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Research Integrity: Critical Markers for Achieving Excellence

Outline

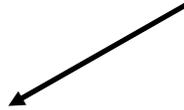
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Introduction: Ethics and Integrity

Dr. Edward Gabriele

Introduction: Ethics and Integrity

Ethics and Integrity --- Reflecting on Definitions



Ethics – regulations (*cf.* regula)

Ethic - organized pattern of regulatory approaches

Ethos - Fundamental character of a person/institution

Legal Adherence/Obedience

“Moral” perfection

Congruence of person with principles, action, “ends,” and resulting responsibility to self, others, culture, cosmos. Allows for continuity and discontinuity.

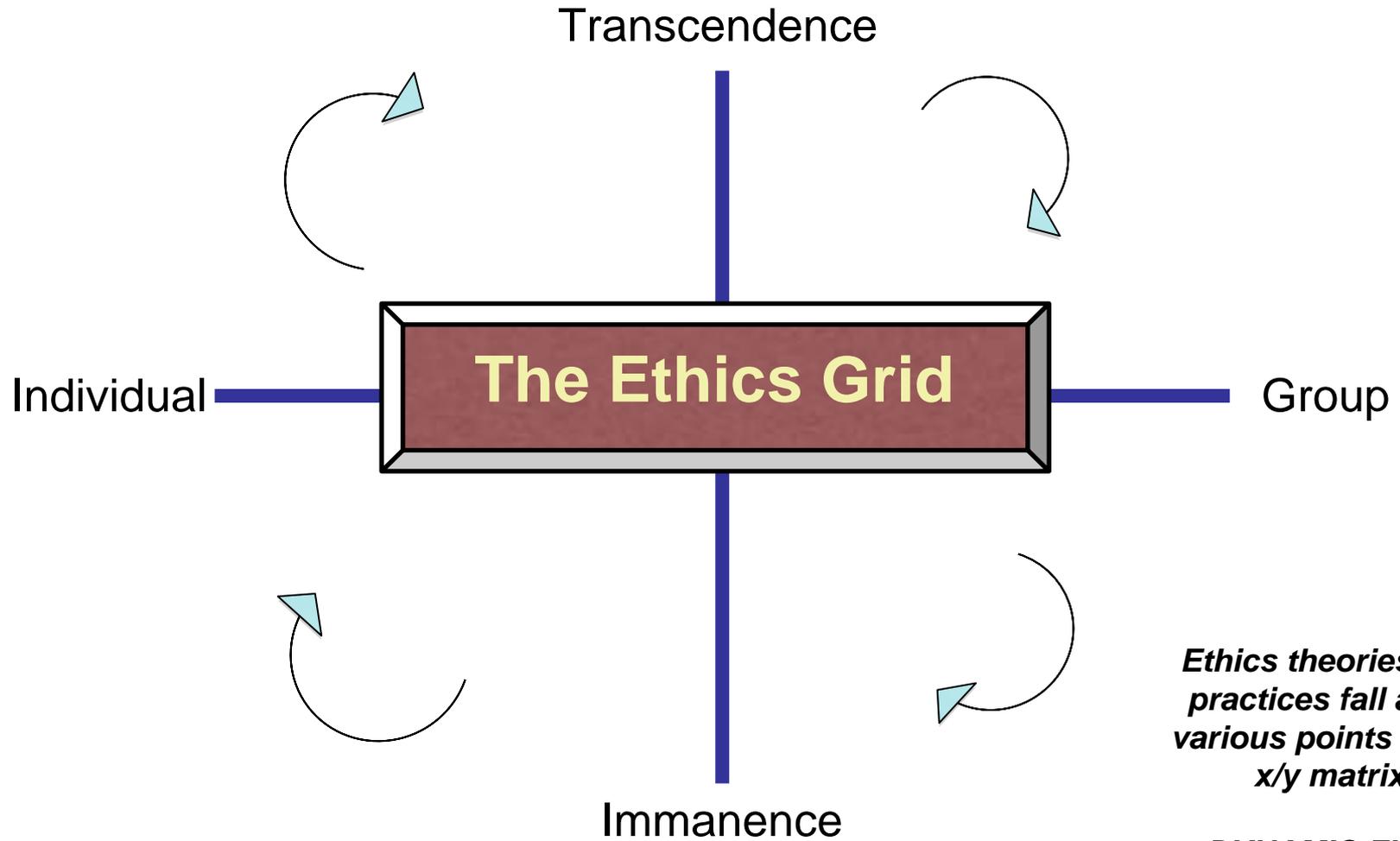
...Difficult to define for all time and in all places.

...Not answers but questions: !!! vs. ???

...Requires: Observation, exploration, enculturation, incarnation.

...Demands reshaping personal/social horizons with “telos.”

Ethics as a Continuum



Ethics theories and practices fall along various points on the x/y matrix.

DYNAMIC FLUX!

Some Brief Historical Notations

...Classical Roots

Hippocrates, Plato, and Aristotle Revisited
Medieval Alchemy, Academia, & Hospitality

...The Science/Ethics Dialectic

Post-Renaissance/Enlightenment Tensions
The Galileo Experience & the Shelley Commentary

...The Incidence of Scientific & Cultural Challenges

Misuses of science

...Modern Quest for Ethics in Science

Nuremberg Code, Helsinki, Belmont, CFR, GCP,
Professional Codes etc

...The 1990's IOM Integrity Movement in Research

1980's Congressional Interest: Evolution Start Point!
OSTP Policy and ORI RCR Guidance of 2000
RCREC Summit of 2001 (***EDUCATION MODEL!!!!***)
NAS "Integrity in Research" of 2002
Emerging new elements in response to new factors
Research Integrity: The Ethos Universal

The RCR Core Elements: An Evolution

Data Acquisition, Management, Sharing, & Ownership

Mentor/Trainee (aka Protégé or Mentee) Responsibilities

Publication Practices & Responsible Authorship

Peer Review

Collaborative Science

Human Subjects

Research Involving Animals

Research Misconduct

Conflict of Interest & Commitment

New Academic, Social and Cultural Factors leading to emerging new elements: e.g. financial stewardship, internationalization, interdisciplinarity, multiculturalism, undue influence etc

The Nature and Challenge of Collaboration in Research

Dr. Sandra Titus

Collaboration – Why on RCR list?

- **Research involves many Steps and Skills:**
 - Construct Hypothesis
 - Develop theoretical or experimental paradigm
 - Collect Data
 - Verify Data
 - Analysis
 - Writing up results
 - Publication
 - Peer Review
- **This is impossible to do alone.**
- **All researchers need skills beyond their own.**

Collaboration Challenges: Understandings Vary

- **Different backgrounds and disciplines.**
- **Cannot assume** others know the same thing you do.
- **Procedures** and methods of care or collecting data may be very **different.**
- Education and **ways of thinking and communicating** by researchers will be different.
- **Rules** in different organizations and cultures will be different.
- **FDA versus non-FDA regulated research.**

Number of Collaborations is Growing

- 48% increase in collaborations between researchers in different institutions (1988-2001)
- 16% of the collaborations were with International collaborations - doubled in 10 yrs.
- 3.9 to 8.4 co-authors – varies by discipline
- All co-authors are not collaborators.

* Nature news April 9, 2008; Vicens, Ten Simple Rules for Successful Collaboration, PLoS Computational Biol, March 2007

Authorship Challenge: Who is first?



Collaboration Break-ups – Why?

- The Ox-Researcher and the Chemist.
- Chemist would not return sample and had not done the analysis.
- Fight over who should keep sample.
- The Researcher: “I feel like I have been hit by a truck. I am going to be very circumspect from now on.”

Collaborations that Fizzle Out

*Cummings S. Res. Policy 36 1620-1634 (2007)

- 491 NSF funded collaborations.
- What they produced – “knowledge outcomes” articles, patents, presentations.
- Finding: Projects involving multiple universities produced fewer outcomes than collaborators in one university.
- Why fizzled out?

Study on Successful Collaboration

- Study on what makes some Broadway plays succeed and sell out while others fail. (Uzzi)
- **Success is not just what you know but also who you know.**
- **Strategic planning that evaluates the composition of the team can make a difference.**

Tempering Need to be in Charge

- Working between disciplines requires careful conversations and listening.
- Disciplines need to imagine the other's perspectives.
- **IRB - protection role**
- **Researchers - science responsibilities**
- **Sponsor - fully accountable**

The Two Way Street on Respect

- Researchers need to be respectful in working with teams outside their own.
- Regulators too need to be respectful.
- Regulations have evolved to promote & protect human subjects and obtain quality research.
- **Lack of respect when enforcing regulations creates difficulties.**
- **Lack of adherence to regulations creates problems for researcher, organization, and participants.**

Caveats on Collaboration

- **No collaboration survives if one person has all the answers!**
- **Are you making an effort to work in a way that you like others to work with you?**

Peer Review and the Commitment to Scientific Excellence

Dr. Cynthia Ricard

Peer Review and the Commitment to Scientific Excellence

“Domestic technology” 1899-1927

William D. Coolidge

Willis R. Whitney

Thomas A. Edison

Charles P. Steinmetz

Irving Langmuir

Ernst F.W. Alexanderson

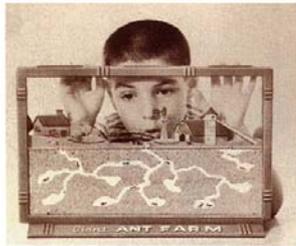
Chester W. Rice

Gerard Swope

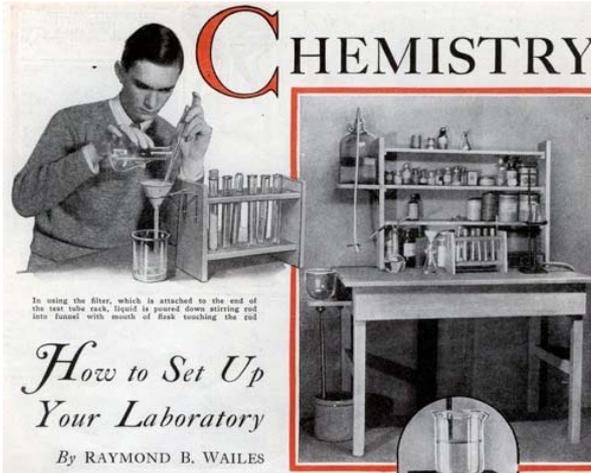


Peer Review and the Commitment to Scientific Excellence

If GE built laboratories in their homes, why did the GE scientists have laboratories at GE also?



Steve Jobs and Steve Wozniak in 1975 with a "Blue Box".



Informal peer review, aka collaboration, inspires ideas.

Peer Review and the Commitment to Scientific Excellence

Why should scientists publish their findings?

Is uploading to a website the same as publishing?

What is the difference between a white paper and a peer-reviewed paper?

Peer Review and the Commitment to Scientific Excellence

What is meant by “**peer review**”?

In your field, your **peers** are experts in the subject and will review your paper.

What is meant by “**confidentiality**”?

The reviewers’ identities will not be revealed to you.

The reviewers will keep your findings confidential (secret).

The reviewers will not take advantage of your work.

The reviewers will not “scoop” you.

Peer Review and the Commitment to Scientific Excellence

The six C's:

Clear

Correct

Concise

Consistent

Complete

Contribution

Peer Review and the Commitment to Scientific Excellence

Possible recommendations after review:

Accepted

Accepted contingent on making revisions

Rejected

Peer Review and the Commitment to Scientific Excellence

A good reviewer may ask to re-review after you have revised your paper.

A good reviewer can help you improve more than only your manuscript.

A good reviewer serves as a mentor to the authors.

The commitment to scientific excellence enables authors and reviewers to work as a team.

As a team, reviewers and authors make a valuable contribution to their field.



Peer Review and the Commitment to Scientific Excellence

Research cannot be performed in a vacuum. We need the infrastructure, assurances, resources, support, safety and inspiration of a community committed to scientific excellence.



Peer Review and the Commitment to Scientific Excellence

Question for you:

How can managers, administrators, and other support personnel share the commitment to scientific excellence?



The Tradition of Mentoring

Dr. Edward Gabriele

The Tradition of Mentoring

Mentoring

- ...Roots in Greek Mythology

- ...Mentor – Friend of Odysseus

- ...Role: To watch over the take care of his son Telemachus

- ...Athena takes the form of Mentor

 - To give Telemachus courage to resist his mother's suitors

 - To prod him with adventure to go out and learn about his father.

- ...Story of Mentor developed into a French 17th century literature

 - Origin of our modern understanding.

But

- ...Mentor as a metaphor:

 - Powerful doorway to an ***experience of guidance*** and passing on knowledge, skills, abilities, and wisdom.

Mentoring and the Professions

The Professions and the Mentoring Experience – Early Development

- ...Originally, medicine, law, theology and eventually education itself
 - ...The model for modern of understanding academics for professional life
 - ...The Guild System: apprentice, journeyman, master
 - ...Normative experience for learning a trade
 - ...Develops into a comprehensive system for:
 - Acquiring knowledge
 - Learning/practicing/perfecting skills
 - Developing abilities
- Note well – the origins of KSA's!
- ...Becomes a basis for what becomes centuries later as professional education and professional degrees.
 - ...Most critical: The Mentoring Experience

Mentoring: Capturing the Experience

A Root Metaphor: A Means for Understanding and Ordering Experience

...The Carnegie Foundation and the Professions

...Signature Pedagogies: Means by which seasoned “elders” pass on the corporate wisdom to “the youngers.”

...*Educare*: to lead out.

...One Carnegie Foundation Professions analysis is helpful:

---Education for Interpretation

---Education for Contextualization

---Education for Formation

---Education for Performance

...Mentoring is a *relationship* to pass on KSA’s but in the context of *passing on* most importantly the *meaning or “telos” of the profession* itself.

...Mentoring is NOT academic advisement or supervision per se (though it can involve these.)

...It is a much larger cultural experience of personal and professional formation.

...*It never ends. One never stops being mentored --- even when you become one.*

Mentoring in Military Medicine

The Military as Culture

Culture:

...cf. Mary Douglas: A dynamic reality: Never Static

...cf Richard Seel:

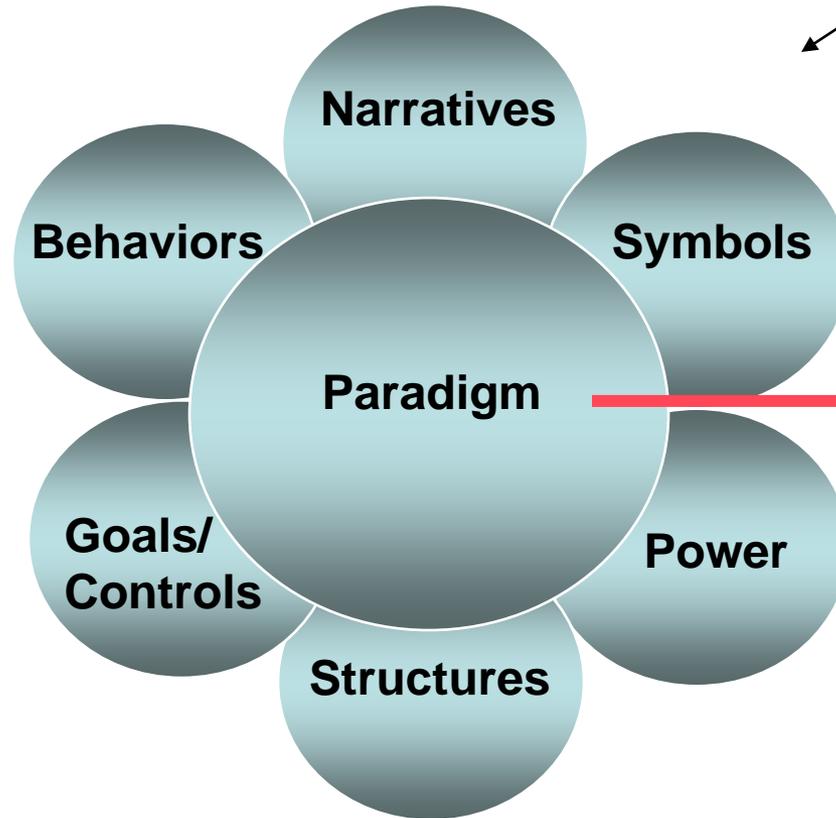
Organization culture is the emergent result of the continuing negotiations about values, meanings and proprieties between the members of that organization and with its environment.

...A dynamic reality that emerges from the ongoing conversations among the organization's or society's constitutive elements and people.

...To change a culture, engage and change the conversations.

Mentoring in Military Medicine

**The Cultural Web
(Adapted from R. Seel)**



***Changing One
Changes All!***

***Ultimate Locus
of Change***

Mentoring in Military Medicine

Education into the Military “Culture”

...Diverse forms:

- Drill instruction/Basic Training Instructor
- Military and PCS Sponsor
- Specialty Leader
- Academic Advisor
- Supervisor/1st and 2nd Line Raters
- Preceptors and Medical Professional Leaders
- Often education or technical. Ends with attainment of goals

...Mentoring:

- Based on long standing DoD Component Practice
- Interactive relationship from more seasoned officer/enlisted person to a newer individual
- Usually a long and in-depth experience: relationship
- Never ending. Goal is not “attainment” but maturity
- Involves both personal and professional *formation, not just information!*

Mentoring in DoD HRPP Context

Process of Professional Excellence: Mentoring in the HRPP Experience

...HRPP Personnel to Researchers and the Institution

- Need to provide educational information to research members
- Policy, procedures, processes
- Facilitate proper information
- Necessary information for regulatory compliance with sponsor information, local community context, patient/subject information
- Communicate information relative to peer review, ethical parameters, regulations, ongoing monitoring etc
- Emphasize subject welfare first as critical context for institutional risk management issues (secondary)
- HRPP is a part of a system of “professional mentoring” for HR KSA’s etc.

...However, is there something more?

Mentoring in DoD HRPP Context

Process of Professional Excellence

...For HRPP Personnel themselves: The Intramural Experience

---Mentoring is not just something that HRPP persons provide to research staff.

---HRPP “excellence” requires a system and experience of mentoring for HRPP personnel themselves.

---Carnegie Foundation Signature Pedagogies: Continuing Education
Relearning Interpretation

Rethinking Context

Retreat of Personal and Professional Formation: Values

Reunderstanding Performance

---Learning about the Self: cf. Higgins: Prevention vs Promotion
Models of Cognitive and Behavioral Focus

---The Problem of Power

...The Ultimate Mentoring Experience:

The Virtue of Humility: Service of Others, Ever Before the Self
Steeped in the military “telos:” *To Defend Those Who Cannot Defend Themselves.*

Discussion