Abstracts

ORI Research Conference on Research Integrity*

(November 2000)

Nicholas H. Steneck, Ph.D.
Mary D. Scheetz, Ph.D.

Conference Co-chairs

(November 2000)

***Co-sponsors include:**

American Association for the Advancement of Science
Association of American Medical Colleges
National Institutes of Health
National Science Foundation

Abstracts

1. Current and Emerging Issues, Sunday, 9:00 -10:15 (Korenman)

Preventing Scientific Misconduct: Insights from "Convicted Offenders"

Mark S. Davis, Justice Research & Advocacy, Inc.

Michelle L. Riske, Justice Research & Advocacy, Inc.

Objective: The purpose of this study-in-progress is to explore from a social psychological perspective the etiology of scientific misconduct and its resulting stigma. Using Cressey's notion of a non-shareable problem, we posit that researchers who engage in misconduct may have a problem such as the inability to perform replicable work or to write successful grants that prompts them to violate principles of ethical conduct. Employing equity theory, we suggest that for some scientists, research misconduct is an attempt to restore real or perceived inequity. Finally, using the labeling perspective we assert that some researchers found guilty of misconduct suffer a unique stigma and, as a result, are subsequently cut off from certain future opportunities, including the chance to re-offend. **Design:** This study employs two sources of data. The first are written summaries prepared from the case files of the Office of Research Integrity (ORI). A data collection instrument has been used to record data including the type of misconduct, the institution's response, whether the accused admitted to the allegations, and the case's final disposition. The second source of data is telephone interviews with selected scientists who have been found guilty by ORI of research misconduct. Manual and computer-assisted content analysis are used to generate frequencies. **Results:** Limited support was found in these data for the existence of non-shareable problems and for the effects of stigma. The consequences of termination of employment and the inability to apply for research funds, in addition to the stigma associated with debarment, appear to have had negative career consequences for a number of the researchers found guilty of scientific misconduct. **Conclusions:** These preliminary data suggest that etiology can be inferred from the concepts extracted from the data, as can a number of preventive strategies.

Ethical Evaluation of Misconduct Cases

Doric Little, University of Hawaii System

Martin Rayner, University of Hawaii System

Objective: to evaluate factors resulting in the effective resolution of recent misconduct cases brought before our Ethics Committee. **Design:** we have evaluated both the processes adopted by the Review Panels and the outcomes of six successive cases in 1999. **Results:** indicate that in each of these cases our Review Panels were instructed to evaluate all major ethical issues involved, rather than to concentrate solely on the validity of the complainant's accusation. Despite the diversity of the initial complaints, ranging from exclusion from authorship to fabrication of data, ethical analysis showed that each of these cases resulted from the breakdown of formerly productive collaborative research efforts. In each instance, we were struck by an almost inescapable parallel to the events associated with rancorous divorces and their subsequent property and custody disputes.

This insight facilitated evaluation of the complex interactions between the participants as well as the levels of ethical misconduct apparent in the behaviors of the participants. **Conclusions:** are that many cases may be more readily evaluated via ethical analysis than where attention becomes too focussed on the validity of the initial complaint. We see a need for Review Panels to evaluate all complaints with a careful and even-handed approach. They may need to pay as much attention to the underlying causes of a problem as to the guilt or innocence of the accused. They should be ready to assist in developing and promulgating guidelines for appropriate behavior in scientific collaborations, whether these occur between individuals of equivalent or of highly disparate rank. Finally, we note that Review Panels appear to reach consensus more readily where ethical evaluations of both parties to a dispute are taken into account.

What is Driving Policies on Faculty Conflict of Interest?

Mildred K. Cho, Stanford University Center for Biomedical Ethics, University of California, San Francisco

Ryo Shohara, Institute for Health Policy Studies, University of California, San Francisco

Drummond Rennie, Institute for Health Policy Studies, University of California, San Francisco

Objective: To describe the factors driving the development of policies on faculty conflicts of interest at US academic institutions. **Design:** Descriptive literature review. **Results:** The factors driving the development of conflict of interest policies include (1) the increase in industry funding of research, (2) the increase in faculty financial interests in companies sponsoring their research, (3) increased public scrutiny of academic-industry ties because of press attention to adverse effects of such ties (especially in research involving human subjects). Furthermore, there is growing evidence that industry ties affect the quality, outcome and publication of research. In response to these factors, the federal government and research institutions have implemented policies on the disclosure and "management" of researchers' conflicts of interest. However, these policies are limited in scope. **Conclusions:** Given the continuing trend in the growth of academic-industry ties, the federal government and research institutions will likely and should rethink current policies, taking into account the following considerations: (1) Conflict of interest policies should be framed in terms of *situations* that place a researcher in a conflicted position, rather than in terms of inappropriate *actions* resulting from financial interests or unwanted *effects* of financial interests, (i.e. conflict of interest is NOT misconduct), (2) Conflict of interest "management" should not be confined to disclosure, (3) Institutions would benefit from conflict of interest policies that are flexible enough to deal with all situations, yet clearly communicate limits on financial interests to researchers and the public, and (4) Policy makers should consider the potential effects of policies being developed and administered by institutions that, in themselves, also have conflicts of interest. Policies on institutional conflicts of interest are necessary.

The Work of the Committee on Publication Ethics (COPE)

Mike Farthing, Editor, Gut; Chairman of COPE

Richard Horton, Editor, Lancet

Richard Smith, Editor, British Medical Journal

Alex Williamson, Publishing Director, BMJ Publishing Group

The Committee on Publication Ethics (COPE) is an informal group founded in 1997 as a response to growing anxiety about the integrity of authors submitting studies to medical journals. Founded by British medical editors--including those of the BMJ, Gut, and Lancet--the committee had five aims:

(1) To advise on cases brought by editors. Cases are presented anonymously, and full responsibility for action remains with the reporting editor. The committee has so far considered 103 cases. In 80 cases there was evidence of misconduct. Several cases have been referred to employers and to regulatory bodies like Britain's General Medical Council. The commonest problems were undeclared redundant publication or submission (29 cases), disputes over authorship (18), falsification (15), failure to obtain informed consent (11), performing unethical research (11), failure to gain approval from an ethics committee (10), and fabrication of data.

(2) Publish an annual report describing the cases it considers. The committee has published two annual reports and established a website (www.publicationethics.org.uk). A third annual report will be published in December 2000.

(3) Draft guidance on these issues. The committee drafted guidelines and after extensive consultation published them in 1999 (available on the website). They have been adopted by many journals.

(4) Promote research into publication ethics. Little has been achieved so far.

(5) Consider offering teaching and training. The committee has run two seminars, and individual members of the committee have lectured and taught on research misconduct.

COPE has also been concerned to ensure that the scientific community in Britain responds to research misconduct. Britain has now had several high profile cases of research misconduct but has yet to make a coherent response to the problem. Several bodies, including the Royal Society and the General Medical Council, are currently considering the problem, and COPE has been important both in spurring these bodies to action and in contributing to a response. COPE might have proved to be a temporary body, but members of the committee judge that its work must continue. It has thus produced a draft constitution that will be published in December 2000.

2. Research Practices and Ideals, Sunday, 10:30-12:00 (Fischbach)

What Would Get You in Trouble: Doctoral Students' Conceptions of Science and Its Norms

Melissa S. Anderson, University of Minnesota

Objective: This paper addresses the question: How do first-year doctoral students conceptualize the normative underpinnings of science? It examines students' perspectives on the normative imperatives to which science is subject, the sources of those imperatives, and mistakes to be avoided in the context of those imperatives. The paper addresses these points in light of students' overall views on the dynamics of scientific work in their fields. **Design:** This paper is based on semi-structured interviews with thirty students at the end of their first year of doctoral study at a major research university. **Results:** Students' conceptualizations of their fields and related norms are dominated by a functional (task-related) orientation, though some exhibit a social or relational perspective on science. Their conceptualizations of instrumental (career-related) and specifically ethical norms are notably inchoate. Many see professional organizations and public funding agencies as highly influential in the development of the normative bases of their fields, and very few exhibit any sense of the construction of scientific norms by the practicing members of the field. Their sense of potential mistakes shows little connection to the scientific work around them, but focuses instead on either violations of interpersonal norms or famous cases of scientific misconduct. **Conclusions:** The findings presented in this paper demonstrate the narrowness of students' conceptualizations of their fields and related norms. Their rudimentary sense of "how science works" and "who makes the rules" suggests that instructional initiatives in the responsible conduct of science may assume a greater sophistication about science than first-year doctoral students have.

Faculty and Graduate Student Perceptions of Questionable Research Conduct Scenarios

Ravisha Mathur, Purdue University

Stuart I. Offenbach, Purdue University

Objective: Mentors “teach” us the culture of science (e.g., honesty, reporting all collected data, etc.), but no one has determined how this happens. In this study, we examined student and faculty perceptions of questionable research practices and their knowledge of those practices. **Design:** 225 faculty members and 47 doctoral students completed questionnaires on their research community, lab climate, basic demographic information, and 38 brief vignettes describing ethical problems in research and their solutions. Similarities and differences of the student and faculty responses were examined. **Results:** Faculty and graduate students believed supportive faculty members provided ethics and values information (72% and 60% respectively). Compared to the students, more faculty members believed professional organizations provided ethics

information (67% vs. 15%). Students relied more on other graduate students, courses, labs, and seminars. Responses to the dilemmas were similar for both groups, but faculty members were more certain of their views than were the students. A factor analysis of dilemma responses yielded five factors: Information sharing in the lab: Truth/Completeness; Plagiarism; Seeking credit; and Consent Issues. There were few substantive differences between the student and faculty factor scores, but there was one consistent and notable gender difference -- women were more concerned with plagiarism than were their male counterparts. We also asked about the role departments should and actually do take in preparing students to recognize and deal with ethical issues. Both faculty and students believed academic departments should take a more significant role than they currently do in training graduate students to recognize and deal with ethical issues. **Conclusions:** Faculty and students believe training in the responsible conduct of research should be supported by their departments. Even without formal training, students and faculty recognize misconduct situations. In addition, faculty members were more certain of their views (probably because of their greater experience).

Diversity in Everyday Research Practice: The Case of Data Editing

Erin Leahey, UNC Chapel Hill

Barbara Entwisle, UNC Chapel Hill

Peter Einaudi, UNC Chapel Hill

Objective: We aimed to document variation in attitudes about editing data and to examine factors that may affect such attitudes. We refer to data editing as a collection of data- and sample-altering procedures used by researchers to "correct" raw data. We hypothesize that a) there will be a wide range of opinion about how to handle problematic data, and b) situational factors and intellectual communities affect such opinions. **Design:** We surveyed 160 faculty members within the disciplines of sociology, anthropology, and psychology across the United States. The focus of the survey was a hypothetical vignette in which a particular data problem and a proposed edit were described. We asked respondents to comment on the problem and the proposed edit. **Results:** We found a wide range of variation in attitudes toward data editing. Many respondents thought that raw, unmassaged data are “pure,” and tampering with data in any way upsets data integrity. Others saw data editing as a regular part of data collection, particularly in qualitative work. Quantification of the vignette responses along two main dimensions (*nature of the objection (if any)* and *type of recommendation provided)* demonstrated that although most respondents objected to the proposed edit, there was much less consensus about what to do instead. In a multivariate framework, we found that specific aspects of the situation (mode of data collection and type of problematic variable – independent or dependent) and membership in intellectual communities (based on discipline but not research experience) affect objections and, to a lesser extent, recommendations for editing data. **Conclusions:** There is some agreement about the acceptability of particular data edits, but there is much less agreement on what researchers should do given problematic data. It appears that normative standards that pervade other aspects of the research process have not yet emerged for data editing.

Ethical Research Practice with Human Participants: Problems, Procedures, and Beliefs of Funded Researchers

Elana Newman, University of Tulsa

Victoria McCoy, University of Tulsa (Presenter)

Anthony Rhodes, University of Tulsa

Objective: This preliminary study examined ethical procedures of federally funded researchers working with human participants. The goals of this study were to document: (1) how researchers implement informed consent procedures; and (2) incidence of "research risk" defined as (a) confidentiality violations for suicide, homicide, and abuse status, (b) participants' condition worsening and (c) complaints filed against a researcher or institution**. Design:** After applying exclusionary criteria, 314 researchers investigating schizophrenia, lung-cardiovascular disease, affective disorders, traumatic stress or normal cognition were contacted by letter and asked to complete a 7-page survey. **Results:** The 102 respondents were mostly Ph.D (72%), male (63%), and Caucasian (95%). Twenty percent (20%) reported training in research ethics during advanced research training. In the most recent study, most (97%) researchers reported using written informed consent, with 55% communicating instances in which confidentiality might be broken (58% of those reported using specific rather than general terms). Breaking confidentiality rarely occurred (7%), although confidentiality dilemmas were encountered (chart to be presented). Only 54% of researchers reported knowing how many participants experienced research related injury, with 12 researchers reporting at least one research related injury (to be presented). Fifteen percent (15%) reported complaints about research staff's conduct. Two percent (2%) reported complaints filed against the institution (none resulting in legal proceedings). Conversely, 77% of researchers reported participants thanking them at least occasionally. **Conclusions:** This study addressed researchers' ethical practice and experience with research risk. Very few researchers reported formal training in research ethics. Researchers varied in the detail that they provide participants about limits of confidentiality. Few researchers were aware of whether participants' experienced a worsening of condition. Regarding research risk, a minority of researchers reported encountering confidentiality issues, worsening of conditions, and complaints from participants. Although the participation rate precludes generalization, these preliminary results provide information that can be useful in designing training and compliance policy.

The Construction of Research Ethics Involving Human Subjects at Michigan State University

Julie Reyes, Michigan State University

Objective: This paper examines whether and if informal communication is the most effective method for transmitting research ethics and values concerning the protection of human subjects among faculty and graduate students at Michigan State University. My research draws upon the Acadia Institute's national survey regarding ethics in higher education, that focused on the effectiveness of research ethics training utilizing formal

and informal interaction. I will discuss how the distinct culture of each department affects the transmission of ethics using formal and informal interaction among faculty members. **Design:** This research was conducted utilizing two anthropological methods, semi-structured, in-depth, open-ended interviews and direct observation of faculty members and graduate students within three departments at Michigan State University. For this research, 35 interviews were conducted, and direct observation occurred in each department (as well as attending one course devoted to teaching ethics) for approximately one year. **Results:** My analysis indicates that those departments that engage in collaborative research both within and outside of their own department have a better understanding of research ethics involving human subjects and are also more likely to engage in informal mechanisms of transmission. In addition, my research shows that the history of the department clearly affects the way in which the culture of ethics is constructed and embedded which also shapes the way research ethics is ultimately transmitted to faculty and graduate students. **Conclusions:** My research indicates that both formal and informal mechanisms for research ethics training are needed to effectively create a culture in which the protection of human subjects is valued and understood. The departments that conduct collaborative research both within and outside of their department are forced to address issues surrounding research ethics and the protection of human subjects, informally, due to the constant communication that is required to conduct the research. Interestingly, the department (which conducted the most collaborative research among the three studied), was also the first department to offer a comprehensive graduate course in research ethics. Finally, it is important to understand that the historical environment of the department clearly shapes the way in which research ethics is engendered among faculty and graduate students.

3a. Integrity and Biomedical Ethics, Sunday, 1:45-3:15 (Shipp)

The Ethics and Value of Research

David Casarett, University of Pennsylvania

Jason Karlawish, University of Pennsylvania

Objective: Ethically sound research should pose risks that are acceptable in proportion to any benefits to the subjects, and to the importance of the knowledge to be gained. Although recent years have seen a great deal of discussion about the analysis of research risks and benefits, far less attention has been devoted to assessing the importance of the knowledge that research produces. In this presentation, we report the results of two empirical studies that describe the ways in which research subjects expect to benefit form the results of the studies in which they participate. **Design:** The results of two studies will be described. One is an interview study of caregivers of patients with dementia who are considering enrolling a family member in a trial to evaluate an investigational therapy. The second is an interview study of patients with chronic pain. **Results:** An analysis both these studies of very different populations reveals a common set of expectations regarding the potential benefits of the results of research. Broadly, these expectations can be categorized as related to: 1) information about treatment that might benefit other patients, 2) information about the subject's current therapy; 3) information about the subject's disease or condition; and 4) future benefits from new therapies that are identified therapy. **Conclusions:** We offer a brief discussion of ways in which investigators can better meet these expectations, and we conclude by suggesting system-wide structural changes that will make this possible.

How to Provide Informed Consent in Minimal-Risk Research: Implementing Procedures that Account for Different Research Contexts

Carolyn L. Funk, Virginia Commonwealth University

Judith Bradford, Virginia Commonwealth University

Objective: This study evaluates whether the procedures commonly used in minimal-risk telephone surveys to provide informed consent work as they are intended. We also test whether these procedures have any unintended effects on participant reactions to the research experience. **Design:** An experimental design embedded in a telephone survey systematically compared participant reaction to explicit and implicit verbal statements related to informed consent. The experimental design was tested in two survey contexts: one, a survey on health behaviors (The Behavioral Risk Factor Surveillance System) and two, a survey on social and political topics (The Commonwealth Poll). In both surveys, random samples of adults living in Virginia were interviewed. **Results:** Dependent measures came from participant ratings of their experience in the survey study. There was no evidence that the explicit statements had the intended effects. Those receiving such assurances were not less likely to express worry over confidentiality issues or the voluntary nature of the research. Nor were those who received such assurances less likely

to ask questions about the research study. Do the explicit statements do any harm? The answer is possibly. There was some indication that explicit verbal statements about confidentiality increase anxiety about the research for some subgroups of participants. **Conclusions:** Explicit statements detailing the voluntary and confidential nature of the research in telephone survey introductions are often thought to constitute the best procedure for providing informed consent. This study finds no evidence that explicit statements of this kind have the desired effects; instead, such statements may have an undesired effect of raising anxiety among some participants. We close with specific policy recommendations that take into account the minimal-risk context of the research setting and address differences between subgroups of subjects in terms of their concern over ethical practices in research.

Conflicts between Clinical and Research Obligations

Charles W. Lidz, University of Massachusetts Medical School

Objective: Clinical co-PIs and research nurses play a critical role in clinical trials and other clinical research. Many such individuals are also involved in routine clinical care and have deep commitments to the norms of personal care that ordinarily guides clinical work. The research has begun to explore the ways in which such individuals manage the conflicting norms of clinical care and clinical research and to describe its implications for the research studies. **Design:** Data comes from two different studies of informed consent to research. Both of these studies involved interviewing patients about their understanding of to what they were consenting. Both studies also involved interviewing clinicians about the nature of the protocols. The interviews with clinicians were not designed to gather data on role conflicts among clinical investigators so that the results are only suggestive of issues. **Results:** A number of different patterns were found. Most affect recruitment. One nurse reported that she was currently recruiting subjects only for a project where the results were already known. Another refused to recruit subjects for several of the protocols that her faculty employer was signed up as a Co-Investigator. Other nurses report that they can get Co-Investigators to recruit subjects to trials only when the Co-Investigators feel that the research drug would be a better treatment than other available treatments. More dramatically, one psychiatric clinical Co-Investigator encouraged patients to try to learn the side effects of the anti-depressant so that they could guess whether they were receiving placebo and not become depressed when the code was broken. **Conclusions:** Although the data is episodic in nature, it suggests that deviations from research protocols in medical research may not simply reflect personal ambitions or other egotistical motives but might be systematically related to ethical conflicts between clinical and research norms.

Responsible Research Conduct That Balances Risks And Benefits Of Deception In Assessing Genetic Screening Utilization For Alcoholism

R. Scott Olds, Kent State University

Dennis L. Thombs, Kent State University

Colleen Mahoney, Mahoney Consulting Group

Objective: It was hypothesized that intensity of current alcohol use, recent history of alcohol problems, family history of drinking problems and readiness to change drinking behavior would predict genetic testing intentions and use for alcoholism in a college student sample. **Design:** A questionnaire was administered to181 students before and after viewing a presentation that accurately explained genetic susceptibility to alcoholism, but misled by offering "a newly available" test; a bogus manipulation. The use of deception was considered essential to accurately assess college student interest in genetic screening for alcoholism susceptibility. Alcohol variables, including frequency and quantity of consumption, frequency of heavy drinking and drunkenness, knowledge of blood relatives with apparent drinking problems and readiness to change drinking behaviors were assessed before the presentation. Test-seeking intention and reasons for and against testing were assessed after the presentation. Research participants were debriefed by letter one week after the presentation and could withdraw their data if so desired. One individual elected to do so. **Results:** Only 6.6% of the sample indicated a strong intention to schedule a test. Regression analysis found that significant predictors of testing intention were being Caucasian, females who were somewhat older than traditional college age and had a history of early drunkenness. **Conclusion:** Results are preliminary because of the small, non-randomized sample. The selected variables accounted for only 8% of the variance in test-seeking intention. Thus, the hypothesis that a range of alcohol measures would predict testing intention was not supported. If screening for alcoholism susceptibility becomes a strategy for prevention, research will be needed to identify ways to promote the service. Ethical, behavioral efficacy and financial questions remain unanswered regarding genetic screening for alcoholism susceptibility.

Increasing Research Integrity through Direct Involvement of People with Disabilities

Kathleen C. Sadao, University of the Pacific, Stockton, California

Nancy B. Robinson, California State University, Chico, California

Objective: The study reported in this paper investigated the direct involvement of persons with disabilities and family members to teach special education and related services professionals. Results are discussed in relation to the efficacy of involving persons with disabilities and family members as teaching and research partners. Person-focused learning approaches are based on the development of interactive teaching models used increasingly in disability-related personnel preparation programs. The involvement of actual families and persons with disabilities in the student learning process promotes application of theoretical knowledge and attitudinal change. In

research and teaching involving people with disabilities, social validity is increased through the direct involvement of people who experience disability daily. Participatory action research, a component of qualitative research, is based on the involvement of key stakeholders in all phases of investigation. In the present study, partnerships with persons with disabilities and family members were established and continued throughout the design, implementation, and evaluation of co-teaching activities. **Method:** The study was completed in the context of three courses at different university sites, with 71 students and 7 families including persons with disabilities. While course content differed across the three sites, teaching methods were similar. Teaching partnerships were implemented according to principles of "Family Centered Care," in which family concerns drive professional interventions. Key steps in the teaching partnership included: (a) determination of family priorities; (b) adaptations to meet family and individual needs; (c) family input in project development; and (d) evaluation of completed projects by family members and persons with disabilities. Student learning outcomes were evaluated with qualitative and quantitative surveys. Family and individual outcomes were identified through structured interviews. **Results and Discussion:** Analysis of student surveys identified seven themes: (a) disability awareness;(b) attitudes; (c) "real life problems"; (d) critical thinking; (e) inclusion preparation; (f) parents' perspectives; (g) self -efficacy; and (h) skills to adapt materials. Family and individual interviews revealed four themes: (a) interaction with students; (b) self-validation; (c) support networks; and (d) alternatives to meet individual needs. Families and individuals commented that they would participate again. Ethical issues identified included the need to (a) respect individual choice in participation; (b) confidentiality; (c) honor individual priorities; and (d) respect family differences. To date, results indicate that direct involvement of persons with disabilities in the teaching process provides authentic learning that cannot be replicated with traditional didactic methods.

3b. Social Science Perspective on Research Integrity, Sunday, 1:45-3:15 (Montgomery)

How to Avoid Reinventing Wheels in Research on Research Integrity

Robert J. Baum, University of Florida

Objective: The goal of this conceptual analysis of the scholarly literature is to illustrate the ways in which researchers on Research Integrity can avoid expending significant amounts of time and effort "reinventing wheels" which already are available "off the shelf." **Design:** I survey some of the most valuable areas where researchers interested in RRI can find many materials that will provide them with theoretical frameworks, empirical data, and protocols and instruments for RRI. I use the field of Accounting as a concrete illustration of a nonscientific field where professionals work extensively with large quantities of data and are subjected to many pressures to falsify, fabricate, “massage” and "interpret" this data. **Results:** The American Institute of Certified Public Accountants has developed a very detailed set of rules, procedures and case interpretations to define and provide guidance to members with regard to Professional Integrity. Literally scores of essays and hundreds of research studies have been published on the concepts of fabrication, falsification, etc. in the accounting context. Not only is the *data* generated by these studies relevant to scientific research integrity, but the *methodologies* and *instruments* used in these studies could be used with little or no modification for studies of FF&P in scientific research. Many other fields have well-developed codes and standards of professional conduct, large theoretical literatures and extensive bases of empirical research studies on defining the concepts of fabrication, falsification and plagiarism. These fields include engineering, journalism, marketing, and securities analysis. **Conclusion:** Researchers on research integrity can learn much from others who have already "been there and done that" in fields outside science.

Scientific Misconduct as Organizational Deviance

Robert Dingwall, University of Nottingham, UK

Objective: To review the relevance of the social scientific study of organizational deviance for the understanding and prevention of scientific misconduct. **Design:** Outline of relevant literature from the study of organizations and of white-collar crime, particularly as synthesized in the work of Diane Vaughan on the Revco fraud and the Challenger shuttle disaster. Its application to press coverage of the Gelsinger case and data from a short period of participant observation in a university genetic science laboratory. **Results:** Some reflections on the organizational basis of scientific misconduct **Conclusions:** Scientific misconduct should be addressed as a matter of organizational culture and design and of inter-organizational relations as much as an object of regulatory rule-making. A legalistic approach may be less effective than one which relies on the reinforcement of social norms within the scientific community.

A Market Approach to Research Integrity

Aditi Gowri, University of Texas

Objective: To broaden our understanding of what research integrity means. **Design:** The working procedure is conceptual analysis of *research, integrity,* and related categories. Tools include a model of science as shared enterprise undertaken by research communities and founded in conventions; the idea of a marketplace of ideas; aspects of the theory of supply and demand; and theories of professional and collective responsibility. **Results:** A field of knowledge may lack integrity even where each of its practitioners conducts honest, legitimate research. The demand for knowledge, manifest in offers to fund research, calls forth a supply of knowledge products corresponding to the interests of grantors by delimiting what questions and research programs can be pursued by most researchers. Hence the body of scientific knowledge is skewed by the market for research funding and may become misleading to this extent. The analytic argument is illustrated by a case study. Studies of the genetic causes of disease and mortality have been generously funded, but environmental and psycho-social causes are not similarly well-funded. Aggregate statistical studies suggest that research into the latter models and causes of disease would be productive. However, since the demand for these types of studies is weak, they have not proliferated. This example is meant to be illustrative only; and the general thesis of the paper stands independent of whether the reader accepts its validity. **Conclusion:** If the community of science is collectively responsible for the integrity of scientific knowledge as a body, then research on research integrity must include attention to the market for and distribution of knowledge producing efforts and not only to the legitimacy and honesty of each separate effort. Further descriptive and analytic studies of this issue are well warranted.

Organizational Influences on Scientific Integrity

Michael D. Mumford, The University of Oklahoma

Whitney B. Helton, The University of Oklahoma

Objective: Broadly speaking, the intent of the present study was to examine the nature and role of organizational influences on scientific integrity. Initially, an attempt was made to assess the relative importance of individual and situational variables in determining unethical behavior. Subsequently, the general situation variables identified in this study were to be used to specify the kind of situational variables likely to influence scientific integrity in organizational settings. **Design:** A series of interlocking experimental and field investigations were conducted to identify the individual and situational factors related to integrity. In the first set of investigations, measures were developed to assess seven individual characteristics related to integrity, including 1) fear, 2) narcissism, 3) outcome certainty, 4) power motives, 5) object beliefs, 6) negative life themes, and 7) lack of self-regulation. In the second set of investigations, measures were developed to assess characteristics of the situation that might influence integrity including 1) alienation, 2) exposure to negative peer groups, 3) stress, 4) exposure to a non-supportive family, 5) exposure to negative roles models, 6) competitive pressure, and

7) financial need. **Results:** When six measures of integrity commonly used to appraise dishonest or unethical behavior were regressed on these measures of individual and situational influences the following three findings were obtained. First, individual variables (e.g., fear, narcissism) were related ($r = .32$) to integrity. Second, the situational variables (e.g., alienation, competitive pressure) were better predictors of integrity than the individual variables producing an average multiple correlation of .47. Third, when the situational variables were added to the individual variables significant ($p < .01$) gains in prediction were obtained with the average multiple correlation increasing to .53. **Conclusions:** The results obtained in the present study indicate that situational variables may be as important, if not more so, in conditioning unethical behavior than characteristics. Subsequently, the ways in which these situational variables might manifest themselves in organizational settings were assessed at the individual, group, and organizational levels. At the individual level, integrity appears linked to overload, lack of collegial support, a focus on extrinsic rewards, and lack of involvement with the work. At the group level, poor leadership, lack of consensus, competitive pressure, and normlessness were identified as significant influences. At the organizational level, the organization's operating environment, specifically its turbulence, munificence, and interdependence, along with the organization's climate, specifically its emphasis on trust, fairness, and openness, were found to be related to integrity. The implications of these observations for minimizing incidents of scientific misconduct were discussed.

Research Integrity for the Social Sciences: Defining the Issues

Robert J. Silverman, The Fielding Institute

Objective: There has been limited attention given to issues of research integrity in fields other than the natural sciences. Forgery has been examined in literature, and there has been some attention to the social sciences through cases and through an examination of plagiarism in the postmodern environment, but there has been relative silence here. Clearly, the silence can be interpreted in a number of ways. This lack of attention, which is not active denial, is likely based on the assumption that the norms of scholarship and their abrogation are the same as in the natural sciences. Even if that were to be the case, which this presentation challenges, the actual production of knowledge in the social sciences, with their methodologically-connected options, such as interpretive/qualitative approaches, makes the discovery of non-normative practices challenging, conditions that have not been addressed by those who operate in a more fully replicable knowledge environment. This presentation does not identify fields or areas by their common names, such as anthropology or feminist studies, but uses a framework in which different scholarship areas are located for the consideration of this problem and need. Over the years, there have been attempts to develop frameworks for the placement of different fields of study, not for the purposes identified here, but to examine, differentially, the nature of academic leadership, the productivity of faculty, and the strategies and tactics of fields as they engage with internal and external interests. Given these different practices, there is no reason to believe that what should be considered "non normative" should not vary as well. **Design:** This paper presents a framework for differentiating among fields of study based on aspects of the academic community and the kind of work with which

the community engages. The framework is presented using concepts with contemporary meaning though its roots can be traced to ancient Greece. It has been re-invented by such philosophers as Richard McKeon and Stephen Pepper. We discuss the meaning of research integrity for the four following domains: 1) a fact-oriented domain, 2) a grand theory/paradigmatic domain, 3) a problem-oriented domain, and 4) a person-oriented domain. **Results:** Research integrity has different meanings in these different academic environments, with fraud, fabrication, and plagiarism having primary significance for only the first. We suggest possible breaches for each of the domains noted above, basing these observations in appropriate material in the philosophy and sociology of science. These include blind and hostile advocacy, failing to recognize one's constructions as such, and failing to listen. The purpose here is not to expand the defining qualities of misconduct for the natural sciences but to create discussion for the social sciences that is central to the work of its engaged research communities. Denying such alternatives by resting in the natural science-based definition, it is claimed, is tantamount to a tacit acknowledgement of the irrelevancy of research integrity issues for much work done in the social sciences. **Conclusion:** Recognizing the heuristic quality of this paper, it closes with a suggested research agenda.

3c. The Influence of Institutions and Professional Societies, Sunday, 1:45-3:15 (Yeager)

Academic Culture and the Development of Professional Identity in the Professorate: Constructing a Personal Model of Research

L. Earle Reybold, The University of Texas at San Antonio

Objective: The purpose of this study was to describe the role of academic culture in determining ethical research practice. The study was framed by research questions concerning professional identity and ethical decision-making in research. **Design:** This pilot study launches a longitudinal investigation of doctoral students' perceptions of their academic preparation and development of professional identity as faculty in education. This phase employed a qualitative case study method; data were collected through semi-structured interviews and guided reflection journal sessions with seven doctoral students at three universities in Georgia and Texas. Data were analyzed using a qualitative software program, and themes were developed using the constant comparative method of analysis. **Results:** While most participants define ethical research dilemmas in terms of methods, their experiences focus more on relationships and issues of power and coercion. Every student in this study has experienced one or more ethical research dilemmas involving a professor. These dilemmas include observation of children without parental consent, data manipulation during analysis, usurping student work, and authorship recognition. Several factors hinder ethical research. First, institutions reward research productivity that translates to an emphasis on publication numbers. A second factor is the role of submission in hierarchical academic relationships. Graduate students are afraid to report ethical violations; they fear losing their assistantships and professorial support. A third factor is the lack of training and exposure to guidelines. Only one participant reports that research ethics were discussed in her doctoral research classes. **Conclusions:** Trustworthy research demands attention to ethics, but academe generally fails to prepare educational researchers to deal with ethical dilemmas. In turn, untrained students become faculty members who perpetuate ignorance of research ethics. Future inquiry will explore (a) the development of professional identity throughout preparation for the professorate, and (b) how this emerging identity impacts professional decision-making as a scholar.

An Exploration of Accountability in Research Science

Kalpana Shankar, University of California, Los Angeles

Objective: The purpose of this study is to describe in detail the relationships between scientific practice, accountability, and the use of records and recordkeeping in an academic research laboratory from the perspectives of those conducting the research. **Design:** Conduct an ethnographic study of approximately eight hours per week, for several months, in one academic research laboratory. The particularly laboratory was chosen because the Principal Investigator is sympathetic to social science research, and employs a number of postdoctoral fellows, graduate students, and undergraduates. Code

field notes for recurring themes for further analysis and for developing a grounded theory base. These themes include research accountability, recordkeeping, scientific "memory", and meanings of science and being a scientist. Conduct interviews with laboratory participants with questions generated from participant-observation component of the study. Open-ended questions will focus on personal concepts of accountability and their use of documents and records. **Results:** Because the study is only in its preliminary stages, it is too early to discuss results. However, I have begun to use the standard ethnographic tools of coding and memoing to create "thick description" and "grounded theory" related to the issues stated in the objective. Some emergent themes based on the research conducted to this date that will be investigated further. These themes include the role of mentoring, the maintenance of adequate records, and the role of the principal investigators in fostering accountability and good scientific practice. **Conclusions:** Ethnographic methods in general do not lend themselves to formal conclusions, but instead help elucidate relationships and themes that can be further explored using less particularistic approaches. However, certain emergent themes can be stated for the group under study at this point in time, which suggest avenues for further exploration: Ethnographic and other qualitative social science methods are useful for understanding how science as a daily practice is conducted. Instilling concepts of integrity and accountability in scientists may be as much a matter of the culture of the workgroup is it is a matter of classroom teaching. Scientific accountability in practice is a complex phenomenon that can be studied at numerous levels – to self, to the profession, to colleagues, to the supervisor, to the employing institution, even to the public and consumers of science.

Research Integrity in Social Work: Status, Issues, and Future Directions

Margaret Gibelman, Yeshiva University

Objective: To identify the emerging themes and issues in regard to research misconduct in social work and explore how these themes inform a research agenda and educational programming. **Design:** Cases of scientific misconduct in the social and behavioral sciences in which allegations have been made and/or violation of ethical research standards have been substantiated were identified by means of a ten year search of the *Chronicle of Higher Education*, major national newspapers, and available data from the National Association of Social Workers and subjected to a content analysis to identify and categorize emerging themes. **Results:** "Bogus" research, plagiarism, and lax informed consent and confidentiality safeguards are among the emerging themes in social work research. The content analysis suggests weaknesses in institutional mechanisms to review research protocols and the lack of adequate jurisdiction of the professional association over cases of misconduct. **Conclusions:** The integrity of social work research has, by and large, been ignored, in part because of the early stage of development of the research enterprise. However, the issue of research integrity takes on increasing importance as social work gains a legitimate role in the conduct of scientific inquiry. The profession is likely to experience a stronger imperative to engage in research as demands for accountability, including measured outcomes of services, continues to grow. A research protocol is proposed to assess the status of institutional mechanisms in higher

education and practice agencies to review and monitor research in social work. Implementation of the proposed “research about research integrity” protocol will produce data to form the basis for developing targeted educational programs for the social work community.

The Relative Efficiency of the Inquisitional and Adversarial Models for Research Misconduct Investigations Involving Personal Injury

Andrew J. Hogan, Michigan State University

Ronald J. Patterson, Michigan State University

Robert L. Sprague, University of Illinois-Urbana/Champaign

Objective: To test whether the presence of personal injury associated with a research misconduct allegation influences the likelihood of a post-investigation proceeding (lawsuit, grievance, legislative hearing, administrative inquiry, etc.) using adversarial or inquisitional models of investigation. **Design:** Using the files of Dr. Robert Sprague of the University of Illinois-Urbana/Champaign containing 1,100 references on the 231 research misconduct cases, we identified 63 cases with adequate documentation of cases of alleged misconduct involving personal injury or injury to the scientific record. A personal injury case was one in which a person directly involved in the misconduct allegation identified some kind of personal loss, usually misappropriation of intellectual property. A scientific record case was one involving some form of contamination of the scientific record, usually falsification/ fabrication but sometimes misappropriation of the intellectual property of non-parties to the allegation. Twenty cases were reviewed twice to establish inter-rater reliability using a data collection tool. **Results:** Logistic regression analysis indicated that the presence of a personal injury increased the odds of a post- investigation proceeding roughly tenfold. Any controversies regarding the role of the university attorney in the research misconduct case tended to increase the likelihood of a post-investigation proceeding, while the allegation being made in the context of a funded grant tended to reduce the likelihood of a post-investigation proceeding. However, these results related to university legal counsel and the grant context were only marginally statistically significant. **Conclusions**: Because we were able to identify virtually no research misconduct investigations employing an adversarial model, we were not able to determine whether that model would result in fewer post- investigation disputes than the inquisitional model.

Factors That Foster And Inhibit Self-Correction In Science

June Price Tangney, George Mason University

Objective: The problem of scientific fraud has been highlighted by several widely publicized cases. In response, many scientists reassure themselves (and others) that science has a built-in self-corrective process in the form of replication. The assumption is that the rare fraudulent report will be promptly discovered by a failure to replicate. How valid is this assumptions? **Design:** Review of documented cases of scientific fraud and survey of scientists' attitudes toward scientific misconduct. Application of theory and

research on “by-stander intervention.” **Results:** Most incidents of scientific fraud have been uncovered not by failure to replicate, but by a colleague's suspicions that were followed up by pointed inquiry. Thus, the key to self-correction lies in the social context of science, with “scientist bystanders” who stumble across grounds for suspicion. Survey results, however, indicate that scientists are generally reluctant to take action when faced with suspicions of scientific fraud. The dilemma facing “observing” scientists closely parallels that of the “innocent bystander,” who has been the focus of much theory and research. Latane and Darley (1970) posit that bystander intervention involves not just one decision, but a series of five sequential decision points, each open to external influence. First, there is the decision to notice the incident. If the incident is not noticed, no action will be taken. Second, the bystander must interpret the incident as an emergency requiring some intervention. Third, the bystander must assume responsibility to take action. Fourth, the bystander must know the appropriate form of action. And finally, the bystander must decide to implement the decision, despite its costs and risks. **Conclusions:** The “bystander” literature suggests specific policies and procedures that can facilitate self-correction in science - specifically, education and awareness, clear guidelines to aid the “scientist bystander” who suspects fraud, continued efforts to improve institutional procedures for responding to allegations, and attitude change within the broader scientific community.

3d. Integrity and Publication Practices, Sunday, 1:45-3:15 (Rennie)

Instructions to the Author: An Integrity Issue

Mary D. Scheetz, Office of Research Integrity, DHHS

Objectives: To determine what topics are covered in the instructions to authors other than manuscript preparation; to assess whether there are clusters and the frequency of the topics addressing particular themes; and to assess what topics related to research integrity are addressed. **Design:** A content analysis of the instructions to authors of those journals contacted by the U.S. Public Health Service requiring correction to the literature due to findings of scientific misconduct between 1992-1999. **Results:** Content themes were not equally represented. Of the 41 journal instructions reviewed, only one of the 44 content themes (copyright) was represented in more than 50% of the journals sampled. Eighteen of the 44 content themes were represented in less than 10% of the journals. Approximately 14 percent of the journals' instructions addressed issues related to correcting the literature due to research integrity concerns. **Conclusions:** Instructions to authors primarily focus on manuscript preparation. Some institutions address research integrity issues pertaining to publications through the use of sign-off forms, requiring the submission of data to a depository, and corrections or retractions of articles. Publishers and editors should consider expanding and standardizing instructions to authors to cover the complexities of communicating science.

Journal Conflict-of-Interest Policies and Their Impact

Sheldon Krimsky, Tufts University

Objective: The following questions are discussed: (1) How many journals have policies that address conflicts of interests (COI) of authors, reviewers, and editors?; (2) What is the nature and frequency of the personal financial disclosures published in journals with such policies?; and (3) What variations exist among journals with COI policies regarding the definition of and criteria for reporting "conflict of interest," and on the methods used to elicit disclosures from the targeted groups? **Methods:** A systematic study was made of 1400 high impact journals selected on the basis of two citation indicators used in the publication of *Journal Citation Reports*: "impact factor" and "times cited factor." **Results:** About 16 percent of the journals in the study sample had COI policies in their "instructions to authors" at sometime during 1997. A subset consisting of 181 journals with COI policies in effect throughout 1997 that were peer reviewed and published original research were analyzed. Rates of personal financial disclosure among journals are reported. Journals that use standardized templates to elicit author COI information are discussed. Alternative hypotheses are explored to explain the low rates of personal financial disclosures among journals with COI policies.

Plagiarism and Research Misconduct

Debra M. Parrish, Parrish Law Offices, Pittsburgh, Pennsylvania

Objective: To explore how plagiarism has been defined and applied in the context of scientific misconduct. Specifically, this study examined the relationship between allegations of plagiarism, copyright infringement, theft of intellectual property, and the different treatment those respective allegations receive depending on whether they are pursued under the Office of Research Integrity model or the National Science Foundation model. The study also explored the possible new treatment under the proposed new definition of scientific misconduct. **Design:** The study explored the various definitions of scientific misconduct used by federal agencies and legal principles of copyright infringement and "false passing off". Agency action was explored by examining the processes used to evaluate the cases, the defenses asserted by persons accused of plagiarism, and how the cases were resolved and the sanctions imposed, were examined by a review of the universe of cases closed by the Office of Research Integrity and the National Science Foundation through 1998 in which a finding of scientific misconduct was made based on plagiarism, and cases closed in which an allegation of plagiarism was made but did not result in a finding of misconduct. **Results:** Whether an allegation of plagiarism constitutes scientific misconduct, and the sanctions imposed, depends on which agency processes the allegation. Even if the new definition of research misconduct is adopted with its articulation of what constitutes plagiarism, cases involving allegations of plagiarism still will require a complex analysis that examines the relationship of collaborators, whether a unique component was plagiarized, the effect on reviewers or the careers of the relevant parties, the defenses asserted (e.g., lack of intent, aggravating and mitigating circumstances), and the practices of the discipline, institution or laboratory. **Conclusions:** The different processes by which federal agencies evaluate allegations of plagiarism affects whether an allegation will result in a finding of scientific misconduct. Although some in the field have asserted that plagiarism is a simple well-defined form of scientific misconduct, the assessment and treatment of allegations of plagiarism reveal a much more complex analysis that will continue even if the proposed definition of scientific misconduct is adopted.

Erratum Citation and Accuracy in the Publication Record

Marshall Thomsen, Eastern Michigan University

Christopher Aubin, Eastern Michigan University

Barbara Hall, Eastern Michigan University

Matthew Knee, Eastern Michigan University

Objective: Recognizing the importance of errata in providing a means to correct the publication record, we set out to determine the likelihood that an erratum would be cited in conjunction with the paper it corrected. A secondary goal was to assess the impact of electronic publication on erratum citation rates. Does the linking of an erratum to its original paper on a web version of the journal increase the likelihood that the erratum will be cited along with the original paper? **Design:** We selected fourteen papers from

Physical Review Letters, each of which has an associated erratum making a nontrivial correction. This particular journal was chosen due to the frequency with which its papers are cited and due to its availability in electronic format. Citations were located using the *Science Citation Index* with spot checking against the *Physical Review Index* for accuracy. **Results:** When there was an overlap in the authorship list of the corrected paper and a subsequent paper citing the corrected paper, we found that in just 42% of the cases (25 out of 59) did that subsequent paper cite the erratum. In the case of no authorship overlap, approximately 17% of papers citing the corrected paper also cited the erratum. This rate is actually less than that reported five years ago in a study that predated the electronic format of this journal. **Conclusions:** There clearly is a tendency not to cite errata in physics literature. The rationale for this tendency is not clear.

4. Problems and Outcomes of Research Ethics Training, Sunday, 3:30-5:15 (Macrina)

Assessing Training Efforts in the Responsible Conduct of Research: Status, Challenges, and Future Directions

Anna Mastroianni, University of Washington

Jeffrey Kahn, University of Minnesota

Objective: To describe institutional approaches to satisfying the NIH training requirement in the responsible conduct of research (RCR), and to draw some preliminary conclusions about the state of RCR education and training. **Design:** The authors reviewed materials describing U.S. training programs in RCR that had been collected by the U.S. Department of Health and Human Services (DHHS) in June-August 1996. The materials were submitted by a sample of grantee institutions in response to a request by DHHS. Institutional and programmatic characteristics were summarized and described. **Results:** Institutions in the sample employed a diversity of approaches to satisfying the training grant requirement. Further, the number of training grants held at the institution had some impact on how the training grant requirement was met. The authors found that two thirds of the 45 institutions represented in the materials provided RCR training only to those trainees whom they were required to train, although among the rest of the institutions, a few required that all trainees receive such training. The training programs studied were quite diverse regarding who was responsible for the program (the principal investigator, the ethics faculty, etc.), what kinds of instruction were given (lectures, seminars, small-group discussions, etc.), course content, and how discipline-specific the focus of instruction. **Conclusions:** This assessment is a valuable first stop in describing institutional responses to the NIH training grant requirement. It indicates the need for further research on institutional approaches to education and training in RCR, including research on characteristics of training programs, effectiveness of training initiatives, and on how to broaden current training efforts to ensure that all scientists in training are prepared to address ethical dilemmas in their professional careers. Obstacles to effective RCR training include the needs for culture change and for sizable faculty, financial, course time, and administrative resources; and the need for proper evaluation of programs. Effective RCR training can be fostered by sharing of resources, identifying competencies, tailoring teaching to individual institution's and department's characteristics, and public-private partnerships.

Research Ethics in U.S. Medical Education: An Analysis of Ethics Syllabi

James M. DuBois, St. Louis University

Jill Ciesla, St. Louis University

Kevin Voss, St. Louis University

Background: Medical education trains future physicians as medical practitioners. For this reason ethics education for medical students has traditionally focused on themes revolving around the patient-physician relationship: veracity, informed consent, fidelity,

confidentiality, beneficence, non-maleficence, and the like. While many of these themes overlap with themes in research ethics, these ethics courses may be inadequate for those future physicians who will engage in research of any kind – including clinical trials, patient surveys, or program assessments. Research ethics introduces new and important themes related to experimental design, interaction with communities, and the dissemination of information. The well being of patients, physicians, and research institutions is at stake when physicians fail to abide by rules for ethical research. Recent, highly publicized failures to follow protocol at major medical centers reinforce the idea that Institutional Review Boards (IRBs) are inadequate to ensure ethical research behavior. These facts give rise to an important research question: *To what extent is research ethics incorporated into the ethics curriculum at medical schools in the US?* **Objectives:** To determine: (a) how many medical schools require formal ethics education, (b) what are the course objectives, teaching methods, course content, and methods of student evaluation in these courses, and (c) among those schools that teach research ethics, what specific topics are covered. **Method:** A survey was sent to all curriculum directors of 4-year medical schools in the US (N=121) listed with the AAMC with a request for course syllabi for all required, formal ethics components in the 4-year curriculum. Syllabi were coded and analyzed to produce a profile of course objectives, teaching methods, course content, and student assessment methods. Those syllabi that address research ethics were then further analyzed for specific content in research ethics. **Results:** Surveys were returned by 72% of the schools (n=87). Seventy-nine percent (n=69) of these schools claimed to require a formal ethics course. Of these schools, 84% (n=58) provided ethics course syllabi. Analysis and codification of all syllabi identified 10 course objectives, 8 teaching methods, 39 content areas, and 6 methods of student assessment. The mean for individual schools was 3 objectives, 4 teaching methods, 13 content areas, and 2 methods of assessment. 23 of the 58 syllabi (39.6%) addressed research ethics in some fashion. Analysis of the research ethics sections of these syllabi revealed 84 specific themes that fall under 17 different general topics (such as clinical trials, embryo research, and the IRB). The average number of general research ethics topics addressed in these 23 syllabi is 6, with individual schools covering anywhere from 1 to 11 topics. Only six topics were covered by more than half of those syllabi that address research ethics. In rank order these are: clinical trials; informed consent; general ethics of human subject research; government committees, regulations and codes; history and background to research ethics; and protecting vulnerable populations. No research ethics topic was covered by more than 31% of all syllabi for required formal ethics components. The number of research ethics topics covered did not correlate significantly with either school enrollment or tuition costs. The significance of these findings will be discussed in the presentation.

Influencing the Moral Dimensions of Professional Practice: Implications for Teaching and Assessing for Research Integrity

Muriel J. Bebeau, University of Minnesota

Implications for teaching and assessing for research integrity are drawn from (1) pretest/posttest data for 18 cohorts of dental students who completed a well-validated

ethics program, (2) pre/post assessments of 28 practitioners referred by a licensing Board for ethics instruction, and (3) efforts in several professions to influence moral judgment development. Ethics curricula were designed to promote functional processes (Rest, 1983) that give rise to morality: (1) ethical sensitivity; (2) moral reasoning; (3) moral motivation and commitment; and (4) ethical implementation. Five measures assess the processes: (1) The Dental Ethical Sensitivity Test (Bebeau, Rest, & Yamoor, 1985) assesses interpretation of ethical issues hidden within professional problems; (2) The Defining Issues Test (Rest, 1979) measures life-span development of moral reasoning and judgment; (3) The Dental Ethical Reasoning and Judgment Test (Bebeau, & Thoma, 1999) assesses application of concepts taught in ethics courses (e.g., informed consent) to real cases; (4) The Professional Role Orientation Inventory (Bebeau, Born, & Ozar, 1993) assesses commitment to privilege professional values over personal values; and (5) a Professional Problem Solving Score (Bebeau, 1994) assesses problem solving and role-playing performance. Analyzing data from the sources cited indicates: (1) striking individual differences among students and practicing professionals on each of the measures; (2) that competence on one of the processes does not predict competence on another; (3) that curricula of rather modest duration can influence performance in measurable ways; and (4) that strengths and weaknesses in each of the processes are linked to real-life ethical behavior. The findings not only support Rest's contention that moral failings can result from deficiencies in one or more of the processes, but support the importance of attending to each when designing curriculum. Further, whether a curriculum promotes ethical development depends on whether that curriculum incorporates the elements of effective instruction.

Teaching Ethics in Biomedical Science: Effects on Moral Reasoning Skills

Elizabeth Heitman, University of Texas, Houston School of Public Health

Patricia J. Salis, University of Texas, Houston School of Public Health

Ruth Ellen Bulger, Uniformed Services University of the Health Sciences, Bethesda, MD

Objective: To determine whether an established lecture/case-discussion course on the responsible conduct of research (RCR) had a measurable effect on the moral reasoning of biomedical science graduate students. **Design:** Following an IRB-approved protocol, a total of 215 graduate students enrolled in a required semester-long RCR course were asked to complete Rest's Defining Issues Test (DIT) at the beginning (pre-test) and the end (post-test) of the 1997 and 1998 courses. Use of individual codes protected students' confidentiality. Computerized scoring by the University of Minnesota Center for the Study of Ethical Development generated P% scores (new validity checks), reflecting the degree of subjects' principled moral reasoning in six scenarios. Our analyses used students' change scores (post-test minus pre-test). We examined differences in change scores between the 1997 and 1998 classes (t-test, independent samples), and variations in change scores that could be attributed to students' sex and country of undergraduate education (analysis of variance, ANOVA). **Results:** 172 students (80% of 215) completed both a pre-test and post-test, 95 students in 1997 (87% of 109) and 77 in 1998 (73% of 106). Change scores did not differ significantly between the 1997 and 1998

classes. ANOVAs of subjects' change scores for the 1997 class, 1998 class, and the two classes combined failed to reveal any significant differences among groups for sex or country of undergraduate education. The interaction between sex and country factors was significant for the 1998 class (p=.03), primarily because the post-test scores of US-educated men (n=17) dropped in comparison to their pre-test scores, whereas for the women and the non US-educated men the post-test scores remained the same or rose slightly. **Conclusions:** Determining effective means of assessing the impact of RCR courses on students' knowledge, awareness, and reasoning will be essential to their success. Evaluations of various courses on professional ethics similar in structure and format to the course evaluated here have used the DIT to demonstrate improvements in students' moral reasoning skills. The finding that no change had occurred after this course suggests a need for more careful definition of specific goals, content, and methods.

Data Manipulation In The Undergraduate Classroom: What Are We Teaching?

Elizabeth W. Davidson, Arizona State University

Heather E. Cate, Arizona State University

Cecil M. Lewis, Jr., University of New Mexico

Melanie Hunter, Arizona State University

Objective: How common is data manipulation in the undergraduate laboratory, and what are its causes? **Design:** A survey of students in undergraduate Biology and Chemistry laboratory courses at Arizona State University was designed to relate the level of data manipulation admitted by students to commitment of the student (major vs. nonmajor), subject level, teaching techniques, the subject itself, the teaching assistant, and the class of the student. Data were analyzed by Spearman correlation. **Results:** From 84% to 91% of undergraduate students openly admitted to manipulating data "almost always" or "often" in the seven classes surveyed as well as in other classes. Manipulation did not decline with progress to upper division or majors classes in either Biology or Chemistry. Students reported observing manipulation by others at the same or higher frequencies. Most attributed motivation to the desire for a better grade. **Conclusions:** The primary motivation for this high level of overt data manipulation appears to be the notion that a "right" answer exists and that the "wrong" answer will lead to a lower grade. Redesign of laboratory exercises to stress the scientific method rather than "cook book" procedures in which students are expected to verify known biological, chemical, or physical laws can eliminate much of this manipulation. Graduate teaching assistants and faculty must eliminate grading based on achieving a preconceived result, in order to change the common conception among students that their grade depends upon producing the "right" answer. Although students must still be evaluated on whether they are using laboratory instruments accurately, laboratory exercises can be designed for training in the hypothetical-deductive process in addition to the specific laboratory technique. We believe this study should raise major concerns about the impact of the techniques used in

designing and evaluating undergraduate laboratory exercises on the ethical standards of future scientists and physicians.

Assessing the Teaching and Learning of Research Integrity: Research Opportunities

Carl Mitcham, Colorado School of Mines

Barbara M. Olds, Colorado School of Mines

Ronald L. Miller, Colorado School of Mines

Objective: Our aim is preliminary identification of aspects of the teaching and learning of research integrity calling for further assessment research. **Design:** Research has involved not only (a) literature review, but also (b) contacting a few key players in the field of research ethics education, and (c) informally surveying colleagues at the Colorado School of Mines, a technological university, about their concerns and needs in the areas of ethics teaching. On the basis of this initial data collection we have attempted to parse out what is and what is not being done, and what may profitably be attempted. **Results:** It is increasingly common at research universities to teach courses or modules on ethics in science and in engineering. To date, however, efforts to measure the effectiveness of such teaching has been limited. Lack of assessment is also common in the efforts of scientific professional societies to promote ethics. Learning assessment techniques have largely focused on confirming the effectiveness of single teaching strategies (mostly case studies) in the acquisition of moral reasoning skills. Comparisons of different teaching approaches and assessment of broad knowledge content acquisition or attitude changes are much less developed. There has also been little if any attempt to build bridges between concerns for scientific research integrity, professional engineering ethics, and public policy. **Conclusions:** One of the "emerging challenges for the responsible conduct of research" must be the development of multiple instruments for the assessment of teaching and learning about research integrity. There are special needs to compare alternative teaching techniques, to enlarge assessment instruments, and to develop consensus goals regarding content that can bridge science and engineering. To provide specific pointers in these direction we share early draft versions of two new instruments: one utilizing a naive cynicism-idealism attitude scale, the other focusing on a general knowledge base to integrate science, engineering, ethics, and public policy.

5. Poster Session, Sunday, 6:00-7:30

The Responsible Conduct of Animal Research

Lida Anestidou, University of Texas, Houston School of Public Health

Elizabeth Heitman, University of Texas, Houston School of Public Health

Objective: To assess the perceived need for more focused education and hands on training in the human use of animals for graduate students in the biomedical sciences, and to determine the feasibility of meeting this need through a structured graduate course in humane animal research. **Design:** We developed a course entitled "The Humane Use of Animals in Biomedical Research", combining historical, ethical, and regulatory considerations, with actual practical training on specific animal methodologies tailored to the educational needs of the individual students. In July 2000, a pilot version of this course enrolled 4 students who completed the didactic and laboratory components of the course and 2 auditors who completed the didactic portion only. The course's content, rationale, schedule, and interdisciplinary teaching faculty were assessed qualitatively by both students and faculty. **Results:** *Positive points*: comprehensive and challenging readings; IACUC regulations and activities; information on alternative methods to animal research; presence and guidance by institutional veterinarians; interdisciplinary viewpoints towards animal research ethics and practicalities; discussion of personal demands of research; enhanced rapport among students and faculty facilitated by intensive class format. *Drawbacks and obstacles*: intensive 2-week commitment very difficult to fit in students' daily schedule; summer faculty assignments difficult and logistically complex; discussion of alternative methodologies not enough; ethical ambiguity an uncomfortable issue for students in science, needs focusing on the links between ethical debate, science policy, and practical demands of research; high costs of laboratory materials for large enrollment. **Conclusions:** Teaching how to use animals in biomedical research should be a priority within advanced research education as it reflects essential training in the responsible conduct of research. It is both possible and desirable to approach education in the humane use of animals in research from a multidisciplinary perspective.

Research Integrity Training – Ethics Workshop Experiences of First Year Graduates

Georgia Ayscue, BS, Appalachian State University

An observational/interview survey of attendees of a recent university three-day workshop on research ethics for graduate students reveals the experiences and attitudes about ethics by first year graduate students. Survey addressed attitudes concerning research ethics prior to/after the workshops and face-to-face interviews were be conducted post workshop to determine the opinions of attendees pertaining to the educational value and impact of this ethics training seminar on topics of research related to human subjects, animals, and function of IRBs. Expected outcomes were greater emphasis placed on the

importance of integrity in research methodologies and enhanced awareness of proper ethical procedures and standards when conducting research on human subjects.

Using a Likert Scale survey/interview, attendees were asked questions about a number of issues prior to attending the workshops. Following attendance of the workshops, a follow-up face-to-face interview was conducted in a classroom setting group discussion format. The survey scale was calibrated accordingly: (SK) Some Knowledge, (ADQ) Adequate Knowledge Level, (VK) Very Knowledgeable, (NA) and Not Applicable. The study was conducted to determine: a) the interest of the students in an ethics training workshop, b) the prior opinions of research integrity held by the students, c) the degree of relevance the topic of research integrity had on their program of study and major.

When given the opportunity to voluntarily attend the workshops, all the students stated they didn't understand why it would be necessary to attend. All but one student stipulated that ethics was not relevant to their chosen major and profession. The student group consisted of first year dietetic interns studying to be registered dietitians who will be having future direct human subject contact in their daily work.

Subsequently, the students were told to attend the workshops as a requirement of class attendance by their departmental professor. After attending all three workshops, the graduate students voiced negative experiences from having participated in the three-day event. The students felt material was presented in a manner "over their heads" and each student continued to fail in recognizing the importance of ethical behavior when conducting scientific research involving human subjects. Using regression analysis on the survey/interview results, it was determined that the structure and presentation of the workshops needed to be reviewed due to the overwhelming negative responses of the graduate students attending.

Teaching the Responsible Conduct of Research to Postdoctoral Fellows: Experiences and Feedback

William Boggan, Medical University of South Carolina

Billy Baggett, Medical University of South Carolina

A Course on the Responsible Conduct of Research has been offered to all postdoctoral fellows and faculty at the Medical University of South Carolina (MUSC) in the fall and spring of each year since the Spring of 1996. The eighteen-hour course was organized in response to the increasing recognition that students and faculty generally lacked such educational experiences. It was formulated by a faculty committee and had a proposed target audience of postdoctoral fellows. Other initiatives targeted at other members of the academic community are also underway.

The format of the course has been a presentation of the current and proposed definition of scientific misconduct, data on the incidence of misconduct and who is involved, and guidelines from Moral Reasoning in Scientific Research by Bebeau et al, 1995 on "Developing a Well-Reasoned Response to a Moral Problem". In addition the bulk of the course consists of informal discussions of case scenarios (taken from Korenman and Shipp, 1994), having to do scientific research ethics. Complimenting these cases are various articles having to do with the topic of interest on a particular day.

The discussions are facilitated by invited faculty, who briefly describe their background and research, as well as by the course directors. Usually a different faculty member is invited to participate in each session. The topics discussed follow those in the Korenman and Shipp book Teaching the Responsible Conduct of Research". Examples include, but are not limited to mentor - student - institution relationships, scientific record keeping, data ownership, intellectual property, authorship, plagiarism, peer review and confidentially, scientific misconduct, use of animals in research, use of humans in research, genetic technology, public money - private gain or for profit science, and whistleblower rights.

As of the fall of 1999, 123 fellows have successfully completed the course, which is defined as attendance of 70% of the sessions. It should be noted that class size is limited to about 20 fellows to facilitate discussion. Fellows attending are predominantly basic scientists and though clinical fellows also attend. The fellows are culturally diverse reflecting the nature of the postdoctoral fellow group at MUSC which is comprised of approximated 70% foreign scientists. This cultural diversity has added an important and interesting dimension to the course and discussions within.

Comprehensive Guidelines for the Responsible Conduct of Researchers

Gregory W. Brock, University of Kentucky

Sandra Sutter, University of Kentucky

Ada Sue Selwitz, University of Kentucky

Objective: Initially our goal was to survey the research integrity literature for standards and guidelines directing the conduct of research and to use the results as a foundation for training researchers at the University of Kentucky. What emerged is a document that presents for the first time a comprehensive set of guidelines for the conduct of researchers. **Design:** Content analysis was applied to an exhaustive list of behavioral guidelines identified in the research integrity literature. Guidelines were sorted and combined into discrete categories. **Results:** Three categories of principles emerged: General-principles (4) apply to all research contexts. Professional-principles (6) define relations among researchers and practices that constitute the scientific method. Focused-principles (4) address discrete aspects of research practice for particular investigations, research contexts, or scientific disciplines. Sub-principles within each principle elucidate contemporary issues rather than identifying all of the components of any principle. **Conclusions:** The guidelines provide a broad based foundation for the safe and effective practice of research across disciplines, settings, methods, and questions. Included as well is the realm of activities constituting the work of researchers that ranges well beyond the conduct of research and that influences the public trust, that affects global well being, and that indirectly affects the scientific record. The inclusion of these activities expands the conceptual and behavioral makeup of RCR training and establishes a comprehensive set of conduct guidelines for researchers.

Conflicts Surrounding Formation of Independent Companies by Faculty Members

Rose S. Fife, M.D., Indiana University School of Medicine

Objective: To discuss issues arising surrounding conflicts of interest arising from formation of independent companies by academic faculty members. **Design:** The types of companies formed by faculty members appear, in a simplistic construct, to fall into the categories of those in which patents or other licenses are involved and those without such formal arrangements. The formulae created by most universities for the sharing of royalty streams generated from patents or licenses are usually straightforward and standardized. However, the issues ensuing from technology or assays that are not covered by such formal agreements are somewhat more complex and may vary from case to case. **Results:** The creation of new companies, many associated with biotechnology related to research arising from work conducted in a faculty member's university laboratory as a result of either internal or extramural funding, is a growing activity in our medical schools. When the work has been conducted with university support, whether it is faculty time, grant support, infrastructure, it is usually deemed appropriate for the institution to take a partial proprietary stake, particularly in the form of royalties or other revenue streams generated. The formulae for such distributions vary from institution to institution. In most cases, a patentable product or process has resulted from the research that has led to the formation of the company, and this patent is of commercial interest, leading to licensing or outright purchase by an external corporate entity. In this case, an investigator may receive an ownership position or stock in addition to his/her royalty share. In the other scenario that may arise, no patent is involved, but there is a process that can form the basis of an independent company, one which might result in subsequent similar revenue-generating processes. If an outside company wants to purchase such an entity, then the revenues can be divided between the investigator and the school, as they would be for a patentable item. However, if there is no such outside purchaser or supporter and the faculty member wishes to create the company and play a role in its operation, then the problem arises as to how much time he/she can devote to it. **Conclusions:** The issue of how large an equity stake a faculty member can own without the perception of his/her being subject to an undue amount of financial remuneration remains in dispute. Since a scenario may apply to a diagnostic tool and may lead to additional diagnostic tools that can be revenue generating, this issue is particularly germane to the clinician who developed the process and to his/her colleagues who might wish to purchase or submit specimens for the process. The resolution of such problems is still in flux and is just one of many increasingly complex issues arising from the progressively more common commercialization of the results of faculty research. We are in the process of developing protocols and formulae to deal with such situations, but it is clear that it will be very difficult to plan in advance for all of the possible issues that will undoubtedly arise in the future.

Educational Program for Promoting Research Integrity

Peggy L. Fischer, Office of the Inspector General, National Science Foundation

Sherrye L. McGregor, Office of the Inspector General, National Science Foundation

The National Science Foundation (NSF), an independent U.S. government agency, is responsible for promoting science and engineering research and education. NSF's Office of Inspector General reviews and investigates all allegations of misconduct in science for NSF programs. Our office is building working relationships with NSF and the scientific and engineering communities to promote the ethical and efficient conduct of research. In consultation with representatives of the scientific community and university officials, we designed a case-based series of seminars to illustrate issues in ethical conduct of research and the responsible handling of investigations into allegations of misconduct in science.

Examples are provided from our seminars for principal investigators, university administrators, and graduate students. The seminars for principal investigators and administrators acquaint attendees with federal and institutional misconduct-in-science policies. The depth of our database (over 400 cases) allows us to tailor the discussions to the interests of each audience and to support these discussions with our experience resolving allegations. The seminar facilitates discussions between administrators and PIs about the host institution's policy and how allegations are handled. Our ethical dilemmas seminar, which addresses ethical issues graduate students may confront as they begin their independent research careers, reviews the federal grant process and covers the commitments and obligations PIs make when submitting proposals or receiving awards. The students are then guided through a discussion of seven ethical dilemmas, including: Data selection and Sharing; Collaborations; Sharing and Using Ideas; Confidential Merit Review; Authorship and Acknowledgements; Paraphrasing and Plagiarism; Mentor and Advisor Problems; and Student Training. By discussing the federal and host institution processes for handling misconduct in science allegations, we can provide insight into how to best process such allegations. We support integrated programs that provide guidance on promoting ethical research and practical advice on overcoming ethical dilemmas in an effort to prevent some allegations of misconduct and reduce the severity of others.

An Effective Short Course on Research Integrity

Bernard S. Gerstman, Florida International University

Objective: It is crucial to promote research integrity in students early in their careers to prevent the development of "bad habits". We discuss a course that we developed that accomplishes this quickly and effectively. **Design:** The course is designed to meet for one hour each week. The initial course meetings are organized like a traditional class with the faculty member explaining various aspects of research integrity and unethical behavior. The middle part of the course switches to a preceptorial structure with faculty led discussions of selected reading material on recent cases concerning violations of research integrity. The final part of the course consists of a half-hour presentation from each student about a case of suspected unethical behavior that they have investigated

through a literature search. The training in the earlier parts of the course are now expected to be used by the student in discussing the researcher's motivation, execution, cover-up, reward, and penalties suffered. **Results:** The design of the course requires the students to play an increasingly active role and is effective in conveying and substantiating the negative impact and consequences of unethical behavior. The class presentation required of each student forces them to "step into the mind" of a scientist behaving unethically and thus makes them aware of how unethical behavior can originate, sometimes innocuously, and the necessity for constant self-vigilance. **Conclusion:** A short course that forces students to take an active role in "thinking unethically" is very effective in conveying the necessity and training for integrity in research.

Effects of Digitization and the World Wide Web on Authorship and Plagiarism

Jaime Henriquez, Ph.D., Independent Scholar

Objective: To test the hypothesis that framing the issue of falsified research in the context of technological change (e.g., digitization/computerization), and social change (e.g., changes in the risk/reward ratio) will be useful in illuminating factors that might otherwise be overlooked. **Design:** The hypothesis is exploratory. Direct experimental testing may be possible for some conclusions, but at this stage the hypothesis is tested for coherence, applicability, and fruitfulness (explanatory power), based on analysis and a reading of the current literature. **Results:** Preliminary results suggest that some aspects of computerization have the potential to aggravate the problem of falsified research. For example, the availability of seamless cut-and-paste obviously makes appropriating pieces of another's research without detection a great deal easier. Also, the reduction of data to media-independent 'ones' and 'zeroes' removes much of the information that can be used to detect alteration or plagiarism. In addition, the fact that research results are now commonly the output of complex and unique computer programs opens the possibility of sophisticated data tampering at that stage. **Conclusions:** The results suggest that looking at the issue in this larger context can bring to light some factors in the apparent increase in falsified research. While attention has rightly focused on the increased reward to malefactors, there are a number of ways in which the risk of plagiarizing or falsifying data has at the same time decreased. This widening gap between risk and reward will inevitably bring opportunists, and our effort should be aimed at narrowing it.

Publication Practices in the Scientific Community

Lorraine Herson-Jones, formerly National Science Foundation, Office of the Inspector General

Crain Allen. National Science Foundation. Office of the Inspector General

Peggy L. Fischer, National Science Foundation, Office of the Inspector General

A duplicate publication, also referred to as self-plagiarism or redundant publication, is considered to be a published paper that substantially overlaps with an author's prior

publication without reference to the original publication and/or editorial permission to republish. Our office recently conducted a preliminary literature review on the subject of duplicate publication. The poster presented at this session gives one example of a duplicate publication and asks participants for their views and comments on our inquiry. A general absence of clearly articulated standards concerning acceptable duplicate publication practices exists within scientific communities. Some scientists consider duplicate publications to be an issue only for papers that are published in primary journals (peer reviewed and archival journals). Journal editors, by contrast, often provide specific instructions about what they consider acceptable practices and describe possible sanctions against authors who submit duplicate publications without appropriate notifications and/or permissions. In evaluating allegations of misconduct in science, our office relies heavily upon the opinions of the scientific community regarding accepted practices. Without a generally understood standard, federal agencies and university committees cannot effectively assess allegations involving duplicate publications.

Protecting Research Integrity in Corrupt or Incompetent Research Institutions: Case Studies of Institutional Corruption and Possible Response Mechanisms

Andrew J. Hogan, PhD, Michigan State University

Ronald J. Patterson, PhD, Michigan State University

Robert L. Sprague. Ph.D., University of Illinois-Urbana/Champaign

Objective: To examine cases where institutional mishandling of research misconduct investigations has been alleged: the Williams and Hogan cases at Michigan State University, Sprague case at Pittsburgh, the Weissman case at Yeshiva, the Demas case at Cornell. Identify common patterns that contributed to the mishandling and propose an approach to support and regulate institutional research integrity offices that will improve the handling of research integrity investigations in the future. **Design:** Examination of the case files of Dr. Robert Sprague of the University of Illinois-Urbana/Champaign, as well as records from Michigan State University, on the 5 mishandled investigations. **Results:** The crucial factors enabling institutional mishandling are: an incompetent or corrupt university administration supporting a dishonest (usually senior) scientist at the expense of an honest (usually junior) scientist, and a funding entity either indifferent to or accepting of the misconduct. An alternative to the second factor is when the misconduct arises outside of a funded research project; in either case, the effect is that there is no external enforcement of impartial investigative standards. **Conclusions:** A possible response to these infrequent but reputationally very damaging cases of institutional mishandling would be an accreditation system for institutional offices of research integrity sponsored by multiple funders, research institutions, scientific societies and scientific publications. Failure to maintain accreditation could result in the partial to near-universal interruption of external research funding for research institutions mishandling research misconduct investigations.

Resources for Instruction in Responsible Conduct of Research

Michael W. Kalichman, University of Calif., San Diego

Francis L. Macrina, Virginia Commonwealth University

Jeffrey P. Kahn, University of Minnesota

Objective: Develop a Web-based resource for current or future instructors of responsible conduct of biomedical research. **Design:** A new Web site was designed to provide: (1) a focus for the community of people interested in promoting responsible conduct of research (RCR) and (2) a step-by-step approach to developing a program for instruction in RCR. Prior to release, the address of the site was given to over 30 external reviewers to rate various elements of the site using a scale of 1 (very low) to 5 (very high). The site was proposed for general release on November 1, 2000. To provide maximum benefit, the site is intended to evolve as new information becomes available; users are encouraged to provide recommendations for improvements in content and format. **Results:** The address of this new Web site is: <http://rcr.ucsd.edu> The site includes five main sections on RCR instruction: Goals, Content, Format, Tools, and Evaluation. Based on external review prior to release, the value of the site was rated as high to very high. The Web site was welcomed, as a much needed, centralized resource for RCR instructors. Many constructive suggestions for additions and improvement were made. **Conclusions:** This Web site is likely to be useful as a centralized resource for new and continuing teachers of RCR.

Being a Scientist: Educating for Ethical Conduct

Chloe D. Little, Western Carolina University

Katherine L. White, Western Carolina University

Scientific misconduct is evident in many spheres. Dishonesty and misrepresentation have become commonplace and acceptable because of less social disapproval, increased competition and increased pressure to produce. Examples of misconduct include medical school faculty applicants misrepresenting research citations, ethic committee members behaving unethically by endorsing unnecessary research, editors of peer-reviewed journals misappropriating authorship and researchers faking data or failing to report unfavorable results. Some researchers suggest that orientation is away from traditional values. Others suggest that fraud and dishonesty in scientific research is the exception, not the rule.

Scientists and institutions must maintain quality and integrity in scientific research if progress and public support are to be sustained. To promote responsible research, college and university faculties must sensitize future scientists to the critical issues in research ethics and institutional guidelines. Although expecting faculties to single-handedly prevent research misconduct is unrealistic, they can create informal learning environments that promote high standards such as engaging students in open discussions of ethical research practices, carefully supervising/mentoring student research, encouraging responsible data management, and engaging in ethical behaviors. Faculties can also create formal methods for integrating the study of scientific values and

misconduct in the classroom. This poster will provide suggestions for developing a modified problem-based learning (PBL) curriculum for first-semester graduate students with their ethical development.

The proposed curriculum will prepare first-semester graduate students for research projects. Problem-based learning, based on small group discussion and clinically based problems, encourages active student learning with a deeper coverage of materials. Instructor-identified objectives assist students to develop effective clinical reasoning including critical appraisal, critical decision making and self-directed learning skills. Topics of investigation include defining scientific misconduct, reviewing the institution's research policies, properly managing data, dealing with conflicting interests, determining authorship, reporting scientific misconduct and publishing research.

An Interactive Website for Ethics Training

Rudolph Marcus, Office of Naval Research, Retired

Objective: Construct and experiment with a computer-based ethics training instrument. **Design:** A web site contains seminars for self-study. Each seminar has a number of sessions. Each session contains a story (as case study) or direction for an exercise with the material of the story. The participant in this seminar encounters the story or does the exercise, and then responds to one or more question(s) stated in the session. The response can be in writing or any other form of expression, and can be telephoned or sent by e-mail or post to the facilitator. The facilitator may comment on the response or suggest additional angles to consider for sharpening the response, and will then send the next session (e-mail) or envelope (paper) of the self-study seminar. **Results:** The web site <http://storiesandquestions.com/> is in operation. One way of assessing effectiveness of the instrument is to compare responses to the same question after earlier and later sessions of the seminar. The comparison showed increased awareness by all subjects (8) of their actions (increased consciousness) and of how their actions influenced results of their work (increased possibility of ethic al action). **Conclusions:** The effectiveness of the computer-based instrument seems to be a function of presenting increments of case study and questions in separate sessions, and of not forcing responses. The computer-based instrument is as effective or more effective than workshops offering similar material, and far more effective than group training based on ethics codes. Other seminars are ready for sequencing and adding to the web site, including four which deal specifically with responsibility in science.

Preventing Research Misconduct and Promoting Research Integrity: A Pyramid of Information Delivered in a Training Program

Martha J. Matza, U.T. MD Anderson Cancer Center

Carleen A. Brunelli, U.T. MD Anderson Cancer Center

Leonard A. Zwelling, U.T. MD Anderson Cancer Center

Objective: The Office of Research Administration (ORA), at the University of Texas M. D. Anderson Cancer Center, is charged with implementing systems to assess and

facilitate the quality of clinical research. **Design:** The systems implemented were based on a pyramid structure. The foundation of the pyramid is made up of the Belmont Report in addition to the policies for the protection of human research subjects that include the Federal Codes, DHHS (45CFR46) and FDA (21 CFR 50). The next level, encompassing the guidelines for Good Clinical Practice (GCP), applies the principles from the Belmont Report and the Federal Regulations. The pyramid is topped by the processes needed to collect, analyze and report accurate information with meaningful results. **Results:** Our processes begin with a scientific review by the investigator's peers that are experts in related fields of the research concept. To ensure the ethical treatment of human research subjects, the Institutional Review Board (IRB) reviews the proposals to ensure that the principles of respect, beneficence and justice are clearly evident. ORA develops and maintains the Protocol Data Management System and the Clinical Oncology Research System for researchers to use as tools to carry out their research. The staff also uses these databases for all functions related to the review, approval and reporting on clinical trials. These database programs are also designed based on processes such as continuing review of research and adverse event reporting and review. **Conclusions:** The outcome has led to the development of professional training for principal investigators, research nurses and data managers. The training modules for the investigators focus on their responsibilities to their human subjects, and to the institution. The development of the modules is ongoing, and changes to meet the needs of the employees as new scientific research technology or new federal regulations are implemented.

Potential Cultural Factors in Scientific Misconduct Allegations

Walter J. Meyer, III, University of Texas Medical Branch, Galveston, Texas

George M. Bernier, Jr., University of Texas Medical Branch, Galveston, Texas

Since 1993, 15 of 16 allegations of Scientific Misconduct at the University of Texas Medical Branchdid not reach the stage of investigation, usually because the complaint involved an authorship dispute or allegations of questionable laboratory practices. **Objective:** We hypothesize that cultural factors might underlie at least some of these allegations. **Design:** A retrospective review of these 15 allegations was done to detect the possible involvement of gender, academic status, ethnic or cultural factors. To determine whether any ethnic or cultural group appeared to be overly represented as complainant or respondent, the cultural/ethnic background status of the entire faculty (and postdoctoral fellow population) was compared to those involved in complaints. **Results:** Seven of the complaints involved individuals from differing national origins or ethnic groups. The remainder of complaints involved individuals of like ethnic or cultural background, but most of those individuals were raised outside North America. There is a great difference in the ethnic distribution of the total faculty compared to those individuals involved in scientific misconduct allegations. Proportionally the Asian group is over represented in the scientific misconduct complaint process. Fewer than expected female faculty were involved in these allegations. Academic status did not appear to be a factor. This retrospective review suggests that cultural and ethnic concerns may account for many of the authorship and other scientific misconduct disputes. **Conclusions:** Since almost all complaints did not involve scientific misconduct as currently defined but rather

reflected a misunderstanding of the process by those individuals not raised in the United States, we need to develop for faculty and postdoctoral fellows a more comprehensive education in the proper use of the scientific misconduct complaint process and to provide other mechanisms to help them resolve conflicts with fellow scientists.

Editors and Research Integrity

Debra M. Parrish, Parrish Law Offices, Pittsburgh, Pennsylvania

Objective: The study explored the response and delays in the communication channels to and from journal editors when an allegation or finding of scientific misconduct is made regarding a manuscript or publication. The study also examined who is responsible to ensure that misconduct appearing in a publication is not published, who is responsible for correcting the scientific literature, when should a correction be made, and how should the scientific community be notified about the allegation or finding of misconduct. **Design:** The study examined communications to and from editors in the universe of cases closed by the Office of Research Integrity from 1993-1997 in which a finding of scientific misconduct was made and that involved a publication. The case involving correction of the NSABP breast cancer study was reviewed in detail. The study examined the delays between the dates of the original allegation, admission, conclusion of institutional investigation, case closed by ORI, publication in the federal register, notification to the journal and correction or retraction. It also examined the responses of editors, authors and institutions when notified of an allegation or finding. **Results:** Substantial delays in notifying the journals and public were observed. The letters of correction and retraction varied in content, timing and authorship. Despite ICMJE standards, most journal notices of correction or retraction did not indicate that a correction or retraction was based on a misconduct allegation or finding. **Conclusions:** Journal editors have been disconnected from the scientific misconduct process and expectations differ regarding the obligations of authors, research institutions, and federal agencies about when to inform editors and the public of alleged misconduct.

Graduate Research Ethics Education

Michael S. Pritchard, Western Michigan University

Tristan Fiedler, University of Miami;

Sara Wilson, University of Virginia

Objectives: To train graduate students in the sciences and engineering to teach research ethics on their campuses and to become leaders in research ethics at the outset of their careers. **Design:** Sponsored by NSF, the Association for Practical and Professional Ethics, the Poynter Center for the Study of Ethics and American Institutions, and the Office of Research and the University Graduate School at Indiana University, GREE has been offering one week summer institutes at Indiana University for 15 graduate students in science and engineering since 1996. **Results:** 1. *Case studies*. Each year GREE participants prepare a volume of case studies and commentaries that reflect issues most pertinent to graduate students. 4 volumes are accessible at http://www.onlineethics.org.

2. *Teaching*. All participants are required to give presentations in research ethics at their home institutions. Several have created courses and/or seminar series in research ethics. 3. *Collaboration*. Beginning in 1999, GREE began annually convening participants from all the summer institutes. Two-thirds of the original 60 participants have reconvened. 4. *Projects*. A handbook for graduate students on research ethics, Research Ethics and the Graduate Experience, is presently being written by GREE participants. Participants are also developing syllabi and teaching materials on research ethics. Finally, collaborations on scholarly research are being encouraged. 5. **Conclusions:** Through its intensive one week workshops and follow-up activities, GREE is generating a community of young scientists and engineers to become leaders in research ethics in higher education in the coming years.

Guidelines on Plagiarism in Writing Manuals Across Various Disciplines

Miguel Roig, St. John's University

Jaclyn de Jacquant, St. John's University

Objective: In the present study we surveyed the writing manuals of various disciplines within the sciences and humanities for their coverage of plagiarism. We were interested in the extent to which definitions of plagiarism, specifically guidelines for correct paraphrasing, (i.e., the extent to which text from an original source should be modified in order for it not to be considered a case of plagiarism) are covered in these manuals. We were also interested in the degree to which such definitions are consistent across disciplines. **Design:** We located the latest available editions of writing manuals for various disciplines and proceeded to review each manual's index and table of contents for entries on plagiarism and paraphrasing. For those manuals that did not provide a listing for such terms, we attempted to locate and review relevant sections where such material might be covered (e.g., citations and copyright). **Results:** Of the 11 manuals consulted, only 3 provided entries for plagiarism and included sections devoted to this type of transgression. Of the 3, two provided coverage of correct paraphrasing. Most manuals that did not include entries on plagiarism did, however, offer varied coverage of citation and quotation procedures relevant to avoiding plagiarism, but without specifically referring to this problem. **Conclusion:** Given evidence that contributors to the biomedical and scholarly literature are not always in agreement as to what forms of writing might constitute plagiarism, writing manuals should provide clear guidelines on this matter. Moreover, because contributions to our knowledge base are increasingly multidisciplinary in scope, such guidelines should be consistent across disciplines.

Raising Awareness of Research Integrity from the Ground Up

Jeremy Sugarman, Duke University

Objective: Although efforts are being made to address the ethical issues that arise in the scientific process at the graduate level, very few initiatives focus on undergraduates. Consequently, we developed the Howard Hughes Institute for Research Ethics (HHIRE) at Duke University to address these issues at the undergraduate level. **Design:** HHIRE

consists of three major activities. First, working with instructors in Hughes Forum seminars to provide normalized ethics education in these science classes. Second, sponsoring a university symposium, *The Courage to Do Right: Keeping Ethics in Science*. Third, designing and implementing an interdisciplinary seminar, *Ethics in the Process and Application of Science*, involving exposure to institutional procedures for ensuring the responsible conduct of research. **Results:** While it is difficult to measure the effects of HHIRE, an anonymous web-based survey (Response rate>55%) of Forum students suggests interest in ethics education, including most standard topics in research ethics. Students preferred ethics discussions in existing science courses, classes in ethics, and visiting speakers, to an ethics "hotline" and the use of videotapes or web-based tutorials. **Conclusions:** HHIRE has taken multiple approaches to raising issues about research integrity and research ethics at the undergraduate level. Such an approach promises to give undergraduates the skills they need to approach science with integrity. In addition, making discussion of these issues explicit on a university campus will hopefully raise awareness and mitigate the likelihood of misconduct.

Integrating Internet Based Materials into a Curriculum for Responsible Conduct of Research

Peggy A. Sundermeyer, University of Minnesota

Objective: To present the advantages of using internet applications in enhancing a comprehensive program of education in RCR. **Design:** The successful deployment of internet based instructional materials follows a series of steps: conceptualization, content development and design, focus group testing, introduction and use, and finally, evaluation. This presentation will highlight the important lessons learned from conceptualization through implementation. **Results:** Three tools designed to support a comprehensive RCR curriculum: 1) Database compendium of instructional materials on ethics, Teaching Ethics in Research, Scholarship and Practice, acts as a research assistant, facilitating inclusion of ethical issues into courses; http://www.research.umn.edu/ethics/; 2) A tutorial on Informed Consent provides both essential information on the basic principles of consent and offers a tool for researchers to construct a consent document, defining required elements and providing simply stated phrases and clear examples on line; http://www.research.umn.edu/consent; 3) The module on Intellectual Property is used in conjunction with in-person discussions of situations encountered in research and scholarship; http://www.research.umn.edu/ethics/modintellectual. **Conclusion:** Advantages of using internet applications are more time for conceptual discussions; instant access to relevant materials; confidentiality of self-assessment; pacing and sequencing of material as well as time and place controlled by the learner; variation in formats to lighten straight passages of text; ease of updating when policies or federal regulations change; access to additional, more in-depth reference materials for further study; and exchanging and sharing information within and between institutions.

Undergraduate Academic Cheating as a Risk Factor for Future Professional Misconduct

Julio F. Turrens, University of South Alabama

Irene M. Staik, University of Montevallo

D. Kristen Gilbert, University of Montevallo

W. Curtis Small, University of South Alabama

John W. Burling, University of Montevallo, Montevallo

Objective: We propose that the increase in cheating at the undergraduate level will lead to an increase the number of future professionals involved in scientific misconduct. **Design:** The proportion of students cheating in US institutions was estimated from information in the literature. In order to determine differences in perception of what constitutes cheating, students and faculty at the University of Montevallo were presented with a variety of examples of academic misconduct, and were asked to rank their perceived severity on a scale from 1 to 5. **Results:** Estimates in the literature reveal that 75% to 98% of college students cheat at least once during their college career. Faculty members often do not report a case of student cheating to the institutional justice system, but prefer to handle each case on an individual basis. An added problem is that faculty and students often do not agree on what actions constitute cheating both in and outside of the classroom. In the study carried out at Montevallo, there was almost a full point difference between students and faculty in their perception of the severity of some scenarios. As the students' academic standards decrease, future professionals may find it easier to engage in scientific misconduct as they will perceive it to be less immoral. A study done with 2,459 sophomore medical students showed that 4.7% admitted to cheating while 66.5% admitted to having heard of cheating among their peers. About 70% of the students that cheated in medical school also cheated in high school and college. **Conclusions:** There is a high incidence of cheating in college. It is not unreasonable to expect that future professional misconduct will also show a positive correlation with previous history. We propose that part of the efforts to promote professional integrity should be devoted to curbing cheating among undergraduates.

6a. Tools and Procedures for Measuring Research Integrity, Monday, 8:30-9:45 (Price)

Research Integrity and Statistics: An Agenda for Research and Reform.

David B. Resnik, Brody School of Medicine, East Carolina University

Objective: To understand the relationship between the use of statistical methods and responsible conduct of research. **Design:** Literature review of articles and books that address the relationship between statistics and ethics; conceptual analysis of the role of statistics in research and the nature of ethical research conduct. **Results:** Although many articles and books discuss or mention the importance of the appropriate use of statistical methods in conducting ethical research, there is little empirical data concerning erroneous or unethical statistical practices in research. More work is need to determine (a) the extent to which the misuse of statistics occurs in science; (b) the sources (or causes) of error and intentional deception in the use of statistics; and (c) the institutional and economic factors that contribute to the misuse of statistics. **Conclusions:** 1) More empirical research is needed on statistics and the responsible conduct of research. 2) Policy responses to this research ethics issue should be based on data about the causes of inappropriate uses of statistical methods. For example, when inappropriate uses of statistics are attempts to deceive the audience, they can be treated as a form of scientific misconduct and should be handled in this fashion, i.e. through investigation, adjudication, and discipline. When inappropriate uses are due to ignorance of statistical methods, then additional education in statistics is an appropriate response. If inappropriate uses of statistics result from errors or "sloppiness," then steps should be taken to reduce errors through quality control mechanisms, such as data auditing. Finally, problems relating to "publication bias" can be addressed by developing alternative methods for disseminating data, such as data registries. The most appropriate policy will probably involve some mix of all of these responses, but additional empirical research is needed in order to implement any particular recommendation or strategy.

Statistical and Mathematical Approaches in the Examination of Questioned Data

James E. Mosimann, ABL Associates, Inc. Rockville, MD

John E. Dahlberg, Office of Research Integrity, DHHS

Nancy L. Davidian, Office of Research Integrity, DHHS

John W. Krueger, Office of Research Integrity, DHHS

Objective: to illustrate the use of statistical and mathematical methods in the investigation of scientific misconduct where data are to be examined for authenticity. We present examples of statistical forensic analyses of questioned data from several cases that illustrate the experience of the Office of Research Integrity. **Design:** generally involves the comparison of "questioned" data with "unquestioned" data from the same laboratory or individuals. Thus, in a typical misconduct scenario *Individual A* claims that an experiment was not done as described, or perhaps, not at all. *Individual B*, the

experimenter, presents data to show that the experiment was in fact performed. The credibility of one of the individuals may be enhanced (or diminished) by contrasting statistical or mathematical properties of the questioned data with corresponding properties of unquestioned data. **Results:** all from actual cases, include: **1**, A demonstration of which of two data sets matches more closely a published graph; **2**, Anomalous behavior of terminal digits in published or recorded numbers; **3**, Terminal *odd* digits in event times that usually exhibit only *even* digits (and why); **4**, Data that are falsified by calculations from computer spreadsheets (detected by the inclusion of an additional digit of accuracy); and **5**, Patterns in terminal digits that were adjudicated by the Departmental Appeals Board (Department of Health and Human Services) to represent idiosyncratic behavior rather than data falsification. **Conclusions:** the statistical examination of numbers that are normally *unrepeatable* under repetitions of experiments, or otherwise of inconsequential meaning, may reveal substantial clues as to the authenticity of questioned data when compared with corresponding numbers in data that are unquestioned.

Statistical Ethics; a Powerful Tool for Research Integrity

John S. Gardenier, CDC/National Center for Health Statistics

Objective: To suggest various ways the official ethics document of the American Statistical Association (ASA) can be used both to promote research integrity and to aid research into research integrity. **Design:** Review of the "Ethical Guidelines for Statistical Practice" and its derivation. Review of professional ethics generally. Review of the proposed federal common definition of research misconduct and the ASA's comments on it. Review of cases in statistical ethics. **Results:** A continuing education short course was prepared and offered at the 2000 Joint Statistical Meetings in Indianapolis, IN. This course emphasized understanding statistical ethics in the context of ethical philosophy and of professional ethics practice generally. It describes how, given a solid foundation of ethical reasoning and basic common sense about workplace politics, any student or practitioner can use the ethics document as a tool to resolve ethical conflicts or issues that arise. **Conclusions:** Virtually all students who took the course stated they were confident that they could use their new knowledge effectively in dealing with problems they confront in their own workplace. Evaluations of the course were very positive and it was invited back for future similar meetings. Future research could evaluate the successes and failures achieved in using this document as a tool and investigate conditions that mitigate for or against its use. This talk will summarize various potential creative applications for use of the tool and invite feedback from the audience on its potential.

Images as Evidence: Forensic Examination of Scientific Images

John W. Krueger, Office of Research Integrity, DHHS

Objective: This talk I) discusses ORI's experience from its oversight review of institutional scientific misconduct cases involving questioned images, II) provides illustrative examples of computer image processing techniques, and III) illustrates how the analysis can contribute to the final determination. **Design/Methods:** The source

material for this presentation was taken from 16 cases in ORI's file that involved images of gels, blots, autoradiograms, and micrographs. Most of ORI's image processing was done on a Macintosh computer using public domain software (NIH Image), or using Adobe Photoshop with the Image Processing Tool Kit plugins. **Results:** I. Most allegations did not arise because the images looked inauthentic, but simply because they were recognized as being from another experiment, another source (plagiarized), and/or as representing claims that a reviewer frankly disbelieved. The image was often the one concern that could not be easily dismissed. Most allegations involved "reuse" of the image to represent data from a purportedly different experiment. Occasionally, photographic prints (or computer images) of gels or blots were "cut and pasted" together in different combinations. Allegations involving the overt manipulation by use of a computer to alter the content and features of the image itself have occurred, at most, in only two cases. II. The selected examples of ORI's image analysis will illustrate the extremes, i.e., from the examination of a bad photocopy of SDS PAGE based analyses (such as a Northern or Western blot), to the computer re-construction of missing data to test the authenticity of the proffered documentation in the notebook. III. Of two institutions that employed computer analysis, only one documented their results. The latter used image enhancement to discover erased labels on an autoradiogram that ruled out honest error. In addition to the basic image processing, a clear follow up analysis is important. Institutional investigative findings are appreciably strengthened when the pattern of reuse of images is demonstrated. **Conclusions:** Few institutions have applied these image processing methods, but the results can be determinative. The most useful and critical case-related image analysis is done with a clear understanding of the experiment in question.

6b. Research Integrity as an International Concern, Monday, 8:30-9:45 (Dustira)

Promoting Scientific Integrity: The Long Road Ahead: Some considerations from Espírito Santo - Brazil

Jaime Roy Doxsey, Federal University of Espírito Santo

Objectives: To examine the need to stimulate institutional awareness and debate on major issues such as production and communication of scientific knowledge, as well as the ethical challenges for developing responsible research practices in the human and social sciences in Brazil. **Design**: A case study of the institutional context of a medium-sized federal university located in Espírito Santo to describe work conditions, the institutional culture and other obstacles for establishing a program to promote research integrity. **Results**: While recent federal resolutions in the areas of health, medicine and medical research have established guidelines for human protocol, research integrity and the protection of human subjects, the Brazilian University system and the National Council for Research (**CNPQ**) have neither acknowledged the relevance of these resolutions for research practices nor incorporated them into grant procedures. At the local level, universities, research institutes, academic centers, departments and graduate programs establish their own policies for the approval research projects and scientific production, dealing principally with the administrative approval of faculty involvement in research as well as release time from academic classroom schedules. No institutional procedures presently exist for handling allegations of scientific misconduct.
Conclusions: The paper confirms the necessity for urgent institutional action at all levels to develop normative standards that promote a responsible research environment and a critical consciousness of the need for training/research in scientific integrity in all areas of knowledge.

Ethics in Medical Research – The Current Scenario in India

Karunakaran Mathiharan, Institute of Legal Medicine, Chennai, India

Objective: This paper deals with some of the ethical issues that confront the medical researchers and the practitioners of medicine in India where the distinctions between the two are often blurred. It also strives to give solution to regulate the ethical issues. **Design:** Situational observations collected from personal experience, interaction with other faculty and practicing members of the profession, journal and media reports **Observations:** There is virtually no research by undergraduate students. But postgraduates of clinical and non-clinical degree courses have to present a dissertation at the end of their course as part of their final exams. Research for doctoral thesis in medical sciences is a rarity. In clinical research involving the living persons, there is no effective monitoring of the research projects for ethical violations. In India, medical practitioners are traditionally held in high esteem and blind faith of the patients to their physician is not uncommon. This fact coupled with the availability of vast illiterate and semiliterate population often tempt the men behind the clinical research involving human subjects to be complacent about adhering to the ethical guidelines. To complicate the issue, the legal age to give consent and the age at which the 'Right to Confidentiality' begins is yet to be defined either statutorily or by the courts. The ethical issues involving the reported and unreported research projects subjecting HIV- positive patients, the disposal of unused embryos that resulted from the IVF, the priority of persons receiving the organs culled from the brain-dead declared persons, and the guidelines governing the research in mental health using mentally ill patients call for immediate attention. **Conclusion:** In India, to strictly implement and monitor the ethical guidelines, a statutory body with adequate powers to punish the ethical violations should be constituted. New guidelines to tackle the emerging ethical issues should be introduced.

Whistleblowers in Environmental Science: Prevention of Repression Bias and the Need for a Code of Protection

Elihu D. Richter, Hebrew University

Colin Soskolne, University of Alberta

Tamar Berman, University of Alberta

Objectives: (1) To report and respond to situations in which environmental scientists are subject to harassment for investigating or reporting health hazards and risks.
(2) To examine the distribution and determinants of such repression bias and to assess its impact on risk assessment and prevention. **Background:** Repression bias from legal harassment, ostracism, job loss, loss of funding, intimidation, abuse, threats, or even force may obstruct the mission of environmental scientists to carry out and report such hazards and risks. The deterrent effect of repression bias will result in delays in responding to and prevention. **Methods:** Literature reviews, anecdotal reports, case histories, casual surveys and investigations of requests for assistance to Philosophy and Ethics Committee of the International Society for Environmental Epidemiology.
Results: (1) Powerful governmental, military, economic and political interests are often

the driving forces and pressures. (2) The high risk settings for exposure to such pressures are those in which unfettered epidemiological investigation is most needed, i.e. where exposures and risks are severe, where there are few epidemiologists. (3) The risks are increased where legal safeguards for human rights are weak, and where access to the communication and publicity is blocked. (4) The high-risk groups for such harassment are younger or less well-known epidemiologists, employees in government or industry, and "whistle-blowers" from the exposed population itself. (5) Reports are less frequent from settings where repression is more severe. (6) Institutional safeguards against harassment remain inadequate. **Conclusions:** Codes for an international institutional standard of protection against harassment of whistleblowers are required.

Characteristics Of Selected Ethics Review Committees In Latin America

Roberto Rivera, Office of International Research Ethics, Family Health International (FHI), North Carolina, USA

Enrique Ezcurra, Reproductive Health Research, World Health Organization (WHO), Geneva, Switzerland

Objective: The Americas Regional Advisory Panel of WHO has established as a goal to promote the development of the ethical review process of research involving human subjects in centers conducting studies with the support of WHO. This study had as particular objectives to identify the main characteristics of the groups responsible for the ethical review and the existence of formal norms and operating procedures. **Design:** Twenty-five WHO collaborative centers in the Americas, conducting research with WHO support, were included in the study. A structured questionnaire was mailed to the 25 centers. Responses were collected in the between January-August 1998. All the 25 centers returned completed questionnaires. **Results:** Twenty-two of the 25 centers (88%) had local review committees, either in the center itself or in the university, school or hospital to which the center was affiliated. The accumulated membership of the 25 centers included 191 individuals. The large majority of the members were physicians (63.4%), followed by PhDs (22%) and lawyers (6.2%). The rest included social scientists, theologians, nurses and community representatives. A total of 79.6% of the committee's members were employees of the same centers. Of those, 55.5% were men and 44.5% women. More than half of the committees (59.1%) were responsible for both the ethical and scientific review of the research projects. A 54.6% of the committees had met more than four times in the previous 12 months, and 72.7% of the committee had written minutes of their meetings. Meeting minutes were not produced by the remaining 27.3% of the committees. Only 45.5% of the committees had formal norms or operating procedures. Also, only 31.8% required progress reports or had follow-up mechanisms in operation. A total of 45% of centers indicated that informed consent was the topic most frequently dealt with in the committee meetings. The participating centers indicated that there had never been a problem with local authorities or international agencies. The main problems identified by the centers themselves were: 1) need to establish and use procedural guidelines; 2) limited experience in some ethical issues; 3) lack of follow-up procedures or mechanisms; 4) a non-diverse membership, comprised mainly by physicians; 5) some researchers have the impression that the ethical review committees

block or make research more difficult; 6) lack of administrative support and resources, and 7) international regulations not well know. **Conclusions:** The results indicate that ethical review is a formally established element of research involving human subjects in most of the collaborative research centers of WHO in the Americas. However, there is a definite need to improve such a review. Some important needs are: 1) provide additional training in research ethics to the committee members; 2) develop and/or update formal operating procedures, including follow-up or monitoring guidelines, and 3) diversify the membership of the committees.

6c. Panel: Lessons Learned at the University of Minnesota Monday, 8:30-9:45 (Kahn)

Fostering Research Integrity through Educational Programs

Jeffrey P. Kahn, University of Minnesota

Peggy A. Sundermeyer, University of Minnesota

Melissa S. Anderson, University of Minnesota

Muriel J. Bebeau, University of Minnesota

Virginia S. Seybold, University of Minnesota

Objective: The University of Minnesota has implemented a comprehensive educational program in the Responsible Conduct of Research (RCR) for principal investigators (PIs). The goal of this session is to promote development and implementation of effective educational programs in RCR by sharing the strengths and challenges of our experience. **Design:** Faculty and staff involved in development and delivery of the curriculum will present information in 4, 10 minute segments and invite questions and comments from the audience between segments. **Results:** The University of Minnesota program in RCR will be presented in the following segments: 1) Policy as framework for education: Institutional policies, channeled through administrative and faculty governance, foster ownership of professional values. 2) Development and delivery of the curriculum: Involvement of faculty who are representative of the diversity of the research community promotes ownership and relevancy of the curriculum. 3) Financial investment: Approximately 2200 faculty will have participated in the University's educational program within one calendar year. Investment includes development of resources, materials, faculty time for participation and administrative costs. 4) Evaluation: In addition to program evaluation, two research designs to assess impact of the educational program will be described. One design focuses on graduate students, the second on faculty. **Conclusion:** The University of Minnesota has designed and implemented an educational program in RCR which continues to evolve through program evaluation and integration into the institution's culture.

6d. Panel: Methods for Research on Research Integrity, Monday, 8:30-9:45 (Frankel/Levine)

Exploring Problematic Issues in the Study of Research Misconduct

Melissa S. Anderson, University of Minnesota

This presentation considers some of the problematic aspects of doing empirical research on academic misconduct, ethical issues and related topics. Some of these difficulties are common to all research on sensitive topics, others are specific to misconduct and ethical issues, and still others relate to higher education as the research setting. Some problems can be addressed by simple methodological strategies, whereas others thus far remain without satisfactory solutions. One imperative for future research in these areas is a greater awareness of contextual effects, both situational and longitudinal, on misconduct. When misconduct, as an object of research, is examined apart from the research context, its complex relationships to ordinary science and inadvertent error are obscured. More sophisticated analyses will examine the roots and consequences of misconduct and will related misconduct to its disciplinary, institutional, social and immediate contexts.

Utilizing the Evaluation Methodology to Study Research Integrity

Joyce Iutcovich, Keystone University Research Corp.

This presentation will provide an overview of the basic components of evaluation research. It will also offer ways in which the methodology can be used to gain an understanding of how institutions can develop strategies/mechanisms to foster an orientation toward and adherence to the principle of research integrity. Evaluation research is a methodology that, ideally, should compliment basic research. While basic research seeks to answer questions about cause-effect relationships and to test hypotheses for the purpose of theory development, evaluation research examines the link between theory and practice. Evaluation research is generally used in the context of social action programming. Programs are developed (based on a theoretical model) to achieve particular goals. Evaluation research assesses the integrity of the implementation (process evaluation) and if a program is effective in achieving its goals (outcome or impact assessment).

How Do We Learn to Do Research with Integrity? Following Academic Science Careers

Rachel A. Rosenfeld, University of North Carolina, Chapel Hill

Although most scientists take formal classes in research methodology early in their education, much of what we know about how to do research comes from other sources across the career, as a number of papers at this conference demonstrate. Having a successful career involves getting opportunities for advancement and rewards, as well as overcoming barriers to moving up or at least moving along. Looking at the academic scientific career as an on-going process of developing research ethics (or not) suggests

points where we might focus study of research conduct. Stages and influences include: undergraduate and graduate school classes, peer influence, apprenticeship, and mentoring; postdoctoral fellowship working arrangements; teaching, co-authorship, mentoring, and pressures to publish as an untenured professor; teaching and research with students, post-docs, and colleagues as a tenured professor; departmental promotion and tenure reviews; university Institutional Review Boards and oversight of research; the broader communities of scholars and networks in which one becomes embedded; peer-reviewed journals' requirements, especially for the possibility of replication; and emphasis of disciplinary and professional societies on norms for ethical conduct of research. This presentation will provide some illustrations of potential research. While the focus is on academic careers, many of the same stages and influences on undertaking research with integrity are part of nonacademic careers.

A Researcher's Guide to Studying Research Integrity

Eleanor Singer, University of Michigan, Ann Arbor

In principle, studying research integrity is no different from studying anything else. In practice, it may turn out to be quite different.

The talk will begin with some general principles of how to go about "research in general," touching on issues of concepts and indicators, operationalization, definition of the population of interest, and measurement. It will then go on to consider special issues arising in the study of scientific misconduct as one kind of deviant behavior. Here, I will consider the problems posed by the fact that deviant behavior is generally not carried on in the open, and hence cannot readily be observed. I will also consider issues of social desirability, and how to encourage honest reporting of socially unacceptable or illegal behavior. I will also consider problems of differential motivation and differential opportunity to engage in scientific misconduct, and how that impacts research strategy.

The talk will conclude with a few examples of questions about scientific misconduct one might study, and will briefly outline some approaches to doing so.

6e. Case Studies, Monday, 8:30-9:45 (Markovsky)

An Epistemic Model for Moral Opportunities and Hazards in Scientific Enterprises

Jean Maria Arrigo, University of Virginia;

Maj-Britt Poulsen, University of Copenhagen

Objective: We seek a comprehensive model of scientific enterprises that captures the dynamics between ethics and the professional activities of scientists. The model should encompass both the ethics of inquiry for insiders and the ethics of impact on outsiders. **Design:** Our model evolved from our interviews with biomedical researchers and military and political intelligence professionals and from archived oral histories of weapons researchers. Review of our model by interviewees improved it iteratively. **Results:** A typical scientific project is a fluctuating dynamic of cooperation and competition, involving moral hazards and opportunities to its participants. Our case study of relations among a virology team and two cellular biology teams suggests conditions that support cooperation, such as demand for complementary skills, and conditions that support competition, such as proximity to project completion and allocation of credits. Intelligence operations exhibit more intense competition in inquiries, as in risk of agents' lives to probe data collected by the adversary. **Conclusions:** In our model, the Enlightenment vision of science constitutes the prototype of a "cooperative epistemology." Political and military intelligence, in contrast, constitutes the prototype of an "adversarial epistemology," which we distinguish from scientific epistemology through five premises. For example, "The ultimate goal of inquiry is advantage over an adversary," and "All observations are vulnerable to deliberate deception by the adversary." The cooperative and adversarial epistemologies stand as opposite poles on a continuum of epistemic commitments. Plant taxonomy and cosmology lie towards the cooperative pole; forensic psychiatry and biological warfare research lie towards the adversarial pole; biometrics, clinical trials, and educational testing occupy intermediate positions. But all scientific enterprises fluctuate between the adversarial and cooperative poles according to project stage, unit and time span of analysis, proprietary commitments, etc. The dynamics between research methods and ethics thus become visible, rendering moral opportunities and hazards predictable.

Waiving Informed Consent: Long Term Consequences for the US Military

Mary L. Cummings, Virginia Tech

Objective: The focal point of this investigation was to examine the ethical issues surrounding the military's requests for informed consent waivers when using investigational drugs. **Design:** The military's management of the informed consent process was examined using documents obtained through the Freedom of Information Act: IRB minutes, consent forms, and protocols for specific investigational drugs. **Results:** In December of 1990 prior to Operation Desert Storm, the FDA granted the Department of Defense (DoD) an unprecedented waiver to the federally mandated

informed-consent requirement for the use of investigational drugs. However, the waiver approval was conditional, and the FDA insisted on several safeguards. Partially in response to the subsequent Gulf War Syndrome debate, the FDA recently evaluated the military's use of investigational drugs during the Gulf War. The FDA cited the military for significant deviations from the approved protocol. Most notably, the military was found to be abusing the Institutional Review Board (IRB) process by convening a second IRB when the first IRB concluded that requesting a waiver of informed consent was unethical. Due largely in part to the military's misuse of investigational drugs, some military members are currently refusing the compulsory anthrax vaccine, which is an FDA approved drug but never meant for combat use. The anthrax vaccination of 2.4 million service members marks the first time soldiers have ever been forcibly inoculated against a biological threat in peacetime. The debate over the anthrax vaccine has directly impacted the military's recruitment and retention efforts, which has adversely affected the already critical military manning shortage. **Conclusions:** I argue that in medical situations, the military is obligated to treat its troops as autonomous persons entitled to basic rights and until it does so, the military will suffer the loss of medical credibility and confidence in leadership.

Omitting Data: Making the "Best" of What You Have

Jagmeet S. Kanwal, Georgetown University Medical Center

Objective: To question and begin to define the criteria by which omission of data can be considered a falsification of data. **Design:** In the practice of neurophysiology and perhaps in some other fields of neuroscience that are aimed at unraveling the complexities of brain function, the guidelines to judge omission of data as a case of falsification of data remain unclear. This is a theoretical study that analyzes the phenomenon of selective data gathering, data editing and analysis for purposes of interpretation and presentation of the results of a study. The analysis is based on research in a field, namely neuroscience, that is continuously challenging because of its complexity. Examples are based on a personal knowledge of and experience in the author's primary field of research, namely auditory neurophysiology. **Results:** In the mustached bat's auditory cortex there are well defined maps of parameters that are important for computing target characteristics for echolocation. These maps are made up of highly specialized neurons. This conclusion was reached after about two decades of research on this system. This organization can be questioned, however, on the basis of recent findings on additional response properties of the same neurons to stimuli that were not tested before. These response properties are important for audiovocal communication, but question some of the principles of auditory processing enumerated from the earlier findings. **Conclusions:** Omission of or failure to obtain relevant data is a subtle yet important means of falsification of data and can influence the experimental outcome and future progress in a field of research. However, the framework and nature of research in which some of the data are obtained/omitted is of critical importance in judging the impact of omitting data on research integrity.

Falsification of Data in Epidemiological Surveys: A Case Study of Detection and Remediation

Charles F. Turner, RTI and CUNY/Queens College and Graduate Center

James N. Gribble, Research Triangle Institute (RTI)

Alia A. Al-Tayyib, Research Triangle Institute

Objective: We report a case study of the belated detection and remediation of falsification in an epidemiological survey and biological specimen collection. **Design:** The 1997-98 Baltimore STD and Behavior Survey was designed to survey STD-related behaviors and to collect urine specimens for STD testing from a large probability sample of adults in Baltimore, Maryland (final validated N = 1,014). Data collection for this project was conducted by one of the nation's leading epidemiological survey organizations. Thirty-six interviewers were recruited as part-time workers who were paid by the hour not by the completed interview. All interviewers (regardless of prior experience) were trained on the procedures to be used in the survey. The survey organization's standard quality control procedures require the independent verification of a sample of all survey interviews. Near the planned end of data collection, one interviewer submitted work that aroused suspicions of falsification. Investigation revealed that many of these interviews were falsified. Furthermore, it was discovered that — without the knowledge of the PI or his research team— interview verification had been discontinued for most interviewers. To identify the full scope of the falsification in this data collection, operational indicators of "suspicious" interviewer performance were developed (e.g., high percent of household screenings yielding a completed interview; unusual male-female ratio of interviewed respondents; etc.). One hundred percent of all interviews submitted by interviewers judged to be "suspicious" were subject to independent verification. In addition, 40 percent of the interviews conducted by all other interviewers were independently verified by interviewers who were not connected with the original study. **Results:** A total of 348 interviews could not be verified. This number included cases of obvious falsification, e.g., “interviews” conducted at buildings that were demolished or vacant at the time of the interview. Examination of timing data suggest that some unverifiable interviews may be actual interviews conducted with households other than those included in the probability sample. **Conclusion:** 1: Detection. Even in the absence of normal field verification, diligent analyses of the outcome of interviewers' household screenings and on-the-fly checking of the distribution of responses to survey questions would have permitted early identification of many interviewers whose work was falsified. 2: Remediation. While late discovery of data falsification was costly in money and time, it was, nonetheless, possible to purge the survey data of the taint of this falsification.

7. Research Integrity in a World of Conflicting Interests, Sunday, 10:00-11:30 (Friedman)

Fraud In Medical Research: An Ethical And Scientific Problem

Frank O. Wells Consultant Medical Adviser, MedicoLegal Investigations, UK

Objective: To demonstrate whether research ethics committees (institutional review boards) have a role to play in the preventative management of research misconduct. **Design:** UK Local research ethics committees (LRECs) were (a) reminded of their responsibility, for any research project, to assess local circumstances, including the suitability and competence of the local triallist; and (b) asked to co-operate in the investigation of any prima facie case of research misconduct by making available the titles and sponsors of any relevant clinical trials which they had approved for the suspect triallist. The ten-year experience of the agency involved in conducting this review (MedicoLegal Investigations - MLI) is that fraudulent trial lists fabricate data time and again. The responses of the LRECs were compared with the situation pertaining before they were asked to become involved. **Results:** With regard to (a), until about four years ago, LRECs did not regularly interview triallists in their districts, tending to rely on their familiarity with the doctor concerned, or on a curriculum vitae. Now they are increasingly frequently asking potential triallists to present protocols in person and to demonstrate that they have the time, experience, facilities and motivation to carry out the research properly. With regard to (b), a 100% response has enabled MLI to ask sponsors of such trials for a list of the identifiers of the subjects in each trial, then the hospital or health authority to interpret these identifiers so that the subjects can be interviewed, revealing whether or not they have consented to take part or been involved at all. Such interviews may provide incontrovertible evidence of patient exploitation and of fabricated data, enabling strict disciplinary action to be initiated without delay. **Conclusions:** Local research ethics committees have two vital roles to play in the prevention and investigation of clinical research misconduct.

Assessing Faculty Researchers' Financial Ties to Industry and the Management of Possible Conflicts of Interest: A Case Study

Lisa A. Bero. University of California, San Francisco

Elizabeth A. Boyd, VA HSR&D Menlo Park and University of California, San Francisco.

Objective: To assess the extent to which faculty researchers have personal financial ties to the industry sponsors of their research; to assess the nature of those financial relationships; and to assess institutional efforts to address disclosed financial relationships and perceived conflicts of interest. **Design:** A case study of the University of California, San Francisco, a major biomedical research institution. Data sources were disclosure forms and official documents maintained by the UCSF Office of Research Administration, from 1980-1999. **Results:** By 1999, almost 8 percent of faculty investigators reported personal financial ties with the industry sponsors of their research.

Those relationships included payment for speaking engagements (34%), consulting agreements (33%), positions on Scientific Advisory Boards or Boards of Directors (32%), and equity ownership (14%). Perceived conflicts were managed by the institutional committee in 26% of the cases, and management strategies included divesting stock holdings, refusing additional compensation for speaking engagements, resigning from management positions, and naming a new Principal Investigator for the project. **Conclusions:** Faculty researchers are increasingly involved in a web of personal financial relationships with industry sponsors of research. Guidelines for what constitutes a conflict and how institutions should manage conflicts are needed if there are to be consistent standards of research behavior within and across institutions.

Conflict of Interest Relationships between Individual Behaviors and Organizational Risk in the Higher Education Institution: A Pilot Study

Michael M. Crouch, University of Pittsburgh

John L. Yeager, University of Pittsburgh

Objective: This paper examines the relationship of individual behaviors in Conflict of Interest (COI) situations, and the consequences for organizational risk. This work draws on paradigms from organizational theory and decision processes for motivational explanations of conflict aversion. The central research premise focuses on whether the individual's response to a conflict situation may be used as an indicator of the employer's institutional risk. **Design:** A preliminary theoretical model of conflict of interest relationships was postulated. A pilot study was developed, utilizing a draft survey instrument. It was mailed to a representative (but non-randomly selected) cross-section of university administrative staff. From a total pilot mailing n=50, a 70% response rate was obtained. Each question, structured in a closed-ended format, posed an administrative scenario entailing discretionary choice. Participants responded to items based on a 5-point Likert scale. Test items corresponded to the four (4) study questions, above.

Results:

Responses to avoidance of Conflict of Interest (COI)	N	Mean	Std. Dev.
family member supervision/nepotism issue	28	3.53	1.26
consulting interests conflict with sponsored research	28	4.39	0.57
faculty operating consulting operations within dept	26	4.77	0.51
anti-compete grant offer	26	3.69	0.93
Responses to management intervention of COI			
unreported spouse income on COI disclosure	28	4.39	0.724
2nd job unreported income exceeds 10% of base income	27	3.41	1.06
cumulative grant time commits exceed 100%	27	4.59	0.68
faculty exceed time limit for consulting	27	3.81	0.92
lax enforcement of COI sanctions	26	4.12	0.86
Responses to perceptions of COI			
faculty board compensation in trust fund to avoid COI	28	3.14	1.15
students attend faculty's for-profit seminars	28	4.14	1.04

faculty book royalties from mandatory textbook assign	27	3.56	0.75
faculty disclose $ interest in subject of journal report	27	3.26	1.06

Responses to Conflict of Commitment	N	Mean	Std. Dev.
faculty with joint appointments; time commits exceed 100%	26	4.27	1.15
interdisciplinary efforts conflict with dept. duties	25	3.08	1.00
public service decrease vs. increased sponsored research	28	3.46	1.00

Conclusions: This pilot study supports a matrix or "boundary map" model that illustrates the relationships between acceptable employee/individual conduct involving nominal conflict of interest, versus egregious acts that may result in institutional liability under sponsored research obligations.

The Commercialization of Academic Science: Conflict of Interest Policies and the Faculty Consultant

Lisa M. Jones, University of Minnesota

Karen Seashore Louis, University of Minnesota

Objective: This study examines life sciences faculty who report earning additional income by consulting for non-profit organizations, industry, and government and their engagement in actual conflict of interest behaviors. **Design:** This study is part of an NIH-funded project on life sciences faculty in U.S. universities. The data originate from a nationwide survey (conducted in 1994-1995) of 3,169 faculty at 50 research institutions (65% overall response) selected from 100 universities with the most 1993 NIH funding. Two non-clinical departments, one clinical medical department, and one clinical non-medical department were selected randomly from each university. Assistant, Associate and Full Professors who do not conduct clinical trials of drugs or medical devices were used in this analysis (N=1032). The study provides descriptive statistics and multiple and logistic regressions for: a) entrepreneurial behaviors (patent application, company start-up, equity, and company-owned patent generated by university research); b) supplemental income amounts; c) research bias- (selection of topics based on commercial potential); d) prior review practices; e) sharing research tools with other scientists; and, f) proprietary censorship. Public/non-profit, private enterprise, and exclusive consultants were compared with non-consultants. **Results:** Both private enterprise and exclusive consultants report more supplemental income and entrepreneurial behaviors. Multiple regressions show modest associations between consulting and entrepreneurial behaviors. The logistic regressions indicate negative associations between consulting with prior review. No statistically significant results show for research bias, withholding, or secrecy. **Conclusions:** Data show that the incidences of behavior that threaten research integrity are limited. These findings support the rationale for disclosure and reporting policies developed by federal funding agencies and academic institutions.

Conflicts of Interest and Scientific Objectivity

Arthur B. Millman, University of Massachusetts, Boston

Objective: What is the most adequate definition of the concept of conflict of interest for dealing with academic-industry research relations and, specifically, how does this concept apply to institutions themselves? **Design:** A theoretical analysis of the concept of conflict of interest was done. Reasons why conflict of interest is objectionable were explored and disentangled. **Results:** Previous conceptual analyses have focused primarily on individual conflict of interest. If one recognizes the ways in which universities and other nonprofit institutions are increasingly behaving like entrepreneurial businesses, one is led to see the need to control institutional conflict of interest and at least provide some oversight of the institutional monitoring of investigators' conflicts of interest. Moreover, the appearance of conflict of interest is of course significant and depends in part on the expectations and assumptions of the public and of policymakers. The view of universities as non-profit institutions deserving of public support is eroded by the pursuit, by faculty or by institutions, of great monetary gain. Doubts in various quarters about the meaningfulness of the notion of scientific objectivity interact with the changing perception of universities to shake confidence in the traditional conception of the scientific ethic. **Conclusion:** Conflict of interest is not an issue of individual integrity alone. We need a clarified concept of conflict of interest that deals directly with institutional conflicts of interest and gives some guidance about when conflict of interest should be eliminated and when it can be managed. It may be that greater government funding with stricter limits on economic incentives is needed to control conflict of interest. A definition of conflict of interest is formulated that applies to institutions and does not conflate an institution's interest with the public interest.

Alphabetical List of Presenters