfortable and ethically responsible reporting potential research misconduct to the appropriate official.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know

- 4. I feel that there is a need for more opportunities for research faculty and staff to learn what they should do when they have evidence of research misconduct.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 5. I think that this institution has made a concerted effort to educate research faculty and staff about whom to report allegations of research misconduct.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 6. I believe that persons who make allegations of research misconduct at this institution need not fear that they will be ostracized or marginalized by colleagues.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 7. I believe that this institution takes appropriate measures to protect persons who make allegations of research misconduct from being the objects of retaliation.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 8. I am confident that the personnel at this institution who are responsible for reviewing allegations of research misconduct are trained and prepared to arrive at a fair and impartial judgment.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 9. It seems to me that this institution could do more to make everyone feel obliged to report misconduct when they suspect it may have occurred.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- 10. I feel that persons who are considering making allegations of research misconduct at this institution should seriously consider the impact it will have on their professional career opportunities.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree, 5. Don't Know
- Section V. People have different ideas about research misconduct and the best way to deal with suspicions about the work of colleagues at their institution. We would like you to indicate whether you strongly agree, agree, disagree, or strongly disagree with the points of view expressed in each of the following statements.
- 1. I would have to be absolutely sure that the actions of one of my colleagues represented research misconduct before I would make such an allegation to an institutional official?
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree
- 2. I would raise the possibility of misconduct with the person I suspected in order to give that person a chance to correct the situation before making an allegation to an institutional official.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree
- 3. I would discuss my suspicions with other colleagues and get their perspectives before I decided whether or not to report a colleague I suspected of research misconduct to an institutional official.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree
- 4. I would immediately report a colleague to an institutional official if I had the slightest suspicion that the person was involved in research misconduct.
 - 1. Strongly Agree, 2. Agree, 3. Disagree, 4. Strongly Disagree

Section VI: This next section starts off with questions about direct experience you may have had at this or any other institution with allegations about research misconduct, and then ends with items that ask for your assessment of factors you think influence whether persons will report research misconduct.

1. That you know of, have you ever had an alleg research at this institution or elsewhere?	ation of research misconduct made about your
	No, never (1) [GO TO 2]
Ves at this	s institution (2)
	s, elsewhere (3)
Yes, here and	d elsewhere (4)
IIE VEC. 1 10 Did this amount on a office	t recover tillinguage to make an allegation of
-	t your willingness to make an allegation of
research misconduct against someone el	
No	(1) (2)
Yes, I am less likely	(2)
Yes, I am more likely	(3)
res, rum more fixery	(3)
2. Have you ever made an allegation of research institution or elsewhere?	misconduct about a colleague at your current
modelation of else where	No, never (1) [GO TO 3]
Voc. at this	s institution (2)
	· ·
	elsewhere (3)
Yes, here and	elsewhere (4)
HE VEC. 12- Didding and a constant of the	4 ::11:
-	t your willingness to make a subsequent
allegation of research misconduct?	
No	(1)
Yes, I am less likely	(2)
Yes, I am more likely	(3)
3. Have you ever given testimony as a witness in made of research misconduct, either at this institu	
	No pover (1) [CO TO 4]
***	No, never (1) [GO TO 4]
	institution (2)
Yes,	elsewhere (3)
	elsewhere (4)
	· ,
[IF YES:] 3a. Did this experience affect	t your willingness to give testimony as a witness
in a research misconduct proceeding?	
No	(1)
	(1) —
Yes, I am less likely	(2)
Yes, I am more likely	(3)

4. Have you ever been a member of an inquiry or investigation committee investigating an allegation of research misconduct, either at this institution or elsewhere?
No, never (1) [GO TO 5] Yes, at this institution (2) Yes, elsewhere (3) Yes, here and elsewhere (4)
[IF YES:] 4a. Did this experience affect your future willingness to serve as a member of an inquiry or investigation committee investigating an allegation of research misconduct No (1) Yes, I am less likely (2) Yes, I am more likely (3)
5. We would like to know how important you think each of the following considerations is in a decision to report suspected research misconduct?
a. The research misconduct could result in people being hurt. Very Important (1) Important (2) Not Important (3)
b. The identity of the person making the report will remain anonymous. Very Important (1) Important (2) Not Important (3)
c That if research misconduct is not stopped, then the scientific record will be severely damaged. Very Important (1) Important (2) Not Important (3)
d. Having first hand evidence of the research misconduct. Very Important (1) Important (2) Not Important (3)
e. Being confident that the matter will be handled fairly and justly. Very Important (1) Important (2) Not Important (3)
f. Knowing to whom reports of research misconduct should be made. Very Important (1) Important (2) Not Important (3)

g. The belief that all scientists are obliged to report research misconduct. Very Important (1) Important (2) Not Important (3)
6. How important do you think each of the following factors is in a person's decision to not report suspected research misconduct?
a. The fear of retaliation by the person accused of misconduct. Very Important (1) Important (2) Not Important (3)
b. The potential for ostracism by colleagues. Very Important (1) Important (2) Not Important (3)
c. Expectation that damage will result to ones own professional reputation and/or career. Very Important (1) Important (2) Not Important (3)
d. Don't know what constitutes research misconduct at the institution. Very Important (1) Important (2) Not Important (3)
e. Too much time will be spent in the allegation resolution process. Very Important (1) Important (2) Not Important (3)
f. Don't know to whom the misconduct is supposed to be reported. Very Important (1) Important (2) Not Important (3)

Section VII: Sometimes it is difficult to identify actions that constitute research misconduct as defined by the Federal regulations. In this final section, we have described instances of researcher behavior that would generally be considered bad practice. Some of these could be considered research misconduct according to Federal regulations. Please indicate for each of the following scenarios whether you think the behavior would likely be considered research misconduct according to the Federal regulations.

1. You are responsible for tracking the radioactive materials received in the labs. It is normal procedure for your colleagues to circulate all manuscripts to lab staff for review and comments. In your review of a colleague's manuscript, you notice that there are more subjects involved in ıat te

experiments using radioactive iodine than were discussed in the lab meeting. You also know that no radioactive stocks have come into the laboratory during the proceeding weeks. You calculate the quantity of radioactive iodine that would have had to be used with the subjects in the experiments and conclude that this was not possible.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 1a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
2. A colleague is clinical investigator on a drug trial sponsored by a pharmaceutical firm. The drug appears to show some efficacy but also has some potentially serious side-effects. A resident tells you that your colleague is recruiting patients into the trial without disclosing to them the existence of a consulting contract with the firm.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 2a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
3. A colleague of yours is doing a study involving guinea pigs. You know that the Institutional Animal Care and Use Committee discussed the study at length because it potentially involved inflicting some serious pain and suffering on the animals. The Committee approved the study after your colleague agreed to procedures that would substantially minimize pain and suffering. You've learned that your colleague is not actually using these procedures.
Likely Research Misconduct (1) Not Likely Research Misconduct (2)

Don't Know If Research Misconduct (3)
[IF LIKELY:] 3a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
4. You are working on a series of related neurophysiology studies in a research group led by a more senior investigator. At a series of group meetings, the group leader assigned leadership and authorship for each of the studies and the expected resulting manuscripts. The group leader then confirmed the assignments with an e-mail to the group. You were assigned one set of experiments and first authorship on the two manuscripts expected to result from them. You conduct the experiments, draft both manuscripts, and send them to the group leader for review. In return, the group leader tells you that he has decided to be first author on both manuscripts despite being only minimally involved in conducting the experiments and writing the manuscripts.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 4a. What would you do in such a situation?
Talk to the more senior investigator (1) Talk to the more senior investigator's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
5. A colleague of yours learned that a technician made up test results and combined them with some legitimate data to make the table in a grant proposal more convincing. The colleague dismissed the lab technician, but because the grant application was due the next day, submitted the grant application as it was with the intention of correcting it later.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 5a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)

6. You head a central data storage and analysis center serving a number of departments. You notice that the statistical tables for two different experiments included in a colleague's manuscript look identical. You point that out to him. He says it was the result of a file error and that he will fix it. Several months later you happen to see the actual publication and the tables for the two experiments have been substantially changed. Curious, you look to see what data files for this work your colleague has sent recently to the data storage facility. There are none that look like those in the publication, and the files you previously found problematic have been deleted.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 6a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
7. You and a colleague have been working together on a clinical trial. As you are writing up the results, you find you have a major disagreement with how your colleague plans to interpret the data. You strongly believe that your colleague is wrong, even misleading, and that her interpretation should not be published because it could lead other researchers down a useless path and give false hopes to patients. Your colleague tells you that she intends to publish the data and her interpretation, and since you disagree, you are welcome to do the same.
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 7a. What would you do in such a situation?
Talk to the colleague (1) Talk to the colleague's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)

enter the collaborator's lab, you overhear his two post-docs talking about your joint research project. They sound defeated and annoyed. One says "This study is no different than all the others we have done. Again, we need to figure out how to get the results he wants to demonstrate." The other responds, "We just will have to figure out what data points to omit so that he gets the results he wants. I really thought this time it would be different because his new collaborator is so well respected by his post-docs."
Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 8a. What would you do in such a situation?
Talk to the collaborator (1) Talk to the collaborator's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
9. You are the principal investigator on an NIH-funded study to examine the incidence of a serious communicable disease in minority sub-populations in several cities. In examining your data set it appears that one of the project's interviewers is very productive and is conducting more interviews than the interviewers in the other four sites. You do a random audit of that interviewer's work and discover that, although the interviews had only recently been conducted, one address is an abandoned house, several phone numbers are either not working or not correct, and in six repeat interviews you are told that the respondent never talked with an interviewer. Likely Research Misconduct (1) Not Likely Research Misconduct (2) Don't Know If Research Misconduct (3)
[IF LIKELY:] 9a. What would you do in such a situation?
Talk to the interviewer (1) Talk to the interviewer's supervisor (2) Report this to the designated institutional official (3) I would do nothing (4)
That is the end of the questions. Please feel free to provide a comment about the survey in the box below.
Thank you.

8. You have recently initiated a working relationship with a new collaborator. One day, as you