# 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 2018-2019

| 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 |

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| 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<br>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 | - Ethical considerations in relation to the care of chronic wounds<br>General concepts<br>Clinical Relationship<br>Rights of patients / users<br>Information and Informed Consent<br>Bioethics<br>- Legal aspects related to chronic wounds: pressure ulcers<br>- Ethical issues in research in humans<br>- Legal Issues in Human Research<br>- Clinical investigations with medical devices<br>- Regulations |

## 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 course forums:<br>The quality of the interventions is assessed in terms of: contribution of clear and relevant answers, demonstration of understanding of concepts, presentation of appropriate questions, contribution of relevant details | Activity evaluation with Virtual Media | Yes | No | 20,00 |
| TOTAL | | | | 100,00 |

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 oh Human Subjects of Research. U.S. Govermment Printing Office, 1978.
Ley 14/2007, de 3 de Julio, de Investigación biomédica.
Real Decreto 1616/2009, de 26 de Octubre, que regula los productos sanitarios implantables activos
Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos
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 acre of pressure ulcer patients: key Concepts for helathcare providers.Consensus paper. Junio 2009