



Teaching Guide				
Identifying Data			2020/21	
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	Optional	3
Language	Spanish			
Teaching method	Face-to-face			
Prerequisites				
Department	Dereito PrivadoDereito Público			
Coordinador	Pereira Saez, Maria Carolina	E-mail	c.pereira.saez@udc.es	
Lecturers	Pereira Saez, Maria Carolina	E-mail	c.pereira.saez@udc.es	
Web	www.udc.es/fcs/ga/index.htm			
General description	Knowledge of the main ethical and juridical guidelines in health sciences investigation with human beings, animals and genetically modified organisms.			
Contingency plan	1. Modifications in the contents: there is not. 2. Methodologies *educational Methodologies that keep : all *educational Methodologies that modify : the magistral sessions will take place through Teams in official schedule. The multiple choice test will take place through MOODLE in official schedule. 3. Mechanisms of personalised attention: email, MOODLE and Teams (previous application by email), in official schedule. 4. Modifications in the evaluation: there is not. *Observations of evaluation: the multiple choice test will take place through MOODLE. 5. Modifications of the bibliography: there is not.			

Study programme competences	
Code	Study programme competences
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	
Understanding the meaning of ethical and legal dimension of research in health sciences		AR3	BC3 CC1
			BC4 CC4
			BC6 CC6
			BC7 CC8
Grasping the basic ethical concepts and principles of research in health sciences		AR3	BC3 CC1
			BC4 CC4
			BC6 CC6
			BC7 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	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	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	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 to 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	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	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	Ordinary class hours	Student?s personal work hours	Total hours
Case study	A3 B3 B4 B6 B7 C1 C4 C6 C8	5	5	10
Guest lecture / keynote speech	A3 B3 B4 C6 C8	11	33	44



Multiple-choice questions	B4	1	4	5
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.
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
Multiple-choice questions	Examen tipo test para a avaliación dos conhecimentos.
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	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
Multiple-choice questions	B4	Examen tipo test para a avaliación dos coñecemento.	50

Assessment comments
The multiple-choice questions is in person.

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 Nüremberg (1947).Declaración de Helsinki (Asociación Médica Mundial, Principios éticos para la investigación en seres humanos, 1964; versión actualizada: 7.ª revisión, 2008).Informe Belmont (Comisión Nacional para la protección de los sujetos humanos de investigación biomédica y del comportamiento, Principios éticos y orientaciones para la protección de los sujetos humanos en la experimentación, 1979).Consello de organizaci3ns internacionais das ciencias m3dicas (CIOMS) en colaboraci3n coa Organizaci3n Mundial da Sa3de (OMS), Pautas internacionais para a investigaci3n biom3dica en seres humanos (2002).Declaraci3n universal sobre Bio3tica e dereitos humanos (UNESCO, 2005).Normativa xur3dicaNormativa xur3dica xeralConstituci3n espa3ola de 1978.Ley 41/2002, de 14 de novembro, b3sica reguladora de la autonom3a del paciente y de derechos y obligaciones en materia de informaci3n y documentaci3n cl3nica.Ley Org3nica 3/2018, de 5 de diciembre, de protecci3n de datos personales.Convenio para la protecci3n de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la Biolog3a y la Medicina (Convenio relativo a los derechos humanos y la biomedicina). Consejo de Europa. Protocolo adicional al Convenio de derechos humanos y biomedicina en relaci3n con la investigaci3n biom3dica.Investigaci3n con seres humanosLey 14/2007, de 3 de julio, de investigaci3n biom3dica.Ley 14/2006, de 26 de mayo, sobre t3cnicas de reproducci3n humana asistida.Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos cl3nicos con medicamentos.Ley 10/2013, de 24 de julio, que modifica la ley 29/2006 de garant3as y uso racional de los medicamentos y productos sanitarios.Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos b3sicos de autorizaci3n y funcionamiento de los biobancos con fines de investigaci3n biom3dica y del tratamiento de las muestras biol3gicas de origen humano, y se regula el funcionamiento y organizaci3n del Registro Nacional de Biobancos para invstigaci3n biom3dica.Investigaci3n con animalesLey 8/2003, de 24 de abril, de sanidad animal.Real Decreto 53/2013, de 1 de febrero, sobre protecci3n de los animales utilizados para experimentaci3n y otros fines cient3ficos.Ley 32/2007, de 7 de noviembre, para el cuidado de los animales en su explotaci3n, transporte, experimentaci3n y sacrificio.Directiva 2010/63/UE del Parlamento Europeo y del Consejo, de 22 de septiembre de 2010, relativa a la protecci3n de los animales utilizados para fines cient3ficos.Investigaci3n con axentes biol3gicos e organismos modificados xen3ticamenteLey 9/2003, de 25 de abril, por la que se establece el r3gimen jur3dico de la utilizaci3n confinada, liberaci3n voluntaria y comercializaci3n de organismos modificados gen3ticamente.Real Decreto 178/2004, de 30 de enero, por el que se aprueba el Reglamento general para el desarrollo y ejecuci3n de la Ley 9/2003, de 25 de abril, por la que se establece el r3gimen jur3dico de la utilizaci3n confinada, libraci3n voluntaria y comercializaci3n de organismos modificados gen3ticamente.Real Decreto 1369/2000, de 19 de julio, por el que se modifica el Real Decreto 822/1993, de 28 de mayo, por el que se establecen los principios de buenas pr3cticas de laboratorio y su aplicaci3n en la realizaci3n de estudios no cl3nicos sobre sustancias y productos qu3micos.
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Complementary	- 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

Programa

Green Campus FCS Para axudar a conseguir

un entorno inmediato sustentable e cumprir cos obxectivos estratéxicos 1 e 2 do

"III Plan de Acción do Programa Green Campus FCS (2018-2020)", os

traballos documentais que se realicen nesta materia:a. Solicitaranse

maioritariamente en formato virtual e soporte informático. b.

De realizarse en papel: -

Non se empregarán plásticos. -

Realizaranse impresións a dobre cara. -

Empregarase papel reciclado. -

Evitarase a realización de borradores.PLAXioA

detección de fraude, copia ou plaxio na redacción do traballo da materia

implicará un suspenso na oportunidade de avaliación afectada (0,0) e a remisión

directa á oportunidade seguinte. Dita circunstancia

comunicarase á Comisión Académica e ao resto de profesores do título. En caso

de que se reitere a irregularidade nunha 2ª avaliación, a Comisión poderá

solicitar ao Reitor a expulsión temporal ou definitiva do/a estudante do título

cursado.

(*)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.