Swiss National Advisory Commission on Biomedical Ethics NCE

Report on the Activities 2015

for the Attention of the Federal Council, Parliament and the General Public

Adopted by the Commission in May 2016
# Contents

**Report on the Activities 2015 of the NCE**  
for the Attention of the Federal Council,  
Parliament and the General Public

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Among the highlights of the year under review was the third Trinational Meeting of German-Speaking Ethics Commissions (Germany, Austria and Switzerland/DACH). Following the previous years’ meetings in Vienna (2013) and Berlin (2014), the NCE invited the German Ethics Council and the Austrian Bioethics Commission to Bern for the event in 2015. At the suggestion of the Swiss Commission, the meeting held on the 16th and 17th of April was devoted to the topic of the Culture of Death and Dying – a perennial subject of intense debate both in Germany and Austria as well as in Switzerland. The aim of the Bern conference was to discuss fundamental questions of life and death freed from the frequently narrow confines of medical, ethical and legal discourse, and to explore the indispensable perspectives of the public and society at large. This was deliberately conceived as a counterpoint to the issue of assisted suicide, which has already been widely discussed.

The event, attended by around 60 participants, began on the 16th of April with a tour of the Parliament Building and an incisive address given by former Federal Councillor Moritz Leuenberger. The following morning, discussions were held at the Bank Council Room of the Swiss National Bank without public attendance; in the afternoon, the topic of “the Culture of Death and Dying” was further discussed in the Swiss Parliament Building with members of the parliamentary Science, Education and Culture Committees (SECC) and Social Security and Health Committees (SSHC). Presentations were given by the chairs of the three ethics committees, with brief contributions from the invited parliamentarians Felix Gutzwiller, Maya Ingold and Guy Parmelin. Also in attendance were delegations from the Central Ethics Committee (CEC) of the Swiss Academy of Medical Sciences (SAMS) and the Federal Ethics Committee on Non-Human Biotechnology (ECNH). This event was skilfully organised by the Commission’s Executive Secretary, and the feedback received from all the participants was highly favourable.

Another highlight was the Commission’s annual two-day regional meeting, held in Sion, which was also devoted to the Culture of Death and Dying. Thanks to the preparations on site made by Professor François-Xavier Putallaz, member of the Commission, and the keynote presentation by Professor Paolo Merlani, member of the Commission, the public panel discussion attracted enormous interest.

In December, after two years of intensive efforts, the Commission unanimously adopted the report
on Biobanks for Research. Biobanks are a new, but increasingly important institution within the healthcare systems. Over the past few years, numerous biobanks (some public, some private) have been established around the world and also in Switzerland. These collections of biological materials linked to donors’ personal data make it possible for medical, pharmacological and biological research to identify associations between the genome and serious conditions such as cancer, Alzheimer’s disease or diabetes. However, these opportunities are accompanied by risks – in particular, risks to privacy and, not least, risks of discrimination. With its Opinion, the Commission aims to raise awareness of the issue of biobanks for research in the Federal Council and Parliament, and especially among the public, to stimulate debate, and to offer recommendations for improvements in the social, political and legal spheres.

This foreword to the 2015 report provides an opportunity for me to look back briefly over my six-and-a-half years as Chair of the Commission. The Opinion on biobanks is the eighth to be issued during my chairmanship. Among the other topics addressed were advance directives, presumed consent to organ donation, “intersexuality” and medically assisted reproduction. In addition, Opinions on the culture of death and dying and on non-invasive prenatal testing (NIPT) are currently being prepared. During my tenure, the Commission’s international activities have been strengthened and expanded. In addition to our participation at international events and in global forums such as the International Bioethics Committee, the Global Summit of National Ethics/Bioethics Committees, the Forum of National Ethics Councils and the European Commission’s International Dialogue on Bioethics, contacts have been established with the relevant European institutions, the above-mentioned trinational DACH meetings were launched, and there have been initial contacts with a view to organising similar meetings with our French- and Italian-speaking counterparts.

In connection with the re-elections scheduled for all extra-parliamentary commissions, my term as Chair came to an end in December of the year under review. I would like to thank all the members of the Commission, the head of the Secretariat and her scientific collaborator for their professionalism and dedication – and for always making it so enjoyable to work together as colleagues.

Tübingen, April 2016
Otfried Höffe, Chair
The Swiss National Advisory Commission on Biomedical Ethics is an extra-parliamentary body, which was established by the Federal Council on the 3rd of July 2001.

In carrying out its tasks, and especially in formulating its Opinion, the Commission is obliged to remain independent of political, industrial and scientific interests.

The legal basis for the Commission is provided by:
- Article 28 of the Reproductive Medicine Act of the 18th of December 1998 (see below) and
- The Regulation on the National Advisory Commission on Biomedical Ethics of the 4th of December 2000 (SR 810.113).
- In addition, the Commission’s deliberations are governed by the NCE Rules of Procedure of the 29th of October 2009.

The Commission’s mandate is to conduct careful and comprehensive assessments of ethical issues arising in the areas of medicine and healthcare, focusing in particular on new scientific knowledge and technological developments. Thus, the Commission contributes to an opinion-forming process at all levels of society, which is guided by evidence-based arguments.

The emphasis is placed on the preparation of Opinions and on discussions with the public. The NCE does not, however, review individual research projects; this remains the responsibility of Switzerland’s cantonal ethics committees.

**Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA)**

of 18 December 1998 (status as of 1 January 2013)

**Chapter 3: National Ethics Commission**

Art. 28

1. The Federal Council shall establish a national ethics commission.

2. The commission shall monitor developments in assisted reproductive techniques and gene technology in the area of human medicine and comment from an ethical perspective, in an advisory capacity, on associated social, scientific and legal issues.

3. In particular, the commission shall have the following tasks:
   - to draw up additional guidelines relating to this Act;
   - to identify gaps in the legislation;
   - to advise the Federal Assembly, the Federal Council and the cantons on request;
   - to inform the public about important findings and to promote debate on ethical matters within society.

4. The Federal Council shall determine the other tasks to be carried out by the commission in the area of human medicine. It shall enact implementing provisions.
2. Opinions

2.1 Overview of Opinions Prepared by the Commission in the Period Under Review

In 2015, the Commission addressed the following topics:

Opinion no. 24/2015
**Biobanks for Research** (adopted on the 10th of December 2015; published on the 2nd of May 2016)

Unpublished response of the 13th of January 2015 to an enquiry, dated the 18th of September 2014, from the Health and Accident Insurance Directorate of the Federal Office of Public Health (FOPH) on “Non-Invasive Prenatal Testing (NIPT)”.

Unpublished response of the 29th of April 2015 to an enquiry, dated the 24th of March 2015, from the Federal Office for Civil Protection (FOCP) on “Tour d’Horizon Biosecurity: Proposal on the Management of Dual-Use Research”.


2.2 Summary of NCE Opinions

Opinion no. 24/2015:
**Biobanks for Research**

Biobanks have to reconcile a wide variety of individual and public interests – the interests of biomedical research, patients and healthcare professionals, donors, the biotech and pharmaceutical sector, and, more generally, Switzerland’s position as a research centre and its healthcare system. At the same time, biobanks affect the rights and interests of individuals whose samples and data are held; of particular relevance are the donors’ right to self-determination and the right to know (or not to know) in relation to genetic predispositions to disease as well as issues of data protection and data security. The public’s trust, therefore, presents a key “resource” for biobanks, which means that effective safeguards are required to prevent any abuse. Trust can be promoted by providing appropriate information about the activities of biobanks; transparency needs to be ensured regarding the motives of the individuals or organisations concerned, and the framework within which biobanks operate. Transparency is also a fundamental requirement for public debate so as to warrant the democratic legitimacy, which is indispensable given the significance of biobanks for society as a whole. Having analysed the benefits and risks from a medical and ethical perspective, the Commission concludes that current research regulations in Switzerland are not equipped to the particular institutional features of biobanks. The Commission also examined instruments for ensuring that the benefits of biobanks serve the public interest as far as possible.
Non-Invasive Prenatal Testing – Enquiry from the Health and Accident Insurance Directorate of the FOPH

The Commission was asked by the FOPH, at the request of the Federal Commission on Health Insurance Benefits and Policy Issues (ELGK/CFPP) – via the Health and Accident Insurance Directorate – to examine four questions of an ethical nature concerning reimbursement of the costs of non-invasive prenatal testing (NIPT) under basic health insurance. Following a clarification of the issues, in which NIPT is considered both as a first-line measure (before or instead of the first-trimester test) and as a second-line screening measure (after the first-trimester test), the Commission provided a nuanced response to the questions raised. Various norms and values appear to be relevant to the discussion of NIPT, such as the protection of autonomy and personal integrity, the protection of the unborn child, non-discrimination, respect for privacy, the prevention of suffering, and solidarity. The Commission then expressed its views as to whether coverage of NIPT under health insurance could contribute to changing perceptions of persons with disabilities, and whether restriction of reimbursement to pregnant women at high risk would not be contrary to the principle of equal treatment or access to healthcare services.

The Commission also emphasized that other issues should be considered with regard to coverage under mandatory health insurance – in particular, fetal sex determination and the ethical risks associated with the possibility of broader genetic analysis (whole-genome sequencing).

Tour d’Horizon Biosecurity: Proposal on the Management of Dual-Use Research – Enquiry from the FOCP

The issue of dual-use research of concern (DURC) relates primarily to the ethical implications of basic and applied research involving microorganisms. While not being the most appropriate partner, the Commission offered a number of reflections, which – going beyond simple awareness-raising among researchers – focus on the limitations of self-regulation by the scientific community, and ethical reflection procedures as well as highlighting the need to develop a DURC policy within the framework of research ethics.

Swiss Influenza Pandemic Plan: Review of the Chapter on Ethical Issues – Enquiry from the Crisis Management and International Cooperation Section of the FOPH

The Commission, which had written Chapter 6 (“Ethical issues”) of the Swiss Influenza Pandemic Plan previously, was requested by the FOPH to make various amendments in connection with the fourth revision of the Plan. Greater emphasis is now placed on individual responsibility (in particular for healthcare professionals with regard to preventive measures) and on solidarity as fundamental attitudes in combating/fighting pandemics.
3. Communication with the Public

In the period under review, the following public events were held by the Commission:

The trinational meeting of the German-Speaking Ethics Commissions (Germany, Austria and Switzerland/DACH) was held in Bern in April 2015 (see below, Section 4).

In conjunction to its annual Two-Day Regional Meeting – held in Sion (Canton Valais) on 22nd/23rd of October 2015 – the Commission once again organised an evening event for the public, including a panel discussion. As in the previous year (in Appenzell Innerrhoden), this event was devoted to the Culture of Death and Dying. It again attracted considerable public attention, and the large audience took a keen interest in the discussions. The event was opened by Hildebrand de Riedmatten (Acting Chair of the Board of Directors of Valais Hospital / HVS), Dr Damian König (Head of Legal and Ethical Affairs and Acting Chair of the Clinical Ethics Committee, HVS) and Dr Sandro Anchisi (Head of the Department of Internal Medicine and Geriatrics, CHVR-HVS, and Head of the Oncology Unit/Department). A brief introduction to the topic was then given by Professor Otfried Höffe, Chair of the Commission. Professor Paolo Merlani (NCE Member and Head of the Department of Intensive Care Medicine, EOC, and Head of Intensive Care, Regional Hospital of Lugano and Mendrisio “Beata Vergine”) spoke on the subject of “Extending Life Versus Quality of Life in Intensive Care”; Geneviève Délèze (Head of Nursing, Maison de Retraite Le Carillon) spoke on “End of Life in a Medicalised Setting (hospital and social/medical care)”. The perspectives of these two experts dealing on a daily basis with questions concerning quality of life, duration of treatment, contacts with family members, hope and sadness, facilitated reflection on different views concerning the end of life and on underlying social trends. For the subsequent panel discussion, the two speakers were joined by Dr Stéphane Biselx (geriatrician, Sierre Hospital) and Professor Pia Coppex-Gasche (HES La Source, President of the Swiss Society of Biomedical Ethics). The discussion was chaired by Dr Bertrand Kiefer, member of the Commission.

In addition, the Commission, its Chair and members had media presence in various contexts and roles throughout 2015. Particular mention merit contributions and interviews on the topics of the culture of death and dying, assisted suicide, biobanks, intersexuality, reproductive medicine and cost-effectiveness in healthcare.
At the national level, the Commission – in cooperation with the Central Ethics Committee (CEC) of the Swiss Academy of Medical Sciences (SAMS) – launched a new series of public symposiums (2015 to 2018) on the subject of autonomy in medicine. The first symposium, entitled “Autonomy and Responsibility: the Tensions Between Individual Autonomy and Social Solidarity”, was held at the Inselspital in Bern on the 2nd of July 2015. This event focused on the concepts and fundamental ideas underlying the notion of “autonomy”. The opening presentations covered practical examples in the areas of mountain and air rescue, assisted suicide and alcohol poisoning. These were followed by talks on the anthropological underpinnings of contemporary bioethics (by Commission member Professor Frank Mathwig) and on the challenges to biomedical ethics posed by social morality (by Walter Lesch, Professor of Ethics at UCL). In the afternoon session, Ulrich Steinvorth, Professor Emeritus of Philosophy at Hamburg University, spoke on the compatibility of individual autonomy and social solidarity, and Alena Buyx, Professor of Medical Ethics at CAU Kiel, spoke on solidarity as a regulatory concept in biomedical practice and research.

As Chair of the Commission, Professor Otfried Höffe spoke on “How does a philosopher plan the end of life?” at a Careum Continuing Education / Bern University of Applied Sciences event in Aarau (on the 10th of March); on “Is it permissible for physicians to assist suicide, and should they do so?” at the University of Tübingen Theologicum (on the 29th of April); on biobanks at the Swiss Union of Laboratory Medicine (SULM) Conference in Bern (on the 25th of June); and on “Openness, diversity, tolerance – fundamental values for a welfare association” at the “Paritätische” association in Kassel (on the 23rd of September).

Professor Brigitte Tag represented the Commission at the parliamentary hearing of the Green Liberal Party on oocyte donation (on the 16th of June). At the 11th Women’s Health Congress, held at the Inselspital, Bern University Hospital (on the 15th of January), Professor Tag spoke on “Modern Reproductive Medicine: the Future of the Family from a Legal Perspective”. She gave a lecture entitled “End of Life: Thoughts on Dying in Dignity” at the Predigerkirche in Basel (on the 2nd of March). At the Japanese-Swiss Aging Workshop in Tokyo (on the 18th–20th of March), she presented the Swiss perspective on end-of-life decisions. At the Palliative ZH+SH conference in Zurich (on the 25th of June), she spoke on advanced directives and the new adult protection law. At the ETH Emeritus Professors Group in Winterthur (on the 29th of June), she gave a presentation on the medical, ethical and legal aspects of preimplantation genetic diagnosis.

Commission member Professor Bernhard Rütsche gave a presentation on “Ethics Committees under the New Legislation in Switzerland” at a colloquium on “Ethics Committees in Medical Research” held by the University of Lucerne, Faculty of Theology/Institute of Social Ethics (on the 30th/31st of October). At a conference at the University of Lucerne on “Autonomy and Third-Party Intervention in End-of-Life Decision-Making” (on the 24th of September), Professor Rütsche discussed the results of an empirical study on end-of-life decisions. At a Zurich University Hospital symposium entitled “Highly effective HCV drugs – does a Limitatio make sense? Ethics versus costs” (3 September), he spoke on “The meaning of restrictions from a legal perspective”.

The Commission had regular exchanges with the Federal Ethics Committee on Non-Human Biotechnology (ECNH), the Expert Commission for Human Genetic Testing (GUMEK), and the Centre for Technology Assessment (TA-SWISS), in whose Steering Committee the Commission’s Executive Secretary, Dr Elisabeth Ehrensperger, has the status of a guest without voting rights. The Commission was also one of the bodies supporting the TA-SWISS study on prenatal genetic diagnosis and participated in the supervisory group. In August, the Executive Secretary attended the annual meeting of the extra-parliamentary social policy commissions. Here, the main topic was the evaluation of the Swiss Centre of Expertise in Human Rights (SCHR) and the proposed creation of an independent national human rights institution. The Executive Secretary represented the Commission at an information event held by the SCHR at Bern Town Hall (on the 9th of November). She also represented the Commission at the “National Palliative Care Days 2015” in Bern (2nd/3rd of December), and at a Swiss National Science
Foundation/Science & Policy Scholarship Foundation event held at Parliament Building (on the 26th of November), entitled “How scientific is Swiss policymaking?”, which examined the importance of scientific findings for political decision-making and the role of scientific experts in the provision of policy advice.

Trinational Meeting of German-Speaking Ethics Commissions in Bern

Since 2013, the national ethics commissions of the German-speaking countries (Germany, Austria, Switzerland/DACH) have met each year, taking turns to host the event. In March 2013 in Vienna, the topics of transplantation medicine and genetic diagnosis were discussed. In March 2014 in Berlin, discussions focused on questions relating to the welfare of the child in a medical context, arguments for and against compulsory vaccination, and the opportunities and risks of personalised medicine in view of increased data collection and networking. For 2015, the Commission had invited the German Ethics Council and the Austrian Bioethics Commission to Bern. The meeting, held on the 16th/17th of April, was devoted to the topic of the culture of death and dying. The emphasis was placed on discussing contemporary conceptions of a good death from a philosophical and sociological perspective – as a counterpoint to the issue of assisted suicide, which has already been widely discussed.

On the morning of the 17th of April, discussions were held without public attendance at the Bank Council Room of the Swiss National Bank, with papers given by Professor Carl Friedrich Gethmann ("agency, autonomy, suicide") and Dr Michael Wunder ("autonomy at the end of life and the culture of dying") of the German Ethics Council; by Professor Markus Zimmermann ("contemporary culture(s) of dying – perception, shaping and interpretation of the end of life from the perspective of social ethics") of the NCE; and by Professor Andreas Valentin ("dying in dignity, recommendations for medical end-of-life measures and related questions") of the Austrian Bioethics Commission.

In the afternoon, the topic of “the culture of death and dying” was further discussed in the Swiss Parliament Building with members of the parliamentary Science, Education and Culture Committees (SECC) and Social Security and Health Committees (SSHC). Presentations were given by the NCE Chair Professor Otfried Höffe (“the culture of living – culture of dying”), the German Ethics Council Chair Professor Christiane Woopen (“the current debate on assisted suicide in Germany – a contribution to the culture of dying?”) and the Austrian Bioethics Commission Chair Professor Christiane Druml (“dying in dignity – the debate in Austria”). Brief contributions were made by parliament members Felix Gutzwiller (Member of the Council of States and of the SECC and SSHC), Maja Ingold (Member of the National Council and of the SSHC), and Guy Parmelin (Member of the National Council and Chair of the SSHC). Also in attendance were delegations from the Central Ethics Committee (CEC) of the Swiss Academy of Medical Sciences (SAMS) and the Federal Ethics Committee on Non-Human Biotechnology (ECNH).

UNESCO

Professor François-Xavier Putallaz, member of the UNESCO International Bioethics Committee (IBC), played an active part in its preparatory activities. Two important reports were finalised at the IBC meeting held in Paris from the 28th of September to the 2nd of October 2015 – the first on the principle of the sharing of benefits, the second on the human genome and human rights. These Opinions, available online, were jointly discussed by the IBC and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST).

United Nations

On the 16th/17th of September 2015, Professor Otfried Höffe was invited to attend the expert meeting on the topic of “ending human rights violations against intersex persons”, held in Geneva by the Office of the United Nations High Commissioner for Human Rights (OHCHR). The Commission’s Opinion no. 20/2012 “On the Management of Differences of Sex Development. Ethical Issues Relating to ‘Intersexuality’” had attracted the attention of various parties – including the Committee Against Torture, the Committee on the Rights of the Child and the Council of Europe – involved in protecting the rights of intersex persons. The Commission was invited to share its experience of developing recommendations in this area.
In the period under review, NCE working groups met to discuss the following topics:

### 5.1. Biobanks

For the elaboration of the draft Opinion, the respective working group called for plenary discussions on four occasions. The focus of this working group was on the ethical and legal challenges associated with biobanks, including health databases. Particular emphasis was placed on active community support to establish biobanks (conceived as a common good); on the potential benefits arising from biobanks making biological materials and personal data available for research; on the potential benefits for patients themselves; on the right of patients or the public to access the research results obtained with the aid of biological materials and data stored in biobanks; and on the appropriate safeguards required to ensure that rights to privacy and informational self-determination are respected; while ensuring that the freedom of research and economic freedom are also maintained.

### 5.2. Culture of Death and Dying

In the year under review, the working group held three meetings, and developed an initial analysis of death narratives. These narratives were conceived as personal experiences of another person's death; i.e. a subjective account of an individual experience, in a one- to three-page description. The working group also defined the most important elements to be included in an Opinion:

- Changing perceptions of the end of life: dying is now becoming an individual and social responsibility. How are these developments to be understood and assessed from an ethical perspective?
- Individual experiences of other people’s death: narrative approaches to the current situation.
- Interpretation of death narratives: What are the critical issues? Experiences of good or bad death? Settings, diversity, trajectories, parties involved, topics, ideals.
- Normative considerations regarding these experiences and ideas: What can be said from an ethical perspective regarding the (e.g., institutional) conditions facilitating a good death?
- Formulation of recommendations for action for interested/responsible parties and institutions in society.

### 5.3. NIPT

In the year under review, the working group held five meetings. The aim was to prepare an Opinion, for submission to and approval by the Commission, on non-invasive prenatal testing (NIPT) on how individual interests (such as reproductive autonomy and the right to know/not to know) are to be interpreted within a broader social context, where the state and civil society play a key role with regard to new screening methods and prenatal genetic analyses. Defining ethical issues arising at the individual and social level constitutes the main challenge to be addressed.
6. Experts Consulted

On the topic of biobanks, the following experts were consulted as part of the plenary meeting held on the 3rd of July 2015:
- Professor Aurel Perren (Professor of Pathology at University of Bern, pathologist FMH and President of the Biobank-Suisse Foundation),
- Dr Martin Götz (Deputy Head of Human Research and Ethics Section, Federal Office of Public Health).

7. Plenary Meetings

In 2015, the Commission held five ordinary plenary meetings (on a total of six meeting days).

With the exception of the two-day meeting, which was held at the Maison Supersaxo in Sion, all the meetings took place in Bern.

8. Secretariat

The NCE Secretariat comprises two employees, representing a total of 1.3 full-time equivalents since September 2015:

The Executive Secretary is Dr Elisabeth Ehrensperger (80% position); Simone Romagnoli, PhD (50% position) works as a scientific collaborator.
Members of the Commission

Chair Otfried Höffe, Prof. Dr. Dr. h.c. mult., Emeritus Professor of Philosophy and Director of the Research Centre for Political Philosophy, Eberhard Karls University Tübingen

Annette Boehler, Prof. Dr. med., Specialist in Lung Diseases FMH and Internal Medicine FMH; Adjunct Professor, Faculty of Medicine, University of Zurich

Kurt Ebneter-Fässler, Dr. med., Specialist in General Medicine FMH, Appenzell

Samia Hurst, Prof. Dr. med., Associate Professor of Bioethics, University of Geneva, Faculty of Medicine

Valérie Junod, Prof. Dr. iur., Adjunct Professor, Department of Law, University of Geneva, and Associate Professor, Department of HEC, University of Lausanne

Bertrand Kiefer, Dr. med., lic. theol., Editor-in-chief of the Revue Médicale Suisse, Geneva

Frank Mathwig, Prof. Dr. theol., Adjunct Professor of Ethics, University of Bern; Theology and Ethics Officer, Federation of Swiss Protestant Churches (SEK)

Paolo Merlani, Prof. Dr. med., Head of the Intensive Care Unit, Lugano Regional Hospital

François-Xavier Putallaz, Prof. Dr. phil., Adjunct Professor of Philosophy, Faculty of Theology, University of Fribourg

Katja Rost, Prof. Dr., Professor of Sociology and Adjunct Professor of Economics, Institute of Sociology, University of Zurich

Benno Röthlisberger, Dr. med., Head of the Medical Genetics Division, Cantonal Hospital of Aarau

Bernhard Rütsche, Prof. Dr. iur., Professor of Public Law and Philosophy of Law, University of Lucerne

Maya Shaha, PD, PhD in Nursing, Senior Lecturer at the University of Lausanne Institute of Higher Education and Research in Nursing, and the Lausanne Medical Centre

Brigitte Tag, Prof. Dr. iur. utr., Professor of Criminal Law, Criminal Proceedings and Medical Law, University of Zurich

Markus Zimmermann, Prof. Dr. theol., Adjunct Professor, Department of Moral Theology and Ethics, University of Fribourg