SUBJECT TEACHING GUIDE

M1386 - Ethical and Legal Aspects

Master's Degree in Health Care Research

Academic year 2016-2017

1. IDENTIFYING DATA					
Degree	Master's Degree in Health Care Research			Type and Year	Compulsory. Year 1
Faculty	Faculty of Nursing				
Discipline	Subject Area: Social and Ethical Aspects Applied to Research Training Module				
Course unit title and code	M1386 - Ethical and Legal Aspects				
Number of ECTS credits allocated	3	Term	Semester based (1)		
Web					
Language of instruction	Spanish	English Friendly	No	Mode of delivery	Face-to-face

Department	DPTO. ENFERMERIA
Name of lecturer	JAIME ZABALA BLANCO
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Other lecturers	JOAQUIN CAYON DE LAS CUEVAS SUSANA GOMEZ-ULLATE RASINES

3.1 LEARNING OUTCOMES
- Describing the history of human experimentation, highlighting the abuses that have conducted to regulation.
- Listing the main ethical codes related to research in humans.
- Defining the ethical principles governing research on human beings
- Describing the contents of the current legal regulations on human research
- Explain the functions of the Research Ethics Committees

4. OBJECTIVES

cquiring the ability to interpret and respect the current law and follow the codes and ethical principles governing research in health sciences and specifically in care research

6. COURSE ORGANIZATION

CONTENTS	
1	LEGAL AND ETHICS GENERAL CONCEPTS RELATED TO RESEARCH IN HUMANS. General concepts. History. Abuses. Codes and declarations. Ethical principles PATIENT RIGHTS IN RELATION TO RESEARCH Teaching methodology: Oral or written contributions, both individually and in teams, supervised by the teachers Preparation, editing and reporting, thematic papers, reports, book reviews, as well as Master Thesis Finding information for the preparation of the tasks entrusted. Study of the theoretical content. Bibliographical and field consultations. Tutoring of students' work.
2	NATIONAL AND INTERNATIONAL REGULATIONS. ETHICS COMMITTEES. Teaching methodology: Oral or written contributions, both individually and in teams, supervised by the teachers Preparation, editing and reporting, thematic papers, reports, book reviews, as well as Master Thesis Finding information for the preparation of the tasks entrusted. Study of the theoretical content. Bibliographical and field consultations. Tutoring of students' work.

7. ASSESSMENT METHODS AND CRITERIA

Description	Type	Final Eval.	Reassessn	%
Written test throughout the development of the course	Activity evaluation with Virtual Media	Yes	Yes	35,00
Active participation in the course forums	Others	Yes	No	20,00
Attendance and participation during presentiality	Others	Yes	No	10,00
Written test throughout the development of the course	Activity evaluation with Virtual Media	Yes	Yes	35,00
TOTAL				100,00

Observations

Observations for part-time students

Observations for part-time students:
Attendance is not compulsory, so that 10% of this part shall be distributed in the evaluation of the other two blocks of the course

8. BIBLIOGRAPHY AND TEACHING MATERIALS

BASIC

The Belmont Report, Ethical Principles and Guidelines for the Protection oh Human Subjects of Research. U.S. Govermment Printing Office, 1978.
Beauchamp TL, Childress JF. Principles of Biomedical Ethics. New York: Oxford university Press; 1979. (existe una traducción al español Principios de ética médica. Barcelona: Masson; 1999).
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).
Ley 14/2007, de 3 de Julio, de Investigación biomédica.
Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

Se irán proporcionando progresivamente los documentos relativos a los contenidos de la asignatura durante el desarrollo de ésta.