Responsible Conduct of Research, Scholarship and Creative Activities (RCRSA)

Responsible Conduct of Research and Importance of Mentoring

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RCRSA Education Coordinator – The Graduate School
Department of Chemistry and Neuroscience Graduate Program Director

Learning Objectives

- **Research and creative activity misconduct** – learn what is it, why it happens and what are best practices for avoidance.

- **Ethics and ethical decision making** – importance for guiding research and creative activities.

- Importance of **quality mentoring** and proper mentor-mentee relationships for ethical research and scholarship.

High Profile Misconduct Cases

Duke University settles research misconduct lawsuit for $112.5 million

By Science News Staff Mar. 25, 2019 , 1:50 PM

Thomas alleged that Duke biologist Erin Potts-Kant—a co-author on numerous papers that are now retracted—included fraudulent data in 60 grant reports and funding applications to U.S. agencies. “Duke discovered the possible research misconduct in 2013 after [Potts-Kant] was fired for embezzling money from the university, which also occurred over the same period,” the university noted in a statement released today. Potts-Kants “eventually pled guilty to two counts of forgery and paid restitution to Duke.”

The Scientist

High Profile Misconduct Cases

OSU Professor Falsified Data on Eight Papers, Resigns

Ching-Shih Chen's research involved anti-cancer therapeutics that were being tested in clinical trials.

April 2, 2018

ORI: Researcher Faked Dozens of Experiments

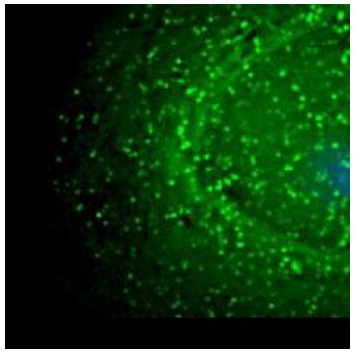
Jeff Akst | May 25, 2016

A former scientist at the University of Michigan and the University of Chicago made up more than 70 experiments on heart cells, according to the Office of Research Integrity.

HIV Scientist Pleads Guilty to Fraud

Bob Grant | Feb 26, 2015

A former Iowa State University researcher faces up to 10 years in prison for faking data involving a study of an HIV vaccine.



The Scientist

RCRSCA Program Objectives

An ethics and RCRSCA education program together with improved mentorship and institutional climate are essential for realizing responsible conduct across all levels of the university.

- Ensuring the integrity of research and scholarship across the university through implementation of ethics and RCRSCA education for **all** stakeholders (faculty, postdocs, technical staff, and graduate and undergraduate students.

Drivers for RCRSCA Education

Considered essential for the preparation of future scholars, scientists and engineers!

- Professional codes of ethics and professional conduct
- Government requirements
- University requirements
- Personal convictions (Good behavior – it is the right thing to do!)

Research Integrity Statement

Safeguarding the integrity of research and creative activities is fundamental to the mission of Michigan State University. We owe no less to the public which sustains institutions like ours and to the governmental agencies and private entities which sponsor the research enterprise.

All members of MSU share responsibility to assure that misconduct or fraud in research and creative activity is dealt with effectively and that MSU's high standards for scholarly integrity are preserved.

Research Integrity Office, MSU

American Chemical Society (ACS) Code of Ethics and Professionalism

The American Chemical Society expects its members to adhere to the highest ethical and safety standards. Indeed, the Federal Charter of the Society (1937) explicitly lists among its objectives **"the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education and attainments..."** The chemical professional has obligations to the public, to colleagues, and to science.

Benefits of University-Wide RCRSCA Education

Why do we require RCRSCA education??

- Development of greater appreciation for the importance of ethical behavior across campus. (It is an expectation!)
- Greater knowledge of and education about misconduct leads to greater avoidance.
- Governmental and university compliance.
- Be more than a “check the box” issue!!

Government Requirements

COMPETES ACT 2007

National Science Foundation (NSF)

- All undergraduate and graduate students as well as postdocs supported on grants **must be** provided with training.
- Institution responsible for content, method of delivery and frequency of training.

National Institutes of Health (NIH)

- Training grant awardees (K and T awards) individual or institutional grants.
- Must include face-to-face discussions plus other modes of delivery (*e.g.*, on-line modules). At least 8 contact hours required.
- Topics: research misconduct, research ethics, conflicts of interest, authorship, data management, human subjects, animal use, lab safety and peer review.

USDA (National Institute of Food and Agriculture (NIFA))

- Training **required** for all program directors, faculty, postdocs, graduate and undergraduate students.
- Institution responsible for content, method of delivery and frequency of training.

University Requirements

The Graduate School requires RCRSCA Education for ALL Graduate Students and Graduate Professionals.

Basic Education Program (Ph.D. Students - Years One and Two)

CITI On-Line Modules (First Semester, Year One)

- Introduction to the Responsible Conduct of Research
- Authorship
- Plagiarism
- Research Misconduct

Additional CITI Modules (Year Two)

- Complete three additional modules

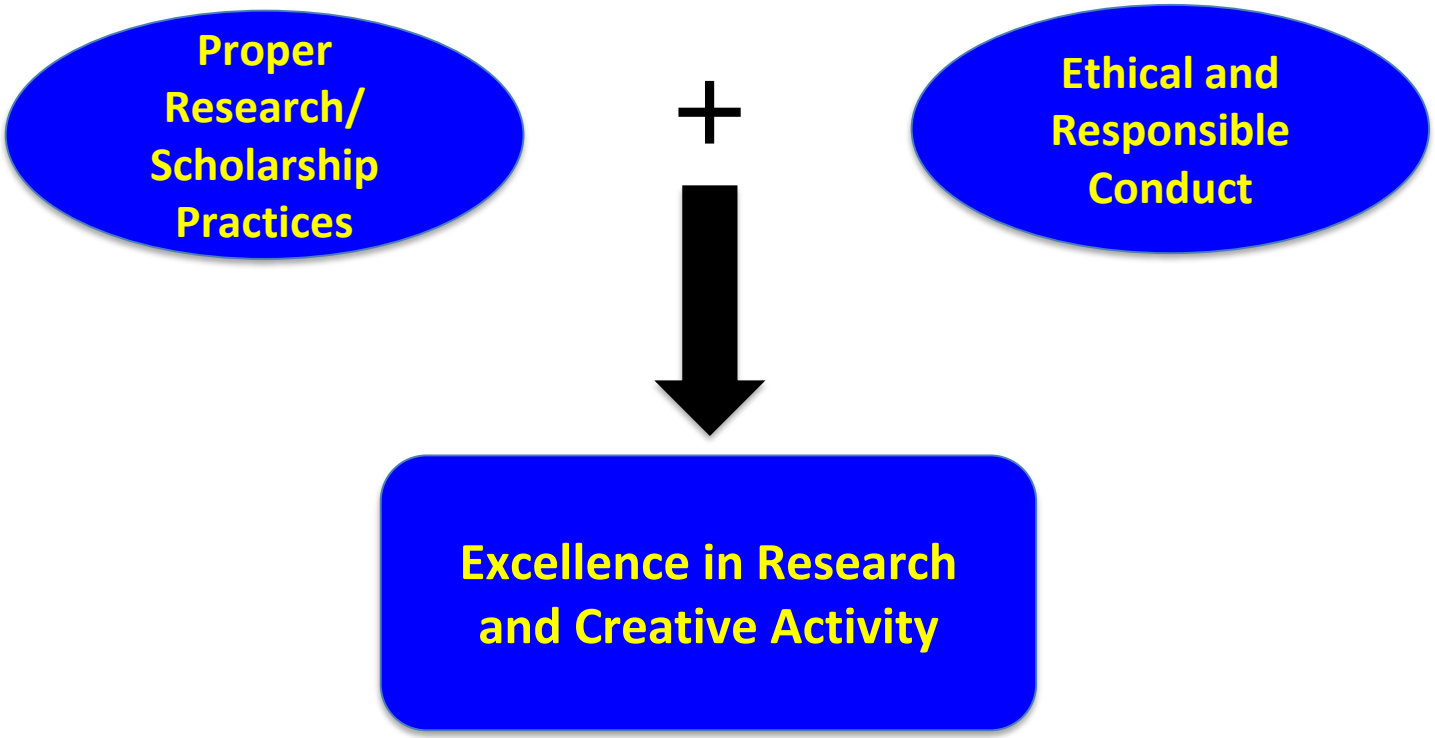
Discussion-Based Workshops

- 6 hours of discussion-based training (4 workshops)
- Eight offered workshops in 2019-2020

(Completion by spring semester, Year Two)

Completion and documentation through Office of Regulatory Affairs (ABILITY) at https://ora.msu.edu/train/

Good Research and Creative Activity Practice



It is the right thing to do!!

What is Research Misconduct?

The Department of Health and Human Services defines research misconduct as: **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing research results.

Image taken from Internet

Research Misconduct

Image taken from Internet

Research Misconduct

Research misconduct means fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication**: making up results and recording or reporting them.

- **Falsification**: manipulation of research materials, equipment, or processes, or changing or omitting results such that the research is not accurately represented in the record.

- **Plagiarism**: the appropriation of another's ideas, processes, results, or words without giving proper credit.

Criteria for Research/Scholarship Misconduct

- Represents a **significant departure** from accepted practices;
- Has been committed **intentionally**, or **knowingly** or **recklessly**; and
- Can be proven by a preponderance of evidence.

Research/scholarship misconduct does not include honest error, misinterpretation of results or differences of opinion.

Image taken from Internet

Slippery Slope to Research Misconduct

Video 4 - Breaking Protocol

This video highlights ethical decision making; a faculty adviser suggests that students should break research protocol to get the desired results.

Office of Research Integrity, HHS

Research Misconduct

Research Integrity Video

NIH Perspective - Addressing Research Misconduct

National Institutes of Health ORI

Why Do People Engage in Misconduct?

- Enhance reputation (low ethical standards)
- Conflict of interest (financial)
- Promotion and tenure (PhD or MS degree)
- Pressure to produce
- Poor training and knowledge of misconduct

Other Reasons for Misconduct

- Career Resources: Publish of Perish
- Desire to “get ahead”
- Character Issues/Laziness
- Ease of Fabrication
- Personal problems
- Cultural Differences
- Poor Oversight and Mentoring

Societal Consequences of Misconduct
(Prof. Len Fleck MSU)

- Can I have a happy and successful life if I do not know whether or not the theory of plate tectonics is correct? Of course!!!!

- Can I lead a happy and healthy life if physicians depend upon medically-relevant scientific information that is false or misleading? That is problematic!!!

- Can I be comfortable crossing a bridge in my car if the engineering of that bridge relied upon false or misleading scientific information regarding the strength of the steel or concrete used to construct that bridge? Sounds unnerving!

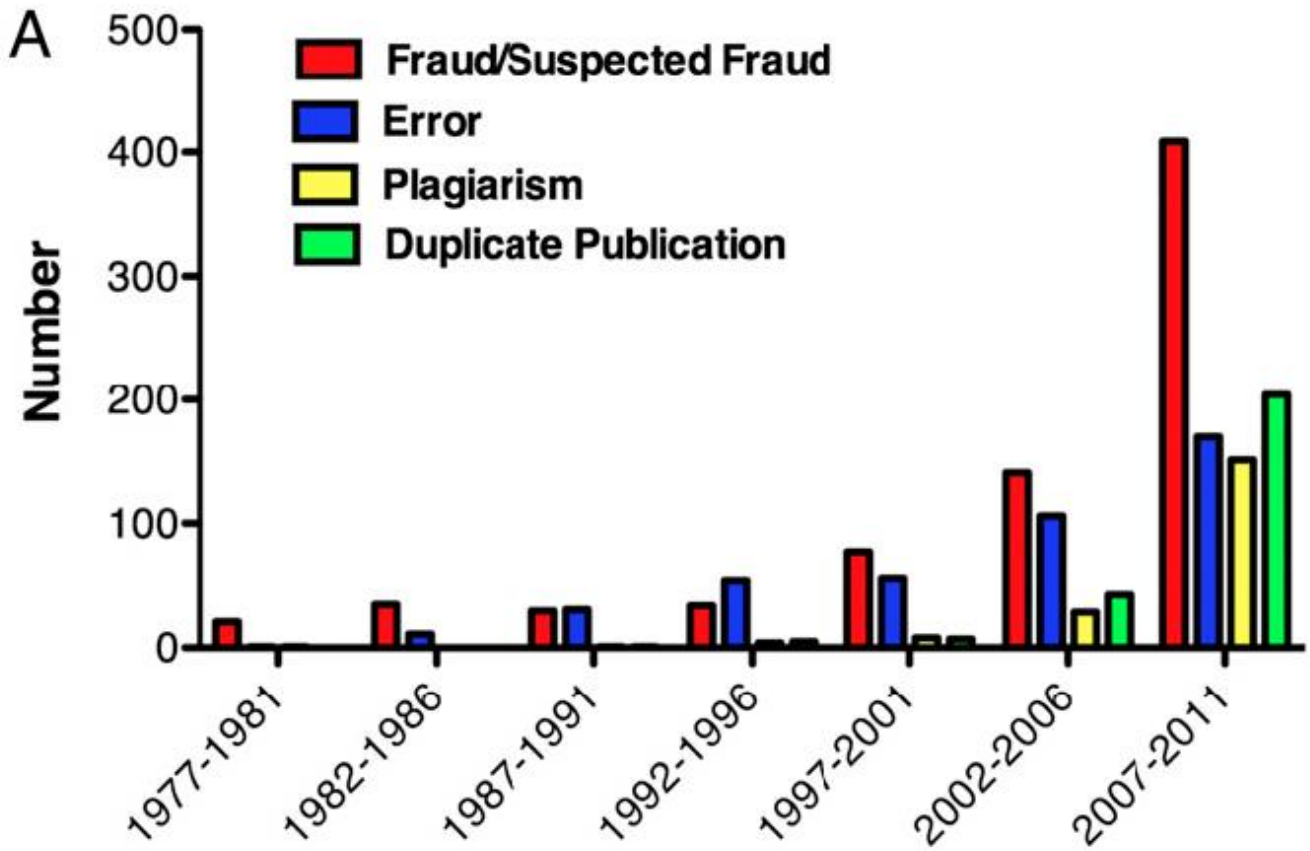
The world as we know it would be impossible if there were no such thing as scientific integrity assiduously respected and protected.

Key Institutional Considerations

Misconduct is a non-zero probability issue!!

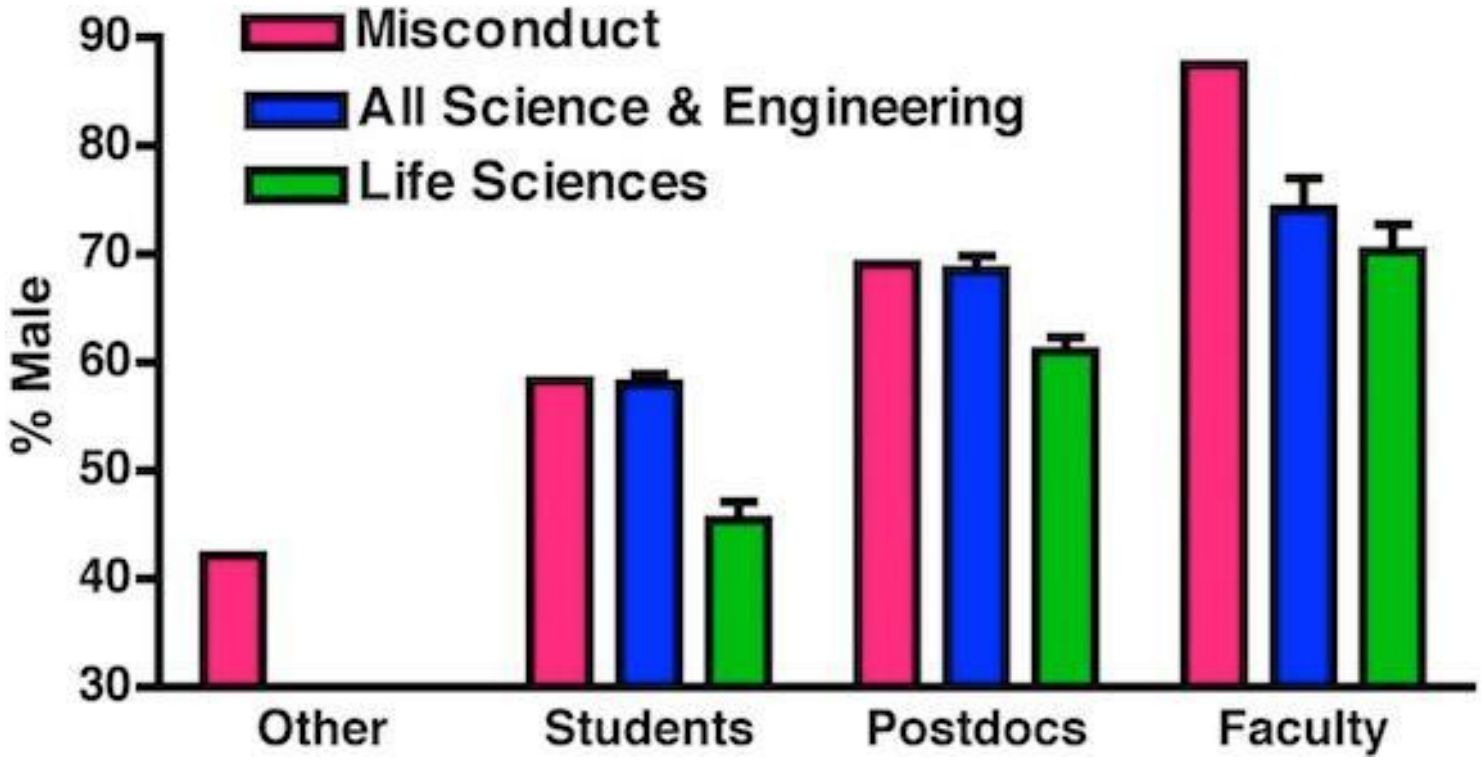
- Enable research, discovery and scholarship
- Public trust
- Institutional integrity and reputation
- Institutional tone and culture
- Balance compliance – commitment to protect the compliance process - and creating a culture of high ethical standards.

The Fact – Misconduct is on the Rise



Proceedings of the National Academy of Sciences (*PNAS*). 2012

All Constituencies Involved



Publication Retractions

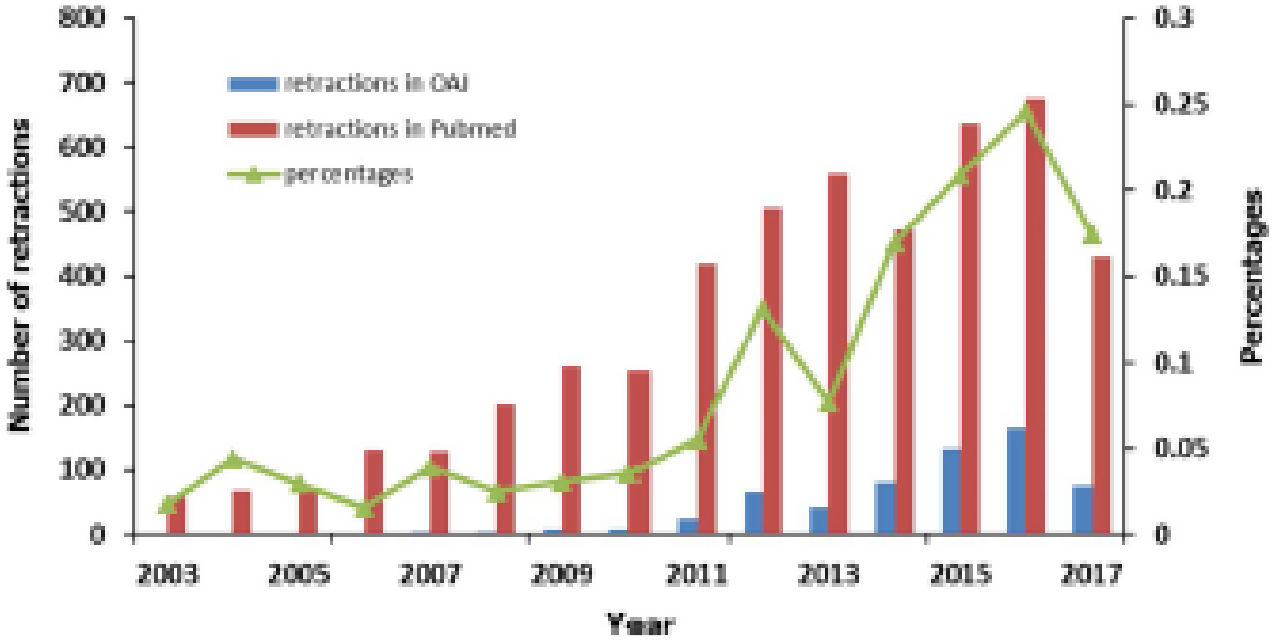
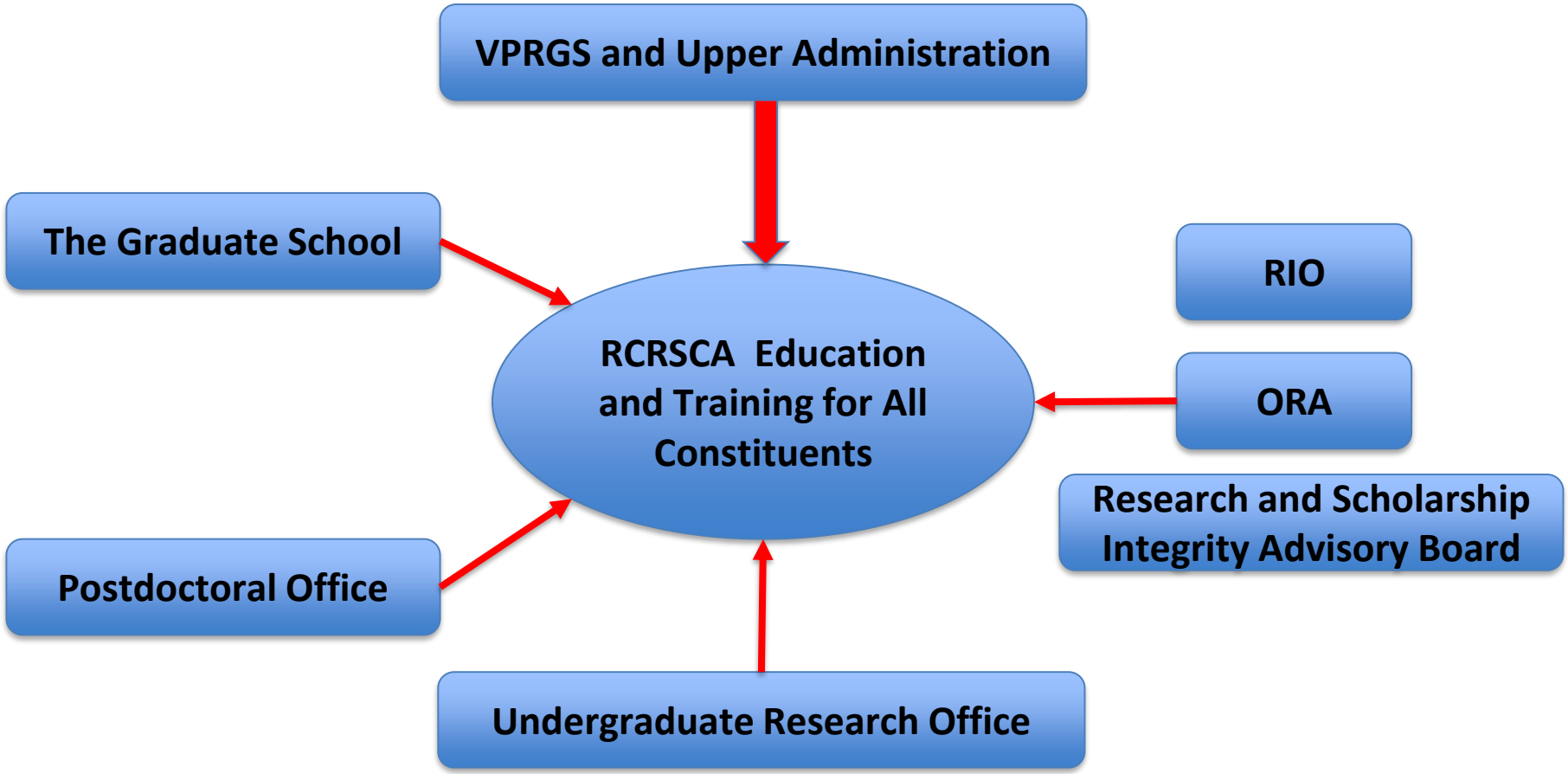


Fig. 1 Number of retracted articles published in Pubmed and OAJs and the percentage of Pubmed retractions that were in OAJs by year of retraction. OAJ Open Access Journal

Misconduct was the primary reason for retraction. The majority of retracted articles were from journals with low impact factors and authored by researchers from China, India, Iran, and the USA.

Partnership at All Levels



If we don't, then……..

FOR IMMEDIATE RELEASE Wednesday, August 21, 2019

Georgia Tech professor pleads guilty to defrauding the National Science Foundation

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Novartis fired two top scientists from its gene therapy subsidiary after the company's CEO learned that manipulated data was submitted as part of an application for the therapy Zolgensma, Stat's D. Garde and M. Herper report. (June 2019)

Duke to pay $112.5 million to settle allegation of falsifying research for federal grants. Monday March 25, 2019

Washington (CNN) - Duke University will pay the US government $112.5 million to settle allegations of falsifying research in order to obtain millions of dollars in federal grants.

Research Integrity Case Study

Crossing the Line into Misconduct (3:45)

Office of Research Integrity, HHS

Examples of Fabrication/Falsification

- Creating data for experiments that were never done.
- Making up subjects.
- Splicing together different images to represent a single experiment.
- Changing brightness and/or contrast of the image.
- Any change that conceals information, even when it is considered not specific.
- Showing only a very small part of the photograph so that additional information is not visible.

Examples of Fabrication/Falsification

- Substituting one subject's record for that of another subject.
- Inflating the number of samples (animals, subjects, etc.) that were used.
- Deleting data points.
- Altering images to appear better.
- Altering images and using them multiple times.

The data are what they are!!!!!

Importance of Ethics in Science and Creative Activities

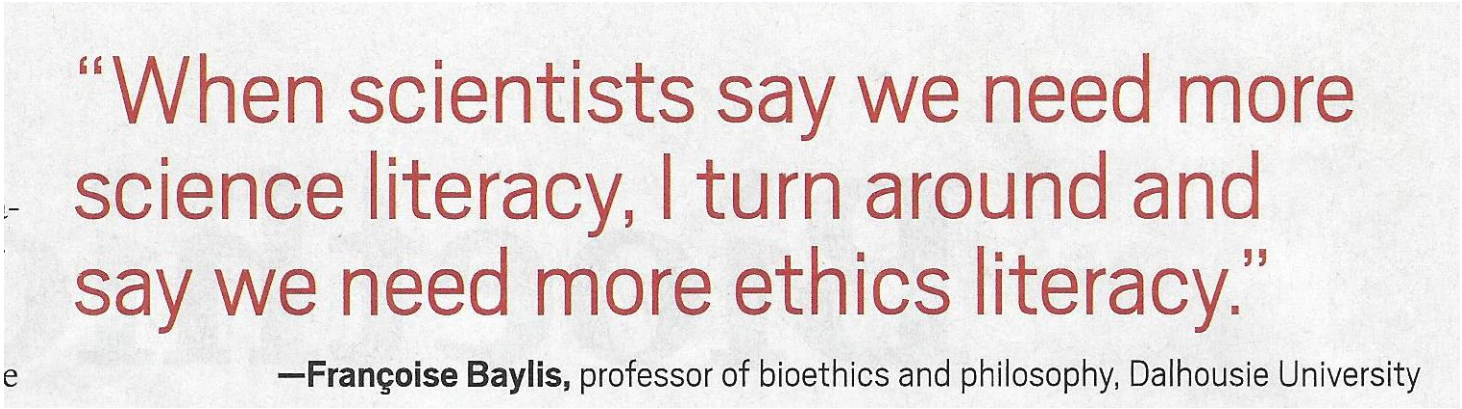
Scientific (scholarship) **ethics** calls for honesty and integrity in all stages of scientific (scholarship) practice, from reporting results regardless to properly attributing collaborators.

This system of **ethics** guides the practice of **science (creative activity)**, from data collection to publication and beyond.

Proper/improper **ethical/unethical** **legal/illegal**

https://www.visionlearning.com/en/library/Process-of-Science/49/Scientific-Ethics/161

Marriage of Ethics and Science



C&EN, August 27,2018

Marriage of Ethics and Science

ASSESSING TECHNOLOGY

Milestones in the ethical pursuit of research and deployment of innovation that have impacted bioethics

1968 Treaty on the Non-Proliferation of Nuclear Weapons
An international treaty under which signatory nations agreed to work to prevent the spread of nuclear weapons technology and advance the use of nuclear energy for peaceful purposes. It was negotiated by the United Nations' Eighteen-Nation Committee on Disarmament and went into effect in 1970.

CREDIT: KEYSTONE PICTURES USA/ALAMY STOCK PHOT

1975 International Conference on Recombinant DNA Molecules
A meeting sponsored by the U.S. National Academies of Sciences, Engineering & Medicine and the National Institutes of Health at the Asilomar Conference Center to draft voluntary guidelines for the safe deployment of recombinant DNA technology. Attendees agreed to a moratorium on research, pending a consensus on safety. The meeting was notable for bringing safety concerns into the public domain, although the 150 attendees were primarily biologists involved in DNA research.

1978 "The Belmont Report"
A report issued by the U.S. National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research listing ethical guidelines for research involving human subjects. Prompted in part by the Tuskegee syphilis study, which took place from 1932 to 1972, the report established social justice as an ethical criterion.

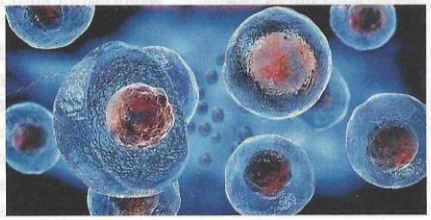
C&EN, August 27,2018

Marriage of Ethics and Science

2006 Hwang Woo-suk controversy
South Korean veterinarian and researcher charged by the Korean government with embezzlement and violating bioethics laws for falsely claiming in 2004 to have created human embryonic stem cells via cloning. Publicity about the case prompted the International Society for Stem Cell Research to draft research guidelines.

2016 Labeling of genetically modified foods
The U.S. Senate passes a bill that would create a national standard for labeling food made with genetically modified organisms. The vote, held after a rash of state laws required labeling of genetically modified foods, put additional pressure on Monsanto, which argued that studies support the safety of consuming engineered foods—a view comporting with the scientific consensus. Bayer acquired Monsanto this year.

2009 Executive Order 13505
An order signed by U.S. President Barack Obama to allow research on human stem cells, including human embryonic stem cells. The order establishes policies and procedures under which the National Institutes of Health will fund such research.



2017 U.S. National Academies recommendations for genome editing
The report "Human Genome Editing: Science, Ethics, and Governance" allows for heritable germ-line editing under certain conditions in a regulated environment where research meets 10 criteria. For example, the report recommends that editing be done only to prevent "a serious disease" and only in the "absence of reasonable alternatives."

C&EN, August 27,2018

Ethical Standards to Guide Scholarship

D. Resnik, Philosophical foundations of scientific ethics. *Proceedings of Ethical Issues in Physics*. Eastern Michigan University, Ypsilanti, MI (July 17-18, 1993).

- Honesty in reporting of scientific data and creative works.
- Careful transcription and analysis of results to avoid error.
- Independent analysis and interpretation of results that is based on data – not external influences.
- Open sharing of methods, data, and interpretations through publication and presentation.

Ethical Standards to Guide Scholarship

- Sufficient validation of results through replication and collaboration with peers.
- Proper crediting of sources of information, data and ideas.
- Moral obligation to society in general and, in some disciplines, responsibility in weighing the rights of animals and human subjects.

https://www.visionlearning.com/en/library/Process-of-Science/49/Scientific-Ethics/161

Tuskegee Syphilis Study – The Dark Chapter

In 1932, the US Public Health Service located in Tuskegee, Alabama, initiated a study of the effects of syphilis in men. When the study began, medical treatments available for syphilis were highly toxic and of questionable effectiveness. Thus, the study sought to determine if patients with syphilis were better off receiving those dangerous treatments or not.

The researchers recruited 399 black men who had syphilis, and 201 men without syphilis (as a control). Individuals enrolled in what eventually became known as the Tuskegee Syphilis Study were not asked to give their consent and were not informed of their diagnosis; instead they were told they had "bad blood" and could receive free medical treatment (which often consisted of nothing), rides to the clinic, meals, and burial insurance in case of death in return for participating.

https://www.visionlearning.com/en/library/Process-of-Science/49/Scientific-Ethics/161

Tuskegee Syphilis Study – The Dark Chapter

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

By 1947, penicillin appeared to be an effective treatment for syphilis. However, rather than treat the infected participants with penicillin and close the study, the Tuskegee researchers withheld penicillin and information about the drug in the name of studying how syphilis spreads and kills its victims. The unconscionable study continued until 1972, when a leak to the press resulted in a public outcry and its termination. By that time, however, 28 of the original participants had died of syphilis and another 100 had died from medical complications related to syphilis. Further, 40 wives of participants had been infected with syphilis, and 19 children had contracted the disease at birth.

https://www.visionlearning.com/en/library/Process-of-Science/49/Scientific-Ethics/161

Nine Pitfalls of Misconduct

Nature 557 (2018) 297

Factors that Lead to Bad Decisions

- **Temptation** (Getting my name on this article would look good on my CV.)
- **Rationalization** (It was only a few data points and the measurements were flawed anyway.)
- **Ambition** (The better the story we can tell, the better the journal we can get the work published in.)
- **Group and Authority Pressure** (PI's instructions don't match proper protocols.)
- **Deception** (I am sure it would have turned out this way.)

Nature 557 (2018) 297

Factors that Lead to Bad Decisions

- **Entitlement** – (I've worked hard on this and deserve it.)
- **Incrementalism** – (It's only a single data point I'm excluding, and just this once.)
- **Embarrassment** – (I don't want to look foolish for not knowing how to do this.)
- **Stupid Systems** – (It counts more if we divide this manuscript into three submissions instead of just one – duplicate submissions.)

Nature 557 (2018) 297

Case Study in Lab Misconduct

https://ori.hhs.gov/TheLab/TheLab.shtml

Office of Research Integrity, HHS

Top "BAD" Behaviors

- Fabricating or 'cooking' research data.
- Ignoring major aspects of human-subject requirements.
- Not properly disclosing involvement in firms whose products are based on one's own research.
- Relationships with students, research subjects or clients that may be interpreted as questionable.
- Using another's ideas without obtaining permission or giving due credit (plagiarism).

"BAD" Behaviors (continued)

- Unauthorized use of confidential information in connection with one's own research.
- Failing to present data that contradict one's own previous research.
- Overlooking others' use of flawed data or questionable interpretation of data.
- Changing the design, methodology or results of a study in response to pressure from a funding source.
- Publishing the same data or results in two or more publications.

What To Do If You Know of or Suspect Misconduct?

- Communicate issues and concerns with your advisor **(Be Your Own Advocate!!!)**
- Talk with the Graduate Program Director
- Report to Research Integrity Officer (RIO)

Research Integrity Officer

https://rio.msu.edu/ James Pivarnik, Ph.D.

Safeguarding the integrity of research and creative activities is fundamental to the mission of Michigan State University. **All members of MSU** share responsibility to assure that misconduct or fraud in research and creative activity is dealt with effectively and that MSU's high standards for scholarly integrity are preserved.

Questions, consultation and reporting.

Research Integrity Officer

Anonymous Allegations

Michigan State University has implemented a telephone and web reporting Hotline to help maintain adherence to ethical practices. The purpose of the Hotline is to provide an anonymous method to report known or suspected misconduct related to fiscal matters, conflicts of interest, employment, medical/HIPAA, research, safety, athletics, discrimination/harassment, privacy, retaliation, or any other area of legal, policy, or ethical concern not specifically listed.

MISCONDUCT HOTLINE

What to Do If You Witness Misconduct?

Research Misconduct Rights and Responsibilities

- If you discover research misconduct, contact the Research Integrity Officer for guidance. You have the right to remain anonymous and are protected from retaliatory acts.

- If you are accused of research misconduct, you are entitled to due process. Contact the Research Integrity Officer for guidance. That office is obligated to protect the confidentiality of the process.

Research Misconduct Process

Stages of the Process

- Submission of allegations
- Assessment
- Sequestration and notification to respondent of allegations
- Inquiry
- Investigation
- Formal finding
- Appropriate disposition

Misconduct Policy - Disposition

Examples of disciplinary actions include:

- Letter of reprimand
- Removal from the particular project
- Special monitoring of future work
- Suspension or expulsion (students)
- Termination of employment (staff)
- Dismissal of faculty member

Ruined reputation!!!

Resolutions to Research Misconduct

Punishment and reprimand take many different forms in these cases and range from the following:

- Loss of status or appointment
- Temporary restrictions on participation in review committees
- Temporary restrictions on submission of proposals to federal agencies
- Monetary fines
- Imprisonment
- Loss of licenses or other credentials

(LaFollette, “The Evolution of the Scientific Misconduct Issue”).

Tenets of Good Institutional Practice

- Discussion of research methods
- Reporting systems
- Training/education in ethics and research standards
- Records (*e.g.*, electronic notebooks)
- Incentives and evaluation
- Enforcement

Proper Mentor-Mentee Relationships and Importance for Responsible Conduct

Proper Mentor-Mentee Relationships

- **Successful mentor/mentee relationships**: Both parties are engaged, flexible, authentic and there is reciprocity.

- **Ground rules**: Be respectful of time and always show appreciation!

Selecting a Research Group/Mentor

There are three major factors to consider when selecting a research group:

- The research program (Does the work excite you?)
- The personality and mentoring style of the Principal Investigator (PI) (Is it the right environment for you??)
- The research environment (Collaborative spirit, ethical?)

https://www.training.nih.gov/mentoring_guidelines

What is a Mentor?

- The best mentors are advisors, coaches, counselors and supporters all at the same time.

- They are experienced faculty who guide your research/creative activity, but also challenge you to develop your independence.

- A good mentor will help you define your research goals, and then support you in your quest to achieve them. He or she will share knowledge, provide encouragement, and hopefully inspire you.

https://www.training.nih.gov/mentoring_guidelines

Proper Mentor-Mentee Relationships

- **Successful mentor/mentee relationships**: Both parties are engaged, flexible, authentic and there is reciprocity.

- Mentoring a less-experienced researcher (scholar) is a professional responsibility of all scientists (faculty) (NAS 1997).

- **Ground rules**: Be respectful of time and always show appreciation!

https://cdn1.sph.harvard.edu/wp-content/uploads/sites/36/2016/06/The-Mentor-Mentee-Relationship-Handout_October-2015.pdf

https://www.apa.org/research/responsible/mentoring/

The Mentor-Mentee Relationship

MENTOR ROLES, RESPONSIBILITIES AND BENEFITS:

A mentor is someone who takes a special interest in helping another person develop into a successful professional.

The mentor's role is to teach, guide and help shape the professional growth and learning of the mentee and to serve as a positive role model.

Remember that every situation is different in terms of the roles, circumstances and outcomes.

The Mentor-Mentee Relationship

Benefits of mentoring for the mentee:

- Assistance in defining career goals, strategies and outcomes.
- Develops a meaningful professional relationship with mentor.
- Increases professional connections and network.
- Gains knowledge of workplace expectations.
- Builds self-advocacy skills and confidence to be successful.
- Access to potential internships and job opportunities.

The Mentor-Mentee Relationship

Mentor Responsibilities:

- Shares information about his/her background, skills and interests.
- Serves as the primary role model for how to properly conduct research and creative activities. Standards of conduct!
- Tells mentee how he/she can help.
- Listens actively.
- Serves as a positive role model.
- Helps mentee set educational/career goals.

The Mentor-Mentee Relationship

Mentor Responsibilities (cont'd):

- Provides encouragement for building self-confidence and self-esteem.
- Offers mentee constructive and meaningful advice and feedback.
- Celebrates milestones and achievements with mentee.
- Acts as a resource for information about careers.
- Educates mentee on workplace expectations.

The Mentor-Mentee Relationship

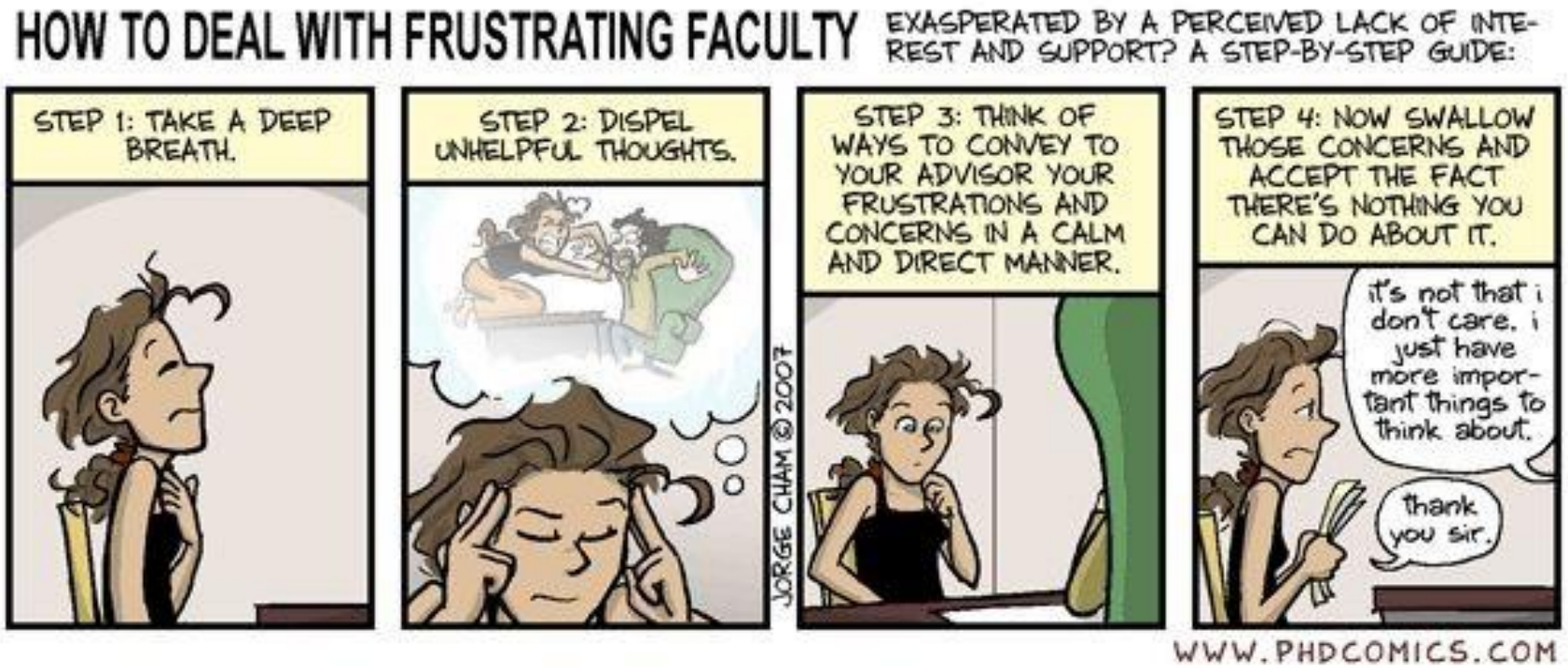
Mentee Responsibilities:

- Takes responsibility for keeping in regular contact with the mentor and actively participates in the relationship.
- Assesses academic/professional strengths, learning and developmental needs, values and short and long-term career goals (self evaluation).
- Develops a plan with the mentor for achieving these goals.
- Follows through on commitments and goals.

The Mentor-Mentee Relationship

Mentee Responsibilities (cont'd):

- Respects the mentor's time.
- Maintains confidentiality at all times.
- Openly shares successes and failures.
- Is receptive to feedback and coaching.
- Takes advantage of opportunities presented by the mentor.



http://research-ethics.org/topics/mentoring/

Summary of Key Concepts

•Ethical conduct in science assures the reliability of research results and the safety of research subjects.

•Ethics in science include: a) standards of methods and process that address research design, procedures, data analysis, interpretation, and reporting; and b) standards of topics and findings that address the use of human and animal subjects in research.

•Replication, collaboration, and peer review all help to minimize ethical breaches, and identify them when they do occur.

Questions??