Universitat Autònoma de Barcelona

2023/2024

Bioethics and Legislation

Code: 101938
ECTS Credits: 3

Degree	Type	Year	Semester
2500890 Genetics	OB	3	2

Contact

Name: Josep Santalo Pedro

Email: josep.santalo@uab.cat

Teaching groups languages

You can check it through this link. To consult the language you will need to enter the CODE of the subject.
Please note that this information is provisional until 30 November 2023.

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, paying special attention to gender perspective

Competences

- Act with ethical responsibility and respect for fundamental rights and duties, diversity and democratic values.
- 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.
- Make changes to methods and processes in the area of knowledge in order to provide innovative responses to society's needs and demands.
- 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.
- Take account of social, economic and environmental impacts when operating within one's own area of knowledge.
- Take sex- or gender-based inequalities into consideration when operating within one's own area of knowledge.

Learning Outcomes

1. Act with ethical responsibility and respect for fundamental rights and duties, diversity and democratic values.
2. Apply knowledge of theory to practice.
3. Apply legal principles to the research and development of products.
4. Apply legislation on the protection of individual genetic data.
5. Apply patent regulations.

6. Apply the basic principles of bioethics.
7. Apply the principles of intellectual and industrial property rights to product research and development processes.
8. Apply valid legislation to biomedical research in accordance with bioethical principles.
9. Appreciate the importance of quality and a job well done.
10. Assume ethical commitment
11. Be able to communicate effectively, orally and in writing.
12. Be sensitive to environmental, health and social matters.
13. Design a proposal on the applications of genetics and report it in an educational setting.
14. Expose the social perception of science and technology and its importance for properly communicating the achievements and risks associated to genetic progress.
15. Make changes to methods and processes in the area of knowledge in order to provide innovative responses to society's needs and demands.
16. Perform pre-conceptual genetic assessment taking into account its ethical and legal implications.
17. Take account of social, economic and environmental impacts when operating within one's own area of knowledge.
18. Take sex- or gender-based inequalities into consideration when operating within one's own area of knowledge.

Content

PART I. PRINCIPLES OF BIOETHICS
Definition of Bioethics
Fundamental ethical theories in Bioethics
Analysis in bioethics
Basic principles in Bioethics
Other relevant principles in Bioethics
PART II. THE ETHICS IN RESEARCH
Ethical principles in scientific practice
Obligations of the 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 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
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
General concerns
Regenerative medicine
Personalized medicine
Reproductive medicine
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.
Patents and utility models.

Patents in chemistry, pharmacy and biotechnology.
Writing of the patent and infringement.
Patent documentation.

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. Alternatively, the methodology of the "flipped lessons" will also be used, in which the topics are previously prepared by the student from material provided by the teacher and later worked with practical cases in the face-to-face sessions. 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.

Annotation: Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			

Lectures on theory	20	0.8	10, 12
Seminars	4	0.16	2, 10, 12, 11, 9
Type: Autonomous			
Case analysis: Group discussion	12	0.48	2, 10, 12, 11, 9
Case analysis: Preparation of discussion work	4	0.16	2, 10, 12, 11, 9
Individual study	29	1.16	2, 10, 12, 9

Assessment

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): ± 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 3,5 or have not submitted to each partial tests of 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 3,5 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 3,5 points in any of the
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

Single assessment

Single assessment consists of a single examination in which the contents of the entire theory programme will be assessed. The test will consist of multiple-choice questions. The mark obtained in this final examination will account for 70% of the final grade for the subject.

The synthesis test will coincide with the same date set in the calendar for the last continuous assessment test and the same recovery system will be applied as for continuous assessment.

In order to use the grade obtained in this synthesis test to average in the final grade of the subject, a grade equal to or greater than 3.5 out of 10 will be required.

Case submissions will follow the same procedure as in continuous evaluation. The grade obtained will represent 30% of the final grade of the subject.

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Evaluation of case comments	30%	1	0.04	1, 18, 17, 2, 7, 3, 6, 4, 8, 5, 10, 12, 13, 14, 16, 15, 11, 9
Evaluation of the public discussion of cases. Seminars (individual assessment)	5%	2	0.08	1, 18, 17, 2, 7, 3, 6, 4, 8, 5, 10, 12, 16, 15, 9
Test of the theory contents: Semiobjective test	24%	1	0.04	1, 18, 17, 2, 7, 3, 6, 4, 8, 5, 10, 12, 16, 15, 11, 9
Test of the theory contents: objective test	46%	2	0.08	1, 18, 17, 2, 7, 3, 6, 4, 8, 5, 10, 13, 14, 16, 15, 11, 9

Bibliography

Basis references:

• Busquets E., Mir J. Fem bioètica. Institut Borja de Bioètica. Universitat Ramon Llull. Esplugues de Llobregat. 2009.

• Carracedo A., Casado M. y González-Duarte R. (Eds) Documento sobre pruebas genéticas de filiación. Observatori de Bioètica i Dret de la Universitat de Barcelona. Noviembre 2006.

•Casado M. (ed.). Materiales de Bioética y Derecho. Ed. Cedecs. Barcelona. 1996.

• Casado M. (ed.) Sobre la dignidad y los principios. Análisis de la Declaración Universal sobre Bioética y Derechos Humanos de la Unesco. Editorial Aranzadi. Cizur Menor. 2009.

• Casado M. y Egozcue J. (Eds) Documento sobre células madre embrionarias. Observatori de Bioètica i Dret de la Universitat de Barcelona. Diciembre 2001.

• Casado M. y Egozcue J. (Eds) Documento sobre donación de ovocitos. Observatori de Bioètica i Dret de la Universitat de Barcelona. Abril 2001.

• Casado M. y Egozcue J. (Eds) Documento sobre investigación con embriones. Observatori de Bioètica i Dret de la Universitat de Barcelona. Julio 2000.

• Casado M. y Egozcue J. (Eds) Documento sobre nanotecnología y bioética global. Observatori de Bioètica i Dret de la Universitat de Barcelona. Abril 2001.

• Casado M. y Egozcue J. (Eds) Documento sobre selección de sexo. Observatori de Bioètica i Dret de la Universitat de Barcelona. Febrero 2003.

• Casado M., Lopez-Baroni M. Manual de bioética laica (I): Cuestiones clave. Edicions de la Universitat de Barcelona. Barcelona, 2018.

• Coughlin S. Case studies in public health ethics (2nd edition). American Public Health Association. Washington, 2009.

• Cuadernos de la Fundación Victor Grífols i Lucas. Problemas prácticos del Consentimiento Informado. Fundación Victor Grífols i Lucas. Barcelona, 2002.

• De Semir, V. La ética, esencia de la comunicación científica y médica. Cuadernos de la Fundació Victor Grífols i Lucas nº 25. Barcelona .2010.

• Egozcue J., Shenfield. F. (eds.). Responses to human cloning. Sèrie Jornades Científiques nº 5. Institut d'Estudis Catalans. Barcelona. 1998.

• García Manrique R. La medida de la humano. Ensayo de bioética y cine. Materiales de Bioética. Associació de Bioètica i Dret de la UB i Observatori de Bioèticai Dret. Barcelona 2008.

• García-Manrique R. (ed.) El cuerpo diseminado. Estatuto, uso y disposición de los biomateriales huamnos. Ed. Aranzadi. Navarra, 2018.

• Harris J. On cloning. Routledge. London. 2004.

• Institut Borja de Bioètica URL (eds.). Bioètica aplicada. Ed. Proteus. Cànoves. 2011.

• Jonsen A.R., Siegler M., Winslade W.J. Ética clínica. Ariel. Barcelona. 2005.

• Kuhse H., Singer P. (eds) A Companion to Bioethics. Blackwell Companions to Philosophy. 2nd edition. Willey-Blackwell. Hong Kong. 2012.

• Llácer M.R., Casado M. Buisan L. (Eds) Documento sobre bioética y big data: explotación y comercialización de los datos de los usuarios de la sanidad pública Observatori de Bioètica i Dret de la Universitat de Barcelona. Enero 2015. ISBN 978-84-475-4210-9

• López Baroni, M. J., Marfany, G., De Lecuona, I., Corcoy, M., Boada, M., Royes, A., Santaló, J., Casado, M. 2017. La edición genómica aplicada a seres humanos: aspectos éticos, jurídicos y sociales. Revista de Derecho y Genoma Humano. Genética, Biotecnología y Medicina Avanzada / Law and the Human Genome Review. Genetics, Biotechnology and Advanced Medicine: 46, 317-340.

• López-Baroni M. Bioética y tecnologies disruptives. Ed Herder. Barcelona, 2021.

• López-Baroni M. El origen de la bioética como problema. Edicions de la Universitat de Barcelona. Barcelona, 2016.

• Macklin R. La ética y la investigación clínica. Cuadernos de la Fundació Victor Grífols i Lucas nª 23. Barcelona .2010.

• Martín A., Martín-Arribas M.C., di Donato J.H., Posada M. Las cuestiones ético-jurídicas más relevantes en relación con los biobancos. Instituto de Salud Carlos III. Madrid. 2005.

• Montero F., Morlans M. Para deliberar en los comités de ética. Fundació Doctor Robert. Universitat Autònoma de Barcelona. Barcelona. 2009.

• Rendtorff J.D. i Kemp P. (eds.) Basic ethical principles in European Bioethics and Biolaw. Institut Borja de Bioètica. Barcelona. 2000.

• Sánchez-Caro J., Abellán F. (eds.) Investigación Biomédica en España. Aspectos Bioéticos, Jurídicos y Científicos. Fundación Salud 2000 y Editorial Comares. Granada. 2007.

• Santaló J. 2011. Ethics and genetics. A quick view. Revista de Bioética y Derecho 21, 40-45.

• Santaló J. y Casado M. (Eds) Documento sobre bioética y edición genómica en humanos. Observatori de Bioètica i Dret de la Universitat de Barcelona. Diciembre 2016. ISBN 978-84-475-4063-1

• Santaló J., Berdasco M. 2022. Ethical implications of epigenetics in the era of personalized medicine. Clinical Epigenetics. doi: 10.1186/s13148-022-01263-1.

• 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 Hinxston 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/

Software

Not applies