



# Ethics and consent

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applied to patients with disabilities

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# General principles of contemporary bioethics in the field of care and research

- **Central principles of Bioethics:**

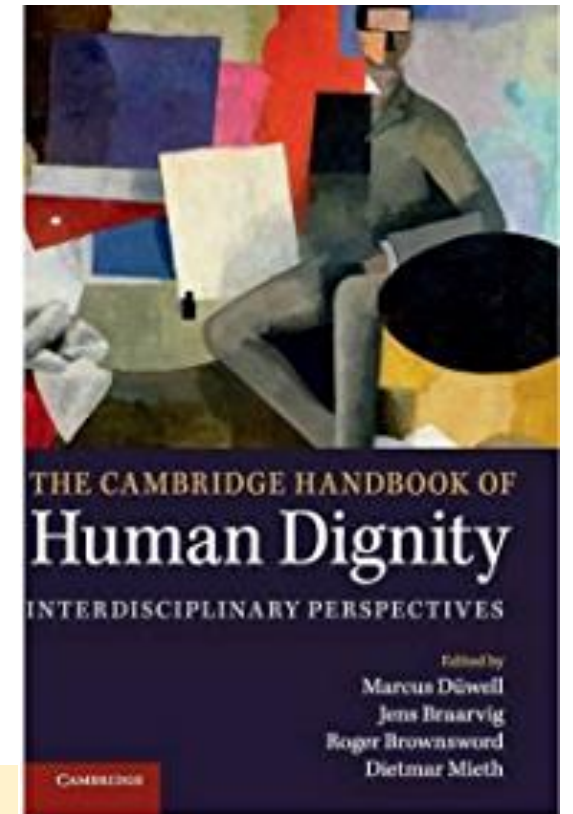
- Respect of inherent **dignity** and **difference**
- **Justice** and **equality** in the access of care
- **Freedom** to make own choices
- Respect of **Autonomy** and right to auto-determination
- **Beneficence**
- **No malficience**
- Respect of **fundamental human rights**
- **Absence of discrimination**



# General principles of contemporary bioethics in the field of care and research

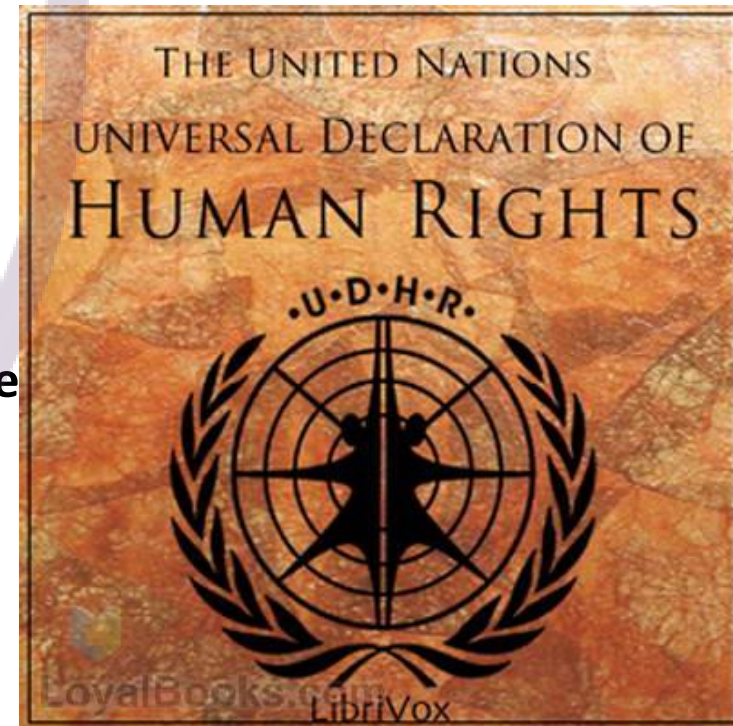
- Respect of **dignity** has an essential significance, especially in the context of patients with disabilities
- Dignity as a founding and universal value
- Different rights and interests are considered regarding the medical, social and psychological situation
- Respect of **privacy** and **confidentiality**
- Harm to human dignity can present under different forms : involuntary institutionalization, absence of consent for medical treatment or clinical research participation, humiliation, exclusion of work or social activities

*The Cambridge Handbook for human dignity – Interdisciplinary Perspectives, 2005,*  
DOI: [10.1017/CBO9780511979033](https://doi.org/10.1017/CBO9780511979033)



# General principles of contemporary bioethics in the field of care and research

- Article I of the Universal Declaration of Human Rights states « ***All human beings are born free and equal in dignity and rights.*** »
- Everyone has these rights and freedom without any distinction based on mental or physical disabilities
- Needs and rights of vulnerable people with disabilities are specifically recognized in the **Convention on the Rights of Persons with Disabilities (CRPD)** of the United Nation
- Main objective is to **protect the right and dignity of persons with disabilities**
- Right to be **included** actively in the society



# General principles of contemporary bioethics in the field of care and research

- Definition of a **person with disabilities** according to United Nations Human Rights:
  - « Disabled person means any person **unable to ensure** by himself or herself, wholly or partly, the necessities of a **normal** individual and/or social **life**, as a result of deficiency, either congenital or not, in his or her physical or mental capabilities ».
  - Disabled persons have the same **fundamental human rights** and must be respected in their singularity
  - Disabled persons have the **right to optimal medical, psychological and functional treatments**
  - **Rights to social rehabilitation and education**



UNITED NATIONS  
HUMAN RIGHTS  
OFFICE OF THE HIGH COMMISSIONER

# General principles of contemporary bioethics in the field of care and research

- **Dignity** is concerned with how people feel, think and behave in relation to the worth or value of themselves and others.
- To treat someone with dignity is to treat them in a way that is respectful of them as valued individuals, that is of particular importance for persons with disabilities
- To promote dignity consists in using respectful language and gestures, considering the person with its qualities and specificities

HUMAN DIGNITY





# General principles of contemporary bioethics in the field of care and research

- A vulnerable person's dignity is dependant of the **relationships with other human beings**



Vlad Andrei Stamate

July 1, 2019 · 🌐

In spatele fiecărui băiat in scaun sta cineva care il împinge!:)

Behind every boy in a wheelchair stands someone who's pushing 😊

- Another aspect of dignity is the right to **auto-determination** and to **take own decisions**
- Importance of integrating persons with disabilities in the discussion about inclusion in clinical trials or medical treatment
- In this way, their own values, qualities, specificities and dignity as human beings are recognized



**HUMAN DIGNITY**



# General principles of contemporary bioethics in the field of care and research

- Close to dignity, **social justice** and **social inclusion** for persons with disabilities must be considered



! Ce înseamnă parteneriatul dintre Fundația Motivation România și Fundația Special Olympics România în domeniul angajării persoanelor cu dizabilități



Motivation Romania and Special Olympics Romania: supporting and encouraging social inclusion of people with disabilities by helping them find adequate employment

- They must be offered equal opportunities in society and the context of medical care
- Absence of discrimination based on cognitive or physical disabilities



# General principles of contemporary bioethics in the field of care and research

- Concept of **informed consent** is fundamental for each procedure of medical care or for inclusion in clinical studies
- Information needs to be clear, fair and easy to understand for the patient
- Particularity of informed consent for patients with disabilities and cognitive limitations
- Importance of **adaptation** to the patients specificities and diversity
- Patient with disabilities must not be excluded systematically from research protocol or innovative therapies



# General principles of contemporary bioethics in the field of care and research

- The concept of **benefit to risk ratio** is of particular importance for persons with vulnerabilities or disabilities
- The expected benefit of a research must never be at the cost of the wellbeing of the participant
- Clear explanations need to be given concerning the potential risks inherent to a procedure or a research
- Possibility to leave the research at any moments needs to be highlighted



# Informed consent for persons with disabilities

- Importance of **cognitive capacity evaluations** for ability to informed consent
- Patients with intellectual disability can understand objectives of clinical studies and make autonomous choices
- A diagnosis of intellectual disability or cognitive limitations does not mean impossibility to participate to research program and contribute to scientific knowledge

Particular **vulnerability** of this category of patients needs to be taken in account with potential risks of exploitation



# Informed consent for persons with disabilities



National Institutes of Health  
*Turning Discovery Into Health*

- Definition of consent capacity by the National Institute of Health (NIH) :
  - *“Ability to understand information relevant to making an informed, voluntary decision to participate in research”*
  - Concerns and doubts about the understanding of the procedure and risks during consent process need to be clarified



# Informed consent for persons with disabilities

- Four main parameters are taken into account **to evaluate the capacity to consent** :
  - Ability to understand relevant informations
  - Appreciation of the consequences of the informations for it's own situation and the **ratio benefit to risk**
  - Potential of analysis and understanding of the different options
  - Communication of a choice





# Promoting the inclusion of persons with disabilities in clinical research trial

- **Ethical committees** tend to protect persons with vulnerabilities or disabilities excluding them from the process of clinical research
- From **ethical and scientific points of view** all the segments of population must be represented in clinical trials, avoiding any discrimination
- Integration of persons with disabilities as active participants and actors and not in a passive way
- Exclusion based on criteria as cognitive limitations or physical disabilities is not acceptable
- Importance of **authorized representative persons** in the context of absence of informed consent capacity



# Promoting the inclusion of persons with disabilities in clinical research trial

- Methodology and sampling strategy needs to allow representation of **disability diversity**
- Avoiding a categorization of patients only in terms of disability
- **Categorization** of persons based on **criteria** like **age, gender, social category, medical history, comorbidities** for an optimal representativity
- Adaptation of the experimental plan, length and intensity to the disabilities in order to **preserve wellbeing** of the participants

Ethical guidance for research with people with disabilities, NDA (National Disability Authority), Ireland, 2009, <http://nda.ie/nda-files/Ethical-Guidance-for-Research-with-People-with-Disabilities.pdf> (accessed Feb 14, 2021)



# Informed consent for persons with disabilities : ethics in practice

- From the **experiment/study design stage** → adaptation and integration of the disabilities
- **Assessment of consent capacity** is an essential step
- **Initial screening** based on simple questions in order to identify persons having difficulties in understanding of procedures or consent-related issues
- **Exclusion** must be discussed if major problems of understanding of the research objectives and risks are identified

Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study. J Policy Pract Intellect Disabil. 2013 September ; 10(3)



# Informed consent for persons with disabilities : ethics in practice

- Use of different means of communication adapted to persons with cognitive impairments
- Material in easy-to-read format for persons with intellectual disabilities can be used
- Considering the problem of accessibility for persons with physical disabilities

Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study. J Policy Pract Intellect Disabil. 2013 September ; 10(3)