

## SUBJECT TEACHING GUIDE

M1367 - Ethical and Legal Aspects of Care and Research in Chronic Wounds

Master's Degree in Integrated Management and Research in Chronic Wounds

Academic year 2020-2021

1. IDENTIFYING DATA					
Degree	Master's Degree in Integrated Management and Research in Chronic Wounds			Type and Year	Compulsory. Year 1
Faculty	Faculty of Nursing				
Discipline	Subject Area: General Aspects Related to Chronic Wounds				
Course unit title and code	M1367 - Ethical and Legal Aspects of Care and Research in Chronic Wounds				
Number of ECTS credits allocated	3	Term	Semester based (1)		
Web					
Language of instruction	Spanish	English Friendly	No	Mode of delivery	Combination of face-to-face and online training

Department	DPTO. ENFERMERIA
Name of lecturer	TAMARA SILIO GARCIA
E-mail	tamara.silio@unican.es
Office	Facultad de Enfermería. Planta: + 2. DESPACHO (223)
Other lecturers	JOAQUIN CAYON DE LAS CUEVAS JAVIER SOLDEVILLA AGREDA

### 3.1 LEARNING OUTCOMES

- Knowing the rights and obligations of users and its historical evolution
- Analyzing the importance of information in the clinical setting
- Describing the process of informed consent and advance directives as tools of management autonomy in health and social-health care
- Describing the different ways of approaching an ethical problem
- Defining the principles of bioethics, the link between them and the aspects related to the field of care and research in chronic wounds.
- Critically analyze both from the legal and Bioethical point of view cases that they have faced in their daily practice in care of patients with chronic wounds
- Describing the ethical and legal aspects in research on humans
- Identifying the general basis of current legislation in Spain in research on humans
- Knowing the current basic regulation in Spain on clinical drug trials and the regulation of active implantable medical devices.
- Knowing the main legal implications related to non-prevention and therapeutic malpractice of pressure ulcers in Spain and other countries of its socioeconomic influence

### 4. OBJECTIVES

Students will acquire the knowledge and skills which enable them to identify, analyze, discuss and argue ethical and legal criteria in solving the problems that arise in their professional work in the field of care and research of chronic wounds

### 6. COURSE ORGANIZATION

#### CONTENTS

- |   |   |
|---|---|
| 1 | <ul style="list-style-type: none"> <li>- Ethical considerations in relation to the care of chronic wounds</li> <li>General concepts</li> <li>Clinical Relationship</li> <li>Rights of patients / users</li> <li>Information and Informed Consent</li> <li>Bioethics               <ul style="list-style-type: none"> <li>- Legal aspects related to chronic wounds: pressure ulcers</li> <li>- Ethical issues in research in humans</li> <li>- Legal Issues in Human Research</li> <li>- Clinical investigations with medical devices</li> <li>- Regulations</li> </ul> </li> </ul> |
|---|---|

### 7. ASSESSMENT METHODS AND CRITERIA

Description	Type	Final Eval.	Reassessn	%
Analysis of a clinical case using bioethics methodology, homework	Work	Yes	Yes	40,00
Analysis of a trial related to chronic wounds	Work	Yes	Yes	40,00
Participation in the forum	Activity evaluation with Virtual Media	Yes	No	20,00
<b>TOTAL</b>				<b>100,00</b>
Observations				
Observations for part-time students				
Observations for part-time students: Students who are enrolled in the part-time basis must meet the same evaluation criteria as other enrolled students				

## 8. BIBLIOGRAPHY AND TEACHING MATERIALS

### BASIC

Ley 41/2002 de 14 de noviembre. Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, nº 274, (15-11-2002).

The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research. U.S. Government Printing Office, 1978.

Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.

Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos

Ley 14/2007, de 3 de Julio, de Investigación biomédica.

Ley 14/2011, de 1 de junio, de la Ciencia, la Tecnología y la Innovación

Real Decreto 1616/2009, de 26 de Octubre, que regula los productos sanitarios implantables activos

Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos

Soldevilla Agreda JJ, Navarro Rodríguez S. Aspectos Legales relacionados con las Ulceras por Presión. Gerokomos 2006; 17(4):203-224

Ayello EA; Leask K; Fife CE; Fowler E; Krasner DL; Mulder G; Sibbad RG; Yankowsky KW. Legal Issues in the care of pressure ulcer patients: key Concepts for healthcare providers. Consensus paper. Junio 2009