

Bioethics and Legislation

Code: 101938
ECTS Credits: 3

Degree	Type	Year	Semester
2500890 Genetics	OB	3	2

Contact

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Use of languages

Principal working language: catalan (cat)
Some groups entirely in English: No
Some groups entirely in Catalan: Yes
Some groups entirely in Spanish: No

Teachers

Xavier Vallve Sanchez

Prerequisites

There are no prerequisites for taking this course. In spite of this, to ensure the proper monitoring of the subject by the student and to achieve the learning outcomes proposed, it is recommended that the student have some basic knowledge about the techniques used in Biomedicine and Genetics as well as associated research, since many of them will appear throughout the development of their content and they will be given as known. On the other hand, in a scientific discipline like Genetics it is frequent to use sources of information, norms and international guidelines, in English. It is therefore recommended that students have some basic knowledge of this language

Objectives and Contextualisation

The subject Bioethics and legislation has a complementary character within the degree and with it, it is intended that the student acquires knowledge about the Ethical and legal aspects related to Genetics and the associated research.

The training objectives are that the student, at the end of the subject, is able to:

1. Do diagnoses and genetic counseling and consider their ethical and legal dilemmas.
2. Apply and assume the basic principles in bioethics.
3. Make preconceptional genetic counseling taking into account its ethical and legal implications.
4. Apply the legislation for the protection of individual genetic data.
5. To elaborate, direct, execute and advise projects that require knowledge of genetics or genomics.
6. Apply the principles of the intellectual and industrial property right in the processes of product development and research.
7. Apply the patent regulations.

8. Apply the legal principles on research and product development.
9. Apply existing legislation to biomedical research in accordance with bioethical principles.
10. Develop strategies of analysis, synthesis and communication that allow to transmit the different aspects of genetics in educational environments
11. Explain the social perception of science and technology and its importance in communicating appropriately the achievements and the risks associated with the advancement of genetics.
12. Be able to communicate effectively, orally and in writing.
13. Apply theoretical knowledge to practice.
14. Assume an ethical commitment
15. the importance of quality and well-done work.
16. Demonstrate sensitivity in environmental, health and social issues.

Skills

- Apply knowledge of theory to practice.
- Appreciate the importance of quality and a job well done.
- Assume ethical commitment
- Be able to communicate effectively, orally and in writing.
- Be sensitive to environmental, health and social matters.
- Develop analysis, synthesis and communication strategies to transmit the different aspects of genetics in educational settings.
- Perform genetic diagnoses and assessments and consider the ethical and legal dilemmas.
- Produce, direct, execute and assess projects where knowledge of genetics or genomics is necessary.

Learning outcomes

1. Apply knowledge of theory to practice.
2. Apply legal principles to the research and development of products.
3. Apply legislation on the protection of individual genetic data.
4. Apply patent regulations.
5. Apply the basic principles of bioethics.
6. Apply the principles of intellectual and industrial property rights to product research and development processes.
7. Apply valid legislation to biomedical research in accordance with bioethical principles.
8. Appreciate the importance of quality and a job well done.
9. Assume ethical commitment
10. Be able to communicate effectively, orally and in writing.
11. Be sensitive to environmental, health and social matters.
12. Design a proposal on the applications of genetics and report it in an educational setting.
13. Expose the social perception of science and technology and its importance for properly communicating the achievements and risks associated to genetic progress.
14. Perform pre-conceptual genetic assessment taking into account its ethical and legal implications.

Content

PART I. PRINCIPLES OF BIOETHICS

Definition of Bioethics

In the plane of nature

In the people's plane

In the social plan

Fundamental ethical theories in Bioethics

Deontological ethics

Utilitarian ethics

Other influential ethics

Analysis in bioethics

The principlism

Casuistry

Basic principles in Bioethics

Autonomy

Charity

No malice

Justice

Other relevant principles in Bioethics

Principle of respect for dignity

Principle of respect for integrity

Principle of non-discrimination

Principle of respect for privacy / privacy and confidentiality

Principle of respect for the right to information

Principle of respect for vulnerability

Principle of precaution / caution

Principle of proportionality

Principle of gratuity in participation and donation

PART II. THE ETHICS IN RESEARCH

Ethical principles in scientific practice

Principle of freedom in research

Principle of transparency: evaluation and control

Principle of the right to information

Obligations of the researchers

With the subjects of study

With society

With the promoters

With other researchers

Codes of Good Practices in Research

Ethical principles of research in Biomedicine

PART III. THE ETHICAL DESIGN OF EXPERIMENTATION WITH ANIMALS

Ethical aspects of animal research

The moral status of animals

Utilitarianism

The theory of natural rights

The theory of social contract: contractualism

The rights of animals

The basic principles: the 3R

Legal aspects of the use of experimental animals: RD 53/2013

PART IV. THE ETHICAL DESIGN OF EXPERIMENTATION WITH HUMAN BEARS

Ethical principles

The subjects

Healthy volunteers

Patients

Research in individuals unable to consent: psychic, cognitive and child lessons.

A special case: the search in embryos

Legal aspects of research in human beings, embryos and reproductive cells: Law 14/2007 and 14/2006

PART V: ETHICAL ASPECTS OF THE NEW TECHNOLOGIES

Medicine

General concerns

Regenerative medicine

Personalized medicine

Reproductive medicine

Genetics

General concerns

Genetic modification

Genetic counseling

Genetic tests incapable of consenting

Use of genetic information

Patents

PART VI: OTHER LEGAL ASPECTS

Law 15/1999

Law 9/2003

Part VII: Patents

Intellectual and industrial property rights. Introduction. Copyright. Brands. Geographical indications

Industrial designs Patents. Industrial secret

Patents and utility models. What is a patent and what is it for? What can be patented? Requirements and exclusions. How to obtain patents? Processing

Patents in chemistry, pharmacy and biotechnology. Inventions in chemistry and pharmacy. Inventions in biotechnology and biomedicine

Writing of the patent and infringement. Read a patent, structure and document information. Writing of the patent application, claims Protection area. Infringement

Patent documentation. Importance of documentation in patents. How to locate patents Free and professional databases. Examples of searches and retrieval of documents. Interpretation of results. Situation of patents

Methodology

The subject consists of theoretical classes and analysis and commentary of cases proposed in a format of Seminars. Organization and the teaching methodology that will be followed in these two types of training activities is described below

Theory classes:

The content of the theory program will be taught mainly by the teacher in the form of master classes with audiovisual support. Presentations used in class by the teacher will be previously available on the Virtual Campus of the subject. It is advisable that students print this material and take it to class, to use it as a support when taking notes. Although it is not essential to extend the content of the classes taught by the teacher, unless expressly requested by the latter.

It is recommended that students consult on a regular basis the books and recommended normative texts in the Bibliography section of this teaching guide in order to consolidate and clarify, if necessary, the contents explained in class.

On the other hand, the student will have to work individually the content of the legal texts referred to in this guide. We will provide the student with documents where the full text will appear and also a clearance of the normative text in order to facilitate this task.

In addition to the attendance to the classes, the follow-up of the subject will also imply an active role of the student, who will have to analyze and comment real cases and assumptions related to the contents of the theory program. It is intended that these cases serve to consolidate the previously worked contents in theory classes and also for students to develop a critical spirit in the face of ethical and legal problems related to research in Biomedicine. Anyway, this commentary of the cases will be done in the form of small work groups is intended to promote in the student the habit of teamwork and the critical argumentation between peers.

Seminars:

The students will do the analysis and commentary of 3 cases proposed outside the class schedule, in work groups between 4 and 6 people chosen by students must train at the beginning of the course. This discussion will be reflected in individual work that students will deliver (two deliveries only by group) in the established deadlines, works that will be evaluated by the teacher, sharing all the members of the group the same note (evaluation group).

Subsequently, there will be 3 seminar sessions, which will be devoted to the analysis and commentary of the cases and assumptions between the different groups. Each of these sessions will be attended by half of the set of groups, all the members of the discussion group being present. This will mean about 30 students in 5-6 groups. After reading the case, the teacher will lead the discussion. The interventions of the different students will also be evaluated by the teacher in the sense of highlighting the brightest and most passive students.

The subject proposal will be done by the teacher at the beginning of the course and will be assigned to each subset of discussion groups. The proposal will include the guidelines and points to treat.

Activities

Title	Hours	ECTS	Learning outcomes
Type: Directed			
Lectures on theory	20	0.8	6, 2, 5, 3, 7, 4, 9, 11, 14
Seminars	4	0.16	1, 6, 2, 5, 3, 7, 4, 9, 11, 13, 14, 10, 8
Type: Autonomous			
Case analysis: Group discussion	12	0.48	1, 6, 2, 5, 3, 7, 4, 9, 11, 13, 14, 10, 8
Case analysis: Preparation of discussion work	4	0.16	1, 2, 5, 3, 7, 9, 11, 13, 14, 10, 8
Individual study	29	1.16	1, 6, 2, 5, 3, 7, 4, 9, 11, 14, 8

Evaluation

The evaluation of the module, which will be a continuous assessment throughout the semester, will consist of the following evaluation activities:

1. Proof of the theory contents (individual assessment): During the semester there will be three partial written tests on the contents

Theoreticians of the subject, which students will have to answer individually. There will be a model of these tests on the Virtual Campus of

the subject These tests will consist of a series of objective and semiobjective questions about the corresponding topics of the

theory The objective questions will usually be questions with multiple option response. Semiobjective questions will be questions from

Short answer, but in which it will be necessary for the student to construct his answer and reason.

2. Evaluation of the comments to the proposed cases (group evaluation): The three papers presented by each group will be evaluated. It will be in

Consideration of the fulfillment of the delivery deadlines, so that the work presented later to the discussion of the cases in

the seminars

3. Evaluation of the public discussion of cases. Seminars (individual assessment): The interventions will be evaluated individually

Shining that take place during the public discussion of the cases, as well as the attitudes of passivity on the part of the students during this activity.

The relative weight of each of these evaluation activities will be:

Proof of theory contents:

Target test: 46% (23% for each test)

Semi-objective test: 24%

Assessment of case comments: 30% (10% for each case)

Evaluation of the public discussion of cases. Seminars (individual assessment): $\pm 5\%$

The objective of these tests is to evaluate not only that students have acquired the conceptual knowledge of the module but, more importantly,

They have bought them and they know how to integrate and interact with each other. On the other hand, it will also be valued that students use terminology

Suitable when dealing with questions raised during the assessment, as well as the ability to work in groups and to argue and discuss critically

and rational the treated subjects.

Recovery test

There will be a recovery test for those students who have not matched or passed a 4, or have not submitted, to any of the tests partial theory.

To be eligible for the retake process, the student should have been previously evaluated in a set of activities equaling at least two thirds of the final score of the course or module. Thus, the student will be graded as "No Avaluable" if the weighthin of all conducted evaluation activities is less than 67% of the final score

The student will have the option of renouncing the grade of any theory test and submitting to the recovery exam.

Review of exams

The review of exams will be done by appointment and within the schedule proposed by the teacher.

Final note

In order to pass the subject, students must complete all the tests of the theory contents. On a total of 10 points, it will be necessary

the student obtains a qualification equal or superior to 4 points in each one of the three partial proofs and an overall rating equal or superior to 5

Points for the total of evaluation tests of the subject. Students who do not attain the minimum mark of 4 points in any of them

Partial tests can not pass the subject and receive a maximum final grade of the subject of 4 points.

NOT EVALUABLES: student will be graded as "No Avaluable" if the weighthin of all conducted evaluation activities is less than 67% of the final score

Evaluation activities

Title	Weighting	Hours	ECTS	Learning outcomes
Evaluation of case comments	30%	1	0.04	1, 6, 2, 5, 3, 7, 4, 9, 11, 13, 14, 10, 8
Evaluation of the public discussion of cases. Seminars (individual assessment)	5%	2	0.08	1, 6, 2, 5, 3, 7, 4, 9, 11, 14, 8
Test of the theory contents: Semiobjective test	24%	1	0.04	1, 2, 5, 3, 7, 9, 11, 14, 10, 8
Test of the theory contents: objective test	46%	2	0.08	1, 2, 5, 3, 7, 9, 12, 13, 14, 10, 8

Bibliography

Basis references:

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Valida

- SEF. Reproducción Humana Asistida. Protocolos de Consentimiento Informado. Madrid, 2002.

- Steinbock B. (ed.). The Oxford Handbook of Bioethics. Oxford University Press. Oxford. 2007.

Links:

Disponibles al Campus Virtual de l'assignatura (<https://cv2008.uab.cat/>)

Boletín Oficial del Estado: <http://www.boe.es/>

Berman Institute of Bioethics: <http://www.bioethicsinstitute.org/>

Clinical Trials: <http://www.clinicaltrials.gov/>

Comissió d'Ètica en Experimentació Animal i Humana de la UAB: <http://www.recerca.uab.es/ceeah/>

Comité de Bioética de España: <http://www.comitedebioetica.es/>

Council of Europe. Steering Committee on Bioethics:

http://www.coe.int/t/dg3/healthbioethic/cdbi/default_en.asp

EuroBioBank: <http://www.eurobiobank.org/>

Fundació Grífols: <http://www.fundaciogrifols.org/es/web/fundacio/home>

Institut Borja de Bioètica: <http://www.ibbioetica.org/es/#&panel1-1>

Observatori de Bioètica i Dret: <http://www.pcb.ub.es/bioeticaidret/>

Stanford Encyclopedia of Philosophy: <http://www.science.uva.nl/%7Eseop/>

The European Group on Ethics in Science and New Technologies:

<https://ec.europa.eu/research/ege/index.cfm>

The Hasting Center: <http://www.thehastingscenter.org/>

The Hinxton Group: <http://www.hinxtongroup.org/>

The Nuffield Council: <http://www.nuffieldbioethics.org/>

UNESCO. International Bioethics Committee:

<http://www.unesco.org/new/en/socialand-human-sciences/themes/bioethics/international-bioethicscommittee/>