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| **Title of module** | **IX Scientific Responsibility in Biomedicine** |
| **Module coordinator** | **Dr. Esther Braun** |

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| **Credit points** | 8 | **Semester(s) in which the module is taught** | 3 |
| **Contact hours** | 4 | **Workload** | 150 hours |

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| **Lecturer(s)** | Bioethics: Braun<br>Legal requirements: Zähres 3CP<br>Laboratory Animals Science: Schmidt 5CP |
| **Type of teaching** | Lecture (2 hours per week)<br>Laboratory Course (10 day compact course)<br><br>Introductory lectures with presentation of papers by the participants and discussion<br>Case Studies concerning legal aspects (solutions for complex issues, e.g. Genetically modified organism (GMO) - risk assessment)<br>10-day full day course consisting of practical exercises with hands-on experience with laboratory animals. |
| **Relation to curriculum** | compulsory |
| **Recommended prerequisites** | Module VIII “Stem Cell Lecture Series” is recommended |
| **Aims** | The module “Scientific Responsibility in Biomedicine” gives a general survey of legal aspects and the role of professional Biomedical Scientists. Students will be introduced to practical work with laboratory animals. Students are expected to have developed a sense of responsibility for their practical work at the end of this module. |
| **Learning outcome** | Knowledge:<br>Students<br>a) acquire knowledge about the contributions of different moral theories to current controversies in biomedical ethics<br>b) understand the peculiarities of normative questions and moral problems,<br>c) recognize moral problems in different areas of applied ethics,<br>d) recognize the German Stammzellgesetz (StZG) and the German Embryonenschutzgesetz (ESG)<br>e) are able to differentiate biosafety levels (1-4) in laboratories where GMOs are handled and assembled; including technical safety precautions on every level, based on the GenTG.<br>f) are familiar with origins and safety regulations related to infectious diseases transmitted by microorganisms such as bacteria, viruses, fungi, BSE, and artificial biological units based on BioStoffV and TRBA<br>g) know the general rules of the animal facility, where procedures are carried out<br>h) know the theoretical background of tasks an investigator is expected to do, so as to safeguard animal well-being and ensure the relevance of scientific advance<br>i) know the basic biology of relevant laboratory animal species<br>j) know the physiology and behaviour of laboratory animals<br>k) are familiar with European and national laws and guidelines relating to the conduct of experimental or other scientific procedures on animals especially the the FELASA guidelines (category B) for the education of persons carrying out animal experiments.<br><br>Skills:<br>Students have acquired the<br>a) ability to identify the strengths and weaknesses of different theories |

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| | b) ability to explain and observe limits of StZG and ESG<br>c) ability to explain biological safety precautions and impact on the environment<br>d) ability to reflect on the moral problems concerning the own research activity<br>e) ability to discuss these problems with others<br>f) ability to describe and explain duties of responsible persons working in a genetic engineering laboratory (e.g. Biosafety Officer, project manager) and describe the assignment of duties to the relevant staff<br>g) ability to analyse and identify different biosafety relevant organisms with regard to the biosafety level.<br><br>Students have also strengthen their argumentation and presentation skills in an interdisciplinary context and the abiltity to read and understand texts of other disciplines, the aquirement about the sources of information on bioethics.<br><br>Competencies:<br>Students have gained the<br>a) capability of putting relevant problems into a scientific as well as legal and ethical context<br>b) capability to deal with stem cell technology in a responsible way<br>c) competence in handling and other techniques investigators are expected to carry out administration of substances, sampling techniques, euthanasia and anaesthesia, analgesia<br>d) competence to plan licensing procedures for biosafety laboratories and genetic engineering<br>e) competence to plan experiments with regard to the biosafety levels and rules, based on GenTG and genetic engineering safety regulation (GenTSV)<br>f) competence to observe and comply with regulations of the BioStoffV and to apply it in a given context<br>g) ability to recognize pain and discomfort, and to assess the welfare status of animals with which the investigator is working<br>h) capability of taking appropriate action when adverse outcomes occur during or following procedures. |
| **Contents of module** | Bioethics:<br>Introduction to ethics and bioethics<br>The moral status of human embryos and fetuses<br>Ethical problems of reproductive medicine<br>Stem cell research and therapeutic cloning<br>Questions of justice and responsibility concerning patents and the protection of intellectual property<br>The ethics of clinical trials<br>Moral problems of clinical trials involving stem cells<br><br>Legal aspects:<br>Security relevant, important parts of GenTG, GenTSV, BioStoffV with regard to the impact on environment and staff.<br>Biosaftey levels of laboratories, technical facilities and working equipment. Licensing procedures according to GenTG.<br>Important parts of StZG with regard to experiments with stemcells. Limitations of these experiments based on StZG.<br><br>Laboratory animal sciences:<br>Lecture<br>1: Legal requirements for animal studies<br>2: Breeding and genetics of laboratory rodents<br>3: Humane methods to sacrifice laboratory animals<br>4: Methods of applications in laboratory animals<br>5: Anaesthesia in laboratory animals |

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| | 6: Surgical procedures in laboratory animals<br>7: Methods of sampling in laboratory animals<br>8: Planning and design of animal studies including statistical analysis<br>9: Feeding of laboratory animals<br>10: Abiotic and biotic standardization in animal husbandry<br><br>Practical part:<br>Basic biology and husbandry of relevant laboratory animal species<br>Physiology, behavior and welfare of laboratory animals<br>Handling, administration of substances, sampling techniques, euthanasia<br>Anesthesia, analgesia and basic principles of surgery<br>Legislation, ethics and the 3R-concept<br>Biometric methods and discussion of experimental design and proposal |
| **Study and examination requirements; Forms of examination** | Students active participation in discussions and interactions in the context of the lecture with lecturers and fellow students and individual oral presentations during the lecture are required;<br><br>The mode of examination of the animal handling course is a one -hour written examination consitsing of 24 multiple choice questions directly after completion of the laboratory course, on which the module mark is based. |
| **Literature** | Bioethics: Tom L. Beauchamp, James F. Childress, Principles of Biomedical Ethics, 6th edition, New York: Oxford University Press, 2008.<br>Cynthia B. Cohen, Renewing the Stuff of Life. Stem Cells, Ethics, and Public Policy, New York: Oxford University Press, 2007.<br>Dena S. Davis, Genetic Dilemmas: Reproductive Technology, Parental Choices, and Children's Futures, 2nd edition, New York: Oxford University Press, 2010.<br>Ezekiel Emmanuel et al. (eds.), The Oxford Textbook of Clinical Research Ethics, New York: Oxford University Press, 2008.<br>Louis M. Guenin, The Morality of Embryo Use, New York: Cambridge University Press, 2008.<br>Jonathan Kimmelman, Gene Transfer and the Ethics of First-in-Human-Research. Lost in Translation, New York: Cambridge University Press, 2010.<br>Michael Kremer, Rachel Glennerster, Strong Medicine. Ceating Incentives for Pharmaceutical Research on Neglected Diseases, Princeton: Princeton University Press, 2004.<br>Paul Lauritzen (ed.), Cloning and the Future of Human Embryo Research, New York: Oxford University Press, 2001.<br>Adrianna Petryna, When Experiments Travel. Clinical Trial and the Global Search for Human Subjects, Princeton: Princeton University Press, 2009.<br>Joseph Stiglitz, Making Globalization Work. The Next Steps to Global Justice, New York: Allen Lane, 2006.<br>Legal aspects:<br>Stammzell-Gesetz (StZG); Gentechnik Gesetz (GenTG); GenTSV; Gentechnik-Aufzeichungsverordnung (GenTAufZV); Gentechnik-Notfallverordnung (GenTNotfV); Biostoffverordnung (BioStoffV), Gute Herstellungspraxis (GMP)<br>https://www.osha.gov/sites/default/files/publications/OSHAfactsheet-laboratory-safety-biosafety-cabinets.pdf<br><br>Laboratory animal sciences:<br>Review Article: A L Whittaker, G S Howarth and D L Hickman<br>Effects of space allocation and housing density on measures of wellbeing in laboratory mice: a review Lab Anim November 2011 la.2011.011049; published ahead of print 23 November 2011, doi:10.1258/la.2011.011049<br>https://www.osha.gov/sites/default/files/publications/OSHAquickfacts-lab-safety-working-with-small-animals.pdf |