2006

ORI Research on Research Integrity Conference

hosted by the

University of South Florida College of Medicine

Safety Harbor Resort & Spa

December 1-3

(Penultimate Program, 9/8/06)

Program Summary

Friday, December 1

1:00-1:30	**Welcome and Opening Comments**
1:30-3:30	**Plenary: Trends, Challenges and New Research Areas**
3:45-5:45	**Plenary: Teaching and Behavior**
6:00 ff.	**Poster Session, continuing on Saturday**
6:30-9:00	**Reception, Dinner & Keynote Address**

Saturday, December 2

8:00-10:00	**Concurrent Track One: The Role of the Individual**
8:00-10:00	**Concurrent Track Two: Journals, Authorship and Publication**
8:00-10:00	**Concurrent Track Three: RCR Instruction**
10:15-12:15	**Concurrent Track One: Panel on the Role of the Individual**
10:15-12:15	**Concurrent Track Two: Panel on Journals, Authorship and Publication**
10:15-12:15	**Concurrent Track Three: RCR Instruction**
1:30-3:30	**Concurrent Track One: The Role of the Individual**
1:30-3:30	**Concurrent Track Two: Journals, Authorship and Publication**
1:30-3:30	**Concurrent: Moral Considerations**
3:45-5:45	**Plenary: Prevalence**
6:00 ff	**Dinner on own or with groups organized earlier in the day**

Sunday, December 3

8:30-10:00	**Concurrent: Climate**
8:30-10:00	**Concurrent Panel on the Design and Conduct of Clinical Trials**
8:30-10:00	**Concurrent: Questionable Research Practices**
10:15:12:15	**Plenary: Impacts and Policy Implications**
12:15-1:00	**Closing Presentation and Discussion**

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Abstracts

(presenters in italics)

Friday: 1:00-1:30 Welcome and Opening Comments

Friday: 1:30-3:30 Plenary: Trends, Challenges and New Research Areas

William Gardner, The Social Cost of Scientific Misconduct and Questionable Research Practices (The Ohio State University)

AIMS. It is difficult to measure the prevalence of misconduct and questionable research practices (QRP), and harder to determine their social impacts. Current discussions focus on the direct costs of known misconduct cases. I present an initial economic theory of the indirect social costs of misconduct and QRP in medical research.

METHODS. I present a model of the social cost of irresponsible medical research, in three parts: 1) Research is time-consuming and expensive. Few studies produce improvements over existing practice. 2) Fraud and QRP make it harder to eliminate bad ideas early, and may induce other researchers to pursue false leads, reducing research efficiency. Therefore, misconduct and QRP increase the cost of discovery and reduce the number of beneficial treatments found. 3) Medical research delivers social goods such as increased longevity. Fewer discoveries damps the rate of increase in production of these goods. These unrealized goods are the social costs of misconduct.

CONCLUSIONS. The model synthesizes several literatures. From studies of the drug discovery process, I derive a stylized model of a multi-step medical research process (part 1). Next, I draw on the theory of securities fraud to develop models for how misconduct and QRP may lead to the misallocation of research funds. These models suggest that even small amounts of fraud or QRP may reduce the number of successful treatments identified per research dollar invested (part 2). Finally, I summarize health economists' estimates of the annual social benefits of medical research. These estimates are on the order of hundreds of billions of dollars per year (part 3). The conclusion is that if misconduct and QRP result in even a small reduction in the rate of delivery of beneficial treatments, the dollar value of these lost benefits will be substantially larger than estimates based on the direct costs of known cases of misconduct. The model to be presented does not (yet) permit us to make point estimates of the social cost of misconduct. It will, however, open a new discussion about the implications of misconduct, raise new questions about how to prevent irresponsible science, and provide theoretically-grounded directions for RRI research. (Help for this paper was received from Dr. Tracy Wang, an economist at the University of Minnesota.)

Carol R. Thrush, James Vander Putten, Use of a Novel Content Analysis Method to Examine Trends in Research Integrity Literature (U. of Arkansas for Medical Sciences & U. of Arkansas-Little Rock)

AIMS. A pertinent indicator of significant and continued maturation of the field of research integrity is the increasing scholarly literature about research ethics and responsible conduct of research. This study uses a novel content analysis method to explore trends in the emergent field of research integrity literature over the past decade

METHODS. Following previously published literature search methods by the Institute of Medicine (2002), the top five periodicals which publish articles on research integrity were examined in Medline for 1996-2005 (Science, JAMA, Academic Medicine, Science and Engineering Ethics, and BMJ). MESH headings and text-word searches for the 36 IOM-published search terms were used as well as 17 additional relevant terms. Article titles were sorted into 21 overarching categories using SPSS Text Analysis for Surveys . Both natural language processing algorithms and investigator judgment were used to categorize article titles. Chi-square analysis was used to examine the categorical distributions for 1996-2000 compared to 2001-2005

CONCLUSIONS. A total of 1,086 article titles were identified, of which 1,056 were categorized into at least one category. Of the 1,056 titles categorized, 43% were published in 1996-2000 and 57% in 2001-2005 representing a 35% increase. There were significant differences in the temporal distribution for 6 of the 21 total categories with 'human subjects,' 'misconduct' and 'inquiries' ($p<0.01$) more frequent in earlier years (1996 -2000), and 'scientific societies,' 'conflict of interest,' 'ethics,' 'mentoring' and 'education' more frequent in 2001-2005 ($p<0.01$) . Results suggest that the terminology of article titles over the past decade reflects important shifts recommended by research integrity leaders. There was a decrease in article titles related to topics about human subjects, misconduct and inquiries, and a growing emphasis on articles about mentoring and the role of academic societies in promoting integrity. The results also suggest the emerging importance of concerns about conflict of interest in research and education-ethics-related discourse.

Jill Rosenbaum, Charles W. Lidz, Applying Dillman's Tailored Design Method to Internet Surveys (University of Massachusetts Medical School)

AIMS. Low response rates are a significant threat to the validity of population surveys. Self-selection biases can only be minimized by low refusal rates. Obtaining high return rates is, therefore, essential to the integrity and generalizability of survey based research. This paper will discuss problems and strengths of using Dillman's Tailored Design Method in conjunction with the web-based survey site, Surveymonkey. We conducted a ORI funded study surveying research integrity with a better than 75 percent response rate.

METHODS. Dillman's Tailored Design Method is a strategy for conducting population surveys which was originally developed for mailed surveys, but has more recently been adapted to web-based surveys. The current investigation followed Dillman's strategy of multiple contacts using different means (snail-mail, email, telephone, etc) allowing for a wider range of coverage. In the current study, data was collected via a web-based survey. Participants were recruited and directed to the survey using this strategy. The survey was sent out to 1,250 doctors, nurses, and other research personnel. Although a very high return rate was achieved, this method also has significant difficulties to overcome.

CONCLUSIONS. Although the study was designed to assess compliance with a clinical trials protocol, the method of data collection was so successful as to merit its own dissemination. Our strategy involved six stages. The first contact always produced more responses than any of the subsequent contacts. It also provided information about the contacts which informed the subsequent steps (e.g., anyone whose email was returned or who had changed their email address was contacted by phone). Calling increased the response rate because either we received a valid email address and could resend the survey, or we eliminated a name from our list. The group of subjects composed exclusively of physicians was, as expected, the least cooperative with a 57 percent response rate. The response rate for mixed groups (doctors, nurses, coordinators, etc.) was over 80 percent. Across all groups, the response rate was 75.2 percent. This compares very favorably to the typical internet survey response rate of 28.5 percent (Schaefer & Dillman 1998). Schaefer, D.R., Dillman, D.A.(1998). Development of a Standard E-Mail Methodology: Results of an Experiment. Public Opinion Quarterly, 62:378-97.

Gwen W. Anderson, **Joan Liaschenko, ***Raymond DeVries, Clinical Trial Registries in Gene Therapy Research: Do They Foster Access to Research and Public Trust? (*San Diego State University, **University of Minnesota, ***University of Michigan)

AIMS. This presentation reports Phase I of an ethnographic study aimed at describing the day-to-day operations and decisions that bear on conducting gene therapy clinical trials and regulatory paper work. Gaining access to active, gene therapy clinical trials in three regions of the U.S via Principal Investigators (PI) or Industry Sponsors has proven to be very difficult.

METHODS. The authors describe and compare four types of Trial Registries and the labor intensive method required to locate, contact and communicate with PIs and Industry Sponsors of all registered 'open' trials. Descriptive statistics are used to document patterns in this Gene Therapy Trial Registration Report Card. Verbatim responses by PIs and Industry Sponsors for their denials and rejections to participate are shared and summarized.

CONCLUSIONS. Possible explanation for inaccurate data in the Gene Therapy Trial Registry include: 1) lack of timely update of inactive trials or changing personnel, 2) mistaken PI designation, 3) lack of timely verification of contact information, 4) mistaken designation of trial type, 5) criteria for PI designation on the registry is different from the clinical site PIs.

A second dimension to this presentation includes a discussion of possible explanations for why neither PIs nor industry sponsors will consent to participate in an ethnographic study; these include: 1) gate keeping, 2) the perception that studying gene therapy clinical trials will expose practices that should not be attributed only to gene therapy research because 'mistakes' are common to all clinical trials, 4) fear of being 'monitored', 5) unwillingness to expose turnover rates and instability of key research personnel, 6) fear of revealing that study coordinators rather than PIs conduct clinical trials, 7) a claim that ethnography is not science, 8) fear of scrutiny by professions other than medicine and by female researchers, and 9) lack of financial incentive to participate.

These findings have significant implications for studying clinical trials because of the ways trial sponsors can avoid scrutiny of their research integrity and ethical obligation to make clinical trial information accessible. This raises the question of what public access means, specifically, whether it means the same to the general public as for social science researchers.

Friday: 3:45-5:45 Plenary: Teaching and Behavior

Dena Plemmons, Michael Kalichman, Goals Reported by Instructors for Teaching of Research Ethics (University of California, San Diego)

AIMS. The effectiveness of research ethics (responsible conduct of research, RCR) training is not yet well understood, in part because we are not clear about the goals or objectives for that training. The purpose of this study was to characterize the range of goals identified by RCR instructors.

METHODS. All new NIH training grant principal investigators funded in 2002 (N=116) were contacted for information about the person(s) responsible for providing the required RCR training. Instructors of RCR courses (N=50, 75% response rate for those identifying themselves as RCR instructors) were surveyed. The survey consisted of several demographic questions and a mix of forced choice and open ended questions about instructional goals within 5 domains: knowledge, skills, attitudes, behaviors, and community. Primary analysis was a quantitative summary of the rankings of items in the categories of knowledge and skills.

CONCLUSIONS. The instructors responded to the open-ended and forced choice questions often from very different personal experiences with teaching RCR, and with different research interests and approaches, subject populations, and student populations. Respondents were generally in agreement about what topics should be covered. However, their goals were surprisingly wide-ranging. The richness of the responses is seen in some of the reported goals, e.g.: (1) to get through it without dying of boredom ; (2) "the reasons behind the policies, why there are guidelines"; (3) " emphasis is on understanding that there

are power differences that exist between researchers and the community"; and (4) " how to make good moral decisions." One interpretation of these results is that there is less clarity about what the goals and objectives of such instruction should be or can be. Required, formal RCR instruction is still relatively new. Until we can be clearer about the goals of this instruction, it will be difficult to define measurable outcomes, much less be effective.

Kenneth D. Pimple, Douglas Adams, The Influence of Opportunity on Research Misconduct (Indiana University, University of Arkansas)

AIMS. Efforts to support research integrity and discourage research misconduct can benefit from the successes of OPPORTUNITY THEORIES of crime and deviant behavior which have been shown in real-world initiatives to reduce crime and police misconduct. We explain the fundamentals of opportunity theory and apply it to scientific research.

METHODS. The commission of research misconduct, like crime, requires two fundamental analytical elements: propensity and opportunity. PROPENSITY includes all psychological conditions that affect individual choice, such as a sense of self-justification. OPPORTUNITY includes all external conditions that facilitate particular actions, such as lack of oversight.

Opportunities for misconduct are embedded in, and enabled / inhibited through, the moral, legal and social dimensions of the research milieu. The moral dimension emphasizes the role of ethics and values; the legal dimension emphasizes laws, policies, and procedures; and the social dimension emphasizes informal norms and choice limitations based on the physical environment.

CONCLUSIONS. To date, efforts intended to understand, prevent, and control research misconduct have emphasized the moral and legal dimensions of the research environment. With few exceptions, greater attention has been placed on affecting individual propensity (e.g., through educational efforts intended to improve moral reasoning or inculcate prosocial values) over components of situational opportunity. In this paper, we focus on the role of opportunity in the enactment of research misconduct with an emphasis on the social dimension while attending to the moral and legal dimensions of the research environment as well. In particular, we discuss several empirically-supported initiatives that show promise in their application to research integrity including:

A. The specification of research setting parameters as derived from ROUTINE ACTIVITY THEORY that increase or decrease the probability of research misconduct, such as a likely offender, a suitable target, and the absence of a capable guardian.

B. Research management practices that facilitate the emergence of increased informal social control within work-groups, such as early intervention systems, limiting the number of direct reports, and assigning subordinate researchers to tasks in pairs.

Melissa S. Anderson, *Brian C. Martinson, Aaron Horn, Kelly R. Risbey, Emily A. Ronning, **Raymond De Vries, RCR Training and Mentoring: Associations with Ethically Questionable Behavior (University of Minnesota, *HealthPartners Research Foundation, **University of Michigan)

AIMS. The aim of this paper is to examine relationships between the extent and types of training and mentoring in ethics that scientists receive and questionable behaviors in which they engage.

METHODS. Our analyses are based on survey data from two samples of NIH-funded scientists: 3,600 who received their first research (R01) grant from NIH in the period 1999-2001, and 4,160 who received postdoctoral training support during 2000-2001. Respondents were asked about their formal training in ethics and the responsible conduct of research, as well as the informal mentoring they received. They were also asked to indicate whether or not they had engaged in a range of questionable behaviors during the preceding 3 years. This paper presents descriptive findings related to training and mentoring, as well as multivariate analyses of these in relation to questionable behaviors.

CONCLUSIONS. Our samples provide a unique opportunity to examine relationships between training and mentoring and responsible research behavior for those who received their terminal degrees largely

before the advent of U.S. federally mandated training in research ethics and those whose graduate training was likely subject to the new requirements. Though our data show that the early-career scientists are more likely than the mid-career group to have received training, we nonetheless see substantial proportions among both groups (15% and 37%, respectively) who report that they had neither courses in ethics nor ethics training integrated with their discipline-based coursework.

Our findings indicate that training in ethics, particularly when delivered both through ethics courses and integrated material, is negatively related to questionable behaviors, but only of certain kinds, such as inappropriate use of data. Overall, we find little relationship between formal training and participation in questionable behaviors. Mentoring, however, shows significant associations with such behaviors -- either positive or negative, depending on the type of mentoring -- among the early-career scientists.

Rebecca Lind, T. Swenson-Leeper, A Preliminary Investigation of Conflict of Interest Sensitivity (University of Illinois at Chicago, Winona State University)

AIMS. The authors apply their experiences assessing *Ethical Sensitivity* to a related construct, *Conflict of Interest Sensitivity*. The objective of this preliminary investigation is to define conflict of interest (COI) sensitivity and test whether it can reliably be assessed. In this study, we provide conceptual and operational definitions of COI sensitivity, and develop/pilot test stimulus materials and coding procedures for assessing COI sensitivity.

METHODS. We adapt our ethical sensitivity measurement techniques to the COI sensitivity context. Two case studies presenting conflicts of interest in research are adapted from the COI literature and other COI resources. We conduct open-ended funnel interviews with a small purposive sample of undergraduate and graduate students from the natural sciences and engineering Interviews are transcribed and subjected to a variation of Axelrod's (1976) cognitive mapping techniques. Cognitive maps represent concepts and causal beliefs, and not only allow identification of the key concepts or issues people raise, but also the ways in which people link or relate these concepts.

CONCLUSIONS. This research is preliminary and descriptive. It represents the necessary starting point for continued examinations of COI sensitivity. As one of the nine core instructional areas of the Responsible Conduct of Research, conflicts of interest -- and people's sensitivity to them -- warrant much scrutiny. Should we succeed at adapting our prior work to this new arena, we will be able to embark on a significant program of research enabling us to create and reliably assess COI-related educational efforts.

Friday: 6:00 ff. Poster Session, continuing on Saturday

David Resnik, A Survey of Research Ethics Practices at the National Institute of Environmental Health Science (NIEHS) (NIEHS/NIH)

AIMS. To describe NIEHS researchers' experience with twenty different behaviors related to the responsible conduct of research pertaining to the work at the NIEHS and elsewhere.

METHODS. An anonymous survey was administered to researchers in the fall of 2004, during training annual sessions for responsible conduct of research. Researchers were told to remain anonymous and they were told that they did not have to participate in the survey. They were allowed to fill out the survey at the end of the session or mail it back. 243/531 people responded to the survey for a 45.8% response rate. They were asked to complete some demographic information and answer to 20 questions about their experiences with ethical problems and issues while working the NIEHS and elsewhere. They were allowed to answer yes, no , or no answer (NA).

CONCLUSIONS. Researchers observed or new about fewer ethical problems or issues at the NIEHS than elsewhere. For some problems, the differences between the NIEHS and elsewhere were large. For example, only 8.64% observed or knew about theft/destruction of property at the NIEHS as compared to 74% elsewhere; 3.7% observed or knew about plagiarism at the NIEHS as compared to 56% elsewhere;

and 4.1% observed fabrication or falsification of data at the NIEHS, as compared to 20.2% elsewhere. For some problems, the differences were noticeable but not large. For example, 1.2% observed or knew about violations of human research regulations at the NIEHS as compared to 3.7% elsewhere (3.7%), and 4.9% observed or knew about intellectual property disputes at the NIEHS as compared to 10.7% elsewhere. For some problems, there was virtually no difference between the NIEHS and elswhere. For example, 25.5% observed or knew about violations of laboratory safety rules at the NIEHS and 25.5% observed or knew about these violations elsewhere; 31% observed or knew about record keeping problems at the NIEHS and 31% observed or knew about these same problems elsewhere; 20.6% observed or knew about data sharing problems elsewhere as compared to 22.6% elsewhere; and 11.5% observed or knew about sexual harassment at the NIEHS as compared to 14.8% elsewhere. Overall, the survey bodes well for the ethical climate at the NIEHS relative to other institutions, but there are still some issues and problems that merit serious attention, such as authorship, record keeping, laboratory safety, mentoring, and data sharing. The rates for fabrication, falsification, and plagiarism are consistent with rates reported in other studies.

Jill Rosenbaum, Charles W. Lidz, How We Got a 75.4% Response Rate on an Internet Survey (University of Massachusetts Medical School)

AIMS. Studying compliance with clinical trial s protocols using survey methods is a difficult task. Response rates to internet surveys are typically in the low double digits. Asking questions about violations of research rules of research staff is not a topic likely to increase survey response rates. This poster will illuminate how using Dillman s Tailored Design Method in consort with the internet survey site, Surveymonkey, generated a response rate of 75.4% to our internet survey nearly tripling the industry average of 28%. In a simple and graphic way we ve outlined the steps and various decisions we made in construction and implementation of our survey to members of the medical research community.

Andrew Stainthorpe, The Organization and Goals of the UK Panel on Research Integrity (UK Panel on Research Integrity)

Wayne T. McCormack, Use of Team-Based Learning in Teaching Responsible Conduct of Research to First-Year Biomedical Science Graduate Students (University of Florida College of Medicine)

AIMS. PhD students are required to take a responsible conduct of research (RCR) course, but existing courses were passive and lecture-driven. The main objective was to promote active learning so students could begin applying the principles of RCR using case scenarios and/or group problem-solving as they begin their dissertation research.

METHODS. The new course Responsible Conduct of Biomedical Research (GMS 7003) was established in Summer 2006 (http://idp.med.ufl.edu/RCR/). The course consisted of six Tuesday lectures followed by Thursday small group sessions, and utilized the instructional strategy known as team-based learning (TBL). TBL consists of pre-class preparation (e.g. lectures, reading), a readiness assurance process involving short individual and team tests, and the application of course concepts through problem-solving team assignments. Readiness assurance tests consisted of 10 multiple-choice questions based on assigned reading from "ORI Introduction to the Responsible Conduct of Research" by N. Steneck (2004). Problem-solving activities were developed with the lecturers.

CONCLUSIONS. Student feedback about the TBL format was obtained via on-line course evaluations at the end of the semester. 68.5% of the respondents (54/65 students) preferred the TBL format over other small group formats used in other courses in our PhD program. 64.5% agreed or strongly agreed with a statement that they were better prepared for class, but only 18.9% thought their team members were better prepared (52.8% were neutral). 72.3% agreed or

strongly agreed that the TBL format resulted in more interaction between students than in small group sessions in other courses, and 51.9% agreed or strongly agreed that they could learn better in team-based learning sessions than in small group sessions in other courses. Team-based learning appears to be a good format to promote active learning of RCR material. Next year s course will include surveys of student attitudes, knowledge, and opinions about RCR issues before and after the course.

Carol R. Thrush, James Vander Putten, Use of a Novel Content Analysis Method to Examine Trends in Research Integrity Literature (University of Arkansas for Medical Sciences, University of Arkansas-Little Rock)

AIMS. A pertinent indicator of significant and continued maturation of the field of research integrity is the increasing scholarly literature about research ethics and responsible conduct of research. This study uses a novel content analysis method to explore trends in the emergent field of research integrity literature over the past decade

METHODS. Following previously published literature search methods by the Institute of Medicine (2002), the top five periodicals which publish articles on research integrity were examined in Medline for 1996-2005 (Science, JAMA, Academic Medicine, Science and Engineering Ethics, and BMJ). MESH headings and text-word searches for the 36 IOM-published search terms were used as well as 17 additional relevant terms. Article titles were sorted into 21 overarching categories using SPSS Text Analysis for Surveys . Both natural language processing algorithms and investigator judgment were used to categorize article titles. Chi-square analysis was used to examine the categorical distributions for 1996-2000 compared to 2001-2005

CONCLUSIONS. A total of 1,086 article titles were identified, of which 1,056 were categorized into at least one category. Of the 1,056 titles categorized, 43% were published in 1996-2000 and 57% in 2001-2005 representing a 35% increase. There were significant differences in the temporal distribution for 6 of the 21 total categories with 'human subjects,' 'misconduct' and 'inquiries' ($p<0.01$) more frequent in earlier years (1996 -2000), and 'scientific societies,' 'conflict of interest,' 'ethics,' 'mentoring' and 'education' more frequent in 2001-2005 ($p<0.01$) . Results suggest that the terminology of article titles over the past decade reflects important shifts recommended by research integrity leaders. There was a decrease in article titles related to topics about human subjects, misconduct and inquiries, and a growing emphasis on articles about mentoring and the role of academic societies in promoting integrity. The results also suggest the emerging importance of concerns about conflict of interest in research and education-ethics-related discourse. Friday: 6:00-6:30 Reception

Friday: 6:30-9:00 Reception, Dinner & Keynote Address

Ana Marusic, Trust but Verify: Strengths, Weaknesses, Opportunities and Threats of Scientific Publishing (Croatian Medical Journal)

Saturday: 8:00-10:00 Concurrent Track One: The Role of the Individual

Jason Hill, Stephen Murphy, Ethan Waples, Michael D. Mumford, Shane Connelly, Lynn Devenport, Ryan P. Brown, Validation of Ethical Decision-Making Measures: Internal and External Validity (University of Oklahoma)

AIMS. Ethical decision-making measures are widely applied as the principal dependent variable in studies of research integrity. However, evidence bearing on the internal and external validity of these measures is not available. The intent of the present study was to assess the validity of a new set of ethical decision-making measures.

METHODS. In the present study, we administered an ethical decision-making measure and other assessments to examine the exposure to ethical breeches and severity of punishments to 102 graduate students. The ethical decision-making measures were scored for ethical practices, day to day decision-making, and the use of social psychological dimensions and cognitive strategies. The exposure to ethical breeches measure was scored on four dimensions: data, study conduct, professional practices, and business practices. Finally, participants were asked to assume a role and judge a misconduct incident on perceived seriousness and frequency of occurrence, as well as the importance and severity of punishment.

CONCLUSIONS. The results obtained point to the validity of the measure of ethical decision-making. Ethical practices were inextricably linked to the use of practical and cognitive strategies. Also, after analyzing the ethical decision-making measure in the context of individual difference dimensions including cynicism, trust, and narcissism, we found that ethical decision-making arises from one's perception of oneself and others. The ethical practices measures and the associated social psychological and cognitive dimensions were related to exposure to ethical events and the severity of punishments in the research environment.
One implication of these findings is that the improvement of graduate students' ethical decision-making may occur through training interventions aimed at senior investigators and targeting laboratory management practices. Moreover, the results of this study suggest that the content and format of responsible conduct of research training should be amended. Traditionally, training has focused on providing information on legal obligations and knowledge regarding appropriate professional behavior. This approach, although a necessary component of ethics training, may not be sufficient to significantly enhance ethical decision-making among researchers. Instead, more emphasis should be placed on educating researchers on the benefits of avoiding personal concerns or motives and analyzing the potential consequences of their decisions for others.

Melissa S. Anderson, *Brian C. Martinson, **Raymond De Vries, Scientists' Normative Orientations: Normative Dissonance and Ethically Questionable Behavior (University of Minnesota, *HealthPartners Research Foundation, **University of Michigan)

AIMS. This paper analyzes the normative orientations of scientists, with particular attention to dissonance among their subscription to norms of various kinds, their own behavior, and their perceptions of their colleagues' behavior. It furthermore examines relationships between scientists' normative orientations and their participation in ethically questionable behaviors.

METHODS. Our analyses are based on survey data from two samples of NIH-funded scientists: 3,600 who received their first research (R01) grant from NIH in the period 1999-2001, and 4,160 who received postdoctoral training support during 2000-2001. These scientists were asked about their subscription to traditional norms of science, alternative norms, and other potential norms

derived from earlier focus-group discussions. They were also asked to indicate whether or not they had engaged in a range of questionable behaviors during the preceding 3 years.

CONCLUSIONS. Our results show dissonance among various measures of normative orientation: in general, scientists see their behavior as falling short of the normative ideals to which they largely subscribe, but they also see their own behavior as better aligned with these ideals than is the behavior of their colleagues. Scientists who have the highest self-report scores on competing with others in the same field, investing their careers in promoting their own findings, and protecting their findings to ensure priority are more likely to report having engaged in questionable behaviors. Conversely, those who see their own behavior as aligned with traditional norms, including the Mertonian norms, are less likely to report having engaged in questionable behaviors.

Alison L. Antes, Ethan P. Waples, Ryan P. Brown, Michael D. Mumford, Lynn R. Devenport, Shane Connelly, Ethical Decision-Making in Research: Exploring the Influence of Personality (University of Oklahoma)

AIMS. The aim of the present study was to explore the influence of key personality variables on ethical decision-making in research settings. Understanding personality variables provides an essential piece of the framework necessary for effectively predicting ethical behavior and implementing research integrity interventions

METHODS. To explore the role of personality in ethical decision-making, 102 first-year doctoral candidates completed ethical decision-making measures along with personality measures postulated to influence ethical decision-making. Decision-making was assessed across four domains (data management, study conduct, and adherence to professional and business standards). In addition, ethical decisions were categorized according to their utilization of one of seven effective strategies for ethical decision-making (for example, recognizing one's circumstances and anticipating consequences) and the primary motivation behind the decision (for example, retaliation, deception, and responsibility avoidance). Correlation and regression analyses were conducted to assess the extent of the relationship between personality variables and ethical decision-making.

CONCLUSIONS. Cynicism, trust, and narcissism were significant predictors of ethical decision-making. Generally, the decisions of participants tended to become less ethical in all four research domains as cynicism increased. As an example, individuals high on cynicism and narcissism but low in trust of others were more likely to make less ethical decisions regarding professional practices such as the protection of public welfare and the exploitation of staff members.

With regard to strategies for effective ethical decision-making, cynicism and narcissism showed a consistent negative relationship with the utilization of these strategies. Participants high on cynicism and narcissism were less likely to engage in the following ethical decision-making strategies: recognizing one's circumstances, questioning one's judgment, controlling one's emotions, and considering others' perspectives. Cynicism was also positively related to decisions that emphasized retaliatory, deceptive, selfish, and responsibility-avoidant motives.

Overall, these findings indicate that one's conception of self and relation to others plays an influential role in ethical decision-making in research. The impact of self-centeredness, along with pessimistic and distrustful views of others, on unethical decision-making may stem from a failure to consider the consequences of one's actions on others in the situation.

Darko Hren, Ana Vujaklija, Ivana Vodopivec, Ana Marusic, Matko Marusic, Development of Moral Reasoning during Medical School (Croatian Medical Journal)

AIMS. To investigate differences in moral reasoning among medical students at different stages of their medical studies.

METHODS. Zagreb University medical students from all six years (n=706) completed DIT-2 test of moral reasoning during winter semester of the 2004/2005 academic year. DIT-2 measures three schemae of moral reasoning - Personal Interest (PI), Maintaining Norms (MN) and Postconventional (P). The main outcome measure, the N2 index is a composite measure that measures how much a person uses the most advanced P-schema, as well as how much a person does not use the least advanced PI schema while deciding upon a moral dilemma.

CONCLUSIONS. Third year medical students had significantly higher N2 scores than first, second and sixth year students (MÒSD of N2 scores for 1st through 6th year were 32.5Ò12.4, 31.7Ò12.2, 37.3Ò11.2, 32.9Ò12.1, 32.9Ò12.0 and 31.4Ò11.7 respectively; F=4.1, p=0.001; One-way ANOVA, Tukey post hoc). These results imply that moral reasoning increases during preclinical years and then stagnates and decreases back to the entrance level during clinical years. Possible explanation for this trend is hierarchical organization of clinical rounds where students, at the bottom of the hierarchy, engage in developing surviving skills through obedience and conformism rather than acting on their ideals or principles.

Saturday: 8:00-10:00 Concurrent Track Two: Journals, Authorship and Publication

Elizabeth Boyd, Karah Popp, Kirby Lee, Lisa Bero, Conflicts of Interest and Editorial Decision-making: How Editors', Peer Reviewers', and Authors' Disclosed Conflicts Affect Decisions to Publish Manuscripts (University of California, San Francisco)

AIMS. Little is known about the actual decision-making processes through which journal editors decide to accept or reject submitted manuscripts, how authors', peer reviewers' or editors' personal or financial conflicts of interest are taken into consideration, or how those conflicts impact editors' decisions to accept or reject submitted manuscripts. Our objective was to determine whether, what type, and how conflicts of interest were discussed by journal editors during manuscript evaluation, and how those conflicts figured into editorial decision-making.

METHODS. We enrolled a prospective cohort of 1,107 manuscripts submitted for publication between January 2003 and February 2004 at three major biomedical journals: the Lancet, the British Medical Journal, and the Annals of Internal Medicine. Additionally, we audio-recorded all editorial meetings in which these manuscripts were discussed. Audiotapes were transcribed verbatim using Jeffersonian transcription notation. Tapes and transcripts were analyzed using discourse and conversation analytic methods. Recurrent features of the discussions and other communicative patterns within and across editorial meetings and journals were qualitatively coded, as were extreme or unusual cases.

CONCLUSIONS. All journals were concerned about disclosed and undisclosed conflicts of interest and their impact on the credibility of a submitted manuscript and subsequent decisions to accept or reject it. A variety of situations warranted extended discussion among journal editors, including pharmaceutical company sponsorship of drug studies, nonprofit or other interest group involvement in studies, personal conflicts among peer reviewers and authors, editors' own conflicts, and the possibility of certain forms of bias, including biases against authors from non-English-speaking countries, and biases against qualitative research. Overt consideration of editorial practice in light of disclosed conflicts occurred often, and papers raising significant

ethical concerns were most often returned to the editorial desk for additional investigation. Overall, journal editors were explicit in their consideration of disclosed conflicts.

William Gardner, Kendr Hecka, Authorship Ethics Requirements in Medical Journals (The Ohio State University)

AIMS. Previous studies have shown that medical journals varied in their requirements that authors document informed consent and human subjects review. Less is known about journals' requirements concerning authorship ethics. This study describes variation in ethical requirements in the instructions for authors of a sample of journals publishing clinical trials.

METHODS. We identified all journals that published articles coded as 'Clinical Trials' by PubMed in 2003. We randomly sampled 181 of those journals, over-sampling the rare journals that published many clinical trials. We retrieved the 'Instructions to Authors' for each journal. We coded whether the instructions set forth any of several authorship ethics requirements, including disclosure of funding, disclosure of conflicts of interest, requirements for contributorship, etc. We used regression analyses (incorporating the sampling weights) to determine whether ethics requirements varied by the disciplinary audience of the journal, where the journal was published, and the number of clinical trials published.

CONCLUSIONS. The space of journals publishing articles coded 'clinical trial' was larger than anticipated (> 1700 journals with at least one 'clinical trial'). The number of trials published by each journal closely fit a power law distribution, meaning that a few journals published many trials, and many journals published few trials. Authorship ethics requirements varied greatly across journals (Mean = 5.6 of 11 possible ethics requirements, SD = 2.8). Older journals ($p < .002$) and journals that published many trials ($p < .02$) had more demanding requirements. Nursing journals had lower while public health and services research journals had higher requirements ($p < .001$). Journals published in the US also had higher requirements ($p < .01$).

Authorship ethics has only partially penetrated medical journal publishing. Understanding variation in journals may become increasingly important, because Internet publishing may facilitate the development of an even larger journal space. Many prior studies of journals' ethical requirements (and other authorship ethics studies) have gathered their data from a few high impact journals. Researchers should understand that journals vary systematically on the factors that have driven selection of journals in prior research, and that such convenience samples are likely to induce selection biases.

Kirby Lee, Elizabeth Boyd, Jayna Holroyd-Leduc, Peter Bacchetti, Lisa Bero, Bias, Quality and Value of Peer Review at Major Biomedical Journals (University of California, San Francisco)

AIMS. We conducted a large prospective study at three major biomedical journals to identify predictors of publication among submitted manuscripts, evaluate whether publication bias occurs at the editorial level, and assess the quality and added value of peer review.

METHODS. Prospective cohort study of three major biomedical journals in England (BMJ, Lancet) and the United States (Annals of Internal Medicine) January 2003-October 2004. 1,107 original research articles were submitted to the journals of which 68 (6.1%) were accepted for publication. We identified predictors of publication using multivariate logistic regression models. Submitted manuscripts were compared to the final publication to identify editorial changes to manuscripts and these changes were qualitatively analyzed.

CONCLUSIONS. Submitted manuscripts with high methodological quality, RCT study design, descriptive or qualitative analytic methods, sample size >73, disclosure of any funding source and the country of residence of the corresponding author to be the same as the publishing journal were more likely to be published. Manuscripts reporting statistically significant results were no more likely to be published than those without suggesting that the source of publication bias is not at the editorial level. Authors often do not disclose potential conflicts of interest or the role of the funding source in submitted manuscripts. Peer review makes a wide variety of contributions to improve the clarity, accuracy and reporting of results but further improvements are needed.

Mihael Rudes, Natasa Kovacic, Matko Marusic, *Ana Marusic*, How Classification of Journal Items by a Citation Database Affects Impact Factor of Small and Large Journals: A Study of General Medical and Science Journals (Croatian Medical Journal, Zagreb University School of Medicine)

AIMS. To investigate how categorization of journal articles by a citation database affects the impact factor, which is calculated as the ratio between the number of citation to all journal items (numerator) and the number of article and review items (denominator) during a certain time period.

METHODS. We analyzed classification of journal items in the Web of Science citation database to the first-ranked journal in the Journal Citation Records category Medicine, General and Internal (New England Journal of Medicine, NEJM; IF=38.570) and the 61-ranked journal (Croatian Medical Journal, CMJ; IF=0.690), as well as the first-ranked journal in the category Multidisciplinary Sciences (Nature, IF=32.182) and the journal with a relative rank of CMJ (Anais da Academia Brasileira de Ciencias; AABC; IF=0.435). We performed full text search of all items for original research data. The analysis included years 2003 and 2004 because they serve for the calculation of 2005 IF. Data for 2-month issues of Nature and NEJM are presented here, to match the number of published items in the CMJ and AABC.

CONCLUSIONS. Out of 154 Nature articles classified as research articles by the database, 150 presented original research data, whereas 27 out of 147 editorial items also contained research data. This decreased the denominator for IF calculation by 14.6% for 2 months. For NEJM, this decrease in the denominator was 13.0% (54 classified articles vs. 61 articles with original research data). In contrast, the categorization of journal items in smaller journals was either correct (AABC, which published only original articles or reviews) or biased towards more original articles (203 CMJ items categorized as articles vs. 196 with original research results, 3.5% increase in the IF denominator). We plan to retrieve data for the full 2-year set of articles for the two first-ranking journals and to analyze how much misclassified journal items contribute to the impact factor of all four journals.

Miguel Roig, Coverage of Authorship and Publication Practices in Scientific Societies' Ethics Codes (St. John's University)

AIMS. Research misconduct often includes components of unethical authorship and publication practices raising the question of what role scientific societies should play in addressing these issues. In this study, publication and authorship guidelines appearing in scientific societies' ethics codes were reviewed for their coverage of these important areas.

METHODS. The ethics codes of scientific societies listed in a recent study (see Bullock & Panicker, 2003. S&EE, vol 9, 159-170) were downloaded and examined for their treatment of elements pertaining to authorship and publication practices within the scope of responsible research conduct. Each code of ethics was reviewed for the presence of terminology and coverage

related to authorship and publication topics, such as plagiarism, dual publication, publication credit, multiple authorship, and authorship with students. The total number of words devoted to these issues was recorded and an estimate of the general quality of coverage was also made.

CONCLUSIONS. Twenty nine of the 44 ethics codes examined (66%) provided some coverage of authorship issues. However, the extent of coverage varied widely with some codes providing a mere two or three sentences which, in some cases, appeared only indirectly related to authorship. Other codes provided fairly extensive and detailed coverage (e.g., American Political Science Association, American Sociological Association). The most frequent authorship areas covered included the need to credit others' work, accuracy of published materials, and the problem of plagiarism. As expected, societies whose members' primary activities had been classified by Bullock & Panicker (2003) as involving research (e.g., American Mathematical Association, American Physical Society) tended to provide more extensive coverage of authorship and publication practices than those whose members engaged primarily in the delivery of services (e.g., American Society for Clinical Laboratory Science, Institute of Electrical and Electronic Engineers). Surprisingly, some areas of misconduct known to occur with some frequency received little coverage (e.g., dual publication) or no coverage (e.g., self-plagiarism). These preliminary findings suggest an urgent need for scientific societies to clarify and/or implement clearer guidelines related to authorship and publication practices.

Saturday: 8:00-10:00 Concurrent Track Three: RCR Instruction

Ethan P. Waples, Stephen Murphy, Michael D. Mumford, Shane Connelly, Ryan P. Brown, Lynn R. Devenport, Responsible Conduct of Research Training: A Solution for Teaching Research Ethics in the 21st Century (University of Oklahoma)

AIMS. Within scientific and academic communities, a number of research misconduct cases have demonstrated the need for ethics training. A Responsible Conduct of Research (RCR) Training Program was developed to address these concerns among professionals and graduate students. Training effectiveness was assessed through an analysis of quantitative and qualitative training assessments.

METHODS. A model for ethical decision-making was created to assist graduate students and professionals in interpreting and confronting complex ethical dilemmas with multiple ethical issues in research contexts. The model includes research guidelines, problems, cognitive strategies (e.g., question your judgment, and consider others' perspectives), and introduces a sense-making perspective. Training participants learned about their susceptibility to personal biases and thinking errors while conducting research. Everyone participated in a real-world role play activity within the 12 hour training session conducted over a two day span. Pre and post ethical decision-making measures were administered and qualitative data were collected to further evaluate training effectiveness.

CONCLUSIONS. The pre and post ethical decision-making measures revealed that participants significantly ($p<.01$) improved their ethical decision-making on two of the ethical dimensions assessed, including data management and professional practices. Other quantitative data yielded an average one standard deviation ($p<.01$) increase on the use of social psychological dimensions and cognitive strategies. Participants also rated the effectiveness of materials, activities, and discussions from low (1) to high (7). The mean exercise self-report ratings were totaled and ranged from 5.56 to 6.67.

Participants generated qualitative training feedback by completing a pre and post self-reflection exercise. Training participants were asked, What makes a decision an ethical decision?

One participant responded by stating, If the decision violates the law and if it causes harm it is bad. When asked to respond to the same question after training the participant said, If all aspects of the environment or problems have been reviewed, documented and considered before a decision was made and if all consequences for all involved parties were considered the decision is ethical.

This Responsible Conduct of Research training program which includes an ethical decision-making model, complex generation activities, cases, and lectures is effective for teaching graduate students how to conduct ethical research in the 21st century.

Terry DiLorenzo, An Examination of Educational Practices and Monitoring for the Responsible Conduct of Research in Behavioral Science Education Programs (Yeshiva University)

AIMS. This two-phase, mixed method (quantitative/qualitative) study examines practices regarding the responsible conduct of research (RCR) in behavioral health educational programs (psychiatry, social work, psychology, counseling, psychiatric nursing). Specifically, we aim to describe research review and monitoring mechanisms and explore the extent to which RCR is included in curricula.

METHODS. Phase I surveyed deans/directors representing the five professions regarding RCR education. Respondents indicated their willingness to complete a follow-up telephone interview (Phase II). The interview is based on survey results and includes questions regarding: 1) research review and monitoring procedures, 2) perceptions regarding adequacy of procedures, 3) identification of problems regarding RCR, 4) curriculum content related to RCR (curricula/syllabi are requested), and 5) research mentoring and collaboration. Fourteen interviews have been conducted. Interviews are content analyzed by two doctoral-level investigators. Recruitment will continue until there are at least five interviews from each discipline, and there is evidence of data saturation.

CONCLUSIONS. Findings from Phase I suggest the under-developed state of education. Specifically, respondents reported that a slight majority of faculty (55.7%) were very familiar with RCR, while only 23.8% of students were very familiar with RCR. Only 6.1% of respondents felt procedures to educate students in RCR were totally adequate. Seventy-eight percent of programs required formal education in RCR. Preliminary analyses of Phase II interviews indicate that: RCR is typically infused into several courses; many institutions require proficiency in RCR, typically demonstrated by completion of a training program, and evidence of passing an examination (but often without a rigorous pass level); and the focus of training and monitoring is on informed consent and research procedures, rather than scientific merit. Besides analyzing additional interviews, we will content-analyze curricula/syllabi to identify the most frequently mentioned RCR topics and teaching and assessment methods. This investigation should identify both deficiencies and best practices in RCR education and research review and monitoring procedures. Results can be used to direct curriculum development and training endeavors.

Angel Griffin, Cultivating a Culture: The Promotion of Research Integrity Through the Environmental Factors of Policy and Educational Programs (RTI-International)

AIMS. Research misconduct undermines the scientific enterprise by comprising the integrity of research. There is currently a lack of evidence concerning the environmental factors that promote research integrity. This analysis examines the efficiency of the environmental factors of educational programs addressing record keeping and policies addressing record keeping in promoting research integrity

METHODS. Semi-structured telephone interviews were conducted with Institutional Officials responsible for handling misconduct allegations at 90 active research universities. The number of misconduct allegations reported by the universities was used as a measure of integrity and provided by the Office of Research Integrity. Using the theory of re-institutionalized customs, it was hypothesized that universities with record keeping policies would have more misconduct allegations compared to universities without policies. Similarly, universities with educational programs addressing record keeping would have more allegations compared to universities without such programs. OLS regression was employed to test the hypothesized relationships.

CONCLUSIONS. OLS regression analysis indicated no statistically significant relationships between the presence of educational programs and the number of allegations or between the presence of record keeping policies and the number of allegations. These results suggest other forces could be exerting stronger influences on researchers' reporting behavior such as a desire to maintain autonomy and the ineffectiveness of formal modes of social control.. More research needs to be conducted examining the effects of these environmental factors while addressing the limitations of the current study, particularly sample size, a measure more sensitve to small changes, and controlling for other factors that influence reporting behaviors.

Michelle Stickler, NancyTuana, Integrating Ethics into Graduate Training in the Environmental Sciences (The Pennsylvania State University)

AIMS. The purpose of this study is to determine whether teaching RCR along with additional science-specific ethics topics results in a better understanding of the principles of RCR and/or attitudes toward ethical issues in research.

METHODS. This study was reviewed and approved by the Institutional Review Board. The team developed an RCR educational module focusing on discussion of ethical situations common to the environmental sciences and several science specific ethical case study modules. Environmental science graduate level classes have been identified within which to deliver the educational modules. The experimental classes will be taught both the RCR module and one of the science specific ethics modules. The control classes will only be taught the RCR module. Two instruments designed to assess understanding of and attitudes toward RCR were developed and pilot tested. Students in all of the classes are administered the two assessments, as well as the Defining Issues Test (DIT2), as pre- and post-assessments at the beginning and the end of the semester, with the curricular modules taking place in between.

CONCLUSIONS. Data collection and analysis are ongoing. Pilot classes were conducted during the Spring 2006 semester in four classes. Preliminary pilot data will be presented. The presentation will include discussion of the nature of the modules developed, the strategy of having all research ethics materials presented by the instructor of the course, and the assessment instruments, including limitations of the pilot data and resulting changes to the research tools and instruments. (Supported by NSF Grant 0529766, to The Pennsylvania State University.)

Saturday: 10:15-12:15 Concurrent Track One: Panel on the Role of the Individual

Heather Culley, The Making of a Conflicted Scientist: How Different Structures and Aspects of the Research Process Create Conflict for a Scientist (University of Washington School of Medicine)

AIMS. In this analysis, we examine responses to a specific vignette posing a publication issue involving negative findings and a politically charged climate, as well as the rationales behind these actions. We identified four themes that were central to researcher decision-making in this

vignette, and may extend to research conduct more broadly. Specific ethical challenges surrounding publication will also be discussed.

METHODS. We used the CRISP database to identify human subjects' investigators in the Pacific Northwest conducting research in: (1) cell/tissue research, (2) clinical trials, (3) population studies, or (4) social science. We conducted semi-structured interviews with 60 participants structured around five vignettes describing different ethical dilemmas. Fifty-two participants responded to a vignette about a political publication dilemma: the research team spent two years on a project regarding access to care for Medicaid enrollees that negative results. There are questions on how and whether to publish these results in a political atmosphere.

CONCLUSIONS. Recently, there has been significant attention in the media on scientific misconduct and the scientist behaving badly. This study looked at some reasons why a scientist may appear to be misbehaving in the realm of publication of negative results. We identified four themes that were central in influencing researcher decision-making around this publication vignette, each with various elements that were considered. These included: (1) Scientific Field, with funding, employment aspects, dissemination of information, and meaning of science as important sub-themes; (2) Publication Structure, with aspects of the journal as a gatekeeper and journal prestige as important sub-themes; (3) Academic Career Structure, with institutional needs, promotion process, resources used, and type of faculty member as important sub-themes; and (4) Scientist as Moral Being, with objectivity, truth-telling, personal integrity, and personal interests as important sub-themes. Each of these elements interact through the process of attempting to publish negative results, and create conflict between the organizational-level themes and within the researcher, who is attempting to act within this research climate to the best of his or her ability.

Helene Starks, Data Ownership: Preserving Reputations and Relationships When Data Get Pulled without Warning (University of Washington School of Medicine)

AIMS. This paper examines the common responses and rationales for actions taken in a data ownership dilemma. Respondents used a combination of negotiation, self-evaluation, and appealing to higher authorities in the interest of promoting their career, getting credit for their work, and preserving their reputation or relationships. Participants had a heightened sense of power and what s at stake; they would seek all possible avenues to a reasonable compromise, mindful of the costs to relationships and career.

METHODS. We used the CRISP database to identify human subjects' investigators in the Pacific Northwest conducting research in: (1) cell/tissue research, (2) clinical trials, (3) population studies, or (4) social science. We conducted semi-structured interviews with 60 participants structured around five vignettes describing different ethical dilemmas. Fifty-one participants responded to a vignette about a data ownership dilemma: a senior person (PI) from a different department pulls the analysis from the respondent and gives it to a colleague without explanation. This happened three years into the project and a grant and several papers are pending from preliminary results from this work.

CONCLUSIONS. The majority of participants (76%) reported first trying to negotiate with the PI and examining their own actions to determine whether the rationale for pulling the data was because: (1) there were unclear expectations or extenuating circumstances; (2) the junior person [respondent] didn't do the work as assigned; (3) the PI was being unreasonable; or (4) the results did not match the PI's theory/expectations. Respondents were told the PI was unavailable for negotiation and asked what else they would consider and why: 75% would appeal to a higher

authority to negotiate on their behalf, in the interest of promoting their career (82%), getting credit for the work done to date (59%), preserving their reputation (57%) or relationships (53%), and fairness (45%). If neither negotiation nor appeal seemed viable options, 69% reported they would move on and cut their losses. Twenty-seven percent would use the data they had to complete the on-going papers and grants and 33% would seek out the new analyst to support and collaborate with that person. Despite the perceived injustice of the PI's actions, most participants would seek all possible avenues to a reasonable compromise, mindful of the costs to relationships and career.

S. Malia Fullerton, En-gendering Thoughts on Research Integrity: Comparing Male and Female Investigators' Responses to Ethical Dilemmas (University of Washington School of Medicine)

AIMS. Recent research has suggested that, among other factors, gender may influence the degree to which investigators report involvement in research misconduct. In our investigation of defined research dilemmas, rather than misconduct self-report, we observed no strong differences in primary responses to vignettes but did observe gender differences in the rationales offered for the responses, suggesting gender may play a role in addressing research challenges

METHODS. We used the CRISP database to identify investigators in the Pacific Northwest currently funded in one of four domains of research involving human subjects: (1) cell and tissue research, (2) clinical trials, (3) population studies, and (4) social science. We conducted semi-structured interviews with 60 participants structured around five vignettes describing different ethical dilemmas. Participants were asked to respond to each vignette (minimum of 3 and maximum of 5 per interview) and offer rationales for their described behavior. Primary responses and associated rationales were linked to the gender of study participants and compared on a vignette-specific basis.

CONCLUSIONS. Recent research has suggested that, among other factors, gender may influence the degree to which investigators report involvement in research misconduct. In our investigation, which focused on investigators' responses to defined dilemmas rather than misconduct self-report, we observed no strong differences in primary responses to hypothetical cases but did observe gender differences in the rationales offered for the responses. For example, in commenting on a vignette describing a late-in-the-day request for second authorship by a team member with promotion concerns, male and female investigators were equally likely (55% and 52% respectively) to respond that their first instinct would be to refuse the authorship request of their colleague. However, whereas men most often justified this choice with respect to acknowledged or implicit 'rules' regarding criteria for authorship (emanating from journals, funding agencies, or similar), a smaller proportion of women referred to such criteria in explaining the rationale for their response, emphasizing instead credit deserved in the context of a team-based research investigation. Similar differences in rationale were observed for other vignette responses. Together, our results suggest small, but potentially important, differences between male and female investigators in the ways in which they approach research-related ethical dilemmas.

Kelly Fryer-Edwards, Stepping Up: Taking Responsibility for Research Integrity (University of Washington School of Medicine)

AIMS. Participants voiced concerns about career and reputation, as well as often competing obligations to science, teams, subjects or society more broadly. In our sample, researchers could acknowledge the competing motivations, but could also work through to creative solutions that

would allow them to satisfy their obligations. We close the panel with some suggestions for changes within the culture and climate of research practice that could enhance research integrity.

METHODS. We used the CRISP data base to identify investigators in the Pacific Northwest currently funded in one of four domains of research involving human subjects: (1) cell and tissue research, (2) clinical trials, (3) population studies, and (4) social science. We conducted hour-long interviews with 60 participants structured around five vignettes, each describing a different ethical dilemma for human subjects' researchers. Participants were asked to respond to the vignette and offer rationales for their described behavior.

CONCLUSIONS. Not surprisingly, several competing motivations were identified by participants. On the one hand, there is a concern about career and reputation, which manifests in worry about publications and grant funding. On the other, participants articulated obligations to science, including an interest in upholding norms like objectivity, obligations to teams (including fairness and preserving relationships), and obligations to subjects or society more broadly. In our sample, researchers could acknowledge the competing motivations, but could also work though to creative solutions that would allow them to satisfy their obligations. Rather than just giving us the "right answer", the interviews demonstrated that "doing the right thing" was facilitated by (1) consulting with colleagues and (2) by honest self-reflection, including an ability to adopt a skeptical perspective. Both of these facilitators were hindered when the climate was more competitive than collaborative. When researchers cannot be honest, even with themselves, about competing motivations, or when they feel too vulnerable to admit skepticism with colleagues, we worry that open discussions will be less likely to happen, and lapses in judgment or motivation may occur. Building on peer review and consultation processes (such as works-in-progress and lab meetings) is a possible area to explore to enhance the collaborative context.

Saturday: 10:15-12:15 Concurrent Track Two: Panel on Journals, Authorship and Publication

Kirby Lee, **Ana Marusic, Elizabeth Boyd, Lisa Bero*, Ethical Considerations about Journal Peer Review: Ways to Improve Accountability, Responsibility and Research Integrity
(University of California, San Francisco, *Croatian Medical Journal)

AIMS. In order to function well, the journal peer review system relies on the integrity and accountability of authors, editors and reviewers. This panel discusses various policies and mechanisms to improve transparency, promote fair review, and facilitate data access for peer review.

METHODS. Panel discussion with researchers and editors currently evaluating the peer review system and developing methods for improvement.

CONCLUSIONS. Peer review is not currently designed to detect fraud, deception, or improper behavior, nor does it certify the validity of research findings. In order to function well, the journal peer review system requires the integrity and responsibility of editors, reviewers, authors and sponsors. This panel discusses possible mechanisms for reducing misconduct by each party involved in peer review including: 1) Improving transparency of the peer review system and publication process. 2) Developing mechanisms to promote fair review. 3) Developing policies to prevent or handle misconduct. Having these checks and balances and enforcing stiffer penalties would improve accountability and responsibility of those involved in the peer review process. Such changes could help to ensure the integrity of research and dissemination of research findings.

Saturday: 10:15-12:15 Concurrent Track Three: RCR Instruction

Celia B. Fisher, Adam L. Fried, Sabrina Goodman, Measures of RCR Mentoring, RCR Department Climate and RCR Student Preparedness in Psychological Science (Fordham University)

Federal regulators and participant advocates have called for empirical data that can aid universities foster scientific integrity of students and faculty. The field of psychology is an ideal venue to pioneer RCR instruments because of its 50 year history of ethical codes covering the conduct of research, the field s expertise in test construction, and an existing set of psychometrically sound instruments for mentoring and departmental influences on scientific training in general. Drawing upon a sample of 400 psychology graduate students nation-wide, this study reports the development and validation of Internet-based measures of RCR mentoring, RCR departmental climate, students' perceived RCR preparedness, and student confidence in the RCR of the discipline.

Camille Nebeker, Foundation for Novice Research Staff to Promote Scientific Integrity (San Diego State University)

AIMS. The purpose of this session is to report evaluation outcomes of a web based training module developed for novice/lay research staff to promote an understanding of basic research concepts. The need for this training was prompted by investigators who involve research staff (e.g., community health workers (CHW), college students and clinical staff) to assist in carrying out research protocols. Preliminary data indicate that most CHWs involved in community health interventions have a high school education and have not received formal training in research methods. Likewise, many undergraduate programs are introducing research component in the curriculum and recognize that a basic foundation of research concepts is necessary for students to understand ethical and responsible research practices.

METHODS. Pre and post test surveys were developed based on tutorial content which was informed by faculty who work closely with undergraduates and/or community health workers. Initial data were collected from 50 undergraduate students during the spring semester. Students were asked to complete a pretest and were then given the link to the web-based tutorial. Following completion of the tutorial, each student completed a post test. Survey questions were designed to assess knowledge of research, research design, descriptive and experimental studies, variables, associations, sampling, random selection and assignment, blinding, data collection methods, reliability and validity, data security and storage, documentation and excluding or changing data within the record. Demographic information included age, gender, major, prior training in research, previous work on a research study, and participation as a research subject.

CONCLUSIONS. Preliminary analyses reveal that the greatest change in knowledge was in understanding of study design and purpose and benefit of random assignment. Those who identified as having no prior coursework or experience in research scored slightly lower at pretest when compared to those who had some prior experience in research. Those without prior training were less likely to understand concepts of validity and reliability. Likewise, at baseline students with no prior training did not think it mattered whether survey administration was standardized or that it was inappropriate to change data.

Leslie Alexander, Ken Richman, Piloting the Waters of Research with Indigenous Staff (Bryn Mawr College)

AIMS. Research extenders (REs) are research staff indigenous to targeted research populations and therefore effective in working with research subjects. This presentation describes lessons learned from the pilot phase of a study of REs, their experiences and their responses to ethical issues involving human subjects. Data and methodological issues are discussed.

METHODS. Six intensive pilot interviews have been conducted using instruments developed with input from a Community Advisory Board. Pilot participants were recruited from community-based organizations in and around Philadelphia, PA. Based on review of the pilot data, data collection instruments and inclusion criteria were substantially revised by the interdisciplinary research team, whose expertise includes research design, research with community-based service agencies, folklore, bioethics and philosophy of science. This presentation offers strategies for developing qualitative data collection instruments and observations from piloting these instruments with the target population.

CONCLUSIONS. Lessons learned include: 1. Research staff have difficulty distinguishing between ethical issues and other practical issues. 2. Many research workers do not fall neatly into categories of professional/non-professional or indigenous/non-indigenous. Careful attention was required to construct screening criteria for recruiting appropriate participants. 3. Scenario-based interview questions were not obviously better than questions about personal experiences for eliciting views on ethics of research-related behaviors. 4. Non-indigenous researchers (NIRs) interviewed for contrast responded differently from REs in expected ways. NIR respondents were more sensitive to issues familiar to professional researchers, such as data integrity and participant autonomy. 5. As in other studied populations, research workers can become experienced research participants in ways that make them inappropriate informants. 6. Qualitative research in this area presents practical and theoretical issues requiring perseverance and creative responses. These preliminary findings enhance knowledge of how an important segment of the research community understand the responsible conduct of research. They point to the need for more targeted and nuanced training approaches for research staff to promote research integrity and the collection of valid data in vulnerable populations. The findings also offer lessons for others seeking to study similar populations.

Joanne Russell, David Barnard, Maurice Clifton, Application of Ethical Principles During the Informed Consent Process for Clinical Trials (University of Pittsburgh)

AIMS. Despite mandatory education in abstract ethical principles, application of these principles, particularly in investigator-subject communication, remains inadequate. The purpose of this project was to develop an educational strategy to increase the competency of investigators and research coordinators related to the informed consent process for clinical trials. This project was supported by the NIH Human Subjects Research Enhancement Program (2S07 RR18239-02).

METHODS. Thirty-two skills based on ethical concepts and communication strategies were defined and incorporated into a one-day workshop. Instructional methods included pre-assigned readings, an interactive video illustrating the skills, and an experiential component in which researchers utilized their protocols to obtain consent from standardized subjects (SSs) who portrayed four challenging subject types: distrustful, overly eager, mild dementia, and adolescent attitude. Knowledge was assessed with pre/post-video questionnaires. Participants' skills were rated by SSs, using a checklist of desired behaviors. Program effectiveness was evaluated by participants at the session and at three months, using a scale of one (lowest) to five (highest).

CONCLUSIONS. Fifteen experienced investigators and coordinators participated in the workshop. Four were investigators with the remaining attendees listing their role as research coordinator. Participants represented 12 specialties, and their protocols ranged from low to high risk. All had completed institutionally-mandated web-based training in the responsible conduct of research (RCR) prior to the workshop. There was a statistically significant increase in the number of desired behaviors identified on the post-video questionnaire (mean 7.1 versus 8.7, $p<0.05$). All but four (75%) of the participants scored above 80% on the SS checklist. Participants reported that the material was new (mean 3.5) and interesting (mean 4.2), the course met their expectations (mean 4.4), and that the course would make a positive difference with communicating with potential subjects (mean 4.5). Self-assessed ability to obtain ethically valid informed consent increased from a mean of 3.5 before the workshop to 4.5 ($P=0.001$) after the workshop, with no decline at three months. All participants reported that they would recommend the workshop to a colleague. This innovative curriculum was well received and effective for facilitating the application of abstract ethical principles pertaining to informed consent in a cohort of experienced researchers.

Saturday: 1:30-3:30 Concurrent Track One: The Role of the Individual

Stephen Murphy, Alison Antes, Michael Mumford, Shane Connelly, Lynn Devenport, Ryan Brown, The Development of Ethical Decision-making: Early Environmental Predictors of Research Integrity (University of Oklahoma)

AIMS. It is commonly held that early career experiences act to influence ethical behavior. One way early career experiences might operate is to influence decisions people make in ethical contexts. The intent of the present study was to examine the influences of career experiences and perceptions of climate on day-to-day ethical decision-making.

METHODS. To test the influence of career experience and climate perceptions, 102 first year doctoral students in the biological, health, and social sciences were asked to complete an ethical decision-making measure along with a series of measures examining career experiences and climate perceptions. Five important dimensions underlying career experience (i.e., professional leadership, poor coping, lack of rewards, limited competitive pressure, poor career direction) and four dimensions of climate (i.e., equity, interpersonal conflict, occupational engagement, work commitment) were found to be meaningful. Further analyses were performed to assess the impact of career experiences and climate perceptions on ethical decision-making.

CONCLUSIONS. Results indicated that climate perceptions were related to ethical decision-making among first-year doctoral students. Occupational engagement, interpersonal conflict, and work commitment were positively related to certain aspects of ethical decision-making. One of the climate dimensions exerted strong, consistent effects across analyses. Perceptions of interpersonal conflict were negatively related to ethical decisions concerning appropriate professional and business practices. Although interpersonal conflict was related to unethical decision-making, the effects of career experiences on ethical decision-making exerted stronger, more consistent results. Regressing ethical decision-making on the five career experience dimensions yielded a significant average multiple correlation of .36. The focus of first-year doctoral students on adapting to their professional field and learning basic operations within their laboratory leads them to be particularly sensitive to certain environmental career experiences. Two key implications emerged from the analyses. First, facilitating students' learning of effective strategies for management of competitive pressure early on in their career is critical. Second, with regard to the advising of first-year doctoral students, mentors should provide entering doctoral students with specific positive feedback that stresses the value of their professional work.

L. Bilic-Zulle, J. Azman, V. Frkovic, M. Petrovecki, Attitudes Towards Plagiarism among Medical Students (Rijeka University School of Medicine)

AIMS. This study is final part of research project on prevalence and attitudes towards plagiarism and dishonesty among medical students. The purpose of study is to build basis for education reform and improvement of university polices on scientific integrity and its promotion among future physicians and biomedical scientists in Croatia.

METHODS. Second year medical students at Rijeka University School of Medicine (N=295, 63% females, during three academic years) were investigated on attitudes towards six fictitious scenarios: three cases dealing with plagiarism (coping paper from fellow-student with and without his awareness and professor coping from junior associate), case of self-plagiarism, exam cheating and issuing a medical report when examination has not been done. Attitudes towards each case were examined using anonymous questionnaire with six questions regarding propriety and justifiability of procedures, penalty, students' willingness to perform similar procedure, admittance of doing it, and awareness of existence of similar cases in their community.

CONCLUSIONS. Findings revealed disturbing data. Although plagiarism cases were considered inappropriate by a majority (67-90%, depending on the case), quarter to half of students find them justified. Majority of students (65%) find case of self-plagiarism appropriate and deserving no penalty (79%). Quarter of students find case of cheating appropriate and half of them thought that it was justified and deserved no penalty. Writing physicians' finding "examination-normal" when it has not been done, was considered inappropriate by 83% of students, but 48% of them would exceptionally do it. Most of students in all cases declared that they did not perform similar procedures, mainly because they were not in position to do that or they thought it was unacceptable half of them would do that all, although exceptionally, but anyway. Only few of them (<10% overall) admitted that they would not do it because of penalty. However, results of research on prevalence of plagiarism among same students (Croat Med J 2005;46:126-31) revealed that 90% of them plagiarized to some extent in their essays when there was no penalty threat. Discrepancy between attitudes and behavior implies that some answers were given as socially desirable and that medical students need clear guidelines and further education on academic and scientific integrity.

Vedran Katavic, Ana Vujaklija, Daniela Salopek, Darko Hren, Research Climate at the University of Zagreb School of Medicine (University of Zagreb School of Medicine)

AIMS. The aim of the study is to assess the research climate and to try to identify various situations that influence research integrity of junior staff in the setting of our School at the University of Zagreb School of Medicine

METHODS. A total of 214 junior members - junior instructors, instructors and research novices prior to their advancement to faculty of our School were sent a questionnaire consisting of 230 multiple-choice questions about individual, group, and institutional background data, as well as the organizational climate, developed by psychologists from the University of Oklahoma.(1) The questionnaire was first translated into Croatian by an unbiased English tutor, and then back-translated into English by a different tutor to check for translation consistency.(2) The scoring protocol was organized according to different constructs measured.

CONCLUSIONS. From our experience (3) the adherence to, knowledge about, and attitudes towards research integrity guidelines in Croatia, including our School are poor. This can, at least partly, be explained by the influence of the immediate research environment, and such an environment can be measured with this instrument. The study is still ongoing, but we hope to achieve at least an 80% response rate to be able to adequately assess the research climate. We will present the results as scores for different constructs, e.g. alienation, professional role models, leadership, unethical norms, accountability, etc. We will also compare the results from our School to the results obtained from other medical schools in Croatia.

1 Gaddis BG, Helton-Fauth W, Scott G, Shaffer A, Conelly S, Mumford MD. Development of two measures of climate for scientific organizations. Accountability in Research 2003;10:253-88.

2 Vodopivec I, Vujaklija A, Hrabak M, Lukic IK, Marusic A, Marusic M. Knowledge about and attitude towards science of first year medical students. Croat Med J 2002;43:58-62

3 Katavic V. Five-Year Report of Croatian Medical Journal's Research Integrity Editor - Policy, Policing, or Policing Policy. Croat Med J 2006;47:220-7.

Karen Louis, *Janet Holdsworth*, Melissa Anderson, *Eric Campbell, Everyday Ethics: How Life Scientists Manage University Policies Governing Research (University of Minnesota, *Harvard University)

AIMS. A largely unacknowledged crisis is emerging as a result of increasing university regulation of life sciences research. This study investigated scientists' perceptions of policies and regulations, examined institutional variations in regulatory climate, and explored how tensions between scientific aims and institutional regulations affect decisions about research agendas.

METHODS. n-depth (1-1.5 hour) open-ended interviews were conducted with 28 highly productive life scientists in four fields: pharmacology, radiation/oncology, neurology, and genetics. We first sampled public and private universities with large departments in two of these fields. Web of Science and NIH data bases were used to determine which faculty members were highly productive as measured by first/last authored articles and research grants. Respondents were randomly sampled from within the eligible population. Because we explored topics that have not been previously studied, we used grounded theory (Glaser and Strauss, 1967) to generate concepts and explanations for ethical decisions.

CONCLUSIONS. Respondents were sympathetic to the purposes of regulations and policies in science. Inappropriate regulation, however, caused significant burdens, and in many cases had significant impacts on research agendas. Among the problems cited in multiple fields and institutions were: (1) Routine oversight assigned to administrators with limited scientific background; (2) Weakened influence by scientists in animal care committees; (3) Uncoordinated oversight - multiple offices with conflicting objectives for monitoring laboratories; (4) Conflicting and inconsistent requirements for similar protocols across different grants. The consequences of increasing problems with regulation ranged from excessive time on grant administration to changing research agendas (for example, not conducting experiments with larger animals) to avoid additional layers of regulation. In some cases, scientists bend the rules when regulations cause laboratories to come to a stop. Based on our findings, there is a significant shift from self-regulation to administrative regulation of science. Most scientists trace this to institutional rather than federal policy. They often feel powerless in this constraining climate and shift their research expectations because they believe that there is little recourse other than compliance. Implications for research, policy and practice are explored and possible alternatives for institutional leaders are explored in this paper.

Saturday: 1:30-3:30 Concurrent Track Two: Journals, Authorship and Publication

Sheldon R. Gelman, Can Multiple Authorship Reduce Scientific Misconduct? (Yeshiva University)

AIMS. This presentation explores the issue of multiple authorship in publication and its impact on scientific misconduct in academia. Academicians are well aware that the pressure to publish can lead to becoming, if not unethical behavior. Multiple authorship and collaborative mentoring may limit cases of plagiarism and data falsification.

METHODS. Academicians are well aware that the pressure to publish can lead to unbecoming, if not unethical, behavior. There are numerous arenas in which the potential for unethical behavior exits, including conflicts of interest, exploitation, plagiarism, and the broad-based category of scientific misconduct. This presentation will integrate, update, and synthesize previously conducted research by Gibelman and Gelman (1999, 2000) on trends toward multiple authorship in the United Sates and Great Britain and research by Gibelman and Gelman (2001, 2003 and 2005) on scientific misconduct and plagiarism. The goal is to develop preventative strategies to minimize the occurrence of scientific misconduct.

CONCLUSIONS. Efforts to understand the pressure for academics of all disciplines to publish or perish and/or to secure grant funding have resulted in the development of protocols for mentoring relationships between collaborators which include: ground rules, expectations, division of labor, assignment and ordering of authorship, and oversight responsibilities regarding data and findings. It is anticipated that collaborative research and publication conducted in accordance with such protocols will have a beneficial effect on the research enterprise and reduce instances of scientific misconduct.

Darko Hren, Ana Ivanis, Dario Sambunjak, Mateka Marcec, Vanja Crnica, Ana Marusic, Matko Marusic, Does Instruction on Authorship Criteria Influence Students' Decisions and Justifications about Authorship Dilemmas? (Croatian Medical Journal)

AIMS. To investigate the effect of instruction on ICMJE authorship criteria on: A) students' decisions regarding ethical dilemmas which involve an authorship problem; B) their justifications of these decisions. Also, to contribute to the theoretical issue of rationalist vs. intuitionist model of moral judgment.

METHODS. Second year medical students were divided in two groups during the course on scientific methodology: control (n=95) and experimental (n=107), which received a lecture on ICMJE (International Committee of Medical Journal Editors) criteria. All students completed DIT-2 test of moral reasoning, and wrote their opinion on three hypothetical dilemmas involving authorship. For each dilemma, students had to make a yes/no decision on whether the protagonist should be considered an author or not, and to justify their decision in a few sentences. Four independent raters rated the answers in terms of whether justification was based on rules or justice.

CONCLUSIONS. Decisions of students who received an instruction on the ICMJE authorship criteria were not significantly more based on these criteria than those of the control group's (_2-test, P>0.050 for all three comparisons). Furthermore, there was no difference in DIT-2 scores between students who did and those who did not decide according to the ICMJE criteria (independent samples t-test, p>0.05 for all three comparisons). However, the two groups differed in their justifications of the decisions, with the students who received instruction basing their judgments significantly more on rules than on justice (_2-test, p<0.001 for all three comparisons). These results favor Haidt's social intuitionist model which states that people intuitively make their

ethical decisions, with moral reasoning as a post-hoc construction generated after a judgment has been reached.

Ana Ivanis, Darko Hren, Dario Sambunjak, Matko Marusic, *Ana Marusic*, Quantification of Authors' Contributions and Eligibility for Authorship: Randomized Trial in a General Medical Journal (Croatian Medical Journal, Zagreb University School of Medicine)

AIMS. To analyze if the structure of the contribution disclosure form influences authors' declaration of their contribution to the manuscript and to test if a form with a rating scale would reduce the final proportion of honorary authors in comparison with a binary contribution disclosure form.

METHODS. Authors (n=865) submitting manuscripts (n=181) with more than one author on the byline to the Croatian Medical Journal from January 18 to July 23, 2005, were randomly allocated into two groups receiving different authorship statement forms. One group was asked to rate their contributions in 12 contribution categories on a scale from 0 - none to 4 - full (rating form, n=456 authors, 94 manuscripts), whereas the other was asked to make yes/no statements (binary form, n=409 authors, 87 manuscripts). The authors were not instructed on the criteria of the International Committee of Medical Journal Editors (ICMJE). There were 9 non-responding manuscripts (39 authors), which were excluded from analysis.

CONCLUSIONS. The groups did not differ in the number of byline authors, affiliations by country, number of affiliated institutions, type of article and research field, and editorial decision . The group answering the rating questionnaire had 5 times fewer authors who did not meet the ICMJE criteria (n=52, 12.1%) than the group answering the binary questionnaire (n=240, 60.8%; _2=212.7, P<0.001). The rating group also had fewer manuscripts with at least one honorary author (n=25, 28.4%) than the binary group (n=71, 84.5%; _2=54.9; P<0.001). Quantification of authors' contributions may be a more accurate method of assessing individual authors' contributions to the published work.

Sharon *Moss, Dean Garstecki, Jennifer Horner, Janis Costello Ingham, Joanne Jessen, Charissa Lansing,* James McCartney, Fred Minifie, Randall Robey, Sarah Slater, Research Integrity in the American Speech-Language-Hearing Association: Scientific Publication Practices (American Speech-Language-Hearing Association (ASHA)

AIMS. The purpose of this session is to report findings from the American Speech-Language-Hearing Association's survey of issues related to research integrity and publication practices. ASHA is keenly interested in the importance of research integrity to its members and to readers of its scientific journals. The ASHA survey was funded by the National Institute of Neurological Diseases and Stroke (RO1 NS44534-01S1) to study education practices and scientific publication practices.

METHODS. The purpose of this session will be to describe scientific publication practices/policies as determined through a 56-item survey instrument. Questions were grouped in eleven policy areas including: scientific misconduct, contributions to the manuscript, peer review, reviewer responsibilities, financial/personal/professional conflicts of interest, publication practices, journal autonomy, statistical evaluation, advertising in ASHA journals, human and animal protection, data management and intellectual property. Three groups of respondents received this survey: 1) editors, associate editors and publication board members; 2) reviewers, authors and members of the Board of Ethics; 3) readers and students.

CONCLUSIONS. The session will explain the development of the 56-item questionnaire around the eleven policy areas, the cognitive interview and subsequent fielding of the survey to each of the three groups. Preliminary data will be presented regarding importance ratings assigned to the 56 items across each of the three groups surveyed.

Saturday: 1:30-3:30 Concurrent: Moral Considerations

Elizabeth Ripley, Paying Research Participants: Attitudes and Practices of Investigators (Virginia Commonwealth University)

AIMS. The ethics of paying research participants has been widely debated; however, there is little empiric data to evaluate current practices and opinions of investigators. This study aimed to evaluate current practices of investigators including how, why, and how much they pay research participants.

METHODS. In order to evaluate investigators attitudes and practices at a single institution, an internet survey was conducted at the Virginia Commonwealth University. Faculty who had been investigators on a research study in the past 5 years were counted as investigators. As a comparison group faculty who had did not qualify as investigators were also surveyed. The survey included general questions as well as short case scenarios where they were asked to state what payment they would consider appropriate for that type of study.

CONCLUSIONS. Two hundred and ten respondents were classified as investigators [male-104 (49.5%), mean age = 46.25 + 9.4 years; and 168 respondents were classified as non-investigators [male-93 (55%), mean age = 48.15 + 10.67 years. The academic ranks were similar between the 2 groups. Investigators and non-investigators felt that risk, time, inconvenience budget and anticipated difficulty recruiting were important factors in determining payment. Non-investigators also felt that demographics of the study population and the number need to recruit were important factors and that the funding source was not important. Both groups showed a wide variation in recommended payment for the case studies from no payment to payment with a completion bonus. The current study points out that the opinions of individual faculty members are varied regarding payment, yet there is no evidence to date that this variability has compromised human research participants. While the guidelines and regulations remain vague, further research regarding the impact of payment on participants should be undertaken in order to assist IRB members and investigators in determining the suitability of payment.

Thomas May, Deception, Cheating and the Normative Legitimacy of IRBs (Medical College of Wisconsin)

AIMS. To examine how recent reports of IRB cheating and deception might call into question the normative legitimacy of IRBs.

METHODS. Moral analysis of the normative legitimacy of regulatory systems.

CONCLUSIONS. Deception, cheating and loopholes within the IRB approval process have received significant attention in the past year. Surveys of clinical researchers that indicate common deception ranging from omitting information to outright lying, and controversy surrounding the FDA's decision not to ban IRB shopping (the practice of submitting protocols to multiple for-profit IRBs until one is found that will approve the protocol) have raised legitimate concerns about the integrity of the IRB process. While at first blush these practices seem to cast aspersions on the integrity of clinical researchers, the moral issues raised go deeper than the

ethics of cheating. To the extent that these practices are common or represent an IRB system that places unreasonable burdens on those seeking IRB approval, we must consider whether non-compliance reflects problems of normative legitimacy for the IRB system itself.

Janet Malek, To Tell or Not to Tell? The Ethical Dilemma of the Would-be Whistleblower (Brody School of Medicine at East Carolina University)

AIMS. In all but the most egregious cases, the question of whether a would-be whistleblower should report suspected research misconduct is difficult to answer with certainty. The goal of this project was to develop a framework to help determine when an individual has a moral obligation to report suspected research misconduct.

METHODS. Paradigmatic cases involving a question about whistle blowing were analyzed using various ethical theories. The insights from these analyses were compared in order to identify the ethical considerations that are relevant to a would-be whistleblower's decision to report suspected research misconduct. A framework for evaluating the weight of each of those considerations was then developed, providing a foundation upon which reasoned conclusions about whether or not an individual should blow the whistle in any given situation can be drawn.

CONCLUSIONS. Several relevant ethical considerations were identified. The consequences of blowing the whistle (as well as of not doing so) for the whistleblower, for the suspected perpetrator, and for third parties must be taken into account. The weightiness of these considerations is determined by the gravity of those consequences and the likelihood that they will come to pass. The obligations derived from an individual's loyalty to the suspected perpetrator and to any third parties also enter into the ethical analysis. The strength of these obligations can vary based upon the type and duration of the individual's relationship with the parties in question. In addition, an individual's duty of integrity - the duty to be true to his own values - can come into play, depending upon the centrality and consistency of those values. Finally, the boundaries of legitimate self-interest and reasonable self-sacrifice must be considered. An individual may have weightier duties to make sacrifices or a stronger claim to protect her self-interest in some roles (e.g. student or department chair) than in others.

Camille Nebeker, Deception in Social Psychology Research: IRB, Investigator, Subject Impressions (San Diego State University)

AIMS. The purpose of this session is to summarize a social psychology study involving deception from various perspectives (investigator, IRB, subject). Evaluating effects of research involving deception is essential to informed decision making by Institutional Review Boards (IRB).

CONCLUSIONS. Differences between groups were detected using one way ANOVAs. A main effect of experimental condition upon ratings of the experience was found only in disclosure of feelings during participation. Participants in the socially rejected condition reporting more positive feelings after being told the true purpose of the study when compared to the happy and accident prone condition participants ($F(1, 33) = 3.63$, $p<.05$). Correlations calculated for survey responses were significant between participants overall rating of their experience participating in the study and feelings reported after debriefing ($r(36) = .53$, $p<.001$). Nearly all participants reported withholding the true purpose of the study was necessary. Likewise, participants reported an overall experience as positive ($M= 1.78$, $SD=0.87$).
Results indicate the debriefing process is essential in minimizing risks. The small sample size may limit generalizability. Future research might replicate this study and also evaluate aspects of

the debriefing process most likely to mitigate negative outcomes for participants. Understanding participant responses to deception research may inform IRB review decisions.

Saturday: 3:45-5:45 Plenary: Prevalence

Sandra Titus, NIH Investigators' Observations on Misconduct: What Do They Report They Observe on Fabrication, Falsification and Plagiarism? (Office of Research Integrity)

AIMS. To describe the incidence and types of misconduct that investigators report that they have observed in the past three years. To examine the implications of these findings.

METHODS. NIH investigators responded to a questionnaire survey asking them if they had observed misconduct; The instrument defined misconduct and instructed the respondent to report cases in the past three years in their department where they had observed or had direct evidence of suspected research misconduct. defined as FFP. They also were asked to give a brief statement describing the misconduct. The narrative content of those statements will be evaluated by knowledgeable coders and will be used to report an "adjusted" incidence rate.

CONCLUSIONS. These data are being analyzed currently.

Barbara Habermann, *Marion Broome, Erica Pryor, Actual Occurrences of Scientific Misconduct: A National Survey of Research Coordinators (University of Alabama at Birmingham, *Indiana University)

AIMS. To conduct a national survey of research coordinators (RC) to describe their attitudes and beliefs about scientific misconduct (SM); their perceptions of factors influencing SM; and their actual experiences with SM.

METHODS. Scientific Misconduct Questionnaire-Revised was mailed to 5,302 research coordinators who were members of research professional organizations. A second mailing was done to non-responders. Mailings were done between February - November, 2004. The Questionnaire consisted of 68 questions with question 68 asking if they had first hand knowledge of a specific instance of SM in the past year. If the responders answered yes to this question, there were 12 open ended questions asking them to describe the instance, including what they did, who they spoke to, if they reported the instance, the outcome, and how they would handle SM if it occurred again. The overall response rate to the survey was 33%. Of this sample 19% (n= 332) reported an actual occurrence in the last year. Content analysis was conducted by three member of the research team of the open ended responses.

CONCLUSIONS. The sample was primarily R.N.'s (62%), holding a bachelor's degree (46%), female (96%), and Caucasian (95%). The type of misconduct most commonly was falsifying data followed by failing to follow protocol, lack of informed consent, and no IRB approval. Almost half of the occurrences of SM were performed by the principal investigator (PI). SM was reported in 95% of the instances with consequences reported in 81% of the instances. Consequences ranged from data being corrected, patient termination from the study, to the PI and/or RC being reprimanded or terminated. The majority of RC's reported they would handle SM in the future in the same manner. In the cases where there were no consequences, most RCs expressed they would be more aggressive in reporting and go to different sources to report.

DISCUSSION. Falsifying data was the most commonly reported occurrence of SM and the PIs were most commonly identified as being responsible. The majority of SM is reported and

consequences are frequent. However, there are instances where no action occurs in relation to reporting of SM.

Matthias Kaiser, Can We Trust Research? Reports from Two Empirical Studies in Norway. (The National Committee for Research Ethics in Science and Technology)

AIMS. Whether or not to trust research can depend on a number of factors. One is whether the scientists carrying out the research engage in scientific misconduct or other ethically problematic behavior. We carried out an empirical study in 1996/97 where we asked university scientists from natural science and social science / humanities about scientific misconduct. We did not only inquire about their direct or indirect knowledge of such behavior, but we also asked them to report problematic behavior they themselves have engaged in. The results suffered from a low response rate, but among those responding we detected an amazingly high occurrence of self-reported irregular behavior.
At about the same time the Norwegian Parliament asked whether one still can trust science and the research carried out under the name of science, when apparently large parts of that research is directly financed by parties with sectorial interests, be they private or governmental parties. After several years of controversy about this assignment, the empirical research was finally conducted and published in 2003. The interesting results were in part from the qualitative section of the study, and in part from the quantitative section, showing among others a significant numbers of cases where the funders tried to control either the methodological aspects of the research or tried to stop publication of the results.

Joan Sieber, A Collegial Defense Against Irresponsible Science (Simmons College & California State University, East Bay)

AIMS. Cases of whistle blowing have attracted publicity, but little is known about behind-the-scenes collegial interventions when invalid or inappropriate research is observed. This project examines such interventions, strategies employed under varying circumstances (e.g., status differentials) and the success or failure of such strategies. An online casebook and manual will be developed successfully and unsuccessfully.

METHODS. Two approaches are employed: (1) A sample of over 10,000 biomedical and social-behavioral researchers drawn from the pool of PHS funding recipients was surveyed online about their experiences dealing with several forms of irresponsible science committed by their peers or students, to learn the rate of intervention, circumstances under which intervention occurs, what differentiates good from poor outcomes, why colleagues decide not to intervene, and what acts are more likely to evoke intervention. (2) An in-depth confidential telephone interview was solicited from survey respondents and through announcements in scientific newsletters to explore more detailed qualitative factors involved in collegial intervention.

CONCLUSIONS. Colleagues who intervene are rarely casual observers, but more likely potential victims or somehow intimately involved in the situation. Most who report intervening report having first spent considerable time uncomfortably trying to figure out what to do. Many developed a strategy in collaboration with someone else, especially in cases where lower-status individuals needed to cope with a higher-status perpetrator or with a larger system. Confidential institutional support was a needed and highly valued resource in many cases. Typically, the colleague s social or political capital was at risk necessitating a win-win solution (letting the perpetrator save face) or a covert strategy leaving the perpetrator powerless to retaliate. Interviewees typically expressed a continuing concern over whether they handled the situation optimally, gratitude for the opportunity to discuss the case, and desire to somehow help others in

similar situations. Many who volunteered to be interviewed wanted to discuss a case that had occurred years ago and still bothers them. Perspective on the value of damage control and the range of strategies that can be employed seemed useful in reducing this tension, and perhaps, one hopes, giving them the needed insight and confidence to intervene again if necessary.

Saturday: 6:00 ff Dinner on own or with groups organized earlier in the day

Sunday: 8:30-10:00 Concurrent: Climate

Timothy N. Atkinson, Power, Integrity and Norms in University Research Administration (University of Arkansas for Medical Sciences)

AIMS. The goal of this study was to gain a better understanding of research administrators perceptions of normative structures present in university research administration. The existence of a stable norm structure should assist ethical behavior. Institutional theory informed analyses of the research environment from both micro and macro analytical levels.

METHODS. A sequential explanatory design was employed in which quantitative analysis was followed by qualitative discourse analysis (Creswell, 2003). The quantitative and qualitative data were collected using a newly designed instrument called the Research Administrator Norm Indicator (RANI). The RANI consists of 42 items eliciting responses rated on a 6-point Likert scale as well as two open-ended questions designed to encourage free-text responses about norms and the research environment. The survey was administered to members of the National Council of University Research Administrators (NCURA) and produced a 26% response rate, with 1,300 responses to the quantitative and 1,000 responses to the qualitative portion.

CONCLUSIONS. Internal consistency of the RANI was very high (Cronbach alpha = 0.95). Results suggest that a normative institutional structure exists in research administration that is defined by these parameters: (1) Community Stakeholder Insensitivity, (2) Authority Structure Misalignment, (3) Professional Conflict Insensitivity, (4) Direct Line Client/Stakeholder Misrepresentation, (5) Stakeholder Boundary Neglect, (6) Institutional Boundary Neglect. Qualitative analysis revealed similar themes, but with a political, or "consent to power" type component that appeared to be assisted by the strong sense of professionalism that administrators exhibit toward their primary client base, the faculty that comprise their institution. Common themes arising from the discourse analysis were: (1) respect for the client, (2) respect for hierarchy and control structures, (3) respect for internal and external boundaries, (4) politicization, and (5) ethics as a central identity component. Future studies on this data will focus on the predictive value of the RANI instrument, gender differences, institutional size, other social control structures, and time-space discourses.

Karen Louis, *Eric G. Campbell, Entrepreneurial Professors and Secrecy in Science: Variations and Impacts (University of Minnesota, *Harvard University)

AIMS. University relationships with industry have been a hot topic for nearly two decades. There are concerns that increasing faculty involvement in research commercialization will affect the exchange of ideas in the scientific community. This paper investigates four different types of faculty entrepreneurship and finds that each type is characterized by different behavior.

METHODS. In 2000, a sample of 2,893 geneticists and other life scientists (OLS) at the 100 most research-intensive universities in the United States were surveyed concerning data withholding and sharing. The instrument was developed and pretested in 1999, and a total of 1,849 faculty responded (64%). Previous publications have examined patterns of data withholding (Blumenthal, Campbell, Gokhale, Yucel, Clarridge, Hilgartner, and Holtzman, 2006). This analysis, using the same data set, takes a different approach by asking the question: what kinds of university-industry relationships do faculty engage in and how does withholding or sharing behaviors affect them? Factor analysis and regressions are used to answer the question.

CONCLUSIONS. Items indicating faculty involvement with commercialization/industry were factor analyzed; four types emerged: research entrepreneurs (getting research support from industry and consulting), innovation entrepreneurs (involvement in patenting and early stage commercialization), leadership entrepreneurs (company founders or executives), and commercializing entrepreneurs (having products at market and earning royalties). Regressions on each of these types used personal characteristics (MD, native born, gender, years since highest degree), communication behaviors (collaboration with other laboratories, denying others requests for information, being denied, having positive or negative experiences with sharing, and research behaviors (# of post-docs supported, number of published articles in last 3 years, and engaging in human subjects research).

The results suggest that: 1) Research entrepreneurs are more likely to be male, to have been born in the U.S., to have many collaborators, and to have had positive experiences with sharing. They are involved with post-docs, less likely to do human research, and have published heavily (R=.37). 2) Innovation entrepreneurs are like research entrepreneurs in that they are more likely to be male, have Ph.D.s, have post-docs, not do research on humans, and have more publications. However they are more likely to have denied information to others, and report negative effects of sharing. (R=.40). 3) Leadership entrepreneurs are less well predicted by the model (R=.17). They are likely to be male, to not ask others for information, and to have had negative sharing experiences. 4) Commercializing entrepreneurs are also less well predicted (R=.18). They are more likely to have MDs, less likely to support post-docs, and more likely to be involved in collaborations with other laboratories. Overall, they do not report significant positive or negative experiences with sharing.

These findings point to the need to look more carefully at specific types of university-industry relationships among faculty members. Two types of entrepreneurship - research and commercializing - are not associated with secretive behaviors, while the other two - innovation and leadership - are. Policy implications for universities and departments are discussed in the paper.

James Vander Putten, Carol Thrush, Organizational Culture for Research Integrity in Academic Health Centers (University of Arkansas-Little Rock, University of Arkansas for Medical Sciences)

AIMS. This quantitative pilot study tested a brief survey to investigate faculty perceptions of academic organizational culture and climate characteristics that promote research integrity. Faculty at one academic health center (n=47) were surveyed, and the results provide initial insights into important dimensions of organizational culture that can promote research integrity.

METHODS. We developed a 26-item survey instrument to assess perceptions of the organizational culture and climate for research integrity. To minimize social desirability bias regarding research integrity attributable to any individual, the instrument focused on respondent assessments of their immediate work unit, rather than on self-assessments of individual characteristics. Respondents consisted of 47 faculty from a medical school in the southern U.S. Principal components factor analysis was used to explore specific dimensions of organizational culture assessed by the survey items. Reliability estimates were computed and a 2x2 factorial analysis compared health center faculty perceptions by rank and gender.

CONCLUSIONS. Factor analysis yielded three dimensions of organizational culture: 1) Leadership/Communication, 2) Awareness of IRB Resources and Procedures, and 3) Faculty Research Productivity. Total variance explained by the factors was 71%. The first factor, Leadership/Communication, consisted of 10 items and accounted for the majority of variance (33%); the second factor, Awareness of IRB, contained 5 items and accounted for 24% of the variance; and the third factor, Research Productivity, consisted of 3 items accounting for 14% of

the variance. A 2x2 factorial analysis of survey responses indicated a high level of consistency in medical school faculty perceptions of the organizational culture and climate. Faculty consistently rated survey items addressing 'pressure to publish' as highly characteristic of the organizational culture with little variance in the spread of scores. Conversely, faculty rated survey items addressing 'socialization to research integrity' as relatively uncharacteristic of the organizational culture with a large amount of variance in the spread of scores. No significant differences in medical school faculty perceptions of the organizational culture and climate were found between males and females, or between senior faculty and junior faculty.

Sunday: 8:30-10:00 Concurrent Track Three: Issues in the Design and Conduct of Clinical Trials (Panel discussion)

Deb DeBruin, Joan Liaschenko, A. Fisher, Re-thinking Clinical Research Ethics: From Protocol Design to Everyday Practice (University of Minnesota,)

AIMS. Research ethics focuses on protocol design and prospective review of clinical trials. Little is known about the everyday work of clinical trials. This presentation will report the results of one of the first empirical studies of moral challenges in this everyday work and discuss the implications for research ethics/integrity.

METHODS. This presentation will report the findings from a qualitative study of nurses working in biomedical clinical trials. This study involved focus groups with nurses because they do most of the day-to-day work of trials. Nurses were recruited from two geographical areas in the U.S. Participants responded to questions about their day-to-day work, the ethical challenges they encounter in this work, and the moral resources necessary to respond to these challenges. The panel will describe the research and present an overview of the findings, discuss particular themes from the data in more depth, and their implications for research ethics and integrity.

CONCLUSIONS. The findings reveal that nurses work in the center of a complex web of relationships with others crucial to the conduct of clinical trials. The quality of these relationships, and the nurses' ability to manage the tensions created by often striking differences in these perspectives, significantly affect the work of trials. Moreover, this work is often invisible to those not involved in it; even principal investigators and Institutional Review Board members often do not understand the demands of the day to day work of trials. The results raise profound questions about the adequacy of the moral guidance usually offered to researchers in the form of the principle-based approach of the Belmont Report and the oversight apparatus that has evolved to govern the work of clinical trials.

Sunday: 8:30-10:00 Concurrent: Questionable Research Practices

Brenda Jeffers, Research Environments and the Research Report Card (Mennonite College of Nursing at Illinois State University)

AIMS. The objective is to present a method for public reporting of research integrity practices within research environments. An internal control model is used to identify and assess key environmental research integrity practices and a sample research report card is formulated.

METHODS. Adoption of an internal control model identifies processes within research environments that promote integrity. Using the model components, questions are formulated and presented that assist in assessment of the research environment's integrity practices. Appraisal of a research environment includes assessment of research integrity risk, risk control, monitoring,

and organizational communication. A sample research report card is formulated using the assessment questions.

CONCLUSIONS. Integrated frameworks provide a useful approach for systematically evaluating research integrity practices and publicly communicating an organization's commitment to research integrity. The research report card is one method of publicly reporting and promoting research integrity within research environments.

Nanyan Cao, Questionable Research Practices (QRP): A Difficult But Important Research Area (Institute of Science, Technology and Society, School of the Humanities and Social Sciences, Tsinghua University)

AIMS. In her RCR teaching, the author noticed that most students are unambiguously against to research misconduct, yet they do not pay enough attention to QRP. Moreover, quite a few of them agree to, or even yearn for QRP. Therefore, the author is engaged in research on college students' attitude to QRP, causes and harms of QRP prevailing in research community, and methods to prevent QRP.

METHODS. The author conducted a survey among nearly two thousand graduate students in Tsinghua University in China. The questionnaire focused on students' responses on QRP, which are either experienced by themselves or by other people. The results of this survey as well as a few studies conducted by other scholars were analyzed to investigate general attitude of students and researchers to QRP. The author also used several case studies, such as duplicate publication, conflict of interest in peer review, and misuse of research funds, to explain the importance and difficulties of QRP research in China. In addition, the author analyzed the epistemological and social causes of prevalence of QRP theoretically.

CONCLUSIONS. The results show that QRP is a prevailing phenomenon in Chinese research community, which undermines science integrity and public trust to science deeply. However, it is a pity that many researchers still maintain ambiguous attitude toward QRP, or even scramble for QRP for the purpose of conducting malfeasance. Epistemologically, QRP is a gray area. For example, sometimes it is hard to differentiate accidental and intentional violation, or determine which behavior is justifiable or unjustifiable among biases caused by conflicts of interest. From social aspect, QRP could be seduced by protection of individual interests and competition pressure to succeed, trusting to the luck of playing edge ball , and the fact that laws will not punish the majority. In addition, some research institutes choose to turn a blind eye to QRP for their own reputation or interests. Therefore, it is quite necessary to formulate specific academic norms in different fields, educate young scholars through case studies, and improve evaluating and encouraging systems of scientific research, such as paying more attention to quality rather than quantity.

Kelly L. Wester, Mark Davis, John Willse, Questionable Research Practices: The Initial Development of a Measure (University of North Carolina at Greensboro)

AIMS. Although questionable research practices and research misconduct have been widely discussed in the research literature, no known measures exist to assess questionable research practices (QRP). The current measure was developed to measure QRP and is theoretically based on ORI's 9 areas of responsible conduct of research.

METHODS. Pilot studies have been conducted to examine the factor structure and relability of the QRP measure. Faculty from social and behavioral science departments at private universities

were randomly selected, with an additional sample selected based on snowball methods, to participate in an online survey of the QRP. Additional measures in the online survey included: demographic information, Personal Reaction Inventory (social desirability), and Perceived Stress Scale. Preliminary reliability and factor analyses have been conducted.

CONCLUSIONS. Initial factor analysis on the QRP indicates that while there are not 9 separate factors (i.e., 9 ORI areas of RCR) the majority of items load on different factors, with one possible overarching QRP dimension. Initial reliability analyses indicate factors on the QRP are reliable, but further exploratory and confirmatory factor analyses are planned. An additional pilot study on the QRP is examining the construct validity against existing measures of general integrity and honesty.

Sunday: 10:15:12:15 Plenary: Impacts and Policy Implications

Dennis M. Gorman, Reanalysis of Data from an Evaluation of the DARE Program using Questionable Data Analysis and Presentation Practices (Texas A&M Health Science Center School of Rural Public Health)

AIMS. In order to assess whether use of irregular and questionable data analysis and presentation practices result in significant overestimation of program effects, we will re-analyze data from a large-scale evaluation of the DARE program using questionable practices employed in evaluations of other widely used drug and violence prevention programs.

METHODS. We will re-analyze data from a large scale evaluation of one of the most well known school-based prevention programs namely, the DARE program - using the questionable data management and analysis techniques found in evaluations of other widely advocated drug and violence prevention programs. A DARE dataset is highly suitable for addressing this particular research question, as DARE is the one school-based drug and violence prevention program that is almost universally considered by researchers to be ineffective. The DARE dataset used in the re-analysis was collected by Richard Clayton in the mid-1980s-mid-1990s from a cohort of 6th graders from 31 schools in Kentucky.

CONCLUSIONS. We are currently nine months into the project which, in addition to the re-analysis of the DARE dataset, involves a systematic review of the data management and analysis practices used in the published evaluation studies of programs that appear on the Substance Abuse and Mental Health Services Administration's list of model substance abuse prevention programs. Thus we have yet to complete the re-analysis of the DARE dataset, and thereforefor do not have any findings and conclusions at this point in time. However, we anticipate having conducted much of the re-analysis by the conference date and should therefore be in a position to present findings and draw some conclusions.

Ambuj Kumar, Heloisa P. Soares, Benjamin Djulbegovic, Unrealistic Expectations of Treatment Effects May Hamper Advancements in Medicine: A Review of Randomized Trials Conducted by Three NCI Cooperative Groups (H. Lee Moffitt Cancer Center and Research Institute)

AIMS. Inconclusive findings from randomized clinical (RCT) trials represent waste of precious resources and ethical breach of contracts with patients who expect that definitive answers will help future patients. Our objective was to find out how often and why results from RCTs are inconclusive

METHODS. We examined 261 RCTs (research protocols/publications) from 3 NCI sponsored cooperative groups enrolling >50,000 patients. We compared the expected effect size with the observed effect size. The results were deemed inconclusive if the 95% confidence intervals crossed the line of the predetermined equivalence and the line of no effect.

CONCLUSIONS. 64% of the results were statistically non-significant (168/261, data were extractable from 148/168 studies). 34% (50/148) of the results were inconclusive. 70% (103/148) of the studies had undertaken a pre-trial power analysis. The actual accrual almost always exceeded the planned target, excluding poor accrual as a reason for inconclusive results. The observed effect size was typically less than the expected, and in many instances it was in the opposite direction from that expected. The investigators typically hoped to detect a large treatment differences (median: 20% improvement; range: 9% to 200%).

Expectation bias appears to be the culprit behind inconclusive findings in cancer RCTs. Unrealistic expectations of treatment effects may hamper advancements in medicine. Making investigators aware of their unrealistic expectations may result in the designing of more realistic studies and optimize the chances of finding smaller, but worthwhile treatment effects.
(Sponsored by the NIH/ORI: grants # R01 NS044417-01 and R01 NS052956-01)

Chuck Lidz, Paul Appelbaum, Steven Joffe, Jill Rosenbaum, Lorna Simon, Steven Banks, Competing Commitments in Clinical Trials Research (University of Massachusetts Medical School)

AIMS. Clinical trials researchers face competing commitments between the best interests of their patients and gathering valid data. Many commentators are concerned that subjects do not get good treatment. Almost ignored has been whether the clinical concerns of researchers have undercut good research practices.

METHODS. We did in-depth interviews with 27 researchers about this issue. We then designed a web survey that was sent to 1000 randomly selected contacts for clinical trials on Centerwatch.com. 189 were no longer working at the site or otherwise unreachable. Of the 811 subjects with valid email addresses, 80% responded to the survey. Because a relatively small proportion of respondents were physicians, we surveyed all the identified physicians on the list. Of these 222 potential subjects, 126 responded for a 57% response rate. In all, we received responses from 189 physicians, 379 nurses and 503 others.

CONCLUSIONS. Results suggest some willingness to violate the protocol or otherwise undercut the validity of the research to help patients . 37% of subjects agreed that patients who are not doing well in standard care should be recruited most actively so that the trial can help them. 40% agreed that when several subjects at a site do worse than ordinarily would be expected that the site should stop recruiting and 19% agreed that researchers should deviate from the protocol if doing so would improve the subject's medical care. Similarly, 11% of subjects agreed that the protocol should be used as a guideline rather than strictly followed in all circumstances. 16% of subjects reported offering a trial to patients who were not technically eligible because it was in their medical interest, 24% reported giving medication restricted by the protocol because it was in the subject's best medical interest and 14% adjusted medication outside the bounds permitted by the protocol. These and other data suggest that clinical trialists must take the competition between clinical and research goals seriously when designing their trials and the importance of educating staff about the difference between their ethical obligations in ordinary treatment and research.

Heloisa P. Soares, Ambuj Kumar, Benjamin Djulbegovic, Lack of Reporting Harms in the NCI Sponsored Phase III Hematological Malignancies Trials Leads to Outcomes Reporting Bias. (H. Lee Moffitt Cancer Center and Research Institute)

AIMS. To make informed decisions, patients and physicians need accurate information both on treatment benefits and harms. However, reports of trials typically focus on description of benefits only. Therefore, our objective is to assess the quality of reporting of treatment-related mortality (TRM) and morbidity (TRMorb) in cancer.

METHODS. We evaluated all randomized controlled trials (RCTs) that have been conducted by six NCI sponsored cooperative oncology groups (COGs). The NCI account almost for 100% of all publicly sponsored phase III trials in the US, and is widely considered as the most important for advancement in treatment against cancer. We included all trials that were completed by 2002. Here we focus on hematological malignancy trials. Data related to TRM and TRMorb were extracted from publications that reported benefits (i.e. survival or event-free survival). Data were pooled using meta-analytic techniques to assess if the harms were worse in experimental vs. standard treatments.

CONCLUSIONS. We evaluated 114 hematological-malignancy trials. Seventy-nine trials studied leukemias, 32 lymphomas and 3 either multiple myeloma or myelodysplastic syndrome. Quality of reporting for the most important methodological domains (such as randomization methodology, power calculation, drop-out rates, use of intention-to-treat analysis) was high. Data related to TRM were extractable from 41 trials (36%) only. (Sponsored by the NIH/ORI: grants # R01 NS044417-01 and R01 NS052956-01)

Sunday, 12:15-1:00: Closing Presentation and Discussion

Nicholas H. Steneck The Past, Present and Future of Research on Research Integrity (Office of Research Integrity, University of Michigan)