



Teaching Guide

Identifying Data					2017/18
Subject (*)	Ethical and Legal Research in Health Sciences		Code	653862203	
Study programme	Mestrado Universitario en Asistencia e Investigación Sanitaria (plan 2012)				
Descriptors					
Cycle	Period	Year	Type	Credits	
Official Master's Degree	1st four-month period	First	Optativa	3	
Language	Spanish				
Teaching method	Face-to-face				
Prerequisites					
Department	Dereito Público				
Coordinador	Vergara Lacalle, Oscar	E-mail	oscar.vergara@udc.es		
Lecturers	Vergara Lacalle, Oscar	E-mail	oscar.vergara@udc.es		
Web	www.udc.es/fcs/ga/index.htm				
General description					

Study programme competences / results

Code	Study programme competences / results
A3	Adquirir un sentido ético da investigación sanitaria.
B3	Compromiso pola calidade do desenvolvemento da actividade investigadora.
B4	Capacidade de análise e de síntese.
B6	Capacidade para traballar de forma colaborativa en equipos multi e interdisciplinar.
B7	Capacidade de establecer unha relación de empatía cos suxeitos implicados no desenvolvemento da actividade investigadora.
C1	Expresarse correctamente, tanto de forma oral coma escrita, nas linguas oficiais da comunidade autónoma.
C4	Desenvolverse para o exercicio dunha cidadanía aberta, culta, crítica, comprometida, democrática e solidaria, capaz de analizar a realidade, diagnosticar problemas, formular e implantar solucións baseadas no coñecemento e orientadas ao ben común.
C6	Valorar criticamente o coñecemento, a tecnoloxía e a información dispoñible para resolver os problemas cos que deben enfrontarse.
C8	Valorar a importancia que ten a investigación, a innovación e o desenvolvemento tecnolóxico no avance socioeconómico e cultural da sociedade.

Learning outcomes

Learning outcomes	Study programme competences / results		
Understanding the meaning of ethical and legal dimension of research in health sciences	AR3	BC3 BC4 BC6 BC7	CC1 CC4 CC6 CC8
Grasping the basic ethical concepts and principles of research in health sciences	AR3	BC3 BC4 BC6 BC7	CC1 CC4 CC6 CC8
Grasping the basic legal concepts and norms of research in health sciences	AR3	BC3 BC4 BC6 BC7	CC1 CC4 CC6 CC8
Adding the ethical and legal dimension to research practice in health sciences	AR3	BC3 BC4 BC6 BC7	CC1 CC4 CC6 CC8



Familiarizarse co manexo dos conceptos, normas e principios éticos e xurídicos na investigación en ciencias da saúde	AR3	BC3 BC4 BC6 BC7	CC1 CC4 CC6 CC8
Achieving the abilities to identify and assess the ethical and legal problems of research in health sciences	AR3	BC3 BC4	CC4 CC6

Contents	
Topic	Sub-topic
Lesson 1. Ethics and Law	<ol style="list-style-type: none"> 1. Why do we need norms? Types of norms and normative systems 2. Why do we need Law? 3. Why do we need virtues? Three models of normative ethics 4. Bioethics and the ethics of research
Lesson 2. Responsible research	<ol style="list-style-type: none"> 1. Research as a practice 2. Facts and values. Is everything technically possible also ethically admissible? 3. The research imperative. Is there a (moral) duty to research? Is there an obligation to participate in research? 4. The freedom of research. Freedom of research as a basic right 5. Research misconduct
Lesson 3. Research on human beings and with human origin materials	<ol style="list-style-type: none"> 1. What is biomedical research? Basic concepts and types of research with human beings and human origin materials 2. History of the ethics of biomedical research 3. Ethical requirements fo biomedical research 4. Legal regulation of biomedical research 5. Controversial issues. Research involving vulnerable subjects. Human embryo research. Genetic research. Posthuman research. Neuroscience
Lesson 4. Animal research	<ol style="list-style-type: none"> 1. The case for animal research 2. Ethical positions concerning research with animals 3. Is licit the research involving animals? Ethical arguments. Scientific arguments 4. Legal regulation of animal research
Lesson 5. Research with biological agents and genetically modified organisms	<ol style="list-style-type: none"> 1. Research, environment, and responsibility 2. Biosecurity and laboratory good practices 3. Biotechnology and moral restraints. The precautionary principle 4. Legal regulation of research with biological agents (BA) and genetically modified organisms (GMO)

Planning				
Methodologies / tests	Competencies / Results	Teaching hours (in-person & virtual)	Student?s personal work hours	Total hours
Case study	A3 B3 B4 B6 B7 C1 C4 C6 C8	3	9	12
Objective test	B4 C1	1	2	3
Guest lecture / keynote speech	A3 B3 B4 C6 C8	11	33	44
Document analysis	A3 B3 B4 B6 C6 C8	4	10	14
Personalized attention		2	0	2

(*)The information in the planning table is for guidance only and does not take into account the heterogeneity of the students.

Methodologies	
Methodologies	Description



Case study	The knowledge of historical evolution and of the ethical and legal requirements of research in health sciences is supplemented by means of the analysis of classical and contemporary cases. The main learning aim of case study is to achieve argumentation, deliberation and decision-making abilities. Case study includes other methodologies: analysis of bibliographical and normative sources, as well as research papers.
Objective test	The exam is an appropriate method for assessing the outcomes of the learning process of subject's contents
Guest lecture / keynote speech	Lectures ease the understanding of the special features, language, and concepts of ethics and law in research, specifying the meaning of bibliographical and normative sources and stressing the main topics for the subject
Document analysis	Ethical and legal answers to research in health sciences are usually stated in normative documents and legal norms. These documents provide both a historical and a systematic explanation of the ethical and legal perspectives of research in health sciences.

Personalized attention

Methodologies	Description
Document analysis	Guidance for searching, managing, understanding, and assessing of teaching materials.
Case study	Guidance for deliberating in concrete cases, implementing the basic ethical and legal concepts and norms.

Assessment

Methodologies	Competencies / Results	Description	Qualification
Case study	A3 B3 B4 B6 B7 C1 C4 C6 C8	Assessment of participation and argumentation abilities. Assessment of understanding and implementation of ethical and legal language and concepts. Analysis of bibliographical and normative (ethical and legal) sources is included.	50
Objective test	B4 C1	Main method for assessing knowledge. Knowledge and understanding of bibliographical and normative (ethical and legal) sources are included.	50

Assessment comments

A proba obxectiva é presencial.

Sources of information



Basic

- Baruch A. Brody (1998). The ethics of biomedical research. An international perspective. New York: Oxford University Press
 - Daniel Callahan (2003). What price better health. Hazards of research imperative. Berkeley: University of California Press, New York: The Milbank Memorial Fund
 - Ezequiel J. Emanuel, David Wendler, Christine Grady (2000). What makes clinical research ethical?. JAMA 283/20 (2000), 2701-2711
 - Ezequiel J. Emanuel et al. (ed.) (2003). Ethical and regulatory aspects of clinical research. Baltimore and London: Johns Hopkins University Press
 - Robert J. Levine (1986). Ethics and regulation of clinical research (second edition). New Haven: Yale University Press
 - Javier Sánchez-Caro, Fernando Abellán (cords.) (2006). Ensayos clínicos en España. Aspectos científicos, bioéticos y jurídicos. Granada: Comares
 - Javier Sánchez-Caro, Fernando Abellán (cords.) (2007). Investigación biomédica en España: aspectos bioéticos, jurídicos y científicos. Granada: Comares
 - Adil E. Shamoo, David B. Resnik (2009). Responsible conduct of research (second edition). New York: Oxford University Press
 - Ezequiel J. Emanuel et al. (ed.) (2011). The Oxford Textbook of clinical research ethics. New York: Oxford University Press
- Documentos éticos
- Código de Núremberg (1947). Declaración de Helsinki (Asociación Médica Mundial, Principios éticos para a investigación en seres humanos, 1964; versión actualizada: 8.ª revisión, 2013). Informe Belmont (Comisión Nacional para a protección dos suxeitos humanos de investigación biomédica e do comportamento, Principios éticos e orientación para a protección dos suxeitos humanos na experimentación, 1979). Consello de organizacións internacionais das ciencias médicas (CIOMS) en colaboración coa Organización Mundial da Saúde (OMS), Pautas internacionais para a investigación biomédica en seres humanos (2002). Declaración universal sobre Bioética e dereitos humanos (UNESCO, 2005). Normativa xurídica
- Normativa xurídica xeral
- Constitución española de 1978 (BOE n.º 311, 29.12.1978). Lei 41/2002, do 14 de novembro, básica reguladora da autonomía do paciente e dos dereitos e obrigas en materia de información e documentación clínica (BOE n.º 274, 15.11.2002). Lei Orgánica 15/1999, do 13 de decembro, de protección de datos de carácter persoal (BOE n.º 298, 14.12.1999). Real Decreto 1720/2007, do 21 de decembro, polo que se aproba o Regulamento de desenvolvemento da Lei Orgánica 15/1999, do 13 de decembro, de protección de datos de carácter persoal (BOE n.º 17, 19.1.2008). Convenio para a protección dos dereitos humanos e a dignidade do ser humano con respecto ás aplicacións da Bioloxía e a Medicina (Convenio relativo aos dereitos humanos e a biomedicina). (BOE n.º 251, 20.10.1999. Rectificación BOE n.º 270, 11.11.1999). Consello de Europa. Protocolo adicional ao Convenio de dereitos humanos e biomedicina en relación coa investigación biomédica. (Estrasburgo, 25.1.2005). Investigación con seres humanos
- Lei 14/2007, do 3 de xullo, de investigación biomédica (BOE n.º 159, 4.7.2007). Lei 14/2006, do 26 de maio, sobre técnicas de reprodución humana asistida (BOE n.º 126, 27.5.2006). Real Decreto 1716/2011, do 18 de novembro, polo que se establecen os requisitos básicos de autorización e funcionamento dos biobancos con fins de investigación biomédica e do tratamento das mostras biolóxicas de orixe humana, e se regula o funcionamento e organización do Rexistro Nacional de Biobancos para investigación biomédica (BOE n.º 290, 2.12.2011). Decreto 63/2013, do 11 de abril, polo que se regulan os comités de ética da investigación de Galicia (DOG núm. 77, 22.4.2013). Investigación con animais
- Lei 8/2003, do 24 de abril, de sanidade animal (BOE n.º 99, 25.4.2003). Lei 32/2007, do 7 de novembro, para o coidado dos animais na súa explotación, transporte, experimentación e sacrificio (BOE n.º 268, 8.11.2007). Directiva 2010/63/UE do Parlamento Europeo e do Consello, do 22 de setembro de 2010, relativa á protección dos animais utilizados para fins científicos (DOUE L276, 20.10.2010). Investigación con axentes biolóxicos e organismos modificados xeneticamente
- Lei 9/2003, do 25 de abril, pola que se establece o réxime xurídico da utilización confinada, liberación voluntaria e comercialización de organismos modificados xeneticamente (BOE n.º 100, 26.4.2003). Real Decreto 178/2004, do 30 de xaneiro, polo que se aproba o Regulamento xeral para o desenvolvemento e execución da Lei 9/2003, do 25 de abril, pola que se establece o réxime xurídico da utilización confinada, liberación voluntaria e comercialización de organismos modificados xeneticamente (BOE n.º 37, 31.1.2004. Corrección de erros: BOE n.º 42, 18.2.2004). Real Decreto 1369/2000, do 19 de xullo, polo que se modifica o Real Decreto 822/1993, do 28 de maio, polo que se



establecen os principios de boas prácticas de laboratorio e a súa aplicación na realización de estudos non clínicos sobre substancias e produtos químicos. (BOE n.º 173, 20.6.2000).



Complementary	<ul style="list-style-type: none">- Stephen G. Post (ed.) (2004). Encyclopedia of bioethics (3rd edition. New York: Macmillan Reference- Carlos M. Romeo Casabona (2011). Enciclopedia de Bioderecho y Bioética. Granada: Comares; Deusto: Cátedra Interuniversitaria Fundación BBVA-Diputación Foral de Bizkaia de D
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Recommendations

Subjects that it is recommended to have taken before

Subjects that are recommended to be taken simultaneously

Subjects that continue the syllabus

Other comments

Para axudar a conseguir una contorna inmediata sustentable e cumprir o obxectivo estratéxico 9 do I Plan de Sustentabilidade Medio-ambiental Green Campus FCS, todos os traballos documentais que se realicen nesta materia serán entregados en formato dixital, sen necesidade de imprimilos. De realizarse en papel:- Non se empregarán plásticos.- Realizaranse impresións a dobre cara.- Empregarase papel reciclado.- Evitarase imprimir borradores.

(*)The teaching guide is the document in which the URV publishes the information about all its courses. It is a public document and cannot be modified. Only in exceptional cases can it be revised by the competent agent or duly revised so that it is in line with current legislation.