



**BIO-455**  
**Introduction to law and ethics**  
**Course synopsis**  
Fall semester 2025

**Sandra Hotz and Elodie Malbois**

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## COURSE DESCRIPTION

- Elective course in the "Life Sciences Engineering" curriculum
- 4 hours per week during the Fall semester 2025–2026 (4 ECTS credits): 2 hours of lectures/week x 14 weeks + 2 hours of exercises/week x 14 weeks
- Group report to be submitted before the end of the course and oral exam during the exam session

### Overview

The aim of this course is to introduce students to the basic legal and ethical concepts relevant to research in the life sciences and its translational application, and to provide them with the essential tools to identify legal and ethical issues in their future professional practice.

### Content

1. Introduction to ethics and law: distinction between law, ethics, and professional standards; sources of law, how they are implemented, structured, and enforced, introduction to ethical thinking and the main theories of ethics.
2. Legal concept of the person, the nature of the human body and its separated parts, and the nature and scope of related rights (personality rights, property and intellectual property rights, etc.).
3. Regulation of research involving human subjects (ethical principles, basic legal concepts); ethical and legal framework for the collection, storage, processing, and transfer of human biological material; data protection; ethical and legal foundations for research involving vulnerable populations.
4. Legal status of animals in constitutional and civil law; animal protection; ethical and legal requirements for animal research; ethical debate on animal experimentation.
5. Basic elements of intellectual property; regulation of medical devices; international law and legal aspects of biotechnology.
6. Ethical and legal aspects of other domains of research (personalized medicine, human enhancement).
7. Scientific integrity and conflicts of interest.

### Learning outcomes

By the end of this course, students should be able to:

- Explain the basic foundations of legal sources and legislative procedures.
- Identify the main branches of law and have the legal background necessary to communicate effectively with legal experts.
- Identify legal and ethical issues related to their future professional practice.

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## Teaching methods

Lectures (ex cathedra) and interactive teaching based on practical examples.

## Assessment method

Student assessment is based on:

1. A group written report, accounting for one-third of the final grade. The written report is structured as follows:

a. Students must form working groups of four by October 7, 2025. Students who do not register by the deadline will be randomly assigned to a group.

b. Each group will be tasked with submitting a joint report addressing a series of questions relevant to the daily practice of a scientist. Each student will be responsible for answering one question individually. Group members will then exchange their drafts and provide peer feedback according to the provided guidelines.

c. The deadline for submitting the reports is December 10, 2025.

2. A 15-minute oral exam, preceded by a preparation period, accounting for two-thirds of the final grade. Students are not allowed any books or notes for the examination.

The final grade will be a weighted average of the oral exam (2/3) and the group work (1/3).

## Course materials

Lecture slides will be made available to students on Moodle.

Modules 1 and 2 of the TRREE online training (Training and Resources in Research Ethics Evaluation: <https://elearning.trree.org/>) must be completed by October 13, 2025 and are part of the required course materials.

Additional required readings will complement the lecture materials and be available on Moodle.

Supplementary references may also be posted on Moodle.

Up-to-date Swiss federal legislation (laws, ordinances, etc.) is available online via the Fedlex Systematic Compilation: [https://www.fedlex.admin.ch/fr/cc?news\\_period=last\\_day&news\\_pageNb=1&news\\_order=desc&news\\_itemsPerPage=10](https://www.fedlex.admin.ch/fr/cc?news_period=last_day&news_pageNb=1&news_order=desc&news_itemsPerPage=10)

Lectures will not be recorded.

## Teachers

Prof. Sandra Hotz (email : [sandra.hotz@unine.ch](mailto:sandra.hotz@unine.ch))

Dr Elodie Malbois (email : [elodie.malbois@unige.ch](mailto:elodie.malbois@unige.ch))

## Plan

Autumn Semester 2025

	DATE	COURS	SPEAKERS
1	09.09.25	Course overview:  <ul style="list-style-type: none"> <li>- Objectives, content, organization</li> <li>- Instructions for group work</li> <li>- Presentation of Modules 1 and 2 of the TRREE online training course: <a href="http://elearning.trree.org">http://elearning.trree.org</a></li> </ul> General Introduction to Ethics	Elodie Malbois
2	16.09.25	Ethical Issues in Experimentation with Humans	Elodie Malbois
3	23.09.25	Introduction to Swiss law	Sandra Hotz
4	30.09.25	Introduction to the Human Research Act	Sandra Hotz
5	7.10.25	Who's body is it anyway ? (Body, body parts and biological material)  <b>Deadline for forming groups on Moodle: 7 October 2025 (midnight)</b>  <b>Students are requested to upload their certificates of completion for Modules 1 and 2 of the TRREE training course to Moodle by 13 October 2025 (midnight)</b>	Sandra Hotz
6	14.10.25	Genetics, Genomics and Law	Sandra Hotz
7	28.10.25	Intellectual Property Law	Astrid Pilottin (PhD defense in medical devices) Sandra Hotz
8	04.11.25	Introduction to European right of biotechnologies : medical devices	Dr. Sylvain Poitras (Avocat, Partner et responsable sciences de la vie chez Appleton Luff, Managing Director de Swiss Peak Technologies) Sandra Hotz
9	11.11.25	Human Enhancement	Elodie Malbois
10	18.11.25	Ethical issues in animal experimentation	Elodie Malbois
11	25.11.25	The status and protection of animals	Xavier Warot

		<b>Deadline for writing texts to be sent to other group members: 26 November.</b>	(Animalerie EPFL)
<b>12</b>	<b>02.12.25</b>	Personalized Medicine  <b>Deadline for submitting comments: 3 December.</b>	Elodie Malbois
<b>13</b>	<b>09.12.25</b>	Scientific fraud and integrity in research.  Ethical support at EPFL and the Research Ethics Committee of the Canton of Vaud  <b>Deadline for submitting the group report: 10 December.</b>	Gaia Barazzetti Elodie Malbois
<b>14</b>	<b>16.12.25</b>	Students share what they have learned from group work  Feedback from teachers on group work  Presentation of the oral exam: procedure and questions	Sandra Hotz

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## BIBLIOGRAPHY

### A. IMPORTANT REFERENCES FOR THE COURSE

- Swiss Law  
[https://www.fedlex.admin.ch/en/cc?news\\_period=last\\_day&news\\_pageNb=1&news\\_order=desc&news\\_itemsPerPage=10](https://www.fedlex.admin.ch/en/cc?news_period=last_day&news_pageNb=1&news_order=desc&news_itemsPerPage=10)
- Decisions of the Swiss Federal Supreme Court  
<https://www.bger.ch/fr/index/jurisdiction/jurisdiction-inherit-template/jurisdiction-recht.htm>
- Federal Gazette (FF) (Official information bulletin of the Confederation)  
<https://www.admin.ch/gov/fr/accueil/droit-federal/feuille-federale.html>
- Swissmedic  
<https://www.swissmedic.ch/swissmedic/en/home.html>
- Guidelines of the Swiss Academy of Medical Sciences  
<https://www.samw.ch/en/Publications/Medical-ethical-Guidelines.html>
- European Union Law  
<https://eur-lex.europa.eu/homepage.html?locale=en#>
- Case law of the European Court of Human Rights  
<https://www.echr.coe.int/knowledge-sharing>
- Training in ethics and regulations governing research involving human subjects  
TRREE  
<https://elearning.trree.org>

## B. REFERENCES FOR EACH CLASS

- 1 09.09.25 **Course overview:**  
 - Objectives, content, organization  
 -Instructions for group work  
 - Presentation of Modules 1 and 2 of the TRREE online training course: <http://elearning.treee.org>  
 General introduction to ethics

**Slides on Moodle**

- 2 16.09.25 **Ethical Issues in Experimentation with Humans**  
**Ethical principles in human research ethics, Research with vulnerable participants**

**Slides on Moodle**

**Required reading :**

Ezekiel J. Emanuel, David Wendler, Jack Killen, Christine Grady, What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research, *The Journal of Infectious Diseases*, Volume 189, Issue 5, 1 March 2004, Pages 930–937, <https://doi.org/10.1086/381709>

World Medical Association, Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Participants (2024), <https://www.wma.net/policies-post/wma-declaration-of-helsinki/>

**Additional Reading :**

CALLAWAY E., Deal done over HeLa cell line, *Nature* 2013 (500), pp. 132-133.

- 3 23.09.25 **Introduction to Swiss Law**

**Slides on Moodle**

**Required reading**

Swiss Federal Constitution, 1999 :

<https://www.fedlex.admin.ch/eli/cc/1999/404/fr>

**Additional reading :**

AMARELLE C., Droit suisse, Le Mont-sur-Lausanne, 2013, (extraits).

La Confédération en bref, 2022 :

<https://www.bk.admin.ch/bk/fr/home/documentation/conf%C3%A9d%C3%A9ration-en-bref/archiv/der-bund-kurz-erklaert-2022.html>

- 4 30.09.25 **Introduction to Human Research Act**

**Slides on Moodle****Required reading :**

Constitution fédérale de la Confédération suisse du 18 avril 1999, RS 101, article 118b Cst : <https://www.fedlex.admin.ch/eli/cc/1999/404/fr>

Loi fédérale du 30 novembre 2011 relative à la recherche sur l'être humain (Loi relative à la recherche sur l'être humain, LRH), RS 810.30 : <https://www.fedlex.admin.ch/eli/cc/2013/617/fr>

**Additional reading :**

Convention pour la protection des Droits de l'Homme et de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine (Convention sur les droits de l'homme et la biomédecine, conclue à Oviedo le 4 avril 1997) : <https://www.fedlex.admin.ch/eli/cc/2008/718/fr>

Supplément national suisse de la formation en éthique de la recherche impliquant des êtres humains TRREE > National supplements > Switzerland : <http://elearning.trree.org/>

Association médicale mondiale, Déclaration d'Helsinki, version 2013 : <https://www.wma.net/fr/policies-post/declaration-dhelsinki-de-lamm-principes-ethiques-applicables-a-la-recherche-medicale-impliquant-des-etres-humains/>

Message sur la loi fédérale relative à la recherche sur l'être humain, FF 2009 7529 : <https://www.fedlex.admin.ch/eli/fqa/2009/1423/fr>

MANAÏ D., Droits du patient et biomédecine, Berne, 2013, pp. 487ss.

TALANOVA. V. SPRECHER. F. Le consentement général : points à améliorer. Bulletin des médecins suisses. Bull Med Suisses. 2020;101(38):1197-1200 : <https://bullmed.ch/article/doi/bms.2020.19143>

ERARD. F. HEUSGHEM. M. PARISATO C. Recherche Biomédicale Et Open Data, In : Jusletter 30 Janvier 2023. : [https://jusletter.weblaw.ch/fr/juslissues/2023/1140/recherche-biomedical\\_4b9e008242.html](https://jusletter.weblaw.ch/fr/juslissues/2023/1140/recherche-biomedical_4b9e008242.html)

SPRUMONT D., Double évaluation des projets de recherche en partenariat nord-sud, in : BMS 2008, N°12-13, p. 510.

SPRUMONT D., JOYE C., PILOTTIN A., Biobanques: il est urgent d'investir dans une loi fédérale, in : Bulletin des médecins suisses, numéro 2016/48, pp. 1693-1695.

ELGER B., Les biobanques, in: Droit de la santé et médecine légale, Chêne-Bourg, 2014, pp. 395-405.

<b>5</b>	<b>07.10.25</b>	<b>Who's body is it anyway ? (Body, body parts and biological material)</b>
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**Slides on Moodle****Required reading :**

Constitution fédérale de la Confédération suisse du 18 avril 1999, RS 101, articles 119 et 119a Cst : <https://www.fedlex.admin.ch/eli/cc/1999/404/fr>

Code civil suisse du 10 décembre 1907, (CC), RS 210, articles 11 à 19d, 27 et 28ss, 641ss CC (extraits) :

[https://www.fedlex.admin.ch/eli/cc/24/233\\_245\\_233/fr](https://www.fedlex.admin.ch/eli/cc/24/233_245_233/fr)

**Additional reading :**

STEINAUER P.-H, FOUNTOULAKIS C., Droit des personnes physiques et de la protection de l'adulte, Berne, 2014, pp. 167-178 (extraits).

STEINAUER P.-H., Les droits réels, Tome I, 5e édition, Berne, 2012, pp. 44-69 (extraits).

DUCOR P., Statut juridique des parties détachées du corps humain : une approche anatomique et fonctionnelle, in : Revue de droit suisse, 2016, no. 1, pp. 251-348.

CORPATAUX V., L'utilisation du sang à des fins thérapeutiques : étude de droit suisse dans une perspective européenne, Bâle, 2012.

**6 14.10.25 Genetics, Genomics and Law**

**Slides on Moodle**

**TBD**

**7 28.10.25 Intellectual Property Law**

**Slides on Moodle**

**Required reading :**

Loi fédérale du 25 juin 1954 sur les brevets d'invention (Loi sur les brevets, LBI), RS 232.14 :

[https://www.fedlex.admin.ch/eli/cc/1955/871\\_893\\_899/fr](https://www.fedlex.admin.ch/eli/cc/1955/871_893_899/fr)

Ordonnance du 19 octobre 1977 relative aux brevets d'invention (Ordonnance sur les brevets, OBI), RS 232.141 :

[https://www.fedlex.admin.ch/eli/cc/1977/2027\\_2027\\_2027/fr](https://www.fedlex.admin.ch/eli/cc/1977/2027_2027_2027/fr)

**Additional reading:**

Convention sur le brevet européen, révisée à Munich le 29 novembre 2000 (CBE 2000), RS 0.232.142.2 :

Traité de coopération en matière de brevets du 19 juin 1970 (PCT), RS 0.232.141.1 : [https://www.fedlex.admin.ch/eli/cc/1978/900\\_900\\_900/fr](https://www.fedlex.admin.ch/eli/cc/1978/900_900_900/fr)

INSTITUT FÉDÉRAL DE LA PROPRIÉTÉ INTELLECTUELLE, Imaginer. Réaliser. Protéger. Marques, brevets, designs et droit d'auteur : le tour de la question, Berne, 2020

OMPI, Comprendre la propriété industrielle :

[https://www.wipo.int/edocs/pubdocs/fr/wipo\\_pub\\_895\\_2016.pdf](https://www.wipo.int/edocs/pubdocs/fr/wipo_pub_895_2016.pdf)

OMPI, Cours général sur la propriété intellectuelle (DL-101) :

[https://welc.wipo.int/acc/index.jsf?page=courseCatalog.xhtml&lang=fr&c=DL101F#plus\\_DL101F](https://welc.wipo.int/acc/index.jsf?page=courseCatalog.xhtml&lang=fr&c=DL101F#plus_DL101F)

TISSOT N., KRAUS D., SALVADÉ V., Propriété intellectuelle- Marques, brevets, droit d'auteur. 2019. Précis de droit. Stämpfli Editions.

DUCOR Ph., Vivant et propriété intellectuelle, in : Droit de la santé et médecine légale, Chêne-Bourg, 2014, pp. 177-183.

## 8 04.11.25 Introduction to European right of biotechnologies : medical devices

### Slides on Moodle

#### Required reading :

Loi fédérale sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPT), RS 812.21  
<https://www.admin.ch/opc/fr/classified-compilation/20002716/index.html>

Ordonnance sur les dispositifs médicaux, RS 812.213  
<https://www.fedlex.admin.ch/eli/cc/2020/552/fr>

Ordonnance sur les dispositifs médicaux in vitro, RS 812.219  
<https://www.fedlex.admin.ch/eli/cc/2022/291/fr>

Ordonnance sur les essais cliniques de dispositifs médicaux, RS 810.306  
<https://www.fedlex.admin.ch/eli/cc/2020/553/fr>

#### Additional reading :

##### Switzerland

Swissmedic, vidéo introductive sur la réglementation du dispositif médical

<https://www.swissmedic.ch/swissmedic/fr/home/notreprofil/publications/video/mep-video.html>

Swissmedic, réglementation des dispositifs médicaux

<https://www.swissmedic.ch/swissmedic/fr/home/dispositifsmedicaux/reglementation-des-dispositifs-medicaux.html>

OFSP, Législation sur les dispositifs médicaux, état au 3 avril 2023

<https://www.bag.admin.ch/bag/fr/home/medizin-und-forschung/heilmittel/revisionmed-prod-verord-mepv.html>

Swiss Medtech, Code SWISS MEDTECH de pratiques commerciales éthiques, 12 juin 2017, en vigueur jusqu'au 31 décembre 2023

<https://www.swiss-medtech.ch/fr/documents#ethik-kodex>

Swiss Medtech, Code SWISS MEDTECH de pratiques commerciales éthiques, 25 mai 2023, en vigueur à compter du 1er janvier 2024

##### European Union

Commission Européenne, vue d'ensemble sur les dispositifs médicaux

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Règlement 2017/745 du 5 avril 2017 relatif aux dispositifs médicaux, modifiant la directive 2001/83/CE, le règlement (CE) no 178/2002 et le règlement (CE) n o 1223/2009 et abrogeant les directives du Conseil 90/385/CEE et 93/42/CEE Page 2 de 2 (version consolidée à jour au 20 mars 2023) <https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:02017R0745-20230320>

Règlement 2017/746 du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic in vitro et abrogeant la directive 98/79 et la décision 2010/227/UE de la Commission (version consolidée à jour au 20 mars 2023) <https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:02017R0746-20230320>

Directive 93/42 du 14 juin 1993 relative aux dispositifs médicaux (ancien droit dont certaines parties demeurent applicables de façon transitoire)

Directive 98/79 du 27 octobre 1998 relative aux dispositifs médicaux de diagnostic in vitro (ancien droit dont certaines parties demeurent applicables de façon transitoire)

Medtech Europe Code of Business Practice, mars 2022

<https://www.medtecheurope.org/wp-content/uploads/2017/06/medtech-europecode-of-ethical-business-practice-2022.pdf>

CAMD (Competent Authorities for Medical Devices) [Autorités compétentes pour les dispositifs médicaux] <https://www.camd-europe.eu/>

AFNOR, les dispositifs médicaux <https://www.afnor.org/dispositifs-medicaux/faq/>

### **Medical devices and large language models**

<https://sites.research.google/med-palm/>

<https://openai.com/blog/chatgpt>

Minssen et al., The Challenges for Regulating Medical Use of ChatGPT and Other Large Language Models, JAMA, Vol. 330, Number 4, 25 July 2023, p. 315

Duffourc et al., Generative AI in Health Care and Liability Risks for Physicians and Safety Concerns for Patients, JAMA, Vol. 330, Number 4, 25 July 2023, p. 313

Kulkarni et al, Artificial Intelligence in Clinical Diagnosis - Opportunities, Challenges and Hype, JAMA, Vol. 330, Number 4, 25 July 2023, p. 317

Singhal et al., Large Language Models Encode Clinical Knowledge, Nature, Vol. 620, 3 August 2023, p. 172

## **9 11.11.25 Human Enhancement**

### **Slides on Moodle**

### **Required Reading**

GIUBILINI, Alberto, SANYAL, Sagar, et al. Challenging human enhancement (chapter 1). In Clarke, Steve, and others (eds) The ethics of human enhancement: Understanding the debate, 2016, vol. 1.

### **Additional Reading**

THOMPSON, Paul B. The opposite of human enhancement: Nanotechnology and the blind chicken problem. Nanoethics, 2008, vol. 2, no 3, p. 305-316.

HENRY, Michael, FISHMAN, Jennifer R., et YOUNGNER, Stuart J. Propranolol and the prevention of post-traumatic stress disorder: Is it wrong to erase the “sting” of bad memories?. The American Journal of Bioethics, 2007, vol. 7, no 9, p. 12-20.

**10 18.11.25 Ethical issues in animal experimentation****Slides on Moodle****Required Reading :**

Swiss academies of arts and science, Weighing of interests for proposed animal experiments. Guidance for applicants (2022), <https://www.samw.ch/en/Projects/Overview-of-projects/Animal-experimentation.html>

**Additional Reading :**

LAFOLLETTE, HUGH, 'Animal Experimentation in Biomedical Research', in Tom L. Beauchamp, and R. G. Frey (eds), *The Oxford Handbook of Animal Ethics*, Oxford Handbooks (2011; online edn, Oxford Academic, 1 May 2012), <https://doi.org/10.1093/oxfordhb/9780195371963.013.0030>.

DEGRAZIA D, BEAUCHAMP TL. Beyond the 3 Rs to a More Comprehensive Framework of Principles for Animal Research Ethics. *ILAR J.* 2021 Sep 24;60(3):308-317. doi: 10.1093/ilar/ilz011.

**11 25.11.25 The status and protection of animals****Slides on Moodle****Required Reading :**

Animal Welfare Act (AniWA): <https://www.fedlex.admin.ch/eli/cc/2008/414/en>

Ordonnance du 23 avril 2008 sur la protection des animaux (OPAn), RS 455.1, Chapitres 6 et 9 ainsi que l'annexe 3 : <https://www.fedlex.admin.ch/eli/cc/2008/416/fr>

**Additional Reading :**

Ethical guidelines for animal experiments (2025): <https://www.samw.ch/en/Projects/Overview-of-projects/Animal-experimentation.html>

HEHEMANN L., The Protection of the Dignity of Laboratory Animals in Switzerland: Different Procedures? Different Standards? *Global Journal of Animal Law*. Volume 6, N°1. 2018.

BOLLIGER G., Animal dignity protection in Swiss law: Status quo and future perspectives (*Schriften zum Tier im Recht* volume 15, Schulthess 2016).

BOLLIGER G., Legal Protection of Animal Dignity in Switzerland: Status Quo and Future Perspectives' (2016) *Journal of Animal Law*, Vol 22.p 311.

**12 02.12.25 Personalized Medicine****Slides on Moodle****Required Reading :**

ÁRNASON, Vilhjálmur. The personal is political: Ethics and personalized medicine. *Ethical Perspectives*, 2012, vol. 19, no 1, p. 103-122.

**Additional Reading:**

SANTALÓ, Josep et BERDASCO, Maria. Ethical implications of epigenetics in the era of personalized medicine. *Clinical epigenetics*, 2022, vol. 14, no 1, p. 44.

**13 09.12.25 Scientific fraud and integrity in research****Slides on Moodle****Required Reading**

EPFL LEX 3.3.2, "Directive concerning research integrity and good scientific practice at EPFL": [https://www.epfl.ch/about/overview/wp-content/uploads/2019/09/3.3.2\\_principe\\_integrite\\_recherche\\_an.pdf](https://www.epfl.ch/about/overview/wp-content/uploads/2019/09/3.3.2_principe_integrite_recherche_an.pdf)

Swiss Academies of Arts and Sciences; "Code of conduct for scientific integrity": [https://api.swiss-academies.ch/site/assets/files/25607/kodex\\_layout\\_en\\_web-1.pdf](https://api.swiss-academies.ch/site/assets/files/25607/kodex_layout_en_web-1.pdf)

Short comics (Pdf will be provided on moodle).

**Additional Reading:**

Serious games about integrity in research:

<https://integgame.eu/>

<https://ori.hhs.gov/TheLab/>

**14 16.12.25 Presentation of the oral exam modalities and questions  
Feedback on group work****Slides on Moodle**