



Science Misconduct: Detection and Risk Mitigation

Ethics, Policy and
Compliance: Achieving a
Culture of Integrity in
Research

Sheryl Tartar Dacso, JD, DrPH
Partner, Brown McCarroll LLP

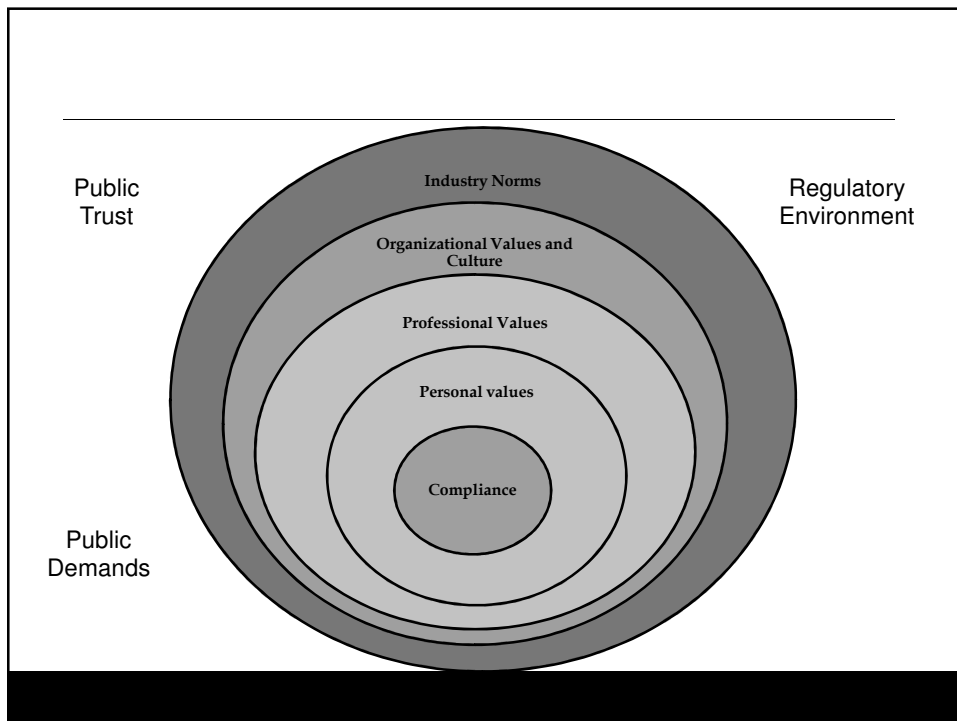
Susan S. Night, JD, LLM
Fellow, Baylor College of Medicine

Agenda

- Introductory Exercise (15 min)
- Research Misconduct
- Ethics, Policy and Compliance
- Research Integrity
- Compliance and Culture
- Putting It Together (20 min)



Introductory Exercise



Identifying Barriers to Achieving Compliance

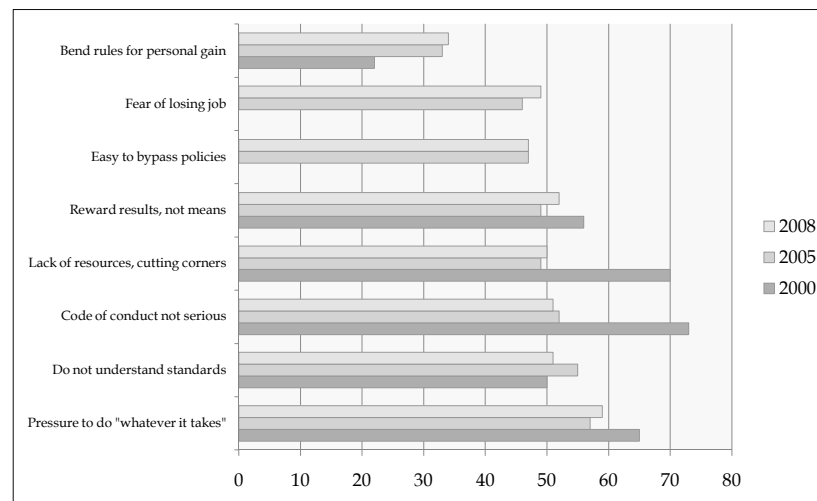
- **Personal Values**
 - Motivations
 - Beliefs
 - Outside obligations
 - Type of research
- **Professional Values**
 - Physician/investigator
 - Code of Ethics
 - CRO, SMO
- **Organizational Culture**
 - Academia, hospital, private practice
 - Attitude toward compliance
 - Sponsor, funder, CRO/SRO, investigator, coordinator, recruiter, clinical
- **Industry Norms**
 - Funding source (private industry, federal government, foundation)
- **Public Trust**
 - Response to type of research (stem cell, gene therapy)
 - Trial recruitment
- **Public Demand**
 - Immediate need/demand for product (Influenza, HIV, SARS)
 - Impact of advocacy groups (cancer, diabetes)
- **Regulatory Environment**
 - Phase I, II, III, IV
 - VA
 - DOD
 - PHS or FDA
 - Domestic or Foreign

Introduction to
RESEARCH MISCONDUCT

Defining Research Misconduct

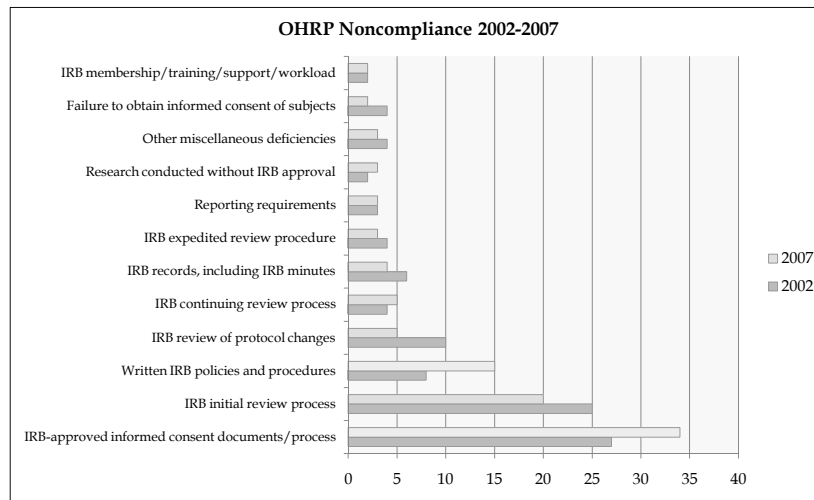
- Research misconduct occurs in many forms including:
 - Fabrication - making up data or results and recording or reporting them.
 - Falsification - manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - Plagiarism - the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - Research involving humans
 - Research involving animals
 - Research that includes testing and evaluating drugs, food and feed additives, human biological products and medical devices
 - Mismanagement of research funds
 - Conflicts of interest
- Research Misconduct does not include honest error or differences of opinion

Root Causes of Misconduct



KPMG Forensic, Integrity Survey 2005-2006 and 2008-2009

Types of Misconduct in Human Subject Research



Weil, C et al, *IRB: Ethics & Human Research* 2010

Why Mitigating Misconduct is Important

- Consequences
 - Harm to research participant
 - Economic
 - Publication and retractions
 - Institutional Suspension
 - Individual Debarment
 - Impact on Public Trust

Introduction to Research
ETHICS, POLICY, COMPLIANCE

Ethical Standards Before Policy Era

- Mertonian “norms” of Science
 - Universalism
 - Disinterestedness
 - Communalism
 - Organized Skepticism
- Values of Science
 - integrity, honesty, trust, curiosity, and respect for intellectual achievement.
- America’s Contract with Science

Reexamination of Ethical Norms

- Human Subject Research
 - Nuremberg
 - Tuskegee
 - Beecher
 - Eugenics
- Basic Science Research
 - Cases of Research Misconduct
 - Congressional Hearings
 - rDNA
 - Regulation



Origins of Research Misconduct Policy

- Human Subject Research
 - 1964
- Animal Welfare
 - 1966
- Basic Science
 - 1974

Extent of Research Regulation and Compliance

- Federal funding is contingent on institutional compliance with multiple policies.

- Definition of research
- Debarment and Suspension
- Drug & Smoke-Free Workplace
- Lobbying
- Financial Conflict of Interest
- Research Misconduct
- Data Management / Sharing
- Research on Fetal Tissue
- Human Embryonic Stem Cell Research
- Inclusion of Women, Children, and Minority Participants
- Seat Belt Use
- USA PATRIOT Act
- Human Subjects/ Education on Protection of Human Subjects (IRB)
- R-DNA / Human Gene Transfer Research (IBC)
- Vertebrate Animals (IACUC)
- OMB Circular A-21 etc.
- RCR Instruction

RESEARCH INTEGRITY

Integrity Defined

Regulation and Policy

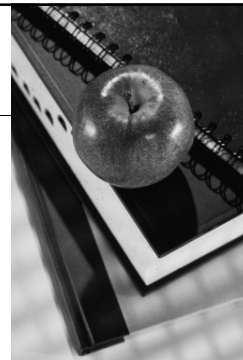
- Integrity is “the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities” (NAS, 1992).
- A researcher’s commitment to intellectual honesty and personal responsibility as reflected in actual research practices. (NAS, 2002)
- Adherence to rules, regulations, guidelines and commonly accepted professional codes or norms

Common Literature

- Integrity has two general senses, wholeness and soundness
- Integrity requires more than honesty
- Integrity requires more than adherence to rules
 - compliance
- Integrity requires
 - Discernment
 - Action
 - Statement

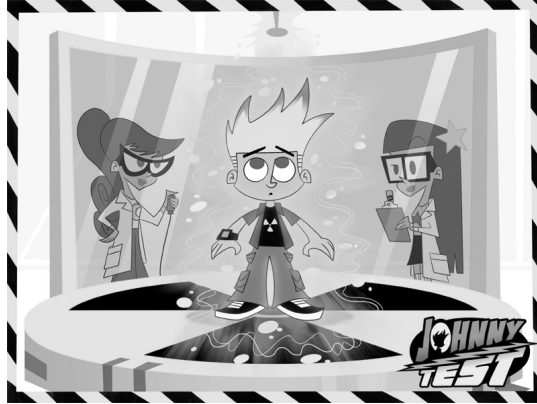
Obstacles to Research Integrity

- Public perception of human subject research
- Good policy does not ensure good practice
- Compliance is necessary but not sufficient
- Compliance generally refers to a “floor” or *minimum* standards, not model behavior
- Emphasis on compliance alone may breed cynicism



Media and Perception of Research

Super-exuberant and imaginative 11-year old Johnny Test has a zest for life and an ambition just one step beyond his ability. Not only does he want to drive monster trucks, hit home runs for his baseball team and be the smartest kid in the class, but he also wants to walk on the moon, breathe underwater and have his own superpowers. That's where his sisters come in. Johnny's super-genius twin sisters, Susan and Mary, give him the ability to live out his dreams – all they ask in exchange is Johnny's participation in their experiments!



<http://www.youtube.com/watch?v=6ohT6DjssO4>

Policy vs. Practice

Guidelines on Human Experimentation

- (4) Any innovative therapy must be justified and performed in accordance with the principles of medical ethics and the rules of medical practice and theory
- (5) Innovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in the light of relevant information provided in advance. Where consent is refused, innovative therapy may be initiated only if it constitutes an urgent procedure to preserve life or prevent serious damage to health and prior consent could not be obtained under the circumstances.
- (7) Exploitation of social hardship in order to undertake innovative therapy is incompatible with the principles of medical ethics.

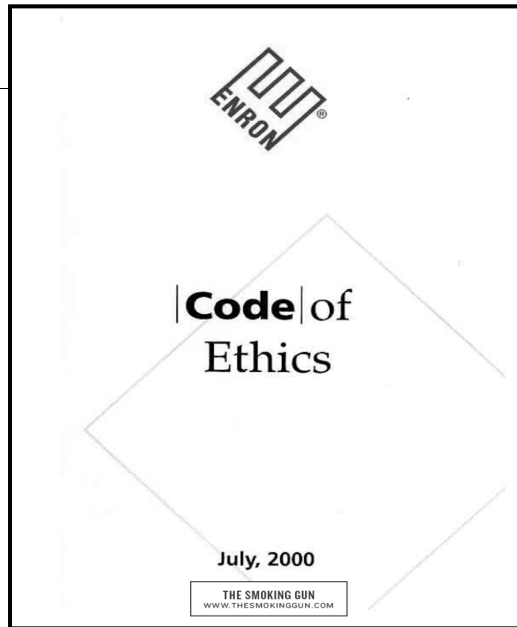
REICHSRUNDSCHREIBEN 1931

- (4) Jede neuartige Heilbehandlung muss in ihrer Begründung und ihrer Durchführung mit den Grundsätzen der ärztlichen Ethik und den Regeln der ärztlichen Kunst und Wissenschaft im Einklang stehen. Stets ist sorgfältig zu prüfen und abzuwägen, ob die Schäden, die etwa entstehen können, zu dem zu erwartenden Nutzen im richtigen Verhältnis stehen. Eine neue Heilbehandlung darf nur vorgenommen werden, wenn sie vorher, soweit möglich, im Tierversuch geprüft worden ist.
- (5) Eine neuartige Heilbehandlung darf nur vorgenommen werden, nachdem die betreffende Person oder ihr gesetzlicher Vertreter auf Grund einer vorangegangenen zweckentsprechenden Belehrung sich in unzweideutiger Weise mit der Vornahme einverstanden erklärt hat. Fehlt die Einwilligung, so darf eine neuartige Heilbehandlung nur dann eingeleitet werden, wenn es sich um eine unaufschiebbare Massnahme zur Erhaltung des Lebens oder zur Verhütung schwerer Gesundheitsschädigung handelt und eine vorherige Einholung der Einwilligung nach Lage der Verhältnisse nicht möglich war.

Policy vs. Practice

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Policy vs. Practice



Compliance Alone

- Failing to “develop an ethical culture, and instead focusing solely on making sure that legal requirements are met are likely to breed cynicism among employees” (Giblin and Meany, *Health Progress*, 1998)
- Too many or too detailed policies, or too broadly written requirements may confuse well-intentioned researchers, leading to cynicism, violations, and the perception of injustice. (Martinson et al., *JERHRE*, 2006)
- Too much focus on the compliance aspects creates systems that can be gamed and cynicism among trainees about research integrity generally. RCR courses aimed at “survival skills” may actually lead to questionable research practices among trainees. (Anderson et al. *Academic Medicine*, 2007)

Integrity is LARGER than Compliance

Less

- Retrospective
- Meeting requirements
- Point in time
- Departmental
- Short-term
- Cookbook
- Getting an answer
- Train
- Creates cynicism

More

- Prospective
- Creating requirements
- Continuing process
- Organizational
- Long-term
- Learning by doing
- Interpreting situations
- Inculcate
- Fosters progress

Creating a Culture of Integrity

■ Compliance^{PLUS}

■ Conflict of Interest

- Investigators and research staff should understand:
 - the organization's COI policy
 - what interests the organization requires to be disclosed
 - how, when and to whom to disclose interests
 - how COI might influence the protection of human participants
 - the need for communication and collaboration with organization to manage COIs.



Compliance	Compliance ^{PLUS}
All covered personnel must complete COI form online	Drop down menus for definitions
Research Compliance offers workshops on COI	Research integrity educators provide on-site or departmental brown bag presentations
COI policy can be downloaded from website	COI education part of new hire orientation
If violation occurs, organization will take corrective measures to protect integrity of the organization	Organizational culture based upon proactive steps including frequent communication with investigators aimed at violation avoidance
COI Committee member may be contacted for additional information	Research integrity offers COI consultation services to investigators

Achieving Integrity in Research through

COMPLIANCE AND CULTURE

Applying a Culture of Research Integrity

- Group 1
 - IRB approval process
- Group 2
 - Informed Consent Process
- Group 3
 - Conflict of Interest

Final Thoughts

- Although the federal government plays a role in the management of misconduct in research, regulation alone cannot foster integrity. This commitment must come from individuals and institutions. (NAS 2002)
- Compliance is an integral part of research integrity
- Culture eats compliance for breakfast!

