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laboratory medicine.

PEARLS OF LABORATORY MEDICINE

Ethics in Laboratory Medicine

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On behalf of the IFCC Task Force on Ethics

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Ethics

“rules of behavior based on ideas about what is morally good and bad”

Merriam-Webster Dictionary

Bioethics

“branch of applied ethics that studies the philosophical, social, and legal issues arising in medicine and the life sciences”

Encyclopedia Britannica

Medical Ethics

“study of moral values and judgments as they apply to medicine”

Wikipedia

Medical Ethics

- Medical professionalism can be traced to Hippocratic Oath
- Written in ~400 BC by Hippocrates
- Taken by physician, pledge to uphold specific ethical standards



A 12th-century Byzantine manuscript of the Oath

Nuremburg Code (1946)

- Voluntary, well-informed, consent of subject
- Experiment aims at positive results for society that cannot be procured in another way
- Based on previous knowledge that justifies the experiment
- Avoids unnecessary physical and mental suffering and injuries
- Should not be conducted if risk of death or disabling injury
- Risks should be in proportion to expected benefits
- Adequately protect the subjects against the experiment's risks
- Staff must be fully trained and scientifically qualified
- Subjects must be free to quit the experiment at any point
- Staff must stop when continuation would be dangerous

Declaration of Geneva (1948)

At the time of being admitted as a member of the medical profession:

I solemnly pledge

to consecrate my life to the service of humanity;

I will give

to my teachers the respect and gratitude that is their due;

I will practice

my profession with conscience and dignity;

The health of my patient

will be my first consideration;

I will respect

the secrets that are confided in me, even after the patient has died;

I will maintain

by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues

will be my sisters and brothers;

I will not permit

considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

I will maintain

the utmost respect for human life;

I will not use

my medical knowledge to violate human rights and civil liberties, even under threat;

I make these promises

solemnly, freely and upon my honour.

Declaration of Helsinki (1964)

- The well-being of the subject prevails over the interests of science and society
- Consent should be in writing
- Introduced the concept of oversight by an independent committee
- Use caution if participant is in dependent relationship with researcher
- Limited use of placebo
- Greater access to benefit



Belmont Report (1978)

- **Respect for persons**: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception;
- **Beneficence**: The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects; and
- **Justice**: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to *potential* research participants — and equally.

The Common Rule (1981)

The main elements of the Common Rule include:

- Requirements for assuring compliance by research institutions
- Requirements for researchers' obtaining and documenting informed consent
- Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.

Protections for certain vulnerable research subjects:

- pregnant women, in vitro fertilization, and fetuses
- prisoners
- children

ISO 15189:2012

"Medical Laboratories: Requirements for Quality and Competence"

- *“there is no involvement in any activities that would diminish confidence in the laboratory’s competence, impartiality, judgment or operational integrity;*
- *management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work;*
- *where potential conflicts in competing interests exist, they shall be openly and appropriately declared;*
- *there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;*
- *confidentiality of information is maintained.”*

Guidelines for Professionals (AACC)

Uphold standards of professionalism, be honest in all professional endeavors, and maintain a high level of personal integrity.

Avoid scientific and professional misconduct including, but not limited to fraud, fabrication, plagiarism, concealment, inappropriate omission of information, and making false or deceptive statements.

Report any health care professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel.

Maintain a high level of quality in the product(s) of my professional endeavors, including validity and reliability of test results, interpretive opinions, publications, and scientific research.

Respect the privacy and confidentiality of protected health information encountered during the course of my professional activities in accordance with legal and ethical obligations.

Continuously strive to augment my professional qualifications, knowledge, and skills, and present them accurately.

Promote the safety and welfare of patients, employees, co-workers, colleagues, the public, and the environment.

Avoid, or promptly disclose and work to resolve, actual or potential **conflicts of interest**.

Encourage open and honest discussion among physicians, other healthcare providers and/or facility managers regarding disclosure to patients of information about medical errors, if such information is material to any patient's well-being.

Comply with relevant laws and seek to change them when they are contrary to the best interests of the patient.

Ethics Education in Laboratory Medicine

Training in Selected Areas of Ethics

Topics taught	Training offered (% of programs)	Training required (% of programs)
Research ethics	28 (35%)	19 (24%)
Medical ethics	23 (29%)	17 (21%)
Professional ethics	16 (20%)	13 (16%)
Business ethics	6 (8%)	3 (4%)
Any of four ethics categories	36 (45%)	26 (32%)
All four ethics categories	3 (3.8%)	3 (3.8%)

Bruns et al. Clin Chim Acta 2015;442:115-118



Ethics in Laboratory Medicine

- Consent
- Confidentiality
- Codes of conduct
- Conflict of interest
- Publishing
- Biobanking
- Medically actionable results
- Proficiency
- Equity/Allocation of resources
- Genetic testing
- Direct access testing



Ethics in the Pre-Analytical Phase

- **Respect for Persons**
 - Consent (implied or expressed)
 - Respect right to refuse (exceptions)
 - Confidentiality
- **Beneficence**
 - Tests should benefit patient
 - Testing should do not harm
 - Additional samples for research only if consented
- **Justice**
 - No preference to certain populations



Ethics in the Analytical Phase

- **Respect for Persons**
 - Respect right to refuse
 - Confidentiality (including POC)
- **Beneficence**
 - Good laboratory practice
 - Proper accreditation, QC, QI, QA
 - Refuse to report if test result compromised
- **Justice**
 - No preference to certain populations (Exceptions)



Ethics in the Post-Analytical Phase

- **Respect for Persons**
 - Confidentiality
 - Patient decides who gets results
 - Respect right to refuse (exceptions)
- **Beneficence**
 - Interpretation by qualified personnel
 - Notification of errors ASAP
- **Justice**
 - All results treated equal
 - Results should not be withheld due to lack of payment
 - Develop policy on use of residual samples



Summary

Ethics:

- The modern history of bio/medical ethics is well-documented and grew out of the Nuremburg trials
- The Belmont Report identifies three core ethical principles: Respect for persons, Beneficence, and Justice
- Laboratory professionals must maintain ethical standards just as any other medical professional
- Many professional laboratory societies have codes of ethics
- The Core ethical principles should be maintained during the pre-analytical, analytical, and post-analytical phases of laboratory testing

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