# **Ethics for Medical Physicists and Biomedical Engineers**

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#### Preamble

A scientist or engineer (S/E) uses understanding, insight and ingenuity to discover new knowledge and to create new technologies that benefit individuals and societies. In pursuing these goals, a S/E must be free to theorize and experiment unimpeded by political pressures, religious dogma or fear of reprisal. Preservation of this freedom is the purpose of the Bill of Rights for Scientists and Engineers. The Bill of Rights is consistent with the Statement on the Universality of Science of the International Council for Science (ICSU).

#### **Article 1**

A S/E is an individual who uses a scientific approach in the pursuit of new knowledge and technologies. A S/E is not required to possess any specific credential such as appointment in an institution, funding by an agency, or membership in an organization.

**Article 2** 

Science and engineering may be practiced in any location; they are not confined to academic institutions, government facilities, or industrial settings. An individual using a scientific approach in a home laboratory is pursuing science or engineering just as is a S/E employed by an institution, industry or government agency. No prejudice towards the work of a S/E shall be exercised based on an individual's affiliation or lack thereof with a particular institution, organization or agency.

#### **Article 3**

A S/E shall not be dissuaded from pursuing scientific inquiry because of political or religious concerns, or because the inquiry deviates from a conventional perspective.

#### **Article 4**

A S/E shall be able to use any approach to new knowledge and technologies, limited only by the restrictions that the approach follows sound scientific principles and does not violate societal ethical precepts.

#### **Article 5**

A S/E shall be free to collaborate with other individuals in the same or other locations, with the understanding that collaboration may require covenants protecting confidentiality and intellectual property.

#### **Article 6**

A S/E shall not be subject to restraints in the presentation and publication of results that are imposed by political or religious entities or because the findings conflict with traditional knowledge. Scientific and engineering results should always be evaluated on their merits and not because of preconceived notions of *'*truth*'*!

#### **Article 7**

A S/E shall decide who should coauthor scientific publications based on wellestablished guidelines for co-authorship. Courtesy authorship to senior personnel in a S/E 5 laboratory or institution is unacceptable.

#### **Article 8**

A S/E shall strive to ensure that scientific results are widely accessible to the scientific community.

#### **Article 9**

A S/E should object to misuse of research findings for political, ideological or financial purposes.

#### Article 10 At all times a S/E shall adhere to universal ethical and moral standards.

# **Requisite Attributes of Healthcare Professionals**

- n Honesty
- **n** Forthrightness
- n Diligence
- **n** Respect for persons
- **n** Service to others
- **n** Continuous self-improvement
- Patients come first (primacy of patient welfare)

# **Requisite Attributes of a Healthcare Profession**

- n Establish standards of conduct for members
- Enforce compliance with standards of conduct
- n Encourage members to function above minimum legal standards of conduct
- Provide educational opportunities for members self-improvement

# **Requisite Attributes of a Healthcare Profession**

- Acknowledge obligations of the profession to serve patients
- Recognize responsibilities of the profession to the public
- **n** Engender the public's trust

## Patient Privacy and Confidentiality of Patient Information

- Philosophical principles (Kant, Mill, etc. —brief)
- **n** Autonomy of the individual
- **n** Privileged position of the professional
- **n** Belmont principles
  - **n** Respect for persons
  - **n** Beneficence
  - n Justice

#### Patient Privacy and Confidentiality of Patient Information

- n HIPAA —origin and status
- **n** Confidentiality of patient information
- **n** Protection of patient records
- **n** Methods for ensuring security
- **n** Penalties

# **Behaviors of Others**

#### **n** What constitutes unethical conduct

- **n** Incompetent performance
- **n** Mental impairment
- **n** Fraudulent or deceptive practice
- **n** Substance abuse
- n Moral turpitude
- **n** Criminal activity

# **Behaviors of Others**

#### **n** Reporting unethical conduct

- **n** Sensitivity of the issue
- **n** Responsibility of the observer
- Protection of the observer (whistleblower)
- Imperfect nature of whistleblower protection

# **Behaviors of Others**

# Appropriate recipients of reported behaviors

- **n** Superiors
- n Hospital board
- **n** Licensing board
- **n** Certification board
- **n** Regulatory authorities

# **Peer Review of a Professional**

- n Review by a qualified professional(s) with appropriate expertise
- **n** Reviewed professional should know of review
- **n** Unrelated others should not know of review
- n Reviewing professional should be independent of reviewed professional or institution

# **Peer Review of a Professional**

- Copy of review report provided to reviewed professional
- Review should not be shared with those without a need to know
- n Review should not unnecessarily jeopardize reviewed professional's position

- n Financial
  - **n** NIH guidelines
  - **n** FDA guidelines
  - **n** Institutional guidelines
  - **n** Other guidelines

#### **n** Professional

- **n** Stature (reputation)
- **n** Inclusion in peer group
- **n** Educational
  - **n** Relationship with mentors
  - **n** Relationship with students

- n Professional
  - **n** Service in societies, boards, leadership roles
- n Research
  - **n** Study objectives vs. patient interests
  - **n** Belmont principles
- n Personal
  - **n** Personal vs. patient welfare
  - **n** Compassion vs. objectivity

- **n** Voluntary disclosure of conflict of interest
- **n** Required disclosure of conflict of interest
  - Publications
  - n Talks
  - **Clinical trials**
  - **n** Experimental therapies
- **n** Sarbanes-Oxley review/update

- **n** Data accuracy
  - **n** Systematic errors
  - Random errors
  - **n** Statistical analyses
  - **n** Deletion of outlier data

- **n** Data confidentiality
  - Patient data
  - **n** Laboratory data
  - **n** Permission to publish

- n Data ownership
  - Research team
  - Institutional claims
  - **n** Publication copyrights

- n Data management
  - **n** Record keeping
  - **n** Maintaining security
  - **n** Transferring institutions

# **Research Misconduct**

- **n** Data fabrication
- **n** Data falsification
- **n** Plagiarism
- **n** Redundant Publication (self-plagiarism)

**Research with Human Participants** 

#### **n** Belmont principles

- **n** Respect for persons —example
- **Beneficence** —example
- **n** Justice —example

## **Research with Human Participants**

#### **n** Institutional Review Board (IRB)

- **n** Composition
- **n** Responsibilities
- **n** Approvals
- **n** Waivers

**Research with Human Participants** 

#### **n USDHHS Office of Research Protections**

- **n** Responsibilities
- **n** Enforcement
- n FDA
- n General Rule
- **n** Institutional certification
- **n** Penalties for noncompliance

# **Research with Animals**

- Philosophical principles (Rosseau, Bentham, Shopenhauer, Singer, et al)
- **n** Ethical foundations
  - Animals in the service of humans
  - **n** Animals with rights
  - Animals as sentient beings equal to humans

# **Research with Animals**

# Protection of research animals USDA AAALAC Animal rights organizations SPCA PETA ALF

**n** Current controversies

## **Vendor-Sponsored** Activities

#### **n** Organizations

- **n** Conflict of Interest
- **n** Guidelines
- **n** Reporting
- n Abuses

## **Vendor-Sponsored** Activities

### n Individuals

- **n** Conflict of Interest
- **n** Guidelines
- **n** Reporting
- n Abuses
- **n** Case studies

### **n** PharMA guidelines and participants

## **Vendor-Sponsored Research**

- **n** Legitimate and illegitimate research
- Research disconnected from sales
- **n** Appropriate and inappropriate expenditures
- n Guidelines
  - n Milestones
  - n Reports
  - n Office of Inspector General Compliance Guidance for Pharmaceutical Manufacturers

## **Vendor-Sponsored Research**

- **n** Restrictions on publication
- **n** Indemnification issues
- **n** Ghost-written articles
- **n** Conflict of Interest reporting

### **Publication - Authors**

- n Types of authors (first, senior, corresponding, co-authors)
- n Authorship requirements —substantial contribution to
  - **n** Conception and design
  - **Data acquisition**
  - **Data analysis/interpretation**
- n Draft/revise manuscript
- **n** Final manuscript approval

## **Publication** — **Reviewers**

#### **n** Reviewer requirements

- **n** Objective/fair
- **n** Expertise
- **n** Knowledge and experience
- n Maturity
- **n** Responsiveness
- n Helpfulness

## **Publication - Reviewers**

- **n** Conflict of interest (disclosure)
- **n** Confidentiality of manuscript
- **n** Confidentiality of review
- Blinded vs. unblinded reviews arguments

# **Education — Teacher Responsibilities**

- **n** Respect for students
- **n** Program completion by students
- **n** Safe and supportive environment
- **n** Intellectual/academic freedom
- **n** Recognition of student work

# **Education — Teacher Responsibilities**

- **n** Fair evaluation
- **n** Nondiscrimination
- **n** Equal opportunity
- **n** Confidentiality
- **n** Consensual relationships

# **Education-Student Responsibilities**

- **n** Adherence to policies/procedures
- **n** Attendance
- **n** Academic integrity
- Acknowledge others' work

# **Education-Student Responsibilities**

- **n** Respect for freedom of expression
- **n** Confidentiality
- **n** Respect for others
- **n** Respect institutional property

## **Employer-Employee Responsibilities**

- **n** Contract negotiations
  - **n** Transparency
  - **n** Completeness
  - n Timeliness

**Employer-Employee Responsibilities** 

- n Honesty
- **n** Responsiveness
- **n** Forthrightness
- **n** Respect for others affected
- **n** Obligations in vacating a position

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