

World Conference on Research Integrity

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*Integrity in Biomedical Research:
The Role of Education*

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Integrity in Biomedical Research: The Role of Education

- Truth and trust forms the backbone of research integrity.
- But research integrity is challenged by a number of threats.
- Therefore it is important to equip researchers with knowledge and cognitive tools in order to prevent misconduct, from the very beginning of their career.
- This is the essential role of an **EDUCATION PROGRAM**.



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Integrity in Biomedical Research: The Role of Education

Threats

Conflict of interests

Secrecy: external pressures

Unfair competition, excessive ambition

Code of Conduct

Research Agency
(national, international)
Academy, University

Scientific research

Education Program

Misconduct

plagiarism

forgery

data manipulation

obliteration

sloppiness



Integrity in Biomedical Research: The Role of Education

Education Program

- The Amsterdam course on Social Responsibility for Medical Students, includes, but goes beyond, bio-medical ethics; it consists of lectures and
 - group discussions,
 - workshops and
 - student-led seminars.
- The core material on the frameworks of ethics is provided in the lectures, while workshops and seminars are used to apply the material to real everyday situations.

This course spans 10 weeks with 2 sessions per week of 3 h duration each.



Integrity in Biomedical Research: The Role of Education

- The success of any course in this field depends critically on the availability of good didactic material and on knowledgeable and well trained lecturers and tutors.
- While didactic material can be available using a Website, competent tutors are irreplaceable.
- The assessment of ethics should be incorporated into all formal examinations. It is recommended that ethics be addressed as part of a wider approach to professionalism in order to promote integration.

Goldie J, Schwartz L, McConnachie A, Morrison J. The impact of a modern medical curriculum on students' proposed behaviour on meeting ethical dilemmas. *Med Educ.* 2004 Sep;38(9):942-9.



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Integrity in Biomedical Research: The Role of Education

Main points in planning an Education program on research integrity in the medical environment:

- 1. Basic framework: concepts of ethics.**
 - Scientific misconduct: forgery, plagiarism, data falsification, obliteration, sloppiness.

- 2. Ethics in biomedical research:**
 - Guidelines - examples of codes of conduct that have been developed in the course of time.
 - Choice of research subject: human and animal research; ethical implications.

- 3. General aspects arising in research practice:**
 - Dilemmas and conflicts of interest.
 - The practice of research: grant applications, collaborations, publications (co-authorships)



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Integrity in Biomedical Research: The Role of Education

1. Basic framework: concepts of ethics.
 - Critical thinking in ethics: what makes a good or bad argument?
 - Insight into the concepts of social responsibility, of freedom and of independence of science.
 - Scientific misconduct:
 - plagiarism** (internet temptations),
 - forgery**,
 - data manipulation**,
 - obliteration**.
 - sloppiness**.



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Integrity in Biomedical Research: The Role of Education

- **From the NUREMBERG CODE (1947)**
- The informed voluntary consent of the human subject is absolutely essential.
- The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
- ***British Medical Journal No 7070 Volume 313,
7 December 1996***



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- The World Medical Association's recommendations adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended several times since:
- From the **HELSINKI DECLARATION**:
- The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor



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Integrity in Biomedical Research: The Role of Education

- **WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI**

When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship

- In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.



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- **World Medical Association International Code of Medical Ethics**, Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 and amended several times, the last at the WMA General Assembly, Pilanesberg, South Africa, October 2006.
- **DUTIES OF PHYSICIANS IN GENERAL:**
- **A PHYSICIAN SHALL** deal honestly with patients and colleagues, and report to the appropriate authorities those physicians who practice unethically or incompetently or who engage in fraud or deception.



Integrity in Biomedical Research: The Role of Education

- Research on animals:
- Three basic ethical principles.
- the instrumental versus intrinsic value of an experimental animal;
- the balance between the human benefit of an animal experiment and the discomfort for the animal;
- the problem of animal rights and animal suffering and pain.



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Experiments on animals:

- Consider alternative methods with special reference to the 3 R's:
 - replacement,
 - reduction and
 - refinement of animal experiments;
- The qualifications (license), education and training of researchers and animal technicians;
- Ethics Committees on Animal Experimentation and their regulations.



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The Global Health Education Consortium (GHEC) is responding to the challenges put forward by the UN Millennium Development Goals, by enhancing awareness of Medical Schools with respect to the **choice of research themes**: this is also an issue of social responsibility.

- In Amsterdam we are involved in an Educational program “Medical Peacework” (poverty and development, violence and conflicts, human rights, etc) coordinated by the University of Trondheim, with collaboration of groups from UK, Germany, Slovenia and The Netherlands that received a Leonardo da Vinci grant from the European Commission.
- <http://www.tavos.org>



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3. General aspects arising in research practice.

➤ **Dilemmas and conflicts of interest.**



Integrity in Biomedical Research: The Role of Education

Discussion of **3 dilemmas**:

- Stem cell research: how far may one go?
- Is the “informed consent” real and solid?
- To whom is the clinical researcher accountable while performing clinical drug trials?



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➤ **Stem cell research:**

- European Scientists(EuroStemCell and ESTOOLS) are calling for harmonisation of current laws in the hope that their European counterparts are able to collaborate on international projects without fear of legal reprisal. **But how far may one go?**
- - should research on stem cells derived from supernumerary embryos after *A.I.be allowed?*
- - should it be *allowed* to create embryos by nuclear transfer, for the sole purpose of stem cell research?



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➤ Is the “informed consent” real and solid?

Ethical dilemmas in the role of “physician-soldier”

- May bio-medical researchers participate in Classified Military Research using soldiers as experimental subjects?
- May medical scientists carry out classified bio-medical research in the field of biological/chemical warfare?
- May medical researchers (psychiatrists/psychologists) participate in development of harsh methods of interrogation of prisoners (Torture)?

www.psych.org/downloads/AMAResolution1Nov05.pdf.

Victor W. Sidel and Barry S. Levy, *Military Medical Ethics*, Volume 1: Chapter 11
PHYSICIAN-SOLDIER: A MORAL DILEMMA?
and point/counterpoint—a response by Dominick R. Rascona



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➤ To whom is the clinical researcher accountable while performing clinical drug trials?

- -If the findings of drug trials remain the property of the sponsor, then how much evidence is never reported ? – problem of obliteration.
- -May the medical researcher not publish results of sponsored drug testing showing no effects, or adverse effects, while positive results are promoted?
- Chalmers I. Underreporting research is scientific misconduct. *JAMA* 1990; 263: 1405-1408.
- Chris A Commens *MJA* 2001; 174: 648-649



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■ **Teaching ethics in Europe.**

Frédérique Claudot, François Alla, Xavier Ducrocq and Henry Coudane.
Journal of Medical Ethics 2007;33:491-49

- Common barriers to medical ethics instruction were stated to be:
 - a lack of time within the curriculum,
 - a lack of qualified teachers.
 -
- However, at the same time, the **importance of introducing ethics into the medical curriculum** has been established by a number of national medical institutions/committees.
- One can only hope that, concomitant with international recommendations, **all medical schools will progressively grant the importance to ethics instruction that it deserves.**



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➤ Conclusions, taking into consideration
Nicholas Steneck's questions:

1. What are the most important challenges facing researchers and policy makers committed to maintaining high standards for integrity in research?
2. What steps can/should be taken to address these challenges?



Integrity in Biomedical Research: The Role of Education

1. What are the most important challenges facing researchers and policy makers committed to maintaining high standards for integrity in research?

- Competition with too strong commercial and/or political pressures may induce foul play and secrecy.
- Too weak social control;
- Lack of appropriate education and training in ethics.



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2. What steps can/should be taken to address these challenges?

- Invest in Education; activate the Universities to establish programs of serious ethical training of researchers (both under – & graduate students) similar as is being done to acquire the license to perform animal experimentation.
- Reinforce the span of action of Research Funding Agencies with respect to monitoring and controlling issues of “research integrity”.