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Research Ethics (Part 1)

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SUMMARY OF TOPICS (Part 1)

- Definition and Goals of Research Ethics
- History of Research Ethics in Palliative Care
- Basic and Additional Principles of Ethics Research
- Ethical Frameworks
- Declarations and legislation
- Informed Consent

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Definition of Research Ethics

Research ethics refers to the analysis of ethical issues that may occur when people are involved as research participants

H2020: Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research

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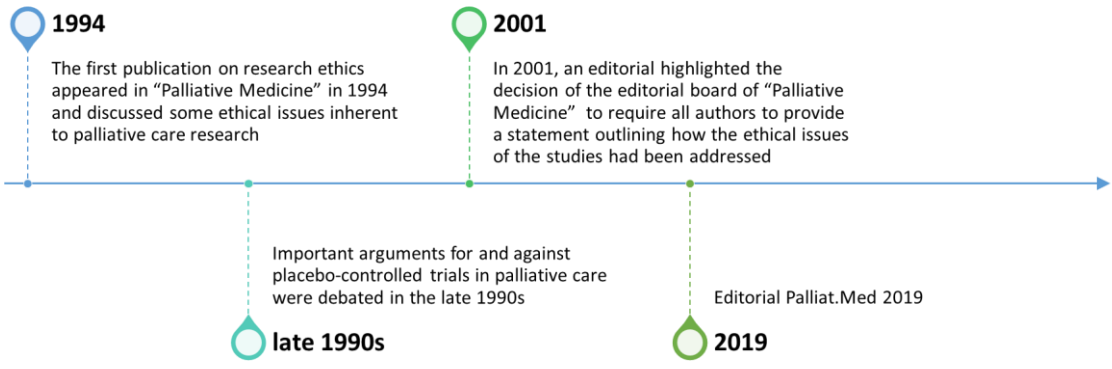
History of Research Ethics In Palliative Care



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Goals of Research Ethics

1. Protect human participants, particularly those who are more vulnerable

2. Ensure that research is conducted in a way that serves interests of individuals, groups, and/or society (research validity)

3. Scrutinize research activities and projects for their ethical soundness, that is :
   looking at issues such as the management of risk
   protection of confidentiality
   the process of informed consent

Editorial Palliat Med 2019

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Ethical Features of Research

ETHICAL PRINCIPLES

DECLARATIONS, CHARTERS & GUIDELINES

ETHICAL FRAMEWORKS

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Basic Ethical Principles

Beauchamp & Childress 1979

- Beneficence
- Non-Maleficence
- Autonomy
- Justice

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Additional Ethical Principles

Integrity

Respect

Dignity

Fidelity

Justification

Schofield G et al., Palliat Med 2021,
Ethical-Framework-for-Integrating-Palliative-Care-Principles-.pdf https://pallcarevic.asn.au/wp-content/uploads/2015/11/

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Basic Ethical Principles

Beauchamp & Childress 1979

- **Beneficence**

Beneficence is the obligation to do good to support the well being of others

- **Non-Maleficence**

Primum non nocere – 'above all, do no harm'

- **Justification**

Defines if a particular act is morally right or wrong

Participation in research is associated with a favorable balance of benefits and risks (harms)
The principle of Double Effect

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Basic + Additional Ethical Principles

- ***Autonomy***

"Auto"+ "Nomos"
Self determination
the right to make choices and
take actions based on personal values and beliefs

- ***Integrity***

Integrity relates to the intactness or wholeness of the self

- ***Respect***

To a person's values, needs and wishes

Basic + Additional Ethical Principles

- ***Justice***

Person : *Avoid over- and under-treatment*
Provide care in the most appropriate setting (resource allocation)

Health care System: *manage finite resources*

Family + Carers: *Consider and address reasonable needs*

Additional Ethical Principles

Fidelity

- Fidelity is the value of remaining true to a profession's values and focus on the patient

Dignity

- Dignity may be related to autonomy and the challenges of respecting it
- ✓ Dignity can also relate to empathetic and equitable care to patients

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Ethics in Everyday Clinical practice

- Principle-based frameworks "Four Principles" (deontological)
- Frameworks on context-based facts, such as : the Four Quadrants approach
  Seedhouse grid
- Outcome-based ethical assessment frameworks, such as: utilitarianism
  virtue ethics
  ethics of care

They more easily incorporate individual context than do rule-based, deontological frameworks

Schofield G et al., Palliat Med 2021

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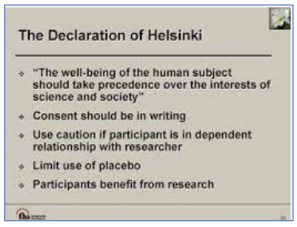
Declarations - Charters – Guidelines



- Declaration of Helsinki
- Nuremberg Code
- CIOMS (Council for International Organizations of Medical Sciences) guidelines
- Charter of Fundamental Rights of the European Union
- European Convention on Human Rights
- EU Regulation No 536/2014 on clinical trials

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Declarations and Regulation on Ethics

- Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials (medicinal products for human use)
- Directive 95/46/EC on the protection of personal data
- Council of Europe – ETS n° 195 - Additional Protocol to the Convention for the Protection of Human Rights and Dignity, Paris, 12.I.199
- Ethical considerations for Clinical Trials on Medical Products conducted with the Paediatric Population http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10/ethical_considerations.pdf
- Ethical aspects of Clinical Research in Developing Countries. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission http://www.cioms.ch/frame_guidelines_nov_2002.htm
- Ethics By Design and Ethics of Use Approaches for Artificial Intelligence. European Commission , November 2021. https://ec.europa.eu › docs › horizon › guidance ›

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The Four Quadrants Approach

Medical Indication • Medical problem (Acute/Chronic/Emergent) • Goals of treatment • Treatment options and alternatives • Likely success of treatment	**Patient Preferences** • Informed of risks • Understands benefits • Patient has decisional capacity? • Preferences • Surrogates
Quality of Life • Baseline functionality • Current lifestyle and independence • Expected time of recovery • Possible deficits resulting from treatment	**Contextual Features** • Conflicts of interest • Personal interests • Financial incentives • Professional biases • Research conflicts • Hospital pressures

Four-box model approach to clinical ethics. Adapted from Jonsen AR, Sieger M, Winslade WJ. Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine. 8th ed. New York, NY: McGraw-Hills; 2015 24 .

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The Seedhouse Ethical Grid

THE ETHICAL GRID

(ref: Seedhouse D.2009. "Ethics: the Heart of Health Care")

A tool to enable the enhancement of human potential. **Limits of use**

The following is the key for this copy of the Ethical Grid:

= **External Circumstances** (Black)

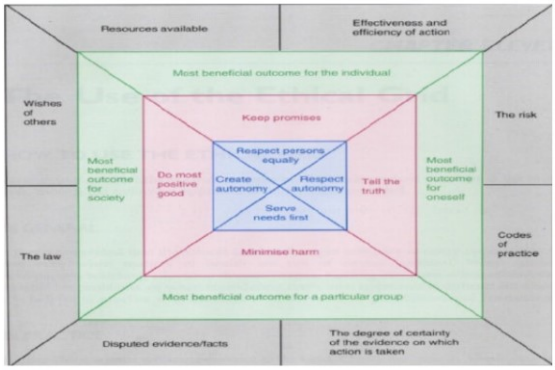
= **Consequences** - Teleology (Green)

= **Duties** - Deontology (Red)

= **Autonomy** (Blue)

Autonomy
Justice

Beneficence
Non Maleficence



Ethical Grid (Seedhouse, 1998)

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Real-world ethics in palliative care: A systematic review of the ethical challenges reported by specialist palliative care practitioners in their clinical practice

Schofield G et al, Palliat Med 2021, Vol. 35(2) 315–334

- 8074 records were screened
- Thirteen studies from nine countries (lack of data from low-& middle- income countries)
- Challenges related to specific scenarios/contexts rather than the application of general ethical principles
- Challenges occurred at all levels (bedside, institution, society, policy)

Challenges were organized into six themes and 23 sub themes:

1. Application of ethical principles
2. Delivering clinical care
3. Working with families
4. Engaging with institutional structures and values
5. Navigating societal values and expectations
6. Philosophy of palliative care

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1. Application of ethical principles (6) :
   - Autonomy, Dignity, Truth telling
   - Doctrine of double effect, Equity in care, Fidelity
2. Delivering clinical care (5) :
   - Clinical care and decision making, Confidentiality
   - Goals of care, Mental capacity,
   - Communication with patients and families
3. Working with families (4) :
   - Care and support for the family,
   - Family decision makers, Genetics, Privacy

4. Engaging with institutional structures values (3):
   - Conflict with institutional policy,
   - Institutional resource allocation,
   - Conflict between health care staff
5. Navigating societal values and expectations (4) :
   - Assisted dying,
   - Conflict with wider societal rules
   - Regulations or laws
   - Access to specialist palliative care
6. Philosophy of palliative care (1) :
   - Philosophy of palliative care

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Table 5. Clinical care and decision-making sub-themes.

Ethical challenge	Description
Administration of antibiotics[15]	Appropriate use of antibiotics, particularly in end of life care.
Advance directives[13,40,45]	Challenges implementing advance directives, particular when family requests may contrast with the directive.
Bloods transfusions[15,44]	Appropriateness of blood transfusions.
Deactivation of permanent pacemakers[45]	Appropriateness and timing of deactivation of cardiac pacemakers.
Do-not-resuscitate decision-making[13,43]	Decision-making about appropriateness of cardiopulmonary resuscitation.
Electrolyte management[15]	Clinical decision-making about management of abnormal electrolyte results.
Hydration and nutrition[13,15,38,40,41,44–46]	A broad range of challenges related to the provision, withdrawal and withholding of routine as well as clinically-assisted oral nutrition and hydration. Also includes issues of force feeding.[13]
Investigations[43]	Decision-making regarding which clinical tests are appropriate.
Sedation incl. palliative/terminal sedation[13,15,39–42,44,45]	Ethical dilemmas concerning use of sedatives for either symptom control or continuous sedation until death.
Symptom management[13,39,45]	Appropriate use of medication, both choice of agent and dose, and the need to balance against unwanted effects.
Use of alternative therapies[44]	Caring for patients who prefer to use alternative therapies; for example, traditional Chinese medicine, as opposed to prescribed medicines.
Use of Opioids[13,15,39,41,43–46]	Dilemmas surrounding the appropriate use of opioids, including under- and over-treatment, and patient and clinician opiophobia.

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Informed Consent

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Informed Consent

- ✓The Nuremberg Code and Helsinki Declaration remain at the foundation of principles of consent in research
- ✓Consent is therefore a process – not simply yes or no
- ✓ It is the process by which potential participants can decide the benefits and risks involved in taking part in a study
- ✓A valid consent is properly informed and also freely given – without pressures such as coercion, threats or persuasion

http://www.ethicsguidebook.ac.uk/Consent-72.html

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An informed consent form is required

When the research involves:

- Patients
- Children
- Incompetent/Incapacitated persons
- Healthy volunteers
- Immigrants
- Others (i.e.prisoners)

When the research uses/collects:

- Human Genetic Material
- Biological samples
- Personal data

https://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf

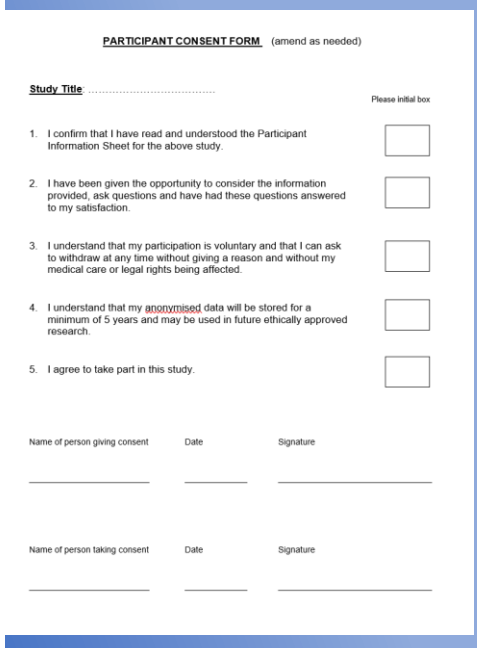
Informed Consent Pre requisitions

Patients must be given sufficient **information**

Are capable of understanding that information (**comprehension**)

Have the power of **free choice** (either give or withhold consent)

Are ensured of data protection



PARTICIPANT CONSENT FORM (amend as needed)

Study Title: .....

Please initial box

1. I confirm that I have read and understood the Participant Information Sheet for the above study. ☐
2. I have been given the opportunity to consider the information provided, ask questions and have had these questions answered to my satisfaction. ☐
3. I understand that my participation is voluntary and that I can ask to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐
4. I understand that my anonymised data will be stored for a minimum of 5 years and may be used in future ethically approved research. ☐
5. I agree to take part in this study. ☐

Name of person giving consent | Date | Signature

Name of person taking consent | Date | Signature

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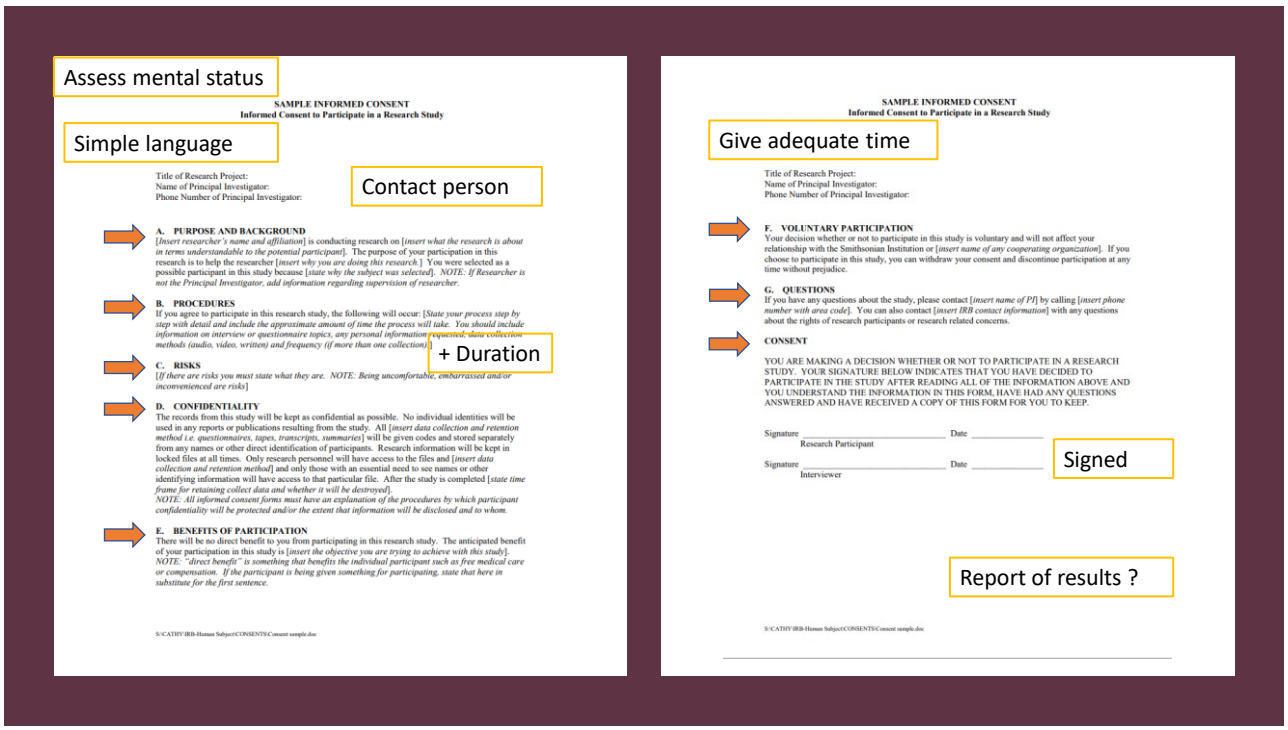
Questions on informed consent

- Do I have to take part?
- What will happen to me if I participate?
- What is the …(drug, approach etc) to be tested?
- What are alternative treatments?
- What are the possible side effects/risks?
- What are the possible benefits (+cost/risk ratio)
- What will happen at the end of the study with the treatment?
- How is my personal data's confidentiality ensured?
- Who will have access?
- Whom can I contact if I need to?



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Other Types of Informed Consent

- Verbal/Non-written consent (must be formally documented and independently witnessed)
- Dual consent (+ assent)
- Advanced consent
- Proxy consent (legal representative)

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Is an Ethical approval always necessary?

NOT for projects which only seek to obtain publicly available information

OR when you are collecting data in a manner that does not allow for identification of individual participants (sage publication)

OR only seeks the professional view of an office holder on the basis of that person's professional role

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- This project has been funded with support from the European Commission.
- This publication [communication] reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

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