

BIOETHICS



INTRODUCTION

Declaration of Helsinki



Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects

Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and as revised 8 times by the World Medical Assembly in Tokyo, Japan in 1975, in Venice, Italy in 1983, and in Hong Kong in 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

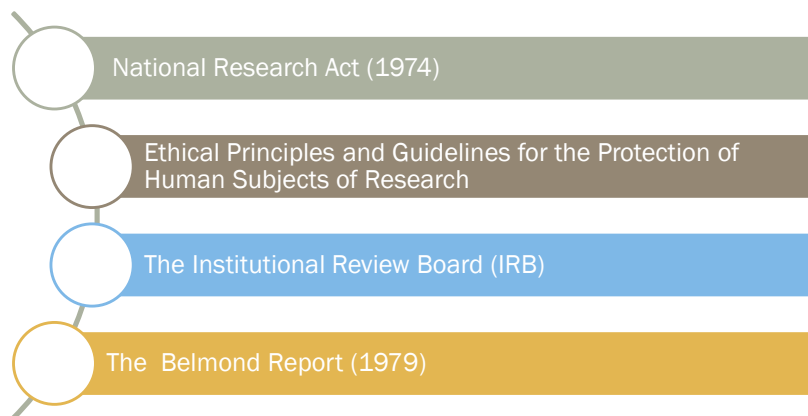
Last version is 2008. 2008 version currently under revision [2014]

“Concern for the interests of the subject must always prevail over the interests of science and society.”

National Research Act

- ∞ 1973 Kennedy Hearings “Quality of Health Care - Human Experimentation”
- ∞ 1974 National Research Act
 - Established the “National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research”
 - Required Institutional Review Boards (IRBs) at institutions receiving HEW support for human subjects research

The Belmont Report (1979)



The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research



The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

Decision-making organizations

- Internal Review Boards (IRB's)

- President's Council on Bioethics
 - 2001

- Independent Citizens' Oversight Committee:
 - Part of California Institute for Regenerative Medicine (CIRM)

The Belmont Report

Basic Ethical Principles:

- ☞ Respect for Persons
 - Individual autonomy
 - Protection of individuals with reduced autonomy
- ☞ Beneficence
 - Maximize benefits and minimize harms
- ☞ Justice
 - Equitable distribution of research costs and benefits

T. Beauchamp and J. Childress, Principles of Biomedical Ethics, 5th edition, New York/Oxford: Oxford University Press, 2001.)

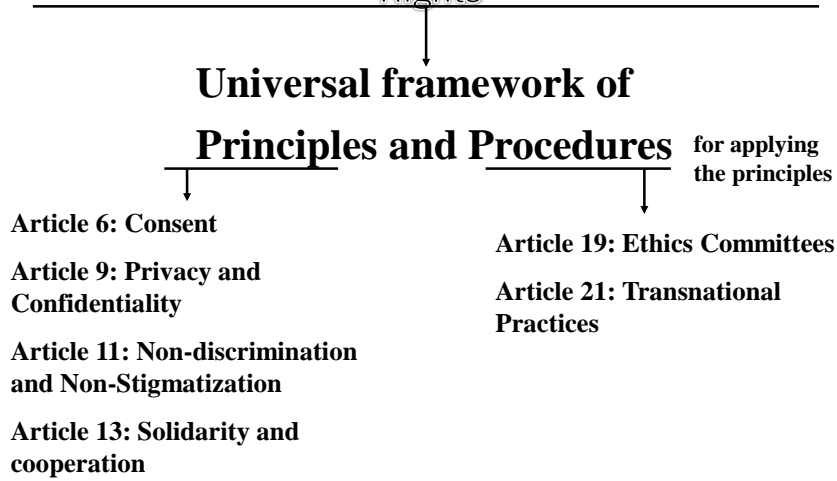
CIOMS Guidelines (1982)

- Council for International Organizations of Medical Sciences Guidelines
- Intend to apply DoH in developing countries
- Specific attention to large-scale vaccine **trials** and medications
- Includes section on compensation for injuries related to research
- Shortcomings: Lacks separate section devoted to risk-benefit ratios





Universal Declaration on Bioethics and Human Rights



A classic bioethical decision



∞ One heart available → who should get it?

17-year old girl



40-year-old school principal



70-year-old woman



PRINCIPLES --- OVERVIEW

∞ AUTONOMY

- SELF-DETERMINATION

∞ BENEFICENCE Benefits must be proportionate to risks

- *Potential harm = potential good*

- NONMALEFICENCE

∞ JUSTICE

- FAIRNESS
- MORALLY RELEVANT DIFFERENCES

∞ PARENTALISM

- PREVENTION OF SELF-HARM

APPLICATION OF PRINCIPLES

∞ COMPATIBILITY OF PRINCIPLES

∞ ADJUSTMENTS TO/LIMITATIONS ON PRINCIPLES

PRINCIPLE OF AUTONOMY

- ∞ A PERSON SHOULD BE FREE TO PERFORM WHATEVER ACTION HE/SHE WISHES, REGARDLESS OF RISKS OR FOOLISHNESS AS PERCEIVED BY OTHERS, PROVIDED IT DOES NOT IMPINGE ON THE AUTONOMY OF OTHERS

ADJUSTMENTS TO AUTONOMY *AUTONOMY IS NOT ABSOLUTE*

- ∞ CONTEXTUAL -- DEPENDING ON VALUES, PRIORITIES, NEEDS, SOCIAL CONFIGURATIONS
- ∞ LIMITS ON CHOICES
 - UNACCEPTABLE MEDICAL PRACTICE
 - NONBENEFICIAL TREATMENT
 - UNCERTAINTIES AND PROBABILITIES
 - VIOLATES *DEEPLY HELD* BELIEFS OF CAREGIVER
 - LIMITED RESOURCES
 - NO DECISIONAL CAPACITY

THE PATIENT SELF-DETERMINATION ACT INSTITUTIONS RECEIVING MEDICARE AND MEDICAID

- ∞ ALL ADULT PATIENTS MUST BE NOTIFIED IN WRITING AT THE TIME OF ADMISSION
 - RIGHT TO REFUSE TREATMENT
 - RIGHTS UNDER STATE LAWS REGARDING ADVANCE DIRECTIVES
 - SUMMARIES OF INSTITUTION'S POLICIES REGARDING WITHHOLDING AND WITHDRAWING OF LIFE-SUSTAINING TREATMENTS
- ∞ INSTITUTIONS MAY NOT DISCRIMINATE ABOUT ADVANCE DIRECTIVES
- ∞ NOTIFICATION MUST BE DOCUMENTED
- ∞ ADVANCE DIRECTIVE INFORMATION MUST BE DOCUMENTED
- ∞ ON-GOING STAFF AND COMMUNITY EDUCATION PROGRAMS ON ADVANCE DIRECTIVES

PRINCIPLE OF BENEFICENCE [RELATED TO BENEVOLENCE]

- ∞ ONE SHOULD RENDER POSITIVE ASSISTANCE TO OTHERS [AND ABSTAIN FROM HARM (MINIMALIST PRINCIPLE OF NONMALEFICENCE) BY HELPING THEM TO ACHIEVE BENEFITS WHICH WILL FURTHER THEIR IMPORTANT AND LEGITIMATE INTERESTS
- ∞ HARM PRINCIPLE AS A FORM OF BENEFICENCE
 - PREVENT AN INDIVIDUAL FROM HARMING ANOTHER

ADJUSTMENTS TO BENEFICENCE

- ∞ PATIENT'S VALUES AND PRIORITIES
- ∞ PATIENT'S EXERCISE OF AUTONOMY
- ∞ NO BENEFIT FROM INTERVENTION
- ∞ DISPROPORTIONAL BURDENS
- ∞ LACK OF COSTWORTHINESS
- ∞ LIMITATIONS ON RESOURCES

∞ **When interventions undertaken by physicians create a positive outcome while also potentially doing harm it is known as the "double effect."**

Eg. the use of morphine in the dying patient. eases pain and suffering while hastening the demise through suppression of the respiratory drive

PRINCIPLE OF JUSTICE

- ∞ ONE SHOULD GIVE TO PERSONS WHAT THEY ARE OWED, WHAT THEY DESERVE, OR WHAT THEY CAN LEGITIMATELY CLAIM, *TREATING EQUALS EQUALLY UNLESS THERE IS A MORALLY RELEVANT DIFFERENCE REQUIRING PERSONS TO BE TREATED UNEQUALLY/DIFFERENTLY*; CONSIDERATION MUST OFTEN BE GIVEN TO A PROPER ALLOCATION OF BENEFITS AND BURDENS WITHIN THE SOCIAL CONTEXT

ALTERNATIVE FORMULATION FOR JUSTICE

- ∞ PERSONS SHOULD BE TREATED IN WAYS THAT ARE CONSISTENT WITH THEIR STATUS
 - TREAT RECOVERABLE PATIENTS AS RECOVERABLE
 - TREAT TERMINAL PATIENTS AS TERMINAL

MORALLY RELEVANT DIFFERENCES

- ∞ A FEATURE WHICH IS CONSIDERED SO SIGNIFICANT THAT IT SEPARATES INDIVIDUALS INTO GROUPS WHICH ARE THEN TREATED IN NOTABLY DISTINCT WAYS
- ∞ WHAT COUNTS AS A MORALLY RELEVANT DIFFERENCE IS DETERMINED IN AN ONGOING DIALOGUE IN SOCIETY WHICH CONTINUALLY REASSESSES THE SIGNIFICANCE OF THE CHARACTERISTIC

POSSIBLE MORALLY RELEVANT DIFFERENCES IN HEALTHCARE

- ∞ DISEASE --- REVERSIBLE VS. CHRONIC VS. TERMINAL
- ∞ AGE
- ∞ NEED
- ∞ MERIT
- ∞ ABILITY TO CONTRIBUTE TO SOCIETY
- ∞ ABILITY TO PAY
- ∞ DOCUMENTED WISHES (ADVANCE DIRECTIVES)

ADJUSTMENTS TO JUSTICE

- ∞ COMPASSION
- ∞ MEDICAL UNCERTAINTIES/PROBABILITIES
- ∞ HIGH TOLERANCE FOR RISKS
- ∞ BORDERLINE MORALLY RELEVANT DIFFERENCES
- ∞ INSTITUTIONAL MISSION CONSIDERATIONS

PRINCIPLE OF PARENTALISM

- ∞ ONE SHOULD RESTRICT AN INDIVIDUAL'S CHOSEN ACTION AGAINST HIS/HER CONSENT IN ORDER TO PREVENT THAT INDIVIDUAL FROM SELF-HARM, OR TO SECURE FOR THAT INDIVIDUAL A GOOD WHICH HE/SHE MIGHT NOT OTHERWISE ACHIEVE

ASSUMPTIONS UNDERLYING PARENTALISM

- ∞ A PRIVILEGED POSITION ALLOWING AN INDIVIDUAL TO THINK HE/SHE KNOWS WHAT IS BEST FOR ANOTHER
 - SOCIAL ROLE
 - PARENT
 - POLITICIAN
 - LAWMAKER
 - SPECIAL KNOWLEDGE
 - RELIGIOUS LEADER
 - PHYSICIAN

FORMS OF PARENTALISM

- ∞ STRONG PARENTALISM
 - RESTRICT THE LIBERTY OF THOSE WHO ARE FUNCTIONALLY AUTONOMOUS
- ∞ WEAK PARENTALISM
 - RESTRICT THE ACTIONS OF THOSE WITH PERMANENT SEVERELY DIMINISHED AUTONOMY
 - TEMPORARILY CONSTRAIN INDIVIDUALS
 - TO DETERMINE IF THEY ARE AUTONOMOUS
 - TO RESTORE THEIR AUTONOMY

ADJUSTMENTS TO PARENTALISM

- ∞ PATIENT'S EXERCISE OF AUTONOMY
- ∞ DEMANDS OF BENEFICENCE
 - PARENTALISM MAY *SOMETIMES* BE BENEFICENT

Animal Research

- MRC Guideline Book 3: Use of animals in research and training (2004) prescribes:
 - Ethical principles involves
 - Ethical code of behaviour for researchers, educators and animal care staff
 - Human obligation/duties
 - A legal mandate for animal studies
 - Ethical review process for animal research

Animal Research (continue)



- **Replacement:** of sentient animals with non-sentient research models or systems
- **Reduction:** of numbers of animals in experiments by design strategies that facilitates the use of the smallest number that will allow valid information to be obtained
- **Refinement:** of animal sourcing to minimise or remove physical or psychological distress

Case 1

- ✎ Jehovah's Witnesses have a belief that it is wrong to accept a blood transfusion. Joshua McAuley, 15, suffered life-threatening injuries to his legs and abdomen after being pinned against a shop front by an out-of-control car as he went to buy sweets.

He survived the crash in Smethwick, West Midlands, and remained conscious, but lost a massive amount of blood and was airlifted to hospital for a transfusion. But Joshua died six hours later, after he refused to consent to the operation because of his faith, church representatives said.

Under medical law, doctors are required to decide whether a child under 16 is competent enough to consent to or refuse medical treatment without the need for parental permission or knowledge.

Read more: <http://www.dailymail.co.uk/news/article-1279252/Jehovahs-Witness-15-dies-refusing-blood-following-crash.html#ixzz3CIG5GzDF>

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Case 2



Case 3

- One clear example exists in health care where the principle of beneficence is given priority over the principle of respect for patient autonomy. This example comes from Emergency Medicine. When the patient is incapacitated by the grave nature of accident or illness, we presume that the reasonable person would want to be treated aggressively, and we rush to provide beneficent intervention by stemming the bleeding, mending the broken or suturing the wounded.