Grant Writing Workshop

Program & Simulated Grants for Discussion

November 2000
ORI Research Conference on Research Integrity*

November 20, 2000

Preface

The *simulated* grant applications that follow are not genuine. *They should not be viewed as model applications*. The personal names used in the applicants do not refer to any particular person. Some of the articles cited in the bibliography are fictitious. Some obvious and some not-so-obvious weaknesses have deliberately been written in to foster discussion about the attributes of successful applications.

Research grant applications pass through a multi-stage review process on their way to a final decision. Applications must be competitive at every stage to succeed.

- At submission grant applications are reviewed for completeness and relevance. Has the application form* been filled out properly? Is all required information included? Is the application complete? Is it relevant to the RFA?
- Complete applications are sent to individual peer reviewers who are familiar with some aspect of the research being proposed. They comment on the credentials of the research team, their familiarity with existing research in the field, and the soundness of the research methods. Has the research been described clearly? Is it likely to succeed? Will the results be significant?
- Finally, the application and peer review comments are reviewed collectively with other applications by a panel of peers, who further comment on the relevance, methods, expertise, budgets, and other aspects of the proposal.

Perceived weakness, confusing explanations, or incomplete information at any stage can undermine the competitiveness of an application.

The interdisciplinary nature of research on research integrity (RRI) increases the challenge of preparing competitive applications. Researchers must understand the research field they are proposing to study. If social-science methods are used, they must be fully described and sensitive to methodological nuances. Proper sampling and statistical analyses must be used. When appropriate, a theoretical framework should be provided. Relevant research in other fields should be brought in to lend support. As a consequence, researchers in any one of a wide range of fields could be asked to comment on the research being proposed in an RRI application.

The final review panel passing judgments on applications could easily include a bench scientist, a health-care professional, a survey researcher, a statistician, a psychologist or sociologist, a lawyer or a philosopher, each of whom is an established scholar in her or his own field. In reviewing the simulated applications that follow, ask yourself how each one would respond to these proposals? Then ask the same question when you get ready to submit your own proposal.

Nicholas H. Steneck

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* Applications for the ORI/NINDS RRI program should use the form for PHS 398 available at: http://grants.nih.gov/grants/funding/phs398/phs398.html.
The RFA and related links can be found at: http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-01-008.html.

Program

1:00-2:30 pm Process, Purpose, and Pitfalls of Research on Research Integrity
Michael Zigmond, Ph.D., University of Pittsburgh
Beth Fischer, Ph.D., University of Pittsburgh
Lilian Pubols, Ph.D., NINDS, NIH

2:45-4:00 pm Mock Grant Review (small group discussions)

Group I
Paul Friedman
Beth Fischer

Group II
Stanley Korenman
Mary Scheetz

Group III
Michael Zigmond
Peter Yeager

Group IV
Frank Macrina
Barry Markovsky

Group V
Lilian Pubols
Mark Frankel

4:15-5:00 pm Lessons and Next Steps Comments:

Contents

I: Assessing Research Integrity on a Major Research University Campus: Applied versus Basic Sciences

CO-PIs:

Susan Robinson, Ph.D. Curriculum Coordinator, Continuing Medical Education, BSU Medical School

Dieter Burr, Ph.D., Research Scientist, Sociology, BSU College of Arts and Sciences

A. Specific Aims

This study will provide a quantitative, discipline-specific analysis of research integrity on a major university campus. Data will be collected by means of an internet-administered survey posted on the university website. Information from the survey will be entered into a database, sorted by discipline, and analyzed, looking particularly at reported behaviors, attitudes toward integrity in research, and knowledge of research regulations and professional norms. We predict, based on prior research in the field, that researchers in applied disciplines will be more aware of research norms and regulations than researchers in basic science disciplines, will have had more research ethics training, but will also report and adopt lower standards for ethical behavior. No similar studies have been undertaken. Information gained from this study will be useful for policy making.

B. Background and Significance

Integrity is undeniably the foundation on which all research lies. Research that lacks integrity lacks credibility and therefore has no value. And yet, despite the importance of integrity in research, very little is know about the current state of integrity in research, the attitudes of researchers toward integrity, and the way research norms are conveyed to researchers in training, particularly within key institutional settings. In public statements, spokespersons for the research community often claim that the level of integrity in research is high, as evidenced by the fact that misconduct in research is supposedly "rare." But in surveys of researchers' knowledge of misconduct, significant numbers report that they are aware of misconduct, that many of the cases they know are not reported, and that they themselves have not reported the misconduct that they have observed (Kalichman 1992; Hals 1993; Swazey 1993; Hals 1994; Bekkelund 1995; Eastwood 1996). The difference between these two views of integrity in research is significant.

Efforts to refine knowledge both of the current state of integrity in research and of the attitudes of individual researchers toward misconduct have tended to focus on particular target groups. Kalichman and Eastwood looked at biomedical trainees (Kalichman 1992; Eastwood 1996). Swazey, Anderson, and Lewis broadened their survey to include faculty and graduate students in several disciplinary areas (Swazey 1993; Anderson 1999). Hals and Bekkelund studied one group of PIs (Hals 1993; Hals 1994; Bekkelund 1995). Korenman and Braxton have looked at small samples of researchers (Korenman 1993; Korenman 1993; Korenman 1998; Braxton 1999; Braxton 1999). The only study of an entire institution by Tangney is now fifteen years out of date (Tangney 1987).

Understanding how integrity functions in institutional settings is vital to understanding research integrity. Researchers essentially work in two overlapping but distinct institutional settings. In one setting, as specialists, their work is grounded in a particular research community, which is organized in different ways. Most formally, the research community is represented by professional societies and journals. Less formally it takes the form of affiliated research groups, bound together through cohort linkages and implicit psycho-social normative frameworks (Bulger, 1990; Bogason, 2000). In the other setting, as employees and academics, the work of researchers rests within and is influenced by the administrative and professional framework of the modern research university. Here too there are formal structures, such as research regulations and administrative guidelines, as well as informal frameworks, such as the "research environment," peer networks, and personal relationship.

This projects seeks to clarify, document with quantitative measures, and deconstruct the role the modern research institution plays in shaping and influencing research integrity by undertaking a comprehensive survey of the attitudes of researchers on the campus of one major research university. We intent to look specifically at the four Mertonian norms commonly used to measure scientific attitudes (Merton 1942). However, we will also look at research integrity through the commonly applied but poorly understood distinction between basic and applied research. It is sometimes argued that financial pressures and conflicts of interest heighten researchers' awareness of the importance of integrity in research but at the same time such pressures and conflicts encourage them to set lower standards for integrity (Lasslo 1994). If this is true, it could have major implications for research integrity policy. However, the link between the pressures of practical application and the funding needs and opportunities that go with these pressures has never been tested. We intend, through our survey and subsequent data analysis, to shed light on this crucial link.

C. Preliminary Studies

Our work in this field has its origin in prior studies of fraud in managed care. Studies have shown that fraud in managed care has an institutional component. While it is true that some fraud can be traced to individual actions, more commonly the presence of and even the amount of fraud, defined as making unjustifiable or unsupported claims for medical reimbursement, can unquestionably be linked to institutional management styles, profits goals, and employment security (Di Giovanni 1995; Blumstein 1996; Blumstein 1996; Jost 1996; Gallagher 1997; anonymous 1998; Chaffee 1998; Kleinke 1998; Jost 2000) Our studies, conducted by a sociologists and a medical education specialist, have shown that fraud is more likely to occur (16/22 (73%); $p < 0.001$) in large, multi-layered organizations that over-emphasize profit and loose sight of the importance of health care delivery (Burr 1998; Fredericks 1998; Richstone 1998).

Our prior work on managed care has pioneered the use of internet-based survey techniques in assessing health care settings. It is well know that internet surveys have the capacity to reach large audiences, but at the risk of confusing survey results (Keller 1996; Arnold 1997; Levine 1999; Schlosser 1999; Sheehan 1999). The internet-administered survey is not as controlled as the personal survey or even the mail survey. We have

designed tools that help us validate results by collecting email addresses and other data on survey participants. This allows us to check survey accuracy and assess who is participating (Ho 1998; Richstone 1998; Burr 1999). We plan to apply these techniques in gaining information about the attitudes of researchers toward research integrity.

D. Research Design and Methods

We have selected BS (big state) University, our home institution, as the target for our study. Based on the size of research budgets, it has been ranked in the top twenty for the last ten years and is classed as a Carnegie One institution. It has about 4,000 "research faculty," counting tenure-track faculty, research scientists, instructors, lecturers, and post-doctoral students. (We are not including graduate students.) BSU has been committed to computer use for about a decade, so we are confident that the majority of faculty have access to the internet. Those who do not have internet access are unlikely to be active researchers and are thus not relevant to our survey.

Period I: Develop survey instrument (2 months)

During the first two months of the project, we plan to develop and pilot our on-line survey. The tentative survey included in this application (Figure 1) represents a sample of likely questions. We are planning to have the survey cover five areas:

- Personal information
- Research environment and orientation
- Knowledge of research norms
- Attitudes toward questionable research behavior
- Research behavior

During the pilot stage we will: 1) refine the questions asked under each area, 2) administer them to a group of volunteer researchers, 3) discuss their answers with them so we can be sure they are understanding the questions, 3) refine the questions as needed, and, finally, 4) produce the final on-line version of the survey.

Period II: Administer Survey (2 months)

Once the survey is refined and on-line, we plan to announce it broadly on campus, using the official campus newspaper (The BS Chronicle) as well as email group names that cover the governing faculty and select departments. Regular mail will not be used since faculty who do not read email will be unlikely to respond to an on-line survey.

After the survey has been on-line for about one month, we plan to correlate responses with the full faculty email list. Faculty who have not responded will be sent a group reminder. A similar process will be followed two weeks later. We anticipate that in the end, we should be able to achieve a minimum of a 60% response rate and ideally more than 80%.

Survey Organization (tentative)	
1. Personal Information	a. department
	b. disciplinary specialty
	c. race and gender
	d. academic rank, position, and salary
2. Research environment	a. laboratory size and organization
	b. major orientation, basic/applied
	c. inter-personal relations – friendly, competitive, supportive
	d. extra-laboratory relations – share information, competitive, hostile
3. Knowledge of R&R	a. Misconduct – definition, reporting, confidentiality
	b. Human subjects – role of IRB, reporting, protocol adherence
	c. Authorship & publication – proper credits, significant publications
	d. Conflict of interest – definition, reporting, compliance
4. Research norms	a. Plagiarism or authorship scenario
	b. Conflict of interest scenario
	c. Human subjects scenario
	d. Data management scenario
5. Research behavior	a. FFP?
	b. Questionable authorship practices?
	c. Conflict of interest?
	d. Improper mentoring?
	e. Failure to report misconduct?

Figure 1

Period III: Analyze data (4 months)

We anticipate that it will take approximately four months to run analyses of the data collected in the survey and draw conclusions. Each section will yield the following information:

Personal information. The data collected in this section will give us a profile of our survey population, including: gender, race, professional rank, primary job description, years in service, salary, primary research orientation, and basic versus applied researcher.

Research environment. This section also provides a profile, in the case of the laboratory environment. Each laboratory or research setting will be coded by: size, level of funding, and source of funding as well as emotive qualities such as competitiveness, openness, attitude toward individuals, and primary goals.

Knowledge of research norms. The questions in this section seek to determine how much researchers know about the rules and regulations governing research. The questions are primarily factual in nature and therefore can easily be graded. Researchers either know or do not know the rules and regulations that govern research.

Attitudes toward questionable research behavior. This section poses a series of hypothetical situations to which researchers must respond. We are seeking to determine which actions they find mesh with accepted norms, which compromise accepted norms. These questions will essential clarify each of the respondents normative framework for

good research practice. We will compare the norms identified by our research community with the four Mertonian norms (universalism, communality, disinterestedness, and organized skepticism).

Research behavior. Having established the normative standards for good practice in research, this section gathers information on whether researchers adhere to those standards. We will ask researchers not only about their own conduct but about the conduct of their colleagues.

Our general approach to data analysis will be to use descriptive statistics to make generalizations about major trends. Links between particular major descriptive elements and single variables will be made though one-way analyses of variance. When more than one variable is being studied, we will turn to regression analysis, using standard tests and measures of significance.

Our primary goal is to assess whether the pressure of applied research has any impact on knowledge of rules and regulations, accepted norms for professional behavior, and reported behavior. As noted, we are anticipating that applied researchers will be more aware of research rules and regulations, that they will perhaps set higher standards for ideal behavior, but that they will report lower standards for actual behavior. We also plan to test whether gender, race, laboratory atmosphere, and other variables play any role in knowledge of rules and regulations, perceptions of normative standards, or actual research practices.

Period IV: Final reports (4 months)

During the final four months of this project we will prepare articles and give at least one presentation at a professional meeting, most likely the annual meeting of the Association for Practical and Professional Ethics. We will also report to our own university and make the results of our research available to the Association of Research Administrators.

E. Human Subject

We intend to use only aggregate personal information from this survey and will make no correlations between individuals (identified by email address) and specific answers. We are also conducting this survey at a public university, whose operations are open to public investigation. Therefore, human subject approval is not needed. The information that will be reported from this project is entirely in the public domain.

F. Vertebrate Animals

N/A

G. Literature Cited

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DD Principal Investigator/Program Director (Last, first, middle): _____

DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY

FROM 2/1/01 THROUGH 1/31/02

PERSONNEL (Applicant organization only) NAME	ROLE ON PROJECT	TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents) SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Susan Robinson	Principal Investigator	9	.2	42,000	8,400	2,100	10,500
Dieter Burr		9	.1	38,000	3,800	950	4,750
Research Assist.		6	1	28,000	14,000	3,500	17,500
Web Programmer		3	.5	38,000	4,750	1,188	5,938
SUBTOTALS →					30,950	7738	38,688

CONSULTANT COSTS

EQUIPMENT (Itemize)

Computer for data analysis plus statistical software package 3,000

SUPPLIES (Itemize by category)

TRAVEL

PATIENT CARE COSTS: INPATIENT; OUTPATIENT

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD $ 3,000

CONSORTIUM/CONTRACTUAL COSTS: DIRECT COSTS; FACILITIES AND ADMINISTRATION COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page) → $ 41,688

PHS 398 (Rev. 4/98) (Form Page 4) Page _____ DD
Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 3a, 3b..

Budget

II: Responsible data Management: Practices and Perceptions

CO-PIs:

Majik Pforinzaler, Ph.D. Organizational Management, School of Business Management, Prestigious University.

Carely Smith, M.D., Ph.D., Department of Family Practice, Prestigious University, and Clinical Chief, Prestigious Hospital.

A. Summary

This study will document in specific detail how data is managed in prion research and assess whether these practices conform to commonly accepted standards for good research practice. Prion research has been chosen because it cuts across many disciplinary lines, is international, is carried out in both public and private research laboratories, has only recently emerged as a major research area, and has relevance to both basic research and clinical studies. We will assess data management practices and perceptions by: a) visiting 30 randomly selected but representative laboratories to document in detail their data management practices, b) reviewing all of the publications from these laboratories to correlate data practices with the use of data in publications, c) formulating a series of normative statements about good data management practices based on the actual research practices of the laboratories visited, d) getting reaction to these practices from researchers in prion research through a presentation and survey form administered at an international meeting of prion researchers, and e) comparing the data management practices and perceptions of prion researchers with other researchers through a nationally administered survey of researchers in other fields. Our published results should provide specific evidence about data management practices and perceptions that will be useful to policy makers.

B. Background and Significance

Prions emerged as a major player in biomedical research in the late 1980s when they were tentatively implicated in Creutzfeldt-Jakob disease or “mad cow disease.” Since then there has been a rapid growth in prion research (Chapman 1993; Keohane 1994; DeArmond 1995; Yokoyama 1995; Buchwald 1996; Roberts 1996; Skjaerpe 1996; Vaughan 1996; Billeter 1997; Hansen 1997; Kondo 1997; Kondo 1997; Sande 1997; Baker 1998; Cohen 1998; Dormont 1998; Fishbein 1998; Gale 1998; Gonzales 1998; Grandien 1998; Hogan 1999; Marcotte 1999; Edskes 2000; Silvestri 2000). Although interest initially was greatest in England, where the outbreak of the disease was linked to the use of sheep bones in cattle feed, researchers world-wide soon turned their attention to prions, essentially creating a new and increasingly well organized research community.

The fact that prion research is newly emerged as a research field makes it ideal for the study of norms for good research practices. Research on group behavior has shown that groups are most aware of their common norms when they are newly emerged or in transition. Long-standing groups tend to act on tradition without conscious awareness of their norms. Practices also tend to be fixed and largely unjustified. Newly emerged groups are more conscious of norms, particularly when they are formed from diverse

communities (Bettenhausen 1996; Corfman 1998; Cosier 1998; Paese 1999; Schwartz 1992; Sims 1997; Schwartz 1994). We therefore predict that attention to norms for data management, which is essential to good research practice, will be more visible in the newly emerging field of prion research.

While good data management practices are essential to responsible research, data management in basic research has not be subject to scholarly investigation. Attention has been paid to clinical data management and the general impact of computers on data management (Keller 1991; Webster 1991; Banks 1995; anonymous 1996; van Es 1996; Dent 1998; Weiss 1998; Finkelsen 1999), but to date the way basic researchers handle data and the perceptions of good data management practices has been discussed primarily in editorials and broad policy statements, without much attention to actual data management practices. Our primary goal, therefore, is to establish a scholarly foundation for the discussion of data management based on actual data practices and the attitudes of researchers, both in the field of prion research and in research communities more broadly, toward those practices.

C. Preliminary Studies

With this project we are bringing expertise gained in research in other fields to bear on a problem of common interest and scholarly innovation. Dr. Pforinzaler is a specialist in organizational behavior, with particular interest in the way norms for good business practices are set. Prior work includes looking specifically at how norms are set in emerging organizations in areas of high innovation (Pforinzaler 1993; Pforinzaler 1996). Dr. Smith has been a pioneer in prion research, pursuing not only basic research but serving on research advisory committees and journal editorial boards (Helpert 1994; Smith 1997).

This project has its origins in a discussion of the future of prion research during the March 2000 meetings of the Neuro-molecular Mechanisms for Pathogenesis Conference held in Washington DC. At those meeting, questions were raised about the procedures researchers were using to collect data and their standards for data management. Several prominent researchers expressed the view that progress in the field was being slowed if not distorted by different management and reporting standards for basic research.

Following this meeting, Drs. Smith and Pforinzaler met to discuss whether research in other fields, such as organizational behavior, might help researchers better understand their own practices, as a way of perhaps establishing better standards for basic laboratory research. Dr. Pforinzaler subsequently visited Dr. Smith's laboratory and interviewed several post-doctoral fellows and two co-investigators to determine whether it was possible to objectify data management practices in a way that would allow correlated between laboratories. Based on these interviews, a data management grid was drawn up and sent to several of Dr. Smith's colleagues in prion research. They found the survey useful and made several suggestions for changes, which were subsequently incorporated into our the research plan sketched out below.

While seeking comments on our data-management grid, we also informally asked the

researchers reviewing the grid if they would be willing to serve as research subjects for this project. All readily agreed, suggesting that we will not have trouble enlisting sufficient laboratories to participate in this study. We also have informal confirmation that we can distribute our findings for comment at the 2001 meetings of the Neuro-molecular Mechanisms for Pathogenesis Conference.

D. Research Design and Methods

We plan to undertake this study in five stages:

1. Random selection of 30 laboratories for study
2. Site visits to the 30 laboratories
3. Compilation of data from site visits into normative practices list
4. Review of the normative practices list by the prion research community
5. Review of the normative practices list by the scientific community

1. Random selection of 30 laboratories for study. To identify 30 randomly selected prion research laboratories for study, we will first construct a comprehensive list of laboratories from the Neuro-molecular Mechanisms for Pathogenesis Society (N-MMPS) mailing list and the lists contained on several comprehensive prior-research websites. The latter will be especially important for identifying industrial laboratories, since N-MMPS is made up primarily of academic researchers. We will then sort the list into three categories: 1) U.S. academic, 2) European academic, and 3) industrial/private (both U.S. and European). By selecting every nth entry, where "n" is derived by dividing the full sample by 10, we will identify an initial pool of 30 laboratories to contact. If all do not agree to laboratory visits, we will continue to select random laboratories until we have a full cohort of 30 laboratories to study.

2. Site visits. During step one above, we will recruit and train three research assistants in the use of the data-management grid and passive observation of data management practices in laboratory settings. They will then visit ten laboratories each over the next ten week, spending about one week in each laboratory. During that time they will conduct a series of structured interviews with all key laboratory personnel and spend at least two days observing laboratory practices. Their notes will be recorded and sent back weekly to the central laboratory for analysis and coding.

3. Compilation of data from site visits into normative practices list. When all of the data has been assembled, we will sort the information in the data-management grid by category and then with the help of the notes from the structured interviews and passive prepare a list of normative practices for data management in prior research. We will also construct around each normative value a range of practices representing higher and lower standards for practice.

4. Review of the normative practices list by the prion research community. The results of our site visit will be presented at the 2001 N-MMPS meetings as part of a panel discussion of research methods. We will also have a single dedicated computer at the meetings, which will have a survey that participants at the meeting can use to comment on the proposed normative practices. Participants will be asked to comment specifically

on whether the existing normative practices for data management, as identified in our study, are appropriate for research in this area or if different standards ought to be encouraged. This information will be quantified by translating the range of practices into a numerical scale that respondents can use to indicate where they would locate ideal practice.

5. Review of the normative practices list by the scientific community. To assess whether the normative practices for data management identified by prion researchers are seen as appropriate by other researchers, we plan to give a similar presentation accompanied by a computer survey at a major national meeting of scientists, such as the annual AAAS meetings. This will not only serve to validate or critique the normative standards used by prion researchers but also to announce the results of our research to the large_ research community. The results will also be drawn together in one or more articles in relevant journals.

E. Human Subjects

This research involves no medical treatments or invasive procedures. Participation is voluntary and by consent. Therefore, human subject approval is not needed.

F. Vertebrate Animals

N/A, no animals are used

G. Literature Cited

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Budget

DD Principal Investigator/Program Director *(Last, first, middle)*: _____

DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY

FROM 1/1/01 THROUGH 12/31/01

PERSONNEL *(Applicant organization only)*	ROLE ON PROJECT	TYPE APPT	% EFFORT	INST. BASE	DOLLAR AMOUNT REQUESTED *(omit cents)*		
Maiik Pforinzaler		12	.50	100,000	75,000	22,500	97,500
Carely Smith	Principal Investigator	12	.50	150,000	112,500	33,750	146,250
Interviewers (3)		6	1.0	40,000	120,000	36,000	156,000
Data entry per.		6	1.0	40,000	40,000	12,000	52,000
SUBTOTALS →					347,500	104,250	451,750

CONSULTANT COSTS

Computer for presentation at meetings — 12,000

SUPPLIES *(Itemize by category)*

Software, phone, mail, miscellaneous office — 20,000

TRAVEL 10 weeks x 3 @ $200 plus air // 3 professional meetings — 50,000

PATIENT CARE COSTS — INPATIENT

OUTPATIENT

ALTERATIONS AND RENOVATIONS *(Itemize by category)*

OTHER EXPENSES *(Itemize by category)*

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD $ 82,000

CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS

FACILITIES AND ADMINISTRATION COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* → $ 533,750

PHS 398 (Rev. 4/98) (Form Page 4) Page _____ DD

Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 3a, 3b..