SCIENTIFIC RESEARCH METHODOLOGIES AND TECHNIQUES

Unit 10: RESEARCH ETHICS

Luis M. Camarinha-Matos
cam@uninova.pt

PhD PROGRAM IN ELECTRICAL AND COMPUTER ENGINEERING

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1. BASIC CONCEPTS

Concept

Ethics are norms for conduct that distinguish between **acceptable** and **unacceptable** behavior.

"Ethics (derived from the Greek *ethos*, meaning character, custom, or usage), or morality (from the Latin synonym meaning manner, custom, or habit), is the philosophical study of normative behavior, the 'shoulds' and 'oughts' the 'rights' and 'wrongs' of our conduct.

Research Ethics is a kind of applied or practical ethics, meaning that it attempts to resolve not merely general issues but also specific problems that arise in the conduct of research. Its goal is to determine the moral acceptability and appropriateness of specific conduct and to establish the actions that moral agents ought to take in particular situation. Research ethics is therefore not merely theoretical. It aims to establish practical moral norms and standards for the conduct of research."

[Peach, 1995]

Why is it needed?

"**Research is a process**, using defensible methods that is done on behalf of **society**, in search of knowledge that can be **shared and used**. Research is usually **supported** through **public** or **private funds**. Research matters because it is judged to be important by knowledgeable peers.

Just as researchers have responsibilities to their colleagues and to the institution in which they work, researchers have responsibilities to **potential and actual funders**, to the **audiences and publishers** to whom they submit their work, and to peers."

Professor Deni Elliot,
University of Montana Research Ethics Center
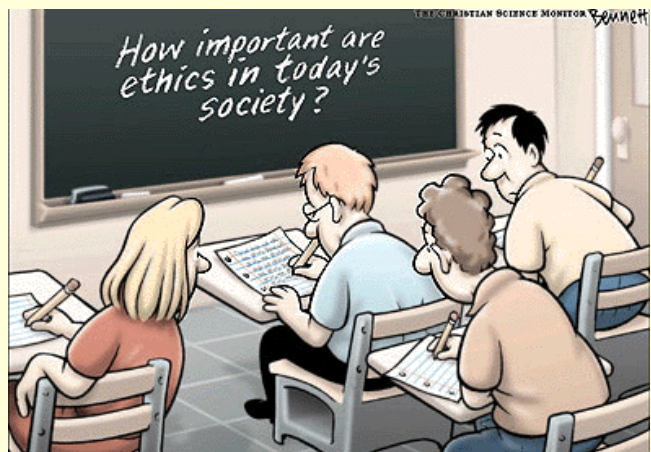
Responsible conduct in research

- **Compliance** means the researcher follows the rules set out by the government, funding agencies and the researcher's institution.

- **Ethics** refers to a responsible behavior towards humans, sentient beings, society and ecosystems. Ethics means promoting good.

- Both **compliance** and **ethics** are required for the **Responsible Conduct in Research**.

- Compliance sets out the **minimum acceptable** ethical behavior in research.
  - Noncompliance results in **Research Misconduct**

  [Choudhuri, 2007]

- Ethical behavior requires more than simply following the rules.
- Ethics is the study of how human action affects other humans, animals, society, or the ecosystem.
- Ethical analysis provides a way of making sense of rules and regulations.

[Ribu, 2005]

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2. MISCONDUCT FORMS

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Fabrication

- **Fabrication is the act of making up data or results, then recording or reporting them as part of the research record.**
  - fabricated data have not been obtained in the manner or by the methods described in the report
  - presenting fabricated results in a research report
- **Fabrication is ethically wrong because it is likely to lead to harm to others.**
- **It is legally required for funding agencies and research institutions to take actions against researchers who fabricate.**

Why is it a problem?

- Scientific research and discovery is a model for collaborative effort.
- Each new discovery is built upon the blocks of earlier discoveries.
- Each researcher is dependent upon the work of researchers who have come before.
- Increasingly, individual research projects require skill sets and knowledge bases from a variety of different disciplines.

[Ribu, 2005]

Fabrication ...

Competition may tempt people into fabrication ...

- **Researchers compete with one another for funding from a limited pool of resources**
- **Labs that are working on similar questions compete to be the first to confirm and publish particular results.**
- **Institutions and labs compete for top researchers, post-docs, and students.**
- **Students often feel that they are in competition for projects, credit, mentoring time and attention.**

  - **The researcher is expected both to share data with other researchers and to be the first, when possible, to publish accurate results.**
  - **The researcher must continually choose between these.**

  [Ribu, 2005]

  - Also a dilemma in collaborative projects!

Falsification / misrepresentation

Falsification - Intentional alteration or presentation of original findings in a way which distorts the result

- scientifically unjustified alteration or selection of data or results
- manipulating research materials, equipment or processes
- misrepresentation to omit results or data pertinent to conclusions

In research ethics, the term *falsification* means changing or misrepresenting data or experiments, or misrepresenting other significant matters such as the credentials of an investigator in a research proposal.

Unlike fabrication, the distinguishing of falsification data from legitimate data selection often requires judgment and an understanding of statistical methods.

www.onlineethics.org/cms/13389.aspx

Falsification is the practice of **omitting** or **altering** research materials, equipment, data, or processes in such a way that the results of the research are no longer accurately reflected in the research record. **Fabrication** is the practice of **inventing** data or results and recording and/or reporting them in the research record.

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Plagiarism

Plagiarism - Presenting someone else's research plan, manuscript, article or text, or parts thereof, as one's own.

- **Plagiarism** - the appropriation of another person's ideas, processes, results or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts.

Internet makes plagiarism even easier than it used to be.

"Cutting and pasting" without giving proper credit

Internet also makes catching plagiarists easier than it used to be.

"Dear Mr. Trent: Since you only *pretended* to write this paper, I only *pretended* to grade it!"

Also specific software:
http://turnitin.com/static/pdf/luton.pdf
www.umuc.edu/distance/odell/cip/links_plagiarism.shtml#detection

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Plagiarism ...

"OIG is currently experimenting with the use of computer software to identify plagiarized text in NSF proposals. There are a number of free or commercially available software packages that have the ability to identify text that is common to multiple documents. Some software packages are designed to perform a side-by-side comparison of two or more documents, while others compare the text of a document to text found on websites.

We obtained one "freeware" package and one commercially available to test their capabilities. Interns with linguistics training ran randomly selected proposals through the software to determine if they contained plagiarism. The interns analyzed over 600 proposals, and found that approximately 2.5% of the proposals contained more than *de minimus* unattributed copied text from other sources. Plagiarism rates were relatively uniform across scientific disciplines, although we noted that the rate of possible plagiarism in NSF CAREER proposals was significantly higher at 15%."

-NSF IG Semiannual Report March 2006

Intellectual theft / Not giving credit

Misappropriation - A researcher illicitly presents or uses in his/her own name an original research idea, plan or finding disclosed to him/her in confidence.

     ... Similar to plagiarism

     ... Access to this knowledge could have been obtained through

         Reviewing others' work (papers, projects)

         Conversations, lab visits, ...

Understatement of other researchers' contribution to a publication.

     ... Particularly critical in team work, projects in consortia

Negligence in referring to earlier findings.

A researcher is not expected to include only new ideas in his/her papers/talks ... But proper citation is needed.

Other forms of misconduct

Violation of Confidential Peer Review
> When reviewing a paper (submitted to a conference, journal,
> ... or even when asked by a colleague)
> When reviewing a project or project proposal

a researcher is obliged to keep confidentiality of all information he/she got access to.

Misrepresenting Credentials – for instance, when someone claims qualifications, experience, etc. he/she does not have.

Pseudo-citations – making citations to important works ... but that you didn't read !

Publication of the same results several times as new (self-plagiarism)
> ... A researcher can certainly build on his/her previous work, and include summaries of it to give a better context, but each new paper MUST have a substantial amount of new results.

Other forms of misconduct ....

"Other deviations" from acceptable research practices:

1. Publishing the same paper in two different journals without telling the editors
2. Submitting the same paper to different journals without telling the editors
3. Not informing a collaborator of your intent to file a patent in order to make sure that you are the sole inventor
4. Including a colleague as an author on a paper in return for a favor even though the colleague did not make a serious contribution to the paper
5. Discussing with your colleagues data from a paper that you are reviewing for a journal
6. Trimming outliers from a data set without discussing your reasons in paper
7. Using an inappropriate statistical technique in order to enhance the significance of your research
8. Bypassing the peer review process and announcing your results through a press conference without giving peers adequate information to review your work
9. Conducting a review of the literature that fails to acknowledge the contributions of other people in the field or relevant prior work
10. Stretching the truth on a grant application in order to convince reviewers that your project will make a significant contribution to the field
11. Stretching the truth on a job application or curriculum vita
12. Giving the same research project to two graduate students in order to see who can do it the fastest <... and then damaging one of them that cannot pursue the work for his graduation>

[Resnik, 2007] www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

Other forms of misconduct ...

13. Overworking, neglecting, or exploiting graduate or post-doctoral students
14. Keeping original data at home or taking it with you when you move
15. Failing to maintain research data for a reasonable period of time
16. Making derogatory comments and personal attacks in your review of author's submission
17. Promising a student a better grade for sexual favors
18. Using a racist epithet in the laboratory
19. Making significant deviations from the research protocol approved by your institution's Animal Care and Use Committee or Institutional Review Board for Human Subjects Research without telling the committee or the board
20. Not reporting an adverse event in a human research experiment
21. Wasting animals in research
22. Exposing students and staff to biological risks in violation of your institution's biosafety rules
23. Rejecting a manuscript for publication without even reading it
24. Sabotaging someone's work
25. Stealing supplies, books, or data
26. Rigging an experiment so you know how it will turn out
27. Making unauthorized copies of data, papers, or computer programs
28. Owning over $10,000 in stock in a company that sponsors your research and not disclosing this financial interest
29. Deliberately overestimating the clinical significance of a new drug in order to obtain economic benefits

[Resnik, 2007] www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

3. PROFESSIONAL RESPONSIBILITY

Scope of responsibility

"Ethical responsibility...involves more than leading a decent, honest, truthful life. . . . And it involves something much more than making wise choices when such choices suddenly, unexpectedly present themselves. Our moral obligations must . . . include a willingness to engage others in the difficult work of defining the crucial choices that confront technological society . . . ." [Winner, 1990]

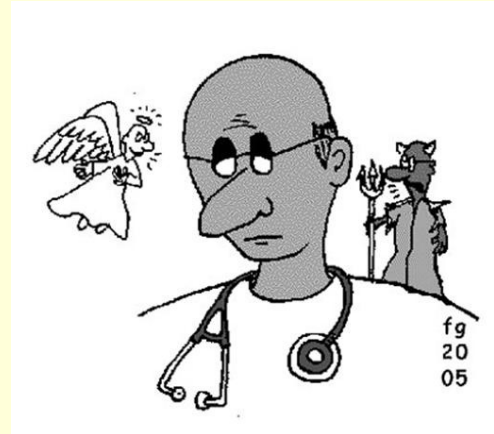**Scope of responsibility**

To comply with:
- **Ethical codes**
- **Good practices in research**

To promote:
- **Research Ethics**
- **Responsible Conduct in Research**
- **Responsible Data Management**

To provide information about:
- **Research Misconduct**
- **Conflict of interest**
- **...**

Why?

"

- **Research is a process, using defensible methodology that is done on behalf of society, in search of knowledge that can be shared and used.**

- **Research is usually supported through public or private funds.**

- **Research matters because it is judged to be important by knowledgeable peers.**

- **Just as researchers have responsibilities to their colleagues and to the institution in which they work, they have responsibilities to potential and actual funders, to the audiences and publishers to whom they submit their work, and to peers. "**

[Ribu, 2005]

Responsible data management

Keeping the integrity of data

- **Trimming**: "the smoothing of irregularities to make the data look extremely accurate and precise."

- **Forging**: "inventing some or all of the research data that are reported, and even reporting experiments to obtain those data that were never performed."

- **Cooking**: "retaining only those results that fit the theory and discarding others."

- Harris, Pritchard, & Rabins, 125-128
- Sigma Xi, Honor in Science (1986), 11-18

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Responsible data management ...

Keeping required privacy & confidenciality

- **Respecting privacy of individuals, when the research involves collecting personal information**
  - Paying carefull attention to existing regulations
  - Taking into account principles of informed consent
    - Potential subjects should be adequately informed of the aims, methods, benefits, hazards and any discomfort.
    - Consent should normally be in writing and records kept.
    - Respect for Vulnerable Persons.
    - Potential subjects are free to withdraw without implication.
    - All subjects should be volunteers, decisions not to participate should not prejudice the subject in any way.

- **Research conducted in private industry or in conjunction with private industry gives access to proprietary information**
  - Mandatory to respect the non-disclosure agreements
  - This also implies special care in handling information in the research environment (how it is stored, who has access to it, ...)

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Proper criteria for authorship

Criteria for Authorship

Authors should:
- Make a substantial contribution to research work
- Write draft of the article or revise it critically
- Provide final approval of the version to be published
- Agree to be named as author

(See IEEE recommendations)

Avoid authorship disputes by discussing plans and general criteria for authorship from the beginning of a collaboration

Acknowledge those who contribute to the research but do not qualify for authorship

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Objectivity and accuracy

- "Objectivity, accuracy, and acknowledgement of uncertainties in research work do not impose merely the negative requirement that research scientists avoid deliberate bias in their own work.

- Objectivity also requires that they attempt to meet a positive demand: to present results in such a way as to avoid their misuses and misapplication by others and to speak out when others appear to misuse or misinterpret them."

[Shrader-Frechette,1994]

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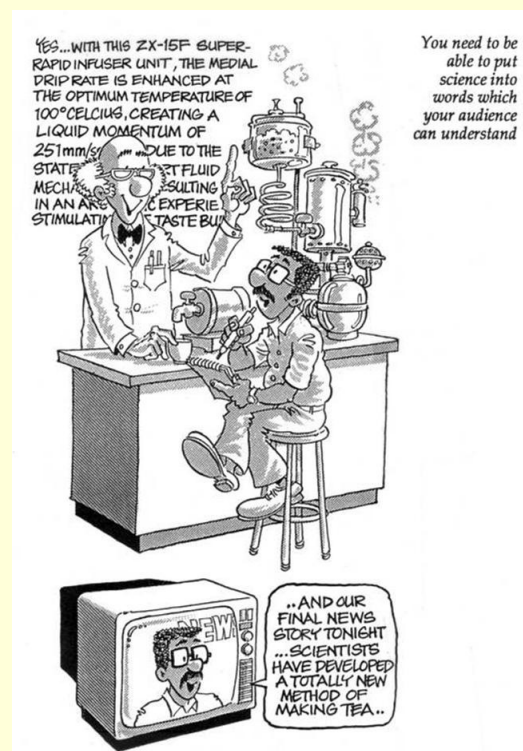
Conflict of interest

- A Person has a conflict of interest if…

  – he/she is in a relationship with another requiring him to exercise judgment in that other's service…

  – he/she has an interest tending to interfere with the proper exercise of judgment in that relationship

  Michael Davis, "Conflict of Interest," Business and Professional Ethics Journal, vol.1, no. 4 (1982), pp. 17-27

"There is nothing unusual or necessarily wrong in having a conflict of interest. How it is dealt with is the important thing. "

Independent Commission Against Corruption (ICAC), Australia

Examples:
-**Evaluation of proposals from your own institute.**
-**Evaluation papers from relatives or colleagues from your organization.**
-**Holding a direct or indirect interest in an outside entity that conducts business in an area closely related to the researcher's employer**
- **Use of the university research facilities to conduct private research work without benefit for the university.**
-**...**

Carefulness

- **Avoid careless errors and negligence;**
- **Carefully and critically examine your own work and the work of your peers.**
- **Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.**

- **Negligent Research**: "insufficient care in a matter where one is morally obliged to be careful."

- **Reckless**: "acts in professional practice [that] ignore dangers that should be obvious to a minimally competent professional so the acts themselves create a presumption of willfully ignoring those dangers together with failing to give them due attention and care"

Whitbeck, *Ethics in Engineering Practice and Research* (1998), Cambridge Press, 215-216

Respect Intellectual Property

- **Honor patents, copyrights, and other forms of intellectual property.**

- **Do not use unpublished data, methods, or results without permission.**

- **Give credit where credit is due.**

- **Give proper acknowledgement or credit for all contributions to research.**

- **Never plagiarize.**   www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

Remember: Other researchers know the literature and probably have access to the same sources of information!

Do not take notes from Internet or papers without including a reference to the source ... Later on you might forget it was copied!
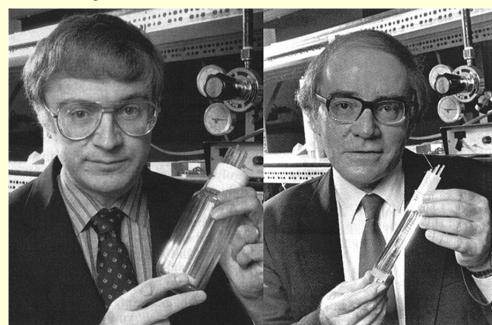

Bad examples

Hwang Woo-suk

Public apology for his **fabrication** on his <u>stem cell</u> research paper.

Stanley Pons and Martin Fleischman

After a short period of public acclaim, the pair were attacked widely for sloppy, unreproducible research and inaccurate results on <u>cold fusion</u>.

Jan Hendrik Schön
Considered brilliant, he was on the fast track in the field of nanoelectronics, having got several prizes.
But his rate of publication (40 a year) and his amazing results began to make some colleagues curious.
Eventually Schön was caught falsifying data when he presented identical graphs in two different papers - and the graphs were supposed to be on different topics.

4. POLICIES

European Commission policy

«All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.»

FP7, Decision N°1982/2006/EC, Article 6 (1§)

«A proposal […] which contravenes fundamental ethical principles […] shall not be selected . Such a proposal may be excluded from the evaluation and selection procedures at any time.»

FP7, Rules for Participation, Article 10

Areas excluded from funding under FP 7, Art. 6 (2§):
A) Research activity aiming at human cloning for reproductive purposes
B) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (Research related to cancer treatment of the gonads can be financed)
C) Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer

European Commission policy ...

ETHICAL ISSUES TABLE
in project proposals submitted to FP7

In case of need, proposals have to go through a specific ethical reviewing process.

	YES	PAGE
Informed Consent		
• Does the proposal involve children?		
• Does the proposal involve patients or persons not able to give consent?		
• Does the proposal involve adult healthy volunteers?		
• Does the proposal involve Human Genetic Material?		
• Does the proposal involve Human biological samples?		
• Does the proposal involve Human data collection?		
Research on Human embryo/foetus		
• Does the proposal involve Human Embryos?		
• Does the proposal involve Human Foetal Tissue / Cells?		
• Does the proposal involve Human Embryonic Stem Cells?		
Privacy		
• Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)		
• Does the proposal involve tracking the location or observation of people?		
Research on Animals		
• Does the proposal involve research on animals?		
• Are those animals transgenic small laboratory animals?		
• Are those animals transgenic farm animals?		
• Are those animals cloned farm animals?		
• Are those animals non-human primates?		
Research Involving Developing Countries		
• Use of local resources (genetic, animal, plant etc)		
• Benefit to local community (capacity building i.e. access to healthcare, education etc)		
Dual Use		
• Research having direct military application		
• Research having the potential for terrorist abuse		
ICT Implants		
• Does the proposal involve clinical trials of ICT implants?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	X	

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Another example: ESRC policy

There are six key principles of ethical research that the ESRC expects to be addressed, whenever applicable:

■ Research should be designed, reviewed and undertaken to ensure integrity and quality

■ Research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific and exceptional research contexts for which detailed guidance is provided in the policy Guidelines

■ The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected

■ Research participants must participate in a voluntary way, free from any coercion

■ Harm to research participants must be avoided

■ The independence of research must be clear, and any conflicts of interest or partiality must be explicit

Economic & Social Research Council, UK

www.esrc.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf

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Codes of ethics

Code of ethics - code of professional responsibility intended to serve as a guide to the everyday professional conduct .

General summary of some ethical principles that various codes address:

Honesty
Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, granting agencies, or the public.

Objectivity
Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or minimize bias or self-deception. Disclose personal or financial interests that may affect research.

Integrity
Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

Carefulness
Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

...cont.

Codes of ethics ...

Openness
Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

Respect for Intellectual Property
Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give credit where credit is due. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

Confidentiality
Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

Responsible Publication
Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

Responsible Mentoring
Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

Respect for colleagues
Respect your colleagues and treat them fairly.

Social Responsibility
Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

...cont.

Codes of ethics ...

Non-Discrimination
Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors that are not related to their scientific competence and integrity.

Competence
Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

Legality
Know and obey relevant laws and institutional and governmental policies.

Animal Care
Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

Human Subjects Protection
When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

* Adapted from Shamoo A and Resnik D. 2003. *Responsible Conduct of Research* (New York: Oxford University Press).

www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

IEEE Code of Ethics

We, the members of the IEEE, in **recognition of the importance of our technologies in affecting the quality of life throughout the world**, and in accepting a **personal obligation to our profession**, its members and the communities we serve, do hereby commit ourselves to the highest ethical and professional conduct and agree:

1. to accept responsibility in making engineering decisions consistent with the **safety, health and welfare of the public,** and to disclose promptly factors that might endanger the public or the environment;

2. to avoid real or perceived **conflicts of interest** whenever possible, and to disclose them to affected parties when they do exist;

3. to be **honest and realistic in stating claims or estimates** based on available data;

4. to **reject bribery** in all its forms;

5. to **improve the understanding of technology**, its appropriate application, and potential consequences;

6. to **maintain and improve our technical competence** and to **undertake technological tasks for others only if qualified** by training or experience, or after full disclosure of pertinent limitations;

7. to seek, accept, and offer **honest criticism** of technical work, to **acknowledge and correct errors**, and to **credit properly the contributions of others**;

8. to **treat fairly all persons** regardless of such factors as race, religion, gender, disability, age, or national origin;

9. to **avoid injuring others**, their property, reputation, or employment **by false or malicious action**;

10. to **assist colleagues and co-workers in their professional development** and to **support** them in **following this code of ethics.**

www.ieee.org/portal/index.jsp?pageID=corp_level1&path=about/whatis&file=code.xml&xsl=generic.xsl

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BMES Code of Ethics

Biomedical engineering is a learned profession that combines expertise and responsibilities in engineering, science, technology, and medicine. Mindful that public health and welfare are paramount considerations in each of these areas, the Society identifies in this Code principles of ethical conduct in professional practice, health care, research, and training. This Code reflects voluntary standards of professional and personal practice recommended for biomedical engineers.

Biomedical Engineering Professional Obligations
Biomedical engineers in the fulfillment of their professional engineering duties shall:
 1. Use their knowledge, skills, and abilities to enhance the safety, health, and welfare of the public.
 2. Strive by action, example, and influence to increase the competence, prestige, and honor of the biomedical engineering profession.

Biomedical Engineering Health Care Obligations
Biomedical engineers involved in health care activities shall:
 1. Regard responsibility toward and rights of patients, including those of confidentiality and privacy, as a primary concern.
 2. Consider the broader consequences of their work in regard to cost, availability, and delivery of health care.

BMES Code of Ethics ...

Biomedical Engineering Research Obligations
Biomedical engineers involved in research shall:
1. Comply fully with legal, ethical, institutional, governmental, and other applicable research guidelines, respecting the rights of and exercising the responsibilities to human and animal subjects, colleagues, the scientific community and the general public.
2. Publish and/or present properly credited results of research accurately and clearly.

Biomedical Engineering Training Obligations
Biomedical engineers entrusted with the responsibilities of training others shall:
1. Honor the responsibility not only to train biomedical engineering students in proper professional conduct in performing research and publishing results, but also to model such conduct before them.
2. Keep training methods and content free from inappropriate influence of special interests.

http://www.bmes.org/pdf/2004approvedcodeofethicsshortform.pdf

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Publishing ethics

Publishers are developing mechanisms to enforce publishing ethics ...

Some publishers (Elsevier, Wiley–Blackwell, Springer, Taylor & Francis and the BMJ Publishing Group) have signed up their entire catalogue of journal titles as COPE members.

http://publicationethics.org/

## Publishing ethics ...

Another example:

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Diversity

When collaborating / interacting with researchers from other geographical regions, it is necessary to be aware of different ethical principles according to different cultures and value systems.

Inglehart-Welzel cultural map of the world, 2005

Different priorities in values

http://margaux.grandvinum.se/SebTest/wvs/articles/
folder_published/article_base_54
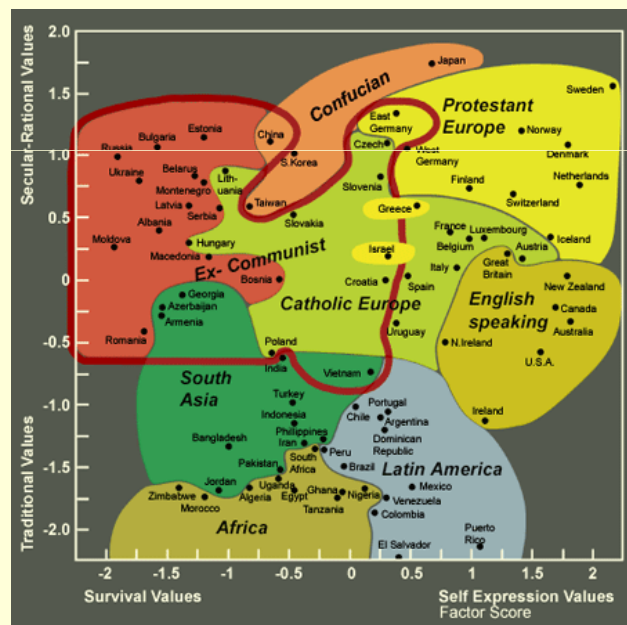
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Diversity ...

"

- The disagreement about values is often not the result of the uptake of different values but of different interpretation or prioritization of values.

- Moral values depend on our self-understanding, conception of good life, which in turn depend on historical events and economic situation, cultural tradition, and religious convictions."

[Sutrop, 2008]

Important to make the collaboration principles explicit (e.g. Consortium Agreement)

Peach, Lucianda (1995) " An Introduction to Ethical Theory," <u>Research Ethics: Cases and Materials</u>, Editor Penslar, Robin Levin, Bloomington Indianan University Press.

Langdon Winner, 1990. "Engineering ethics and political imagination." Pp. 53-64 in Broad and Narrow Interpretations of Philosophy of Technology: Philosophy and Technology 7, edited by P. Durbin. Boston: Kluwer. Cited in Herkert, J.R. Engineering ethics education in the USA: Content, pedagogy and curriculum. European Journal of Engineering Education, 25, 303-13, 2000.

Shrader-Frechette, K (1994). Ethics of Scientific Research. Lanham, MD: Rowman & Littlefield Publishers, p. 55.

Sutrop, M. (2008). Are European moral principles universal? International Conference on Human Rights and Biomedicine, Rotterdam, 10-12 December 2008. www.erasmusobservatoryonhealthlaw.nl/Uploads/Rotterdam_Sutrop_111208.ppt