1. Current and Emerging Issues, Saturday, 3:30-5:15 p.m. (Montgomery)

A Taxonomic Approach to Understanding Scientific Misconduct

Blaine Gaddis, The University of Oklahoma

Lynn Devenport, The University of Oklahoma

Shane Connelly, The University of Oklahoma

Ryan Brown, The University of Oklahoma

Michael Mumford, The University of Oklahoma

Ginamarie Scott, The University of Oklahoma

The purpose of this paper is to describe the development and construction of a taxonomy of events that adequately reflect the ethical contexts in which science occurs and the unethical events that are likely to occur during scientific study. This taxonomic system is intended to serve as a unifying frame of reference to unify ethical frameworks across multiple scientific research domains. Specifically, the taxonomy will be used to establish a common language for discussing research ethics across scientific fields, integrate ethical frameworks across occupations for understanding, classifying, and measuring incidents of ethical misconduct, develop reliable and valid measures of scientific ethics as they apply to research settings, and establish a common knowledge base across scientific disciplines about what aspects of integrity are being discussed at any given time.

Misuse of Statistics: Honest Error or Misconduct?

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

The paper aims to help working scientists and engineers to make reasoned judgments about the validity of statistical work in their field and about the severity of any misuses they may encounter. In the 2000 RCRI Proceedings, Gardenier and Resnik demonstrated that misuse of statistics covers a broad spectrum of scientific lapses from honest error to egregious misconduct. This paper suggests a categorization of misuses including some that are both "research misconduct" and also "generally accepted practice," a situation the common federal definition of research misconduct presumes not to exist. If true, this suggests that policy should focus on improvement in the generally accepted standards of research conduct first. Pursuit of sanctions against individual researchers who commit these forms of

misuse/misconduct must come later. Meanwhile, the paper also suggests some categories of misuse of statistics that may be considered to constitute falsification of the research record within the current understanding. Subsequently, empirical research may be pursued to estimate the prevalence of misuse of statistics in each of the categories.

Beyond FFP (Falsification, Fabrication and Plagiarism): Scientist's Perceptions of Research Misconduct

Raymond de Vries, University of Minnesota and St. Olaf College

Melissa S. Anderson, University of Minnesota

Brian C. Martinson, HealthPartners Research Foundation

Objective: Those who study research integrity focus on falsification, fabrication and plagiarism - admittedly serious problems - but few have asked if these are the problems scientists themselves find the most egregious, most worrisome, and most common. Our objective is to discover scientists' perceptions of misconduct - what they regard as misconduct. **Method:** We conducted six focus groups with a total of 51 participants. The groups included researchers from a wide range of scientific disciplines at three "first tier" research universities in the Midwest and East. Participants from the postdoctoral through associate professor ranks of biomedical, clinical, biological, and behavioral disciplines were recruited via their universities' web sites and personal email invitations. At each institution, one focus group included postdoctoral fellows and assistant professors and the other had only associate professors. The focus group sessions lasted between 90 minutes and two hours and were guided by targeted, open-ended questions. Our analysis is based on verbatim transcripts and field notes. **Conclusions:** Among the several topics covered in our focus groups, we asked participants to identify the types of misconduct they observed in the course of their work. Nearly all of our subjects were aware of, and mentioned, the problems of FFP, but the majority felt violations of this sort are relatively uncommon. In scientists' eyes misconduct is generally more subtle; it emerges from the uncertainties that attend work at the frontiers of knowledge. Life on this frontier requires scientists to negotiate: 1) The meaning of data, 2) The rules of science, 3) The profession of science, and 4) Life with colleagues. In negotiating these different spheres, scientists are constantly forced to judge what is acceptable and what is misconduct: the boundary between those two is not always clear. Seen in this light, misconduct arises amid the ambiguities and everyday demands of scientific research.

The Moral Climate of Research in the United States Today

Kenneth D. Pimple, Ph.D., Indiana University-Bloomington

Objective: To assess the moral climate of research in the United States and determine the salient factors contributing to, or detracting from, research integrity. **Method:** Literature search and analysis using five major databases. **Conclusions:** Analysis of the available empirical research suggests the following three major facets of the moral climate of research: (a) The rate of unethical research. This is unknown, but most researchers have first- or second-hand *knowledge of unethical behavior* by other researchers. *Inaccuracy, duplicate publication*, and *publication bias* occur at nontrivial rates. (b) Factors contributing to ethical and unethical research practices. It seems that *pathological mental conditions* account for some research misconduct, but this has not been shown empirically. The overall rate of *ignorance of ethical standards* has not been measured. Research has shown substantial *ambivalence toward the norms of science* and troubling *differences between researchers' and institutional representatives' attitudes* toward research norms, investigating and punishing misconduct, and the kind of punishment appropriate. It has been clearly established that *moral reasoning ability* can be measured and improved, but no wide-spread effort has been made to gauge it among researchers. The current high level of *competition for employment and research funds* among researchers is well known, as is the increasing *commercialization of research findings*, but their moral consequences are not. *Authorship practices* are key to success in research, but little is known about how authorship is assigned within research teams or interpreted by employers and granting agencies. (c) Mechanisms for protecting and improving the moral climate of research. Research has shown that the *self-correcting* qualities of science provide inadequate protection against misconduct. *Peer review* is a powerful and robust, but imperfect, system. Newer efforts are becoming well-established and apparently improving, including mechanisms for the *oversight of research* and efforts to foster *education* in RCR.

The Causes of Research Misconduct: Evidence from ORI Case Files

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

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

Objective: The aim of this research was to empirically explore the etiology of research misconduct. The discursive literature on the subject mentions a wide range of purported causes including individual pathology, the pressure to publish and win grants, and the lack of training in ethics and

sound laboratory procedures. The research team specifically sought to test the role of non-shareable problems and "techniques of neutralization" in the genesis of research misconduct. **Design**: The data for this study derived from cases of the Office of Research Integrity (ORI) in which there was a finding of scientific misconduct. Information included in the case files was drawn from the investigation reports submitted by the research institutions, as well as information contained in ORI reports, correspondence, and transcripts from the hearings. The data analysis process utilized a format adopted from the qualitative phenomenological research strategy where the data collection instrument is scanned for statements or phrases that could account for why the misconduct occurred. The data collection instruments were visually scanned by two different coders in order to establish inter-rater reliability. The data were also analyzed using cross classification analysis and multi-dimensional scaling. **Conclusions:** Initially, the 44 concepts identified from the case file reviews were grouped into Professional/Structural, Organizational, Personal, factors attributed to Equity Theory and Rationalization Techniques. Multidimensional scaling yielded additional insights into how the concepts clustered. The researchers considered the range of possible conceptualizations from 4-cluster solutions to 10-cluster solutions. A nine cluster solution appeared to be the most meaningful. Construct #1 primarily represents a constellation of concepts related to Pressure to Produce. Construct #2, which we refer to as Psychological Problems, consists of personal insecurities and emotional difficulties of the respondent. Construct #3 solidly points to deficiencies in the Work Environment. Construct #4 shows respondents Blaming Others. Respondents in this category have not owned up to responsibility for the alleged misconduct, but instead have pushed the blame on others. Construct #6 portrays Frustration on the part of the respondent. Construct #7 casts respondents as disliking the work environment. Fear perhaps best describes this set of particular insecurities. Construct #5, #8 and #9 were not interpretable.

2. Conflict of Interest, Sunday, 8:30-10:00 a.m. (Mazzaschi)

Management Decisions in Financial Conflicts of Interest

Elizabeth A. Boyd, Ph.D., University of California, San Francisco and Keck Graduate Institute of Applied Life Sciences

Lisa A. Bero, Ph.D., University of California, San Francisco

Objective: To describe how academic institutions identify and manage financial conflicts of interest among faculty researchers receiving industry sponsorship for their research. This project examines the nature and extent of faculty-industry relationships at seven University of California campuses over a five-year period (1996-2001) and the administrative processes and management practices used at each campus. **Design:** We reviewed archived records of positive financial disclosures, correspondence, and conflict of interest committee decisions from 1/1/96-6/30/01, accessed each institution's related web pages, and interviewed each campus's Conflict of Interest Administrator. **Results:** There were 1998 positive financial disclosures for the study period. The number of positive disclosures per campus varied from 15 to more than 450 for the study period. More than half of the disclosed financial interests involved simple situations – a single payment for a lecture; a day of consulting on a clinical protocol; or equity ownership in a publicly traded company. More complex relationships involved investigators with long-term, well-compensated (>$20,000/year) consulting agreements in areas closely related to the sponsored projects or investigators who founded companies, held over 10% equity in the company and/or held management positions. The degree to which the respective conflict of interest committees allowed or managed disclosed relationships also varied. Three campuses allowed virtually all relationships. Two campuses implemented an actual or virtual ban on any relationship for investigators doing clinical trials; another campus held clinical trials to strict methodological scrutiny. Some (n=3) managed nearly all relationships. **Conclusions:** Although all the campuses are subject to identical state, federal, and system-wide policies, there is variation in the administrative processes for disclosure, educational efforts made to reach investigators, definitions of appropriate financial relationships, and strategies for managing conflicts. This variation has important implications for policymakers seeking to encourage the responsible conduct of research.

Does Declaration of Competing Interests Affect Reader Perceptions?

A Randomised Trial

Samena Chaudhry, Clegg Scholar, Sara Schroter, Research Fellow, Richard Smith, Editor, BMJ Editorial Office, BMA House, Tavistock Square, London WC1H 9JR, Julie Morris, Head of Medical Statistics, Medical Statistics Department, Education & Research Centre, Wythenshawe Hospital, Southmoor Rd, Wythenshawe, Manchester, M23 9LT

Objective: Does declaration of a financial competing interest influences readers' perceptions of the interest, importance, relevance, validity, and believability of a study. **Design:** 300 *BMJ* readers were randomly selected from the British Medical Association's membership database. All readers were sent a short report indicating that the impact of pain from herpes zoster on patients' daily functioning may be substantial. Readers in Group 1 (competing interest declared) were sent a version of this paper with different named authors to the original and with a declaration that they were employees of Tohen Research Laboratories, Connecticut (fictitious company) who potentially held stock options in the company. Readers in Group 2 were sent a version of the same paper with the same named authors as in Group 1, but with a statement that these authors were from, an ambulatory care centre, Turotu, in Connecticut and no competing interest was declared. Readers were asked to rate the study in terms of interest, importance, relevance, validity, and believability on 5-point Likert scales. Differences between groups were tested using independent t-tests. **Results:** 10 readers were excluded as not eligible. 170/290 (59%) questionnaires were returned (86 Group 1, 84 Group 2). Non-responders were significantly younger (mean age=40.7 (SD 13.9), range 19-93yrs) than responders (Group 1 mean age= 44.7 (SD 15.5), range 20-82yrs; Group 2 mean age= 44.8 (16.9), range 19-86yrs), t (276.2) =-2.3; p=0.022, but responses were poorly correlated to age. *T-tests* demonstrated that readers in Group 1 reported the study to be significantly less interesting, important, relevant, valid, and believable) than readers in Group 2. **Conclusions:** Our findings are the first to show that a declaration of competing interests can have a significant effect on readers' perceptions of the scientific credibility of published medical research. Future research should evaluate the effects of using different types of statements of competing interest such as statements about employment by companies versus statements about giving lectures for the company, different types of manuscripts, and different readership samples.

Quantifying Idealism: The Limits of Measuring Mission Drift

John W. Hanold, Ph.D., The Pennsylvania State University

Objective: A possible premise of research on research integrity is that measurable trends can be discovered regarding the way institutions behave in the current research environment. This paper considers whether the existence of academic idealism limits our ability to measure such trends. **Conclusions:** Where all members of a population behave in a "realistic" fashion (such as consumers in a market or bees in a hive), it becomes relatively easy to generalize their behavior. Idealists frustrate this predictability by holding onto principles, at least some of the time, even in the face of considerable pressures to compromise. A single eloquent voice can occasionally overcome a seemingly overwhelming institutional trend. And in a university setting, realists are often forced to mouth the words of idealism, perpetuating principles that are not their own. As an example, universities are frequently pressured by their industrial sponsors to accept publication restrictions that may at times violate academic freedom and the public trust. But the extent to which universities are likely to accept such restrictions may not be easily predictable, because institutional decisions hinge to a large degree on the ideological commitments of a small number of people. Since both quantitative and qualitative research regarding changes in institutional behavior are likely to have mixed results, it may be necessary to formulate public policy in the absence of complete research findings. It is unfair to the lonely idealist to expect him or her to continue to cry out in the dark while researchers struggle to determine the extent to which industrial interests may be corrupting research integrity in our colleges and universities. It may be necessary to rescue the idealist for no other reason than because our own idealism compels us to do so.

Preserving Trust in Research: A Call for Robust Financial Disclosures

Richard Sharp, Ph.D., National Institute of Environmental Health Sciences

Objective: To illustrate how common assumptions about the management of financial conflicts of interest in research fail to treat research volunteers with the full measure of respect they are due. To argue in support of more robust financial disclosure practices as essential to the promotion of informed public trust in biomedical research. **Design:** We draw upon Western philosophical and bioethical traditions in developing our arguments. We also draw upon our previous work on institutional trustworthiness and apply those concepts to the management of financial conflicts of interest in research. Finally, we develop a partnership-oriented framework for determining what financial relationships require disclosure. This analysis is largely unique to our work. **Conclusions:**

Although the moral hazards of financial conflicts of interest have been recognized by clinical investigators for decades, accelerated growth in industry-academic partnerships has renewed interest in institutional policies regarding the management of financial relationships in research. A recurring theme in these recent discussions is that disclosures of financial conflicts of interest to administrative officials are integral to the preservation of public confidence in research and the integrity of research organizations. We question this common view of the relationship between financial disclosures and the preservation of public trust. In contrast to other commentators, we argue that institutional policies requiring disclosures to administrative officials play at best a modest role in promoting and preserving trust. If one takes seriously the notion that biomedical research is best understood as a partnership between clinical investigators and those persons who volunteer their bodies in the service of the common good, then financial relationships must be far more perspicuous and open to scrutiny. Proceeding with the assumption that institutional policies should promote meaningful partnerships between clinical investigators and research volunteers, and that such partnerships are the foundation upon which ethical research is based, we describe a range of financial disclosures to community advisory committees, institutional review boards, and potential research participants that are especially pertinent to the promotion of public trust. Our aim is to show how this robust set of financial disclosures is necessary if biomedical research is to be conducted in an ethical manner.

3a. The Role of Institutions in Research Integrity, Sunday 10:20-11:50 a.m. (Frankel)

Ethical Codes in the Mental Health Professions: Protecting Integrity

Margaret Gibelman, D.S.W., Yeshiva University

Elizabeth DuMez, M.S.W., National Association of Social Workers (ret.)

Objective: The paper analyzes professional codes of ethics from seven core mental health disciplines regarding the nature and breadth of principles and standards pertaining to scientific conduct, that is, the promotion of research integrity. Codes of Ethics for the professions generally aim to promulgate the principles that reflect the profession's core values and to present ethical standards to which the general public can hold the profession accountable. Do codes of ethics developed by mental health professions protect the integrity of the research enterprise? This paper provides an analysis of the ethical codes of the core mental health disciplines: addictions counseling, counseling, marriage and family therapy, pastoral counseling, psychiatry, psychology, and social work. The findings form the basis for a more specific research agenda for the mental health professions regarding the extent to which codes of ethics can be used to inform behavior among members of the professions and to enforce standards. **Design:** Copies of the applicable codes of ethics were obtained from the relevant professional societies. A data collection tool was developed to record and rate the major scientific conduct themes emerging from the literature: informed consent; plagiarism; accuracy of data; voluntary participation; misrepresentation/deception; authorship credit; replication studies; collaboration with students; protection of human subjects (IRB reviews); acknowledgement of contributors; conflict of interest; duplicative submissions; and respect for confidentiality. The two authors independently reviewed the codes and completed the data collection form. Differences in coding and rating were discussed and reconciled. **Conclusions:** The analysis of the codes reveals varying levels of specificity and comprehensiveness of coverage of the identified subject areas. The codes of ethics of the smaller mental health disciplines, in terms of number of practitioners, have the least specific provisions in regard to research. Although this finding is not surprising, it does raise concerns because members of these disciplines are also, in general, the least experienced researchers and thus may need the most specific ethical guidance through their professional societies. A key issue facing all professional societies is the lack of applicability of the codes to professionals who opt not to be members. Such researchers, particularly those without academic affiliations, may be subject to no ethical guidelines.

Development of A Measure of Biodata for the Scientific Community

Whitney Helton-Fauth, The University of Oklahoma
Ginamarie Scott, The University of Oklahoma
Blaine Gaddis, The University of Oklahoma
Amber Shaffer, The University of Oklahoma
Shane Connelly, The University of Oklahoma
Michael Mumford, The University of Oklahoma

Objective: The aim of this paper is to describe the development of a set of career event scales that will be applicable to the scientific community. Such a measure is intended to identify those experiences unique to scientific work that may influence research climate at the individual, group, and organizational levels. Specifically, this measure will be used to predict integrity in the early part of a scientist's career based on various situational exposures occurring at individual, group, and organizational levels in university and research settings.

Is Research Misconduct Contagious? Evidence from the Swazey, Louis and Anderson Survey

Andrew J. Hogan, Ph.D., Michigan State University
Ronald Patterson, Ph.D., Michigan State University
James William Coleman, Ph.D., California Polytechnic State University

Objective: To test for evidence of differential association in the proliferation of research misconduct in university research settings, i.e. that research misconduct is a specialized form of white-collar crime that does not require abnormal psychology and may arise within organizational units that behave like deviant subcultures. Scientists joining such units would be differentially associating with other dishonest scientists and would be expected to come to adopt or at least tolerate the norms of the deviant subculture. **Design:** Re-analyzed of the data set for the NSF funded survey conducted by Swazey, Louis and Anderson in the early 1990s. We tested whether the distribution of research misconduct and other questionable research practices across universities and academic disciplines was consistent with the deviant subculture hypothesis. We developed 2 questionable research practice dependent variables from Question 14 in the Swazey et al survey form: FFP (number of Fabrication/Falsification and Plagiarism misconduct exposures reported by a respondent) and OQRP (number of Other Questionable Research Practice exposures). In addition to independent variables for

demographics and affiliation identifiers, we developed AWARENESS (aware of existence and content of department/university research integrity policies) and RETALIATION (likelihood of retaliation against a whistleblower) to explain the variation in FFP and OQRP exposures. **Conclusions:** Both AWARENESS and RETALIATION were positively associated with FFP and OQRP exposures and had high intraclass correlations within DEPARTMENT clusters requiring random effects modeling. The results demonstrate the non-random nature of the variation in research misconduct and other questionable research practices across DEPARTMENTs, consistent with the deviant subculture hypothesis. Consistent with the Broken Window Hypothesis, exposure to other questionable research practices is correlated with exposure to research misconduct (FFP).

Balancing Equity and Effectiveness in Corporate Governance: Towards a Stakeholder Systems Model of Action Research

John Simmons, Liverpool Business School, Liverpool John Moores University

Objective. The paper proposes a stakeholder systems approach to issues of equity and effectiveness in corporate governance with particular focus on examples from collaborative research projects ('action research') between companies and universities, and from human resource management. Its theme is that effective governance can be aligned with social responsibility, and that the incorporation of stakeholder views in decision-making processes enhances organisational performance, integrity and commitment. Design: The action research model presented derives from two sources. The main one a recent study of performance appraisal systems in UK universities incorporating interviews and questionnaires with salient stakeholder groups. Views on system effectiveness and integrity were obtained, and related to concepts of organisational justice. The other a small scale case study analysis of organisation-university collaboration in the UK pharmaceutical industry. Here also conclusions are based on the perspectives of key stakeholders and related to corporate social responsibility literature. Conclusions: address topical issues in corporate social responsibility and human resource management practice, and offer a structured methodology for achieving effective and ethical systems of governance. Research findings reaffirm the benefits of gaining contribution and commitment of those most centrally affected by the emergent system, and transparency in system purpose and process. The stakeholder systems model advocated delineates design, operation and evaluation stages, links these to dimensions of organisational justice, and

suggests how qualitative and quantitative measures can be combined to assess system effectiveness. The paper responds to research institution and company concerns regarding social responsibility and organisational justice issues in collaborative projects, and to the HR profession agenda of identifying 'high performance people management practices'

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3b. Investigative Techniques, Sunday, 10:20 a.m.–Noon (Markovsky)

Software to Compare Documents for Recycled Text

Louis Bloomfield, Ph.D., Department of Physics, University of Virginia

Objective: Reuse of language in written work is a concern in a variety of contexts. When it occurs between different authors, it is often the hallmark of plagiarism or derivative work. When it occurs within a single author's writing, it can indicate multiple submission of work that is ostensibly original and unique. However, detecting this reuse of language is difficult, particularly when you don't know where to look for it. Computer software that rapidly sifts through documents for recycled prose solves this "needle in the haystack" problem. **Design:** The software I have developed (WCopyfind) rapidly compares pairs of documents for matching phrases. Taking advantage of modern computers, with large amounts of memory and fast processors, it can compare tens of thousands of manuscripts per second. When it finds documents that share common phrases, it prepares marked up copies that facilitate human inspection of those pairs. By calling attention to documents with suspicious relationships and identifying those relationships, WCopyfind allows the user to concentrate on understanding those relationships, rather than simply trying to find them in the first place. **Conclusions:** The software works quite effectively at finding recycled language in documents. In addition to its obvious uses in the academy, it has been used to track the authorship of language in legislation, literature, and forensic documents. It is freeware and has been widely downloaded internationally. I now have substantial experience using such software in an academic setting to find and investigate possible academic fraud. Among the issues I have had to deal with are equal protection and fundamental fairness questions, copyright, privacy, statistical validity, and the cultural and institutional effects of suddenly uncovering hitherto undetectable academic misbehavior.

Using On-Line Publication Databases in Research on Research Integrity

William Gardner, Ph.D., Center for Research on Health Care, University of Pittsburgh
Charles W. Lidz, Ph.D., Center for Research on Health Care, University of Pittsburgh

Objective: A principal theme in research integrity is preservation of the integrity of the research record, a primary component of which is the research publication. Thus, the research publication is a fundamental unit of analysis. For example, research on the associations between investigators' financial conflicts of interest and the outcomes of clinical trials is conducted through surveys of authors of clinical trials. This requires the identification of a population of such authors. In this

report, we present a methodology that uses on-line databases to identify, and sample from, populations of research publications defined by sub-disciplines of clinical medicine. **Design:** This report is about a method in a research project to survey published clinical trials investigators about problems in research integrity. To identify a population of such investigators, we need to identify a population of publications of clinical trials. We have developed a set of text-pattern-matching computer programs that mine data from the Cochrane Database of Systematic Reviews, an online collection of meta-analytic reviews published by the Cochrane Collaboration, a coalition of clinical researchers who conduct research reviews according to a common set of methods. The Cochrane Reviews are on-line articles that summarize all known reports on the effectiveness of a given drug or treatment. Our programs read the Cochrane reviews and extract the references to the clinical trials, as well as meta-data about them, and deposit that information in a database. We can then generate stratified samples of authors from that database, and mail them surveys. **Conclusions:** As of April 2002, the 53 active Cochrane Review Groups had published 2310 topic reviews about medications, although about half of these describe uncompleted reviews. In a test, we applied our programs to the first 10 Cochrane Review Groups. These groups accounted for 275 published reviews. Of these 275 reviews, 157 (57%) focused on drugs as opposed to other therapies. When we analyzed these 157 reviews, we obtained 2943 references, of which 935 were to publications since 1995. We are currently extracting information about all pharmacologic clinical trials referenced in the 2310 topic reviews. At the conference, we will present a complete characterization of the information available in the Cochrane Database about these trials and their authors. We will contrast this method for obtaining a sample of research reports with an alternative method, the MEDLINE search. Our methods provide an operational way to describe and access an important layer of the research record in a clinical discipline. There are some limitations. The most important is that the publications are limited to the medical topics covered by the Cochrane Collaboration. There are also important advantages to this method. The Cochrane Reviewers search exhaustively and as domain experts, they are able to find studies that Integrity researchers likely cannot. Moreover, Cochrane reviews summarize important information about the studies in a research field, including evaluations of the quality of research methodology, which may be of use in studies of research integrity.

Digital Authentication of Research Notebooks

Geoffrey F. Grant, Ph.D., University of North Texas Health Science Center at Ft Worth

Objective: To utilize digitally signed files to establish credible authentication of Research notebooks. Research notebooks have suffered as a consequence of the increased use of the computer in research and research analysis. The modern economic atmosphere as applied to university research requires that notebooks are completely validated as increasingly university research is being patented which will lead, in the future, to increased pressure for notebook validation in Intellectual Property litigation. To utilize, to sign and validate your research computer files, in a manner, exactly parallel, and as equally effective and legal, as manual, handwritten signatures in your research notebooks. **Design:** Digital signatures are becoming a standard in the e-commerce arena, Additionally public/private key encryption technology has been incorporated into current versions of internet web browsers. The incorporation of a recently patented business methods innovation has facilitated the signing, encryption, and transmission of vital components of that signature process to be recorded with pertinent temporal data to provide non-reputiated digital receipt for those signatures. **Conclusions:** Digitally authenticated research notebook [DARN] techniques allow all research data to be recorded and saved on the computer, signed, date stamped, stored in a non-tamperable, irrefutable file. DARN fulfills all criteria necessary for legal validation and authentication that could possibly be required for intellectual property dispute litigation. Additionally, the technology preserves confidentiality as is desired for most trade secrets and preserves it to a much greater degree than the archaic 'witnessing' methods. The DARN technology results in a marked reduction or the complete elimination of manual note and record keeping. Instead of manual signatures you use computer generated digital signatures. Digital Signed files are Non-forgeable, irrefutable, legal, foolproof and offer the additional benefit of an audit trail that can establish what was recorded, who entered the data, network date and time stamping and an assurance that the integrity of the data is intact.

Color Tagging for Interpreting Overlap in Questioned Gray Scale Images

John W. Krueger, Ph.D., Scientist-Investigator, Division of Investigative Oversight, ORI

Objective: This is a demonstration of a simple image processing method to facilitate comparison of two questioned, continuous tone images having distinct features and background, such as bands in autoradiograms and blots. **Software/Methods:** I use either ImageJ (public domain) or Photoshop© (Adobe) supplemented with plugins from the Image Processing Tool Kit© (Reindeer Games, Inc.).

The first image is set up to have red features against a black background, and the second image to have black features against a cyan background. The overlapped images are viewed in the "difference" mode. The identity of the combined features can be confirmed via gray scale reference labels, but it can also be deduced by assigning the following coordinates [R,G,B] in computer color space: Red = [255,0,0]; Cyan =[0,255,255]; White = [255,255,255]; and Black = [0,0,0]. Thus, adding algebraically in the combined image, features that match show as red bands with uniformly shaded edges, and backgrounds that match show as cyan. *Features that don't match* produce white bands from the 1st image and black bands from the 2nd image. C **Results:** The selectivity of the method appears to be immune to areas of false positives (i.e., a false indication of overlap and/or matching of features). Discrete reds areas of higher saturation require the intensities and the higher contrast that automatically promote either the white or black areas that identify non-overlapping features. Conversely, examination of the overlapped references labels indicates that where areas of intermediate intensity occur in the separate images the technique is subject to a false negative (absence of visible red). However, this problem can be addressed by enhancing the contrast in each layer, while simultaneously observing the effect on the morphology of overlapping features. **Discussion:** The method emphasizes the morphological features common to two images while retaining the identity of components which differ. This facilitates presentation of evidence showing purposeful manipulation of image content. The utility for ORI's examinations of falsified scientific images will be demonstrated. The method can be automated, and matching features (red, with uniform boundaries) can be extracted by edge detection and segmentation for subsequent statistical treatment.

Detecting Data Irregularities Using Digital Analysis

Shangqian (Daniel) Qi, M.D., Johns Hopkins University Center for Clinical Trials
Nancy Min, Ph.D., Johns Hopkins University Center for Clinical Trials
Susan Tonascia, Sc.M., Johns Hopkins University Center for Clinical Trials
Curtis Meinert, Ph.D., Johns Hopkins University Center for Clinical Trials

Objective: To investigate whether or under what conditions clinical trials data conform to Benford's Law, and assess if Benford's Law and/or digital analysis can be used to detect data irregularities in clinical research. **Design:** A variety of datasets from clinical trials and clinical research using animal model were used to examine the conformity of data to Benford's Law, specifically, to test whether the digit distributions of the combined data of several variables of the

same outcomes or of different outcomes follow the expected distributions of the 1st-digit, the 2nd-digit, based upon Benford's Law. Chi-square test and the comparison of mean absolute deviation (MAD) were used to determine significant deviation from the Law. Analyses were also conducted by data collection sites for multi-center study. **Results:** Usually, data from one variable does not conform to Benford's Law. For example, the Benford's expectation of 1st-digit distribution is 30.1%, 17.6%, 12.5%, 9.7%, 7.9%, 6.7%, 5.8%, 5.1%, and 4.6% for digit 1 to 9; while the 1st-digit distribution for a variable of survival time were 24.1%, 20.0%, 5.3%, 17.6%, 16.4%, 6.8%, 3.9%, 3.0%, and 2.9%. When more variables were combined, the distribution became closer to Benford's Law. When 10 variables were combine, the 1st-digit distribution (for 1, 2, 3, …, 9) were 34.2%, 23.4%, 16.6%, 10.3%, 6.1%, 3.9%, 2.3%, 1.6%, and 1.6%. Certain types of variables, for example, hematology-related data and HIV load in blood, were found to have similar distribution pattern to Benford's Law even examined the variable alone. Cross-site comparison of digital analysis was found to be effective in detecting data irregularities. **Conclusions:** Even though most data of individual variable from clinical trials do not closely conform to Benford's Law, the general features of this Law were observed in data combined from various types of data. Some types of data have more similar pattern as that of the Law. Cross-site comparison of digital analysis was found to be effective in detecting data irregularities.

4a. The Role of IRBs in Research Integrity, Sunday, 1:15–2:45 p.m. (Korenman)

Ethical Considerations in Social Science Research in the Canadian Forces and the Department of National Defence

Sarah A. Hill, Ph.D., Canadian Forces Leadership Institute

This paper examines issues of ethical review of social science research in the Canadian Forces (CF) and Canadian Department of National Defence (DND). An examination of existing practice reveals that there is a marked lack of consistency in obtaining ethical review of research in the CF/DND. Further, internal (CF/DND) practice has not kept pace with evolving external standards for ethical review. Differences appear to be largely a function of location (i.e., unit in which research is conducted) rather than attributable to individual differences among researchers. Evidence reveals that some researchers do make efforts to obtain ethical review of their work, and in some units adherence to this practice has been institutionalized. Issues underlying the requirement for ethical review, both generally and in the CF/DND context, (respect, privacy, confidentiality, accountability, transparency, integrity, voluntary participation, informed consent, social responsibility, fairness, the chain of command, and objectivity) are discussed. The complications introduced by intertwining organizational self-monitoring and "pure" research are also considered. Tensions between the ethical codes of social science disciplines (psychology, sociology, history, political science) and the reality of social science research in and for the CF/DND are discussed and some recommendations for practice made. The emphasis on ethical behaviour in the CF demands ongoing debate of these issues, consistent support for researchers who endeavour to follow ethical guidelines in their work, and a broader understanding by non-researchers in the organization of the value of, and requirement for, ethical review of social science research.

The IRB Paradox: Do the Protectors Also Stimulate Scientific Misconduct?

Patricia Keith-Spiegel, Ph.D., Children's Hospital, Boston and Harvard Medical School
Gerald P. Koocher, Ph.D., Children's Hospital, Boston and Harvard Medical School

Can perceived unjust actions taken by IRBs be an antecedent of dishonest responses by science investigators? We already know that scientific dishonesty occurs for many different reasons, such as intense pressures to produce findings, excessive ambition, inadequate socialization into the role of scientist, and character flaws. However, given the pervasiveness of investigator complaints about

IRBs and the unacceptable rate of scientific dishonesty reported in anonymous surveys, a systematic investigation of a possible connection between the two seems long overdue. We are exploring the hypotheses that IRB justice issues have a critical bearing on investigators, and that some acts of scientific dishonesty by otherwise ethical investigators result from perceived injustice by the very mechanism established to protect participants and, in the process, uphold the ethical conduct of science. Although, at first blush, this hypothesis appears paradoxical, organizational justice theory provides a solid framework from which to explore this relationship. Strong statistical associations exist between employees' perception that their employers are fair and employees' good citizenship behaviors. Conversely, management actions perceived as unfair or unjust by employees often result in negative reactions, including the commission of dishonest acts. Business settings, the context in which almost all organizational justice research has been conducted, differ in significant ways from research settings. However, when organizational justice theory is applied to research settings, strong negative reactions to perceived injustice are also predicted. We will present actual critical incidents that illustrate the relationships between perceived unjust IRB treatment and investigators' responses that are, to varying degrees, dishonest. We will also present preliminary findings from a large, national survey of biomedical and social scientists assessing the relative importance of just and fair treatment compared to other functions of IRBs.

A Case Study Comparing Structure and Implementation of Institutional Review Boards at Carnegie Doctoral/Research-Intensive and Master's Comprehensive I Universities

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Abdul Turay, Ph.D., Western Carolina University

Objective: Prestigious research universities and medical centers throughout the southeast recently received intense scrutiny by federal investigators and lay press for breaches of research integrity, including failure of Institutional Review Boards (IRB) members and researchers to disclose conflicts of interest and properly monitor research. Office of Human Research Protection (OHRP) is responsible for assuring ethical and safety compliance of federally funded research projects; but the OHRP has insufficient staff to provide supervision of all federally funded research. IRB compliance is mainly built on trust that institutional gatekeepers will adequately monitor themselves. The purpose of this study is to compare the structure, implementation and guidelines used by Institutional Review Boards at Carnegie doctoral/research-intensive and master's comprehensive I universities.

Design: IRB procedures at 19 institutions in four states (GA, NC, SC, TN) were surveyed to obtain in-depth understanding of structure and implementation of IRBs at responding institutions. Surveys involve two interviews: institutional information via telephone with IRB chairpersons and member information via web-surveys, accessible to identified IRB members only. **Results: Institutional Findings:** 89% of surveyed institutions (17) had functioning IRB committees with 41% (7) meeting monthly. 41% (7) had no method for disclosing conflicts of interest. 71% (12) conducted training for IRB members using various instructional methods (online tutorials, workshops, printed materials, etc). 68% of institutions had never been reviewed by OHRP. **Member Findings:** Response rating to web-surveys was 36% (67 of 187). 46% of respondents "agreed" they received adequate training while 24% "disagreed." Majority of respondents believed their institutions had adequate procedures to monitor research and conduct audits of research projects but 19% disagreed. Only 69% believed one of their roles was to ensure adequate procedures existed to monitor responsible research. **Conclusions:** Limited OHRP institutional review and IRB members who report they do not believe one of their roles is to ensure adequate monitoring of research procedures suggest a need for additional study to determine the effectiveness of internal review.

Informed Consent Form Readability Standards vs. Actual Readability: A Survey of U.S. Medical School Institutional Review Boards

Michael K. Paasche-Orlow, M.D., M.P.H., Holly A. Taylor, Ph.D., M.P.H., and Frederick L. Brancati, M.D., M.H.S., Departments of Medicine (MKP-O, FLB), Health Policy and Management (HAT), and Epidemiology (FLB), and the Phoebe R. Berman Bioethics Institute (MKP-O, HAT), The Johns Hopkins University, Baltimore, Maryland.

Objective: Institutional review boards (IRBs) are charged with safeguarding people with limited literacy, but may play an inadvertent role in promulgating unreadable consent forms. We hypothesized that text authored by IRBs in informed consent forms fail their own readability standards and that readability is influenced by research activity, local literacy rates, and federal oversight. **Design:** To test these hypotheses, we conducted a cross-sectional study linking data from several public-use sources. American medical school websites (N=114) were surveyed for readability standards and informed consent form templates. Actual readability was measured with the Flesch-Kincaid scale, which calculates the reading level of English text (range 0 to 12^{th} grade). Rank of National Institutes of Health funding in 2001, illiteracy rate by congressional district according to The National Institute for Literacy, and reports from The Office for Human Research Protections were obtained from organizational websites. **Results:** IRB authored text score 10.6 (95

percent confidence interval: 10.3 to 10.8) on the Flesch-Kincaid scale. Specific target readability standards found in 54 percent (61/114) websites ranged from 5th to 10th grade. Actual Flesch-Kincaid scores averaged 2.8 (95 percent confidence interval: 2.4 to 3.2, P<0.001) grades higher than targeted standards. Readability was associated neither with level of research funding (P=0.89) nor with local rates of illiteracy (P=0.92). However, schools that underwent oversight by The Office for Human Research Protections (42 percent; 52/114) had lower Flesch-Kincaid scores (10.2 vs. 10.9, P=0.005). **Conclusions:** IRBs commonly provide informed consent form text that falls short of professed readability standards. Federal oversight is associated with better readability.

Research Access: The Views of Prospective Research Participants

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James L. Abruzzese, M.D., The University of Texas M.D. Anderson Cancer Center

Objective: To evaluate prospective participants' views on the fairness of criteria and conditions controlling access to investigational drugs. **Design:** We interviewed 100 of the first 130 persons referred to a Phase I trial of human recombinant endostatin. Positive media coverage had resulted in high demand for access to the trial, but M. D. Anderson trial investigators accepted referrals only from M. D. Anderson physicians. **Results:** The median age of respondents was 56 years. 86% were white. 69% had some college education. 1/3 reported income of more than $80,000 a year. 93% of respondents had some form of medical insurance: 81% private; 35% public. Most respondents (77%) were not motivated by a belief that participation was the best way to pay for cancer treatment. 70% asserted patients have a right to get investigational drugs. 55% agreed investigational drugs should be restricted to patients on a research study, while 30% agreed that investigational drugs should be given to anyone who wants them. 63% thought it was too hard to get investigational drugs in the US, 19% thought access was just right. No respondent thought it was too easy. Asked the fairest way to determine who gets investigational drugs, 11 stated the drugs should be given to those

who will benefit most. 31% stated the drugs should be given to those who need them the most. 27% indicated that the most appropriate access criteria are those best for science. 5% thought the drugs should go to the most fit to withstand the trial. 7% advocated a first-come, first-served approach. Only 2% supported random selection. **Conclusions:** These potential research participants believe research access is a right and is presently too restrictive. While their views reflect a belief that the drugs offer potential benefit to recipients, nearly a third favor scientific criteria as the allocation determinant.

4b. Student Attitudes, Sunday, 1:00-2:45 p.m. (Friedman)

Data-Sharing and Withholding Among Trainees in Science: A Progress Report

Eric G. Campbell, Ph.D., Institute for Health Policy, Harvard Medical School

Objectives: 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 engineering. The specific aims of this research are: 1. To investigate the attitudes of trainees towards data-sharing and -withholding and the factors that predict their attitudes. 2. To investigate the data-sharing and -withholding behaviors of trainees and the factors that predict their behaviors. 3. To investigate the consequences, if any, of data-sharing and -withholding on trainees' educational experiences. **Design:** The study relies on qualitative and quantitative data. Qualitative data collection consists of two focus groups and 10 personal interviews of trainees in the sciences. The quantitative data will involve 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. The survey will be constructed using questions adapted from previous surveys as well as new items. The instrument will be pre-tested using cognitive interviews and a formal mailed pretest. The survey itself will collect information regarding the prevalence, nature, extent and consequences of data sharing and withholding on trainees in science. Hypotheses will be tested using univariate and multivariate statistical techniques. Results will be disseminated through publications in peer-reviewed journals and presentations at scientific meetings. **Results:** As of April 10, 2002, we have completed two focus groups (one in Minneapolis MN and one in Boston MA) of trainees in the life sciences, computer science and chemical engineering. The results of the focus groups, consisting of hours of taped discussion were analyzed by the research staff. Because some trainees found it difficult to be completely frank in focus groups, we complemented the focus groups with 5 confidential, personal interviews of trainees. The personal interviews focused on understanding trainees' personal beliefs, attitudes and experiences with data-sharing and -withholding as well as the consequences, if any, of these experiences on their education. These interviews were recorded and summarized. Based on the findings from the focus groups and the interviews conducted to date, we have identified several different types of data withholding among trainees including delays in publishing, withholding pertinent information in articles, not discussing research with other scientists, refusing to share biomaterials and scientific approaches with other trainees and intentionally giving incomplete or inaccurate information to other scientists. As a result of these

experiences several trainees reported that they were unable to complete their research as planned, some were significantly delayed in completing their work and two terminated their training in a lab due to data-withholding issues. Trainees identified their advisor as the primary determinant of their of data-sharing and withholding attitudes and behaviors. Prior to the conference we will complete the remaining 5 personal interviews, finish summarizing the qualitative data, develop the survey instrument, pretest the survey instrument and collect the survey sample. At the conference we will share the results of these activities as well as other important insights gained from these activities.

Plagiarism in Academia: Are Students Emulating (Bad) Faculty Role Models?

Sheldon R. Gelman, Yeshiva University, Wurzweiler, School of Social Work

Margaret Gibelman, Yeshiva University, Wurzweiler, School of Social Work

Objective: This paper provides an analysis of media accounts concerning plagiarism on the part of students and faculty. Key themes are abstracted in terms of: (1) case facts (what occurred); (2) how the matter was handled (with what consequences); and (3) the fallout (longer-term impact and lessons learned). To date, accounts of plagiarism among students and faculty are largely anecdotal and have been reported and analyzed on a case-by-case basis. This paper seeks to provide an empirical analysis of the cases of plagiarism that have "made the news" and aggregates the cases over a seven year period. An exploration of trends in these cases provides insight into the normative behavior that promotes and allows cheating in the form of plagiarism. **Design:** A content analysis of media reports of instances of plagiarism by students and faculty over a seven year period was conducted to identify issues and trends - what happened, to whom, why, and with what consequences. The subject of analysis was articles appearing in daily, weekly, or monthly newspapers and the Chronicle of Higher Education. Two primary search engines were used to identify and obtain news articles: Lexis-Nexis and ProQuest. The search was conducted in early 2002 for the time frame 1995-2001. The search was initiated using the key words "plagiarism" and "cheating". The initial search was then refined to include the term "higher education", with an expected smaller yield of articles resulting. The remaining articles were analyzed by the use of qualitative content analysis. Descriptive categories about the situations or events reported were identified, i.e., nature of the allegation, parties involved, legal status of the case, if any, penalties imposed on the student or faculty member, and longer-term consequences for the parties involved. **Results:** The initial analysis indicates that over the time period of investigation, the incidence of reported plagiarism has increased significantly. Many of these reports involve the inappropriate use

of free or purchased web-based resources by college students and the availability of software programs designed to detect such use. Some cases involve academicians and administrators who have "borrowed" and utilized the work of others in their published written work and/or public speeches without acknowledgment or attribution. Other cases involve academics who have gained a high level of visibility and prominence as best selling authors; still other cases deal with claims of authorship for non-existent publications. Lessons from the case analysis are alarming in regard to the prevalence of plagiarism and the potential that faculty are role modeling illegal and unethical behavior. After-the-fact resolutions in the form of penalties negate the responsibility of the academic community to exercise diligence in monitoring student and collegial work. Analysis of the media reports provides a baseline for exploring possible explanations for plagiarism, including weaknesses in student and peer monitoring, lack of communication about plagiarism and other forms of misconduct and their consequences, and weaknesses in the educational climate, in which getting by, earning a higher grade, or getting published erroneously justify any means. Expressions of outrage about student cheating are obviated by behavioral role modeling of academic conduct (or misconduct). "Do as I say, not as I do", is a poor model of ethical behavior. Suggestions are offered in terms of student assignments, student socialization, behavioral standards, peer review, and enhanced training in ethical conduct that may help build and maintain an educational milieu in which plagiarism just doesn't happen - on the part of faculty or students.

Exposure = Misconduct: How "Misleading" Were the Swazey, Louis and Anderson Survey Results?

Andrew J. Hogan, Ph.D., Michigan State University
Ronald Patterson, Ph.D., Michigan State University,
James William Coleman, Ph.D., California Polytechnic State University

Objective: Safir and Kennedy (1998) suggested that the research misconduct results of the Swazey, Louis and Anderson survey, as reported in the popular press, were substantively and statistically misleading: substantively misleading because there was no independent process to determine if the perceived misconduct actually constituted misconduct; statistically misleading because many individuals could be exposed to a single case of misconduct, overstating the true incidence of misconduct. We evaluated the extent to which the general public might have been "misled" by the reporting of the results of the exposure to research misconduct of the Swazey, Louis and Anderson survey. **Design:** Using Question 14 in the Swazey et al questionnaire, we determined the minimum

number of faculty or students engaging in research misconduct in a department to be the largest number reported by a single exposed department member. The maximum number of individuals engaging in misconduct is the sum of all the exposures reported by all department members -- assuming no overlapping exposures. The true number of department members engaging in misconduct will lie somewhere between these bounds. **Results:** The range between the upper and lower bounds of the incidence of research misconduct was generally modest: graduate student plagiarism had an exposure rate of 27% with lower and upper bounds of 18% and 55%; faculty plagiarism had an exposure rate of 8% with lower and upper bounds of 8% and 14%; student falsification/fabrication had an exposure rate of 15% with lower and upper bounds of 11% and 27%; faculty falsification/fabrication had an exposure rate of 7% with lower and upper bounds of 6% and 12%. Thus average exposure rates were closer to the lower bound of estimated misconduct, not to the upper bound as suggested by Shafir and Kennedy (1998). The issue of substantive bias (perceived misconduct ≠ adjudicated misconduct) could not be addressed.

Attitudes Toward and Knowledge About Science of Medical School Students

Darko Hren B.S., Zagreb University School of Medicine
Ana Marusic M.D. Ph.D., Zagreb University School of Medicine
Ivan Kresimir Lukic M.D. M.S., Zagreb University School of Medicine
Ivana Vodopivec student, Zagreb University School of Medicine
Ana Vujaklija student, Zagreb University School of Medicine
Maja Hrabak student, Zagreb University School of Medicine
Matko Marusic M.D. Ph.D., Zagreb University School of Medicine

Objective: To explore the relationship between teaching scientific methodology at the second year of medical curriculum and students' attitudes towards and knowledge about science and scientific methodology. **Design:** We conducted an anonymous questionnaire survey at the Zagreb University School of Medicine, Croatia involving 932 students (response rate 58%) from all six years. Main outcome measures were scores on the attitude scale with 45 Likert-type statements (developed for this purpose) and on the knowledge test consisting of 8 multiple choice questions. **Results:** All students' average attitude score was 166±22 out of maximum 225, indicating positive attitude towards science and scientific research. Their average score on the knowledge test was 3.2±1.7 out of 8 questions. Students who finished the second year of study had the highest attitude (173±24) and knowledge (mean 4.7±1.7) scores compared with other study years ($p<0.001$, ANOVA and Tukey post-hoc test). For students who attended the course (third to sixth year) multiple linear regression

analysis showed that knowledge test score (B=3.4, SE=0.4, 95% confidence interval 2.5-4.2; p<0.001) and average grades (B=7.6, SE=1.5, 95% confidence interval 4.6 to 10.6; p<0.001) were significant predictors of attitude toward science, but not sex or failure to pass a year (B=-0.6, SE=1.7, 95% confidence interval -3.9 to 2.6, p=0.707; and B=-3.1, SE=1.9, 95% confidence interval -6.8 to 5.7; p=0.097; respectively). **Conclusions:** Medical students have generally positive attitude towards science and scientific research in medicine. Attendance of a course on research methodology is related to positive attitude towards science.

Prevalence, Features, and Attitudes About Plagiarism in Biomedical Sciences: A Pilot Study

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Lidija Bilic-Zulle, Dept. of Computer Science, Rijeka Uni. School of Medicine, Rijeka, Croatia

Objective: Investigation of attitudes and behavior of medical students on plagiarism, fraud and scientific misconduct. We present preliminary data based on survey conducted among second year medical students. **Design:** Students answered to six comprehensive questions about possible (fictitious) cases dealing with misconduct. Up to date of abstract submission two cases were revealed: plagiarism case with student copying a seminar paper, and fraud with MD writing results of routine physical examination before surgery as normal while hasn't done it. **Results:** Survey completely filled 105/115 students. Plagiarism was found unethical in 100 students and fraud case in 97 students, with no difference between groups (p=0.391). Thirty-one percent of students thought that plagiarism case had reasonable excuse, while only 13% of them thought that fraud had reasonable excuse (p=0.003). No significant difference was found between cases considering attitude: 66% of students would do the same in plagiarism case and 59% of students in fraud case (p=0.294). Also, 78% of students in plagiarism case and 68% in fraud case (p=0.115) reported having heard about such a case or even witnessing it. Interestingly, about 85% of students considered that subjects in both cases should be punished, with no significant difference in proportions (p=0.925). This suggests that students opinion on cases is mostly correct, basically – students find cases not ethical. But, it seems that students felt that case subjects did not perform serious and dangerous actions, i.e., they found cases trivial. Indeed, although 66% (plagiarism) and 59% (fraud) students said they would do it, all of them (99% in both cases) agree they would do it rarely, only under the exceptional circumstances. **Conclusions:** Lack of knowledge in recognizing scientific and academic misconduct and distinguishing it from criminal act implicates that medical students need further education in research integrity.

5. Posters and Demonstrations (*Break)* 2:45-3:15 p.m.

Software to Compare Documents for Recycled Text

Louis Bloomfield, Ph.D., Department of Physics, University of Virginia

Objective: Reuse of language in written work is a concern in a variety of contexts. When it occurs between different authors, it is often the hallmark of plagiarism or derivative work. When it occurs within a single author's writing, it can indicate multiple submission of work that is ostensibly original and unique. However, detecting this reuse of language is difficult, particularly when you don't know where to look for it. Computer software that rapidly sifts through documents for recycled prose solves this "needle in the haystack" problem. **Design:** The software I have developed (WCopyfind) rapidly compares pairs of documents for matching phrases. Taking advantage of modern computers, with large amounts of memory and fast processors, it can compare tens of thousands of manuscripts per second. When it finds documents that share common phrases, it prepares marked up copies that facilitate human inspection of those pairs. By calling attention to documents with suspicious relationships and identifying those relationships, WCopyfind allows the user to concentrate on understanding those relationships, rather than simply trying to find them in the first place. **Results:** The software works quite effectively at finding recycled language in documents. In addition to its obvious uses in the academy, it has been used to track the authorship of language in legislation, literature, and forensic documents. It is freeware and has been widely downloaded internationally. I now have substantial experience using such software in an academic setting to find and investigate possible academic fraud. Among the issues I have had to deal with are equal protection and fundamental fairness questions, copyright, privacy, statistical validity, and the cultural and institutional effects of suddenly uncovering hitherto undetectable academic misbehavior.

A Set of Online Instructional Modules in Research Ethics

Nell Kriesberg, Division of Multidisciplinary Studies, North Carolina State University, Raleigh, North Carolina

The Research Ethics Initiative at North Carolina State University, funded by the National Science Foundation from 1998 through 2002, was intended to create an infrastructure for research ethics training across the curriculum. This project, directed by the Graduate School, consisted of both pedagogical training for faculty and PhD students, and the development of a set of online instructional modules in key areas of research ethics (Kriesberg, et. al.).

These instructional modules fit into the overall plan to integrate research ethics training across the curriculum by providing instructional materials suitable either for self-study or classroom use at the discretion of individual faculty. Every page in each module is planned so that it can stand alone as a springboard for class discussion or personal reflection. Each module was planned, written and reviewed in consultation with a faculty expert in each key area: six of the ten modules have a central essay by that faculty expert. Each module has a similar structure, broken down into in seven sections. 1) Introduction- a brief overview of the major issues in that topic; 2) Applied Ethics- explication of a particular issue; 3) Central essay or central readings- a book chapter or several key articles; 4) Theme- institutional compliance issues – usually a presentation of the rules/regulations at NC State University; 5) Case Study; 6) Study Exercises or "Thinking Outside the Box"— a particularly challenging question related to the topic; 7) Resources-annotated bibliography, videos, URLs. All the modules are available via the World Wide Web in Adobe format, with the selected readings available via the North Carolina State University Library Electronic Course Reserves system; the readings are hyperlinked directly through the firewall protection for NC State University faculty, personnel and students. The ten modules are as follows: 1) Research Ethics: an Introduction 2) Responsible Authorship and Peer Review; 3) The Mentoring of Graduate Students; 4) Animal Subjects in Research; 5) Professional Responsibility and Codes of Conduct; 6) Human Subjects in Research; 7) Research and Rightdoing; 8) Intellectual Property: Copyright Issues; 9) The Responsible Use of Statistical Methods; 10) Science and the Media: Ethical Issues. The URL for the modules is: http://www.fis.ncsu.edu/Grad/ethics/modules/index.htm

Color Tagging for Interpreting Overlap in Questioned Gray Scale Images

John W. Krueger, Ph.D., Scientist-Investigator, Division of Investigative Oversight, ORI

Objective: This is a demonstration of a simple image processing method to facilitate comparison of two questioned, continuous tone images having distinct features and background, such as bands in autoradiograms and blots. **Software/Methods:** I use either ImageJ (public domain) or Photoshop© (Adobe) supplemented with plugins from the Image Processing Tool Kit© (Reindeer Games, Inc.). The first image is set up to have red features against a black background, and the second image to have black features against a cyan background. The overlapped images are viewed in the "difference" mode. The identity of the combined features can be confirmed via gray scale reference labels, but it can also be deduced by assigning the following coordinates [R,G,B] in computer color space: Red = [255,0,0]; Cyan =[0,255,255]; White = [255,255,255]; and Black = [0,0,0]. Thus, adding algebraically in the combined image, features that match show as red bands with uniformly

shaded edges, and backgrounds that match show as cyan. *Features that don't match* produce white bands from the 1st image and black bands from the 2nd image. **Results:** The selectivity of the method appears to be immune to areas of false positives (i.e., a false indication of overlap and/or matching of features). Discrete reds areas of higher saturation require the intensities and the higher contrast that automatically promote either the white or black areas that identify non-overlapping features. Conversely, examination of the overlapped references labels indicates that where areas of intermediate intensity occur in the separate images the technique is subject to a false negative (absence of visible red). However, this problem can be addressed by enhancing the contrast in each layer, while simultaneously observing the effect on the morphology of overlapping features. **Discussion:** The method emphasizes the morphological features common to two images while retaining the identity of components which differ. This facilitates presentation of evidence showing purposeful manipulation of image content. The utility for ORI's examinations of falsified scientific images will be demonstrated. The method can be automated, and matching features (red, with uniform boundaries) can be extracted by edge detection and segmentation for subsequent statistical treatment.

Computerized Awareness Training for Research Integrity in the Sciences

Rudolph J. Marcus, Ph. D., Stories and Questions, Occidental, CA

Use of the web site <http://storiesandquestions.com/> to present, and to test on knowledge of, codes, case studies, and awareness training was discussed and demonstrated at the RRI 2000 conference. Since then, the four seminars demonstrated on the web site have been approved as home study of scientific ethics for continuing education credits, earning CEU for license renewal (CA MFT and LCSW, Provider # PCE 2494). The aim here is to add seminars dealing specifically with research in the sciences to existing web site and to demonstrate augmented web site at the meeting. Seminars are based on mythical stories, prose or poem dramas which have great power because of their age and their seemingly universal applicability. Five seminars added to the web site are Daedalus - Icarus, Helius - Phaeton, Faust - Mephisto, Prometheus - Zeus, and Metis - Zeus. I have used story material and questions from four of those five seminars since 1996 as case studies for RCR in national tour lectures for the American Chemical Society. Note a pair of names in each title, two protagonists in each drama. That is because each polarity is present in an ethics problem, regressive and progressive, wrong and right, one and two masters, etc. The researcher with an ethics question finds oneself in a continuum between those two polarities and searches for help in balancing them. Those dramas provide practice for the RCR trainee in making ethical choices within such a

continuum which mirrors actual work situations. That kind of practice is not provided by study of ethics codes which only provide one of the two polarities and suggest that one be followed rigidly and the other be suppressed or denied. The multiplicity of ethics codes to which a researcher is subject, and the conflicts between them, have been discussed by the author in an encyclopedia chapter. The five seminars added to the web site are dramatic representations of five stages in the ethical development of a scientist: personal carelessness, knowing one's own limits, reaching too far, willingness to suffer pain for having dared, and wisdom/feeling. Each of the seminars is self standing. Together they form a history of the development of scientific ethics.

Bibliometric Analysis of the Literature on Scientific Misconduct

Shigeaki Yamazaki, Ph.D., Aichi Shukutoku University

Objective: The purpose of this bibliometric analysis is to show the growth of papers on scientific misconduct, and also to identify the key journals and key authors in the field of scientific misconduct. **Design:** From the PubMed database, we searched the literature on scientific misconduct by using major MeSH (Medical Subject Headings) term "scientific misconduct" for the period from 1980 to 2001. In September 2002, 1520 papers on scientific misconduct were obtained, and downloaded in ProCite/personal database for operating its records. Based on the number of papers, ranking lists of the key journals and key authors in scientific misconduct were arranged. **Results**: The volume of papers on scientific misconduct increased 4 times during 1989 to 1990. We found many papers on the topics in the first half of 1990s; scientific misconduct became an important topic in this period. General science and medical journals, for example Nature, Science, BMJ, and Lancet, published many papers on scientific misconduct. The New York Times and Washington Post also published many articles on this topics, Science Engineering Ethics is an important journal for specialists in this field. The most productive author is C. Anderson who published 32 papers on the Nature and Science. We can find many personnel names of science writers, editors, and correspondents in the list of top productive authors, but names of researchers in academic position are very few. **Conclusions:** The topic of scientific misconduct was mainly discussed not in the universities but in the scientific journalism community. More surveys on scientific misconduct and research integrity have to carry in academic field, especially in universities.

6a. Clinical Research 3:15-5:00 p.m. (Shamoo)

Preservation of Ethical Principal of Equipoise is A Key to Unbiased Clinical Design

Benjamin Djulbegovic, H. Lee Moffitt Cancer Center & Research Institute,
University of South Florida

Objective: The empirical evidence shows that flawed results from "poorly designed and reported trials can mislead decision making in health care at all levels". Inadequate conduct and reporting seriously compromise integrity of the research process when biased results receive false credibility. Previous research has identified methodological issues in the design and conduct of randomized controlled trials (RCTs), which, if left unaddressed, may lead to biased results. Current guidelines for the design and reporting of randomized trials, such as the CONSORT statement (2001;285:1987)do not address the choice of the comparator intervention. We argue that an adequate control group can be selected if people designing a trial explicitly take into consideration ethical principle of equipoise (or "the uncertainty principle"). **Design:** We investigated the effect of all key quality dimensions highlighted by the CONSORT statement, and also the source of funding and the type of control intervention. Data was collected from 136 RCTs in multiple myeloma published from 1966 to 1998. We hypothesized that studies with placebo or no active treatment as the control intervention would be associated with larger treatment effects, as would trials sponsored by the pharmaceutical industry. We also expected that inadequate reporting of the key quality domains would be associated with larger treatment effects. The main results presented here are the odds ratios (OR) for obtaining a result in favor of the standard or experimental group in RCTs. **Results:** We used a multivariable logistic regression analysis to investigate the relative impact of all quality domains on the treatment effect . The choice of control intervention was strongly associated with treatment effects. If the control group was placebo or no active treatment, the odds ratio for having a result that was in favor of the new treatment was 9.03 (95%CI 2.69-30.29). In a multivariable analysis, the only other quality dimension that was associated with statistically significant overestimation of the treatment effects was lack of double blinding. Trials which did not use double blinding were more likely to find that the new treatment was better (OR=6.92, 95%CI 1.56-30.76). However, we could not account for publication bias as an explanation of our findings. **Conclusions:** Choice of control intervention may be the most important element of an RCT design. This aspect of the control trial is exclusively intentionally controlled by those involved in a trial design and conduct. Studies in which the intervention and control groups are believed to be non-

equivalent violate the key ethical principle of human experimentation-equipoise-and may result in biased findings. Our results showed that unbiased scientific results can be best achieved by preserving the ethics of human experimentation. CONSORT and other documents prescribing a research in humans should include explicit acknowledgement of existing uncertainties about relative values of competing treatment alternatives as a part of its checklist.

Evidentiary Criteria as a Research Integrity Issue: The Case of Gender Assignment for Intersexed Infants

Aditi Gowri, Ph.D., University of Texas

David Armstrong, Ph.D., University of Southern California

Objective: To illuminate the boundary between experimental and standard medical treatment; to show that this boundary is not always clearly defined and that its construction and location by researchers is an integrity issue. **Design:** Medical research literature and case histories concerning clinical treatment of intersexed infants—-and in particular medical and surgical assignment of gender—will be studied as an illustrative case study. Researchers' statements on the evidentiary basis of treatments for the intersexed are analyzed using an emergent category approach. Particular attention is paid to researchers' implicit cultural premises about gender and justification of medical practices in terms of these premises. **Results:** Medical practitioners understand and perform gender assignment treatments as though they were well supported by clinical evidence. As a consequence, the level of patient (usually surrogate) informed consent that is considered adequate for medical gender assignment is less stringent than would be required for experimental treatment. However, the evidence on which practitioners have relied may be questioned on several grounds. There has never been a clinical study of any control group of unassigned or non-medically assigned intersexed infants. Follow-up studies on gender assignment procedures are rare; and those that are pursued generally end long before a patient's adult, sexually active life begins. Conversely, physicians' belief that gender assignment treatments are a standard medical practice seems to be conditioned by their local, contingent cultural premise that persons along with their genital organs must conform clearly to one gender identification of the other. **Conclusions:** The example of gender assignment illustrates that cultural premises as well as research-based evidence enter into medical practitioners' understanding of a medical treatment as standard rather than experimental. The findings of this case study suggest that research on practitioners' understanding and application of evidentiary criteria should include attention to their culturally contingent beliefs about health.

Structural Conditions Promoting Research Integrity in Clinical Trials

Charles W. Lidz, Ph.D., University of Massachusetts Medical School
William Gardner, Ph.D., University of Pittsburgh Medical School

Objective: Pharmacological clinical trials are an important site for concerns about research integrity and financial conflicts of interest. On one hand, the research is time consuming and expensive, on the other hand, it is heavily subsidized by the pharmaceutical manufacturers. We wanted to learn more about clinical investigators' views about a) what research integrity problems were most important in pharmaceutical clinical trials, and b) what structural conditions in the conduct of trials promote or hinder such violations. **Design:** As a preliminary phase to developing a survey of pharmacological clinical investigators, we did intensive interviews with 13 clinical investigators each with substantial experience in various aspects of clinical trials. Investigators saw issues of research integrity as legitimate problems and shared their experiences with designing and implementing trials and their difficulties. The interviews were transcribed and thoroughly reviewed to identify areas of concern to the interviewees and the pressures that they saw as promoting these violations. The methodology is limited in that the sample is small and includes only university medical researchers. **Results:** Our interviewees participated in both federally-sponsored trials and industry-sponsored trials, but investigators reported that industry trials were the locus of integrity problems. Interestingly, investigators reported little concern about data fabrication. Instead, they focused on concerns about subject recruitment and the reporting of results. Concerning recruitment, interviewees reported concerns that other investigators manipulated clinical data about patients who were potential subjects to justify including those patients. Companies were seen as designing studies with inclusion criteria that limited the study to unrepresentatively healthy patients, to maximize the drug's apparent effectiveness and safety. Integrity issues were also described in the reporting of results. Investigators were perceived as signing papers that they had not written, or even adequately reviewed, and as sometimes using company prepared slides that were not consistent with the findings. Companies were described as failing to report negative data (especially for new uses of approved medications) and "spinning" the discussion section of articles. The interviewees also noted that companies sponsored many ghost written articles and slides. Investigators described factors that may contribute to integrity problems in recruitment, including large per capita payments and authorships on scientific papers as rewards for high recruiters. These incentives were particularly important when combined with financial and publication pressures in university based medical

centers. The primary factors promoting problems in the reporting of results included large disparities between industry research support compared to federal support, and the high level of sponsor control in many industry trials compared to investigator control in federal trials. Investigators felt that violations by companies were more likely when there were extraordinary financial stakes (e.g. in biotech startups). However, they also noted that intense industry concern about data quality and documentation (and the FDA's careful monitoring of it) may make the actual *data*, as opposed to their interpretation, more reliable in industry trials.

Normative Models of Data Management

David B. Resnik, Ph.D., Department of Medical Humanities, The Brody School of Medicine, East Carolina University

A normative model of human behavior posits prescribes norms (or principles or standards of conduct) that people should follow in a particular activity. The norms in such a model are based on overall understanding the goals of the activity. While a normative model can be useful in providing general guidance, it can help us to understand and explain variations in human behavior, including conformity to the norms posited by the model as well as deviations from those norms. This presentation will propose, describe and discuss six normative models of data management: the peer review model, the personal notes model, the laboratory management model, the intellectual property model, the compliance model, and the patient safety model. These six models can be distinguished insofar as they endorse different goals for data management. The peer review model holds that the goal of data management is to produce replicable results; the personal notes model claims that the goal of data management is to provide the researcher with notes that will be useful in the discovery process; the laboratory management model holds that the goal of data management is to facilitate communication among researchers in the same laboratory; the intellectual property model contends that the goal of data management is to establish and protect intellectual property claims; the compliance model holds that the goal of data management is to conform to federal regulations and to avoid fraud and misconduct; and the patient safety model holds that the goal of data management is to enable researchers to protect patients from harm during clinical trials. More than one model of data management may apply to any given research context; in some situations, such as clinical trials, all six models may come into play. Since the norms associated with these different models may sometimes conflict, researchers may therefore face ethical dilemmas concerning data management practices.

Vaccine Safety: A Case Study of the Impact of Privacy Concerns on Public Health Research

Deborah Shatin, Ph.D., Center for Health Care Policy and Evaluation, UnitedHealth Group
Bharati Manda, M.S., Center for Health Care Policy and Evaluation, UnitedHealth Group

Objective: This two-phase vaccine safety study with CDC and other managed care organizations investigated the relationship between the childhood rotavirus vaccination and intussusception. Medical record abstraction for case validation took place at two times, providing a unique opportunity to compare the effect of privacy concerns over time. **Design:** We identified potential cases of intussusception using administrative claims, followed by medical record validation of case and vaccination status (exposed and unexposed cohorts). The research was conducted in two stages since there was a need for both immediate (Phase I) and long term results (Phase II), allowing for empirical comparison of the ability to abstract records before and after passage of HIPAA (December 2000). Phase I took place from 11/1/99 to 1/31/00 and Phase II between 5/1/01and 9/30/01.* **Results:** For Phase I, 35 potential cases of intussusception were identified from claims data of 8 UnitedHealth Group-affiliated health plans. Medical record abstraction was completed for all 63 records (35 cases), a 100% completion rate. In Phase II (after HIPAA was passed but not implemented), of the 37 medical records identified, 27 charts (23 cases) were abstracted with a 73% completion rate. Ten could not be abstracted: 4 (11%) with no record; 4 (11%) refused to release the chart or did not respond, and 2 (5%) required site-specific IRB approval (obtained) and informed consent, although the study had IRB approval with a waiver of informed consent. **Conclusions:** The difference in our ability to conduct medical records research (73% vs 100% completion rate) due to concerns about privacy, raises questions about the future conduct of scientific public health research. There was greater reluctance by providers to release charts during Phase 2. Also, time and effort for medical abstraction activities increased substantially. Finally, nurse abstractors expressed concern about HIPAA and patient privacy.

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*Results of the initial study were published in *The Pediatric Infectious Diseases Journal* in April 2001 (20(7):410-416.

6b. Instruction in the Responsible Conduct of Research, Sunday, 3:15-5:00 p.m. (Bebeau)

Assessing Teaching and Learning in the Responsible Conduct of Research

Kenneth D. Pimple, Ph.D., Indiana University-Bloomington

Objective: To establish whether, and to what degree, the responsible conduct of research (RCR) can be taught, the quality of student learning in RCR can be assessed, and the effectiveness of programs in teaching RCR can be evaluated. RCR is understood as a proper understanding of responsible research practices and the ability to recognize and solve ethical problems in research. **Design:** Literature search and analysis. **Results:** The report distinguishes *student assessment* from *program evaluation*, describes available *methods for teaching and assessment*, summarizes some of the *distinctive challenges* inherent in teaching and assessment in ethics, and touches on the generally *underdeveloped state of assessment and evaluation* of teaching in research ethics. The report also *describes the five teaching modules* in the responsible conduct of research, all offered in colleges and universities in the United States, uncovered by the literature search. All five include some description of assessment or evaluation and use either case study discussion or role playing, requiring students' active involvement rather than passive reception of information. The report also summarizes *publications about eight courses or training programs* in the responsible conduct of research. Again, all of the publications include some description of assessment and/or evaluation; the level of rigor varies. Special attention is devoted to *moral reasoning*, a particularly well-studied and well-developed field that can be easily applied to RCR. **Conclusions:** This study demonstrates that methods for teaching, assessing, and evaluating research ethics exist, but additional methods would be welcome. It is clear that (a) research ethics can be taught, (b) the quality of student learning in research ethics can be assessed, and (c) the effectiveness of programs in teaching research ethics can be evaluated.

Making Connections: Strategies in Teaching Responsible Conduct of Research to Undergraduates

Thomas G. Pistole, Ph.D., University of New Hampshire

Most instructional programs for teaching responsible conduct of research (RCR) are aimed at individuals with significant experience in research. Undergraduate students often have difficulty relating to the examples and case studies that accompany such programs. The teaching experience reported here was designed to bridge this gap by providing direct experiences relating RCR

instruction to undergraduate students. The RCR topic chosen was authorship and peer review. Junior and Senior students majoring in the biological sciences participated in a double-blinded process for peer review in which each student served as both author and reviewer. Each author received 2-3 peer reviews plus an overall assessment from the instructor/editor. In some cases students were invited to resubmit manuscripts based on the reviewers' comments. These students had written papers but, until this experience, such papers were evaluated by a single person—the instructor. Few had had prior experience with formal peer review. Based on six cohorts of students totaling ~130, these activities provide the following experiences. *A.* Students understand the challenges of writing to anonymous reviewers rather than a known instructor. *B.* Students face the challenge of reviewing manuscripts from classmates. *C.* Students experience the ambivalence of receiving differing and, in some cases, conflicting assessments of their writing. *D.* Students are given a context for evaluating their comments as a reviewer compared to those from others reviewing the same manuscript. *E.* Students have the opportunity to respond to the peer reviews, either by modifying the manuscript or by challenging the reviewers' comments. Following this experience, these students are better able to understand the challenges inherent in peer review, including the potential for abusing this widespread form of professional assessment.

Research Ethics and University Study of Science

Edward Sankowski, Ph.D., Currently at University of Oklahoma

Objective: The aim of this paper is to describe a process by which a university might reasonably foster doctoral science student education about the ethics of scientific research. **Design:** The paper outlines a possible process (somewhat resembling an actual ongoing academic planning process in which the author is involved) by which a science department at a research university could develop an “ethics of scientific research” aspect of its doctoral program. The paper not only describes such a process practically, but also offers a rationale for why this is a desirable process. **Results:** Some needed innovations in doctoral science education at present arguably include educating prospective scientists about the societal context of scientific research, including normative ethical and political (also legal) aspects of research activity. There are national-level initiatives aiming to produce experiments in doctoral education. One form such experimentation can reasonably take is clarifying in graduate science education ethical attitudes already part of scientific research activity, and examining their justifiability in changing circumstances. Another form such experimentation can take is the interdisciplinary incorporation into science education of some subject matter and methods

about ethics not usually thought of as part of science. This paper suggests that a science department can often progress by making one appropriate ethics course available to its doctoral science students. This course and other curriculum changes might address a variable mix of topics, including, for example, the ethics of federal regulation of research. "Ethics" should be conceived as continuous with the normative ethics of democracy. **Conclusions:** Course and curriculum changes should clarify the obligations of research scientists at universities to inform themselves about and reflect on ethical issues themselves, as well as to educate their doctoral students. Empirical (and ethically informed) study of the effectiveness of such a course and related possible initiatives will be important.

Web-Based Training in Research Ethics: Protecting Privacy and Confidentiality of Research Participants

Angela R. Holder, Duke University
Carole Cain, Duke University
Ann Bushyhead, Duke University
Jeremy Sugarman, M.D., M.P.H., M.A., Duke University

Objective: Those involved with research with human participants and its oversight must be aware of their ethical and legal obligations to protect the confidentiality and privacy of research participants. These issues have become increasingly complex as a result of the new requirements of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). We developed a web-based educational module for researchers, key research personnel, and members of Institutional Review Boards detailing these obligations hoping to provide an accessible method of teaching the responsible conduct of research concerning these aspects of data management and of the responsible conduct of research. **Design:** We reviewed the regulations issued by the Department of Health and Human Services under HIPAA and reviewed articles on protecting privacy and confidentiality in the ethics, medical, and legal literature. Based on this review we set four learning objectives: 1) distinguish between privacy and confidentiality; 2) describe the importance of these concepts in the context of research; 3) describe the possible effects on participants whose information is wrongly disclosed; and 4) describe the federal requirements for maintaining confidentiality. We then created a script, slides to emphasize important content areas, and a content quiz. Experts on the ethics and regulation of research, and on the computerization of medical and research records, then reviewed the draft materials. Revised materials were pilot tested with

researchers and underwent further revision. A professional narrator recorded the presentation. Three viewing options were created: streaming audio and slides; web based text and slides; printable text and slides. **Results:** Data from the first 367 learners suggest that the module was well received and was successful in meeting the learning objectives. Learners used each of the viewing options, but the majority (70.4%) elected to use text and slides, with 20% using streaming audio, and 9.6% the print version. Most (89.5%) learners found this online approach to be convenient, were satisfied with the content (88% mostly or completely satisfied) and the presentation style (86.6% mostly or completely satisfied). The overwhelming majority (81.3%) rated the presentation to be above average or outstanding. Similarly, 79.4% found the content to be above average or outstanding. In terms of meeting each the learning objectives, learners indicating "mostly" or "completely" were: 90.2% for distinguishing between privacy and confidentiality; 90.2% for describing the importance of these concepts in the context of research; 86.3% for describing the possible effects on participants whose information is wrongly disclosed; and 85.8% for describing the federal requirements for maintaining confidentiality. Preliminary qualitative analysis of open ended-responses supports the idea that this module accomplished these objectives, with many suggesting that learners intend to change their practice based upon the information gleaned from the module. We conclude that web-based modules can be a useful and accessible means of teaching some aspects of the responsible conduct of research.

Teaching Research Integrity and Bioethics to Undergraduate Students

Julio F. Turrens, Ph.D., Department of Biomedical Sciences, University of South Alabama
W. Curtis Small, Ph.D., Division of Science and Mathematics, Jacksonville University

Four years ago we introduced a course entitled "Issues in Biomedical Sciences" aimed at increasing students' awareness about bioethical questions and issues of academic and research integrity. At the end of the course students completed an anonymous survey to estimate whether the course changed their perception of some of these issues. This abstract summarizes the results from 54 surveys returned out of approximately 125. Almost 80% of the students stated that as a result of having taken this course: a) their initial approach to bioethical issues as well as their ability to articulate their views concerning these issues, has improved; b) despite of their initial "gut reaction", they now look at both sides of the problem before reaching a conclusion, and they are more likely to question their initial reactions. We also asked students if they perceived changes in their attitude towards issues concerning academic integrity. Half of the respondents stated that they had knowingly cheated,

while 43% indicated that they had cheated but were not aware of it at the time. Of these, 90% and 83% indicated that they would be less likely to commit acts of academic misconduct as a result of the course. Ten percent of those who cheated indicated that the course did not change their attitudes. Yet, 65% of all the surveys indicated that they would be less likely to indulge in unethical behavior. Incidentally, last year two students plagiarized the complete text of their paper from the Internet. In summary, although it is impossible to determine at this point if the students' personal attitudes will change as a result of a single course, it appears that most undergraduate students benefit from a candid discussion on what constitutes appropriate ethical behavior. It is our hope that their heightened perception will strengthen their professional standards.

7. Publication, Monday, 8:30-10:00 a.m. (Silverman)

Rejected Authors' Perceptions of the Review Process at a General Medical Journal

Helen Barratt, British Medical Journal

Sara Schroter, Ph.D., British Medical Journal

Richard Smith, M.D., British Medical Journal

Objective: The selection of research published can impact upon the integrity of the scientific research record. It is important that authors understand why their research has been rejected as this may influence the content of their future submissions. We investigated whether authors who received no explanation of why their paper was rejected were more or less satisfied with the review process than authors who received a standardised form indicating main reasons for their rejection.

Design: Consecutive authors whose papers were rejected by *BMJ* without peer review were randomised to two groups to receive either a standard rejection letter providing no reasons (Group 1) or a standardised form indicating main reasons for rejection (Group 2) as well as a questionnaire measuring level of satisfaction with the review process, time taken, method of rejection and their likeliness to submit to *BMJ* in the future. Differences between groups were tested using independent t-tests. **Results:** 101/218 (46%) response rate. No significant difference between groups for each satisfaction item ($p>0.05$); a similar level of dissatisfaction was reported by both groups, suggesting that it was not the method *per se*, but the rejection itself that influenced this. Several authors in both groups felt that their paper had not been given due consideration. Whilst some in Group 1 disliked the lack of reasons given for rejection, some in Group 2 felt that the reasons given were insufficient.

Conclusions: Few studies have evaluated the process by which papers are rejected from a journal. Ours is the first to investigate the impact of different methods of rejection on author satisfaction. This is potentially of importance not only to the research community at large, as the experience of rejection might influence researchers' likelihood of submitting future articles and consequently what gets published, but also to individual journals as they seek to maintain high quality research input.

Analysis of Research Contributions in a Small Journal: A Study of Contributorship Statements by Corresponding Authors in the Croatian Medical Journal

Matko Marusic, M.D., Ph.D., Zagreb University School of Medicine
Jadranka Bozikov, M.D. Ph.D., Zagreb University School of Medicine
Vedran Katavic, M.D., Ph.D., Zagreb University School of Medicine
Darko Hren, B.S., Zagreb University School of Medicine
Marko Kljakovic-Gaspic student, Zagreb University School of Medicine
Ana Marusic, M.D., Ph.D., Zagreb University School of Medicine

Objective: To analyze the authors' contributions described by the corresponding author in the Croatian Medical Journal and examine their qualification for authorship according to the authorship criteria of the International Committee of Medical Journal Editors (ICMJE). **Design:** We analyzed statements on research contribution of individual authors of 114 research articles submitted to the CMJ from 1999 to 2000 representing 475 authors. The corresponding authors chose the contributions of every coauthor from the ICMJE authorship criteria list A) conception and design, or analysis and interpretation of data; B) drafting the article or critical revision of the manuscript; and C) final approval of the article. Authorship was defined as A AND B AND C. We also considered relaxed authorship criteria: A OR B OR C. **Results:** Only 6.5% of authors met the ICMJE criteria for authorship, whereas nearly 45% satisfied the relaxed criteria. Among all manuscripts, true authorship according to the strict criteria was found for only 20%, while the rest met the relaxed criteria. Percentages of authors satisfying each of the three conditions A-C were 70%, 55%, and 39% respectively, indicating that the final approval of the article was the weakest part of the authorship definition. **Conclusions:** Adherence to ICMJE authorship criteria is poor. It is likely that corresponding authors do not read the authorship definitions provided on the contributorship form but rather share offered categories of contributions among the authors in the byline. We need to redefine the authorship/contributorship definition.

The Role of Journals in the Responsible Conduct of Research: An Area for Further Research

Stanley G. Korenman, M.D., David Geffen School of Medicine at UCLA

Recently, there has been renewed attention to the ethical responsibilities of scientific journals their reviewers and editors. Responsible publication has always been a critical element in science because

of the interdependence of investigations and the incremental nature of scientific progress. It is only because grievous errors are relatively uncommon that science progresses so well. However, many papers are wrong or misleading, and that is particularly pertinent to clinical investigations where the promotion of ineffective or unsafe agents or devices can directly affect many lives. Scientific and professional journals attempt to maintain the integrity of the research record by: 1) Requiring accountability from authors, 2) Maintaining a competent and objective review process, 3) Ensuring adherence to ethical practices, 4) Publishing errata, retractions and letters to the editor, and 5) Disclosing conflicts of interest. I propose to argue that even major publications continue to fulfill these responsibilities poorly and that recent policy revisions while improvements, leave much to be desired and that further research will clarify their role in research integrity. I focus on reports of sponsor-supported clinical trials although the problems are much more pervasive. The recent agreement by major journals on identification of sources of funding and contributions of each author as well as explicit acknowledgement of additional contributors and sources of information constitute useful advances. Author accountability is difficult to attain in large multicenter trials. One area of particular importance is serious adverse events (AEs). These must be reported to the sponsor and the FDA but individual investigators might see their views, particularly as to whether an AE was related to the intervention, ignored. For clinical trials, Data and Safety monitoring Boards (DSMB) are required and they provide very important monitoring and review functions. Do they have a role in the editorial review process? In multicenter trials all information has been held in the hands of the sponsor who paid for it and, for good reason, wants sample testing and procedure evaluations to be carried out centrally. The editors' requirement for independent data review and analysis is highly commendable but the nature of the review group has not been spelled out and conflicts of interest may be prevalent. In the realm of competent and objective review, do editors with COIs routinely recuse themselves and are potential reviewers asked explicitly about conflicts of interest prior to receiving an article. How about Journal COIs? There are benefits to publishing positive clinical trials. Is the perception that large clinical trials receive relatively poor reviews correct? The problem is that the review doesn't focus enough on whether the study is well designed as a whole. Publication issues surrounding adherence to ethical practices should perhaps go beyond ensuring that the study made it through an IRB. Should reviewers separately consider coercion, therapeutic misconception, risks vs benefits, justification of use of placebo, disclosure of COIs, attention to cultural differences? These will be discussed in terms of a research agenda.

Recycling Portions of Text from the Same Author/s' Previously Published Papers in Psychology: An Exploratory Study

Miguel Roig, Ph.D., St. John's University

Objective: The present study was conducted to explore the extent to which authors of journal articles use portions of text from their previously published papers. **Design:** Nine journal articles were selected as 'target' papers from an issue of a psychology journal published in 2002. Up to 3 of the most recent references written by either the senior author or a co-author of the target paper were obtained. Using a conventional scanner, each of the target papers and their associated references were converted to electronic text files. These files were then compared using a computer program designed to identify strings of words common to two text files (i.e., target and reference). **Results:** Only one of the 9 target papers was found to contain text strings from one of its references. For this target paper, at least 30 text strings of 6 words or longer were identified in one of the reference papers. No single sentence from the target paper, however, was found to be identical to any other sentence in the reference paper. To determine whether text recycling might occur elsewhere, the reference papers from each of the target articles were compared against each other. The new comparison revealed 6 separate pairs of articles that shared text in common with one another. An analysis of these instances of text recycling indicated a similar pattern of appropriation as described above. Furthermore, in 5 of the 6 cases, the recycled text was typically confined to "Subjects" and/or "Procedure" subsections of "Method" sections, though text strings having as many as 50 consecutive words were found to be identical in one set of papers. **Conclusions:** The results suggest that same-authored text recycling may not be uncommon, but when it does occur it is usually confined to complex methodological descriptions of a research design or procedure.

8. Medical Ethics, Monday, 8:30-10:00 a.m. (Friedman)

Exception from Informed Consent for Emergency Research: The Experience of the Public Access Defibrillation Trial

Vincent N. Mosseso, Lawrence H. Brown, Shannon W. Stephens, Tom P. Aufderheide, Richard A. Craven, Terri A. Schmidt, Andrew Travers, Myron L. Weisfeldt, Leon Greene and the PAD Investigators

Objective: The Public Access Defibrillation (PAD) Trial is a multicenter randomized-controlled study examining the effectiveness of placing automated external defibrillators in public places for use by trained non-medical volunteers. The aim of this paper is to describe the experiences of the PAD sites in obtaining Institutional Review Board (IRB) approval for the study under the guidelines for exception from informed consent for emergency research (21 CRF 50.24). **Design:** Twenty-four North American sites are participating in the PAD trial. The central coordinating center tracked IRB submission and approval dates and collected each site's protocol and methods for meeting the requirements of 21 CFR 50.24, including their community consultation (CC) and public disclosure (PD) activities. **Results:** All 24 sites were successful in gaining IRB approval for the PAD study. Thus far, 101 different IRBs have approved the PAD protocol. The primary IRBs requested an average of 2 revisions (range 0 to 7), with an average of 1 major revision (range 0 to 6). Ten (42%) of the sites found the IRB process significantly harder than usual, 6 (25%) found the process a little harder than usual, 7 (29%) found the process neither harder nor easier than usual, and 1 (4%) found the process a little easier than usual. No common procedure was used by all of the IRBs for demonstrating compliance with the 21 CFR 50.24 requirements. Most commonly sites submitted the international PAD protocol (n=20) and other appendices (n=19). There was also great variability in the types and numbers of CC/PD activities required at each site. The reported costs for the CC/PD activities totaled $31,560. **Conclusions:** Although there is great variability in the administration of the regulations enabling exception from informed consent, the PAD Trial experience suggests that multi-center studies can be successfully completed under the 21 CFR 50.24 regulations.

Reactions to Research Involving Sensitive Issues in Two Vulnerable Groups: Implications for Institutional Review Boards

Mary Ann Dutton, Ph.D. Georgetown University Medical Center
Cathy Spatz Widom, Ph.D., UMDNJ - New Jersey Medical School

Objective: The purpose of this paper is to address the potential concern of research with human subjects involving vulnerable populations' response interview questions pertaining to prior experiences of a traumatic nature and other sensitive issues, including invasive biological methods. Specifically, we report descriptive data concerning research participants' reactions to their involvement in two separate studies, both of which focus on participants' experience involving traumatic life events. Second, we examined differences in respondents' reactions to involvement in these studies based on gender, race, and on whether they currently meet criteria for posttraumatic stress disorder (PTSD). Finally, correlations between measure items and subscales are considered. **Design:** Participants in two longitudinal studies were asked to complete questions pertaining to their reactions to participating in the research project using the 18-item Reactions to Research Participation Questionnaire (RRPQ; Newman, et al., 2000). Items were rated using 5-point Likert-type scales. High scores indicated more positive ratings. Participants in Study 1 were 406 battered women recruited into a longitudinal study from domestic violence courts and a shelter in the Mid-Atlantic region. The sample was predominately urban African American (81.3%) and low income. The mean age was 32.5 years (S.D. = 8.7). Participants in Study 2 were 502 individuals who had grown up in the midwest during the late 1960s and early 1970s and who had a range of life experiences, including childhood trauma. The sample was 55.6% female, 64.3% white, and 33.7% black. The mean age of the sample was 39.8 years (SD = 3.5). The sample is skewed toward the lower end of the socio-economic spectrum. **Results:** Across the two studies, mean item scores ranged from 2.5 to 4.9, indicating that participants rated all items at or above the median in the direction of positive appraisal. Mean score ratings for the five RRPQ subscales indicate uniformly positive mean ratings (range from M = 3.0, SD = 1.3 for Emotional Reaction to M = 4.9, SD = .4 for Research Participation measuring general satisfaction). Examination of factors related to participants' ratings of their reactions to involvement in research interviews found no significant differences for race (Study 1) or gender (Study 2). Participants with PTSD rated their experience significantly more positively on four of eight items from the RRPQ included in this study (Study2). Examination of PTSD comparisons in Study 1 involved subscale scores. Participants with PTSD in

Study 2 rated their participation as involving greater emotional reaction than those without PTSD. However, PTSD+ participants were no different in their ratings of the other subscales measuring general satisfaction with participation, personal benefits, drawbacks, or evaluation of research practices. Correlations between RRPQ subscales in Study 1 revealed that higher Emotional Reaction was weakly correlated with a higher Personal Benefit (r = -.18. $p \leq$;001), but also higher Drawbacks (r = .12. $p \leq$;05). These findings are similar to those with college students in the normative sample (Newman et al., 2000). Finally, correlations in Study 2 between two items measuring intense emotions were positive correlated with finding the study meaningful (r = .29, $p \leq$;001 for raised emotional issues; r = .34, $p \leq$;001 for experienced intense emotions). These findings provide preliminary evidence to suggest that participation in research with vulnerable populations involving sensitive information about their trauma experiences overall is rated positively by participants. Further, participants' greater emotional reactions are related to greater benefit. Implications for consideration of human subjects issues will be discussed.

Can Tuskeegee Happen Again? A Survey of Physicians About Lack of Consent in Research Trials

Neil J. Farber, M.D., Christiana Care Health System, Wilmington, DE;
Jerry Castellano, Pharm.D., Christiana Care Health System, Wilmington, DE;
Brian M. Aboff, M.D., Christiana Care Health System, Wilmington, DE;
Maria R. DeJoseph, M.D., Christiana Care Health System, Wilmington, DE;
Joan Weiner, Ph.D., Drexel University, Philadelphia, PA;
E. Gil Boyer, Ed.D., St. Joseph's University, Philadelphia, PA

Objective: We surveyed physicians on their attitudes about entering patients who did not give informed consent or who were of a vulnerable population into clinical trials. **Design:** A survey instrument asked physicians about whether 10 hypothetical patients, who could not give informed consent due to cognitive deficits or who were of a vulnerable population, could be enrolled in phase I trials. The association of demographic variables with the number of scenarios viewed as completely or somewhat acceptable was analyzed via student's T tests or ANOVA as applicable. All significant ($p < 0.01$) variables were entered into a multiple logistic regression model. **Results:** Of the 961 surveys which were received by subjects, 400 (42%) were completed and returned. Many of the physicians approved of entering the patients of the 10 scenarios into clinical trials; 84% indicated that at least one of the case scenarios was acceptable. Having performed clinical trials was

associated with fewer scenarios as being viewed as acceptable ($p = 0.006$), while having served in the military ($p = 0.036$) and approving of the death penalty ($p < 0.001$) were associated with a larger number of approved scenarios. However, a majority of all subgroups including those who conduct clinical trials and who sit on institutional review boards (IRBs) approved of at least one case scenario. **Conclusions:** Physicians approved of the entry of at least some patients who cannot give informed consent or who are of a vulnerable population into clinical trials, despite both ethical and federal guidelines to the contrary. Training in these issues was not associated with physicians' decisions. More effective education on the ethical and federal guidelines involving clinical research should be made available. There should also be assurance that physicians who conduct clinical trials or who sit on IRBs have the requisite knowledge about the ethics of clinical research.

The Level and Probability of Risk in Conducting Late-Night Blood Alcohol Level Testing with College Students

R. Scott Olds, Ph.D., Kent State University

Dennis L. Thombs, Ph.D., Kent State University

Objective: Field research in the behavioral sciences typically involves minimal risk. However, sometimes IRB members may not accurately interpret minimal risk because they tend to (a) overestimate the prevalence of risk behavior in the environment and (b) focus on "worst-case scenarios." The *probability* and *level* of risk are two criteria that should be weighed in determining minimal risk in behavioral science field research. This proposal illustrates the importance of applying these dual criteria in a field study that assessed blood alcohol levels (BAL) among college students returning home late at night. **Design:** The late-night prevalence of blood alcohol levels on the campus of Kent State University was assessed over a course of a seven-month period. On Wednesday through Saturday nights, students were intercepted between the hours of 10:00 p.m. and 3:00 a.m. as they returned to their residence hall for the evening. They were asked to voluntarily and anonymously respond to a brief set of interview questions and to provide a breath sample (to determine their BAL). Feedback about their BAL was withheld out of concern that some might be disappointed in their reading and return to drinking that night to raise their level of intoxication. The project's objectives were to (a) compare campus BAL data and campus self-report data as means of estimating intoxication levels achieved by students and (b) to test the hypothesis that college students generally overestimate the amount of drinking done by peers. **Results:** In reviewing the proposed study, members of the university IRB were concerned about the ethics of not intervening, that night

and the next day, with students who registered "high" BALs. Some IRB members believed that the risks of identifying high BALs were so severe that they would generate an obligation to provide these students with special assistance to address their alcohol abuse. While other members disagreed, there was no attention given to the *probability* of identifying high BALs. After considerable debate, the IRB granted approval to conduct the study. The findings from the field research suggest that IRB's might consider placing greater emphasis on risk probability in determining minimal risk. During the course of the study, 49.8% had BALs of 0.00 (no drinking), and less than less than 14.3% of students were found to have BAL measures greater than or equal to .10, the illegal limit for impaired driving in Ohio. Furthermore, less than 1% of the students had a BAL greater than or equal to .20, a reading indicating severe intoxication. The researchers believe that both the probability and level of risk of intoxication to the students, as a group, was very low in this study. The problem of undergraduate drinking is controversial, and students under the age of 21 are violating state law by consuming alcohol. Nevertheless, the IRB application process and the subsequent findings of this study suggest that the protection of human subjects would benefit from a revision and clarification of standards for determining minimal risk in behavioral science field research. Where the research literature on a risk behavior is inadequate or where probability of risk to human subjects is difficult to estimate, IRB's may consider permitting small pilot studies to identify the parameters of risk that will be identified or created by a study procedure.

9. Assessing Integrity in Research, Monday, 10:30 a.m. - 12:30 p.m. (Yeager)

Development of a Measure of Climate in Scientific Organizations

Blaine Gaddis, The University of Oklahoma
Shane Connelly, The University of Oklahoma
Michael Mumford, The University of Oklahoma

The purpose of this paper is to describe the development and construction of a new measure of organizational climate. Specifically, this measure was developed in order to understand the various ethical and creative aspects of organizational climate, or academic departmental climate in university settings, in organizations where scientific and academic research is conducted. A new and comprehensive measure with applications and utility across multiple scientific and academic research contexts is developed for the purpose of investigating how scientists' differential exposures and perceptions of organizational climate interact with the complex nature of scientific work to influence ethical decision-making. These applications will meet needs currently not addressed by existing organizational climate inventories.

Development of Two Measures of Scientific Integrity

Whitney Helton-Fauth, The University of Oklahoma
Ginamarie Scott, The University of Oklahoma
Blaine Gaddis, The University of Oklahoma
Amber Shaffer, The University of Oklahoma
Michael Mumford, The University of Oklahoma
Lynn Devenport, The University of Oklahoma
Shane Connelly, The University of Oklahoma
Ryan Brown, The University of Oklahoma

The intent of the current paper is to describe the development of two measures of scientific integrity, the *Review Board Measure* and the *Ethical Decision-Making Measure*. These measures were developed as unobtrusive measures intended to evaluate integrity in scientific endeavors. These measures are expected to evaluate the likelihood of making ethical scientific choices in various types of situations. Additionally, they will assess how the tendency to make more quality or creative decisions may be related to integrity in scientific contexts.

Gatekeeping Scientific Research: The Case of Data Editing

Erin Leahey, Ph.D., University of Arizona

Editing data is a common and significant step in all kinds of quantitative research. There is much evidence that individual data editing strategies can have both scientific (i.e., it can affect results) and ethical (i.e., it can further support hypotheses) implications. In previous research, I found that when researchers confront data that are seemingly anomalous, illogical, or wrong, they respond in a wide variety of ways because there are few formal sources of guidance on how to clean dirty data. This diversity of practice may further compromise scientific validity and comparability. Given a) the significance of data editing, b) the paucity of instructional guidance, and c) the traditionally strong influence that gatekeepers have over research practice, I investigated the extent to which gatekeepers monitor data editing practice. I conducted 30 in-depth interviews with scientific gatekeepers, including journal editors, funding agency directors, and Institutional Review Board chairs. Analyses of these data suggest that gatekeepers' typical authority over research is limited when it comes to data editing. While IRBs and funding agencies assess research proposals and journal editors assess research products, no gatekeeping body oversees middle stages of research where data editing is likely to occur. Moreover, IRBs review research ethics, and funding agencies and journals review research methods, but no gatekeeping body oversees practices that span these domains, such as data editing Given the limited influence that gatekeepers have over data editing, but with an understanding of the limitations of regulations (due to the specificity of each situation as well as the autonomy of professional scientists), I ruminate about the possibilities for promoting responsible data cleaning practice in the social sciences. I recommend that gatekeepers encourage scientists to identify, define, and openly discuss data editing practices that currently fall outside the domains and stages of gatekeeping activity.

Survey of Quality Assurance Procedures Used in Clinical Trials

Yuan-I. Min, Ph.D., Johns Hopkins Center for Clinical Trials
Susan Tonascia, S.cM., Johns Hopkins Center for Clinical Trials
Janet Holbrook, Ph.D., Johns Hopkins Center for Clinical Trials
Shangqian Qi, M.D., Johns Hopkins Center for Clinical Trials
Harry Marks, Ph.D., Johns Hopkins Center for Clinical Trials
Curtis Meinert, Ph.D., Johns Hopkins Center for Clinical Trials

Objective: Data quality and data integrity are of paramount importance for valid conclusions to be drawn from clinical trials. However, few data are available assessing quality assurance procedures that have been used across clinical trials. The aim of this study is to describe quality assurance procedures that have been used in clinical trials and their perceived utility in ensuring data quality and data integrity. **Method:** A survey questionnaire has been developed to collect information on quality assurance procedures used and their perceived utility in clinical trials. Trials to be surveyed were identified and sampled from publications between 1995 and 2001 in five major medical journals including Annals of Internal Medicine, British Medical Journal, Journal of American Medical Association, Lancet and New England Journal of Medicine with National Library of Medicine (NLM) designation "clinical trial" and "journal article" as publication type. Sampling was stratified by "multicenter" versus "non-multicenter" trials according to NLM designation of publication type and 250 publications from each stratum were selected using systematic random sampling technique sorted by year of publication. Survey questionnaires are being mailed to the corresponding authors for the selected publications to complete. Quality assurance procedures used will be compared and contrasted by trial characteristics, such as trial design and funding source, which will be abstracted from published reports. Reporting of quality assurance procedures in the publications also will be tracked. **Results:** The research team has finalized the survey questionnaire and obtained IRB approval. The questionnaires are now being mailed out to solicit participation. No finding is yet available. We will report progress of the project and are expecting some results in the following areas: 1) Quality of clinical trial publications in terms of providing information, such as trial design, necessary for evaluating trial results, 2. Reporting of quality assurance procedures in clinical trial publications, 3. Quality assurance procedures used and their perceived utility in clinical trials. Quality assurance procedures used will be compared and contrasted by trial characteristics, and 4. Areas for improvement may be identified.

Alphabetical List of Presenters