Friday 11/12 - 1:45 - 3:15 PM, Plenary: Overviews of Current Research and

Nicholas H. Steneck, ***Research on Research Integrity: 2004 Update.***

Aims: The goal of this presentation is threefold: 1) to present a brief summary of the major research on research integrity that has been undertaken since the 2000 RRI conference, 2) to provide an overview of the development of the ORI/NIH Research on Research Integrity Program, and 3) to identify problems and areas that are in need of additional investigation.

Findings: 1) Empirical information is still lacking on the prevalence of research misconduct. Progress has been made in understanding authorship and publication practices, conflict of interest, data management, RCR training, and integrity in clinical trials. 2) Applications for ORI/NIH RRI funding come from a wide range of fields, degrees, and positions. Successful applicants tend to hold more than one advanced degree and have some grounding in the field of research they are studying. 3) Significant areas of research, such as privately funded and state-supported research, have not been studied and more effort is needed to link general findings to particular research areas and fields of investigation.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 1:45 - 3:15 PM, Plenary: Overviews of Current Research and

Lawrence Rhoades, ***Institutional Research Misconduct Activity: 1991-2000.***

Aims: To provide a preliminary analysis on the reporting of research misconduct activity (the conduct of inquiries and investigations) by institutions conducting research supported by the Public Health Service from 1991-2000. On the basis of this analysis suggestions will be made for future research on research misconduct and the implementation of the research misconduct regulation (42 CFR Part 93).

Methods: This is a secondary analysis of data on misconduct activity reported by institutions on their Annual Report on Possible Research Misconduct from 1991-2000. Each institution annually reports the number of inquiries and investigations conducted and the type of research misconduct alleged. This database has been augmented with the ranking of each reporting institution in the NIH funding hierarchy and the number of research misconduct findings made. Multi-variate analysis will be conducted using funding rank, case outcomes, and 5-year periods as controls. Descriptive statistics - frequency and percentage – will be utilized.

Findings or general conclusions: The number of institutions reporting research misconduct activity has steadily increased over the 10-year period. Institutions vary considerably in the frequency with which they report research misconduct activity. Few institutions regularly report research misconduct activity; most institutions report one case or none. Although the reported research misconduct activity is concentrated in the top 75 funded institutions, institutions throughout the funding hierarchy report such activity. Levels of funding and misconduct activity appear positively related. Overall, little is know about the organizational setting of research misconduct and the implementation of the research misconduct regulation. More research is needed.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 1:45 - 3:15 PM, Plenary: Overviews of Current Research and

Brian C. Martinson, Melissa S. Anderson, Raymond De Vries, *Scientists' Perceptions of Working Conditions and Self-Reported Misbehaviors.* NIH/ORI RRI Program researcher.

Aims: The aim of this paper is to investigate relationships between scientific misconduct and other behaviors that may compromise the integrity of science and scientists' perceptions of their working conditions. We base our analysis on the social-psychological frameworks of work strain theory, equity theory, and organizational justice, augmented by the concept of alienation.

Methods: Data for the study are based on responses to a survey of 7,760 postdoctoral fellows and early-career scientists supported between 1999 and 2001 by NIH funding (T32/F32 or R01 support, respectively). The survey was conducted in the fall of 2002 and attained an overall response rate of 47%. With regard to misconduct and questionable research practices, respondents reported on their own behavior over the preceding 3 years. They also responded to items measuring their work effort and consequent rewards, job control, social support, and sense of alienation within the scientific arena.

Findings: Overall, 4% of our respondents indicated that they had engaged in one or more forms of FFP (plagiarism, fabrication, falsification) in the preceding 3 years. Also, 38% of the R01 sample and 28% of the postdoctoral sample had engaged in behaviors that a consulting panel of university compliance officers identified as very serious. Likewise, 50% and 45% of the respective samples reported engaging in careless behaviors that could compromise the integrity of science. In multivariate analyses, both work strain and alienation are positively associated with misbehavior.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 3:30 - 5:30 PM, Plenary: The Impact of the Research

Eric G. Campbell, Melissa Anderson, Lisa Jones, Melissa Anderson, ***Data-withholding Among Trainees in Science: Results of a National Study.*** **NIH/ORI RRI Program researcher.**

Aims: The purpose of this research is to explore the phenomena of data-sharing and withholding among doctoral students and post-doctoral fellows (trainees) in the life sciences, computer science and chemical engineering.

Methods: The study involved a mailed survey of a random sample of 2000 trainees in the life sciences, computer science and chemical engineering in the most educationally intensive institutions in the US. Of the 2000 trainees sampled, 164 subjects were ineligible. Of the remaining, 1836 trainees 1077 responded yielding an overall response rate of 58.7%. Response rates varied by strata with 62.7% (n=382) in chemical engineering, 47.3% (n=297) in computer science and 66.4% (n=398) in the life sciences.

Findings: About one quarter (23.0%) of trainees were denied access to published information, data or materials by another academic scientist. Trainees in the life sciences were 2.67 times more likely to be denied than chemical engineering trainees. Industry supported trainees were 3.65 times more likely to be denied access to published information data and materials, controlling for gender, race/ethnicity, level of competition with the lab, and scientific field ($p<.05$). Trainees denied access to published resources reported their own research was delayed by more than 4 months compared to 1.6 months for trainees who were not denied access to published information.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 3:30 - 5:30 PM, Plenary: The Impact of the Research

Melissa S. Anderson, Sarah Bunton, ***Willingness to Share Scientific Information: Generational or Maturational Effects?.***

Aims: The purpose of this paper is to examine differences between faculty members and early-career scientists in willingness to share scientific information with other scientists. It models both willingness to share and actual sharing behavior as functions of contextual and individual variables, such as normative systems and industry involvement.

Methods: This investigation is based on data from two national surveys of faculty members (N=3,000) and graduate students and postdoctoral fellows (N=1,836) in the sciences. The first survey was administered in 2000 and yielded a response rate of 65%; the second was fielded in 2003 and had a 59% response rate. The multivariate analysis examines the effects of normative systems, training, scientists' perceptions of the dynamics of science as a field, their experiences with sharing, and their involvement with industry on their willingness to share. It then examines the effects of these variables on their actual sharing behavior.

Findings and General Conclusions: In the abstract, scientists show a notable willingness to share information with other scientists. This attitude is affected in rather predictable ways by subscription to norms and by training (positive effects) and by negative past experiences with sharing (negative effects). The interesting part, however, comes in contrasting these findings with effects on actual sharing behavior: training, having been scooped, and industry involvement all show significant, negative effects on sharing behavior, effects that are not present in the models that predict willingness to share. Furthermore, faculty members are significantly more willing to share with colleagues than are their younger counterparts.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 3:30 - 5:30 PM, Plenary: The Impact of the Research

Lisa M. Jones, Eric G. Campbell, ***Gender Differences: Competition and Collaboration in Scientific Research.*** **NIH/ORI RRI Program researcher.**

Aims: The aims of this study are to investigate gender differences among trainees in life sciences, computer sciences, and chemical engineering in the areas of: competitiveness of the research field, influences on data sharing, industry financial support, productivity, intentional withholding, willingness to share, and attitudes about how academic scientists should behave.

Methods: Using data from the National Science Foundation, we identified 50 institutions in each field that granted the largest number of Ph.D.s (fiscal year 2000). We generated a random sample of 2000 trainees (advanced doctoral students and postdoctoral fellows) distributed evenly across life sciences, computer sciences, and chemical engineering. A pre-tested survey was sent by mail between January 2003 and March 2003. Of the 2000 in the initial sample, 164 subjects were ineligible determined by their leaving school, changing schools, or who left the country on medical leave from their program. The overall response rate was 59%.

Findings: Males view their fields as more competitive than females. More females report that they have been encouraged to share by their lab director/mentor compared to males. Males are more likely to agree that academic scientists should keep their newest findings secret and are more likely to agree that academic scientists should get direct benefits from sharing. Males more frequently withhold information at seminars at other universities in department seminars. Females find that lab group members from other labs are more willing to share with them. Finally, more females report that industry agreements have no influence on sharing than males.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 3:30 - 5:30 PM, Plenary: The Impact of the Research

Karen S. Louis, Eric G. Campbell, Durwin A. Long, ***The Effect of Mentoring, Unit Size, and Workplace Climate on Individual Productivity Among University-Based Researchers in the Life Sciences.*** **NIH/ORI RRI Program researcher.**

Aims: The purpose of the present research is to investigate effects of workplace climate on the training of doctoral students and post-doctoral fellows at Research I universities. Student characteristics, attitudes, behaviors, and experiences as well as structural factors such as departmental size are analyzed in relation to research productivity.

Methods: The top 50 Ph.D.-granting U.S. universities in chemical engineering, computer science, and life sciences were identified using National Science Foundation data. Department chairs at 115 institutions identified advanced doctoral students and post-doctoral fellows. From a population of 6,734 researchers, a random sample of 2,000 was selected, of whom 1,836 were considered eligible for participation. A survey was developed through focus groups, individual interviews, and a literature review; it was pre-tested through nine interviews with scientists. Surveys were mailed to eligible participants between January and March, 2003. Respondents totaled 1,075, of whom 397 were from the life sciences.

Findings: Departmental, contextual factors are critical to the development of productive scientists who will conduct their work with integrity. Common explanations of research productivity among doctoral students and post-doctoral fellows consider individual talent, motivation, and effort as primary explanatory factors. Without challenging these assumptions, the present research indicates that, for researchers in the life sciences, environmental factors such as unit size and workplace climate also significantly impact the development of researchers. The present research contributes to theory by suggesting components to an overall model of researcher productivity; it contributes to practice by suggesting department-level actions that may enhance researcher development.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Madeline Alexander, Wendy Reed Williams, ***The Use of Focus Groups to Identify Responsible Conduct of Research Training Needs of International Postdoctoral Fellows.***

Aims: The specific training needs of international postdoctoral fellows have not been considered in the development of responsible conduct of research programs.

Methods: As part of an ORI Resource Development Award, we conducted focus groups with predominantly international postdocs to identify beliefs, attitudes and behaviors that may impact interpretation and acceptance of research guidelines. Eighty-four postdocs at the Children's Hospital of Philadelphia were asked to participate in a single 2-hour session to discuss one of three topics: Data Ownership and Management (3 groups), Intellectual Property (2 groups) or Research Misconduct (3 groups). The majority of participants were foreign nationals (68%; representing 23 countries) and over half received their doctoral training outside the United States. Using cases, mini-surveys and draft guidelines, postdocs were asked to provide insight from past experiences and training; assess the value of institutional guidelines; and offer suggestions about teaching responsible research behavior. A content analysis identified themes that emerged across the groups.

Findings: We will present the results of this analysis as well as the data from brief surveys administered at the beginning of each group. Implications for curriculum development will be discussed.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Kirsten A. Barrett, Francis L. Macrina, Carolyn L. Funk, ***Research Methods and the Study of RCR Instruction.*** **NIH/ORI RRI Program researcher.**

Aims: This poster will describe, from a methodological perspective, how an interdisciplinary group of researchers carried out a longitudinal study to investigate the effectiveness of training in the responsible conduct of research (RCR).

Methods: A microbiologist and two survey researchers conducted a longitudinal study of NIH F32 postdoctoral trainees to evaluate the effectiveness of RCR instruction in the area of authorship and publication practices. The study involved a 3-wave telephone survey and a series of web-based case studies. This presentation will include: the target population and sampling frame, the process of survey development, a description of the telephone and web-based survey methodologies, a description of monetary incentives and response rates, and an overview of data management strategies. In addition, unanticipated challenges will be described.

Findings: From a methodological perspective, there were interesting "lessons learned" from the study. First, although the target population was well defined, obtaining an accurate sampling frame was initially difficult. Also, contact information for some of the F32s changed. Additional staff time was required to locate F32s that had re-located between interview waves. Finally, frequent decisions needed to be made about logistical aspects of the study such as the timing for mailing prenotification letters and the subsequent initiation of telephone interviews. We anticipate that our experience will provide valuable guidance for those interested in studying topics related to RCR via survey methodology. (Supported by USPHS Grant NS042494 to Virginia Commonwealth University).

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Ruth Ellen Bulger, Elizabeth Heitman, ***Assessing the RCR Educational Literature for Core Content.*** **NIH/ORI RRI Program researcher.**

Aims: To determine a generally agreed upon core content for RCR instruction, content analysis was done for each of the ORI's nine core areas of RCR as presented in key educational resources.

Methods: Content analysis focused on the key resources' original material; references and reprinted articles were categorized and tabulated using EndNote. The key resources cited a large number of widely varying primary references (approximately 600); repeated citations often came from the National Academy of Sciences' evaluative reports. For each of the ORI's nine areas, a list of covered topics was created, starting with the content of the two most comprehensive textbooks, and adding new topics as they appeared in other key resources. The frequency of appearance of topics was tabulated.

Findings: Although a wide variety of references were cited in the key resources, the specific topics addressed were generally consistent. However, key resources varied greatly in organization and in the depth in which they covered specific core areas. Collaboration and peer review were generally addressed under other core areas, particularly authorship. Mentoring discussions generally referred only to the mentor's relationship to the trainee, ignoring other important mentoring relationships in the research environment. Additional "non-core" issues were often discussed, such as values in science, ethical principles and codes, creativity and objectivity, moral reasoning, genetics, epidemiologic and environmental issues, and scientists' societal roles. We recommend that the ORI core area "scientific misconduct" by expanded to "the responsible conduct of research" and include many of the related topics not now mentioned.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Chuani Christine, ***Developing Capacity for Collaborative Research: The Experience of the College of Health Sciences, Moi University, Kenya.***

Aims: To promote local and international research collaboration of the Institutional Research and Ethics Committee (IREC) by focusing on development of structures, systems and processes for expeditious and reciprocal review and approval of collaborative research taking cognisance of the local values of the institution and adhering to internationally accepted research practices.

Methods: IREC oversees research activities at Moi University Faculty of Health Sciences and Moi Teaching and Referral Hospital, Kenya. Upon its establishment, it was apparent that there was need to develop regulations and procedures governing research ethics and build the capacity of IREC to achieve its mandate. This was achieved through training of the committee and faculty members locally through specialized training sessions, short courses and fellowships and led to the development of Standard Operating Procedures (SOPs). IREC's capacity was enhanced further through partnership with Indiana University School of Medicine (IUSM) which was formalized through signing a Memorandum of Understanding.

Findings: The development of SOPs led to improvement of both administrative organization of IREC and review of research protocols. The Committee gained recognition with the National Council of Science and Technology (Kenya) and the Office for Human Research Protections (USA). Other achievements include establishment of a Research and Sponsored Projects Office and training of personnel. It is envisaged that policies and procedures will be developed with IUSM to enhance ethical research. Plans are underway to promote collaboration with local and international organizations involved in research ethics while considering the values of each institution and upholding the general principles of research ethics.

Conflict of Interest Statement: Statement pending

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Tony Hecimovic, David Sullivan, ***How a Masters University I Fulfills OHRP Requirements to Protect Human Research Participants.***

Aims: The aim of this poster presentation is to demonstrate that a small, regional masters university I with a modest research agenda can and does meet the spirit of OHRP guidelines for the protection of human research participants.

Methods: The step-by-step process that has been employed by Montana State University – Billings in setting up and maintaining its Institutional Review Board will be shared in this presentation. The process in which the institution engaged involved minimal resource allocation. We believe that the proactive systemic process employed can serve as a model for other similar institutions.

Findings: While there have been some challenges to overcome and continual refinement has taken place, the establishment of the Institutional Review Board has had a positive effect at multiple levels of the institution. Difficult budget times should not be a seen as a reason to not comply with Federal guidelines for the protection of the stakeholders while in pursuit of a research agenda.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Rudolph J. Marcus, ***I Didn't Know I Had.***

Summary: A postdoc gets a choice tenure-track position and immediately competes with his former mentor in the mentor's field of research. A bold-face caption by his picture (*Science*, 27 February 2004, pp. 1276-9) quotes the senior investigator: "This has run me through so many emotions, some of which I didn't know I had," Can what "I didn't know I had" affect my conduct of research? Yes, because the researcher is the last stage of any observation whether it is instrumental, field work, or modeling. It is the researcher who reads the instrument, writes down the observation, or determines the fit of model. When a "call" has to made or benefit of doubt has to be given, it is the researcher who makes that choice. What if "I didn't know I had" exerts pressures or provides contexts driving that choice? And, if so, how do I find out some of what "I didn't know I had?" The seminars of the web site <http://storiesandquestions.com/> are good vehicles for that. For the case of postdoc and mentor described in the four-page *Science* news article, work with any one of those seminars would have quickly called to mind the father-son situation driving that discord and suggested remedial attitude changes to both protagonists.

A new seminar has been written and will be demonstrated, along with the rest of the web site. The material deals with selfworth and is taken from *Inner Chapters* by Chuang Tsu, a fourth-century B. C. follower of Lao Tse. Three different seminars of the web site have now been used by two other facilitators, demonstrating that material and questions from the web site can be used by other leaders for live seminars.

Conflict of Interest Statement: Statement pending

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Jesus Gonzalez, Ruth Ellen Bulger, Ana Maria Burga Vega, Marcela Cancino Silva, Pablo Grajeda Ancca, Elizabeth Heitman, Leo Lecca Garcia, Ricardo Lopez Ingunza, Gladys Ramirez Prada, Maria H. Sjogren, ***The Peru – U.S. Forum for Research Ethics.***

Objectives: To undertake collaborative international research with human volunteers in foreign countries, knowledgeable members and staff of local research ethics committees must be able to review and approve proposed studies. A Peru- U.S. Forum for Research Ethics, supported by a NIH grant to USUHS, was formed to provide training.

Methods: The Peru – U.S. Forum, with members from USUHS, WRAMC, the Peruvian Ministry of Health (Instituto Nacional de Salud), the Pan American Health Organization (PAHO), and faculty from Cayetano and San Marcos Universities in Peru, established training for individuals able to conduct reviews using Peruvian research ethics committees. The series of instructional activities included a six-week practicum for seven Peruvian train-the-trainers in the U.S. (2003), a week-long Introductory Course for 250 Peruvian participants (2003) and an Advanced Ethics Course for 100 Peruvian participants (2004). Participants were selected in conjunction with the Peruvian Ministry of Health.

Findings: Tests to evaluate the trainee's knowledge, lecturing skills and materials' preparation were administered during and/or after each activity, as appropriate. Each lecture was evaluated by trainees. In addition, opinions on various aspects of the training environment were collected. The members of the Peru-U.S. Forum have reviewed these results. To further extend availability of the course contents, and the use of material produced by the Forum, a CD of the introductory course materials and a web link have been created (www.bioetica.ops-oms/forum/ihome.htm).

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

David B. Resnik, ***Using Electronic Discussion Boards to Teach Responsible Conduct of Research.***

Aims: 1. To describe the use of electronic discussions boards in teaching courses on the responsible conduct of research.
2. To explore the advantages and disadvantages of electronic discussion boards.
3. To summarize student comments about electronic discussion boards.

Methods: For several years, I have used electronic discussion boards as part of a graduate level course in the responsible conduct of research. Students have been required to develop a case study to post to the board. The case study includes a description of the case as well as an ethical analysis of the case. Other students are required to comment on the case study. The instructor serves as a moderator for the discussion board. Students develop cases based on the own experience, discussions with peers, articles published in scientific journals or the media, or online resources.

Findings: Electronic discussions boards have been a very effective tool for stimulating student discussion and debate outside the classroom and within in it. Most students found the discussion board format to very useful and stimulating. The discussion board also models the collaboration and peer review occur in scientific research.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 6:00 - 7:30 PM, Poster Session

Ginamarie Scott, Jazmine Espejo, Laura Sohl, Samuel T. Hunter, Katrina Bedell, Shane Connelly, Michael D. Mumford, ***Historical Misconduct Cases: Content Coding the Bad Guys.*** **NIH/ORI RRI Program researcher.**

Aims: The objective of the present study is to investigate situational influences on scientific misconduct using a set of objective behavioral markers to content code historical cases.

Methods: After conducting literature reviews, twenty variables indicated important situational influences on scientific integrity (e.g., accountability, munificence, and leadership). Multiple behavioral markers were then generated under each construct to reflect objective instances of each variable as it relates to scientific careers (e.g., "required weekly lab meetings"). These behavioral markers were written in a checklist format made up of approximately 500 items. The sample in this study was comprised of eight individuals found guilty of varying levels of scientific misconduct by ORI . Multiple sources of archival information (e.g., refereed journal articles, newspaper articles, and ORI website information) detailing events in the careers of these individuals were gathered to obtain converging accounts of the life and circumstances of these particular individuals. The checklists of behavioral markers were then applied to each individual's background archival material.

Findings: Markers of competitive pressure, production pressure, and low accountability were identified most frequently in a majority of the cases of scientific misconduct. In addition, substandard leadership was evident among factors present in these cases. Surprisingly, indices of organizational turbulence and munificence appeared the least frequently. However, this could be due to the nature of the source material available. These findings suggest that immediate and interpersonal variables are important in incidences of scientific misconduct, and this study provides insight into potential controls to mitigate such problems (e.g., increased accountability through teamwork).

Conflict of Interest Statement: Statement pending

Friday 11/12 - 7:30 - 9:00 PM, Plenary: Reflections on RRI Methods

John M. Kennedy, ***A Guide to the Use of Survey Methods in Research on Research Integrity.***

Aims: Research on research integrity (RRI) can use survey methods as an effective research technique. However, many researchers do not have sufficient expertise in survey research to use it effectively. This presentation will describe techniques that researchers can use to develop surveys related to research integrity issues.

Methods: This presentation will present an overview of survey methods as they relate specifically to RRI. The presentation will focus on the appropriate sampling techniques, choice of survey mode, methods of question and questionnaire development and testing, and other issues related to survey development. The presentation will contain theoretical, methodological, and practical issues directly related to conducting RRI surveys.

Findings: RRI is a relatively new research topic that can effectively use survey methods as a tool to better understand important issues. However, the method is relatively sophisticated and many researchers are not aware of the theoretical and practical difficulties of conducting useful survey research. Researchers who develop sound research designs using the appropriate survey methods, sampling techniques, and instrument development will provide more valuable outcomes to the RRI community.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 7:30 - 9:00 PM, Plenary: Reflections on RRI Methods

Wayne Sullender, Scott Snyder, Sam Tilden, Dale Benos, Jo Rae Wright, ***Assessment of Perceptions of Research Integrity.***

Aims: We propose research integrity (RI) is a developmental process with progression from a simpler to a more complex form influenced by multiple factors as described in an open-systems model. The goal is to develop a multidimensional measure to assess expected behaviors in RI situations.

Methods: An item pool was constructed based on a two-dimensional typology. The first dimension represented core performance areas and the second dimension represented 3 domains of RI, defined here as honesty and accuracy, collegiality and adherence to mutual responsibilities among investigators, and protection of the rights of human subjects and animals. Rasch scaling will describe the nature of dimensions of RI across performance areas, identify factors that mediate performance, and monitor changes in scores. Trainees and faculty will be assessed at various career levels.

Findings: A pilot measure was administered. All items reflected a range of responses. Analyses indicated that the item statistics separate items into clear levels of relative difficulty. The general conclusions are the instrument has potential for measuring at least one dimension of RI and it is amenable to Rasch analysis. Effective education will require understanding the timing of acquisition of knowledge and opinions about research integrity among students, trainees, and investigators. The scale under development will be used to assess this timing and to monitor the outcomes of educational and other interventions designed to promote RI.

Conflict of Interest Statement: No conflicts

Friday 11/12 - 7:30 - 9:00 PM, Plenary: Reflections on RRI Methods

Douglas Adams, Kenneth D. Pimple, ***The Flaw in the Ointment: What Research on Research Integrity can Learn from Research on Crime.***

Aims: The flaw in the ointment of efforts to understand and control research misconduct is an individualistic orientation similar to that held for 200 years by criminologists as they attempted to associate deviant and criminal behavior with psychological states (such as immorality or imprudence) as well as social conditions that produce these states (such as poverty). In the last 25 years, however, criminological perspectives have emerged that place greater emphasis on situational factors that enhance or restrict the opportunity for imprudent behavior (including unethical and criminal behavior). Opportunity theories assume a plentiful and continually replenished supply of potential offenders. Therefore, strategies intended to deter imprudent behavior through education and enhancement of pro-social values, however admirable, are of limited practical value. Scholars of situational crime prevention have empirically documented practices that reduce imprudent behavior through an emphasis on easily implemented procedures that minimize opportunities to engage in such acts.

Methods: In this paper we describe aspects of opportunity theory that are most readily translated from criminology to research integrity. We also describe several interventions, including: (a) methods of data collection and analysis that provide valid and reliable estimates of the nature and distribution of unreported acts of victimization; and (b) administrative procedures, methods of record keeping, and emergent and normative practices through which police departments supervise the activity of patrol officers, utilize unobtrusive data to identity and correct imprudent behavior, and engage in peer intervention that escalates appropriately based on the persistence and severity of the acts of misconduct.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, RCR I: Assessing the Impact of RCR

Michael Kalichman, Andrea Paik, ***Instructor Perceptions of Goals for Teaching Responsible Conduct of Research.***

Aims: Teaching of responsible conduct of research (RCR) occurs nationwide, but little is known about either the effectiveness or purposes of such training. To create a framework for defining goals and assessing effectiveness, the objective of this project is to characterize the self-described goals of those who now teach RCR courses.

Methods: This study was reviewed and approved by the Institutional Review Board. Teachers of RCR courses were identified by contacting directors for NIH training grants newly awarded in 2000. Instructors were interviewed by phone or in person using a survey instrument developed through informal survey, focus group discussion, and pilot testing. The survey consisted of both forced choice and open-ended questions. Respondents were asked to characterize the history and audience for their courses, to rank the importance of specified goals for teaching, and to identify important goals not already listed.

Findings: Data collection and analysis are ongoing. To date, interviews have been conducted with 44 teachers of RCR courses. The range of goals identified includes: knowledge, skills (especially ethical decision-making, but others as well), attitudes (about responsible conduct of research), behaviors (avoiding research misconduct and promoting RCR), and community (increased discussion about RCR in and out of class). Overall, it appears that the goals of RCR instruction are multiple and varied. Characterization of existing perceptions of goals is a necessary first step for proposing ideal goals and developing measures to assess success in achieving those goals. (supported by the NIH: K01 AI01591).

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, RCR I: Assessing the Impact of RCR

Elizabeth Heitman, Ruth Ellen Bulger, Cara H. Olsen, ***New Graduate Students' Baseline Knowledge of RCR.*** **NIH/ORI RRI Program researcher.**

Aims: 1) Evaluate the baseline knowledge of core RCR concepts in a cohort of new graduate students at four universities; 2) identify the sources of their knowledge of RCR; and 3) assess the variability in their knowledge in relation to their gender and the country in which they received their undergraduate training.

Methods: An objective, multiple-choice, computer-scored, paper and pencil test was developed from a comprehensive analysis of the core educational literature in RCR. This test was combined with a short survey of demographic characteristics and academic experience based on questions raised by graduate students in the biomedical sciences who participated in focus groups on RCR in undergraduate science education. The final instrument was administered to new graduate students at four universities to measure their baseline knowledge of core RCR concepts. Scores were analyzed by students' gender, country of undergraduate institution, previous science education, and experience with hands-on research.

Findings: Participating students' test scores were highly variable, with few achieving what would be a passing score in a typical graduate-level course. Participants' low scores substantiate the belief that graduate students in the biomedical sciences need formal education in the principles and standards of RCR. However, the variability of students' scores argues against many graduate programs' practice of using one-size-fits-all instructional methods, materials, and contexts for RCR education. Providing effective RCR education requires faculty to have insight into students' knowledge of and experience in hands-on research, as well as a definition of a satisfactory basic level of knowledge in the field.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, RCR I: Assessing the Impact of RCR

Dena Plemmons, Michael Kalichman, ***Student Perceptions of Outcomes for Responsible Conduct of Research Courses.***

Aims: Although there is evidence that moral reasoning can be improved through some teaching methods, little else is clear about the purpose or effectiveness of research ethics teaching. To better define outcomes, students were asked for their perceptions of what they learned following completion of research ethics courses.

Methods: This study was reviewed and approved by the Institutional Review Board. The study consisted of a voluntary, anonymous survey sent to students enrolled in selected research ethics courses at ten research institutions. The survey instrument was developed through a combination of focus group discussion and pilot testing. Students were recruited by the course instructors and were invited to participate in the survey via an email or printed letter. Survey questions addressed basic demographic information and the expectations and lessons learned from the research ethics course. Both forced choice and open-ended questions were included.

Findings: Although some students in every course emphasized changes in skills or attitudes, it is noteworthy that courses were perceived to have the greatest impact on providing new and specific information. Preliminary analysis of open-ended responses (207, 77% of the 268 respondents) shows that a majority listed the specific kinds of information they had learned, while some talked about how they learned to think about the information. Analysis of the quantitative responses (267, >99% of respondents) reinforced the qualitative impressions: students were statistically significantly more likely to report that courses had an impact on their knowledge base rather than on skills or attitudes. (supported by the NIH: K01 AI01591).

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, RCR I: Assessing the Impact of RCR

Carolyn L. Funk, Francis L. Macrina, Kirsten A. Barret, ***Effectiveness of RCR Instruction: Initial Findings.*** **NIH/ORI RRI Program researcher.**

Aims: There has been little systematic effort to determine if mandated instruction in the responsible conduct of research (RCR) has measurable, desired effects. Our research is aimed at evaluating the effectiveness of RCR instruction on student awareness, attention, and behavioral judgments related to research ethics.

Methods: We are conducting a national longitudinal study of postdoctoral trainees supported by NIH F32 Fellowships to evaluate the effectiveness of RCR instruction. RCR instruction is required of all F32 Fellows. The study includes a 3-wave telephone survey and web-based case study vignette to measure awareness, attention to, and behavioral judgment pre- and post-RCR instruction in one core area of RCR content: authorship and publication practices. A total of 431 F32 Fellows have been interviewed.

Findings: 37% of the sample completed RCR training by the time of first interview and 60% had completed some other kind of formal training in responsible research conduct. Comparisons between those who have and have not completed RCR training show few significant differences between groups. Awareness of authorship guidelines and ethically appropriate behavioral judgments were common among both groups, raising the possibility of ceiling effects. F32 Fellows have, on average, 8.7 years research experience and 6.4 publications. This research provides preliminary evidence on the effectiveness of RCR instruction and suggests strategies to improve it. (Supported by USPHS Grant NS042494 to Virginia Commonwealth University).

Conflict of Interest Statement: Macrina is the author of the textbook "Scientific Integrity" (2000) ASM Press. Washington, DC.

Saturday 11/13 - 8:00 - 10:00 AM, Authorship & Publicaton I: Rules and

Darko Hren, Ana Ivanic, Ana Marusic, Matko Marusic, ***How Intuitive are ICMJE Criteria for Authorship?*****.**

Aims: To analyze how "naive" medical students perceive 11 possible research contributions as criteria for authorship established by International Committee of Medical Journal Editors (ICMJE).

Methods: Second year medical students (n=85), not familiar with ICMJE authorship criteria, evaluated importance of eleven possible contributions as authorship criteria (1-low importance; 4-high importance). They also wrote down contributions they considered a single authorship criterion, then combinations of two or three contributions qualifying for authorship. Average importance and frequency of a contribution as single or partial criterion for authorship was calculated, followed by hierarchical cluster analysis.

Findings: "Conception and design of the study" was seen as the single most important contribution of all 11 ($p<0.001$, ANOVA with Tukey post hoc test). "Analysis and interpretation of data" and "Drafting the article" were seen as second most important contributions ($p<0.001$, ANOVA with Tukey post hoc). Cluster analysis based on a contribution's percieved importance and frequency of appearance as a single or partial criterion revealed a five cluster solution. The first two clusters included the main ICMJE criteria, except "Final approval of the article."

Conclusion: ICMJE criteria for autorship can be seen as intuitive because "naive" participants who had no previous experience with scientific publishing gave more importance to the contributions qualifying for ICMJE criteria. "Final approval of the article" was regarded as an unimportant contribution.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Authorship & Publicaton I: Rules and

Miguel Roig, Amanda Marks, ***Integrity in "Instructions to Authors": An Exploratory Study in a Sample of Psychology Journals.***

Aims: Scheetz (2002) reviewed the instructions to authors (IA) in a sample of biomedical journals to determine the extent to which such journals promote research integrity. In the present study we used a similar methodology to explore the same theme in a sample of psychology journals.

Methods: Using the search terms *correction* and *retraction*, we searched the PsychInfo® electronic database and obtained several entries. Only those entries that described either a correction of a previously published article or a retraction of an article were selected for the study. Next, we recorded the journal that published each of these entries and then located its Internet homepage. Each journal's IA were then retrieved and analyzed by noting how many of the categories related to research misconduct originally identified by Scheetz, were addressed in each of these journals.

Findings: Our results were similar to those obtained with biomedical journals with the exception of two categories: simultaneous submissions and notification of prior publication. Over 80% of the journals identified through the PsychInfo database included warnings against these two types of infractions. The corresponding figures reported by Scheetz for biomedical journals were 10% and 44% respectively. Several key areas of potential misconduct were addressed by only a few of the psychology journals. Given that IA represents an ideal opportunity for promoting scientific integrity, editors and publishers should be strongly encouraged to augment these sections with relevant material.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Authorship & Publicaton I: Rules and

Ana Marusic, Tamara Bates, Ante Anic, Matko Marusic, ***Authorship Criteria and Contributions Disclosure: Comparison of Three General Medical Journals with Different Author Contribution Forms.***

Aims: To determine the number of named authors who do not meet ICMJE criteria for authorship in 3 medical journals with different contribution disclosure practices.

Methods: Observational study of stated authors' contributions in research articles published in 2002 volumes of Annals of Internal Medicine (n=72), BMJ (n=107), and JAMA (n=81). BMJ asks authors to describe research contributions in their own words; Annals asks authors to choose from a list of coded contributions, and JAMA uses structured checklist with instructions on contributions qualifying for ICMJE criteria. Honorary authorship was defined as the lack of contribution from the first ICMJE criteria (study conception and design, or acquisition of data, or analysis and interpretation of data) and/or second (drafting the article or critical revision for important intellectual content) ICMJE criterion.

Findings: The number of honorary authors was highest in Annals (121/562 authors, 21.5%), followed by BMJ (46/482, 9.5%), and JAMA (3/641, 0.5%) (_2=146.67, df=2, P<.0001). The number of articles with honorary authors was 60% in Annals, 21% in BMJ, and 4% in JAMA. In all 3 journals, honorary authors had fewer published contributions than authors who met ICMJE criteria and were positioned more towards the end of the byline. Honorary authors either lacked contributions for both ICMJE criteria (10% in Annals and 22% in BMJ), or contributions to the second ICMJE criterion (75% in Annals, 67% in BMJ, and 2 out of 3 in JAMA).

Conclusions. General medical journals differed in prevalence of honorary authors according to published research contributions. Different authorship/contributorship policies and procedures should be explored as a possible explanation for the differences in contributions disclosed by authors among these journals.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Authorship & Publicaton I: Rules and

Vesna Ilakovac, Ana Marusic, Matko Marusic, ***Authorship: Contributions Disclosure for All Authors as Stated by the Corresponding Author or by the Individual Authors.***

Aims: To analyze authors' contributions described by the corresponding author and individual authors in the *Croatian Medical Journal* (CMJ) and satisfaction of authorship criteria of the International Committee of Medical Journal Editors (ICMJE).

Methods: We analyzed contributions of all authors of a research paper as stated by the corresponding author or by each individual author listed in the byline. The sample comprised 201 research articles with two or more authors submitted to the CMJ from 2001 to 2002, representing 919 authors. The authors chose their contributions from the list of 11 categories, five of which were not related to ICMJE authorship criteria. Authorship was defined as true if all three ICMJE criteria were met, partial if any of the criteria was met, and false if none of the criteria were met.

Findings: Out of 718 non-corresponding authors, 201 (28.0%) fully met the ICMJE criteria for authorship according to statement given by the corresponding author. When they themselves described their own contributions, this prevalence increased to 40.0% (difference -12%; 95% confidence interval (CI) -15.2 to -8.7%). Prevalence of partial authors was higher in the contribution disclosure of the corresponding author comparing to individual authors (difference 8.5%; 95% CI 4.7 to 12.3%). Prevalence of false authors was lower according to individual authorship statements than to corresponding author statement (difference 3.5%; 95% CI 1.4 to 5.7%). Corresponding authors described their contributions on both group and individual authorship statement. None of 201 corresponding authors was a false author. Prevalence of corresponding authors who fully met the ICMJE criteria for authorship was significantly higher according to their individual authorship statement than to statement where they described their contributions along with contributions of other authors (difference -13.0%; 95% CI -19.8 to -5.9%).

Conclusions: Authorship statements provided by corresponding authors only may not be a true reflection of authors' contributions to the research described in a published article.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, FFP & QRP I: Numbers, Causes, and

Lawrence Rhoades, ***PHS Research Misconduct Investigations: 1994-2003.***

Aims or objective: To present a preliminary analysis of 260? investigations conducted by institutions, PHS agencies, or the Office of Research Integrity (ORI) on allegations of research misconduct involving research supported by the U. S. Public Health Service from 1994 to 2003. On the basis of this analysis suggestions for further research on research misconduct and the implementation of the research misconduct regulation (42 CFR Part 93) are made.

Methods: Data for this secondary analysis were collected from the research misconduct case database maintained by ORI to administratively track the progress made in processing cases. Variables included in the analysis are frequency of allegations, case flow, types of misconduct, organizational locations of misconduct activity, rank, degree and gender of whistleblowers and respondents, frequency of misconduct and no misconduct findings, administrative actions taken by the PHS and institutions, size of inquiry and investigation panels, and length of inquiries and investigations. Comparative analysis focuses on the two 5-year periods and the outcome of the investigations. Descriptive statistics – frequency and percentage – will be utilized. Chi-squares will be computed when appropriate.

Findings or general conclusions: There has been a substantial decrease in allegations, cases, and misconduct findings between the first and second half of the 10-year period. Misconduct investigations have become increasingly centered in medical schools. Male Ph.Ds. play the predominant role as whistleblowers and respondents. Allegations and misconduct findings are made more often against junior members of the research team. Overall, little is known about research misconduct and the institutional implementation of the research misconduct regulation. Much more research is needed.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, FFP & QRP I: Numbers, Causes, and

Sheldon R. Gelman, Margaret Gibelman, ***An Analysis of Cases of Scientific Misconduct and Implications for Behavioral Health Research.*** **NIH/ORI RRI Program researcher.**

Aims: Scientific misconduct or, more positively, appropriate conduct in the realm of research inquiry, is a topic that has received very little attention in the behavioral health professions. This paper offers an empirical analysis of a body of cases of scientific misconduct, as reported in the media, in the behavioral health disciplines. Two groups of cases are examined: substantiated cases that highlight trends between 1990 and 2003; and alleged cases of misconduct that have emerged in the last year but have not yet been adjudicated or are in process of judicial or administrative review.

Methods: Cases of scientific misconduct were drawn from a search of national newspapers and higher education newsletters, such as the *Chronicle of Higher Education*. This search revealed hundreds of articles, but the majority addressed issues related to the hard sciences and/or bio-medical fields. Articles pertaining to fields or professions such as nursing, psychology, psychiatry, and the social and behavioral sciences were then culled and classified according to the case circumstance, type of alleged or confirmed misconduct, disposition/resolution of the cases, and the consequences to the accused parties and institutions. Content analysis methods were used to identify themes.

Findings: Approximately 90 cases of alleged or confirmed scientific misconduct in behavioral health professions for the 1990-2003 period were identified. Common themes included plagiarism, falsification and fabrication of data, misrepresentation, and conflict of interest. The penalties for these wrongdoings ranged from criminal prosecution and jail to resignations, restitution and disqualification for federal research funds. More than half of these cases have been disclosed between 1999 and 2003. This number suggests that either the incidence of misconduct is increasing or that the vigilance of review and monitoring procedures is being felt.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, FFP & QRP I: Numbers, Causes, and

Mark S. Davis, Kelly L. Wester, Bridgett King, ***Narcissism, Entitlement and Ethical Compromises in Research.***

Aims: Speculation on the causes of research misconduct has included individual-level factors such as personality. Narcissism seems a likely personality type for many of those who engage in misconduct. We hypothesize that the more narcissistic researchers are, the more likely they are to compromise research ethics.

Methods: To test these hypotheses we conducted a Web-based pilot survey of a random sample of members of the Association for Counselor Education and Supervision, an organization affiliated with the American Counseling Association (ACA). The survey included vignettes describing various departures from the responsible conduct of research. These vignettes were grounded in the ACA Code of Ethics. Other measures included the Narcissistic Personality Inventory, the Psychological Entitlement Inventory, socio-demographic items and measures of respondents' involvement in research.

Findings: Contrary to expectations, narcissism was not significantly related to the tendency to compromise ethical standards for those holding academic positions. However, entitlement was significantly related to the tendency to compromise the responsible conduct of research. We discuss the findings and conclude that certain individual factors such as personality attributes may indeed play a role in research misconduct. We also suggest additional studies that could build on this line of research.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, FFP & QRP I: Numbers, Causes, and

Joe G. Delap, ***Employing a Least Invasive Procedure (LIP) Model for Responding to Research Misconduct Allegations and Cases.***

Aims: Based on a case study involving allegations of multiple counts of falsification in reporting of research data brought administratively to the institution by the DIO, this paper delineates case-specific handling procedures and then expands them into a more generalized model. The resulting protocol is a variation on the PHS model for policies and procedures that balances the needs and requirements of Division of Investigative Oversight (DIO) officers/ case workers for thoroughness and rigor with those of research integrity officers and respondents for limitations on such issues as the number and types of parties involved and access to sensitive records. The described procedure helps 1) prevent damage to respondent reputation and 2) preserve individual research protocols, while 3) remaining methodical.

Methods: This study investigates a practical application for the findings of the Research Triangle Institute's *Survey of Accused but Exonerated Individuals in Research Misconduct Cases: Final Report* (June, 1996). The *Final Report*'s "Executive Summary" describes these findings as "likely to protect the reputations of respondents." The proposed presentation seeks to draw conclusions about the findings' implications for cases in general by introducing a new investigative model. This "Least Invasive Procedure" (LIP) model for resolving cases brought by the DIO involves balancing the fulfillment of proprietary, often sensitive documentation from respondents with a healthy dose of respect for preserving the confidentiality and integrity of intellectual property, patent claims and other necessary components of free and ethical conduct of research while upholding the reputation of the respondent.

Findings: Parties traditionally involved in cases concerning allegations brought forward by outside whistleblowers, including DIO staff, campus research integrity officers and case respondents, each of whom works under separate time and resource constraints (as well as at different levels of appropriate experience, diplomatic skills and emotional quotients), could benefit from an understanding of and a broad application of this model. The proposed set of protocols augments and improves on policies and procedures recommended by PHS. Although not framed in these exact terms by the RTI *Final Report*'s conclusions, it can be said that minor steps in the direction of civility and common sense go a long way toward insuring a thorough investigation while also reassuring respondents of the necessity for and safeguards provided by the investigative process.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Clinical & IRB I: IRB Role, Ideals, and

Patricia Keith-Spiegel, Gerald P. Koocher, Barbara G. Tabachnick, ***What Scientists Really Want: The Ideal IRB*****. NIH/ORI RRI Program researcher.**

Amis: In laboratories and scientific commentary literature, researchers often complain about Institutional Reviews Boards. However, no systematic studies exist describing what investigators would see as an ideal IRB.

Methods: 2283 biomedical and social / behavioral science recipients of NIH funding received a survey asking them to rate the importance of 45 items describing actions and functions of ideal IRBs, to compare their ideal IRB to their actual IRB, and to provide information regarding gender, type of institution, research area, and IRB membership within the last 5 years. 886 responded with usable data for a return rate of 38.8%.

Findings: We hypothesized that the "ideal" IRB would differ for biomedical as compared to social/behavioral investigators, such as those typically conducting exempt research and those whose research requires more extensive review, and those who recently served on an IRB to those who never served. However, almost no statistically significant differences were found, indicating that researchers in any setting or specialty want the same kind of IRB. The most important features of an ideal IRB are timely review of protocols, no preconceived biases, balance between upholding participants' rights while facilitating the conduct of research, lack of suppression of sound research even though it might cause outside criticism, and a high degree of knowledge about IRB procedures and federal policy. Overall, items that related to procedural fairness and competence were most important whereas IRB outreach and committee functioning were least important. The survey can serve as an institutional assessment technique. Items and survey sample norms will be provided.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Clinical & IRB I: IRB Role, Ideals, and

Laura Stark, ***Practicing Morality: Psychological Research Practices and the Rise of Human Subjects Regulations in Postwar America.***

Aims: This paper argues that during the 1970s, the research practices defined by professional psychologists as morally acceptable for their own discipline would form a piece of the newly created US federal human subjects regulations. The argument is developed by showing how the American Psychological Association (APA) created the profession's first code of ethics through the early 1950s, and revised the code in the 1960s—this time writing a narrow and detailed new version of the code based on thousands of survey responses attesting to the questionable treatment of human subjects by their colleagues. Importantly, this new version of the code would be reworked countless times over three years because of the outcry, particularly from experimental social psychologists, claiming that their experimentation would be impossible under such ethical restrictions.

Methods: This research involves: 1. archival research using primary texts from the American Psychological Association's administrative records (1946 – 1976) housed at the Library of Congress, and 2. a synthesis of published federal records regarding human subjects regulations on deception.

Findings: The specifications of acceptable research practices outlined in federal human subjects regulations, such as the use of deception in research, were shaped in part by the practical demands of professional organizations. This incorporation of disciplinary demands into federal regulations extends the reach of such practices beyond their disciplinary origins and into other social sciences. The case of psychology illustrates empirically how commitments to the proper way to conduct experimental research came into conflict with ideas about the appropriate ways to treat people.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Clinical & IRB I: IRB Role, Ideals, and

Jim Vander Putten, T. Gregory Barrett, ***Exploring Organizational Culture and Climate for the Responsible Conduct of Research in the Social-Behavioral Sciences.***

Aims: This qualitative research study investigated perceptions of University IRB Chairs, IRB Administrators, and IRB members regarding organizational culture and climate characteristics that promote the responsible conduct of human participants research in the social and behavioral sciences. What characteristics are critical to creating a positive culture and climate for ethical research?

Methods: Semi-structured long interviews were conducted with IRB Chairs, IRB administrators, and IRB members at six institutions representing three institutional types (Public DoctoralłResearch-Extensive, Urban/Metropolitan Universities, and Private DoctoralłResearch-Extensive) regarding organizational culture and climate for the responsible conduct of human participants research in the social and behavioral sciences.

In addition, documentary evidence of each institution's attempts to foster a positive culture and climate for research was also gathered to achieve data triangulation. This data included documents to publicize RCR education efforts, location and accessibility of online RCR resources, and documents advertising new faculty orientation and returning faculty professional development workshops on campus.

Findings: This study yielded a series of five conceptual components of IRB Chairs, administrators, and members' perceptions of organizational culture and climate dimensions for the responsible conduct of human participants research in the social and behavioral sciences. These conceptual components describe culture and climate at the 'organizational unit' level, defined by interviewees as the individual academic department:

- Identification of an RCR official
- Articulating a culture of respect
- Effective RCR communication
- Awareness of Human Subjects Research training opportunities
- Point of contact for regulatory communication

Future research will investigate academic discipline influences on organizational culture and climate characteristics.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 8:00 - 10:00 AM, Clinical & IRB I: IRB Role, Ideals, and

T. Gregory Barrett, Jim Vander Putten, ***Outliers: Social Scientist Frustration with IRBs – Implications for Culture and Climate.***

Aims: This qualitative case study explored perceptions of twelve full-time social science faculty members regarding the culture and climate for the responsible conduct of research and frustration with their university's Institutional Review Board. What factors cause social scientists to criticize and rebel against Institutional Review Board (IRB) submissions and decisions?

Methods: Two "outlier" faculty members at six institutions were interviewed using a semi-structured protocol. Each social scientist had expressed frustration with their institutional review board. All participants maintain active research agendas, supervise research activities of students, and are employed at one of three institutional types (Public DoctoralResearch-Extensive, Public DoctoralResearch-Intensive, and Private DoctoralResearch-Extensive). Documentary evidence of each institution's attempts to cultivate a culture and climate for the responsible conduct of research was gathered to achieve triangulation. Interview data was tape recorded and transcribed verbatim. Data analysis was accomplished by coding to a conceptual framework and by identifying unexpected "surprise" responses.

Findings: Regulations Originally Developed for Biomedical Research Faculty members decried application of guidelines for protection of human subjects that were not developed by social scientists for the social sciences. Additionally, faculty members assailed the make-up of the IRB for being heavily composed of scientists trained in positivist methodologies. One faculty member, an ethnographer, noted that it was becoming increasingly difficult to apply the principles of ethnography to her studies because the standardized interview protocols required by the IRB don't allow for the conversational interaction needed to achieve deep emersion in the culture of an ethnic group.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 10:20 - 11:50 AM, Plenary: Data and the Accuracy of the

Ken Wilson, Alan Schreier, Angel Brantley Griffin, David Resnik, ***Scientific Record Keeping and the Responsible Conduct of Research.***

Aims: 1) To obtain a better understanding of actual record keeping practices in research. 2) To identify and describe, both quantitatively and qualitatively, some of the problems with scientific record keeping that institutional officials encounter when they investigate and adjudicate allegations of misconduct.

Methods: The study reported here is Phase I of a larger project. In this phase, we conducted semi-structured phone interviews with institutional officials responsible for investigating and adjudicating research misconduct recruited from the top 150 research universities, based on total research and development expenditures. To date, 70 interviews out of an anticipated 100 have been analyzed. The interview questionnaires included questions that ask for quantitative and qualitative information. The interviews were audio taped and transcribed. Responses to the qualitative (or open-ended) questions were reviewed, and coding categories developed. CATI survey software was used to record and analyze the interview data.

Findings: Half of the officials reported problems with research record keeping that significantly impaired their ability to conduct misconduct inquiries or investigations. Incomplete/inadequate documentation was the most frequently mentioned type of problem (31% of responses), followed by lack of physical access to records (16%), disorganized records (12%), and missing records (9%). Officials also reported problems with obsolete software (4%) and altered or destroyed records (4%). The officials also rated the seriousness of the problems on a Likert scale from 5 (profoundly serious) to 1 (minor). The most serious problem encountered by officials was altered records (mean score: 3.7), followed by missing or incomplete records (3.4).

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 10:20 - 11:50 AM, Plenary: Data and the Accuracy of the

Mike Rossner, ***Digital images and the journal editor.***

Aims: At *The Journal of Cell Biology*, we have implemented a completely electronic workflow, whereby all figures are submitted to the journal as electronic files. This has enabled us to examine all figures of accepted manuscripts for evidence of manipulation. We have had to create protocols for examination of images, definitions of inappropriate manipulation, and policies for action when evidence of inappropriate manipulation is detected. Each of these components will be discussed with examples from actual cases.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 10:20 - 11:50 AM, Plenary: Data and the Accuracy of the

Sandra Titus, ***Descriptive Study: Research Integrity Measures Used in Biomedical Laboratories.***

Aims: 1. To describe the diversity in the reports by lab directors regarding their reported methods on data storage, use of written procedures, degree of supervision, and training of researchers. 2. To raise questions that could lead to further research questions about lab behavior (or any research groups behavior).

Methods: Over 3000 lab directors participated in an ORI contracted questionnaire study about research behaviors that occurred in their lab. From this data set we will be able to describe the self report by lab directors on procedures they use in the lab: (1) methods to preserve original data, (2) use of written guidelines for publication practices, (3) time issues to supervise, do own research and do other things, (4) supervising and reviewing data sets, (5) views of directors on their preparation to be a good mentor

Findings: Specific findings will be highlighted in a manner that raises questions for future research questions: 1. There is great diversity in how data is stored (loose-leaf, permanent bound, digital files, AV record). Thus, labs need to have their own rules on what is appropriate. Alternatively, disciplines need to create standards. Is it important to study data retention that research groups use? How do we further research this? Observational study? Mentors and Mentees self report? 2. Directors report that they have written guidelines less than 5 % of the time for authorship issues, fragmenting publications, multiple submissions, reproducibility, retractions, and data sharing. They say that these behaviors are discussed verbally (48-70% of the time). How do we get labs and all research groups to promote the use of written procedures on this and related issues? Studying guidelines (not only on authorship but all research guidelines) would be a good research topic. In addition to whether they exist we need to know if they are used by the faculty as well as the graduate student. 3. Directors report that they spend on average 30 hours per week on their own research, 19 hours per week on other activities, and 11 hours per week with mentoring. On average they mentor 6 individuals. What would adequate supervision/mentoring look like? Is it possible for a PI to supervise 20 individuals? Is an observational study the best way to get a sense of how labs supervise? If large labs have an "absentee mentor" how is supervision occurring? How else would you study supervision?

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, RCR II: Training Programs

Francis L. Macrina, Kirsten A. Barrett, Carolyn L. Funk, ***RCR Education and NIH F32 Awards: Trainee Profiles and Instructional Formats.*** **NIH/ORI RRI Program researcher.**

Aims: We are testing whether mandated instruction in the responsible conduct of research (RCR) has measurable effects. NIH F32 postdoctoral fellowship awardees are being interviewed and evaluated at different points in their training to determine their awareness, attentiveness, and behavioral judgments related to research ethics.

Methods: We are conducting a national longitudinal study of postdoctoral trainees supported by NIH F32 fellowships to evaluate the effectiveness of mandated RCR instruction. Our study includes a 3-wave telephone survey and web-based case study vignette to measure awareness, attention to, and behavioral judgment in pre- and post-RCR instruction in one core area of RCR content: authorship and publication practices. We have tabulated and analyzed the data on the properties of the participants under study and of those who have already completed RCR instruction.

Findings: Of 431 F32 fellows, approximately 37% had completed their RCR training prior to their fellowship. About 44% had not taken formal RCR training, and approximately 17% were unaware of the RCR training requirement for F32 awardees. About 25% of the respondents who had completed RCR instruction took a course for credit while about 75% did not. Other instructional formats included tutorials (electronic format), seminar series, and workshops or conferences. Between 35 and 50% of trainees who had completed the requirement received training in one of more of these latter formats. Participants reported that frequent in-person discussion groups were part of their instructional format about 50% of the time.(Supported by USPHS Grant NS042494 to Virginia Commonwealth University).

Conflict of Interest Statement: Macrina is the author of the textbook "Scientific Integrity" (2000) ASM Press. Washington, DC.

Saturday 11/13 - 1:00 - 2:30 PM, RCR II: Training Programs

Julka Almquist, Steven Jacobsen, Richard McGee, ***Efficacy of RCR Training: Influences of Trainee Experience and Lasting Impacts.*** **NIH/ORI RRI Program researcher.**

Aims: Despite requirements for training in Responsible Conduct of Research (RCR), very little is known about the impact of such training beyond simple survey responses. We sought, through an interview-based qualitative research study, to better understand if and how an RCR course influences participants. Initial focus was on how trainee's prior experiences influenced what they took from the course and the future behaviors they projected as a result of what they learned.

Methods: In the first phase of the study separate groups of beginning graduate students and postdoctoral fellows participated in focus groups that followed weekly RCR course sessions. In the second phase individual interviews were conducted with course participants before the RCR course and immediately following the sessions on Authorship and Conflict of Interest. Semi-structured questions elicited reflections on prior knowledge and experiences, reactions to course content and how the session might have influenced their approaches to RCR issues in the future. Data were analyzed using the grounded theory method.

Findings: The three most important observations were: 1) what individuals "hear" and "take away" from sessions was dramatically dependent on their stage of research training and prior experiences; 2) participants easily articulated how their future behaviors might be influenced by what they had learned from the class; 3) differences between espoused normative behaviors and what individuals saw in real life were very troublesome to all levels of trainees. These results demonstrate the importance of RCR training throughout the development of scientists and that it should be tailored to the level of experience. Moreover, the results highlight the impact of ambiguous normative behavior of the research community.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, RCR II: Training Programs

Margaret Gibelman, Terry DiLorenzo, Nigel Bark, ***Educating for Responsible Research Conduct: The Case of Behavioral Health.*** **NIH/ORI RRI Program researcher.**

Aims: This paper will report on the findings of an exploratory, cross-disciplinary study funded through the National Institutes of Health, Office of Research Integrity to: (1) identify and compare the research review and monitoring mechanisms utilized by the educational programs representing five key behavioral health professions: psychiatry, social work, psychology, counseling, and psychiatric nursing; and, (2) explore the extent to which content related to responsible research conduct is included in respective professional curricula.

Methods: A questionnaire was constructed and piloted specific to this study and mailed to the deans/directors/department chairs representing all educational programs for the five behavioral health professions under study (n=1,500). Further, a web site was created to provide an optional means of responding. Survey administration was based on the Total Design Method modified to meet the specific requirements of the current project to maximize response rates. As part of the survey, syllabi which incorporate relevant content (e.g., content pertaining to ethical research conduct) was requested. As of this writing, the surveys have been mailed and a follow-up, exclusively by electronic means, will be conducted in May, 2004. Curricula collected will be subjected to content analysis. Using the Statistical Package for the Social Sciences, frequencies, cross-tabulations, and analyses of variance will be conducted.

Findings: Data analysis will be conducted between May and August, 2004. The conference presentation will present the preliminary findings of the first phase of the research, specifically, the results of the survey of the total universe of educational programs in the five behavioral health professions. The second phase of the project will be underway and will focus on a qualitative and in-depth exploration of the status of and issues in educating for responsible research conduct.

Conflict of Interest Statement: Nigel Bark has been a Consultant to BristolMyers Squ in the past year and have a pending Research Grant from Pfizer. I do not believe that eith of these pose any conflict of interest but declare them in case anyone sees it differenlty. Nigel Bark

Saturday 11/13 - 1:00 - 2:30 PM, Authorship & Publication II: The Role of

Kirby Lee, Elizabeth A. Boyd, Lisa A. Bero, ***Evaluation of the Editorial Decision-Making Process at Major Biomedical Journals.*** **NIH/ORI RRI Program researcher.**

Aims: To identify factors influencing editors' decisions to accept or reject original research articles for publication in biomedical journals and to identify sources of systematic bias in the editorial review process.

Methods: We observed editorial practices and conducted semi-structured interviews with editors at three leading international biomedical journals. Questions fell within four domains for each journal: 1) describe the editorial process whereby articles are evaluated for acceptance/rejection, 2) describe the peer review process, 3) identify factors that influence editors' decision-making process, and 4) describe editor characteristics. Transcripts were qualitatively analyzed to identify recurring themes within the domains. We also assessed the methodological quality of accepted versus rejected articles using a validated instrument in a sample of 1,043 articles submitted for publication between January 2003 and April 2003 at the three journals.

Findings and Conclusions: Editorial policies and procedures varied among the three journals regarding editorial practices, peer review processes, and experience and composition of editors. The majority of submitted articles were outright rejected (50-80%) by one or two editors prior to external peer review based on the following factors: 1) topic lacked novelty, 2) topic unsuitable for journals' readership, 3) weak methodology, and/or 4) topic lacked impact to change current clinical practice. Accepted original research articles (n=50) were of higher methodological quality than rejected articles at submission (P<0.001), suggesting that the editorial process contributes to the publication of high quality research.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, Authorship & Publication II: The Role of

Anne Victoria Neale, Justin Northrup, Ellen Marks, Judith Abrams, *Correction and Use of the Literature Following Scientific Misconduct.* NIH/ORI RRI Program researcher.

Aims: To determine how users of bibliographic databases and e-journals become aware of publications affected by misconduct and the particular problems with affected publications, we investigated compliance with directives for corrections and retractions, as represented in PubMed.

Methods: Between 1993 and 2001, 103 articles were named in either the *NIH Guide for Grants and Contracts* ("Findings of Scientific Misconduct") or Office of Research Integrity annual reports as needing retraction or correction. Through PubMed, we determined which of the 103 affected articles had been corrected or retracted, and the extent to which these actions are apparent to database users. The Web of Science was used to determine subsequent authors' citations of the affected articles.

Findings: 99/103 articles were cited in PubMed. 83 had indexed corrections: 47 were retracted; 26 had an erratum; 10 had a correction in the "comment" field. 16 had no correction, but 11 were linked to the *NIH Guide,* leaving only five articles with no indication of sanction. As of 01/09/04, there were 5,164 citations to the 103 articles, with a median of 25 citations per article (range 0-580). Researchers should be alert to comments linked to the *NIH Guide*, as these are open access, and the "Findings of Scientific Misconduct' are often more informative than the statements about the retraction or correction found in the journals.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, Authorship & Publication II: The Role of

Robert J. Silverman, ***Journal Peer Review and Its Relation to Research Integrity.***

Aims: The purpose of this paper is to establish the relationship between journal peer review practices and research integrity and to demonstrate that there are ideal review models that support alternative epistemologies. It is this seamless logical web, from the origin to the judging of scholarship, which creates a beneficent research climate.

Methods: This research was informed by earlier work by this author that established four epistemologies or research contexts, with classical origins, but which for current purposes were labeled: fact, idea, context, and individual-oriented. Scholarship norms were identified and/or created for each social science research environment that reflected various combinations of regulative and constitutive dimensions. The current project, bringing a new community-situated view related to research integrity, extended this work by interviewing six "exemplary" editors, from three to six hours each, in the various epistemological contexts to identify their experiences with research misconduct and to understand the review processes, which they created, and through which submitted manuscripts were filtered.

Findings: Editors, as gatekeepers, faced few problems with research misconduct in relation to their social science journals. However, as active scholars themselves and having developed or reestablished peer review practices in highly turbulent social science areas, they created review patterns that, as it turns out, are highly complementary to the epistemological patterns reflected in the preponderant number of manuscripts received and published. That is, there are four distinct review environments that support the logics in use by scholars in their epistemological locations. This suggests the importance of scholarship communities, through their journals, in creating and maintaining research environments whose "process integrity" may relate to "research integrity" itself.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, FFP & QRP II: International

Nanyan Cao, ***Characteristics of Research Misconduct in China during Social Transforming Period.***

Aims: The characteristics of research misconduct (RM) are different in every nation and period. This study empirically explores the main characteristics of RM in current China, in order to search for effective measures preventing RM and improve research ethics education according to China's circumstances, meanwhile to get experiences from other countries.

Methods: This study provides an analysis of typical cases of RM revealed in China recent years and compares these cases with those taken place in USA. After discussing the main characteristics of RM, the author explored the etiology of RM and puts forward strategies to promote integrity in research. The data for this study derived from an investigation conducted by Science Association of China in 2003, which the author participated, from author's questionnaire survey at Tsinghua University in 2004, and from chief Chinese academic journals and newspapers since 1980's.

Findings: The main characteristics of RM in China during social transforming period include, but not limited to, (1) most cases of unethical behavior in research are related to plagiarism, falsification and fabrication, however, those misconducts are often tolerated; (2) other types of ethically wrong behavior, such as conflict of interest in peer review or collaborative research with industry, are prevalent, but they are often not regarded as serious misconduct; (3) misconduct of institutions and units is prevailing, and many institutions are often reluctant to initiatively reveal misconduct occurred inside; and (4) the restricting system of misconduct is defective.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, FFP & QRP II: International

Hanne Andersen, ***Ignorance or Misconduct? A lesson from "The Sceptical Environmentalist".***

Aims: To analyze the ruling of the Danish Committee on Scientific Dishonesty on the controversial book "The Sceptical Environmentalist" and the debate following this ruling. The analysis will focus on how this case illustrates a series of problems regarding the distinctions between misconduct and bad practice in multidisciplinary research.

Methods: The paper is based on a thorough philosophical analysis of the Danish definition of scientific dishonesty and how they originate in well known, traditional positions from the philosophy of science. This provides the basis for a philosophical analysis of the documents of the case of "The Sceptical Environmentalist" and of the subsequent debate in the Danish research community, showing how the definitions of misconduct/dishonesty and of bad practice come to bear in the ruling and in the subsequent public debate.

Findings: The analyses show that a number of distinctions are presupposed in handling cases like "The Sceptical Environmentalist", but that these distinctions are blurred in many interdisciplinary research areas. Further, the case shows that the peer-review process may be facing special problems in dealing with multi-disciplinary research and that it is essential that these problems are brought to light and addressed.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, FFP & QRP II: International

N. Raghuram, ***Research Sans Integrity: Case Studies from India.***

Aims: India does not have separate policies or offices of research integrity at the level of scientific institutions or funding agencies, and cases are generally dealt with under the rules of employee conduct through commissions of enquiry. Society for Scientific Values, an autonomous body of concerned scientists established in 1986 played the role of an independent watchdog with some success in investigating and highlighting cases, but enforcement is left to the employers.

Methods: With the help of a few Indian controversies that this author brought to light in different capacities and different ways, he explores how research integrity often has a major bearing on 'scientific' policy making, and how researchers and their institutions are often at the core of the very controversies that they tend to resolve or 'scientifically' arbitrate. The first case pertains to the selective use of data to refute the unpleasant conclusions of a Scientometric analysis of Indian science published by this author in Nature in 1996, and unsuccessful attempts to find data that suited the establishment. The second case pertains to the questionable research practices and conflict of interest in environment impact assessment with regard to the alleged air-polluting industries around the Taj Mahal, a world wonder and heritage monument. The third case pertains to the strange peer approval for a research climate that condoned students' misconduct and punished those that brought it to light.

Findings: In each of these cases, independent inquiries eventually vindicated the author's characterization of the problem that integrity issues arise not only due to erring individuals, but systemic problems that are inherent to the institution(s) in question and the society at large.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, Clinical Trials & IRBs II: Collaboration

Ben Djulbegovic, Heloisa P. Soares, Ambuj Kumar, Fadila Serdarevic, ***Equipoise Principle is Not Violated in the NCI-sponsored Clinical Trials.*** **NIH/ORI RRI Program researcher.**

Aims: Studies in which the control intervention is believed to be inferior violate ethical and scientific principle of equipoise, may result in biased findings, and could ultimately harm research subjects. Placebo or no-therapy controlled trials are particularly susceptible to this bias. We aimed to determine if equipoise principle was violated in the NCI-sponsored trials.

Methods: all published and unpublished randomized controlled trials (RCTs) that were conducted and completed to date by four NCI cooperative groups (COG, NSABP, NCCTG and RTOG) were analyzed. Outcomes were analyzed for all trials that included placebo or no therapy interventions as the control group. We hypothesized that if the outcomes consistently and predictably favored active interventions over placebøno therapy this would indicate a systemic bias in the choice of control intervention. A meta-analysis was performed to quantitatively assess the effects of treatments on survival. In addition, the investigators judgments about the relative value of active interventions vs. placebøno therapy were deduced.

Findings: Data from 57 trials enrolling 13,806 were synthesized. Placebo therapy treatments were as likely as experimental treatments to be successful in affecting survival [Hazard ratio: 1.01 (99%CI 0.94-1.09), p=0.77]. In 34 (52%) of 65 comparisons, the control arm was classified as superior by the trials' investigators (p=0.71).

Conclusions: The finding that placebøno therapy has equal chance to result in the outcomes similar to active interventions indicates that the NCI investigators were truly uncertain (in equipoise) when they designed their studies. Hence, we conclude that there is no evidence of violation of equipoise in this set of the NCI RCTs.

Acknowledgement: this study was supported by the Research Program on the Research Integrity, an Office of Research Integrity/NIH collaboration, grant No: 1R01NS/NR44417 -01.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, Clinical Trials & IRBs II: Collaboration

Wayne Sullender, Sam Tilden, Sheila Moore, Rich Whitley, ***Developing Multicenter Collaborative Studies of an Emerging Infection: Time and Variability of IRB Approval.***

Aims: Emerging infections and bioterrorism require multi-center trials to implement strategies to prevent or treat infections. The trials must be performed expeditiously while maintaining protection of human subjects. We describe the development of 2 multi-center trials of West Nile Virus (WNV), including the time required for institutional review board (IRB) approval.

Methods: The Collaborative Antiviral Study Group (CASG), at the request of NIAID, developed two WNV protocols, a natural history study and an antibody therapy trial. WNV infections present seasonally; therefore, studies can only be performed when the infections are occurring. The CASG coordinated protocol development, federal approvals and managed active sites. Each participating institution obtained approval from their local IRB. Communications among investigators and IRBs were reviewed and the time from distribution of the protocols to local sites to final IRB approval of each protocol was determined, as well as the type of review performed, and other relevant factors assessed.

Findings: Protocol development and obtaining federal approvals extended into the WNV season. Time required for IRB approval varied, but was approximately 2 months for each study, with similar time spent with investigators and with IRBs. Most sites had not obtained approval in time to enroll patients during the 2003 WNV season. There was variability in the type of review (expedited or full) performed. Rapid assessment of management of biological threats will require streamlining the entire process from protocol development to local site initiation, including shortening IRB approval times while maintaining protection of human subjects.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 1:00 - 2:30 PM, Clinical Trials & IRBs II: Collaboration

Yuan-I Min, ***Survey on Quality Assurance in Clinical Trials.*** **NIH/ORI RRI Program researcher.**

Aims: Quality assurance (QA) is an important component in clinical trials to ensure the validity of trial results. However, little is available in published literature on how it is practiced. We conducted a survey of trialists to describe the practice 'norm' of QA procedures in trials and the perceived utility of selected QA procedures in ensuring data quality and integrity.

Methods: Survey participants were randomly selected from the corresponding authors of trial publications in five major medical journals between 1995 and 2001. The response rate was 54% after two mailings. Preliminary results from 107 multicenter RCTs are reported here.

Findings: Most QA procedures surveyed such as: having a centralized data center, a data and safety monitoring board, a centrally administered randomization schedule, a formal training program for study personnel, ongoing data processing, data editing, and performance monitoring were implemented in a majority of the trials (76-99%). Site visits were regularly conducted as were data audits. Sponsors' involvement in the final decision of the design, conduct, analysis and publication of trials was low (13-28%). Areas for improvement may include a formal process for assessing the understanding of the protocol (52%), a formal process for certifying study personnel (32%), regular feedback of performance to clinical personnel (40%) and trial leadership (49%), and a written disclosure of conflict of interest (61%). In terms of perceived utility in ensuring data quality and data integrity, among the items surveyed, the integrity of the randomization process ranked the highest, a written conflict of interest policy the lowest.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Research Integrity and Medical Students

Sean Powell, Matthew Allison, Michael Kalichman, ***Effectiveness of Research Ethics Courses for Medical Student Researchers.***

Aims: Attending a class about responsible conduct of research (RCR) is a requirement for many student researchers nationwide, but little is known about what RCR courses achieve. The objective of this project is to measure the efficacy of an RCR course at UCSD. The project also aims to create a framework for evaluating the efficacy of RCR courses.

Methods: This study was reviewed and approved by the Institutional Review Board. Some UCSD medical students participate in an NIH-funded summer research program. For the purpose of this project, those who participated in the past 2 years were identified by the program director. These students were surveyed using an instrument developed through focus group discussion. The survey consisted of questions to measure student knowledge, attitudes, behaviors, skills, and community involvement. Surveys were administered before and after the Summer 2003 ethics course, as well as to alumni of the courses given in Summer 2002 and 2001.

Findings: The number of surveys returned for analysis is sixty-six (66). The surveys are being analyzed for student performance in the areas of knowledge, skills (especially ethical decision-making), attitudes (about responsible conduct of research), behaviors (not just avoiding research misconduct), and community (increased discussion about RCR in and out of class). Initial findings suggest only a minor impact of this summer course on knowledge, and no significant change in attitudes. Scoring of ethical decision-making skills is underway. (supported by the NIH: K01 AI01591).

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Research Integrity and Medical Students

Lidija Bilic-Zulle, Mladen Petrovecki, ***Prevalence of Plagiarism among Medical Students.***

Aims: No doubt that plagiarism exists but is hard to investigate and rarely quantified. Aim of this study was to find the rate of plagiarism among medical students while writing papers, and to find out influence of covariates (sex, paper subject, clear warning of plagiarism prohibition, examination grade) on plagiarism rate.

Methods: During two years we evaluated student papers written in electronic form on Medical Informatics (MI) curriculum. Four source papers from MI journal were offered to students, two of them also in electronic form (web). Papers were assigned as less or more complicated, one of each in paper/electronic form. Group of students was not given warning about plagiarism, and the other was clearly advised not to copy from source text. Papers (N=199) were compared with source using WCopyfind 2.1 program (Louis Bloomfield), adjusting comparison rule parameters according authors recommendations. The rate of plagiarism was calculated from total and copied word count.

Findings: Median plagiarism rate was 19% (0-88%, 5th-95th%). There was no difference in plagiarism rates between males and females (p=0.535), publishing form (electronic vs. traditional, p=0.855), source complexity (p=0.155) and warning on plagiarism (p=0.320). Our students obviously still do not use computer copy/paste function more than copying text directly by typing. Warning itself is not strong enough to reduce plagiarism. Only significant difference was found in plagiarism rate related to MI examination grade (p=0.033), which was not influenced by quality of paper. Finding proves that better students with higher grades are more responsible and plagiarize less than students with lower grades.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Research Integrity and Medical Students

Darko Hren, Ranka Ivanisevic, Ana Vujaklija, Matko Marusic, Ana Marusic, ***Moral Reasoning, Machiavelianism and Deception among Medical Students entering a Science Course.***

Aims: To investigate moral reasoning and some characteristics, possibly critical for future research integrity, of second year medical students entering a science methodology course.

Methods: Second year medical students (n=208; 129 female) filled the Defining Issues Test (DIT2), Machiavelianism scales and Deception scales at the beginning of the science methodology course.
DIT2 scores were compared to the mean score of american sample of sophmores (n=1028). Sex differences were investigated, as well as relationships of these variables.

Findings: Students scored around the middle of the possible range on both, Machiavelianism scales (MDecieving=23.9±4.61; MAmorality=19.6±4.29; MCinicism=18.7 ±4.37; MFlattering=18.8±4.37; range 6 – 30), and Deception scales (MSelf-deception=11.5 ±3.81; possible range 0 – 24; MImpression management=9.5±3.55; possible range 0 – 20). Croatian medical students obtained higher N2-score than the sample of american sophmores (MN2cro=35.8±11.28, MN2usa=31.2±14.94; $p<0.001$, one sample t-test).
Female students obtained higher N2-score on the DIT2 than their male peers ($p<0.001$, independent samples t-test), but also scored higher on "Decieving" ($p=0.037$, independent samples t-test) and "Impression management" ($p=0.044$, independent samples t-test). Male students scored higher on "Self-deception" ($p=0.041$, independent samples t-test). Significant correlation was found between "Decieving" and "Impression management" ($r=0.33$, $p<0.001$), as well as between "Flattering" and "Impression management" scores ($r=0.17$, $p=0.035$). No correlations were found between scores on Machiavelianism or Deception scales and DIT scores.

Conclusions: Female students were more advanced in moral reasoning than their male peers, but were also more prone to use social strategies that involve manipulation. Moral reasoning showed to be independent from constructs such as Machiavelianism, Self-deception and Impression management.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Role of Mentoring in Promoting

David Wright, Jered Cornelison, Sandra Titus, ***Mentoring and Research Misconduct: What do we know?.***

Aims: 1. To describe university based case histories and empirical research data about misconduct and mentoring. 2. To analyze ORI case files (n = 57) on misconduct cases involving graduate students and post docs to determine if there is supporting evidence that poor supervision/mentoring was present. Based on university based case histories, we believe that the lack of good mentoring can create a research environment in which graduate students are more likely to falsify and fabricate data. We further predict that there are critical moments in the mentor/trainee relationship where good mentoring is especially critical to assure the integrity of research.

Methods: We will review ORI case files on graduate student and post doctoral student respondents to see whether and how mentoring (or lack to) was an issue in the institution's and in ORI's review of the case.

Findings: Our preliminary analysis of ORI data supports our hypothesis that graduate students are more likely to ignore scientific rules (ffp) when they have mentors who are arguably negligent, or worse. For example, in one case the advisor actually allowed a disbarred student to continue on the faculty's government-sponsored research project and apparently aided the student in falsifying identification to avoid detection of the student's continuing involvement. This is likely to be a case at the egregious end of the continuum. We will describe a range of cases highlighting moments when effective mentoring may have prevented misconduct. This is critical to understand more fully because ORI data demonstrate that those who need supervision (graduate students and other respondents) are proportionately more likely to be found guilty of misconduct (66% of the time) than faculty researchers (33% of time). The consequences of a finding of misconduct are severe because most often the graduate student's career in the sciences is likely to be over. We will also highlight some of the research questions on mentoring that other researchers might study.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Role of Mentoring in Promoting

Sandra Titus, ***Laboratory Directors' Views on Mentoring and on "Absentee Mentoring".***

Aims: 1. To analyze and describe qualitative statements offered by 149 lab directors on qualities that they believe are essential for research integrity and which can best be conveyed by a mentor. 2. To promote discussion on the implications and the need for further research on the "absentee mentoring" and "Train the Trainers" programs.

Methods: Over 3000 lab directors participated in a study about research behaviors that occurred in their lab. Over 1600 of the directors made recommendations to ORI on how they think that the research environment could be improved. Of the 1600 responses, 149 specifically wrote their thoughts on the importance of mentoring. These responses are coded on dimensions the mentors indicate are critical mentoring issues for mentors and for institutions.

Findings: The qualitative analysis identified three qualities/issues of good mentoring which promote integrity of the research process: (1) comprehensive supervision by mentors of the entire process, (2) awareness of mentors regarding the pressures and critical time lines of mentees, (3) realization that the mentors span of responsibilities changes when a lab is large. The mentors suggest the need for "Train the Trainers" programs as well as NIH and institutional involvement. Many voiced their concern that funding is promoting "absentee mentoring" and that this problem is growing and is largely unrecognized.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Role of Mentoring in Promoting

Caroline Whitbeck, ***Authorship and Mentoring Concerns in Faculty-Trainee Discussions.***

Aims: This paper reports on concerns of faculty members and trainees in various disciplines and research institutions about authorship and mentoring and on their state of knowledge about 1) emerging standards of responsible conduct, 2) each other's practices and expectations, 3) institutional means for addressing problems.

Methods: Instruction for group learning was developed on five research integrity topics including Responsible Authorship and The Supervisor-Trainee (or "Mentor") Relationship. Responses observed and collected from both participating faculty members and trainees at over two dozen sessions on these two topics. These were the two topics for which trainees and faculty of sponsoring departments or laboratories most often offered new descriptions of problem situations, hereafter called "scenarios." These new scenarios supplemented existing ones that representatives of the sponsoring department selected as relevant to their conditions of research. Participants completed a brief anonymous (except for faculty-trainee status) questionnaire at the session that included evaluation of the relevance of the scenarios and, in some cases, prior knowledge. Qualitative observations of the discussions were also recorded.

Findings: Differences were found in authorship and mentoring concerns across disciplines, across institutional settings, and between faculty members and trainees. For example, scenarios submitted by trainees tended to involve faculty behavior that trainees regarded as problematic to which trainees did not know how to respond. Faculty members submitted scenarios designed to teach lessons and warn trainees of pitfalls, but also those about decisions that they had found difficult. There were notable differences in authorship and mentoring concerns depending on the presence or absence of post-docs in departments and disciplines.
This work was partially supported by PHS grant # T15 AI07592.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Effectiveness of Professional and

Rebecca Lind, ***An Evaluation of the Accessibility and Effectiveness of Research Integrity Policies at Major Research Institutions.***

Aims: This research is part of a larger project assessing the impact of changing financial relationships on research integrity, and has two aims: *(1) Evaluate the accessibility of universities' policies addressing research integrity*; and *(2) Evaluate the effectiveness of such policies.*

Methods: A content analysis of top-ranked research universities' websites will first determine the ease of accessing RI policies on each site, and then evaluate the policies using a two-dimensional system inspired by Rhoades' (2003) "mimimal-useful" distinction. According to Rhoades, "minimal" policies and procedures merely meet the letter of the law (e.g., "Allegations should be reported to the department head"), while "useful" policies and procedures provide sufficient guidance so that the parties involved know how to proceed and have the protection they deserve (e.g., specifying whether the allegations can be anonymous or must be identified, whether they should be oral and/or written, what to do if the department head is involved, and what will happen if the whistleblower does not wish to proceed).

Findings: The proposed research is preliminary and descriptive, and as such is guided by research questions rather than hypotheses. Subsequent research will be able to use the results of this study to investigate the relationship between relative effectiveness of resources designed to enhance research integrity and other variables such as (but not limited to) the number and type of integrity cases brought forth, or the extent of entrepreneurial activity allowed. This preliminary research is likely to reveal a wide range of relative effectiveness of resources, and may well show that universities are not doing as good a job as they could in enhancing research integrity.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Effectiveness of Professional and

Camille Nebeker, ***A Model to Develop RCR Curriculum Targeting Lay Research Staff.***

Aims: Research conducted within Latino communities increasingly rely on Community Health Advisors/Promotores to deliver public health interventions. The project objective is to develop a culturally tailored, content-appropriate, Spanish language research ethics curriculum for training Community Health Advisors/*promotores*. The curriculum development model will be presented and samples of training materials provided.

Methods: Six focus groups were held with project managers/investigators who possess first hand knowledge in developing, directing and implementing research studies in the Hispanic/Latino community, where members of the Hispanic/Latino community are employed as research staff. Two focus groups with Promotores were also convened. Participants commented on training objectives, format, curricular content and priorities, delivery media and assessment of training goals. Each focus group lasted approximately two hours and was audiotaped and transcribed verbatim for thematic analysis using NVIVO software.

Findings: Content and design recommendations from key stakeholders (investigators/managers (n=9), and promotores (n=19)) obtained during focus groups and interviews mirrored some of our expectations for standard course content, format for training ethical principles and also identified cultural barriers that may challenge or compromise the responsible conduct of research. Not anticipated was the need to include instruction in basic research design and methodology. Format recommendations focused on simplicity of presentation and use of culturally relevant scenarios/case studies (video, role-plays) that allow for demonstration of the ethical principle/concept using examples/case studies depicting real examples from the field.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, The Effectiveness of Professional and

Sharon E. Moss, E. Aldredge, D. Garstecki, J.Horner, J. Ingham, M. Jeffries, C. Lansing, J. McCartney, F. Minifie, S. Slater, ***Research Integrity in ASHA: Educational Practices.*** **NIH/ORI RRI Program researcher.**

Aims: The purpose of this session is to report data collected by the American Speech-Language-Hearing Association on patterns of teaching and learning about issues of research integrity and the conduct of science. Wide-spread surveys were conducted of educational programs devoted to the preparation of individuals in communication sciences and disorders. ASHA has a keen interest in learning about the exposure provided to students in academic programs in the discipline of communication sciences and disorders (CSD) curricula in the realm of research ethics. The Association was recently awarded a grant from the National Institute of Neurological Diseases and Stroke (R01 NS44534-01S1) to identify factors that encourage and/or discourage scientific integrity in research by members of the Association. The project has four areas of focus; two of which address education practices, two of which address publication practices.

Methods: The purpose of this session will be to share data gleaned from two of the survey instruments (education practices) designed to identify patterns of teaching and learning relative to issues of responsible conduct of research by educational programs in CSD. The presenters will review the process used for developing, piloting, and fielding the survey instruments.

Findings: The presenters will review data that describe what is being taught in educational programs that are preparing students for careers in CSD, and what is being learned by students enrolled in such programs. Data addressing how this content is presented and the modes through which students learn specific topics of information, will also be discussed. Finally, data will be shared that describe the perceived importance and perceived sufficiency of coverage (by students and faculty) of approximately 40 topics related to research ethics, scientific integrity, and the responsible conduct of research.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Conflict of Interest and Institutional

William Gardner, ***Authors' Financial Conflicts of Interest and their Control Over Clinical Trials Research.*** **NIH/ORI RRI Program researcher.**

AIMS: One of the most important issues encountered in research ethics is that of ethical problems in the authorship of clinical trial research. Clinical trials are the principal source of evidence on the efficacy and safety of medical treatments, and they have great financial consequences for manufacturers. Therefore, it is essential that the results of clinical trials be collected and presented in an objective, reliable, and unbiased way. However, there are several documented ethical problems in the authorship of reports of clinical trials. These concerns include: 1) a reported increase in the role of private sponsors in the design and presentation of clinical trial results; 2) the discrepancy between accepted norms for authors' contributions to publications and their actual contributions; and 3) possible biasing effects from investigators' conflicts of interest on the conduct and reporting of trials. In response to these ethical problems, there have been calls for authors to increase their independence from sponsors in designing trials and reporting their results, as well as an increase in author accountability. However, there are few data on the relationship between ethical issues in the authorship of scientific papers and authors' conflicts of interest.

Methods: We conducted a mail survey of 549 authors who had published reports of pharmaceutical clinical trials from 1998 to 2001. Replies were received from 322 (64% return rate of authors for whom we had valid addresses). In the survey, we asked questions about authorship roles and author's financial conflicts of interest with clinical trial sponsors. We asked authorsto rate how much influence they had over several aspects of the design of the clinical trial, and how much influence the sponsor had. When authors had a financial relationship with the sponsor, they had less influence on the study ($p = .003$), and the sponsor had substantially more influence on the study ($p < .0001$), than when authors did not have a relationship. We also asked authors about the roles that they and the other investigators played in actually carrying out the study.

Findings: When the author did not have a relationship with the drug manufacturer, the investigators almost invariably collected, managed, and analyzed the data. When the author had a relationship, this was significantly less likely to be the case ($p < .0001$). We asked authors whether they owned their data or had a written agreement with the giving them the right to publish the data. Authors whose research was privately sponsored or who reported conflicts of interest with the drug manufacturer were less likely to own the data or have such an agreement ($p < .001$). In summary, when research is privately supported or authors have conflicts of interest, then a) authors have less influence over the design of the study and sponsors have more, b) authors have less access to the data, and c) authors have weaker rights to publish the results of the clinical trial.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Conflict of Interest and Institutional

Michelle M. Mello, David M. Studdert, ***Legal Relationships in Industry-Sponsored Clinical Trials.*** **NIH/ORI RRI Program researcher.**

Aims: To study institutional norms and practices concerning the contractual provisions that allocate control over clinical trials between academic investigators and industry sponsors.

Methods: Structured mail surveys were mailed in March 2004 to research administrators in offices responsible for negotiating and administering clinical trial agreements with industry sponsors in all medical schools in the United States, except those in Puerto Rico (n=122). Within each institution, the research administrator identified as most knowledgeable about standards and practices for negotiating clinical trial agreements with industry sponsors was approached for participation.

The survey addressed the negotiation and structure of legal contracts for industry-sponsored clinical trials. Topics included institutional policies and procedures, the acceptability of specific sponsor controls over clinical trials, sources of conflicts with industry sponsors, and perceived pressures in the research environment. Data were analyzed descriptively, and chi-square analysis and Cuzick's extension of the Wilcoxon rank-sum test were used to compare subgroups.

Findings: The survey was completed by administrators at 107 institutions. The adjusted response rate, after exclusion of 4 institutions determined to be noneligible because they did not conduct clinical trials, was 90.7%. Administrators exhibited a strong degree of agreement about several contractual provisions relating to control over publications, but considerable heterogeneity in their views regarding other provisions. Among the deepest schisms were in perceived acceptability of allowing the sponsor to insert its own statistical analyses in manuscripts (24% allow, 47% disallow, 29% not sure); allowing the sponsor to draft the manuscript (50% allow, 40% disallow, 11% not sure); and prohibiting investigators from sharing research data with third parties after the trial was over (42% allow, 34% disallow, 24% not sure). Greater consensus was observed in administrators' views toward the utility of written policies for negotiating trial agreements, and in sources of tension and disputes with industry sponsors. Academic medical centers exhibit considerable variation in standards for certain restrictive provisions in clinical trial agreements with industry sponsors. Greater transparency and information-sharing regarding legal relationships with industry sponsors is desirable in order to build consensus about appropriate standards.

Conflict of Interest Statement: No conflicts

Saturday 11/13 - 3:00 - 4:30 PM, Conflict of Interest and Institutional

Elizabeth A. Boyd, Lisa A. Bero, ***Defining Conflicts and Managing Relationships: An Analysis of University Conflict of Interest Committee Decisions.*** **NIH/ORI RRI Program researcher.**

Aims: This study investigates how university conflict of interest committees actually implement financial disclosure policies, define conflicts of interest, and decide appropriate management strategies for investigators reporting personal financial relationships with industry sponsors of their research.

Methods: We observed and audio-recorded three regularly scheduled meetings of the Conflict of Interest committees at three different University of California campuses (N=9 meetings). Each committee discussed three to six individual cases per meeting for a total sample of 34 cases. The recordings were made using an unobtrusive audio-recorder placed in the center of the conference table. Recordings were transcribed verbatim and analyzed according to the methods of Conversation Analysis. Data were coded for recurrent communication behaviors related to the presentation and discussion of each case of financial disclosure, conflict of interest, and management strategy. We also conducted semi-structured interviews with members of the committees.

Findings and Conclusions: Across all committees, initial discussion consistently focused on determining the facts of the case and the relevant institutional categories, based on the financial disclosure forms filed by the investigator. Committees struggled to define the specific nature of the conflict, define activities that constitute "research," and establish the boundaries between "industry work" and "academic work." Committee members rarely assessed the actions of a particular investigator as "ethical" or "problematic." Instead, assessments focused on the nature of the proposed work and its perceived susceptibility to bias or influence. Campus committees differed in their application of management strategies, differentially expressing concerns about the protection of students and trainees, the perception of bias, and the requirements of formal policies as motivation for particular decisions. We conclude that the selection of particular management strategies may reflect broader institutional values that the committees seek to protect.

Conflict of Interest Statement: No conflicts

Sunday 11/14 - 8:00 - 10:00 AM, Dealing with FFP and QRP in Clinical

Marion E. Broome, ***Scientific Misconduct: The Role of the Research Coordinator.***
NIH/ORI RRI Program researcher.

Aims: Research Coordinators (RCs) hold a unique position in clinical trials management and can be expected to be aware of and even influence the scientific integrity with which the research is implemented and the findings disseminated. The purpose of this study is to conduct a national survey of clinical research coordinators in order to describe their beliefs, attitudes about and experiences with scientific misconduct.

Methods: We are conducting a national survey of RCs in order to describe their perceptions and beliefs about a) scientific misconduct and the factors in their institution that influence it, b) the prevalence of specific types of misconduct in their environment, c) any actual misconduct that has occurred and how they reported it, c) what happened if, or when, they reported it. RCs who are aware of an actual incident of scientific misconduct respond to 8 open-ended questions at the end of the SMQ-R and describe their experiences. To date the Scientific Misconduct Survey-Revised (SMQ-R) has been sent to a random selection of 1, 000 research coordinators from a mailing list from the Association of Clinical Research Professionals.

Findings: To date 217 eligible RCs (22%) completed the SMQ-R (22%return); 21% indicated awareness of SM occurrences within the last year; 17% described an actual occurrence. The most common types of scientific misconduct reported were violations of subject enrollment (74%) and protocols (84%), but most described their frequency as seldom. RCs believed the chances for getting caught were high (74%%) and penalties would be severe (78%). Worksite investigator competitiveness was rated high by 54%. At least 25% identified funding pressures, need for recognition, insufficient involvement or low interest of PI; and number or intensity of protocols for which the RC was responsible for and intensity of protocols as strong influences on scientific misconduct.

Conflict of Interest Statement: Statement pending

Sunday 11/14 - 8:00 - 10:00 AM, Dealing with FFP and QRP in Clinical

Joan Liaschenko, Anastasia Fisher, ***Nurses: Research Integrity in Clinical Trials.***
NIH/ORI RRI Program researcher.

Aims: In discussions of clinical trials, research ethics focuses nearly exclusively on the perspective of principal investigators. Yet nurses are key in implementing clinical trials, that is, they perform much of the day-to-day work. However, there is virtually no research on the ethical concerns and challenges confronting nurses working in clinical trials. There is some evidence indicating that their perspective differs from that of physician-researchers at least in certain circumstances. In order to move towards a more complete knowledge of the ethical issues arising in research, a study employing a focus group methodology was designed to explore the ethical concerns of nurses working in biomedical clinical trials. The specific aims of the study were to describe the work and ethical concerns embedded in the day-to-day work of conducting clinical trials.

Methods: A total of seven focus groups were held in two different geographical locations in the U.S.; four groups in the Midwest and three on the West Coast. There were a total of 47 participants who worked in a variety of research contexts, including major medical research universities, private physician practices, medical device companies, and pharmaceutical companies.

Findings: Preliminary analysis demonstrates that this work involved ongoing negotiation that enabled them to balance several tensions inherent to clinical trials. These included: 1) shifting meanings of their identity as patient advocates and data producers; 2) balancing pressure to have study participants remain in the study against the recognized right of the patient to withdraw; 3) strategies used to balance the tension between treatment and research; 4) the critically important work of establishing and maintaining networks of collaboration necessary to the completion of the study; 5) concerns with the meaning and adequacy of informed consent; and 6) negotiating the sources of authority for determining serious adverse effects. In this paper, we will discuss these findings and the implications for research integrity.

Conflict of Interest Statement: Statement pending

Sunday 11/14 - 8:00 - 10:00 AM, Dealing with FFP and QRP in Clinical

Katrina A. Bramstedt, ***A Study of Warning Letters Issued to Clinical Investigators by the US Food and Drug Administration.***

Aims: To understand the frequency and content of Warning Letters issued to clinical investigators by the US Food and Drug Administration (FDA) with regard to the conduct of drug, device and biologics research studies.

Methods: The on-line FDA Warning Letter Index was reviewed for letters issued to drug and device researchers in the USA and Canada under the violation subject "Clinical Investigator" for the period February 2002 through February 2004. The resultant letters were evaluated for the medical research specialty, as well as the presence of seven research ethics themes: 1) deviation from investigational plan; 2) informed consent; 3) adverse event reporting; 4) study reporting; 5) study supervision; 6) institutional review board approval; and 7) misconduct.

Findings: Thirty-six (36) FDA Warning Letters were issued to researchers during this 24-month period. These letters addressed non-compliance in 58 clinical research protocols. Most letters were issued to clinical investigators researching the areas of pulmonary medicine, oncology, and cardiology. The most common areas of non-compliance were deviation from the research plan, a flawed or non-existent consent process, and failure to report or late reporting of adverse events. Most Warning Letters identified non-compliance in at least three of the seven research ethics themes. Eight percent (3 of 36) of Warning Letters mention study misconduct including data fabrication. Using these Letters as a teaching tool, researchers can learn from the mistakes of others, enhancing study integrity and research subject safety.

Note: This research will be published in Clinical and Investigative Medicine 2004, volume 27.

Conflict of Interest Statement: Statement pending

Sunday 11/14 - 8:00 - 10:00 AM, Dealing with FFP and QRP in Clinical

Michael R. Hamrell, ***The Role of the FDA Oversight Program in Detecting and Deterring Misconduct and Questionable Research Practices in Clinical Trials.***

Aims: The key to the successful execution of a clinical trial relates in part to the commitment and practices of all the parties involved to Good Clinical Practice. These regulations govern the conduct of the trial, ethical considerations and are designed to produce quality data with integrity.

Methods: This presentation will discuss key FDA considerations and concerns in the conduct of clinical audits. This will be presented using excerpts from FDA 483 and Warning Letters to illustrate key points of compliance and integrity in research from actual FDA findings.

Findings: The findings over time have indicated that FDA's oversight program for clinical trials can detect ethics and integrity problems and their consequences do tend to act to deter this behavior.

Conflict of Interest Statement: No conflicts

Sunday 11/14 - 8:00 - 10:00 AM, The Impact of Politics and Personal Factors

Bryan Benham, ***Deception in Social-Behavioral Research: How Much is Too Much?.***

Aims: This project examines researchers' and IRB members' judgments about proper or improper use of deception in experiments with human subjects and compares these judgments to ethical and policy limits on the use of deception in social-behavioral research. The objective is to explore whether researchers and IRB members share a common conception of the ethical dimensions of the use of deception in research.

Findings: Preliminary indications suggest there are significant differences. However, current policy doesn't appear to adequately address this disparity. In this project I contend that current policy is inadequate because it employs an overly simplified conception of deception. For instance, discussion about the ethics of deception tend to focus on two features only: the possible harm posed to subjects and the validity of studies that use deception. The current study shows that judgments about the propriety of deception in research fall along many different dimensions; these include task specific features of experiments, degree of manipulation of the experimental environment, the status of the experimental subject, validity of the experimental design, lasting effects of deception, and others. If these findings are representative, then current debates and guidelines about the use of deception in social-behavioral research are too narrow in their treatment of deception. A "model" of deception, and how this might aid in the ethical evaluation of deception in social-behavioral research, is proposed as a means of reconciling the current disparities.

Conflict of Interest Statement: No conflicts

Sunday 11/14 - 8:00 - 10:00 AM, The Impact of Politics and Personal Factors

Nancy L. Jones, ***Scientific Professionalism and A Code of Ethics for Bioscience.***

Aims: Medical professionalism is synonymous with the Hippocratic tradition. In contrast, for science, more work has identified what is considered substandard rather than ideal professionalism. However, bioscience has an embedded ethos and standard for professionalism. This work attempted to codify scientific professionalism and the implicit norms for the practice of bioscience.

Methods: First, cultural norms of the bioscience community were identified through codes of ethics from professional societies. Next, a literature review identified addition recognized principles for the practice of science. Finally, using "Project Professionalism" of the American Board of Internal Medicine as a template, potential virtues or character aspirations were compiled. Then scientists, science educators and ethicists were given drafts of a code and allowed to comment and modify the principles for the practice of science and virtues for the code. A refined document of goals of research, principles for the practice of science, and virtues for scientists was developed.

Findings: Bioscientists have implicit role obligations. The practice of science is governed by several principles; objectivity, questioning certitude, research freedom, research reproducibility, respect for subjects, and normalization through the Scientific Community. Scientists aspire towards several virtues; integrity, accountability, altruism, excellence, and respect for colleagues. Two keys for agreement with the code were explicit definitions of terminology and recognition that scientific activity as a human endeavor means perfection is unobtainable. Codification of principles and virtues as a teaching tool formalizes the expectation of what an *ideal* professional scientist aims for and emphasizes assimilation and identification as a member of the scientific profession.

Conflict of Interest Statement: No conflicts

Sunday 11/14 - 8:00 - 10:00 AM, The Impact of Politics and Personal Factors

Bradley D. Freeman, Carie R. Kennedy, Craig M. Coopersmith, Barbara A. Zehnbauer, Timothy G. Buchman, ***Perceptions and Attitudes of Genetic Research Held by Surrogate Decision Makers for Critically Ill Patients.***

Aims: Clinical studies conducted in critically ill individuals are ethically problematic because consent for participation is frequently granted by surrogate decision makers (SDM) . These studies increasingly entail collection of genetic material. Our objective was to determine attitudes and perceptions of SDM regarding the biological and social implications of genetic testing.

Methods: All patients admitted to the surgical and medical intensive care units of Barnes-Jewish Hospital were screened to identify sedated individuals requiring mechanical ventilatory support for at least 48 hours. Anonymized clinical and demographic information was recorded and SDM (i.e., individuals empowered to provide informed consent for purposes of medical procedures and/or participation in clinical research) were invited to participate in an interview-based questionnaire examining several aspects of genetic testing (including willingness to undergo genetic testing or participate in gene-based clinical research, views regarding disclosure of genetic information, trust in various organizations to perform investigation). Standard statistical techniques were employed.

Findings: We screened 504 admissions (January-March 2004), identified eligible 45 patients, and interviewed 33 SDM. While 94% of SDM expressed willingness for critically ill patients to undergo genetic testing to diagnose treatable conditions or guide drug prescription, only 48% felt assured that genetic test results would remain confidential, and 45% expressed concern regarding potential for employment or insurance discrimination. Greater trust was placed in universities and non-profit organizations than in either federal agencies or pharmaceutical companies to conduct gene-based clinical research ($p<0.0001$).

Conclusions: Increased understanding of genetic testing may allow more informed decisions regarding participation in clinical investigations for critically ill individuals.

Conflict of Interest Statement: No conflicts

Sunday 11/14 - 8:00 - 10:00 AM, The Impact of Politics and Personal Factors

Dan Laitsch, ***Political and Policy Constraints on Scientific Practice, Research, and Research Integrity: Scientifically Based Research, the What Works Clearinghouse, and the Legislating of Methodology in Research.***

Aims: The presentation will explore the practice, ethical, and policy implications of the defining of research methodologies in Federal law—specifically the effect on the integrity of research when policymakers mandate scientific methodologies that emphasize experimental random assignment studies within the social sciences.

Methods: The presenter uses interviews with policymakers, researchers, and scientists; reviews of legislation and regulations, news reports, and research literature; and examination and analysis of financial documents and tax forms to address four subtopics:
1. An overview of Federal definitions and structures that institutionalize constraints on research.
2. The ways in which scientifically based research requirements effect researchers. Discussion of the methodological issues.
3. The implications of defining research methods in law for the scientific community beyond education.
4. The role/reaction of scientists, and scientific organizations, and a review of the relationship between the scientific community and the Federal government.

Findings: The legislating of methodologies has applied and theoretical implications. Research methodologies should be driven by the questions asked and not constrained by legislation, such that the integrity of research is fundamentally corrupted in the current policy environment. Concurrently, control mechanisms are being institutionalized, and without a significant change effort, these issues will likely continue to challenge researchers. Recommendations include strengthening sunshine laws, increasing scientific outreach and education efforts, revising the legislative language of scientifically based research, building coalitions across professional scientific organizations, and increasing efforts to protect the integrity of scientific practice through advancing a professional ethic of science.

Conflict of Interest Statement: No conflicts