



Teaching Guide

| Identifying Data | | | | | 2016/17 |
|----------------------------|----------------------------------------------------------------------------|---------------|-----------------------|----------------|-----------|
| Subject (*) | Aspectos Éticos e Xurídicos na Investigación en Ciencias da Saúde | | | 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 Especial | | | | |
| 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 | | | | | |

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 afrontarse. |
| 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 | <p>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.</p> <p>The main learning aim of case study is to achieve argumentation, deliberation and decision-making abilities.</p> <p>Case study includes other methodologies: analysis of bibliographical and normative sources, as well as research papers.</p> |
| 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 | <p>Ethical and legal answers to research in health sciences are usually stated in normative documents and legal norms.</p> <p>These documents provide both a historical and a systematic explanation of the ethical and legal perspectives of research in health sciences.</p> |

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 | <p>Assessment of participation and argumentation abilities.</p> <p>Assessment of understanding and implementation of ethical and legal language and concepts.</p> <p>Analysis of bibliographical and normative (ethical and legal) sources is included.</p> | 50 |
| Objective test | B4 C1 | <p>Main method for assessing knowledge.</p> <p>Knowledge and understanding of bibliographical and normative (ethical and legal) sources are included.</p> | 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 2223/2004, do 6 de febreiro, polo que se regulan os ensaios clínicos con medicamentos (BOE n.º 33, 7.2.2004). Lei 29/2006, do 26 de xullo, de garantías e uso racional dos medicamentos e produtos sanitarios (BOE n.º 178, 27.7.2006). 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). Real Decreto 1201/2005, do 10 de outubro, sobre protección dos animais utilizados para experimentación e outros fins científicos (BOE n.º 252, 21.10.2005). 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).Real Decreto 1697/2003, do 12 de decembro, polo que se crea a Comisión Nacional de Biovixilancia (BOE n.º 310, 27.12.2003).



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| 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.