ANALYSIS OF GUIDELINES FOR THE CONDUCT OF RESEARCH ADOPTED BY MEDICAL SCHOOLS OR THEIR COMPONENTS

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Prepared for:

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EXECUTIVE SUMMARY

The existence of guidelines for the conduct of research at an institution may provide an educational tool for new or visiting researchers and an easily accessible guide for experienced researchers. Such guidelines can help promote a positive environment and avoid situations that have the appearance of, or indeed constitute, poor research practices.

The current study, conducted between August and December 2000, was undertaken to address the questions:

- How many accredited U.S. medical schools have guidelines that relate to the conduct of research?
- At what organizational level were the guidelines developed?
- What topics are addressed by the guidelines?
- What behaviors are recommended by the guidelines?

Packages, each consisting of a letter requesting all guidelines related to research conduct, a checklist for categories of research guidelines, and a postage-paid return envelope, were sent to the deans of 125 accredited medical schools nationwide. All schools that did not respond were contacted at least three times, with follow-up phone calls being made to the medical school's dean and research integrity officer. Responses were obtained, either as a direct reply to the request for guidelines or in the form of guidelines obtained from the institution's public web site, from 99 of the 125 medical schools. This represents a response rate of 79.2 percent. All but one responding school had guidelines. Thus, at a minimum, 98 of the 125 accredited medical schools, or 78.4 percent, currently have some form of research conduct guidelines. Most guidelines submitted (63 percent), were developed at the university level and apply to the medical schools as well as to the other university departments. Guidelines submitted by 30 schools (31 percent) were developed at the medical school level. The six remaining schools (6 percent) provided some guidelines developed by the medical school and others developed at the university level.

At first review, the increase in the number of guidelines related to the conduct of research between 1990, when only 13 percent of medical schools had guidelines, [1] and the current study, showing a minimum of 78 percent, is very encouraging. However, with a more in depth examination of the topics discussed in the guidelines, the picture changes. Thirty two percent (n=31) of the guidelines examined in this study are related solely to legal issues concerning conflict of interest and intellectual property, and 96 percent (n=94) discuss these issues. One explanation for this emphasis may be changes in the scientific environment with the emerging importance of commercialization of biomedical research. In the past there was much less need for policy regarding these legal issues. Their current prominence in the submitted guidelines may relate to their economic significance. While intellectual property issues are pertinent to the process of doing research, some specifics covered under conflict of interest focus on how prod-

[1] Nobel, J.J. (1990). Comparison of research quality guidelines in academic and nonacademic environments. *JAMA* 263 (10):1435–37.

ucts of research are handled, principally in terms of financial gain. These issues are somewhat tangential to the actual process of performing research that the guidelines discussed here relate to.

Guidelines from the majority of medical schools were found to exist in several different documents rather than centralized in a single location. In addition, most guidelines focus on a narrow range of topics and do not provide a comprehensive, well-rounded perspective on all aspects of the conduct of research.

To facilitate examination of the content of the guidelines examined, areas they address were organized in a hierarchical fashion into *clusters* that are composed of *topics*, which are in turn composed of *content areas*. All items found in guidelines have been grouped into four clusters: data management; publication and data dissemination; investigators' roles and responsibilities; and legal issues. These clusters represent the major divisions in areas addressed by guidelines. Clusters were further divided into eight topics: data management; publication practices; authorship; peer review; principal investigator; mentoring; conflicts of interest; and intellectual property. To provide completeness and increased precision in discussing the areas addressed by guidelines for the conduct of research, and to provide a framework for a clearer discussion of individual behaviors the guidelines recommend or discourage, the eight topics were broken down into a total of 48 content areas. The complete analytic framework is shown in Exhibit 1 of the report.

A total of 94 (96 percent) of guidelines discussed legal issues, whereas only 36 (37 percent) discussed publication and data dissemination. Consistent with this finding, the content areas of conflicts of interest (88 percent of guidelines) and intellectual property (66 percent), which compose the legal issues cluster, were the most frequently discussed. Next most frequently discussed were issues related to the role of the principal investigator (49 percent) and data management issues (46 percent). Least frequently discussed was the issue of peer review (8 percent of guidelines). Fifty five of the 98 guidelines examined (56 percent) cover only two of the eight topic clusters.

DATA MANAGEMENT

An emphasis was placed on the role of proper recording, organization, use, and retention of data to document the validity of the research process. Often this was phrased in terms of keeping records that might be produced if challenges to reports of results were received.

Guidelines suggest that every step of a research project, from conceptualization, study design, and analysis plan, through data collection, data analysis, and generation of reports of results be carefully documented. The appropriateness of analytic approaches, inclusion of all data, and reporting of supporting and conflicting results are discussed. Study data should be retained for a sufficiently long period to safeguard against any charges of misconduct and provide a source that can be used to respond to questions about accuracy and authenticity. The importance of members of the scientific community being able to replicate published research results is also mentioned in some guidelines. Some specifics concerning possible requirements for recording of data and quantitation of the length of time data should be retained are included in some guidelines. It is clear that guidelines for the conduct of research must find a balance between

providing specifics for procedures that will promote high-quality research practices while not being inordinately burdensome in requiring specific provisions when these may not be necessary in many cases.

Clinical research involves additional issues to which guidelines refer. These issues include proper attention to obtaining informed consent and keeping these documents in an easily accessible location. The importance of confidentiality is a primary concern. The role of the patient's or subject's personal physician is also discussed.

The importance of accessibility of data to collaborators, the institution where the research is being conducted, financial sponsors of the research, and the research community as a whole is described.

PUBLICATION AND DATA DISSEMINATION

Guidelines stress the importance of quality over quantity when discussing research publications. The pressure to publish, often measured, formally or informally, in terms of numbers of publications, is acknowledged in some guidelines. This is generally viewed in an extremely negative fashion. Although not discussed very frequently, peer review is described as a process that should benefit the interests of the authors of the work being reviewed and not the reviewer.

Avoidance of the simultaneous submission of the same manuscript to several journals, publication in the "least publishable unit," and inclusion of preliminary or fragmented data is recommended in guidelines for the conduct of research. Limitations on the number of publications evaluated for academic promotions are sometimes suggested.

Limitation of authorship to those who have made an intellectual contribution to the research being reported is strongly advised. Establishing a lead author who has overall responsibility for a manuscript and can describe the roles of all collaborators is also recommended.

In terms of peer review, issues of confidentiality; avoiding conflicts of interest, provision of timely, thoughtful feedback, and prohibition against using the position of reviewer for any type of personal gain are discussed.

INVESTIGATORS' ROLES AND RESPONSIBILITIES

Guidelines emphasize the seriousness of the responsibilities of principal investigators in terms of intellectual/scientific and fiscal management of research. Mentoring of junior staff is discussed in terms of both professional and personal aspects of the relationship. Delegation of these responsibilities to others is, in general, frowned upon.

A number of guidelines describe the responsibilities of principal investigators with respect to intellectual/scientific management of projects, fiscal oversight, supervision of project staff and assignment of reasonable tasks to individuals in different positions, and compliance by all staff with institutional and government policies, including laws and regulations regarding human subjects, animal welfare, biological and occupational safety, conflicts of interest, and civil rights. Responsibilities of mentors are discussed in terms of both professional and personal aspects. Frequent meetings that allow for reasonable supervision, limits on the number of mentees assigned to a single investigator, attention to professional development including establishment

of independence, assignment of appropriate professional activities, and ensuring that mentees are familiar with and are following all institutional and government policies relating to research are included in the mentor's responsibilities. In addition, some guidelines specifically address the responsibility of the mentor to be aware of the mentee's personal life, changes in behavior that may result from stresses of research or cultural differences, and personal aspects of professional development.

LEGAL ISSUES

Most medical schools have very similar guidelines pertaining to the legal issues involved in conflicts of interest and intellectual property. In general, definitions are provided, the promptness of disclosure of all activities that may be construed as involving conflict of interest or ownership of intellectual property is emphasized, and procedures for resolution and appeals are discussed. Quantitation is provided in a number of guidelines, especially in terms of minimum financial interests that constitute a legal conflict of interest, and in terms of the amounts of time investigators can allot to activities separate from their institutional responsibilities. Prompt disclosure of new inventions is strongly advised.

The rapid disclosure of financial involvements on the part of investigators to the appropriate institutional officials is stressed. Many guidelines indicate who these officials are, and what official groups are available to resolve any disputes.

There is general agreement that the institution should own intellectual property unless it has made no substantial contribution to its development. In terms of commercialization, the groups that should share in any profits are often described, with a variety of percentages of allocation of profits sometimes suggested in the guidelines. Some guidelines specify periods of time that institutions have to pursue commercial development before all rights revert to the investigator.

Strategies for resolution of conflict are suggested in several guidelines. Some guidelines provide details for resolution procedures and appeal processes.

SUMMATION

This study provides an update on the status of guidelines for the conduct of research within the medical school community. The summation of recommendations contained in all guidelines presents a reasonably complete picture of what ideal guidelines should look like. However, most individual institutional guidelines suffer to some extent from limited focus and fragmentation in the development of guidelines.

While the past 10 years have shown an improvement in the number of medical schools with some form of guidelines for the conduct of research, there is still a great need for development of more comprehensive written guiding principles. The educational value of such guidelines is currently being emphasized, as they provide a valuable aid to established investigators and medical school officials in the process of training new investigators and students. They can also form part of the curricula for courses on research conduct. It is hoped that the information provided in this report will prove useful to medical schools in developing new guidelines or updating existing guidelines.

I. INTRODUCTION

In its 1989 report titled *The Responsible Conduct of Research in the Health Sciences*, the Institute of Medicine (IOM) recommended that all medical schools develop written guidelines for the responsible conduct of research. The absence of such guidelines, the IOM argued, could result in a small number of individuals producing sloppy or unsound research, which could potentially taint the integrity of the entire research process.

The National Academy of Sciences (NAS), in its 1992 report titled *Responsible Science: Ensuring the Integrity of the Research Process*, expanded on this idea, suggesting that written guidelines should ideally be formulated by researchers themselves, and added that guidelines imposed from outside would be less effective and less likely to be followed. In addition, the NAS found that research policies existing at that time tended to be "disjointed and piecemeal," with different pieces written by different academic units. Such fragmentation, NAS argued, would make it much more difficult for researchers to determine proper conduct.

Medical schools are the primary extramural locations for the conduct of biomedical research in the United States. In the document titled *Scientific Misconduct Investigations 1993–97*, the Office of Research Integrity (ORI) reports that over the 5-year period of the study, 68 percent of the investigations and 58 percent of the misconduct findings came from medical schools. Medical schools received an estimated 44 percent of National Institutes of Health (NIH) extramural research funds and an estimated 65 percent of extramural research funds awarded to higher education institutions in fiscal year 1999.[2]

However, earlier studies revealed that the majority of medical schools did not have guidelines in place. For instance, in a 1990 study, Nobel surveyed medical schools regarding research guidelines and found that only 13 percent had general institutional guidelines and 19 percent were considering developing guidelines.[3] Sixty-eight percent stated that they neither had nor were considering developing or adopting guidelines.

The major objectives of the current study include answering the following questions:

- How many accredited U.S. medical schools have guidelines that relate to the conduct of research?
- At what organizational level were the guidelines developed?
- What topics are addressed by the guidelines?
- What behaviors are recommended by the guidelines?

ORI will use the results of this study in its education and prevention programs. ORI will make the results available to the research community through its web site, conferences/workshops, and publications. Medical schools will potentially be able to use study findings to develop and/or refine their research guidelines.

[2]According to award data on the NIH web site, http://grants.nih.gov/grants/award/award.htm.

[3]Nobel, J.J. (1990). Comparison of research quality guidelines in academic and nonacademic environments. *JAMA* 263(10): 1435–37.

II. METHODOLOGY

This study was designed to perform a content analysis of guidelines, adopted by accredited U.S. medical schools, that address the following topics:

- Authorship
- Collaborative Research among Scientists
- Mentoring
- Peer Review
- Conflicts of Interest
- Data Management
- Laboratory Management
- Role of Principal Investigator
- Publication Practices
- Other

Attention to one or more of these topics was recommended by the 1989 IOM report and the 1992 NAS report. These topics are also covered in many courses on research ethics. In addition, a preliminary analysis of institutional guidelines for the conduct of research previously completed by ORI suggested several of these topics. The use of humans and animals in research and the handling of allegations of research misconduct were not included in this study because institutions are required by regulation to develop policies in these areas.

DATA COLLECTION

Solicitation packages, each consisting of a letter, a checklist for categories of research guidelines, and a postage-paid return envelope, were sent to the deans of the 125 accredited medical schools nationwide.[4] Copies of the solicitation letter were sent to individuals listed as university research integrity officers. The mailing went out on August 28, 2000. Copies of the letter and checklist can be found in Appendices A and B, respectively.

As of October 10, 2000, 38 (29 percent) schools had responded. At that point, follow-up calls to medical school deans and research integrity officers commenced. Follow-up calls had two purposes:

- To find the appropriate individual from whom to obtain a response.
- To remind schools to send promised guidelines.

The script used for these conversations is included in Appendix C. In many cases, the deans and research integrity officers provided referrals to other individuals within their respective institutions to furnish the guidelines. If guidelines were not received within 7 to 10 days of the first call, additional follow-up calls were made. Follow-up calls continued through November and early December, and data collection closed on December 8, 2000.

All schools that had not responded were contacted three times at minimum, and often four or five times. At least two of these calls were made to the medical school dean's office. Calls were also made to the research integrity officers. In addition, the AAMC sent a reminder e-mail to all medical school deans on an electronic mailing list in late November.

[4]The cover letter was developed in collaboration with the Association of American Medical Colleges (AAMC). Deans were asked to fill out and return the checklist along with available guidelines.

ANALYSIS OF RESPONSE

Study response is summarized below:

- Out of 125 accredited medical schools, 82 (65.6 percent) responded to the study by sending completed checklists and/or guidelines. Thank-you letters were sent to each school that responded; a copy is included in Appendix D.
- An additional 17 schools (13.6 percent), while not directly responding to the study, had guidelines available on school web sites.
- In all, 99 medical schools (79.2 percent) either responded to the study or had publicly available guidelines via school web sites.
- Of these 99 medical schools, 98 had guidelines. This indicates that, at minimum, 98 (78.4 percent) of the 125 accredited U.S. medical schools have guidelines for the conduct of research.

To assess possible nonresponse bias, comparisons were performed between the 99 schools that responded to the study or had guidelines available on school web sites (respondents) and the 26 schools that did not respond (nonrespondents). The following characteristics were compared across the two groups of schools:

- Total enrollment;
- Total NIH research funding for the year 2000;
- Region of the country; and
- Whether the school is public or private.

All of this information except total NIH research funding was available from the *Directory of American Medical Education* by the AAMC in 1999. Information about total NIH research funding was obtained from the NIH web site.

Table 1 shows a breakdown of the findings. For total enrollment and total NIH funding, means and standard deviations for respondents and nonrespondents are given. For region of country and public/private designation, total numbers and percentages for respondents and nonrespondents are listed.

Table 1. Characteristics of Respondents and Nonrespondents

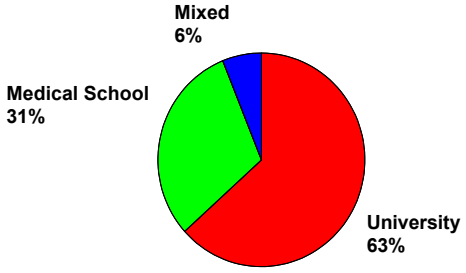
Characteristics		Respondents	Nonrespondents
Total	N = 125 (100%)	99 (79.2%)	26 (20.8%)
Enrollment		Mean = 544 (SD = 202)	Mean = 532 (SD = 234)
Total NIH Funding in Thousands ($) (FY 2000)		Mean = 63,199 (SD = 65,479)	Mean = 31,877 (SD = 54,428)
Region			
Northeast	29 (23.2%)	22 (22.2%)	7 (26.9%)
South	46 (36.8%)	40 (40.4%)	6 (23.1%)
Midwest	31 (24.8%)	24 (24.2%)	7 (26.9%)
West	16 (12.8%)	13 (13.1%)	3 (11.5%)
Caribbean	3 (2.4%)	0 (0%)	3 (11.5%)
Public/Private			
Public	74 (59.2%)	62 (62.6%)	12 (46.2%)
Private	51 (40.8%)	37 (37.4%)	14 (53.8%)

To summarize the results:

- There were no meaningful differences in total enrollment between respondents and nonrespondents.
- It appears that total NIH funding is higher for respondents than for nonrespondents. However, the ranges in funding are wide, and these differences are not statistically significant.
- Public institutions were more likely to respond to requests for research conduct guidelines than private institutions.
- For respondents, the geographical distribution more closely mirrors that of the total population of medical schools than it does for nonrespondents. None of the three medical schools located in the Caribbean responded. Medical schools located in the South were slightly more heavily represented among respondents than among nonrespondents.

Sixty-two (63.3 percent) of the participating medical schools provided guidelines that were developed at the university level; these guidelines apply to the medical schools as well as to other divisions of the university. Thirty (30.6 percent) of the schools furnished guidelines developed by the medical school itself. Six schools (6.1 percent) provided some guidelines that were developed by the medical school and some that were developed at the university level (Figure 1).

Figure 1. Percentage of Institutional Level at Which Guidelines Were Adopted



As the NAS found in 1992, school guidelines typically consisted of several different documents, sometimes assembled by different departments of the university. For instance, guidelines regarding publication practices might have been provided by the university's Office of Research Integrity, whereas guidelines regarding conflicts of interest might have been assembled by the university's legal department. Occasionally, schools would provide one document that contained all guidelines.

For the purposes of this analysis, the term "guideline" applies to all materials provided by a given school. Therefore, the 99 participating schools provided 98 guidelines.

DATA ANALYSIS

In-depth content analyses of the guidelines received revealed that the topics addressed by them could be grouped at three levels to facilitate analysis. These are defined for the purposes of this study as clusters, topics, and content areas.

Four "clusters" of overarching topics were identified: Data Management; Publication and Data Dissemination; Investigators' Roles and Responsibilities; and Legal Issues. The clusters can be used to broadly categorize the data.

The topics used for the next level of analysis mirror closely the topics presented in the original checklists sent to the medical schools, with a few exceptions:

- The guidelines received did not contain elements that easily fit into the "Collaborative Research among Scientists" topic, and so it was deleted. Some of these issues seemed to fit more closely in the topic of "Authorship." In addition, so many detailed guidelines were

received addressing "Intellectual Property" that this was added as a topic.

- Few guidelines contained information that fit easily into the "Laboratory Management" topic. However, a few guidelines discussed maintenance of laboratory data notebooks. Consequently, these issues were included under the topic "Data Management," and the topic "Laboratory Management" was deleted. Guidelines describing laboratory management, other than laboratory data notebooks, seemed to discuss research group management in general, rather than being specific to a laboratory (as opposed to a clinical or epidemiologic research group).
- No guidelines received could be labeled as "Other," or outside the preexisting framework. Therefore, the topic "Other" was deleted.

Table 2 demonstrates how the topics fit into the clusters.

Table 2. Topics by Cluster

Clusters	Topics
Data Management	Data Management including study design, data notebooks, data retention, etc.
Publication and Data Dissemination	Publication Practices, Authorship, Peer Review
Investigators' Roles and Responsibilities	Principal Investigator, Mentoring
Legal Issues	Conflicts of Interest, Intellectual Property

Finally, guidelines were analyzed at a more detailed level by using "content areas." These content areas had two sources:

- Subtopics on the original checklist. For instance, under the topic "Publication Practices," the subtopics "multiple submissions" and "corrections" were two of the content areas mentioned. When it came time to do the actual analysis, some of these content areas were deleted if no guidelines mentioned them. For instance, under the topic "Mentoring," the content area "types of assignments given" was deleted, since no guidelines discussed this issue.
- Sometimes topics with some similarity were merged for conciseness. For instance, under the topic "Publication Practices," although "multiple submissions" and "duplicate publications" are different practices, they have some similar elements, and are discussed together under "multiple submissions/duplicate publications". In the context of this report, "multiple submissions" refers to the practice of simultaneously submitting the same article to several journals for review, and printing it in the first or "best" journal that accepts it while withdrawing it from others, while "duplicate publication" refers to the practice of publishing the same data in more than one journal article. This includes multiple articles where the majority of the data is the same, as well as situations where results from one type or set of experiments are included as new data in multiple publications rather than having later articles cite the initial publication of the data.

- Content areas not on the original checklist that emerged from data collection. Some content areas were added during the analysis, as it was observed that schools were discussing these issues. For instance, guidelines discussed the

topic "Conflicts of Interest" in more detail than had been originally anticipated. Many content areas under the topic were added, including "disclosure process," "appeals process," and "committees for review of potential conflict of interest."

Table 3 provides a complete list of content areas by topic. Also, see Exhibit 1 for the final analysis framework.

A detailed analysis plan, along with a revised analysis framework and Microsoft Excel shell tables, was submitted to the Project Officer on January 17, 2001. Subsequent feedback on the analysis plan from the Project Officer was received and incorporated.

Guidelines received via mail or fax (i.e., hard copies) were scanned into electronic form. Those obtained from Internet web sites were downloaded. All guidelines were saved as ASCII text files, eliminating all formatting, including tabs and hard returns.

Table 3. Content Areas by Topic

Topic	Content Areas
Data Management	Study design, analysis, and reporting; data notebooks; data retention; issues unique to clinical data; ownership, sharing, and access
Publication Practices	Multiple submissions/duplicate publications: Inclusion of fragmented, preliminary, or unpublished data in publication; corrections and retractions; acknowledgments
Authorship	Qualifications for authorship; responsibilities of authorship; gift, honorary, or ghost authorship; order of authorship; textbook authorship issues
Peer Review	Responsibilities of reviewers; conflict of interest; treatment of confidential information
Principal Investigator	Qualifications of a PI; responsibilities of the PI; laboratory training; laboratory supervision
Mentoring	Responsibilities of mentor; number of individuals being mentored; foreign students and fellows; assistance with establishment of independence; mentee responsibilities
Conflicts of Interest	Definitions of conflict of interest; examples of conflict of interest; exceptions, not qualifying as conflict of interest; disclosure process; confidentiality of financial disclosure; committees for review of potential conflict of interest; standards for resolution; appeals process; record keeping; conflicts of commitment; consulting; use of university name
Intellectual Property	Definitions; university versus individual ownership; distribution of revenue from commercialization; copyrights; patents; signing of agreements; disclosure regarding inventions; evaluation committees; if university declines patent; appeals process

Files were then imported into QSR NUD*IST (Non-numerical Unstructured Data Indexing Searching and Theorizing) software.

NUD*IST is a software program designed for the management of qualitative data in preparation for analyses. This data management software package facilitates analysis of large amounts of qualitative data by grouping responses from multiple sources by category and topic, organizing particular sets of data by codes assigned, before and/or after data entry, into the software. In this case, codes were determined prior to analysis using the clusters, topics, and content areas detailed in the analysis framework. However, as discussed above, as the data analysis proceeded, some codes were eliminated, some were merged, and some were added, as changes to the analysis framework were made to reflect the data received.

III. RESULTS

A comparison of the numbers of medical schools with some form of research conduct guidelines in 1990 and in the present data collection effort is shown in Figure 2. The increase in the number of medical schools that have guidelines is clearly indicated. The content of these guidelines is discussed below.

Figure 2. Percentage of Medical Schools Having Guidelines for Conduct of Research

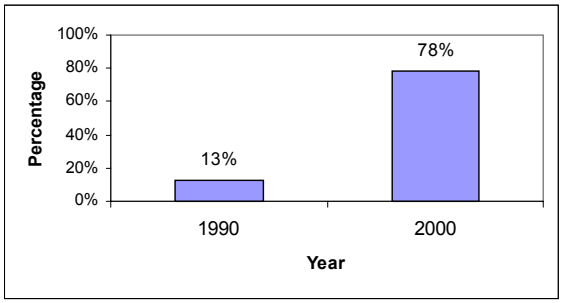


Table 4 lists the number of guidelines addressing each cluster. Ninety-four schools (i.e., almost every responding school) had guidelines relating to legal issues; 55 schools had guidelines relating to investigators' roles and responsibilities; 45 had guidelines relating to data management; and 36 had guidelines relating to publication and data dissemination.

Table 4. Number of Guidelines Discussing Each Cluster

Clusters	Number of Guidelines
Data Management	45
Publication and Data Dissemination	36
Investigators' Roles and Responsibilities	55
Legal Issues	94

Table 5 lists the number of guidelines discussing each topic. Of the eight topics, the most frequently mentioned by schools were conflict of interest (86 schools) and intellectual property (65 schools), followed by principal investigator (48 schools), data management (45 schools), authorship (34 schools), and mentoring (23 schools). Least frequently mentioned were publication practices (16 schools) and peer review (8 schools).

Table 5. Number of Guidelines Discussing Each Topic

Topics	Number of Guidelines
Data Management	45
Publication Practices	16
Authorship	34
Peer Review	8
Principal Investigator	48
Mentoring	23
Conflicts of Interest	86
Intellectual Property	65

TYPICAL GUIDELINES

CLUSTERS

As demonstrated in Table 6 and Figure 3, 33 guidelines discussed just one cluster of issues, 22 discussed two clusters, 17 guidelines discussed three issues, and 26 discussed all four clusters. Thus, more than half of current guidelines cover no more than two of the four clusters.

If guidelines discussed just one cluster, it was almost always Legal Issues (31 out of 33 guidelines, or 94 percent). If guidelines discussed two clusters, they tended to be Legal Issues and Investigators' Roles and Responsibilities (15 out of 22 guidelines, or 68 percent). If guidelines discussed three

clusters, they tended to be Legal Issues, Investigators' Roles and Responsibilities, and Data Management (10 out of 17 guidelines, or 59 percent). Interestingly, issues relating to Publication and Data Dissemination were most often brought up only when all of the other clusters were discussed.

Table 6. Frequency of Cluster Groups

Number of Clusters in Guideline	Number of Guidelines	Most Frequent Cluster(s)
1	33	Legal Issues 31 (94%)*
2	22	Legal Issues + Investigators' Roles 15 (68%)
3	17	Legal Issues + Investigators' Roles + Data Management 10 (59%)
4	26	All clusters addressed
Total	**98**	

* Percentage given is percentage of guidelines in the row

Figure 3. Number of Guidelines by Number of Clusters

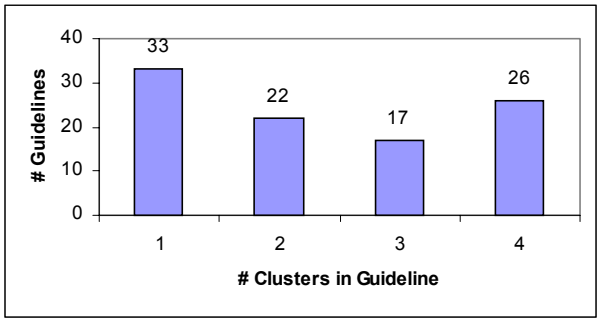
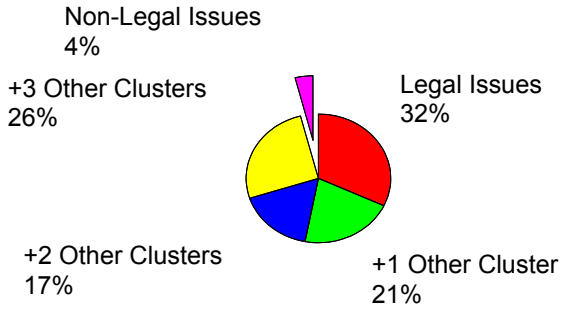


Figure 4 demonstrates the emphasis placed on legal issues by current guidelines. Only 4 percent of medical schools have guidelines that do not deal with legal issues. Thirty two percent of guidelines deal only with legal issues, and an additional 21 percent deal with legal issues and one other cluster area. At least some of the issues addressed under the legal issue cluster relate more to handling of products of research and financial gain from these products, than they do to the actual process by which research is accomplished. They are thus somewhat tangential to the purpose of research guidelines, as examined by this analysis.

Figure 4. Percent of Guidelines Discussing



Legal and Non-Legal Issues

TOPICS

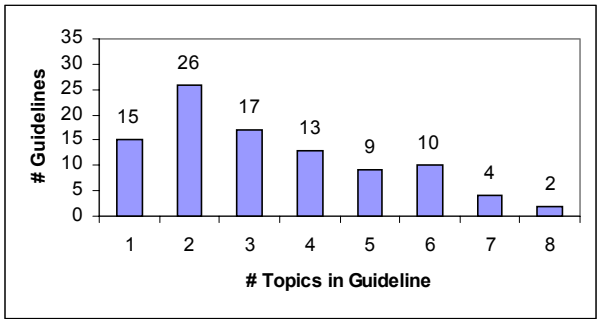
Table 7 and Figure 5 address the number of topics typically covered by the guidelines. It can be seen that more than half of the guidelines examined cover no more than three of the eight topic areas.

Table 7. Frequency of Topic Groups

Number of Topics in Guideline	Number of Guidelines	Most Frequent Topic(s)
1	15	Conflict of Interest 10 (67%)*
2	26	Conflict + Intellectual Property 19 (73%)
3	17	Conflict + Intellectual Property + Principal Investigator (PI) 7 (41%)
4	13	Conflict + Intellectual Property + PI + Data Issues 9 (69%)
5	9	Conflict + Intellectual Property + PI + Data + Authorship 4 (44%)
6	10	All but Peer Review and Intellectual Property 6 (60%)
7	4	All but Peer Review 3 (75%)
8	2	All topics addressed
Total	**98**	

* Percentage given is percentage of guidelines in the row

Figure 5. Number of Guidelines by Number of Topics



If guidelines covered only one topic, it tended to be conflict of interest (10 of 15 guidelines, or 67 percent). If guidelines covered two topics, they tended to be conflict of interest and intellectual property (19 of 26 guidelines, or 73 percent). If guidelines covered three topics, they tended to be conflict of interest, intellectual property, and principal investigator. Only two guidelines discussed all eight topics. If guidelines discussed six or seven topics, the ones that were typically left out were publication practices, peer review, and—surprisingly—intellectual property.

As can be seen from Table 3, the topics of conflict of interest and intellectual property compose the legal issues cluster. Table 7 reemphasizes the frequency with which medical school guidelines concentrate solely on these areas. It is interesting that peer review is not included in large numbers of current medical school guidelines.

CONTENT AREAS

Table 8 and Figure 6 demonstrate how many content areas the guidelines typically discuss. Thus, over half of guidelines examined cover no more than 10 of the possible 48 content areas.

Only one guideline discussed more than 25 of the 48 content areas. Typically, guidelines focused on a relatively narrow set of content areas: 38 guidelines covered 6 to 10 content areas, 23 discussed 11 to 15 content areas, and 19 discussed 1 to 5 content areas.

Table 8. Frequency of Content Area Groups

Number of Content Areas in Guideline	Number of Guidelines
1–5	19
6–10	38
11–15	23
16–20	14
21–25	3
26+	1
Total	**98**

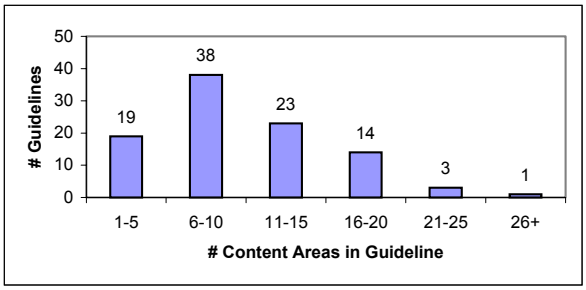


Figure 6. Number of Guidelines by Number of Content Areas

Table 9 examines the numbers of content areas individual guidelines contain for each of the topics they address. The number of content areas under each topic, along with the number of guidelines addressing that topic are presented. For guidelines discussing the topic, the average, median and range of number of content areas addressed is shown.

The above findings indicate that guidelines tend to zero in on a relatively small number of topics and content areas and that typical guidelines tend not to be extremely comprehensive.

Table 9. Frequency of Content Areas for Each Topic

Topic	Number of Guidelines Dealing with Topic	Number of Content Areas	Average Number of Content Areas	Median Number of Content Areas	Range
Data Management	45	5	2.0	2.0	1-5
Publication Practices	16	4	2.0	2.0	1-4
Authorship	34	5	2.2	2.0	1-5
Peer Review	8	3	1.8	1.5	1-3
Principal Investigator	48	4	1.6	1.0	1-3
Mentoring	23	5	2.2	2.0	1-4
Conflicts of Interest	86	12	5.2	6.0	1-10
Intellectual Property	65	10	4.0	4.0	1-10
Total	**98**	**48**	**10.5**	**10.0**	**1-31**

ANALYSIS OF CONTENT

The purpose of the content analysis is to provide information on the range of behaviors recommended under the various content areas, as well as the degree of consensus that exists on specific behaviors. Guidelines, grouped by cluster, topic, and content area, were analyzed for patterns. Specific behaviors and recommendations are noted, and counts of relevant behaviors or recommendations are provided to demonstrate the degree of consensus. Special attention is paid to examples of quantitation, as well as to examples of behaviors that schools present in strong negative or positive lights. Specific examples of common language and phrasing are also included in the analysis.

CLUSTER 1
ISSUES RELATING TO DATA MANAGEMENT

Forty-five guidelines (46 percent) address issues relating to data management.

Many guidelines frame data management issues in terms of preventing allegations of scientific misconduct. If data are carefully recorded, reported, and retained, guidelines point out, it becomes much more difficult to impugn the integrity of the research. As one guideline articulates, in the majority of allegations of misconduct, the investigator has had his or her credibility "considerably eroded" by the inability to provide verifiable data. Accurate and accessible data, according to this guideline, are "not only the keystone of science, but also the wellspring of documentation in the event of an accusation of impropriety." Table 10 lists the number of guidelines discussing each content area in this cluster.

Table 10. Number of Guidelines Discussing Each Content Area: Cluster 1

Content Area	Number of Guidelines
Data Management	
A. Study Design, Analysis, and Reporting	9
B. Data Notebooks	9
C. Data Retention	41
D. Issues Unique to Clinical Data	7
E. Ownership, Sharing, and Access	23

TOPIC I. DATA MANAGEMENT

FORTY-FIVE GUIDELINES (46 PERCENT) DISCUSS DATA MANAGEMENT.

A. Study Design, Analysis, and Reporting

Nine guidelines specifically discuss the importance of careful study design, data analysis, and reporting to the research process.

Guidelines recommend:
- Carefully describing the statistical design and analysis
- Using appropriate statistical testing
- Reporting data that support **and** fail to support the desired conclusion
- Documenting each step of the analysis

- Four guidelines emphasize that the research plan should carefully detail the statistical design and that the analysis used to report the results should coincide with the planned analysis. If such a plan does not exist, as one guideline points out, a researcher's "subconscious bias" may lead him or her to steer the analyses to fit his or her hypothesis.
- Two guidelines state that statistical testing should be appropriate to the study and should involve consultation with knowledgeable persons during study planning.
- Four guidelines emphasize the importance of reporting data that are both supportive and unsupportive of the desired conclusion to eliminate any sug-

gestion of selection bias. As one guideline discusses, in a pilot or exploratory study, it is permissible to handle outliers in a way that permits the investigator to emphasize the most important findings. However, this practice would not be acceptable in a hypothesis-testing or confirmatory study. Dropping inconvenient outliers or describing unusual observations as technical failures might constitute unacceptable data "trimming."

- Finally, four guidelines emphasize the importance of careful documentation of each step in the evolution of the analysis, including decisions to exclude data, so that results can be easily replicated. One guideline stated that, in general, investigators "may do anything with the data, as long as the original data are preserved and the experimental record clearly documents what was done by way of manipulating those data."

B. Data Notebooks

Nine guidelines discuss proper recording of data in laboratory notebooks.

- Six guidelines, using very similar language, advise investigators to use bound laboratory notebooks, with numbered pages, to which extra pages cannot be added. If successive notebooks are used, the volumes should be numbered sequentially.

Guidelines recommend:
- Using bound laboratory notebooks
- Using a heavy grade of high-quality paper if looseleaf notebooks are used
- Affixing computer-generated data to the notebooks
- Making entries in permanent ink
- Using an index
- Signing and dating all entries
- Routine checking of notebooks by supervisors

- In contrast, three guidelines state that either bound or looseleaf notebooks can be used, depending on the type of research and on personal preference. One of these guidelines points out that whereas bound notebooks provide better physical documentation of chronology and less chance for loss or misordering of pages, looseleaf notebooks lend themselves better to inclusion of documentation that is not handwritten, such as computer output, spreadsheets, graphics, photographs, and autoradiograms. However, bound notebooks are preferred for patent records and "issues of priority." If looseleaf notebooks are to be used, a heavy grade of high-quality paper should be used, as standard three-hole paper ages poorly and tears out easily.
- Five guidelines discuss affixing computer-generated data to the notebook. Two of these guidelines simply state that computer output should be affixed to or referenced from the laboratory notebook. Three of the guidelines, however, suggest that hard-copy printouts of computer data be generated on a regular basis and bound into the notebook but acknowledge that if this is not possible, notebooks should still record descriptions and chronologies of the experiments performed, descriptions of the instrumentation used, and the location and form of the data. One of these guidelines adds that each sheet of the printout should be signed and dated and corroborated by a witness.
- Four guidelines point out that all entries and corrections should be made in permanent ink.
- Four guidelines suggest using an index to facilitate access to data.
- Four guidelines state that all entries must be signed and dated, and one of these guidelines points out that subsequent entries must be made on the line immediately following the previous entry.

- Three guidelines suggest the routine checking of laboratory notebooks of technicians, graduate students, and postdoctoral fellows by superiors.
- One guideline delineates a process by which any individual making entries should have another technically knowledgeable person read and corroborate the notebook entries, a process that should occur at least once every two weeks. It is mandated that this corroborator write, sign, and date a form after the most recent entry, indicating that he or she has read and understood the material.

C. Data Retention

Forty-one guidelines discuss appropriate time periods for data retention.

Guidelines recommend:

- Obtaining and retaining informed consent
- Obtaining permission from attending physician
- Minimizing bias and ensuring accuracy
- Storing data without identifying information

In almost every case, the stated purpose of retaining data is to protect against accusations of misconduct and to enable researchers to respond to questions about accuracy and authenticity. Twenty-eight guidelines give specific quantitative examples of appropriate time periods.

- Sixteen guidelines recommend retaining data for 5 years.
- Eight guidelines recommend a 3-year period.
- Two guidelines recommend a 7-year period.
- Two guidelines recommend a time period of 3 to 5 years.

In addition, several guidelines indicate that certain sponsoring agencies may specify a longer time period for data retention. For instance, one guideline mentions that the U.S. Food and Drug Administration requires that data associated with certain clinical trials be retained for a minimum of 2 years following final approval of the respective drug, but, the guideline points out, that is likely to be a substantially longer period than 5 years after completion of the research project.

Guidelines that do not give specific quantitative examples of appropriate time periods of data retention tend to discuss in more general terms the importance of maintaining data for an "adequate" or "sufficient" period of time to allow responses to questions regarding the research.

Although many guidelines suggest specific data retention periods, none indicate precisely when this period should commence. For instance, would a 5-year data retention period begin after data collection ends? Or would it begin after the study is published? Or when the grant is closed out? The issue of who has the responsibility for retaining the data is not specifically discussed, nor is the associated issue of who must agree before sharing of retained original data occurs.

D. Issues Unique to Clinical Data

Seven guidelines discuss issues unique to the handling of clinical data.

- Four guidelines point out that clinical research requires special attention to issues of informed consent and confidentiality. Specifically, signed copies of informed consent forms must be placed with clinical records as well as with research records.

- One guideline emphasizes that investigators must obtain permission from a prospective participant's attending physician, although retrospective studies of patient records do not require such permission if the patient's identity is kept confidential.
- One guideline discusses the ethical implications of conducting clinical research. Specifically, because results of health services research may be less replicable, and because the results of such research can have health policy implications affecting entire populations, researchers have a particularly strong ethical obligation to minimize bias and ensure accuracy.
- Two guidelines discuss specific safeguards to patient confidentiality in terms of data retention. For instance, questionnaires should be stored without identifiers, using only code numbers to link them to computerized files, and records should be redacted to remove names and key identifiers.

E. Ownership, Sharing, and Access

In all, 23 guidelines discuss the issues of ownership, sharing, and access/availability of data in their guidelines.

These issues must often be examined at different levels of analysis. For instance, issues of ownership and availability among the collaborating researchers, as well as between the researchers and other entities, such as the university, must be considered.

Guidelines recommend making data available to:

- Scientific community
- University administration
- All research group members
- External sponsors and government officials
- The public

Ownership among Researchers:

- One guideline states that data generated by a principal investigator (PI), or by assistants under the direction of the PI, belong to the PI. Data generated by a PI and faculty colleagues, or by the PI and postdoctoral fellows, graduate students, or research trainees who had significant intellectual input, are considered the joint property of all collaborators.
- Another guideline mentions that work produced through group collaboration is not "owned" by any individual member of the group and that no person should claim group-produced work as his or her own.

Ownership by Institutions versus Individuals:

- One guideline says that while the Public Health Service (PHS) has stated that the grantee institution is the owner of data resulting from PHS-funded research, the school is only concerned with access to data, not ownership.
- In contrast, three guidelines state that all research data are the property of the institution, not the researchers or the PI. The PI serves as "custodian" of the data.

Custody of Data if Researchers Depart

Twelve guidelines discuss custody of data in the event researchers leave the institution. In general, guidelines agree that when researchers leave the university, they may take copies of research data for projects on which they have worked, and the original data remain in the custody of the PI. If a PI leaves, however, and a project is moved to another institution, ownership may be transferred with approval of university officials and with written agreement from the new institution guaranteeing access to the data for the original institution.

Access and Sharing

Seventeen guidelines emphasize the importance of data availability. There are multiple levels of data availability to be considered in guidelines for scientific research. These levels include availability to collaborators, institutions where research was conducted, sponsors of research, and the research community as a whole.

- Ten guidelines state, using very similar language, that investigators have an obligation to the general scientific community to share data, which will facilitate independent confirmation or refutation of reported outcomes.
- Six guidelines emphasize that data must be available to the university administration upon request.
- Five guidelines emphasize that data must be readily available to all research group members.
- Three guidelines state that data must be available to representatives of external sponsors or designated government officials, as appropriate.
- One guideline points out that the public has rights of access to data, after data have been prepared for publication. Caveats include limitations on access to confidential patient data.
- The small numbers of guidelines discussing each of these issues and the lack of specifics concerning conditions under which access and data sharing occur or the mechanisms involved should be noted.

Summary of Cluster 1: Issues Relating to Data Management

Guidelines should articulate concrete, easy-to-follow procedures for researchers so that steps followed in their scientific discoveries are clear and so that other researchers are able to replicate findings. Researchers should treat data with care to avoid allegations of misconduct. "Ideal" guidelines should include the following behaviors:

- Documenting every step of each study, including the design, data collection, and data analysis methods so as to facilitate response to future questions and concerns;
- Retaining all study data for a long enough period (e.g.,5 years) to prevent accusations of misconduct and enable response to questions about accuracy and authenticity;
- For clinical studies, ensuring that proper informed consent procedures are followed, that the informed consent of study participants is kept and easily reachable, and that procedures to protect participant confidentiality are observed;
- Making data available to collaborators, the institutions where the research was conducted, to the research sponsors, and (as some schools require) to the research community as a whole.

CLUSTER 2
ISSUES RELATING TO PUBLICATION AND DATA DISSEMINATION

Thirty-six guidelines (37 percent) address issues relating to publication and data dissemination.

Table 11. Number of Guidelines Discussing Each Content Area: Cluster 2

Content Area	Number of Guidelines
Publication Practices	
A. Multiple Submissions/Duplicate Publications	14
B. Inclusion of Fragmented, Preliminary, or Unpublished Data	10
C. Corrections and Retractions	1
D. Acknowledgments	4
Authorship	
A. Qualifications for Authorship	23
B. Responsibilities of Authorship	31
C. Gift, Honorary, or Ghost Authorship	9
D. Order of Authorship	9
E. Textbook Authorship Issues	1
Peer Review	
A. Responsibilities of Reviewers	4
B. Conflict of Interest	3
C. Treatment of Confidential Information	5

TOPIC II: PUBLICATION PRACTICES

SIXTEEN GUIDELINES (16 PERCENT) DISCUSS ISSUES RELATING TO PUBLICATION PRACTICES.

A. Multiple Submissions/Duplicate Publications

Fourteen guidelines address the issue of multiple submissions/duplicate publication of data.

Without exception, guidelines view the practice of submitting multiple similar manuscripts for publication as negative, frequently describing it as "inappropriate" or "improper." Two of the guidelines use the term "self-plagiarism" to describe this practice.

Guidelines recommend:
- limiting the number of publications to be reviewed at faculty appointment or promotion

If guidelines broach the issue of why multiple submissions should be discouraged, they explain that they "waste resources". Multiple submissions can vastly increase the workload of editors and reviewers to little purpose. Submitting the same, or very similar, articles to multiple journals involves duplication of review processes, useless work by reviewers, and can lead to the problem of duplicate publications.

Duplicate publications, the actual appearance of the same or very similar data in multiple articles, when discussed in guidelines, is said to "make it difficult for reviewers and readers to follow a complete experimental sequence, waste resources, and can serve to mislead the public about the original amount of supporting data."

Several guidelines acknowledge that these practices may result from the pressure to have a long list of publications in order to achieve tenure or other recognition. One possible solution that four guidelines suggest is to limit the number of publications to be reviewed at times of faculty appointment or promotion in order to reward "quality over quantity." Two of these guidelines specifically suggest that no more than five papers be reviewed for appointment to Assistant Professor, no more than seven be reviewed for tenure decisions and promotion to Associate Professor, and no more than 10 for promotion to Professor.

B. Inclusion of Fragmented, Preliminary, or Unpublished Data in Publication

Ten guidelines discuss the inclusion of fragmented, preliminary, or unpublished data in publication and uniformly condemn such practices as improper.

Guidelines recommend *avoiding:*
- Publication of fragmented data
- Using preliminary data in publications
- Implying that cited work is published if it is not

- Nine guidelines discuss publication of fragmented data, all in a negative manner. Three guidelines describe the practice of dividing research into incomplete fragments in order to produce greater numbers of publications as "salami" publication, which should be "eschewed." One of these guidelines describes this as publishing in "least publishable units," a practice that "overtaxes the peer review system, complicates literature searches, increases journal costs and, most importantly, compromises the integrity of science by serving narrow self-interests rather than the broader and more altruistic goals of science and scholarship."
- Four guidelines, using very similar language, describe using preliminary data, without taking the time to test reproducibility or assess significance, as a practice to be avoided.
- One guideline states that, when citing unpublished work, the author should be careful not to imply an unwarranted status of a manuscript. In other words, papers should not be listed as "submitted." They should be listed as "accepted for publication" or "in press," and then only if the author has received galley or page proofs.

C. Corrections and Retractions

One guideline states that retractions or corrections of published research should be made "promptly" when necessary. Because so few guidelines deal with the issue of corrections and retractions, there are multiple concerns that guidelines do not address. Who should submit corrections and retractions? The authors? The institution? Do all authors have to agree to a correction or retraction? Can the institution submit corrections and retractions if the authors will not? If authors disagree about corrections or retractions, what process should be used to reach resolution? At what point do the institutions involved play a role?

D. Acknowledgments

Two guidelines point out that minor contributions to a publication (i.e., those not warranting authorship) should be acknowledged in the text or a footnote.

Two guidelines suggest that published papers should credit any sponsors of the work and the source of funding of the research should be clearly identified in the publication.

TOPIC III: AUTHORSHIP

THIRTY-FOUR GUIDELINES (35 PERCENT) DISCUSS ISSUES RELATING TO AUTHORSHIP.

As discussed in Topic II, schools are concerned that the "publish or perish" ethic in academia has led to an overemphasis on quantity rather than quality of papers. This ethic may also result in individuals being included as authors who actually made no significant contribution to the published research. Specifically, one guideline cites a phenomenon known as "author inflation," in which the number of coauthors on papers has increased dramatically in recent years. As this guideline states, this practice may

"be linked, or at least predisposed, to the publication of fraudulent research." Another guideline asserts that authorship practices are "important to the reputation, academic promotion, and grant support of the individuals involved, as well as to the strength and reputation of their institution." Consequently, many guidelines specifically address authorship.

A. Qualifications for Authorship

Twenty-three guidelines discuss the issue of who qualifies as an author, many using very similar language.

Guidelines recommend that coauthors be involved in:

- Initiating or planning the study
- Analysis or interpretation of the results
- Writing or revising drafts
- Approving the final version

All of the guidelines agree that authorship should be limited to those who have contributed in a meaningful way to the intellectual content, including the conceptualization, design, execution, interpretation, or writing of the work involved. The following are examples from guidelines that delineated more specific criteria:

- Two guidelines maintain that all coauthors must have been involved in *all* of the following: (1) planning some component of the work that led to the paper or interpreting at least a portion of the results, (2) writing a draft of the article or revising it for intellectual content, and (3) final approval of the version to be published.
- One guideline suggests that coauthors be involved in *some* of the following: (1) initiating or planning the study, (2) making some of the reported observations or generating some of the data, (3) interpreting the observations or data and deriving from them the conclusions, (4) taking part in the writing, and (5) reading the paper and assenting to its publication before submission.
- One guideline states that authors should assume responsibility for at least *one* activity in the following *three* categories: (1a) conception or design of the study or (b) analysis and interpretation of the data, (2a) drafting of the article or (b) revising it for critically important intellectual detail, and (3) final approval of the version to be published.

Three guidelines offer examples of activities that would *not* qualify individuals for authorship, including providing laboratory space or use of instrumentation, providing funding, involvement in patient care or providing patient samples, routine technical work, proofreading or editing of manuscripts, having a supervisory position, or providing encouragement.

B. Responsibilities of Authorship

Thirty-one guidelines discuss responsibilities of authorship.

Guidelines recommend:

- Designating one lead author who has overall responsibility for the entire manuscript
- Having each coauthor verify participation through a signed statement

- Twenty-one guidelines point out in relatively general terms, and using very similar language, that once an individual accepts authorship of a publication, he or she assumes responsibility for all work reported within his or her area of expertise. Many guidelines state the following: "In recent years, a gradual dif-

fusion of responsibility for multi-authored or collaborative studies has led to the publication of papers for which no single author was prepared to take full responsibility." To address this problem, guidelines recommend (1) designating one author who is responsible for the validity of the entire manuscript, and (2) active participation of each coauthor in verifying that portion of the manuscript that falls within his or her specialty area.

Designating one author: Fourteen guidelines advocate designating one individual as the primary author. Typically, guidelines suggest choosing a "responsible" author, who is accountable for methods and results and can provide a description of the role of all coauthors on the project upon request. This is usually the first author, unless the phrase "to whom correspondence may be addressed" is associated with another author.

Coauthors verifying participation: Seven guidelines suggest that every author sign a standard form or statement of verification attesting to the authenticity of the manuscript. The primary author is typically responsible for coordinating this process.

C. Gift, Honorary, or Ghost Authorship

Nine guidelines discuss granting of gift/honorary/ghost authorship, and each one regards this practice as highly negative.

As one guideline defines it, honorary authorship is "a type of unjustified authorship wrongly granted to someone who has played no, or virtually no, role in the study, but whose name might be perceived to add prestige to the publication." Four guidelines describe this practice as "deplorable," two use the term "unacceptable," and one describes it as "intellectually dishonest."

D. Order of Authorship

Nine guidelines discuss criteria for determining order of authorship of a publication.

- Seven guidelines state that order of authorship has no generally agreed-upon meaning but emphasize that authors should decide the order together, preferably before the study commences.
- One guideline states that in the biological sciences, it is generally agreed that the first author is the person who made the largest intellectual contribution and is usually the person responsible for designing, performing, and analyzing the largest portion of the work. The last author is generally the laboratory director.
- Another guideline states that the name of the individual who made the principal contribution should be listed as first author, with subsequent names listed in order of decreasing contribution. In some instances, someone may be listed as last author to identify the research unit in which the work was done. Other instances in which authorship order does not reflect relative contributions, such as alphabetical listing of author names, should be explained in a footnote.
- One guideline points out that the "responsible author" should resolve disagreements over authorship, and if he or she cannot, individuals may present their controversy in writing to the department chair.

E. Textbook Authorship Issues

Textbook authorship involves a number of issues that differ from those involved in authoring manuscripts containing only original research. One guideline delineates detailed suggestions for textbook authorship.

- The ultimate responsibility for selection of an appropriate form of attribution remains with the discretion of the editor.
- Whenever plans are made to revise a textbook, the editor should notify each contributor to the prior edition and establish the nature and extent of the prior contribution, regardless of whether the individual's participation will be sought for the revised edition.
- Attribution of contributions from a prior edition of a textbook should be acnowledged by name, title, and address.
- Editors of medical textbooks are responsible for maintaining academic standards of scholarship and proper attribution, a responsibility that should not be abdicated to the publisher.

TOPIC IV: PEER REVIEW

EIGHT GUIDELINES (8 PERCENT) DISCUSS ISSUES RELATING TO PEER REVIEW OF MANUSCRIPTS, AS WELL AS GRANT APPLICATIONS.

A. Responsibilities of Reviewers

Four guidelines discuss specific responsibilities of peer reviewers.

Guidelines recommend that reviewers should:
- Be qualified experts
- Strive to be unbiased and reasonable
- Provide support for negative opinions
- Provide timely feedback

Schools tend to view the peer review process as crucial to the quality and integrity of the biomedical sciences.

- Three guidelines state that the reviewer should be a qualified expert in the field, and if that individual feels unqualified, he or she should not agree to review the manuscript or grant application.
- Three guidelines mention that reviewers should strive to be unbiased, fair, and reasonable, especially when requesting additional data.
- Two guidelines emphasize that reviewers should not provide a negative opinion without demonstrating the logic for it, and should preferably back up their opinion with evidence from the published literature or their own research. This way, the author can respond with appropriate revisions or a rebuttal.
- Two guidelines mention that reviewers should provide feedback in a timely fashion.

B. Conflict of Interest

Three guidelines discuss the issue of conflict of interest among peer reviewers.

One guideline points out that this issue may arise often, as relatively few individuals are sufficiently expert to review work within a particular field. Consequently, journals and sponsoring agencies tend to call upon a relatively small pool of people to review manuscripts.

Guidelines recommend that:
- Reviewers recuse themselves if there is potential conflict of interest
- Authors have the right to request that specific individuals not serve as reviewers
- Reviewers avoid using new information garnered from review to further their own research

- One guideline defines conflict of interest in peer review as reviewing a manuscript from a principal investigator at the same institution; a potential personal financial gain or loss based on the decision; a direct scientific advantage based on review; and holding a competitor's manuscript unduly long to delay publication.

- One guideline states that authors have the right to request that specific individuals do not review a manuscript if the author fears unfair bias or advantage.
- Two guidelines recommend that if conflicts of interest arise, reviewers should recuse themselves from the review process. However, if the potential reviewer feels that an unbiased review is possible, he or she must disclose the nature of the conflict to the journal or funding agency before proceeding.
- All three guidelines emphasize that under no circumstances should reviewers use new information garnered from the review process to further their own scholarly endeavors before the information has been made public.

C. Treatment of Confidential Information

Five guidelines discuss the treatment of confidential materials received in the process of performing a peer review.

Guidelines state that:

- Material received for review must not be revealed to anyone
- Reviewers may share material with colleagues to enhance the review, if such review is in the best interest of the author(s), but must disclose this to editors

- Three guidelines simply state that any material received to review is confidential and the contents must not be revealed to anyone.
- Two guidelines state that there are exceptions to the general rule of confidentiality. For instance, it is permissible to discuss parts or even all of a submitted work with trusted colleagues to obtain a second opinion in instances when the reviewer is unfamiliar with the methodology or considers the author to be mistaken. In these situations, the reviewer should identify the various assisting colleagues to the overseer of the review. One of these guidelines expands on this policy by saying that such collaboration should first be approved by the journal editor, but this often does not happen, and the colleague simply adds his or her name to the review. If the second reviewer is selected because that person would directly benefit from knowing the state of research in the field, then the confidentiality rule of peer review has been violated. The primary reviewer must ascertain that the review process is served only to the benefit of the authors of the manuscript.

Summary of Cluster 2: Issues Relating to Publication and Data Dissemination

Effective guidelines should demonstrate ways in which personal interest and bias in publication and data dissemination can be diminished to the extent possible. First and foremost, guidelines should acknowledge the intense pressure that researchers face to publish their findings. To combat this pressure, and to promote the quality of publications as opposed to the quantity, guidelines should recommend limiting the number of papers considered for faculty review and promotion. A climate with less intense pressure may make it easier for researchers to observe the following recommended behaviors:

- Avoiding multiple submissions of similar manuscripts for publication and avoiding inclusion of fragmented or preliminary data;
- Limiting authors to those who have contributed in a meaningful way to the intellectual content of the publication (e.g., conceptualization, design, execution, interpretation, or writing). A lead author should be accountable for the methods and results and able to describe the roles of all coauthors on the project.
- As a peer reviewer, acting only in the best interest of the author(s) by maintaining confidentiality, avoiding conflicts of interest, and providing astute feedback, including justification for negative review.

CLUSTER 3
ISSUES RELATING TO INVESTIGATORS' ROLES AND RESPONSIBILITIES

Fifty-five guidelines (56 percent) discuss issues relating to individuals' roles and responsibilities.

These guidelines address interpersonal relationships pertaining to the conduct of research.

Table 12. Number of Guidelines Discussing Each Content Area: Cluster 3

Content Area	Number of Guidelines
Principal Investigator (PI)	
A. Qualifications of a PI	15
B. Responsibilities of the PI	32
C. Laboratory Training	9
D. Laboratory Supervision	5
Mentoring	
A. Responsibilities of Mentor	20
B. Number of Individuals Being Mentored	13
C. Foreign Students and Fellows	1
D. Assistance with Establishment of Independence	4
E. Mentee Responsibilities	4

TOPIC V: PRINCIPAL INVESTIGATOR (PI)

FORTY-EIGHT GUIDELINES (49 PERCENT) DISCUSS ISSUES REGARDING PRINCIPAL INVESTIGATORS AND THEIR ROLES AND RESPONSIBILITIES.

A. Qualifications of a PI

Fifteen guidelines delineate specific requirements that individuals must meet to qualify for PI status.

Most guidelines state that:

- Any faculty member may serve as PI

A few guidelines state that:

- Only certain individuals, such as University Board of Regents appointees, may serve as PI

Most guidelines state that:

- Exceptions may be made to these policies, with permission from appropriate university officials

- Nine guidelines state that *any* faculty member (e.g., tenure-track, nontenure-track, instructor, adjunct, emeritus, librarian, curator) may serve as PI on externally funded research. Two of these guidelines stipulate that this individual

must be appointed at 50 percent time or greater.

- One guideline states that only individuals who are members of the Academic Council may serve as PIs on externally funded research, since these individuals are responsible for determining the intellectual direction of the research and for training graduate students. However, members of the school's "Medical Center Line Professoriate" may also be permitted to act as PIs on externally funded research, as long as the research is compatible with their training. All other members of the academic staff may qualify as "associate investigators."
- One guideline states that although the terms "project director" and "principal investigator" are often used interchangeably, the school differentiates them as follows: the project director has the administrative responsibility for the project, and the principal investigator has specific investigatory responsibility. The project director must be a tenured or tenure-track faculty member, whereas the PI can be any faculty or professional staff member approved by the department chair and dean.
- One guideline states that the primary criteria for determining PI status is the individual's capability to provide scientific leadership and fiscal and administrative management of the project. The department head or dean must make this judgment.
- One guideline states that only University Board of Regents appointees may serve as PIs.

Overall, nine guidelines state that exceptions may be made to their policies and that other members of the university community may be granted PI status with permission from the relevant department chair, school dean, and/or the dean or vice president of research. However, one of these guidelines explicitly states that postdoctoral fellows and graduate students may not serve as PIs.

B. Responsibilities of the PI

Thirty-two guidelines discuss specifics of responsibilities of the principal investigator.

- Fourteen guidelines specifically mention total responsibility for fiscal/ budget issues, including financial management of the contract.
- Thirteen guidelines state that the PI is responsible for staff compliance with all government and university policies, including laws and regulations relating to human subjects, animal welfare, biohazards and biosafety, occupational health and safety, conflicts of interest, and civil rights and affirmative action.
- Ten guidelines mention that the PI is responsible for training staff on laboratory protocol and closely supervising staff progress.

Guidelines recommend that PI's responsibilities include:

- Fiscal/budget issues, including financial management
- Staff compliance with government and university policies
- Training and supervising staff on laboratory protocol
- Overall scientific and technical integrity of the project
- Compliance with terms and conditions of the award
- Completing work in a timely fashion
- Data maintenance and storage
- Quality control of all data and materials
- Determining authorship
- Ensuring that the project is in the best interest of the department

- Nine guidelines state that the PI is responsible for the overall scientific and technical integrity of the project, including issues concerning design and conduct, reliability and validity of results, and manuscript preparation.
- Five guidelines mention that the PI is responsible for compliance with the specific terms and conditions of each award, as set forth by the sponsoring agency. One of these guidelines mentions that the PI is also responsible for the compliance of any subcontractors.
- Four guidelines mention that the PI is responsible for completing work in a timely fashion.
- Four guidelines state that the PI is responsible for data maintenance and storage.
- Three guidelines state that the PI is responsible for quality control of all data and materials generated from his or her laboratory.
- One guideline states that the PI is responsible for ensuring that any project he or she assumes is consistent with the interests of the department, that it has academic merit, and that the project can be realistically completed within the proposed timeframe and budget.
- One guideline states that the PI has the sole responsibility of determining authorship, and another guideline states that the PI must ensure adequate citation of contributions from those within and outside each research group.

C. Laboratory Training

Nine guidelines discuss the issue of staff training in laboratory regulations.

All guidelines indicate that principal investigators and/or laboratory managers are responsible for ensuring that all staff are properly trained.

- Seven guidelines mandate training in safety issues and potential laboratory hazards, including biohazards (e.g., human immunodeficiency virus, oncogenic viruses, other infectious agents), chemical hazards (e.g., carcinogens, chemotherapeutic agents), and radioactive materials.

Guidelines recommend that training include:
- Safety issues and potential laboratory hazards
- Humane treatment of animal and human subjects
- Proper use of equipment

- Three guidelines emphasize the importance of training in humane treatment of animal and human subjects.
- One guideline emphasizes the importance of training in the proper use of equipment, including calibration or validation procedures.

D. Laboratory Supervision

Five guidelines mention the importance of supervision of staff by the principal investigator, laboratory manager, or project leader.

Guidelines recommend that supervision involve:
- Routine checking of laboratory notebooks
- Ongoing peer review process
- Active involvement of supervisor
- Annual training for laboratory director regarding staff management

- Three guidelines suggest the routine checking of laboratory notebooks of technicians, graduate students, and postdoctoral fellows by superiors.
- Two guidelines suggest an informal, ongoing peer review process in each research unit. As one of these guidelines comments, "Some form of informal on-

going peer review process should be implemented in each research unit. The format is variable, there can be periodic conferences, seminars, staff meetings, etc.; but the continual exposure of departmental or research unit faculty to the progress of investigators within it is critical."

- One guideline suggests active involvement of a project leader who will supervise all aspects of the study, as opposed to simply editing manuscripts. This guideline recommends that the ratio of research personnel to project leaders be small enough to allow for such close interaction but does not suggest specific numbers.
- One guideline mandates that the laboratory director receive annual training, provided by the Office of the Vice Provost for Research, in the appropriate management of laboratory staff.

TOPIC VI: MENTORING

TWENTY-THREE GUIDELINES (23 PERCENT) DISCUSS ISSUES RELATING TO MENTORING OF GRADUATE AND MEDICAL STUDENTS.

A. Responsibilities of Mentor

Twenty guidelines discuss the responsibilities a mentor has when advising postdoctoral/medical fellows and graduate/medical students.

- Fourteen guidelines emphasize the importance of regular meetings between mentor and mentee. However, only one guideline defined "regular"—at least once a month.
- Nine guidelines state that the mentor is responsible for ensuring that the trainee is familiar with all academic and non-academic policies, including course requirements and timetables, authorship policy, environmental health and safety, and treatment of human and animal subjects. Five additional guidelines state that mentors should impart to their mentees knowledge about research integrity and ethics and should serve as role models.
- Six guidelines, using almost identical language, emphasize the importance of careful supervision of mentee work. The guidelines used a variation of the following when discussing supervision: "Careful supervision of new investigators by their preceptors is in the best interest of the institution, the preceptor, the trainee, and the scholarly or scientific community. The complexity of scientific methods, the necessity for caution in interpreting possibly ambiguous data, the need for advanced statistical analysis, and accurate recording and preservation of data all require an active role for the preceptor in the guidance of new investigators. There is growing recognition of the advantages of mentoring at all levels of faculty and student interactions. There are personal and shared responsibilities for assuring that the supervision will be effective and complete."
- Five guidelines state that mentors should always treat mentees with professional courtesy.
- An additional four guidelines point out that mentors should ensure that mentees' best interests are always kept in mind. For instance, several guidelines point out that the trainees should be involved in meaningful training and educational experiences, and "not those that merely further the interests of the mentor or the group."
- Three guidelines suggest that mentors involve their mentees in small-group research unit meetings, which can serve to both contribute to the scientific efforts of the group and to provide informal peer review.

- Three guidelines advise that mentors offer candid advice to their mentees, including feedback about performance.
- Three guidelines mention that mentors should encourage their mentees to view employment prospects realistically.
- Three guidelines state that there should always be avenues available to students who feel that their advising situation is inadequate. For instance, students should be able to approach the department head or other officials with these concerns.
- One guideline stated that mentors should be alert to mentees' behavioral changes that could possibly indicate personal or academic stresses or substance abuse. In these situations, the mentee might need more careful supervision.
- One guideline makes a careful distinction between supervision and advising/mentoring. According to this guideline, not all researchers are suited by personality or temperament to be good advisors. Some researchers are better suited to direct technicians to perform experiments but may not be suited to providing the time, advice, guidance, and evaluation that a mentor or advisor must.

In addition, two guidelines discuss mentoring and advising in a great deal of detail and include an analysis of the philosophical history of mentoring in their guidelines. One guideline cites an individual who describes the mentoring relationship as "one of the most complex and developmentally important" in a person's life, and states that the most important function of a mentor is to "assist in the realization of a dream." The guidelines point out many positive examples of mentoring activities, including:

Guidelines recommend that mentor responsibilities include:

- Holding regular meetings with mentees
- Ensuring that mentees are familiar with academic and nonacademic policies
- Carefully supervising mentee work
- Treating mentees with professional courtesy
- Keeping mentees' best interests in mind
- Involving mentees in small-group research unit meetings
- Offering candid advice
- Encouraging mentees to view job prospects realistically
- Being alert to behavioral changes indicating mentee stress

- "Get to know other aspects of your mentee. Is he or she married? Any children? Any hobbies? Share similar information about yourself. You may want to conduct this first meeting away from the office, or go to your mentee's 'space.'"
- "With your mentee, write out one-year and three-year goals for your mentee's career. At the end of the year, re-examine those goals and determine if they've been met."
- "Invite him or her to social events as your guest and introduce him or her to other senior members of the specialty."

B. Number of Individuals Being Mentored

Thirteen guidelines state, using almost identical language, that "the ratio of trainees to preceptors should be small enough to permit scientific exchange, as well as oversight of the research at all stages." However, no guidelines provide a specific number or ratio.

C. Foreign Students and Fellows

One guideline mentions that mentors may often encounter trainees with different cultural values and personality traits. Conse-

quently, mentors should avail themselves of the services of the Office of International Students, which can provide cultural information for the faculty about foreign students and fellows.

D. Assistance with Establishment of Independence

Four guidelines discuss the mentor's role in helping mentees establish independence.

- Two guidelines discuss writing letters of recommendation, and one of these guidelines delineates proper procedure for writing them. For instance, the recommendation should be candid and forthright, and the letter should begin with a description of the sources of the information and the closeness of the relationship between the writer and the subject.
- One guideline states that the mentor should assist in career counseling, job placement, and obtaining independent funding.
- One guideline states that periodically scheduled career planning sessions should take place, particularly to avoid potential conflict between mentor and mentee. Issues such as hypothesis ownership and plans for collaborative versus independent studies should be discussed.

Guidelines recommend that mentors:

- Write candid letters of recommendation
- Assist in career counseling and job placement
- Schedule career planning sessions to monitor progress and avoid conflict

E. Mentee Responsibilities

Four guidelines discuss responsibilities that mentees have in the mentor-mentee relationship.

Guidelines recommend that mentees:

- Conduct themselves in a mature manner
- Be mindful of mentor time constraints
- Avoid overidentification with the mentor
- Be proactive in terms of career direction

All of these guidelines emphasize that the mentee should take initiative in asking questions, developing an active and ongoing exchange, and steering the direction of his or her education.

- Three guidelines emphasize that mentees should conduct themselves in an ethical and/or mature manner.
- Two guidelines suggest that mentees be mindful of mentor time constraints.
- One guideline recommends that mentees avoid overidentification with the mentor, as this may lead to development of his or her less desirable traits, or traits that do not mesh with the mentee's own lifestyle (e.g., sitting on so many committees that there is no time for personal interests).

Summary of Cluster 3: Issues Relating to Investigators' Roles and Responsibilities

Although not explicitly stated, many guidelines emphasize the gravity of the role of the PI or graduate mentor. "Ideal" guidelines should emphasize that the responsibilities inherent in these roles must be taken seriously, and not delegated to others.

- Most guidelines state that PIs must take responsibility for the financial management of the project as well as its overall scientific and technical integrity, supervise project staff and make sure they comply with all government and university policies, including laws and regulations regarding human subjects, animal welfare, biological and occupational safety, conflicts of interest, and civil rights. *Explicitly stating PI responsibilities in written format may help discourage inappropriate delegation of authority.*
- Similarly, most guidelines regarding faculty mentors working with postdoctoral/medical fellows and graduate/medical students include having regular meetings with mentees, ensuring they know about academic and nonacademic policies, serving as role models, imparting knowledge about research integrity and ethics, and assisting mentees in establishing independence. *However, some of these responsibilities are a bit more abstract and difficult to define than PI responsibilities*. For instance, how does one go about "serving as a role model" or "getting to know" one's mentee? "Ideal" guidelines should provide very concrete, specific examples of how to interact with a mentee.

CLUSTER 4
LEGAL ISSUES

Ninety-four guidelines (96 percent) discuss legal issues.

Schools are far more likely to have guidelines on legal issues, including conflict of interest and intellectual property, than on any other area. In contrast to the other clusters described in this report, however, there is little variability in school guidelines concerning these areas, with many schools providing extremely similar policies. It appears that many schools seem to have drawn from similar sources when developing their guidelines in this area.

Guidelines regarding legal issues tend to provide concrete definitions of conflict of interest and/or intellectual property, and delineate specific procedures that researchers must follow when disclosing such issues to the university. Procedures for handling and resolving these issues are also described. In many cases, specific quantitative examples of university regulations are provided (e.g., distribution of revenue from commercialization of intellectual property, definition of significant financial interest).

Table 13. Number of Guidelines Discussing Each Content Area: Cluster 4

Content Area	Number of Guidelines
Conflicts of Interest	
A. Definitions of Conflict of Interest	74
B. Examples of Conflict of Interest	33
C. Exceptions	43
D. Disclosure Process	74
E. Confidentiality of Financial Disclosure	10
F. Committees for Review of Potential Conflict of Interest	45
G. Standards for Resolution	54
H. Appeals Process	24
I. Record Keeping	34
J. Conflicts of Commitment	21
K. Consulting	22
L. Use of University Name	15
Intellectual Property	
A. Definitions	22
B. University versus Individual Ownership	42
C. Distribution of Revenue from Commercialization	47
D. Copyrights	23
E. Patents	32
F. Signing of Agreement	5
G. Disclosure Regarding Inventions	41
H. Evaluation Committees	27
I. If University Declines Patent	11
J. Appeals Process	4

TOPIC VII: CONFLICTS OF INTEREST

EIGHTY-SIX SCHOOLS (88 PERCENT) HAVE GUIDELINES REGARDING CONFLICTS OF INTEREST that arise when researchers' personal goals and interests potentially conflict with the interests of the university with which they are affiliated. Many issues that arise in this area relate directly or indirectly to university and or individual investigator finances.

A. Definitions of Conflict of Interest

Seventy-four guidelines provide definitions of conflicts of interest, most of which are strikingly similar.

Typically, guidelines define conflicts of interest as situations in which employees could influence academic or business decisions in ways that could advance personal gain.

Most guidelines use variations of the following definition: "Conflicts of interest are situations in which a University employee may have an opportunity to influence University administrative, business, or academic decisions in ways that could lead to personal gain or give improper advantage to others. The potential of real and perceived conflict exists when employees are simultaneously involved in more than one organization. Under all circumstances, actual conflict situations, as well as the appearance of conflict, should be avoided."

"Involvement" in an organization is most frequently defined as having a financial interest, including, but not limited to, salary or other payments for services, equity interests, allowance, interest in real or personal property, dividends, royalties derived from the licensing of technology, rent, capital gain, and intellectual property rights.

Sixty-seven guidelines give specific quantitative definitions of "significant" financial interest, and these definitions are markedly similar. In almost all cases, $10,000 is the stated threshold above which a financial interest becomes significant. Guidelines defined significant financial interest as variations of the following: "Monetary value will be considered significant if (1) an equity interest that exceeds $10,000 in value as determined through reference to public prices or other reasonable measure of fair market value or represents more than a 5 percent ownership interest in any single entity, when aggregated for the Investigator and his or her family members; (2) salary, royalties, or other payments are significant if they are expected to exceed $10,000, when aggregated for the Investigator and his or her family members over the twelve months following the date of disclosure."

In most cases, $10,000 is the threshold above which a financial interest becomes "significant."

B. Examples of Conflict of Interest

Thirty-three guidelines provide specific examples of situations involving potential or actual conflict of interest.

These include the following:

- A researcher uses his laboratory to do product-testing research, paid for by a company in which he is a 20 percent owner and founder, that seeks to validate advertising claims made about a product sold by that company.
- A clinician makes patient referrals to a diagnostic company in which his or her immediate family has a significant ownership interest.
- A researcher is on the board of a company that sells a service, and the pro-

posed research might make that service obsolete.

- A researcher owns a private treatment facility that can help patients for whom the experimental protocol fails.
- A researcher uses students or employees of the institution to perform services for a company in which a faculty member has an ownership interest.
- A researcher gives well-paid lectures for companies or organizations whose economic or political interests are affected by an investigator's scholarly work.

C. Exceptions, Not Qualifying as Conflict of Interest

Forty-three guidelines list situations that do ***not*** *qualify as conflicts of interest.*

These include the following:

- Participation in scientific or professional association activities, editorial responsibilities, or service on scientific review boards and panels;
- Acceptance of honoraria for commissioned papers and occasional lectures;
- Performance of professionally related activities such as consulting, textbook authorship, involvement with professional societies;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and
- Salary, royalties, or equity that when aggregated for the investigator and his or her family members over the next 12 months are *not* expected to exceed $10,000.

D. Disclosure Process

Seventy-four guidelines discuss the necessity of disclosure of significant financial interest, often on an annual basis, to the relevant university officials.

These officials include the vice chancellor of health affairs, the director of the Office of Sponsored Programs, the dean of the medical school, and the board of trustees.

E. Confidentiality of Financial Disclosure

Ten guidelines emphasize the importance of confidentiality of financial disclosures.

F. Committees for Review of Potential Conflict of Interest

Forty-five guidelines state that if the designated university official is unable to determine whether a conflict of interest exists, he or she will forward the matter to a Conflicts of Interest Review Board or Committee.

G. Standards for Resolution

Fifty-four guidelines discuss standards for resolution of conflicts of interest.

Examples of possible solutions include the following:

- Approval of the activity;
- Periodic peer review of the activity by individuals independent of the employee;
- Modification of the plan of work;
- Public disclosure of the significant financial interest;
- Assignment of different employees without a financial or business interest;
- Disqualification of the investigator in all or a portion of the research affected by the significant financial interest; and
- Severance of the relationship producing the conflict.

H. Appeals Process

Twenty-four guidelines delineate the process by which an investigator may appeal the findings of the Conflicts of Interest Committee.

Generally, appeal may be made to the provost, chancellor, or president.

I. Record Keeping

Thirty-four guidelines discuss maintenance of records of all financial disclosures and actions taken by Conflicts of Interest Committees.

Guidelines recommend retaining financial disclosure records for 3 years beyond completion of the research. However, one guideline recommends a 7-year retention period.

Thirty-two of these guidelines recommend retaining these records for 3 years beyond the termination or completion of the research, while one guideline recommends a retention period of 7 years.

J. Conflicts of Commitment

Twenty-one guidelines discuss the issue of conflict of commitment, which is generally defined as private interests or non-university activities that interfere with an employee's ability to carry out assigned duties effectively.

Three guidelines specifically state that faculty are allowed to spend no more than one day per week on outside interests.

K. Consulting

Twenty-two guidelines discuss outside consulting by faculty members.

Most guidelines state that consulting can be an enriching experience that can benefit both the individual and the university. However, seven guidelines place limits on the amount of time that can be spent on consulting.

- Four state that faculty members may not spend more than 1 day a week on these activities.
- One guideline states that faculty may not devote more than 11 days each quarter to consulting.
- One guideline says that faculty may not spend more than 40 days on outside consulting during the academic year, including holidays. For those appointed on a 12-month basis, time spent on consulting should not exceed 50 days per year, including holidays.
- One guideline states that faculty may not spend more than 13 days each academic quarter on consulting.

L. Use of University Name

Fifteen guidelines discuss the issue of use of university name in outside activities.

In general, employees may not use the university's name in connection with outside activities without explicit, written permission to do so. However, in contrast, one guideline states that all faculty members must cite their academic affiliation with the medical college in all scientific publications but does not specify that these publications must have been produced under the auspices of the medical college.

TOPIC VIII: INTELLECTUAL PROPERTY

SIXTY-FIVE GUIDELINES (66 PERCENT) DISCUSS INTELLECTUAL PROPERTY.

These guidelines help delineate the complex issue of ownership of research products (tangible or intangible) developed under the auspices of the university.

A. Definitions

Twenty-two guidelines provide definitions of intellectual property, most of which are very similar.

Most guidelines agree that the university should own intellectual property created under its auspices or with its resources.

Typical are the following two definitions:

- "Any invention, discovery, improvement, copyrightable work, integrated circuit mask work, trademark, trade secret, and licensable know-how and related rights. It includes but is not limited to records of confidential information generated or maintained by the University, data, texts, instructional materials, tests, bibliographies, research findings, organisms, cells, viruses, DNA sequences, other biological materials, probes, crystallographic coordinates, plant lines, chemical compounds and theses."
- "The tangible or intangible results of research, development, teaching, or other intellectual activity. Intellectual property can include the following categories—(1) inventions, discoveries, or other new developments which are appropriate subjects of patent applications, (2) written materials, sound recordings, videotapes, films, computer programs, computer-assisted instruction materials, works of art including paintings, sculpture, and musical compositions, and (3) tangible research property such as biological materials including cell lines, plasmids, hybridomas, monoclonal antibodies, and plant varieties, computer software, data bases, integrated circuit chips, prototype devices and equipment, circuit diagrams, etc."

B. University versus Individual Ownership

Forty-two guidelines discuss the issue of ownership of intellectual property.

In general, most guidelines agree that the university should own the intellectual property created under its auspices or with its resources. Intellectual property is only considered the exclusive property of the inventor if (1) the university has contributed nothing substantial or essential to the production and development of such intellectual property in funds, space, facilities, or time of a faculty or staff member or student; (2) the intellectual property is not related or similar to any university research then in progress known to the faculty member, or to which the university is committed, and with which, in either case, such faculty or staff member or student is connected; and (3) the intellectual property was developed by the inventor or author on his or her own time without any expense to the university.

C. Distribution of Revenue from Commercialization

Forty-seven guidelines discuss the distribution of revenue from commercialization of intellectual property, including royalty distribution.

Forty-four of these guidelines give specific quantitative examples of percentage distribution among the inventor and various university departments and officials. There is a great deal of variability among the guidelines in the formulas used; the following are some examples.

- 25 percent to the inventor, 25 percent to a university campus account for support of the inventor's research, 25 percent to the inventor's university department, and 25 percent to an account for the benefit of the university.

- First $100,000/year: 50 percent to inventor, 20 percent to inventor's department, 10 percent to inventor's school, 20 percent to research office. Second $100,000/year: 40 percent to inventor, 20 percent to inventor's department, 15 percent to inventor's school, 25 percent to research office.
- 50 percent to inventor, 10 percent to university president for support of research, 30 percent to executive vice president of campus area (e.g., medical center) in which the inventor holds an academic appointment, 10 percent to inventor's department or center.
- 33 ☐ percent to inventor, 33 ☐ percent to Office of Vice President for Research, 8 percent to inventor's college or school, 25 ☐ percent to inventor's department, division, or center.

D. Copyrights

Twenty-three guidelines provide definitions of copyrights.

Typically, guidelines define a copyright as "the intangible right granted to the author or creator of an original work fixed in a tangible form of expression, whereby the author or creator is invested, for a limited period, with the sole and exclusive privilege of reproducing, publishing, and/or selling copies of that work. Unlike the protection provided by a patent, copyright does not protect the idea itself, only the idea once fixed in the tangible medium."

E. Patents

Thirty-two guidelines discuss the patent review process.

As most guidelines define it, a patent is "a property right that gives the patent holder the right to exclude others from making, using, or selling the invention covered in the claims of the patent, absent the patent owner's permission. The grant lasts for a defined period of time, generally 15 to 20 years."

To qualify for patent coverage, most guidelines state that a discovery must be "novel" (i.e., not previously published, known to the public, or an obvious extension of publicly available knowledge) and useful.

F. Signing of Agreement

Five guidelines state that they require all faculty, staff, student employees, graduate students, and postdoctoral fellows to sign an agreement stating that they will abide by university policies regarding intellectual property, before they are allowed to perform any research.

G. Disclosure Process Regarding Inventions

Forty-one guidelines discuss the importance of prompt disclosure of inventions by the creator to the university.

No guidelines define "prompt" disclosure.

H. Evaluation Committees

Twenty-seven guidelines mention the use of evaluation committees of intellectual property to determine what interest the university has, if any, in commercialization.

I. If University Declines Patent

Eleven guidelines state that if the university decides not to pursue intellectual property development, all rights may revert to the inventor/author upon written request.

Three guidelines provide specific time limits for this process:

- One guideline states that if the school decides not to pursue development or takes no specific action within 120 days, rights may revert back to the inventor. If the school says it wants to pursue development, yet fails to do so within 270 days, rights may revert back to the inventor.
- One guideline states that if the school fails to act within 3 months of a disclosure, rights can revert back to the inventor.
- One guideline states that the university must apply for patent within 1 year of the date of disclosure.

J. Appeals Process

Four guidelines describe the appeals process for inventors who disagree with the decision of the Intellectual Property Committee.

Summary of Cluster 4: Legal Issues

Ideally, guidelines regarding legal issues should be clear and concise, so that researchers completely understand policies relating to conflicts of interest and intellectual property. Many guidelines in this area are filled with legal jargon that may confuse researchers. However, some guidelines are written from a "layman's" perspective, and clearly delineate university policy with a minimum of jargon. Most guidelines emphasize clear communication between researchers and university officials, including the following recommendations:

- Researchers must disclose any potential conflict of interest, especially a significant financial interest to the appropriate university officials;
- University officials should refer the case to a Conflicts of Interest Review Board or Committee if they cannot determine whether a conflict of interest exists.
- Guidelines should indicate different strategies for resolving such conflicts and describe how researchers can appeal the findings of a Conflicts of Interest Board or Committee.
- There is agreement that the university should own the intellectual property unless it contributed nothing substantial or essential to the property's development and production; the property is unrelated or different from any university research in progress; and the property was developed by the inventor or author at his/her own expense and on his/her own time;
- The inventor must promptly disclose new inventions to the university;
- Revenue from commercialization of intellectual property, including royalty distribution should be shared among the inventor, the university account supporting his/her research, his/her university department, and the benefit of the university;
- Committees should be formed to evaluate intellectual property to determine what interest, if any, the university has in commercialization.

IV. CONCLUSIONS

Previous reports have suggested that guidelines for research conduct be formulated by researchers and that they not be "disjointed and fragmented." When applying these criteria to the guidelines examined here one can ask: Do these guidelines appear to result from an organized, goal-oriented approach to their development, ideally involving input from those most concerned, the researchers? The answer to this question is that in most cases they do not.

Although there has been a sharp rise in the number of medical schools with research guidelines in place since 1990, a large percentage of the guidelines focus on legal issues. In fact, 32 percent of current guidelines examined in this study are related solely to legal issues, and 96 percent of the guidelines discuss legal issues. Guidelines tend to zero in on a small number of topics and content areas. The emphasis on legal issues may be related to the rapid growth of the biotechnology industry over the past two decades and to increasing possibilities for commercialization and potential for profit based on actual products and/or expectations. In addition, these legal issues are relatively new in biomedical research as compared with issues of peer review and publication practices. These changes have contributed to bringing about situations that need to be addressed from a legal perspective. The legal profession, by its nature, has a greater tendency to provide written regulations or codes than do academic researchers.

Typical guidelines thus tend not to be very comprehensive. Medical schools may want to determine if developing more balanced guidelines addressing topics such as peer review, publication practices, and mentoring will facilitate education of young researchers and avoidance of situations that appear to or in fact do constitute poor research practice.

There also is a great deal of fragmentation, in that school guidelines are found in multiple documents, and guidelines may be assembled by different university divisions or departments. As the NAS warned in its 1992 report, such disjointed guidelines may make it much more difficult for researchers to be fully aware of and understand them. In terms of young researchers, it is also much more difficult to deal with isolated items of recommended behavior than to deal with a single source that can be consulted for a variety of situations. It may be that having a single location or document containing all guidelines for research may suggest a higher priority than needing to look to multiple sources.

Most medical school guidelines appear to have been developed by the university rather than specifically by the medical school. They may thus not relate as well to medical school research situations. In addition, as the NAS pointed out, if medical school researchers have not been involved in developing the guidelines, they may be less inclined to follow them and less inclined to point them out to junior colleagues and students.

Many topics in current guidelines are discussed in a general fashion, with the exception of guidelines related to legal issues. Guidelines with greater specificity might be

easier to interpret more precisely. On the other hand, many situations can be handled in a flexible fashion and still be consistent with good research practices. The ideal guideline will be balanced in its provision of recommended specific behaviors while not being over burdensome and restrictive.

The results of this study should be a valuable source of information to medical schools that plan to develop and/or revise their research guidelines. Summaries at the end of each cluster of items may be beneficial since they bring together the majority, if not all, issues covered by current guidelines for research conduct at medical schools in the United States.

EXHIBIT 1
REVISED ANALYTIC FRAMEWORK

Cluster 1 - Issues Relating to Data Management

I. Data Management
   A. Study design, analysis, and reporting
   B. Data notebooks
   C. Data retention
   D. Issues unique to clinical data
   E. Ownership, sharing, and access

Cluster 2 - Issues Relating to Publication and Data Dissemination

II. Publication Practices
   A. Multiple submissions/Duplicate publications
   B. Inclusion of fragmented, preliminary, or unpublished data in publication
   C. Corrections and retractions
   D. Acknowledgments

III. Authorship
   A. Qualifications for authorship
   B. Responsibilities of authorship
   C. Gift, honorary, or ghost authorship
   D. Order of authorship
   E. Textbook authorship issues

IV. Peer Review
   A. Responsibilities of reviewers
   B. Conflict of interest
   C. Treatment of confidential information

Cluster 3 - Issues Relating to Investigators' Roles and Responsibilities

V. Principal Investigator (PI)
   A. Qualifications of a PI
   B. Responsibilities of the PI
   C. Laboratory training
   D. Laboratory supervision

VI. Mentoring
   A. Responsibilities of mentor
   B. Number of individuals being mentored
   C. Foreign students and fellows
   D. Assistance with establishment of independence
   E. Mentee responsibilities

Cluster 4 - Legal Issues

VII. Conflicts of Interest
- A. Definitions of conflict of interest
- B. Examples of conflict of interest
- C. Exceptions, not qualifying as conflict of interest
- D. Disclosure process
- E. Confidentiality of financial disclosure
- F. Committees for review of potential conflict of interest
- G. Standards for resolution
- H. Appeals process
- I. Record keeping
- J. Conflicts of commitment
- K. Consulting
- L. Use of university name

VIII. Intellectual Property
- A. Definitions
- B. University versus individual ownership
- C. Distribution of revenue from commercialization
- D. Copyrights
- E. Patents
- F. Signing of agreement
- G. Disclosure regarding inventions
- H. Evaluation committees
- I. If university declines patent
- J. Appeals process

Appendix A
Solicitation Letter

Form approved: OMB No. 0090-0241
Expires: 6/30/2001

August 23, 2000

Dean, Degree
School Name
School Address

Dear Dean:

One of the core responsibilities of the Office of Research Integrity (ORI) is the promotion of responsible research practice by providing educational and other resources to the scientific community. Through consultation with its academic colleagues, ORI identifies where the greatest needs are and fulfills them in a way that enables institutions to uphold their own responsibilities to ensure the integrity of their research efforts. These contacts, and ORI's experience more generally, have pointed to the importance of institutions articulating clear expectations of research conduct through codes, guidelines, and other means. Many institutions have made great strides in this regard, whereas others are just embarking on such efforts. ORI believes that the experience of the former could greatly benefit the latter, and thus would like to compile information on the content of institutional codes or guidelines for the purpose of creating a helpful educational resource for institutions.

In support of this project, ORI asked ROW Sciences, Inc., to analyze such guidelines adopted by accredited medical schools in the United States to (1) ascertain what topics are addressed in the guidelines and (2) identify the behavior described under each topic to determine the range of possible responses.

Study results will be presented to the research community in a conference designed to discuss and promote responsible research practices and on the ORI web site. The conference will be co-sponsored by the Association of American Medical Colleges (AAMC) and ORI. The resource document for developing or revising such guidelines will be patterned after the AAMC publication, *Developing a Code of Ethics in Research: A Guide for Scientific Societies.* Participating institutions will receive copies of the study report and the resource document.

Because the information we are requesting may be titled differently in medical schools and may exist in more than one document, we have enclosed a checklist which indicates the general categories and specific topics on which information is requested. If such guidelines do not exist at the medical school level, please submit any university-level guidelines or guidelines that have been developed by departments or other units within the school or college.

Please return the enclosed checklist indicating whether or not your institution or its units have such guidelines and please be sure to submit a copy of those guidelines with the checklist. If the guidelines are posted on your institutional web site, you only need to provide the address for the documents. A postage-paid, self-addressed envelope has been enclosed for your convenience.

Your response, of course, is voluntary. Analyses will refer to aggregate information rather than responses from specific institutions. I hope that you will be able to fit a response to this request into your busy schedule by September 15, 2000.

If you have any questions, please contact me at (301) 294-5729, or Julaine King at (301) 294-5690. Your participation in this important study is greatly appreciated.

Sincerely,

Marsha E. Reichman, Ph.D.
Senior Scientist
ROW Sciences, Inc.

cc: RIO
RIO - Title

Appendix B
Checklist

SurveyID

Request for Guidelines for the Conduct of Research

Please enclose or provide the web site address for any written guidelines developed by your institution that address the topics listed below, or other topics you deem pertinent. Possible content is provided after each topic to clarify what the written guidelines may address. Please check the topics for which guidelines are enclosed or provide their precise web site address:

_____ **Authorship:** Qualifications; responsibilities; gift, honorary or ghost authorship; clearance prior to dissemination. Web site address _____

_____ **Data Management:** Recording data; retaining data; ownership of data; sharing data; access to data. Web site address _____

_____ **Collaborative Research Among Scientists:** Expectations for outcomes/products; defining expected contributions; allocating responsibilities; sharing data and materials; criteria for assigning credit; rights and obligations regarding intellectual property.
Web site address _____

_____ **Laboratory Management:** Responsibilities and authority of director; recording, retention and review of data; quality control; training; supervision.
Web site address _____

_____ **Mentoring:** Responsibilities of mentor; number of mentees per mentor; types of assignments given. Web site address _____

_____ **Principal Investigator:** Responsibilities; qualifications, recording, retention and review of data prior to dissemination. Web site address _____

_____ **Peer Review:** Responsibilities of peer reviewers; maintaining confidentiality of manuscripts and grant reviews; use of confidential information; conflict of interest.
Web site address _____

_____ **Publication Practices:** Duplicate publications; multiple submissions; corrections; retractions. Web site address _____

_____ **Conflicts of Interest:** Intellectual, financial, social in conduct of research or reviewing proposals or manuscripts; commitment to institution; relationships with for-profit organizations. Web site address _____

_____ **Other:** _____
Web site address _____

_____ **None**

Appendix C
Follow-Up Telephone Call Script

INTRODUCTION

Hello, my name is **(INSERT YOUR NAME)** and I am calling from ROW Sciences, Inc. on behalf of the Office of Research Integrity (ORI). May I please speak with **(INSERT NAME OF RESPONSIBLE OFFICIAL)**?

IF OFFICIAL IS AVAILABLE

MATERIALS RECEIVED: Hello **(INSERT NAME OF RESPONSIBLE OFFICIAL)**, my name is **(INSERT YOUR NAME)** and I am calling from ROW Sciences, Inc. on behalf of the Office of Research Integrity (ORI). You participated in the Office of Research Integrity's study, "Analysis of the Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components," and I am calling to say thank you for your time, effort, and
participation in the study. As a result of your participation among others, it is anticipated that the survey results will be beneficial in developing a resource guide that will be useful to medical schools in formulating or updating their guidelines. We will send you a copy of this document. Also, ORI and AAMC are planning on co-sponsoring a conference to present these study findings to the biomedical research community. Again, thank you for your time and study participation.

MATERIALS "NOT" RECEIVED: Hello **(INSERT NAME OF RESPONSIBLE OFFICIAL)**, my name is **(INSERT YOUR NAME)** and I am calling from ROW Sciences, Inc. on behalf of the Office of Research Integrity (ORI). About three weeks ago, we sent you a letter asking for your participation in an ORI study, "Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components." According to our records we have not received a response. I was wondering if you remember receiving the request?

IF NO, We are assisting the Office of Research Integrity (ORI) in conducting a study endorsed by the Association of American Medical Colleges (AAMC) which is directed at learning about the nature and extent to which accredited medical schools have established guidelines or policies for the conduct of research. We are requesting that you send in a copy of any written guidelines your institution has and also fill out a short checklist of about 10 items to indicate if they are covered in your guidelines. The AAMC and ORI are planning on co-sponsoring a conference to present these study findings to the biomedical research community. Furthermore, we feel your participation will be beneficial to the medical school community in that it will contribute to developing a written resource useful for formulating or updating guidelines. This resource will include a content analysis of all guidelines received, without indicating the specific schools they are received from; and it may be of assistance to you and your institution in terms of reviewing or establishing your own guidelines. Would you be willing to participate in the study?

IF YES, INFORM RESPONDENT THAT THERE IS NO QUESTIONNAIRE FOR THIS STUDY AND ASK RESPONDENT IF NOW IS A CONVENIENT TIME TO DISCUSS OBTAINING THE GUIDELINES. *IF CONVENIENT*, ASK RESPONDENT WHETHER GUIDELINES EXIST AT THEIR INSTITUTION AND WHETHER THE "*MOST RECENT*" GUIDELINES ARE ON THE INTERNET. IF GUIDELINES ARE NOT ON INTERNET, SUPPLY RESPONDENT WITH ROW SCIENCES' MAILING ADDRESS, FAX NUMBER, OR E-MAIL ADDRESS. THEN, GO OVER CHECKLIST. THANK AND END.

***IF NOT CONVENIENT*, ESTABLISH WHETHER GUIDELINES EXIST AND A CONVENIENT TIME TO CALL BACK. IF CALL BACK IS NOT CONVENIENT, INFORM RESPONDENT THAT STUDY MATERIALS WILL BE MAILED AGAIN. THANK FOR PARTICIPATION AND END.**

IF NO, PROBE WHETHER GUIDELINES EXIST, THANK, AND END.

IF YES, We have not received your response. I was wondering, have you sent one?

IF NO, We would greatly appreciate your time, effort, and participation in this study. It will result in a resource document, useful to medical schools updating or setting up guidelines. It may be helpful to you and your institution

in this way. The AAMC and ORI are also planning on co-sponsoring a conference to present these study findings to the biomedical research community. Furthermore, we want you to understand that all analyses of content will be done without any mention of specific schools. So again, we would truly appreciate your participation. **(INFORM RESPONDENT THAT THERE IS NO QUESTIONNAIRE FOR THIS STUDY AND ASK RESPONDENT IF "NOW" IS A CONVENIENT TIME TO DISCUSS OBTAINING THE GUIDELINES. *IF CONVENIENT*, ASK RESPONDENT WHETHER GUIDELINES EXIST AT THEIR INSTITUTION AND WHETHER THE "*MOST RECENT*" GUIDELINES ARE ON THE INTERNET. IF GUIDELINES ARE NOT ON INTERNET, SUPPLY RESPONDENT WITH ROW SCIENCES' MAILING ADDRESS, FAX NUMBER, OR E-MAIL ADDRESS. THEN, GO OVER CHECKLIST. THANK AND END.)**

***IF NOT CONVENIENT*, ESTABLISH WHETHER GUIDELINES EXIST AND A CONVENIENT TIME TO CALL BACK. IF CALL BACK IS NOT CONVENIENT, SUPPLY RESPONDENT WITH ROW SCIENCES' MAILING ADDRESS, FAX NUMBER, OR E-MAIL ADDRESS. THANK FOR PARTICIPATION AND END.**

IF YES, Well, thank you. We truly appreciate your time, effort, and participation in the study. **(FIND OUT HOW LONG IT HAS BEEN SINCE SENDING THE SURVEY MATERIALS AND NOTE DATE.)**

IF OFFICIAL IS "NOT" AVAILABLE

(*Call back)* When is the best time to reach **(INSERT NAME OF RESPONSIBLE OFFICIAL)**? We will call back at that time. Thank you. **(TRY TO REACH OFFICIAL TWICE BEFORE LEAVING MESSAGE.)**

MATERIALS RECEIVED:

(*Leave Message*) **(INSERT NAME OF RESPONSIBLE OFFICIAL)** participated in the Office of Research Integrity's study, "Analysis of the Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components," and I am calling to extend our thanks for **(his/her)** time, effort, and participation in the study. We have received your school's research conducting guidelines and the survey checklist. Thank you.

MATERIALS "NOT" RECEIVED:

(*Leave Message*) We are currently conducting a survey endorsed by the Association of American Medical Colleges (AAMC) for the Office of Research Integrity under the Department of Health and Human Services. We sent **(INSERT NAME OF RESPONSIBLE OFFICIAL)** a letter inviting **(his/her)** participation. However, according to our records, we have not received a response, so we are following up. Can you please have **(INSERT NAME OF RESPONSIBLE OFFICIAL)** call me. Again, my name is **(INSERT YOUR NAME)** and I can be reached at **(INSERT YOUR TELEPHONE NUMBER)** between the hours of **(INSERT WORKING HOURS).** Thank you.

Appendix D
Thank-you Letter

Date
Respondent Name
Respondent Address

Dear Mr./Ms./Dr. [Respondent Name]:

We thank you for participating in the Office of Research Integrity (ORI) study, "Analysis of the Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components." Your time and effort are very much appreciated.

Your participation and that of others will enable the ORI to develop a valuable resource guide that will assist medical schools and other research institutions to formulate or update their guidelines. In addition, the ORI and the Association of American Medical Colleges (AAMC) plan to co-sponsor a conference that will present the study findings to the biomedical research community.

Again, thank you for your participation.

Sincerely,

Jennifer Douglas-Vidas, M.A.
Research Analyst/Project Manager
ROW Sciences, Inc.
1700 Research Boulevard, Suite 400
Rockville, MD 20850