

# REPORT OF CURRICULAR UNIT

## Ethics and Integrity in Health, Science and Technology

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Report about a Curricular Unit within the scientific area or specialty of Health Sciences, Technologies and Well-Being: Nursing submitted to Universidade de Évora for the awarding of the Academic Title of Aggregated, as established by the Portuguese Decree-Law n.º 239/2007 of June 19th, line b) of Article 5<sup>th</sup>, updated by the Portuguese Decree-Law n.º 64/2023 of July 31st, and by the Universidade de Évora Circular Letter 2/2009 of March 13th.

Relatório sobre uma Unidade Curricular no âmbito do ramo do conhecimento ou especialidade de Ciências e Tecnologias da Saúde e Bem-Estar: Enfermagem submetido à Universidade de Évora para a atribuição do Título Académico de Agregado, conforme establecido pelo Decreto-Lei n.º 239/2007 de 19 de junho, alína b) do Artigo 5.º, atualizado pelo Decreto-Lei n.º 64/2023 de 31 de julho, e pela Circular n.º 2/2009 da Universidade de Évora.



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## Sumário Executivo

Este documento constitui-se como o Relatório sobre uma Unidade Curricular no âmbito do ramo do conhecimento ou especialidade de Ciências e Tecnologias da Saúde e Bem-Estar: Enfermagem submetido à Universidade de Évora para a atribuição do Título Académico de Agregado, conforme estabelecido pelo Decreto-Lei n.º 239/2007 de 19 de junho, alínea b) do Artigo 5.º, atualizado pelo Decreto-Lei n.º 64/2023 de 31 de julho, e pela Circular n.º 2/2009 da Universidade de Évora.

A unidade curricular designa-se *Ética e Integridade na Saúde, Ciência e Tecnologia*.

Este relatório sobre uma unidade curricular encontra-se redigido em língua inglesa, conforme previsto no Artigo 18.º do Decreto-Lei n.º 239/2007 de 7 de Junho.

## Executive Summary

This document refers to the Report of a Curricular Unit within the scientific area or specialty of Health Sciences, Technologies and Well-Being: Nursing submitted to Universidade de Évora for the awarding of the Academic Title of Aggregated, as established by the Portuguese Decree-Law n.º 239/2007 of June 19th, line b) of Article 5th, updated by the Portuguese Decree-Law n.º 64/2023 of July 31st, and by the Universidade de Évora Circular Letter 2/2009 of March 13th.

The Curricular Unit is entitled *Ethics and Integrity in Health, Science and Technology*

This report is written in English language, as foreseen in Article 18<sup>th</sup> of the ‘Decreto-Lei n.º 239/2007 de 7 de Junho’.



## 1. Introduction

This Report of a Curricular Unit consists in the description of a post-graduate level curricular unit entitled *“Ethics and Integrity in Health, Science and Technology”* that I will present to Universidade de Évora for the awarding of the Academic Title of Aggregated, as established by the Portuguese Decree-Law n.º 239/2007 of June 19th, line b) of Article 5th, updated by the Portuguese Decree-Law n.º 64/2023 of July 31st, and by the Universidade de Évora Circular Letter 2/2009 of March 13th. This Curricular Unit fits well within the scientific area or specialty of Health Sciences, Technologies and Well-Being: Nursing. In addition, it is aligned with the strategic vision on research and post-graduate education programs of Universidade de Évora in this specific field.

As a background information, this curricular unit is based on an international course that I created, coordinated and taught at the Católica Doctoral School (CADOS), Universidade Católica Portuguesa. This new upgraded curricular unit has been designed, introducing major changes to comply with the purpose of the post-graduate level curricular unit entitled *“Ethics and Integrity in Health, Science and Technology”*.

This report is structured in nine sections: First, a brief background and rationale for the development and presentation of the curricular unit is provided. Second, information about the scientific area of the curricular unit is given and its transversal nature is highlighted and justified. Third, the structural features, such as the course, academic year, curricular year, semester, ECTS and other organizational features are presented. Fourth, the learning objectives and outcomes are listed. In the fifth section, the contents of the program are provided and described with enough detail to provide an understanding of what specific contents and topics will be taught. Sixth, the coherence between the contents and the learning objectives and outcomes is postulated. Section seven follows with the description of the teaching methods and students' assessment approach and methods. Section eight describes the coherence between the teaching methods and students' assessment. Finally, a comprehensive list of bibliography and a list of other sources is presented as part of the bibliography. This report follows and is adapted to comply with the standard format of the templates used when submitting curricular units of graduate programs for accreditation to the Portuguese Agency for the Evaluation and Accreditation of Higher Education (*Agência de Avaliação e Acreditação do Ensino Superior - A3ES*).<sup>1</sup>

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<sup>1</sup> A3ES is a full member of the European Association for Quality Assurance in Higher Education and a member of the Council for Higher Education Accreditation (CHEA) International Quality Group. A3ES is listed in the European Quality Assurance Register for Higher Education.

## 2. Report of the Program for the Curricular Unit: Ethics and Integrity in Health, Science and Technology

A comprehensive report and overview of the curricular unit “Ethics and Integrity in Health, Science and Technology” is provided together with its program. As aforementioned, beyond other elements required by A3ES, the background, justification, objectives, contents, methodologies and bibliography of the curricular unit are presented with a detailed description of their inherent coherency and alignment.

### 2.1. Background

Research ethics is the analysis of the ethical issues that may occur when conducting research.<sup>2,3</sup> It provides the conceptual and practical frameworks for the responsible conduct of research in order to ensure that research is performed with high ethical standards. The main goal of research ethics is threefold: (i) to protect human participants, particularly those who are more vulnerable; (ii) to ensure that research is conducted in a way that serves interests of individuals, groups, and/or society; and (iii) to scrutinize research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality, and the process of informed consent.<sup>2</sup>

To be ethically sound, research needs to ensure a core set of elements, namely: Social and/or scientific value; Scientific validity; Fair selection of participants; Favorable risk-benefit ratio; Independent review; Informed consent process; and Respect for potential and enrolled participants.<sup>4</sup> While these elements appear to be self-explanatory, their operationalization in research practice, particularly in health research, might be challenging and doubts may arise on how to best implement them.

Research ethics is becoming an area of expanding interest. The new advances in health sciences and technologies (e.g., the expanding fields of -omics, artificial intelligence) together with the gradually more complex healthcare needs and inherent health research requiring the development and implementation of more complex healthcare interventions and research for their development makes research ethics a cornerstone for sound research. It is thus unsurprising that ethical frameworks, guidelines, and international legislation coexist to address the ethical features of research, particularly in health sciences and technologies. For instance, the Nuremberg Code,<sup>5</sup> the

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<sup>2</sup> Walton N. Ethics in clinical investigation: from bench to bedside to round table. *Clin Invest Med.* 2003 Feb;26(1):12-4.

<sup>3</sup> Pereira SM, Hernández-Marrero P. Research ethics in palliative care: A hallmark in Palliative Medicine. *Palliat Med.* 2020 Feb;34(2):NP1-NP2. doi: 10.1177/0269216319827178.

<sup>4</sup> Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA.* 2000 May 24-31;283(20):2701-11. doi: 10.1001/jama.283.20.2701.

<sup>5</sup> The Nuremberg Code [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, DC: U.S. G.P.O, 1949–1953], [https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/nuremberg\\_code.pdf](https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/nuremberg_code.pdf)

Declaration of Helsinki,<sup>6</sup> the CIOMS (Council for International Organizations of Medical Sciences) guidelines,<sup>7</sup> the Charter of Fundamental Rights of the European Union,<sup>8</sup> and the European Convention on Human Rights<sup>9</sup> are all well-known frameworks and guidelines that constitute the foundation for national legislation and codes of research ethics. Moreover, regulations exist and play a relevant role, such as the General Data Protection Regulation (GDPR) of the European Union,<sup>10</sup> the new EU regulation on medical devices,<sup>11</sup> and the recently published EU Act on Artificial Intelligence (AI),<sup>12</sup> which is the world's first comprehensive AI law. These guidelines commonly constitute the foundation for national legislation and codes of research ethics and conduct.

However, it is recognized that the mere existence and knowledge of these frameworks and documents are not enough to ensure that research is ethically sound.<sup>3</sup> To be so, researchers not only need to acquire the knowledge expressed in their content, but they also need to integrate their inherent principles, translate them into everyday research practices, and become critically competent to mobilize them when facing ethical issues and challenges directly relevant to their research.<sup>3</sup>

These are the foundations of the transversal International Curricular Unit entitled **“Ethics and Integrity in Health, Science and Technology”**.

## 2.2. Scientific Area of the Curricular Unit

This is a core and transversal curricular unit placed at the intersection of four main scientific areas,<sup>13</sup> which are listed as follows: 720. Health Sciences, 420. Life Sciences, 310. Social Sciences, and 226. Philosophy and Ethics. In other words, this curricular unit encompasses a series of analyses of all the ethical issues, challenges and implications of conducting research in health sciences, natural and life sciences and engineering, and social sciences and humanities.

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<sup>6</sup> World Medical Association. Declaration of Helsinki—ethical principles for medical research involving human subjects, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

<sup>7</sup> Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for health-related research involving humans. 4th ed. Geneva: CIOMS, 2016.

<sup>8</sup> European Parliament. Charter of Fundamental Rights of the European Union. Official Journal of the European Communities. 2000/C 364/01, [http://www.europarl.europa.eu/charter/pdf/text\\_en.pdf](http://www.europarl.europa.eu/charter/pdf/text_en.pdf)

<sup>9</sup> Council of Europe, European Court of Human Rights. European Convention on Human Rights. Strasbourg: Council of Europe, 2010, [https://www.echr.coe.int/Documents/Convention\\_ENG.pdf](https://www.echr.coe.int/Documents/Convention_ENG.pdf)

<sup>10</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

<sup>11</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)Text with EEA relevance.

<sup>12</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance).

<sup>13</sup> Ministério das Atividades Económicas e do Trabalho. Portaria n.º 256/2005 de 16 de março. CNAEF - Classificação Nacional de Áreas de Educação e Formação

## 2.3. Course, Academic Year, Curricular Year, Semester and Number of ECTS

The following table (Table 1) systematizes the information about the structural and organizational features (e.g., course, academic year, curricular year, semester and number of ECTS) of the curricular unit entitled “Ethics and Integrity in Health, Science and Technology”.

**Table 1. Structural and Organizational features of the Curricular Unit “Ethics and Integrity in Health, Science and Technology”**

Structural and organizational features	Specificities of the curricular unit “Ethics and Integrity in Health, Science and Technology”					
Course	Core post-graduate (master and doctorate programs) courses for all the students in the fields of Health Sciences, Technologies and Well-Being					
Academic Year	The curricular unit runs every academic year					
Curricular Year	Not applicable. Each student can choose in which year he/she wishes to attend.					
Semester	2 <sup>nd</sup>					
Duration	15 weeks					
Total number of working hours	234 hours					
Total number of contact hours	30 hours					
	Interactive Lectures	10 hours	Seminar	4 hours	Tutorial Supervision	16 hours
Total number of independent student work	204 hours					
Number of ECTS	9 ECTS					
Language – teaching	English, Portuguese					
Language – tutorials	English, Portuguese					
Frequency	Presential					
Sustainable Developmental Goals (SDG)	SDG3. Ensure healthy lives and promote well-being for all at all ages SDG4. Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all SDG10. Reduce inequality within and among countries SDG11. Make cities and human settlements inclusive, safe, resilient and sustainable SDG16. Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels SDG17. Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development					
Coordinator	Sandra Martins Pereira					
Faculty Members	Sandra Martins Pereira					
International Invited Faculty	To be defined					

## 2.4. Learning Objectives and Outcomes

The curricular unit “Ethics and Integrity in Health, Science and Technology” is built to ensure that researchers, particularly junior researchers, master and doctoral students (i) learn the basic foundations, frameworks, ethical principles and values inherent to research ethics and integrity in science, (ii) discover how to manage research participants in sensitive and appropriate ways, and (iii) understand the importance and strategies to conduct research in a way that allows other researchers and society to have trust and confidence in the methods and findings resulting from their research.

After completing this curricular unit, students will be able to:

- (1) understand and apply conceptual frameworks of research ethics and integrity, and of the nature of ethical decision-making and its role to ensure ethics and integrity in science;
- (2) draw on main theories, principles and concepts in order to critically analyze and ethically evaluate particular examples of research;
- (3) analyze, interpret and evaluate what research is and of how it is regulated;
- (4) analyze, interpret and evaluate the quality of good research with high ethical standards and appropriate researchers' behaviors;
- (5) understand the role of research ethics committees, and analyze and interpret the implications of their assessments and views for the evaluation and recognition of high-quality research;
- (6) understand the nature and importance of participant selection, analyze risk-benefit assessments, and interpret and evaluate valid informed consent processes in research ethics;
- (7) apply measures to properly ensure respect for privacy and confidentiality and understand their role in research ethics;
- (8) understand, analyze, interpret and evaluate the main ethical challenges in nowadays research (e.g., international and collaborative research, research involving vulnerable participants, and artificial intelligence);
- (9) understand, analyze, interpret and evaluate the main ethical challenges in health and biomedical sciences, and in social sciences and humanities;
- (10) recognize and understand the importance of developing research and ethics with and for society, applying sound co-participation and public involvement strategies;
- (11) critically understand, analyze, interpret and evaluate what concrete actions can be put into place to ensure that the research conducted in various scientific fields is ethically sound;
- (12) understand and apply the core principles and practice of the European Code of Conduct for Research Integrity;
- (13) analyze, interpret and evaluate experiences related to the application of core virtue ethics concepts and how they relate to research integrity in real world research practices.

## 2.5. Contents

The curricular unit “Ethics and Integrity in Health, Science and Technology” is composed of the following contents:

1. General principles of research ethics and integrity in science
  - a. Concepts and foundations
  - b. The concept of “Goodness” in research
  - c. Research ethics frameworks, policies, and procedures
  - d. Ethical principles and values applied to research
2. Research Ethics Committees: Exemplary Case Studies
  - a. Conceptual and legal frameworks
  - b. The role and practice of Research Ethics Committees
3. Research Ethics and Data Protection
  - a. Ethics principles and values underpinning data protection
  - b. The General Data Protection Regulation (GDPR) of the European Union
  - c. Operationalization of the GDPR in research projects
4. Ethical challenges in international collaborative research
  - a. International collaborative research
  - b. Different types of international collaborative research and their ethical implications
  - c. Multi-jurisdictional research: challenges and strategies
  - d. Research conducted in low-resource settings: ethical challenges and implications
5. Research ethics in health and biomedical sciences
  - a. General concepts and frameworks
  - b. Human research
  - c. Animal research
  - d. Operationalization of data protection and privacy
  - e. Environmental research
  - f. Engineering or technological research
6. Research ethics in social sciences and humanities
  - a. General concepts and frameworks
  - b. Ethical dimensions of research methodology in social sciences and humanities
  - c. Use of deception in research
  - d. Covert research
  - e. Internet research and social media data in research
  - f. Research with and for society
7. Ethical challenges in times of Artificial Intelligence (AI)
  - a. The EU Act on Artificial Intelligence
  - b. Ethics-by-design and the use of AI
8. Ethical challenges in research with vulnerable participants and persons unable to consent
  - a. Research involving children and minors
  - b. Research involving persons at the end-of-life
  - c. Research involving persons with dementia

- d. Research involving persons with cognitive impairment
- e. Research involving persons with severe persistent mental illness

9. Special cases I: Health, Biomedicine and Biotechnology

- a. Discussion of special cases in healthcare research
- b. Discussion of special cases in clinical research (e.g., clinical trials)
- c. Discussion of special cases in biomedical research
- d. Discussion of special cases in biotechnology and environmental research

The discussion, analysis and evaluation of special cases will be tailored to students' needs, scientific fields, and based on research priorities of the European Commission. This will be conducted as part of the tutorial supervision.

10. Special cases II: Social sciences and Humanities

- a. Discussion of special cases in psychology
- b. Discussion of special cases in sociology
- c. Discussion of special cases in behavioral sciences

The discussion, analysis and evaluation of special cases will be tailored to students' needs, scientific fields, and based on research priorities of the European Commission. This will be conducted as part of the tutorial supervision.

11. Integrity in scientific research and responsible conduct of research

- a. Concepts and foundations
- b. Integrity in scientific research
- c. Responsible conduct of research and innovation
- d. Case study analyses of conflicts related to research integrity
- e. The Embassy of Good Science – Exercises

## 2.6. Coherence between the contents and the learning objectives and outcomes

The objectives of this curricular unit focus on the acquisition of knowledge, development of the capacity of understanding, applying, analyzing and evaluating ethically complex situations in ethics and integrity in health, science and technology. The contents are aligned with the learning objectives and expected learning outcomes. Table 2 shows the interrelation between the learning objectives and outcomes and the contents of this curricular unit.

**Table 2. Interrelation between Learning Objectives and Outcomes and the Contents of the Curricular Unit**

Learning objectives and outcomes	Contents
To understand and apply conceptual frameworks of research ethics and integrity, and of the nature of ethical decision-making and its role to ensure ethics and integrity in science	General principles of research ethics and integrity in science

To draw on main theories, principles and concepts in order to critically analyze and ethically evaluate particular examples of research	
To analyze, interpret and evaluate what research is and of how it is regulated	
To analyze, interpret and evaluate the quality of good research with high ethical standards and appropriate researchers' behaviors	
To understand the role of research ethics committees, and analyze and interpret the implications of their assessments and views for the evaluation and recognition of high-quality research	Research Ethics Committees: Exemplary Case Studies
To understand the nature and importance of participant selection, analyze risk-benefit assessments, and interpret and evaluate valid informed consent processes in research ethics	Research ethics in health and biomedical sciences
To apply measures to properly ensure respect for privacy and confidentiality and understand their role in research ethics	Research Ethics and Data Protection
To understand, analyze, interpret and evaluate the main ethical challenges in nowadays research (e.g., international and collaborative research, research involving vulnerable participants, and artificial intelligence)	<p>Ethical challenges in international collaborative research</p> <p>Ethical challenges in research with vulnerable participants and persons unable to consent</p> <p>Ethical challenges in times of Artificial Intelligence (AI)</p>
To understand, analyze, interpret and evaluate the main ethical challenges in health and biomedical sciences, and in social sciences and humanities	<p>Special cases I: Health, Biomedicine and Biotechnology</p> <p>Special cases II: Social sciences and Humanities</p>
To recognize and understand the importance of developing research and ethics with and for society, applying sound co-participation and public involvement strategies	<p>Research ethics in health and biomedical sciences</p> <p>Research ethics in social sciences and humanities</p>
To critically understand, analyze, interpret and evaluate what concrete actions can be put into place to ensure that the research conducted in various scientific fields is ethically sound	<p>Special cases I: Health, Biomedicine and Biotechnology</p> <p>Special cases II: Social sciences and Humanities</p>
To understand and apply the core principles and practice of the European Code of Conduct for Research Integrity	<p>Integrity in scientific research and responsible conduct of research</p>
To analyze, interpret and evaluate experiences related to the application of core virtue ethics concepts and how they relate to research integrity in real world research practices	

## 2.7. Teaching Methods and Students' Assessment

This curricular unit will combine different methodologies to facilitate the learning process. First, all students will be required to attend and participate in a core and common set of classes (synchronous, in person, sessions) and activities (asynchronous sessions, both in person and online, sessions). Second, depending on their scientific areas and interests, students will participate in a series of sessions focusing on the analysis and discussion of “special cases”. During the asynchronous sessions, students will be required to read and discuss topics, contents and materials provided beforehand by the professor responsible for those sessions. In the synchronous sessions, lectures will be given by a faculty member and invited international researchers recognized as experts in that specific content. Depending on the topics, international speakers will be invited to share their experiences and foster the forum discussions. Table 3 systematizes the various teaching methods that will be used in this curricular unit.

**Table 3. Teaching Methods**

Teaching Approach	Teaching Method	Definition / What students do	Activities
Professor-Centered	Lecture	Professor will present material and answer students' questions that arise. Students receive, take in and respond.	Presentation, slideshow, note-taking, questions (convergent).
	Directed Discussion	Class discussion that follows a pre-determined set of questions to lead students to certain realizations or conclusions, or to help them meet a specific learning outcome.	Direct, specific, or open-ended questions that are connected to learning outcomes.
	Direct Instruction	Lecturing with time for guided and independent practice.	Create mind/concept maps, free writes, one-sentence summary, brainstorming.
	Just-in-Time Teaching	Professor adjusts class activities and lectures to respond to the misconceptions revealed by assessing students' prior knowledge.	Warmups, Conceptual questions (usually a quiz) to motivate students to do the readings.
Student-Centered	Interactive Lecture	A lecture that includes 2-15 minute breaks for student activities every 12-20 minutes.	Multiple-choice items, solving a problem, comparing and filling in lecture notes, debriefing a mini case study, pair-compare, pair-compare-ask, reflection/reaction paragraph, solve a problem, concept mapping activities, compare and contrast, paraphrase the idea, answer knowledge and comprehension questions.
	Experiential Learning	Students focus on their learning process through application, observation and reflection.	Debates, panel discussion, policy briefs, symposium, reflection journals.

	Case-based learning	Students apply course knowledge to devise one or more solutions or resolutions to problems or dilemmas presented in a realistic story or situation.	Case study analysis, collaborative scenario-based discussions.
	Inquiry-based or Inquiry-guided learning	Students learning or applying material in order to meet a challenge, answer a question, conduct an experiment, or interpret data.	Worked examples, process worksheets, analyze informed consent forms, evaluate evidence, apply findings to a situation or problem and synthesize resolution(s), answer probing questions about a given research study, ask and answer “What will happen if...?”, “What would you do if...” questions.
	Problem-based learning	Student groups conducting outside research on student-identified learning issues (unknowns) to devise one or more solutions or resolutions to problems or dilemmas presented in a realistic story or situation.	Review and critique research studies, work in groups/teams to solve a specific open-ended problem.
	Project based learning	Students applying course knowledge to produce something; for example, applying the acquired knowledge to their own master or doctoral research project proposals.	Research ethics study, learning based on individual research project proposals.
	Role plays and simulations	Students acting out roles or improvising scripts, in a realistic and problematic social or interpersonal situation. Students playing out a hypothetical situation that abstracts key elements from reality (e.g., role playing a research ethics committee)	Real-life situations and scenarios, debates, interviews, frame simulation.
	Fieldwork and Clinicals	Students learning how to conduct research and make sound professional judgments in real-world situations.	Internships, assistantships, shadowing.
Adapted and modified from Nilson <sup>14</sup>			

Students' assessment is integral to the design of this program and to the learning journey of all students. Assessment is about process and outcomes. Therefore, within this curricular unit, students' assessment will be twofold: (i) Summative, which is comprehensive in nature and is fundamentally concerned with learning outcomes; and (ii) Formative, which involves the evaluation of student learning over the course of time with the purpose of enhancing student learning during the learning process. The following assessment methods will be used and combined to ensure an optimal learning process and outcome for all students.

<sup>14</sup> Nilson LB. *Teaching at Its Best: A Research-Based Resource for College Instructors (Fourth)*. John Wiley & Sons; 2016.

**Summative assessment:**

- i. **Written assignment (75% of the final grade):** Individual project consisting of a written essay based on the ethics evaluation of each student's own scientific project proposal. Ideally, this assignment will be based on the ethics self-assessment, evaluation and reporting of all the potential ethical challenges and implications within each student's master or doctoral research project proposal. Should any student not have his/her master or doctoral research project proposal defined at the time the curricular unit starts, a research project will be assigned to this student for the purpose of this written assignment.
- ii. **Oral presentation of the individual work developed in the written assignment (25% of the final grade).**

Detailed information on the format of these assignments and specific evaluation criteria will be provided within the syllabus of the curricular unit at the beginning of the course.

**Formative assessment:**

Throughout the curricular unit, specific moments will be dedicated for the implementation of formative assessment methods, such as self-assessment quizzes, peer discussions, and one-to-one feedback during tutorial sessions between students and professors.

## 2.8. Coherence between the teaching and assessment methods and the learning objectives and outcomes

Considering that this curricular unit is focused on post-graduate students (master and doctoral students), teaching and assessment methods are focused on their needs and expectations of their programs. This will allow students to optimize and capitalize on the learning process within the curricular unit and translate the acquired knowledge into the development of their own master and doctoral research project proposals. Teaching methods will be mixed and tailored to students' needs, expected learning outcomes, and contents. Therefore, multiple teacher-centered and student-centered approaches will be used and integrated within the different types of sessions. Assessment methods will be dynamic, summative and formative; hence, student centered.

## 2.9. Bibliography

ALLEA - All European Academies. *The European Code of Conduct for Research Integrity. Revised Edition*. 2023. Berlin: ALLEA - All European Academies; 2023. ISBN 978-3-9823562-3-5. doi: 10.26356/ECOC.

Cohen IG, Gerke S, Kramer DB. Ethical and Legal Implications of Remote Monitoring of Medical Devices. *Milbank Q.* 2020;98(4):1257-1289. doi: 10.1111/1468-0009.12481.

Council for International Organizations of Medical Sciences (CIOMS). *International ethical guidelines for health-related research involving humans*. 4th ed. Geneva: CIOMS, 2016.

Council of Europe, European Court of Human Rights. European Convention on Human Rights. Strasbourg: Council of Europe, 2010, [https://www.echr.coe.int/Documents/Convention\\_ENG.pdf](https://www.echr.coe.int/Documents/Convention_ENG.pdf)

Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-11. doi: 10.1001/jama.283.20.2701.

European Parliament. Charter of Fundamental Rights of the European Union. Official Journal of the European Communities. 2000/C 364/01, [http://www.europarl.europa.eu/charter/pdf/text\\_en.pdf](http://www.europarl.europa.eu/charter/pdf/text_en.pdf)

Goodwin M. Vulnerable Subjects: Why Does Informed Consent Matter? *J Law Med Ethics*. 2016;44(3):371-80. doi: 10.1177/1073110516667935.

Gordon JS, Rauprich O, Vollmann J. Applying the four-principle approach. *Bioethics*. 2011;25(6):293-300. doi: 10.1111/j.1467-8519.2009.01757.x.

London AJ, Kimmelman J, Emborg ME. Research ethics. Beyond access vs. protection in trials of innovative therapies. *Science*. 2010;328(5980):829-30. doi: 10.1126/science.1189369.

Olimid DA, Olimid AP, Ifrim Chen F. Ethical governance of the medical research: clinical investigation and informed consent under the new EU Medical Devices Regulation (2017/745). *Rom J Morphol Embryol*. 2018;59(4):1305-1310.

Pereira SM, Hernández-Marrero P. Research ethics in palliative care: A hallmark in Palliative Medicine. *Palliat Med*. 2020;34(2):NP1-NP2. doi: 10.1177/0269216319827178.

Raven-Gregg T, Shepherd V. Exploring the inclusion of under-served groups in trials methodology research: an example from ethnic minority populations' views on deferred consent. *Trials*. 2021;22(1):589. doi: 10.1186/s13063-021-05568-z.

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)Text with EEA relevance.

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance).

Rendtorff JD. Basic ethical principles in European bioethics and biolaw: autonomy, dignity, integrity and vulnerability - towards a foundation of bioethics and biolaw. *Med Health Care Philos*. 2002;5(3):235-44. doi: 10.1023/a:1021132602330.

Resnik DB, Shamoo AE. The Singapore statement on research integrity. *Account Res*. 2011;18(2):71-75. doi:10.1080/08989621.2011.557296

Shepherd V. An under-represented and underserved population in trials: methodological, structural, and systemic barriers to the inclusion of adults lacking capacity to consent. *Trials*. 2020;21(1):445. doi: 10.1186/s13063-020-04406-y.

Shepherd V. Research involving adults lacking capacity to consent: the impact of research regulation on 'evidence biased' medicine. *BMC Med Ethics*. 2016;17(1):55. doi: 10.1186/s12910-016-0138-9.

TellÉus PK, Jensen W. Ethical Assessment and Reflection in Research and Development of Non-Conformité Européene Marked Medical Devices. *Camb Q Healthc Ethics*. 2020;29(4):592-606. doi: 10.1017/S0963180120000341.

Ten Have H et al. *The UNESCO Universal Declaration on Bioethics and Human Rights. Background, principles and application*. France: UNESCO; 2009.

The Nuremberg Code [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, DC: U.S. G.P.O, 1949–1953], [https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/nuremberg\\_code.pdf](https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/nuremberg_code.pdf)

Veatch RM, Guidry-Grimes LK. *The Basics of Bioethics*. Fourth Edition. New York: Routledge; 2020.

Walton N. Ethics in clinical investigation: from bench to bedside to round table. *Clin Invest Med*. 2003;26(1):12-4.

Wilkinson MD, Dumontier M, Aalbersberg IJ, et al. The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data*. 2016;3:160018. doi: 10.1038/sdata.2016.18.

World Medical Association. Declaration of Helsinki—ethical principles for medical research involving human subjects, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

### **Other sources:**

COPE (Committee on Publication Ethics): <https://publicationethics.org>

Council of Europe: <https://www.coe.int/en/web/portal/home>

Conselho Nacional Ética para as Ciências da Vida: <https://www.cnecv.pt/en>

EQUATOR Network: Reporting Guidelines to enhance the quality and transparency of health research. <https://www.equator-network.org/>

International Committee of Medical Journal Editors: <http://www.icmje.org>

Singapore Statement on Research Integrity: [https://www.jsps.go.jp/english/e-kousei/data/singapore\\_statement\\_EN.pdf](https://www.jsps.go.jp/english/e-kousei/data/singapore_statement_EN.pdf)

UNESCO: <https://en.unesco.org>

World Conference on Research Integrity WCRI (2010). Singapore Statement on Research Integrity: [www.singaporestatement.org/statement.html](http://www.singaporestatement.org/statement.html)

NOTE: In the syllabus of this curricular unit, a full list of bibliographic references will be provided aligned with each content of the program listed above.