

# **Ethics Assessment in Different Countries**

# Austria

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#### Annex 4.a

# Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries \*Deliverable 1.1\*

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#### 1 Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation in Austria, both for the public and private sector. It analyses how the national government has put into place organisational structures, laws, policies and procedures for ethical assessment, how both publicly funded and private research and innovation systems address ethical issues in research and innovation, and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs). Ethics assessment, as used in this report, not only refers to the field of biomedical research and innovation, in which the term "ethics assessment" is traditionally used, but also to other fields in which the balancing of risks and benefits is of importance.

In terms of methodology, the report is based on desk research and semi-structured interviews of at least one stakeholder of each category of ethics assessor discussed in this report.

In order to avoid duplication and exploit synergies between projects that currently investigate different aspects of Responsible Research and Innovation (RRI) within FP7 and Horizon 2020, the authors decided after discussion with their respective coordinators to carry out a joint survey on ethics assessment in Austria. They created a shared questionnaire that covered questions relevant for the Res-AGorA and the SATORI project and carried out interviews with relevant experts. In this way it was not only possible to avoid duplication but to gain additional and more detailed information. The interviews were carried out by Erich Griessler from the Res-AGorA project (www.res-agora.eu).

In total 20 interviews were carried out. The largest part of them concerns the chair people of non-statutory ethics committees at Austrian universities (8). In addition interviews were carried out with representatives of public and private research funding organisations, industry, government as well as an agency dealing with research integrity. The interviews were recorded, fully transcribed and analysed according to thematic analysis.

We will start with providing some basic information about Austria and the ethics assessment institutions in the country. Austria had a population of 8.43 million in 2012, the reference year for the new population projection. According to the assumptions for fertility, mortality and migration, the total population will increase to 8.99 million people (+7 per cent) until 2030 and to 9.37 million (+11 per cent) in 2060.

Austria is a democratic republic. Its head of state (the Federal President) and its legislative organs are elected by the populace. Citizens of Austria have been guaranteed basic rights and freedoms (such as freedom of belief and conscience) since 1867. Austria has ratified the European Convention on the Protection of Human Rights and Fundamental Freedoms of November 4, 1950.

Austria is a federal republic, composed of nine constituent federal states: Burgenland, Carinthia, Lower Austria, Salzburg, Styria, Tyrol, Upper Austria, Vienna and Vorarlberg. Vienna is also the nation's capital.

Austria has a highly developed economy. Competitiveness is regarded as one of the major driving forces for economic development. In average the Austrian economy performed better than the economies of the rest of the Euro-zone. The gross domestic product (GDP) has increased by 0.3% in 2013 and is expected to perform even better in the coming years. Competitiveness of the Austrian economy is secured through the strengthening of small and medium-sized enterprises (SMEs), simplification of bureaucracy, and strengthening the industrial base. As regards research and

Bundesministerium für Wissenschaft, Forschung und Wirtschaft, *Wirtschaftsbericht Österreich*, Wien, 2014. http://www.bmwfw.gv.at/Wirtschaftspolitik/Wirtschaftspolitik/Documents/Wirtschaftsbericht%20%C3%96sterreich%202014.pdf

<sup>&</sup>lt;sup>1</sup>The information in this section is based on:



development (R&D) Austria invested 9,32 billion € in 2014. This represents an increase of 2,7% compared to 2013. R&D expenditure represents 2,88% of GDP in 2014. 44,5% of R&D expenditure was provided for by the private economy. 38,7% were provided for by the public sector. The rest of R&D investment was provided for by multi-national companies who perform research in Austria.

Ethics assessment in Austria at governmental level mainly relates to policy guidance which is performed by advisory councils. Field specific mandatory ethics assessment is provided for by Research Ethics Committees and the National Agency for Animal Research. Other issues such as dual use, data protection, Environmental Impact Assessment, or genetically modified organism (GMOs) are regulated by specific provisions. These provisions do however not particularly focus on research. The related procedures are not performed by Ethics Committees.

The public research and innovation system is presented in this report in respect to the higher education system, policy advisory bodies, and platforms for standard setting, funding organisations, and the funding of universities, research institutions, and research performing institutions.

Research funding is provided for by the Austrian Research Promotion Agency, and the Austrian Science Fund. Besides that, individual ministries fund high level research on project level, such as the Federal Ministry of Science, Research and Economy, and the Federal Ministry of Transport, Innovation and Technology.

Policies and initiatives to support ethics practices in private industry mostly concern *corporate social responsibility (CSR)*. The Austrian business council (ABC) for sustainable development is Austria's leading platform for CSR and sustainable development. As an example the report present the CSR strategies of three large Austrian companies: The OMV-Group, the Borealis-AG, and the voestalpina-AG.

There are a number of Austrian associations for the various research and innovation professions, which vary in their level of involvement in ethics assessment. Some associations are merely focusing on enhancing their members' career opportunities within the profession, other organisations, especially in the field of medicine, also engage in the elaboration of guidelines or recommendations.

Austrian CSOs are very active in engaging in public discussion, particularly in the field of environmental protection, animal rights, human rights, and patient / disabled organisations based on the tradition of consensus politics, which was practiced in Austria since the end of the Second World War.



# 2 National government institutions and policies

This chapter will provide a discussion of Austrian national government institutions and policies relating to ethics assessment in research and innovation. In this section the following will be examined: The general institutional structure of the Austrian government and government-controlled institutions; governmental institutions with a role in ethics assessment; non-statutory ethics assessment; and national laws and policies for ethics assessment.

#### 2.1 General institutional structure

In this section, the general institutional structure of Austrian government and government-controlled institutions, as it relates to research and innovation, will be discussed. Included in the discussion will be the form of government, the nature of and relations between executive, the legislative and judicial branches, the major ministries and government organisations, and the role of government in research and innovation in the private sector. Parts of this section will present findings of qualitative research based on interviews.

# **General structure of government**

Austria is a federal republic. Federal legislation is enacted by the two chambers of Parliament, the "Nationalrat" and the "Bundesrat". The latter chamber represents the interests of the federal states. The 183 deputies in the "Nationalrat" are elected by the populace every five years. The members of the state diets are elected by the population of the federal state concerned. The members of the "Bundesrat" - currently 61 - are nominated by the state diets.

The supreme federal executive organs are the Federal President and the members of the Federal Government, headed by the Federal Chancellor. The supreme state executive organs are the State Governments, each headed by the State Governor.<sup>2</sup>

The Cabinet is entrusted with the highest administrative duties of the Republic of Austria. The Cabinet is composed of the Federal Chancellor, the Vice-Chancellor, and the other Federal Ministers. As a collegiate branch of government it executes only those duties which have been expressly entrusted to it by law (or upon decree by the Federal President). All other governmental duties reside with the ministers of the responsible ministry. The Cabinet's most important constitutional responsibility is its function to pass bills. The Cabinet passes resolutions unanimously. There is no majority decision making.<sup>3</sup>

The research and innovation system depends on federal legislation, which is the reason for why regional legislation and policies are not analysed further in this report.

# Government organisations relevant to research and innovation

Within government, responsibility for research and innovation policy is divided chiefly between two ministries: The Ministry of Science, Research and Economy <sup>4</sup> and the Ministry of Transport, Innovation and Technology.<sup>5</sup>

The Ministry of Science, Research and Economy is responsible for basic research and for strategic positioning of Austria as an international research centre. The Ministry of Transport, Innovation and Technology is responsible for the promotion of applied research.

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<sup>&</sup>lt;sup>2</sup> http://www.bmeia.gv.at/en/foreign-ministry/austria/government-and-politics/political-system.html

<sup>&</sup>lt;sup>3</sup> http://www.bundeskanzleramt.at/site/3539/default.aspx

<sup>&</sup>lt;sup>4</sup> http://www.en.bmwfw.gv.at/Seiten/default.aspx

<sup>&</sup>lt;sup>5</sup> http://www.bmvit.gv.at/en/



The government adopted an R&D Strategy in 2011 focusing on the following in order to reach the EU goal of 3,76% of GDP R&D expenditure (EU 2020 Strategy):<sup>6</sup>

- Review of the Austrian education system with the view of combining the education and innovation system;
- Promotion of basic and applied research and their respective institutions and infrastructure;
- Promotion of innovation in businesses (technological performance, R&D transfer, promotion of innovation systems in public procurement);
- Optimization of the funding system;
- Promotion of strategic positioning of Austria as an international research centre.

#### 2.2 Governmental institutions for ethics assessment

The following is a list of national governmental and government-funded bodies that have a role in ethics assessment (e.g., in terms of setting standards, or providing advice to government) and related areas.

# **Advisory Councils**

Three policy oriented ethics bodies can be identified for Austria: The Austrian Bioethics Commission, the Advisory Board on biotechnology and genetic engineering, and the National Committee for the protection of animals used for scientific purposes. The following describes institutional issues and tasks of these bodies.

#### Austrian Bioethics Commission

The Austrian Bioethics Commission was established in 2001 at the Federal Chancellery. The constituent meeting was held on 2 July 2001.<sup>7</sup> The task of the Bioethics Commission is to advise the Federal Chancellor from an ethical point of view on all social, natural scientific and legal issues arising from the scientific developments in human medicine and human biology. This includes in particular:

- Providing information and promoting discussion within society on key findings in the fields of human medicine and biology and the related ethical issues;
- Submitting recommendations for practical use;
- Submitting suggestions concerning necessary legal measures;
- Preparing expert reports on particular issues.

# Advisory Board on biotechnology

The Advisory Board on biotechnology and genetic engineering was established by the Genetic Engineering Act at the Ministry of Health in 1994.<sup>8</sup> The task of the Advisory Board on biotechnology and genetic engineering is to:

- Advice the authorities in relation to basic questions of genetic engineering in relation To GMOs in contained use, the deliberate release and placing on the market of GMOs, and to genetic analysis and genetic therapy in human beings;
- Take the final decision on the revision of the "Genetic Technology Codex", which summarises the status quo of genetic engineering;
- Prepare a report on the development of genetic engineering every three years, which is submitted to Austrian Parliament (starting from 1998).

<sup>&</sup>lt;sup>6</sup> https://www.bka.gv.at/DocView.axd?CobId=53215

<sup>&</sup>lt;sup>7</sup> http://www.bundeskanzleramt.at/site/3575/default.aspx

<sup>8</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826



#### National Committee for the protection of animals

The National Committee for the protection of animals used for research purposes (*Tierversuchskommission*) was established by the Act on the Protection of Animals Used for Scientific Purposes<sup>9</sup>, which is the transposition of the respective European Union Directive. <sup>10</sup> The Directive stipulates that each Member State shall establish a National Committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. These committees shall also exchange information on the work of animal-welfare bodies and project evaluation and share best practice within the European Union.

# **Environmental impact assessment agencies**

The Environment Agency Austria (*Umweltbundesamt*) has a central role in environmental impact assessment and provides advisory services across a wide range of areas, mainly in the fields of climate change mitigation and adaptation, energy efficiency and renewable energy, air quality, water quality and resources, biodiversity, GMOs, nature protection, waste and resource management, chemicals, environmental legal advice as well as data management, including monitoring and reporting.<sup>11</sup>

# Watchdog bodies

The Austrian data protection authority (*Datenschutzbehörde*) is a governmental authority charged with data protection. The data protection authority is the Austrian supervisory authority for data protection, the equivalent of a national data protection commissioner in other countries.<sup>12</sup>

# **Ethics Committees in Human Subject Research**

At present there are 27 research ethics committees (RECs) in Austria of which one is presently about to merge its work with another REC.<sup>13</sup> Due to the fact that regular hospitals are under the legal competence of the "Bundesländer", whereas university hospitals are under the competence of the federal state, the RECs depend on different legal provisions. The Austrian legislation stipulates ethics review for clinical trials of medicinal products, medical devices, new therapies, and applied research.

In line with the Clinical Trial Directive, <sup>14</sup> Austria has entrusted 7 RECs in dealing with national multicentre drug trials by providing a single opinion. These leading RECs are:

- REC of the Medical University of Vienna,
- REC of Vienna,
- REC of the Medical University of Innsbruck,
- REC of the Medical University of Graz,
- REC of Lower Austria (Niederösterreich),
- REC of Upper Austria (Oberösterreich),
- REC of Salzburg.

The supervising authority for RECs is the Federal Office for Safety in Health Care. 15

<sup>9</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20008142

<sup>&</sup>lt;sup>10</sup> European Parliament and the Council, Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

<sup>11</sup> http://www.umweltbundesamt.at/en/services/environmental consulting/#

<sup>12</sup> https://www.dsb.gv.at/DesktopDefault.aspx?alias=dsken

<sup>&</sup>lt;sup>13</sup> See also: European Network of Research Ethics Committees http://www.eurecnet.org/information/austria.html

<sup>&</sup>lt;sup>14</sup> Please note that the legislation is presently under revision.

<sup>&</sup>lt;sup>15</sup> Bundesamt für Sicherheit im Gesundheitswesen.



# **National Agency for Animal Research**

Animal research projects need to be approved by the respective national agencies (Ministry of Science and Research for Universities or *Landeshauptmann* for projects in the *Länder*). The agencies are supported by experts, which have expertise in the specific scientific field of the project, the writing of protocols (particularly statistical expertise), veterinary practice of the specific scientific field of the project, and stockbreeding. <sup>16</sup> The experts do not form standing committees.

# 2.3 National laws and policies for ethics assessment

This section deals with providing an overview of the most significant national laws, policies and regulations in Austria concerning ethics assessment and related activities. Basically, this answers the question what general and field-specific legal frameworks a researcher needs to deal with a-priori or during his or her research. Both the strictly legal framework as well as stipulated policies — in the forms of codes of conduct or protocols — will be part of the assessment.

# Legal provisions for ethics assessment

On the level of national law, most provisions with regards to ethics assessment in scientific research are fairly abstract, formulated as general values, such as the freedom of research. Freedom of research is guaranteed by Article 17 of the Basic Law on the General Rights of Nationals (*Staatsgrundgesetz*). This regulation declares science and its teachings as "free". The definition of "science" is to be understood in its formal sense, namely as an "intellectual activity that, in form, content and aim, constitutes a serious attempt to obtain new findings in a methodical, systematic and verifiable way" or as the "locating of new findings or the consolidation of older findings in a particular field of knowledge". That the search for findings is also recognised by society is not necessary for it to be scientific. The selection of the object of research and the research method, as well as the development of theories, the review of the research achievements of others, the recording and publication of research findings and also the purely oral expression of scientific doctrines are all covered by this protection.

The scientific literature implies<sup>20</sup> that any interventions regarding the freedom of research in Austria are prohibited. Such an intervention would be the case if a law completely prohibits the research of a particular object or the application of certain research methods<sup>21</sup> or makes such research dependent on authorisation, notification, report or review, which could be the case for ethics assessment. An intervention in the freedom of research would also exist if the legislator allows a scientific project but binds its execution to certain regulations, e.g. making research findings available to the public,<sup>22</sup> respectively the obligation to researchers to publish all research findings, even those of a negative nature.

The question of whether or not rules of good scientific practice intervene in the freedom of research, which are not considered as ethics assessment, is assessed differently in the literature. Interventions

<sup>&</sup>lt;sup>16</sup> Act on Animal research, § 29 (3)

<sup>&</sup>lt;sup>17</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10000006

<sup>&</sup>lt;sup>18</sup> Art. 17 Staatsgrundgesetz: Die Wissenschaft und ihre Lehre ist frei. ("Science and its teachings are free")

<sup>&</sup>lt;sup>19</sup> The arguments in the following section are based on the line of argument of the Austrian Bioethics Commission. Austrian Bioethics Commission, *Codification of Legislation on Medical Research*, Opinion, Wien, 2011. http://www.bundeskanzleramt.at/DocView.axd?CobId=45816

<sup>&</sup>lt;sup>20</sup> See literature referred to in: The arguments in the following section are based on the line of argument of the Austrian Bioethics Commission. Austrian Bioethics Commission, *Codification of Legislation on Medical Research*, Opinion, Wien, 2011. http://www.bundeskanzleramt.at/DocView.axd?CobId=45816 <sup>21</sup> Ibid.

<sup>&</sup>lt;sup>22</sup> Austrian Bioethics Commission, *Codification of Legislation on Medical Research*, Opinion, Wien, 2011. http://www.bundeskanzleramt.at/DocView.axd?CobId=45816



regarding the prohibition of falsification or manipulation of data, the appropriation of the ideas of others, and the sabotaging of the research of others, are not being considered interventions in the freedom of research.<sup>23</sup>

Although Article 17 of the Basic Law on the General Rights of Nationals declares science and its teachings as free, this does not, however, mean that interventions in the freedom of research are completely prohibited; they need an appropriate justification.

The freedom of research can e.g. be restricted by other fundamental rights, such as the right to life (Article 2 ECHR), the prohibition of inhuman or degrading treatment (Article 3 ECHR), the right to private and family life (Article 8 ECHR), or the freedom of expression (Article 10 ECHR). Interventions in the freedom of research must at the same time be proportionate (i.e. the mildest means are to be employed), e.g. to protect test persons from threats to their integrity. The less detriment to the integrity of and risk for test persons there is, the harder it will become to justify restrictions to freedom of research.<sup>24</sup>

In addition, the principle of equality (Article 7 of the Constitution<sup>25</sup> and Article 14 of the ECHR), obligates the legislator, also beyond matters of discrimination, to make legal decisions for purely factual reasons.<sup>26</sup> This obligates the legislator to only call upon sufficiently qualified bodies in making decisions on research restrictions. If a research law requires specialised technical knowledge for certain types of research, then the body that decides whether this prerequisite exists should at least consist mainly of persons who possess the necessary technical skills.<sup>27</sup> The specific national laws provide for the composition of the bodies.

As regards medical research Austria follows a trend, which can be witnessed since the Second World War, towards normative regulations. Examples of this international "bioethical soft law"<sup>28</sup> in the field of medical research are the Nuremberg Code of 1947, the Helsinki Declaration of the World Medical Association of 1964, including its numerous later modifications, the relevant recommendations issued by the bodies of the Council of Europe and by the WHO, the UNESCO Declarations on the Human Genome of 1997, on the protection of genetic data of 2003 and on Bioethics and Human Rights of 2005

Research requiring permissions or opinions of Ethics Committees is related to human subject research and animal research. The respective international provisions are the following:

- Regulation on clinical trials on medicinal products for human use (2014/536/EU),
- Council Directive concerning medical devices (93/42/EEC),<sup>29</sup>
- Directive on the protection of animals used for scientific purposes (2010/63/EU).

These international provisions have been transposed into national legislation.<sup>30</sup> It has to be noted that the present Austrian legislation will need to be adapted according to the Regulation on clinical trials

<sup>&</sup>lt;sup>23</sup> Ibid.

<sup>&</sup>lt;sup>24</sup> Ibid.

<sup>&</sup>lt;sup>25</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10000138

<sup>&</sup>lt;sup>26</sup> Austrian Bioethics Commission, *Codification of Legislation on Medical Research*, Opinion, Wien, 2011. http://www.bundeskanzleramt.at/DocView.axd?CobId=45816

<sup>&</sup>lt;sup>27</sup> Ibid. On procedural aspects for Ethics Committees in relation to freedom of research: Eberhard, Harald, *Ethikkommissionen – Stand und Perspektiven*, zfhr, 2011, p. 147.

<sup>&</sup>lt;sup>28</sup> See also Austrian Bioethics Commission, *Codification of Legislation on Medical Research*, Opinion, Wien, 2011. http://www.bundeskanzleramt.at/DocView.axd?CobId=45816

<sup>&</sup>lt;sup>29</sup> The Directive is subject to reform.

<sup>&</sup>lt;sup>30</sup> See University Act 2002 (Universitätsgesetz) § 30:

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20002128; Hospital Act 1957 (Kranken- und Kuranstaltengesetz) § 8c:

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285; Medicinal Products Act 1983 (Arzneimittelgesetz) §2a (6) and (7), §32, § 37a, § 40; §41, § 43, § 47:



on medicinal products for human use (2014/536/EU). The process of adaption has started and will be finalised by spring 2016. As regards human subject research the consultation of an Ethics Committee is obligatory.

Animal research projects need to be approved by the respective national agencies (Ministry of Science and Research for Universities or *Landeshauptmann* for projects in the *Länder*). The agencies are supported by a committee.

Other issues such as dual use, data protection,<sup>31</sup> Environmental Impact Assessment,<sup>32</sup> or GMOs<sup>33</sup> are regulated by specific provisions. These provisions do however not particularly focus on research. The related procedures are not performed by Ethics Committees.

# Policy provision for ethics assessment

Next to legal frameworks there are guidelines which apply, especially in the field of medical research: the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)-Guidelines on "good clinical practice", the guidelines of the OECD on Human Biobanks and Genetic Research Databases and the Charter for Researchers issued by the European Commission, which can be regarded forming part of the national Austrian policies in relation to ethics assessment.

The research and innovation system depends on federal legislation, which is the reason for why regional legislation and policies are not analysed further in this report.

# 3 Public research and innovation systems

This chapter will provide a discussion of ethics assessment of R&I in public research and innovation systems. In the sections below, the following will be discussed, respectively: the general structure and the role of government; the role of standard-setting bodies; the role of research funding organisations; and, finally, the role of research performing institutions. The general structure can be summarised in the following table:<sup>34</sup>

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441; Medical Devices Act 1996 (Medizinproduktegesetz) § 3 (9) and (14), § 40, § 44, § 51 (9), § 52a (5), § 56, § 57, § 58: http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003 Animal Research Act 2012 (Tierversuchsgesetz) § 35, § 36:

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20008142

<sup>&</sup>lt;sup>31</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10001597

<sup>&</sup>lt;sup>32</sup> Environmental Impact Assessment Act 2000:

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010767

<sup>33</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826

<sup>&</sup>lt;sup>34</sup> Please note that the competences have shifted. The competence of the former Ministry of Education, Science and Culture is now with the Ministry of Science, Research and Economy. Please also note that ARCS has transformed into the Austrian Institute of Technology (AIT).



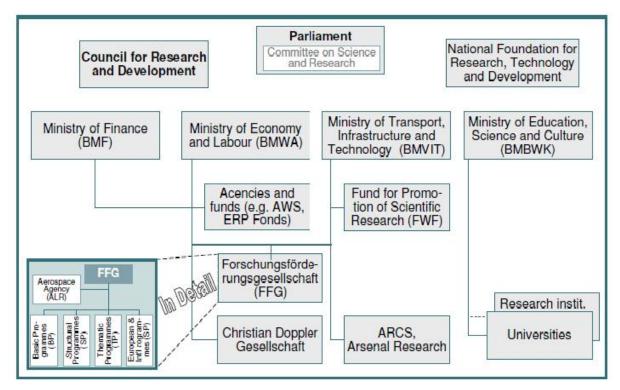


Figure 1: Public sector actors of the Austrian Science and Innovation System

Source: http://ec.europa.eu/invest-in-research/pdf/download en/psi countryprofile austria.pdf

# 3.1 General structure and the role of government

This section aims at providing an overview of the general structure of the publicly funded and controlled R&I and higher education system and the role of government herein in Austria. The section will in particular focus the Austrian Agency for Research Integrity and on non-statutory Ethics Committees and Platforms established at the majority of Austrian universities and will also present findings of qualitative research based on interviews. The questions regarding the added value of ethics assessment compared to other forms of assessment (e.g. peer-review) will also be discussed with in this section.

# System of higher education

The highest state organ for the university sector is the Federal Minister of Science, Research and Economy. The federal provinces have no direct competencies for university matters.<sup>35</sup>

For the universities, a governance system was introduced comprising of three-year performance agreements and global budgets between the universities and the federal authorities in 2002. The activities of the Federal Ministry regarding administration are essentially limited to legal supervision, negotiating the performance agreements and a three-year global budget, receiving the performance reports, as well as controlling and monitoring. The Federal Minister has set up University Councils (*Universitätsräte*) as independent self-administration bodies, as additional implementing bodies. These

<sup>&</sup>lt;sup>35</sup> Wadsack, I., H. Kasparovsky, *Higher Education in Austria. Ministry of Education, Science, and Culture*, 2004. http://www.eui.eu/Documents/MWP/AcademicCareers/Countries/Austria/AustriaHigherEducation.pdf; Österreichischer Wissenschaftsrat, *Universität Österreich 2025, 2009*. http://hochschulplan.at/wp-content/uploads/2012/06/Universit%C3%A4t-%C3%96sterreich-2025 WR-2009.pdf



councils comprise external stakeholders, especially from the Private Sector.<sup>36</sup> Their main task relates to the planning and supervision of the university's activities.

The central state organ for the Universities of Applied Sciences (*Fachhochschulsektor*) is the Council for Universities of Applied Sciences (*Fachhochschulrat*). The Universities of Applied Sciences are administered by the statutory overall conditions and the regulations provided by the Council.

The Accreditation Council (*Akkreditierungsrat*) is the central state organ for private universities. It works under the supervision of the respective Federal Minister. There are no special legal provisions regarding the administration of the private universities, only regulations laid down by the Accreditation Council.<sup>37</sup>

#### Role of government in the Austrian research and higher education system

With regards to the role of the Austrian government in influencing and sustaining the research and higher education system it can be observed that the relationship between the government and the universities is dominated by the prevalence of autonomy since 2002. The strategic tool which is used by the government is the three year performance agreement between the universities and the federal authorities.<sup>38</sup>

Policies in regard to ethics assessment mainly concern research integrity and good scientific practice. The University Act<sup>39</sup> provides for the following:

- §74 (2) The results of an examination, academic paper or art masters of diploma submission shall, further, be annulled if such result was obtained by fraudulent means, in particular by the use of unauthorized aids.
- §89 The governing body responsible for study matters shall revoke and recall the notice of award if it subsequently transpires that a title has been obtained by fraudulent means, in particular the use of counterfeit certificates.

For the implementation of research integrity and good scientific practice most universities have elaborated individual guidelines. There is no common system for how implementation of guidelines of good scientific practice is secured, as this depends on the legal quality of these guidelines, which differ between the different universities due to their autonomy.

#### **Austrian Agency for Research Integrity**

The Austrian Agency for Research Integrity<sup>40</sup> is an association consisting of 36 members (public universities, funding organisations, Christian Doppler Society (CDG), and other Research Institutions such as the Institute of Science and Technology Austria (IST Austria), Joanneum Research, and the Austrian Academy of Sciences). The Agency was founded due to acute external pressure (case of Strasser, which was reported in *Nature* "something seems rotten in the state of Austria".)<sup>41</sup>

The Agency is responsible for investigating alleged cases of scientific misconduct in Austria in a professional manner, evaluating the severity of each violation and proposing consequential measures with the first two tasks being assigned to the Commission for Research Integrity, an independent body

<sup>&</sup>lt;sup>36</sup> http://ec.europa.eu/invest-in-research/pdf/download en/psi countryprofile austria.pdf

<sup>&</sup>lt;sup>37</sup> Wadsack, I., H. Kasparovsky *Higher Education in Austria. Ministry of Education, Science, and Culture*, 2004. http://www.eui.eu/Documents/MWP/AcademicCareers/Countries/Austria/AustriaHigherEducation.pdf

<sup>&</sup>lt;sup>38</sup> Universitätsbericht 2014,

http://www.bmwfw.gv.at/Presse/AktuellePresseMeldungen/Documents/Universitätsbericht\_2014.pdf

<sup>&</sup>lt;sup>39</sup> University Act 2002:

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20002128

<sup>40</sup> http://www.oeawi.at/en/index.html

<sup>&</sup>lt;sup>41</sup> Interview 2.6.2014.



consisting of distinguished non-Austrian scholars, which is regarded as the actual added value in the system. Universities also have to have Commissions on good scientific practice. However internal investigations have the problem that opponents in a conflict, e.g., about authorship, might not accept them as impartial because of possible informal connections between commission members and a party.<sup>42</sup>

The Agency for Research Integrity has in principle neither an arbitrary nor an adjudicative function but offers a neutral and factual platform for investigating thoroughly and impartially (alleged) cases of scientific misconduct. In practice, as regards authorship quarrels, the Agency does act as a kind of arbitration board. The normative power of the Agency's work results from its impartial and factual reviewing of cases, which represents an important benchmark for research integrity in Austria. The "judgement" of the Agency in the case of proceedings is non-binding. This does however not reduce its impact. 44

Any individual as well as any institution in Austria can approach the Agency for Research Integrity which is free to decide whether an allegation is to be pursued. The approach taken is a procedural one. It is not about what kind of research is being done and a possible responsibility towards society. Most cases relate to falsification of data (in science) or to plagiarism (in the social sciences and the humanities) or authorship questions.<sup>45</sup>

As regards the promotion of research integrity, creating awareness was difficult in a country such as Austria, where there did not even exist a term for research misconduct or integrity. In the Anglophone states everybody knows what the concept of research integrity consists of. In Austria the concept had to be explained and formed.<sup>46</sup>

The Agency also gives courses on research integrity and good scientific practice, which meet the demands of PhD students and young researchers. A difference can be witnessed in the different disciplines: in the humanities there is quite some awareness for e.g. citation practices. In the natural sciences, citation practices are not being taught. As there is still little awareness among established researchers for skills related to good scientific practice, they do not insist on it among their students. There is some doubt about the ability of some established researchers to be able to teach issues of good scientific practice, as they themselves do not have a clear concept of what good scientific practice entails.

# Non-statutory Ethics Committees or Platforms at universities

Besides for Medical Universities where the establishment of RECs is provided for by law, there is no central piece of legislation which stipulates the necessity of establishing Ethics Committees at the other Austrian universities, which offer a full programme including PhD courses. At present it is at the universities' discretion whether an Ethics Committee is established or not. A general trend towards establishing Ethics Committees can however be noted, as the latest three-year performance agreements between universities and the Federal Ministry contain the obligation of setting up non-statutory Ethics Committees at universities. The Committees are independent. Their main task relates to producing reviews on individual research projects or to advise the rector or the university senate on ethics.

The legal quality of the reviews is questionable. As a general rule it can be noted that a negative opinion does not have a binding character, but has the legal quality of a recommendation.

<sup>&</sup>lt;sup>42</sup> Interview 2.6.2014.

<sup>&</sup>lt;sup>43</sup> Interview 2.6.2014.

<sup>&</sup>lt;sup>44</sup> Interview 2.6.2014.

<sup>45</sup> Interview 2.6.2014.

<sup>&</sup>lt;sup>46</sup> Interview 2.6.2014.

<sup>&</sup>lt;sup>47</sup> Interview 2.6.2014.

<sup>&</sup>lt;sup>48</sup> Interview 2.6.2014.



Nevertheless, a negative opinion de facto hinders the researcher or research team to continue the research at the given university. The standard practice in this case would be to revise the project according to the opinion of the Ethics Committee. In addition each university issued individual guidelines on good scientific practice<sup>49</sup>.

The following non-statutory Ethics Committees or Platforms have been established and will be discussed in detail:

The Ethics Committee of the University of Vienna<sup>50</sup> was established in 2011 based on the university statutes. Ethics review used to be provided for by the faculty of medicine before 2004. In 2006, after the separation of the Medical University and the University in 2004, an Ethics Committee at the faculty of psychology was formed. In 2004 the general opinion at the university was rather critical of the establishment of an Ethics Committee, as an additional "control" organ was seen as unnecessary. There was however need for such a committee at the faculty of psychology, as publishers used to insist on ethics review, as psychologists usually publish in medical journals. In addition there was also some need within the department to reflect on the ethics of their research. This Ethics Committee at the faculty of psychology was closed in 2011 as a consequence to the establishment of the Ethics Committee at university level.<sup>51</sup>

The Ethics Committee consists of eleven members representing the following fields of research: life-sciences, (natural) sciences, social sciences and economy, psychology, law, theology, philosophy, and sports and care. They are nominated by the dean and appointed by mutual agreement of the rector and the senate. The Committee is responsible for ethics review of all projects which relate to human subject research, but do not fall under the competence of other bodies. The projects reviewed by the Ethics Committee mostly relate to sports science, psychology, and life sciences. Obligatory review relates to a possible infringement of physical or psychological integrity, of the right to privacy, of other subjective rights, or of interests of a research subject. The Committee also evaluates whether the aims of research are ethical and examines whether research in animals complies with the respective legislation.

A special feature of the procedure at the University of Vienna is that the researcher has to disclose the reason why he or she consults the Ethics Committee (e.g. requirement of a funding organisation or a publisher).<sup>52</sup> Ethics assessment at present is not obligatory, but researchers can ask for ethics review of

Vienna:http://www.meduniwien.ac.at/files/7/8/goodscientificpractice.pdf; Medical University of Graz: https://www.medunigraz.at/images/content/file/forschung/gsp/GSP\_Standards.pdf; Medical University of Innsbruck: https://www.i-med.ac.at/mitteilungsblatt/2004/27.pdf; University of Vienna: http://www.phd-structural-biology.at/content/file/SL\_005\_Regulations\_relating\_to\_good\_scientific\_practice\_infoblatt.pdf University of Graz: http://www.uni-graz.at/zvwww/gesetze/satzung-ug02-04.html; University of Salzburg: http://www.uni-

salzburg.at/fileadmin/multimedia/Molekulare%20Biologie/Qulit%C3%A4tssicherung/richtlinien\_zur\_sicherung \_guter\_wissenschaftlicher\_praxis.pdf; University of Innsbruck: http://www.uibk.ac.at/fakultaetenservicestelle/handbuch-fuer-lehrende/#Richtlinien zur "Sicherung guter wissenschaftlicher Praxis" Donauuniversität Krems applies the rules of the European Charter for Researchers: https://www.i-med.ac.at/mitteilungsblatt/2004/27.pdf; Graz University of Technology:

http://portal.tugraz.at/portal/page/portal/Files/Services/files/RL\_GuteWissPraxis.pdf; University of Natural Resources and Applied Life Sciences:

http://www.boku.ac.at/fileadmin/data/H05000/H13000/Ombudsstelle/Guidelines.pdf; Vienna University of Veterinary Medicine:http://www.vetmeduni.ac.at/uploads/media/GoodScientificPractice\_01.pdf Vienna University of Technology:

http://www.tuwien.ac.at/dle/universitaetskanzlei/richtlinien\_und\_verordnungen/code\_of\_conduct\_fuer\_wissensc haftliches arbeiten/

<sup>&</sup>lt;sup>49</sup> Guidelines of good scientific practice: Medical University of

<sup>50</sup> http://ethikkommission.univie.ac.at/satzung/

<sup>&</sup>lt;sup>51</sup> Interview 19.5.2014.

<sup>&</sup>lt;sup>52</sup> Interview 19.5.2014.



individual projects if they think there is need for it. PhD students and scientific staff can directly address the Ethics Committee. For Bachelor- and Masterstudents, the supervisor has to apply for ethics clearance. The vote of the Ethics Committee is non-binding. The Ethics Committee usually poses questions to the researcher/research team in regard to the project, which are then reconsidered.

The university also has a code of conduct, which provides for ethical behaviour of the individual researcher. It remains unclear what exactly ethical behaviour is, in doubt however, the Ethics Committee shall be consulted. In the past ethical behaviour was rather regarded as part of the principle of scientific freedom, used to include individual ethical behaviour. <sup>53</sup> Only after some cases of plagiarism and data falsification, there was a call for more awareness of ethics in research, which is now being implemented inter alia via Ethics Committees.

The aim of the Committee is - rather than to tick boxes for approval - to create a culture of watchfulness and awareness via deliberations and reflection. Monitoring of compliance is not foreseen. The impact relates to the creation of a culture of watchfulness.<sup>54</sup>

The Ethics Committee of the University of Graz<sup>55</sup> was established in 2008 based on a senate resolution and is legally based on the University statutes. The Ethics Committee consist of seven members of the following scientific fields: theology, philosophy, (natural) sciences, law, social sciences and economy, and two other members. The members are elected by the university council. The right to suggest members lies with the senate. The Committee is responsible for ethics review of all projects which relate to human subject research or animal research, but do not fall under the competence of other bodies. Obligatory review in relation to human subject research relates to a possible infringement of physical or psychological integrity, of the right to privacy, of other important rights, or of interests of a research subject or their relatives. The reason for the establishment of the Ethics Committee was the fact that the Medical Faculty transformed into an independent university. The Ethics Committee of the Medical University was therefore no longer responsible for evaluation of human subject research at the University of Graz, which created a need for such an institution.<sup>56</sup>

The Ethics Committee can take up cases if it deems it necessary, it can be approached in case of complaints, and it can initiate educational measures. The driving force for ethics review is the growing need for positive ethics votes which need to be provided to international funding organisations (in particular of the European Union). There are many cases in which the need for an ethics review is not based on the content of the project, but on procedural needs for funding.<sup>57</sup>

The research fields which apply for ethics review are mainly psychology and humanities. Projects concerning research in the field of law have never been submitted. As regards content, ethics review is mostly about questions regarding empirical studies (what questions can be asked and about the level of compensation), the inclusion of minors (informed consent of parents) and incidental findings, or animal research in case the projects do not fall under the Animal Research Act and the respective procedures. The Committee also evaluates whether the aims of research are ethical. This is usually however limited to projects which raise also other ethical questions, e.g. the inclusion of minors in a project in which it is difficult to track the high aim of research.<sup>58</sup>

As regards procedures, critical research projects have to be submitted to the Ethics Committee by the researcher in case it is not an interdisciplinary (multicentre) study and has been reviewed by another Ethics Committee. In case of interdisciplinary (multicentre) studies the researcher has to notify the

<sup>&</sup>lt;sup>53</sup> Interview 19.5.2014.

<sup>&</sup>lt;sup>54</sup> Interview 19.5.2014.

<sup>55</sup> http://www.uni-graz.at/ethikkommission/

<sup>&</sup>lt;sup>56</sup> Interview 15.5.2014/I.

<sup>&</sup>lt;sup>57</sup> Interview 15.5.2014/I.

<sup>&</sup>lt;sup>58</sup> Interview 15.5.2014/I.



Ethics Committee of the existence of the project and the outcome of the ethics review of the other institution.

In principle the Ethics Committee can reject projects, which is usually not the case. The Committee would formulate recommendations which have to be respected by the research team. Ex-post evaluations of whether these recommendations have been followed are not performed by the Committee.<sup>59</sup>

The Ethics Committee of the University of Salzburg<sup>60</sup> was established in 2011 based on the university statutes. Again, the establishment became necessary because the medical school separated and, as a consequence, the university did not have an ethics committee of its own. At present the Committee consists of eight members with the following scientific background: law, psychology, philosophy, theology, sports, forensics, and medicine (external member). The Committee is responsible for ethics review of all projects which relate to human subject, but do not fall under the competence of other bodies. Obligatory review relates to a possible infringement of physical or psychological integrity, of the right to privacy, of other important rights, or of interests of a research subject or their relatives. Most projects which are evaluated are in the field of sport sciences or in psychology. Project in the field of humanities, political science, sociology or natural sciences are rare. The driving force for researchers to ask for the vote of the Committee relates to the demands of publishers. The shared ethics assessment framework relates to risk assessment (protection of participants), free and informed consent, and data protection. Researchers have become more sensitive towards ethics. In former days it was not seen as an ethical problem to use e.g. bone chippings of deceased persons for research without consent. This has changed considerably in recent years. <sup>61</sup>

The Committee issues recommendations, which are not legally binding as such. The researcher would be asked to amend the proposal, which is usually followed by the researcher.

The **Ethics Advisory Board of the University of Innsbruck**<sup>62</sup> was established in 2010 on the initiative of the vice-rector for research. There was a need to establish these new procedures, after the Medical Faculty of the University of Innsbruck became an independent university. Before that, all projects related to human subject research were dealt with in the Research Ethics Committee.

The Ethics Advisory Board at present consists of eight members, which are appointed by the rector. Members should represent all faculties. In principle the Board is consulted by the vice-rector on projects. The vice-rector gives clearance of the projects after ethics review. In practice the Board established procedures for review within the faculties (Review Boards). Only ethically challenging projects will be brought to the Board. The approval of the project is always communicated to the applicant by the vice-rector. Projects submitted usually relate to sports science, psychology, and experimental economy. The ethics assessment framework relates to good scientific practice, such as free informed consent, conflicts of interest, insurance and vulnerability. Particular importance is given to free informed consent of students participating in projects as research subjects.

The Board or the departmental Review Boards do usually not evaluate the aims of the research.<sup>63</sup> Even if a member of the Board considers a projects as scientifically without added value, the Board or the departmental Review Boards do not militate against the project as long as the criteria of good scientific practice are respected (free and informed consent, no conflicts of interest, vulnerability).<sup>64</sup>

<sup>&</sup>lt;sup>59</sup> Interview 15.5.2014/I.

<sup>60</sup> http://www.uni-salzburg.at/index.php?id=31053

<sup>&</sup>lt;sup>61</sup> Interview 6.6.2014.

<sup>62</sup> http://www.uibk.ac.at/rektorenteam/forschung/ethikbeirat.html

<sup>&</sup>lt;sup>63</sup> Interview 5.6.2014.

<sup>&</sup>lt;sup>64</sup> Interview 5.6.2014.



A negative vote by the Committee or the Review Boards would lead to a rejection of the project by the vice-rector. Usually however, the procedure ends with recommendations regarding the project. 65 Researchers do usually follow these recommendations, as they realise that they help to improve the project design. Nevertheless there is still some hesitation towards ethics review, as the "culture" of deliberations regarding ethics has not yet been fully accepted. 66

The Ethics Committee of the Danube University Krems<sup>67</sup> was established in 2012 based on the university statutes. The Ethics Committee consists of five members of which one has to be a legal expert. One member is supposed to represent the faculty of health/medicine, one the faculty of economy/globalisation, and one the faculty of education/arts/architecture. The members are appointed by the rector after consultation of the senate. The Committee is responsible for ethics review of all projects which relate to human subject research, but do not fall under the competence of statutory bodies. Up to now only projects of the faculty of health/medicine have been submitted to the Ethics Committee, which do not fall under the clinical trial legislation.<sup>68</sup>

The major principles which are assessed in the review relate to scientific relevance, protection of personal data, informed consent, and voluntary nature of participation, risk management (insurances) as well as compliance with national legislation. As regards relevance, the applicant has to plausibly explain the relevance of the research. It mainly depends on the other ethical issues (protection of personal data, informed consent, voluntary nature of participation, risk management) whether the research project gets a positive review. So far no projects have been rejected.<sup>69</sup>

Ethics assessment is not obligatory and recommendations are non-binding. Nevertheless, there is a certain pressure towards compliance with the opinion of the Ethics Committee, as research results may not be published without a positive vote of the Committee ("chances on the publication market place"). The main motive to apply for clearance to the ethics committee is to guarantee access to scientific publications in high ranking scientific journals.

A new practice is about to develop regarding the outcome of the research. Researches are asked to keep the Ethics Committee informed about final results via the submission of publications on the respective research.<sup>70</sup>

The **Graz University of Technology** established a Commission for Scientific Integrity and Ethics in 2006 based on a resolution of the rector. <sup>71</sup> The Commission consists of 12 members. The members are nominated by the faculties, the gender equality commission and are appointed by the rector. Further obligatory members are the vice-rector for research and technology, the chair of the senate, a representative of academic employees, and a senior professor of the university, who also chairs the Commission. The Commission is responsible for questions regarding scientific integrity and good scientific practice. As regards scientific integrity accusations of plagiarism are treated in the Commission as well. Projects are submitted by the researcher to the Commission (usually the head of department).

The fields which are covered by the assessment relate mainly to medical research and technical research due to the scope of research which is done at the university. In regard to project review processes, the commission relates to the following ethical principles: integrity, non-maleficence,

<sup>&</sup>lt;sup>65</sup> Interview 5.6.2014.

<sup>&</sup>lt;sup>66</sup> Interview 5.6.2014.

<sup>67</sup> http://www.donau-uni.ac.at/imperia/md/content/donau-uni/mitteilungsblaetter/2012/duk\_mb\_2112.pdf

<sup>&</sup>lt;sup>68</sup> Interview 23.4.2014.

<sup>&</sup>lt;sup>69</sup> Interview 23.4.2014.

<sup>&</sup>lt;sup>70</sup> Interview 23.4. 2014.

<sup>71</sup> http://portal.tugraz.at/portal/page/portal/Files/Services/files/RL\_GuteWissPraxis.pdf



autonomy, precautionary principle, misuse in particular in regard to human beings, animals, plant and the environment (special emphasis on invasive research).<sup>72</sup>

There are no direct legal consequences of a negative vote on a given project, as the Committee gives recommendations. In case of a negative vote and non-compliance of the researcher, the rector would be informed. In practice however, the recommendations are usually welcomed by the researchers. Negative votes are practically non-existent.<sup>73</sup>

Researchers acknowledge the added value of the Commission.<sup>74</sup> The Commission was e.g. able to help researchers to implement new research procedures in relation to the use of human corpses for experiments. As researchers lack the overview of possible legal and ethical provisions and are limited to their field of research, the interdisciplinary review by the Ethics Committee is received very well.<sup>75</sup>

The **Vienna University of Natural Resources and Life Sciences** established an Ethics Platform in 2011<sup>76</sup> based on the university statutes. The Ethics Platform was established as a response to "very displeasing" outside critique, as some fields of teaching were heavily criticised by some media as being non-scientific and an animal research project was challenged in regard to its ethical soundness in Austrian tabloids.<sup>77</sup>

The Platform consists of one member nominated by the rector, one member nominated by the senate, one member of each department, and one member of each scientific initiative, two representatives of the students' union, and two representatives of non-academic employees. The Platform is responsible for identifying relevant ethics questions for the university, providing information to the public on ethics issues, supporting the rector in his public relations regarding ethics, putting together information regarding the possible establishment of an Ethics Commission or University Ethics Codex, and coordinating relevant ethics research projects at the University. At present the university's guiding principle relates to sustainability, in its economic, ecological, and social dimension. Other aspects are usually not discussed due to the anxiety that discussion might lead to the hindrance of the research.<sup>78</sup>

At present there is no ethics committee at the university. The work of the Platform does at present not relate to individual projects, but to general aspects of teaching and research. The main tool which is being developed is an ethics charter, which is about to be finalised soon. Individual projects need to be submitted at the university, but the relevant application forms have only two boxes, which can be ticked by the applicant: Ethically questionable or ethically not questionable.<sup>79</sup> There has never been a project which was classified as ethically questionable by the applicant. Individual researchers always classify their projects per se as ethically sound (individual ethics).<sup>80</sup>

The ethics charter which was under negotiation at the university during the interviews is a first step to raise awareness for ethics. The idea of ethics as an open discussion has not gained ground yet.<sup>81</sup> Procedural instruments, such as an ethics committee, can only be developed at a later stage, but should not include general prohibitions of research or sanctions on individual and contractual basis.<sup>82</sup>

A further issue relates to the consequences which could possibly arise from the ethics charter once adopted. Employees could be asked to sign it when signing their contract. A breach should however

<sup>&</sup>lt;sup>72</sup> Interview 15.5.2014/II.

<sup>&</sup>lt;sup>73</sup> Interview 15.5.2014/II.

<sup>&</sup>lt;sup>74</sup> Interview 15.5.2014/II.

<sup>&</sup>lt;sup>75</sup> Interview 15.5.2014/II.

<sup>&</sup>lt;sup>76</sup> https://www.boku.ac.at/fileadmin/\_/zgwn/Ethik/GO\_EthikPlattform2106\_2.pdf

<sup>&</sup>lt;sup>77</sup> Interview 28.4.2014.

<sup>&</sup>lt;sup>78</sup> Interview 28.4.2014.

<sup>&</sup>lt;sup>79</sup> Interview 28.4.2014.

<sup>80</sup> Interview 28.4.2014.

<sup>81</sup> Interview 28.4.2014.

<sup>82</sup> Interview 28.4.2014.



not lead to disciplinary measures, as this would hinder an open, transparent discussion of ethics issues.<sup>83</sup>

The **Vienna University of Veterinary Medicine** <sup>84</sup> established an Advisory Committee for the scientific use of live animals (*Ethik- und Tierschutzkommission*, *ETK*) in 2005. The Committee consists of 11 regular members chaired by a vice rector; 10 members are experts of the university; one member represents the students' union. The Committee was established due to some negative media reports on animal research projects allegedly conducted at the university. The Committee is a kind of one-stop-shop or a clearance body of the university with regard to ethical and legal questions. Before its establishment overall information on the kinds of projects involving animals conducted at the university had been lacking. With the Committee as a clearance body, there is a good overview of what research is being conducted.

The Committee does not have an official role according to the Animal Experiments Act (*Tierversuchsgesetz 2012*), but functions as an internal body to ensure that the projects submitted to the official authorisation process are in line with the necessary scientific and regulatory standards.

The Vienna University of Economics and Business, the University of Linz, the University of Klagenfurt, the Vienna University of Technology, and Montanuniversität Leoben<sup>85</sup> have not yet established an ethics body.

#### Added value of non-statutory ethics assessment and respective procedures

Ethics Committees are regarded as an additional track to peer review. Ref Compared to peer-review, there is added value, as the Ethics Committee can discuss general issues related to a certain research area or discipline. Peer review concentrates on purely scientific issues. The difference in regard to peer-review is that the Ethics Committees evaluate projects from different angles, as Ethics Committees are usually interdisciplinary Committees.

The impact of the Ethics Committees relate on the one hand to awareness raising and on the other hand to making the projects better through interdisciplinary dialogue. The sensibility for the fact that ethics is of importance has increased. 89 As a consequence project proposals are formulated differently and are clearer on critical issues. This brings an added value for the evaluators as well as for the researcher. Especially if research is concerned in which it is not totally clear from a legal point of view whether it is problematic or not, the view of the Ethics Committee adds to its "legalization" respectively "acceptability". 90

All other assessments e.g. accusations of plagiarism, or the breach of research integrity do not stimulate debate, but are related to individual misconduct. A more general reflection can therefore not be provided by those instruments.<sup>91</sup>

As regards procedures a shared ethics approach enshrined in the legal system is not regarded as desirable by interviewees. The legal system could provide for some procedural issues such as the fixing of quotas within the Committees. The Committees' powers are closely linked to an internal dynamic, which creates an attitude of responsibility. Structures built into the legal system would entail

<sup>&</sup>lt;sup>83</sup> Interview 28.4.2014.

<sup>84</sup> http://www.vetmeduni.ac.at/en/

<sup>85</sup> https://www.unileoben.ac.at/en/2765/

<sup>&</sup>lt;sup>86</sup> Interview 23.4.2014.

<sup>&</sup>lt;sup>87</sup> Interview 5.6.2014.

<sup>88</sup> Interview 15.5.2014/I.

<sup>89</sup> Interview 15.5.2014/II.

<sup>&</sup>lt;sup>90</sup> Interview 15.5.2014/I.

<sup>&</sup>lt;sup>91</sup> Interview 19.5.2014.



many questions in relation to the organisational structure and procedures, including a system of monitoring and sanctions. The intention of creating ethical behaviour is best served by "constructive anarchy", which will lead to shared values which could never be reached through sanctions provided for by the legal system, 92 as ethical behaviour is developed in pre-legislative deliberations. 93 The possible content of ethical behaviour, in addition, is a moving target and is therefore not fit for legislative provisions; only standardised procedures could add to transparency and legitimacy. 94

# 3.2 National research associations and standard-setting bodies

This section aims at providing an overview of the research associations and standard-setting bodies in Austria as well as at analysing their role in ethics assessment. Firstly, we will discuss the main standard setting bodies: The Austria Science Board and Austrian Council for Research. Secondly it will present several platforms dealing with developing a culture of evaluation.

#### Policy advisory bodies

The Austria Science Board<sup>95</sup> (Wissenschaftsrat) is an advisory body to the legislator, the respective Minister and the universities relating to matters of universities and the Austrian R&D system.

The Austrian Council for Research and Development is the central advisory body for research, technology and innovation of the federal government. It can be considered as a standard setting body for research, technology and innovation. The task of the Austrian Council for Research and Development includes the definition of a long-term national research and technology development (RTD) strategy, the monitoring of its implementation, the definition of guidelines for national research and technology programmes and for promoting RTD institutions, recommendations for national RTD programmes and for strengthening Austria's position in international programmes and co-operations, proposals for improving the co-operation between science and industry and guidelines for the evaluation of institutions. <sup>96</sup> In the R&D Strategy research ethics is considered as an integral part of research integrity. Individual standards have not been defined. <sup>97</sup>

#### Platforms for standard-setting

Policy makers, implementing institutions and other actors of the Austrian Science and Innovation System have taken joint initiatives to encourage better and more transparent strategic planning and evaluation of research and innovation policies in Austria and to develop a culture of evaluation. <sup>98</sup> Ethics assessment has however not been a particular focus in this field.

The *Platform for Research and Technology Policy Evaluation*<sup>99</sup> documents and refines evaluation approaches and methods, based on current international evaluation practice. For this purpose, the platform monitors international methodological know-how and experiences in the field, organises symposia and workshops with national and international experts and makes this information available to all actors of the research and innovation community and to a broader public. Founded in 1996 as an informal cooperation, the Platform Research & Technology Policy Evaluation aims at presenting approaches and methods of evaluation, discussing the current evaluation practice on an international level and thus contributing to the development of a culture of evaluation in Austria. In November 2006, its members re-founded the Platform Research & Technology Policy Evaluation as a society.

<sup>&</sup>lt;sup>92</sup> Interview 23.4.2014.

<sup>&</sup>lt;sup>93</sup> Interview 5.6.2014.

<sup>&</sup>lt;sup>94</sup> Interview 15.5.2014.

<sup>95</sup> http://www.wissenschaftsrat.ac.at/en/

<sup>&</sup>lt;sup>96</sup> http://ec.europa.eu/invest-in-research/pdf/download en/psi countryprofile austria.pdf

<sup>97</sup> http://wissenschaft.bmwfw.gv.at/fileadmin/user\_upload/forschung/FTI-Strategie.pdf

<sup>98</sup> The section is based on:http://ec.europa.eu/invest-in-research/pdf/download en/psi countryprofile austria.pdf

<sup>99</sup> https://www.zsi.at/de/object/project/2305



The platform focuses on the development of evaluation standards and a framework and code of conduct for evaluators, authorising institutions and those evaluated and the elaboration, cultivation, application and reinforcement of minimum requirements are priority fields of action.

The programme *Technology – Innovation – Policy Consulting* (TIP)<sup>100</sup> has been commissioned by the involved ministries as a platform for the provision of background and methodological information relevant for Austrian research, technology and innovation policy, *the* diffusion of knowledge from international studies and organisations. As a joint project, *TIP* involves Austria's leading research institutes in the field, e.g. the *Austrian Institute of Economic Research* (WIFO), *Joanneum Research* and AIT (former *ARC Systems Research GmbH*). TIP produces information and recommendations relevant for Austrian research, technology and innovation policy, which contribute to improving welfare as well as to maintaining and increasing the competitiveness of the Austrian economy within a dynamic international environment.

# 3.3 Research funding organisations

This section will provide a discussion of how research funding organisations include ethics assessment in determining how to spend their funding, and whether attention to ethical issues is a condition for basic funding of Austrian universities. This section will also present findings of qualitative research based on interviews.

#### Research and innovation funding organisations

Austria has two major research funding institutions, the *Austrian Research Promotion Agency*<sup>101</sup>, and the *Austrian Science Fund* (FWF)<sup>102</sup>. Besides that, individual ministries fund high level research on project level, such as the Federal Ministry of Science, Research and Economy, and the Federal Ministry of Transport, Innovation and Technology.

The Austrian Research Promotion Agency and the FWF do not have individual Ethics Committees for project selection, as they rely on ethics clearance of universities, where the projects are implemented.<sup>103</sup> For research in the life sciences, they rely on ethics evaluation in respect to good clinical practice and animal research regulated by the following instruments:

- Regulation on clinical trials on medicinal products for human use (2014/536/EU),
- Council Directive concerning medical devices (93/42/EEC), <sup>104</sup>
- Directive on the protection of animals used for scientific purposes (2010/63/EU).

The Austrian Research Promotion Agency and the FWF ask for copies of the positive ethics review by the competent national body for ethics clearance.

#### **Austrian Research Promotion Agency**

Ethical issues at the Austrian Research Promotion Agency are taken into account at programme level rather than at project level. The gender aspect was e.g. introduced into all programmes in 2011, which was a major change, as consensus had to be built on how gender aspects relate to the programmes, and as there was quite some misunderstanding in terms of how this aspect relates to the given programmes. Training measures of internal staff as well as for evaluators were necessary to raise understanding for the issue and to find common understanding on implementation. In the deliberation on gender aspects there was a long discussion on the implications on research, as the principle was first received by some

<sup>100</sup> http://www.tip.ac.at/about/

<sup>&</sup>lt;sup>101</sup> FFG. https://www.ffg.at/en/content/about-ffg

<sup>102</sup> http://www.fwf.ac.at/en/index.asp

<sup>&</sup>lt;sup>103</sup> Interview 15.1.2015.

<sup>&</sup>lt;sup>104</sup> The Directive is subject to reform.



as unnecessary and hindering research. Benefit in this regard was only seen in regard to user interests in connection to market acceptance. 105

As regards open-access strategies the Austrian Research Promotion Agency is more hesitant than other organisations, as the projects are closer to the market than projects of other funding organisations. Innovations which are to have success on the market cannot be made public without any restrictions. In terms of open-access priority lies in the transparent communication on topics which are researched and the respective consortia. This transparency has an added value in regard to the formation of future research teams. <sup>106</sup>

As regards program development the inclusion of citizens is not foreseen by the Austrian Research promotion Agency. Open programmes without a precise focus give a good insight into what happens in the research area. The Austrian Research Promotion Agency usually draws on these topics for future programming in bottom-up research. An important prerequisite for the implementation of general strategies in funding is the question whether the funding organisation follows a top-down or a bottom-up strategy. Top-down strategies give room for the inclusion of not purely scientific aspects, as there is an underlying policy aspect (e.g. market-failure) which should be tackled through the respective programme. In bottom-up strategies the scientific aspect is dominant. There is less room for the inclusion of policy aspects. <sup>107</sup>

As regards the inclusion of stakeholders in research itself the Austrian Research Promotion Agency is also very cautious, as in applied research, which is close to the market, there is potential conflict with EU state-aid rules. The question of compliance with EU state-aid rules is a permanent challenge for the Agency. 108

#### **Austrian Science Fund**

The FWF tackles ethical issues, such as the inclusion of society through individual programmes, e.g. the existing programme for science communication. In addition there are ideas about initiating a citizens' science programme. The initiative has been launched by the Ministry of Research and Science on the basis of the Austrian Research Action Plan. The idea is to provide funds through a "matching fund model". Funds provided by the FWF for this programme would be doubled by the Ministry. The idea behind the citizens' science programme is to include citizens in research (e.g. amateur-astronomers in order to interpret/evaluate new Hubble-telescope-pictures as evaluation by researchers is impossible due to a lack of staff). In addition the FWF makes sure that all projects have a convincing dissemination strategy. However in principle, the FWF sticks to the bottom-up-principle meaning that scientists should propose topics for research.<sup>109</sup>

As regards gender aspects the FWF does not intervene in the recruiting practice of universities. In case the gender balance is really poor in the research teams, the Fund would ask for convincing arguments regarding the gender miss-balance (e.g. low rate of female experts).<sup>110</sup>

As regards open access, the FWF has an existing strategy, which is being implemented at present encouraging and supporting leading Scientific Austrian Journals to provide open access to their publications.<sup>111</sup>

<sup>&</sup>lt;sup>105</sup> Interview 9.12.2014.

<sup>&</sup>lt;sup>106</sup> Interview 9.12.2014.

<sup>&</sup>lt;sup>107</sup> Interview 9.12.2014.

<sup>&</sup>lt;sup>108</sup> Interview 9.12.2014.

<sup>&</sup>lt;sup>109</sup> Interview 15.1.2015.

<sup>&</sup>lt;sup>110</sup> Interview 15.1.2015.

<sup>&</sup>lt;sup>111</sup> Interview 15.1.2015.



# **Seedfinancing-Programme**

As regards funding from the Austrian Federal Ministry of Science, Research and Economy ethics clearance is provided for by an expert committee in its Seedfinancing-Programme in the framework of the Austrian Economic Service (Austrian *Wirtschaftsservice*).<sup>112</sup>

The Ethics Committee of the Seedfinancing-Programme was established in 2012. The Committee consists of five members, who are appointed by the Federal Ministry of Science, Research and Economy. They represent the fields of ethics, medicine, animal research, and law. The Committee is responsible for the review of projects regarding research in humans, human embryo research, processing of sensible data, and animal research. 14 projects have been submitted to the Committee until the end of 2013.

For the Seedfinancing-Programme the applicant is asked to fill in the ethics declaration in the proposal submission-phase. In case the ethics declaration does not indicate any ethically relevant areas, which is checked by the Austrian Economic Service, the project is not submitted to ethics evaluation. In case ethical issues are identified in the ethics declaration, they need to be elaborated further in the ethics section in respect to the aim of the research, the methodology, possible implications of the results of the research, and compliance with national legislation. The Ethics Committee can:

- Give ethics clearance: the applicant does not have to fulfil further ethical requirements;
- Formulate ethics requirements: the applicant needs to fulfil the requirements formulated. The Austrian Economic Service is tasked to check compliance with ethics requirements according to an ethics requirement plan which is established in the meetings of the Ethics Committee.
- Reject the proposal on ethical grounds. The applicant needs to rewrite the proposal.

# Conditions for funding of Austrian universities and other public research institutions

A large part of the annual funding of research by Austrian universities and public research institutions is provided by the Austrian Federal Ministry of Science, Research, and Economy. For the universities, a governance system was introduced comprising of three-year performance agreements and global budgets between the universities and the federal authorities. Conditions for funding are set in bilateral agreements between the universities and the Ministry of Science, Research, and Economy. As regards ethics the latest three-year performance agreements contain the obligation of setting up Ethics Committees at universities.<sup>115</sup>

# 3.4 Research performing institutions

This section will present major Austrian research performing institutions and will provide a discussion of ethics assessment in three of those institutions (Ludwig Boltzmann Gesellschaft, Institute of Molecular Pathology, and Christian Doppler Society), based on interviews. The information on research performing institutions which is also based on interviews is presented first. The rest of the research performing institutions are presented in alphabetical order. It has to be noted that some of these institutions can be considered as public-private partnerships, as their funding relays on public and private sources.

http://www.bmwfw.gv.at/Presse/AktuellePresseMeldungen/Documents/Universitätsbericht\_2014.pdf

<sup>112</sup> http://www.awsg.at/Content.Node/hochtechnologie/foerderungen/48257.php#1317

<sup>113</sup> https://www.awsg.at/Content.Node/files/ergaenzendeinfos/aws\_Seedfinancing\_Ethikrat.pdf

<sup>&</sup>lt;sup>114</sup> The information is based on the personal experience of the author of this report, who is member of the Ethics Committee of the Seedfiancing-Programme.

<sup>&</sup>lt;sup>115</sup> Universitätsbericht, 2014.



# **Christian Doppler Society**

The CDG supports application-oriented fundamental research and enables member companies to have a direct access to new knowledge with the aim to bridge fundamental research and its application. Its research centres are set up in universities and non-university research institutions in collaboration with Private Sector members. Through this, enterprises have direct access to new scientific findings and fundamental research receives at the same time valuable new impulses from their practical experience.

Projects at CDG are selected by the scientific senate, consisting of 36 members of different disciplines with a background in academia or the respective enterprise. In principle the senate at first only checks whether the application criteria are fulfilled. The application is send on for review by three international scientists. The reviews are then discussed in the senate. Ethical questions are usually raised in relation to human subject research and animal research (3R principles). Clearance of this research by national competent bodies is not checked by the CDG, as the research itself is conducted at universities, which are responsible for ethics clearance. In the process of the review the following question is posed to reviewers: "Do you want to add comments on any ethical or social implications of the proposal." Reviewers do usually not have any comments. Project selection mainly relates to qualifications of the team leader, and the scientific quality of the proposal.<sup>117</sup>

Other issues such as gender, open access, diversity, open science or participation are usually not an issue. As regards gender there is a willingness from the side of the CDG to support women. The problem is that women are rare in field of research covered by CDG. The CDG offers information workshops in regard to gender, as a strategic element.<sup>118</sup>

Societal benefit of research is only a question in regard to market chances of a future product, e.g. a project was once turned down, because it focused on the segment of professional athletes, rather than the general public.<sup>119</sup>

#### **Ludwig Boltzmann Gesellschaft**

The Ludwig Boltzmann Gesellschaft (LBG) was founded in 1960 and is the parent organisation of the 13 Ludwig Boltzmann Institutes (LBIs) and five Ludwig Boltzmann Clusters (LBCs). The institutes and clusters conduct cutting-edge research in life sciences as well as social sciences, humanities, the arts and cultural studies. The LBG is financed by a mix of public and private funding, and the LBIs and LBCs employ a total of approximately 380 people. Since the comprehensive reorganisation of the LBG in 2002, LBIs can only be established on the basis of calls for proposals and must operate under the scrutiny of international expert review. 120

As regards ethics at the project level the LBG is convinced that ethics is an integral part of research which is respected by the researchers. The only possibility to check compliance with ethical standards is the scientific interim evaluation. Ex-ante evaluation is not done, as researchers do not present research projects, but research programmes which last for a couple of years. The programmes consist of projects, which are usually implemented in cooperation with other institutions, such as universities. The ethics clearance happens on the project level and is not done by the LBG. 121

<sup>&</sup>lt;sup>116</sup> Country Profile Austria. http://ec.europa.eu/invest-inresearch/pdf/download en/psi countryprofile austria.pdf

<sup>&</sup>lt;sup>117</sup> Interview 19.1.2015.

<sup>&</sup>lt;sup>118</sup> Interview 19.1.2015.

<sup>&</sup>lt;sup>119</sup> Interview 19.1.2015.

<sup>120</sup> http://www.lbg.ac.at/en/themen/ludwig-boltzmann-gesellschaft-science-the-people

<sup>&</sup>lt;sup>121</sup> Interview 26.1.2015.



Other ethics issues are dealt with on a meta-level within LBG. The LBG e.g. involves stakeholders in priority setting of topics when there is a call for the setting up of new institutes; e.g. in the process of setting up an institute in the health sector, the regional authorities of Vienna and Upper Austria as well as the Health Fond were involved. 122

Participatory aspects are also present in programmes such as "meet the expert". This however does not focus on the general public, but gives young researchers the opportunity to meet with experts in a particular field of research. In terms of priority setting for future financing, at present there is no tool for the involvement of the public. 123

A new approach of the LBG in relation to the inclusion of society into research relates to the concept of open innovation in science. The project aims at thinking all research procedures anew and to break with traditional ways of doing science. About 15 to 20 researchers take part in this pilot training programme. The curriculum includes experts form Copenhagen Business School, Harvard University, Stanford University, and the University of Vienna. Particular aspects of this project relate to open data and communication of science. The added value of open innovation processes relate to the meeting and tackling of needs and problems of society, something which is also of great importance since about 50% of research e.g. in medicine is conducted without field studies in relation to the actual need of this innovation.<sup>124</sup>

As regards open access the LBG lags behind the international concepts. In principle there is a policy in regard to publication of research results, which is supported due to the fact that the LBG is a public non-profit organisation. A full open access policy is however not implemented due to a lack of staff resources. 125

#### **Research Institute of Molecular Pathology**

The Research Institute of Molecular Pathology (IMP)<sup>126</sup> in Vienna is a basic biomedical research institute largely sponsored by the pharmaceutical company Boehringer Ingelheim. With over 200 scientists from 35 nations, the IMP is committed to scientific discovery of fundamental molecular and cellular mechanisms underlying complex biological phenomena. Research areas include cell and molecular biology, neurobiology, disease mechanisms and computational biology.

As regards the inclusion of ethics into research the IMP takes the position that basic research is in principle neutral. The question of responsibility becomes relevant when scientific findings are transformed into applications. At that point researchers have to start the dialogue with the public. As basic research is about systematic understanding of processes, the only acceptable limitations to it are the infringement of basic human rights such as freedom, health, and the well-being of human beings. The notion of responsible research at IMP mainly relates to the possibility to reproduce results and the fundamental principle of falsification. The search is in principle of the possibility to reproduce results and the fundamental principle of falsification.

Research priorities of IMP are set through the recruitment of researchers, mainly the Principle Investigators, who are recruited in an open recruitment process in which they have to present their research interest and are then employed by the Chief Scientist, who is assisted by a Scientific Advisory Board (open positions are announced in the leading journals "Science" and "Nature"). In the recruitment procedure it is mainly scientific questions which are of importance. In actual research ethical questions mainly relate to animal research, as IMP does not engage in clinical trials. Ethics

<sup>&</sup>lt;sup>122</sup> Interview 26.1.2015.

<sup>&</sup>lt;sup>123</sup> Interview 26.1.2015.

<sup>&</sup>lt;sup>124</sup> Interview 26.1.2015.

<sup>&</sup>lt;sup>125</sup> Interview 26.1.2015.

<sup>126</sup> http://www.imp.ac.at/

<sup>&</sup>lt;sup>127</sup> Interview 16.1.2015/II.

<sup>&</sup>lt;sup>128</sup> Interview 16.1.2015/I.



clearance for animal research is given by the competent authorities (Ministry of Science and Research). There is one in-house ethics board which deals with animal welfare aspects of the laboratory animals at the venue.<sup>129</sup>

As regards ethical behaviour researchers of IMP are bound by a Scientific Code of Conduct. The Code of Conduct specifies "good research behaviour", in particular in regard to biomedical research, which relates to research integrity. An additional issue which is of importance in this regard is the creation of a hype. Biomedical research, as conducted by IMP researchers, is basic research. Researchers have to be aware that what works in the mouse model might not work in humans. Care has to be given to the communication of results, as there is a tendency to overestimate results vis-à-vis the public or other funding institutions in order to create interest and to receive additional funding.<sup>130</sup>

Ethical questions at IMP mainly relate to the methodology of research. Safeguards in respect to methodology at IMP relate to the publication practice. Publication of results starts with the discussion of research findings at scientific conferences. The evaluation process starts among peers. At this point in time findings are not yet in the public space. The IMP itself announces major finding in press statements.<sup>131</sup>

In order to safeguard research integrity through transparency within IMP there are regular group meetings in which the advances in research are presented. This mainly helps to prevent data falsification, which is perceived as one of the most important problems in relation to research integrity within biology.<sup>132</sup>

Banning of research topics on the basis of them potentially being unethical does not happen at IMP, due to the fact that IMP researchers work in cell-cultures only, which is a very early state in the research process. Banning research at that stage would militate against a scientific approach towards research and the freedom of research. Research at IMP is about "scientific curiosity". Research and research questions are always a moving target in basic research.<sup>133</sup>

As regards science education, IMP participates in several initiatives, such as the open science initiative or the Vienna Open Lab, which aim at presenting bimolecular research to the public.<sup>134</sup>

As regards open-access, the IMP is aware of the impact of commercial journals such as "Cell", "Nature", and "Science". The financial burden for institutes to have access to these journals is however increasing. The idea of publications in open access journals is therefore of great interest to institutions. IMP itself is trying not to solely tie the career of a research to his or her publication record, as some of the most excellent researchers do have a rather small publication record. Nevertheless publication behaviour does have an impact on career development and the higher ranking the journals are the better. For IMP it is difficult to strike the balance between research integrity and the need to communicate results to the (scientific) public.<sup>135</sup>

# Austrian Academy of Sciences / Institute of Technology Assessment

Based on its legal mandate and with its diverse fields of activity, the Austrian Academy of Sciences (OAW)<sup>136</sup> contributes to the further development of Austria as a scientifically successful and research-friendly country and to the establishment of Austria as one of the most innovative knowledge-based

<sup>&</sup>lt;sup>129</sup> Interview 16.1.2015/I.

<sup>&</sup>lt;sup>130</sup> Interview 16.1.2015/1.

<sup>&</sup>lt;sup>131</sup> Interview 16.1.2015/II.

<sup>&</sup>lt;sup>132</sup> Interview 16.1.2015/II.

<sup>&</sup>lt;sup>133</sup> Interview 16.1.2015/I.

<sup>&</sup>lt;sup>134</sup> Interview 16.1.2015/I.

<sup>&</sup>lt;sup>135</sup> Interview 16.1.2015/I.

<sup>136</sup> http://www.oeaw.ac.at/oesterreichische-akademie-der-wissenschaften/



societies in Europe. At the OAW institutes, scientists participate in applied and open basic research that is on par with internationally recognised scientific standards. The goal is to gain new insights, even apart from current research trends, and point out potential benefits for political economic usage without being restricted by immediate applicability.

The Institute of Technology Assessment (ITA), which forms part of the OAW deals with the impacts of new technologies on society, the environment and the economy. It carries out scientific technology assessment (TA) on a variety of topics. The results of this work support policy-makers, administration and the public with regard to issues of technology policy.

#### **Austrian Institute of Technology**

The Austrian Institute of Technology (AIT)<sup>137</sup> is Austria's largest non-university research institute. The Republic of Austria has a share of 50.46%, while the Federation of Austrian Industries owns 49.54% of the AIT through the VFFI (Verein zur Förderung von Forschung und Innovation - "Association to Promote Research and Innovation"). The AIT provides research and technological development to realize basic innovations for the next generation of infrastructure related technologies in the fields of Health & Environment, Energy, Mobility and Safety & Security. These technological research areas are supplemented by the competence in the area of Innovation Systems.

# Institute for Science and Technology Austria

The IST Austria<sup>138</sup> is an international institute dedicated to basic research and graduate education in the natural and mathematical sciences. Established jointly by the federal government of Austria and the provincial government of Lower Austria, the Institute was inaugurated in 2009.

# National Foundation for Research, Technology and Development

The *National Foundation for Research, Technology and Development* was established in 2003 by law with the objective to enable long-term-oriented research and to contribute to the excellence of Austrian research in an international comparison. Its funding decisions are taken by the foundation board on the basis of strategic inputs of the Council for Research and Technology Development, whose chairman is also a member of the foundation board.<sup>139</sup>

<sup>137</sup> http://www.ait.ac.at/?L=1

<sup>138</sup> https://ist.ac.at/en/

<sup>139</sup> http://ec.europa.eu/invest-in-research/pdf/download\_en/psi\_countryprofile\_austria.pdf



# 4 Private research and innovation systems

This chapter will provide a discussion of ethics assessment of R&I and CSR in private research and innovation systems. First, the general structure and the role of government will be examined. Then, the role of industry associations and accreditation, certification and standard-setting organisations will be reviewed. Finally, the role of industry itself will be discussed.

# 4.1 General structure and the role of government

In this section, the following will be discussed: The Austrian industry landscape; the major Austrian organisations that represent industry and the Austrian government policies and initiatives that support ethics assessment and *CSR* in private industry. For information on public private partnerships in research and innovation see section 3.4 on research performing institutions.

# Austrian industry landscape

Austria has strong material well-being and quality of life. Steady growth in GDP per capita has been combined with comparatively low income inequality, high environmental standards and rising life expectancy. Supportive conditions for a dynamic business sector, generous cash benefits allowing families to provide extensive "in-house" services, a wide supply of public services and a well-functioning social partnership system have helped achieve this performance. <sup>140</sup>

The Austrian industry employs about 420,000 persons and consists of about 8,000 enterprises. <sup>141</sup> 45 per cent of research and development expenditure are mobilised by the industrial sector. A further annual 1.2 billion euro is invested in environmental protection. Regular investments in the preservation, restoration and expansion of production facilities support the economy's competitiveness. <sup>142</sup>

# **Organisations that represent industry**

Important Austrian industry-representing organisations include:

- The Federation of Austrian Industries<sup>143</sup>
- The Austrian Economic Chamber. 144

The Federation of Austrian Industries, currently comprising about 4,200 members, is a voluntary body representing the interests of Austrian industry. Besides the nine independent Regional Groups, the Federal organisation and an office in Brussels provide a broad range of services for the members of the Federation of Austrian Industries. The Federation of Austrian Industries has set itself the goal of representing the interests of its members both in Austria and at the European level. The Federation of Austrian Industries is a member of BUSINESSEUROPE, the Confederation of European Business.<sup>145</sup>

The Austrian Economic Chamber, including 18 professional organisations for the different industrial sectors, <sup>146</sup> is a leading force in policymaking at the level of industries and regions, as well as at national and EU level. The Economic Chamber Organisation sets the agenda in representing the interests of Austrian business and companies and offers extensive information, advice, and training for its members.

<sup>140</sup> http://www.oecd.org/eco/survevs/economic-survey-austria.htm

<sup>&</sup>lt;sup>141</sup> https://www.wko.at/Content.Node/BS-Industrie--Industrielehre/oesterreichs-Industrie.html

<sup>142</sup> http://www.iv-net.at/bm50

<sup>143</sup> http://www.iv-net.at/bm50

<sup>144</sup> ttps://www.wko.at/Content.Node/wir/Austrian Economic Chambers Home.html

<sup>145</sup> http://www.iv-net.at/b1373m114/the-federation-of-austrian-industries-iv/

<sup>146</sup> https://www.wko.at/Content.Node/branchen/oe/Wir-ueber-

uns/Fachverbaende/Fachverbaende der Industrie.html



# Government policies and initiatives to support ethics assessment in private industry

The Directive 2003/51 on the annual and consolidated accounts of certain types of companies, banks and other financial institutions and insurance undertakings<sup>147</sup> was transposed into Austrian legislation and obliges joint stock companies and groups of companies to report on environmental and employee issues in their annual status reports. Austria has not produced an Action Plan on Business and Human Rights as advised by the UN Working Group on the issue of human rights and transnational corporations and other business enterprises. Nor has Austria committed to elaborating such an Action Plan.<sup>148</sup>

# 4.2 Industry associations, and accreditation, certification and standard-setting organisations

This section will provide a discussion of the role of the Austrian Business Council (ABC) for sustainable development, which is an association, a network and a standard-setting body for industry in the setting and enforcement or promotion of standards and practices with regard to CSR in industry. The extent to whether industry makes use of independent, external ethics committees to evaluate their R&I will also be discussed.

Policies and initiatives to support ethics practices in private industry mostly concern *CSR*. The ABC for sustainable development is Austria's leading platform for CSR and sustainable development. The association was formed in October 2007. The platform is led by businesses and is financed through the contributions of its member companies, the Austrian Federal Economic Chamber, <sup>149</sup> the Federation of Austrian Industry, <sup>150</sup> the Federal Ministry of Science, Research and Economy, <sup>151</sup> the Federal Ministry of Labour, Social Affairs and Consumer Protection <sup>152</sup> and the Federal Ministry of Agriculture, Forestry, Environment and Water management. <sup>153</sup>

The council's most important activities are related to leadership on CSR and sustainability, exchange of best practices, knowledge transfer and education as well as the establishment and administration of a national CSR network. The council comprises about 300 Austrian companies, 154 which have all adopted an internal branch specific CSR policy.

The council published guidelines which aim at helping businesses to recognise their social responsibility. Intended for use by any Austrian company, the guidelines list objectives for responsible business activity based on five fields of action:<sup>155</sup>

- Leadership
- Marketplace
- Workforce
- Environment
- Society

The dimensions of environment and society are of interest in relation to ethics assessment. The dimension of environment is based on the idea that every form of economic activity has an impact on the environment. The responsibility of companies therefore goes beyond compliance with

<sup>147</sup> http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:178:0016:0022:en:PDF

<sup>148</sup> http://www.ohchr.org/EN/Issues/Business/Pages/NationalActionPlans.aspx

<sup>149</sup> https://www.wko.at/Content.Node/wir/Austrian Economic Chambers Home.html

<sup>150</sup> http://www.iv-net.at/

<sup>151</sup> The Federal Ministry of Science, Research and Economy, http://www.bmwfj.gv.at/

<sup>152</sup> The Federal Ministry of Labour, Social Affairs and Consumer Protection. http://www.bmask.gv.at/

<sup>&</sup>lt;sup>153</sup> The Federal Ministry of Agriculture, Forestry, Environment and Water management.

http://www.lebensministerium.at/

<sup>154</sup> https://www.respact.at/site/mitglieder/text/article/3468.html

<sup>155</sup> https://www.respact.at/leitbild/en/home



environmental legislation in respect to conservation, protection and precaution. Measures need to be taken in relation to resource efficiency, energy efficiency, and mobility and transport.<sup>156</sup>

The dimension of society relates to Human Rights and cultural diversity, development cooperation and the struggle against poverty for those companies, which are active on the global market including active engagement in setting Human Rights standards in regions where Human Rights are not respected. The fight against poverty is not considered a business responsibility per se, but as an opportunity to contributing to creating jobs and income in the target region. Social commitment and responsibility are regarded as core values for companies in any market including the home market. The proposed measures relate to funding or in-kind donations of societal actions.<sup>157</sup>

It can be observed that Austrian CSR guidelines differ from the European Commission's definition of CSR, as they do not include the dimension of ethic. 158

#### **External ethics committees**

By Austrian law, all medical-scientific research involving human subjects and animal experimentation requires a permit or a review by the competent national body. Human subject research is reviewed by Research Ethics Committees, whereas animal research is to be approved by the respective national agencies (Ministry of Science and Research for Universities or *Landeshauptmann* for projects in the *Länder*). <sup>159</sup> These provisions are also to be observed by industrial research.

# 4.3 Industry

In this section, it will be discussed how Austrian industrial businesses engage in CSR and ethics assessment. It can be noted that through the activities of the ABC for sustainable development, CSR is well established within Austria. SMEs, as well as large companies, who are active on the global market, have individual CSR strategies. The focus of this section will primarily be on large Austrian corporations, whose CSR strategy will be presented. This section will also provide findings of qualitative research based on interviews.

# **Examples for CSR in large Austrian corporations**

The following three large Austrian companies have been selected for a discussion of their individual CSR strategy, as they represent three major different branches of Austrian industry: OMV-Group, Borealis-AG, and Voestalpina-AG. The section on the OMV-Group is also based on interviews, as an example for ethics assessment in industry.

# **OMV-Group**

The OMV-Group has a workforce of around 25.500 employees in 2014 and is one of Austria's largest listed industrial companies. In Upstream, the OMV-Group has a strong base in Romania and Austria and a balanced international portfolio. In Downstream, the OMV-Group has an annual refining capacity of 17.4 million tonnes and approximately 4.100 filling stations in 11 countries as of end of

<sup>156</sup> https://www.respact.at/leitbild/en/home

<sup>157</sup> https://www.respact.at/leitbild/en/home

<sup>&</sup>lt;sup>158</sup> EC definition of CSR: "Respect for applicable legislation, and for collective agreements between social partners, is a prerequisite for meeting that responsibility. To fully meet their corporate social responsibility, enterprises should have in place a process to integrate social, environmental, ethical, human rights and consumer concerns into their business operations and core strategy in close collaboration with their stakeholders (...)" http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF

<sup>159</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010767

<sup>&</sup>lt;sup>160</sup> For the individual strategies, see: https://www.respact.at/site/mitglieder/text/article/3468.html



2014. The OMV-Group operates a gas pipeline network in Austria and gas storage facilities in Austria and Germany. 161

The OMV-Group has long been actively involved in sustainability management taking responsibility for the environment and the society. They have now created the resourcefulness strategy which reaches beyond environmental and societal aspects.

CSR activities<sup>162</sup> which are focused upon in the so called *Resourcefulness Strategy* relate to education and development (skills to succeed-programme), environmental management (eco-efficiency-programme), new technologies (eco-innovation-programme), engagement for resourcefulness, sustainability controlling (development of indicators for resourcefulness and their evaluation), and diversity (internationality and gender-programme).

The Strategy of Resourcefulness was elaborated to ensure sustainability in the shared value chain of the OMV-Group focussing on human resources and natural resources and to mark a new approach in contrast to CSR, which is strongly connected to charity in public perception. The strategy consists of different strands related to Health, Safety, Security, and Environment (HSSE), Business ethics, Human Rights, diversity, stakeholder engagement, skills to succeed, eco-efficiency, and eco-innovations. <sup>163</sup>

The notion of HSSE relates to measures in relation to the employees' safety, security, and health. As the OMV-Group is active in different regions, they have developed internal systems in relation to health checks, medical care, etc. at the different venues of operation.<sup>164</sup>

Business ethics mainly relates to anti-corruption measures. On the one hand giving guidelines to employees regarding gifts and donations; on the other hand the OMV-Group has installed an "anonymous telephone" to report on cases of corruption (whistleblowing).<sup>165</sup>

As regards Human Rights the OMV-Group developed an internal human rights matrix in cooperation with human rights experts. Due to its engagement in different regions, the human rights aspect and the analysis of consequences of the human rights situation in a specific country is of special importance to make the right business decisions. <sup>166</sup>

Diversity mainly relates to internal OMV-Group policies in regard to gender (quantitative aim regarding females in top positions).<sup>167</sup>

Stakeholder engagement is organised to discuss different topics with the public. Stakeholder engagement also includes the analysis of the stakeholder environment in order to develop a stakeholder strategy, which is of importance for the implementation of some projects. The OMV-Group has already experienced drawbacks in stakeholder involvement in regard to shale gas projects within Austria, which led to a de-facto stop of shale gas projects in Austria. 168

Eco-efficiency relates to the reduction of CO<sub>2</sub>, water management (water footprint), and the shift to natural gas from other fossil fuels. 169

Eco-innovation relates to research in new products reducing the dependence on fossil fuels. 170

<sup>161</sup> http://www.omv.com/portal/01/com/omv/OMV\_Group/About\_OMV

<sup>162</sup> https://www.respact.at/site/english

<sup>&</sup>lt;sup>163</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>164</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>165</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>166</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>167</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>168</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>169</sup> Interview 2.2.2015.



The programme "skills to succeed" focuses on education, cooperation with universities (Vienna University of Economics and Business and Montanuniversität Leoben) and on gender issues. The educational aspect relates to employability of the indigenous population in the regions in which the OMV-Group is active. The cooperation with universities includes a mentoring programme of students. The gender issue is tackled in a programme called "technique-queens" trying to mobilise girls aged between 14 and 16 to begin a technical training.<sup>171</sup>

The Resourcefulness Strategy is implemented through Management by Objectives. Employees have to relate one of their annual targets to the Strategy. These targets are evaluated and connected to a financial bonus system.<sup>172</sup>

It has to be noted that the Resourcefulness Strategy only relates to the internal functioning of the OMV-Group. The principles of the Strategy do not manifest themselves in the industry's position on ethics / CSR on a more global level e.g. emission trading, as repeatedly taken up by the Austrian Chamber of Commerce. 173

#### **Borealis-AG**

Borealis currently employs around 6,400 people and operates in over 120 countries.<sup>174</sup> It generated EUR 8.1 billion in sales revenue in 2013. The International Petroleum Investment Company (IPIC) of Abu Dhabi owns 64% of the company, with the remaining 36% owned by the OMV-Group, the leading energy group in the European growth belt. Borealis provides services and products to customers around the world in collaboration with Borouge, a joint venture with the Abu Dhabi National Oil Company (ADNOC).

Borealis and Borouge aim to proactively benefit society by taking on societal challenges and offering solutions. Both companies are committed to the principles of Responsible Care, an initiative to improve safety performance within the chemical industry, and contribute to solve the world's water and sanitation challenges through product innovation and their Water for the World programme.<sup>175</sup>

CSR and sustainable development are regarded as creating a win-win situation for the economy, the environment and the society. Central dimensions in this regard are responsibility (responsible care initiative in regard to health, safety, and environment), necessity (careful use of resources), and opportunities (innovation).

CSR activities relate to ethical behaviour (zero tolerance policy on corruption), where guidelines have been established;<sup>176</sup> to health and safety (motto: If we can't do it safely, we don't do it at all), where a workplace health survey has been introduced for internal safety and the commitment to responsible care secures product safety; to environmental protection in order to reduce the company's CO<sub>2</sub> footprint; to resource efficiency, including a strategy for recycling by producing recyclable materials.

# Voestalpine-AG

Voestalpine is represented in more than 50 countries on five continents. The Group consists of four divisions. The Group is one of the leading partners to the automotive and consumer goods industries in Europe and to the oil and gas industries worldwide. The voestalpine-Group is also the world market

<sup>&</sup>lt;sup>170</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>171</sup> Interview 2.2.2015.

<sup>&</sup>lt;sup>172</sup> Interview 2.2.2015.

https://www.wko.at/Content.Node/iv/presse/wkoe\_presse/presseaussendungen/pwk\_132\_15\_WKOe-Schwarzer:--Keine-Erhoehung-der-CO2-Preise-.html

<sup>174</sup> https://www.respact.at/site/mitglieder/profilecsr/profile/641.html

<sup>175</sup> http://www.borealisgroup.com/en/company/about-borealis/about-borealis/



leader in turnout technology, special rails, tool steel, and special sections. In the business year 2013/14, the voestalpine-Group reported revenue of EUR 11.2 billion and an operating result (EBITDA) of EUR 1.4 billion; it had around 48,100 employees worldwide.<sup>177</sup>

The CSR policy relates to actively developing and applying environmentally-friendly steel manufacturing processes, as well as waste management measures and an active environmental protection policy. Social obligations relate to safety measures, a Group-wide health management system, and a wide variety of opportunities for continued professional development. Environmental aspects are covered by research into products, which indirectly reduce CO<sub>2</sub>, consideration of life cycle assessment (LCA). The CSR measures are summarised in a Corporate Responsibility Report.<sup>178</sup>

CSR activities relate to responsible corporate leadership (code of conduct, which forms the basis for ethically and legally sound employee behaviour, anti-trust laws, avoiding corruption and observing human rights); to research and development (innovation for creating solutions in the energy efficiency and mobility sectors, as well as in reducing costs and improving raw materials efficiency); to risk management (identification and mitigation of risks at an early stage); to environment and ecology (active environmental protection and conserving finite resources); to employees (safety at work, and particularly accident prevention); to society and culture (support of social, cultural, and educational affairs).<sup>179</sup>

# 5 Professional groups and associations in the R&I field

This chapter will provide a discussion of the role in ethics assessment of R&I of professional associations in R&I or the ethics assessment thereof (and related fields).

# 5.1 National associations for R&I professions

There are a number of Austrian associations for the various R&I professions, which vary in their level of involvement in ethics assessment of R&I. Some associations are merely focusing on enhancing their members' career opportunities within the profession.

Other associations do much more, and engage their members on research themes within the profession by organising lectures, facilitating discussions, such as the Kurt Gödel Society engaging in the promotion of research in the areas of Logic, Philosophy, History of Mathematics or the Sigmund Freud Society, which in close cooperation with the International Psychoanalytic Association (IPA) and her branch organisations as well as other scientific and cultural institutions in Austria and abroad wants to make visible the broad range of the psychoanalytic field and cultivates public scientific and pedagogic efforts in these matters.

Other organisations, especially in the field of medicine, also engage in the elaboration of guidelines or recommendations e.g. the Austrian Association for Internal and General Intensive Care and Emergency, <sup>181</sup> the Federation of Austrian Societies for Intensive Care Medicine, <sup>182</sup> the Austrian Association for Anaesthesia, Reanimation and Intensive Medicine, <sup>183</sup> and the Austrian Association for Reproductive Medicine and Endocrinology. <sup>184</sup> The guidelines do per se not have a legal status, but

<sup>177</sup> http://www.voestalpine.com/group/en/group/overview/

<sup>&</sup>lt;sup>178</sup> https://www.respact.at/site/mitglieder/profilecsr/profile/3889.html; http://www.voestalpine.com/group/en/group/corporate-responsibility/

<sup>179</sup> http://www.voestalpine.com/group/en/group/corporate-responsibility/

<sup>180</sup> http://www.sigmundfreudgesellschaft.at/home.php?il=30&l=eng

<sup>181</sup> http://www.intensivmedizin.at/index.php/publikationen

<sup>182</sup> http://www.dachverband-intensivmedizin.at/index.php/dokumente

<sup>183</sup> https://www.oegari.at/esa-guidelines.asp

<sup>184</sup> http://oegrm.at/AKTUELLES.aspx#hormonelleStimulationsbehandlung



they are helpful in determining national standards; in case of court proceedings, they can play a decisive role in order to determine the "lege artis" criteria.

# 5.2 National associations for (ethics) assessors

The *Forum of the Austrian Ethics Committees*<sup>185</sup> represents all Austrian Research Ethics Committees. It was established in 1997. The Forum serves as contact for the legislative and the supervising authorities and as platform for cooperation of the Austrian Research Ethics Committees. The organs of the Forum are the general assembly and the board. The general assembly meets once a year during the annual Forum meeting, board meetings are scheduled once or twice a year.

# 6 Civil society organisations

This chapter will provide a discussion of the role in ethics assessment of R&I by CSOs. First, the CSO landscape will be discussed, and then the role of CSOs in ethics assessment will be reviewed.

# 6.1 The CSO landscape

This section will provide an overview of national legislation and regulation for CSOs, major CSOs and their societal roles, funding sources of CSOs, and the role of CSOs in research and innovation.

# National legislation and regulation for CSOs

Most CSOs are organised as "registered societies". They have to observe the rules laid down in the Act on Associations/Societies (*Vereinsgesetz 2002*)<sup>186</sup> (non-profit organisations acting for the purpose of public and common benefit). The following presents a selection of CSOs active in Austria.

Religious organisations

The following religious groups are recognised by the state (in alphabetical order):

- Altkatholische Kirche Österreich<sup>187</sup>
- Armenisch-apostolische Kirche Österreich<sup>188</sup>
- Evangelische Kirche A.B./H.B. 189
- Evangelisch-methodistische Kirche Österreich<sup>190</sup>
- Freikirchen Österreich<sup>191</sup>
- Griechisch-orientalische Kirche in Österreich<sup>192</sup>
- Islamische Alevitische Glaubensgemeinschaft Österreich<sup>193</sup>
- Islamische Glaubensgemeinschaft Österreich<sup>194</sup>
- Israelitische Religionsgemeinschaft<sup>195</sup>

Kirchengemeinde zur Hl. Dreifaltigkeit, Rumänisch-griechisch-orientalische Kirchengemeinde zur Hl.

Auferstehung, Russisch-orthodoxe Kirchengemeinde zum Hl. Nikolaus, Serbisch-griechisch-orientalische Kirchengemeinde zum Hl. Sava

<sup>185</sup> http://www.ethikkommissionen.at/

<sup>186</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001917

<sup>187</sup> http://www.altkatholiken.at/

<sup>188</sup> http://www.aakg.at/

<sup>189</sup> http://www.evang.at/

<sup>190</sup> http://www.emk.at/

<sup>191</sup> http://www.freikirchen.at/

<sup>&</sup>lt;sup>192</sup> Griechisch-orientalische (= orthodoxe) Kirche in Österreich: Bulgarisch-orthodoxe Kirchengemeinde zum Hl. Iwan Rilski, Griechisch-orientalische Kirchengemeinde zum Hl. Georg, Griechisch-orientalische

<sup>193</sup> http://www.aleviten.at/

<sup>194</sup> http://www.derislam.at/

<sup>195</sup> http://www.ikg-wien.at/



- Jehovas Zeugen Österreich<sup>196</sup>
- Katholische Kirche<sup>197</sup>
- Kirche Jesu Christi der Heiligen der Letzten Tage Österreich<sup>198</sup>
- Koptisch-orthodoxe Kirche Österreich<sup>199</sup>
- Neuapostolische Kirche Österreich<sup>200</sup>
- Österreichische Buddhistische Religionsgesellschaft<sup>201</sup>
- Syrisch-orthodoxe Kirche Österreich<sup>202</sup>

#### Environmental organisations

- Global 2000<sup>203</sup>
- Greenpeace<sup>204</sup>
- WWF Austria<sup>205</sup>
- Ökosoziales Forum Österreich<sup>206</sup>

#### Civil liberties/human rights organisations

- Amnesty International Austria<sup>207</sup>
- Homosexuelle Initiative<sup>208</sup>
- Österreichische Liga für Menschrechte<sup>209</sup>

#### Consumer organisations

• The Austrian Consumer Protection Association (Konsumentenschutz Verband Österreich)<sup>210</sup>

# Developmental organisations

- Care Österreich<sup>211</sup>
- Dreikönigsaktion<sup>212</sup>
- EZA Fairer Handel<sup>213</sup>

### Animal rights organisations

- Vier Pfoten Österreich<sup>214</sup>
- WWF Austria<sup>215</sup>

# Patient/disabled rights organisations

• Österreichischer Zivil-Invalidenverband<sup>216</sup>

<sup>196</sup> http://www.jehovas-zeugen.at/

<sup>197</sup> http://www.katholisch.at/

<sup>198</sup> http://www.kirche-jesu-christi.at/

<sup>199</sup> http://www.kopten.at/kopten/

<sup>200</sup> http://www.nak.at/

<sup>&</sup>lt;sup>201</sup> http://www.buddhismus-austria.at/

<sup>&</sup>lt;sup>202</sup> http://www.suryoyezentrumwien.at/

<sup>&</sup>lt;sup>203</sup> https://www.global2000.at/

<sup>204</sup> http://www.greenpeace.org/austria/de/ueber-uns/organisation/greenpeace-in-a-nutshell/?gclid=CPiejueCo8QCFWbKtAodIQQAhw

<sup>205</sup> http://www.wwf.at/

<sup>&</sup>lt;sup>206</sup> http://www.oekosozial.at/

<sup>&</sup>lt;sup>207</sup> https://www.amnesty.at/

<sup>&</sup>lt;sup>208</sup> http://www.hosiwien.at/

<sup>209</sup> http://www.liga.or.at/

<sup>&</sup>lt;sup>210</sup> http://www.konsumenten-schutz.at/

<sup>&</sup>lt;sup>211</sup> https://www.care.at/

<sup>&</sup>lt;sup>212</sup> http://www.dka.at/

<sup>&</sup>lt;sup>213</sup> http://www.eza.cc/

<sup>214</sup> http://www.vier-pfoten.at/

<sup>&</sup>lt;sup>215</sup> http://www.wwf.at/



- Lebenshilfe Österreich<sup>217</sup>
- Dachorganisation der Selbsthilfegruppen<sup>218</sup>

#### Migration organisations

- Caritas<sup>219</sup>
- Diakonie Flüchtlingsdienst<sup>220</sup>
- Verein LEFÖ<sup>221</sup>

## Social partners

Following the Second World War Austria is dominated by a policy of consensus, which is based on balancing the interests of employers and employees. The organisations which form the social partnership are the following:

- Arbeiterkammer (Chamber of Employees)<sup>222</sup>
- Österreichischer Gewerkschaftsbund (Austrian Trade Union Federation)<sup>223</sup>
- Wirtschaftskammer Österreich (Austrian Economic Chambers)<sup>224</sup>
- Landwirtschaftskammer (Austrian Agricultural Chamber)<sup>225</sup>

#### **Funding sources of CSO's**

Cooperation with CSOs is regarded as a major component of sustainable development cooperation and policy in Austria. The expertise of CSOs in conducting activities in developing countries and education in Austria are essential and are supported by the Austrian Development Agency (ADA). Through the Funding Civil Society Department, ADA supports projects implemented by Austrian CSOs in cooperation with local partner organisations in developing countries, as well as development communication and education projects in Austria. 226

#### Role of CSOs in research and innovation

Several CSOs are building their own expertise in their field of action, especially large environmental / animal rights or human rights organisations, such the WWF, Greenpeace or Global 2000, or Amnesty International have departments providing independent expertise.<sup>227</sup>

#### 6.2 The role of CSO's in ethics assessment

This section will provide a discussion of the role of CSOs as stakeholders in public discussion, and as participants in ethics assessment.

<sup>&</sup>lt;sup>216</sup> http://www.oeziv.org/

<sup>&</sup>lt;sup>217</sup> http://www.lebenshilfe.at/

<sup>&</sup>lt;sup>218</sup> http://www.selbsthilfe-oesterreich.at/

<sup>&</sup>lt;sup>219</sup> http://www.caritas-wien.at/

<sup>&</sup>lt;sup>220</sup> http://fluechtlingsdienst.diakonie.at/

<sup>221</sup> http://www.lefoe.at/

<sup>222</sup> http://www.arbeiterkammer.at/index.html

<sup>223</sup> http://www.oegb.at/cms/S06/S06 11/english

<sup>&</sup>lt;sup>224</sup> https://www.wko.at/Content.Node/wir/Austrian\_Economic\_Chambers\_Home.html

<sup>225</sup> https://www.lko.at/

<sup>&</sup>lt;sup>226</sup> http://www.entwicklung.at/en/funding/funding-civil-society/

http://www.wwf.at/de/ueber-uns/, http://www.greenpeace.org/international/en/about/victories/; https://www.global2000.at/themen, https://www.amnesty.at/de/ziele-und-aufgaben/



#### CSOs as stakeholders in public discussions

Austrian CSOs are very active in engaging in public discussion, particularly in the field of environmental protection, animal rights, human rights, and patient / disabled organisations. Due to the fact that Austria has a strong tradition of consensus politics, governmental policies are usually prediscussed with CSOs. Stakeholders can therefore actively participate in the forming of governmental action. A particular position is taken by the Austrian Catholic Church, which has direct, however recently decreasing, influence on the Austrian Conservative Party (ÖVP) and thus on Austrian politics. <sup>228</sup>

#### CSOs as agents engaging in ethics assessment

CSOs engage in ethics assessment mainly in the field of environmental impact assessment, in which they are considered as a party according to the Environmental Impact Assessment Act.<sup>229</sup>

# 7 Discussion

The report provides an overview of ethics assessment in research and innovation in Austria. Ethics assessment as used in this report does not only refer to the field of biomedical research and innovation, in which the term "ethics assessment" is traditionally used, but also to other fields in which the balancing of risks and benefits is of importance. The report sets out national institutions and policies and legislation in regard to ethics assessment, ethics assessment in public and private research and innovation systems; it describes the role of professional groups and associations in research and innovation, and gives an overview of relevant civil society organisations in Austria and their impact.

Ethics assessment in Austria at governmental level mainly relates to policy guidance which is performed by advisory councils, in particular the Austrian Bioethics Commission, the Advisory Board on Biotechnology and Genetic Engineering, and the National Committee for the Protection of Animals used for Scientific Purposes, which cover the fields of biomedical research, genetic engineering, and animal experiments. Environmental impact assessment is provided for by the Environment Agency Austria offering advisory services across a wide range of areas, mainly in the fields of climate change mitigation and adaptation, energy efficiency and renewable energy, air quality, water quality and resources, biodiversity, genetically modified organisms, nature protection, waste and resource management, chemicals, environmental legal advice as well as data management, including monitoring and reporting. The area of data protection is covered by the Austrian data protection authority.

Field specific mandatory ethics assessment is provided for by Research Ethics Committees and the National Agency for Animal Research. In addition universities offering a full programme including PhD courses engage in ethics assessment. Respective Committees or platforms are at the universities' discretion and are not provided for by law (non-statutory ethics assessment). In order to investigate alleged cases of scientific misconduct the Austrian Agency for Research Integrity was founded consisting of 36 members (public universities, funding organisations, Christian Doppler Society, and other Research Institutions such as IST Austria, Joanneum Research, and Austrian Academy of Sciences).

On the level of national law, most provisions with regards to ethics assessment in scientific research are fairly abstract, formulated as general values, such as the freedom of research. Freedom of research is guaranteed by Article 17 of the Basic Law on the General Rights of Nationals. This regulation declares science and its teachings as "free".

<sup>&</sup>lt;sup>228</sup> http://diepresse.com/home/politik/innenpolitik/4662609/OVP-Kirche\_Eine-schwierige-Dauerbeziehung; http://derstandard.at/2000007871782/Spurensuche-nach-einem-OeVP-Erbe-Die-christliche-Soziallehre; http://www.dobusch.net/pub/jour/200305art.pdf

<sup>&</sup>lt;sup>229</sup> http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010767



As regards medical research Austria abides to the respective international soft law ("Nuremberg Code" of 1947, the Helsinki Declaration of the World Medical Association of 1964, including its numerous later modifications, the relevant recommendations issued by the organs of the Council of Europe and by the WHO, the UNESCO Declarations on the Human Genome of 1997, on the protection of genetic data of 2003 and on Bioethics and Human Rights of 2005). Research requiring permissions or opinions of Ethics Committees is related to human subject research and animal research. The respective international provisions are the following:

- Regulation on clinical trials on medicinal products for human use (2014/536/EU),
- Council Directive concerning medical devices (93/42/EEC),
- Directive on the protection of animals used for scientific purposes (2010/63/EU).

These international provisions have been transposed into national legislation. It has to be noted that the present Austrian legislation will need to be adapted according to the Regulation on clinical trials on medicinal products for human use (2014/536/EU). The process of adaption has started and will be finalised by spring 2016. As regards human subject research the consultation of an Ethics Committee is obligatory.

Animal research projects need to be approved by the respective national agencies in line with the Directive on the protection of animals used for scientific purposes (2010/63/EU).

Other issues such as dual use, data protection, Environmental Impact Assessment, or GMOs are regulated by specific provisions. These provisions do however not particularly focus on research. The related procedures are not performed by Ethics Committees.

Next to legal frameworks there are guidelines which apply, especially in the field of medical research: the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)-Guidelines on "good clinical practice", the guidelines of the OECD on Human Biobanks and Genetic Research Databases and the Charter for Researchers issued by the European Commission, which can be regarded forming part of national policies in relation to ethics assessment.

The public research and innovation system is presented in this report in respect to the higher education system, policy advisory bodies, and platforms for standard setting, funding organisations, and the funding of universities, and research performing institutions.

The highest state organ for the university sector is the Federal Minister of Science, Research and Economy. For the universities, a governance system was introduced comprising of three-year performance agreements and global budgets between the universities and the federal authorities in 2002. Policies in regard to ethics assessment mainly concern research integrity and good scientific practice. For the implementation of research integrity and good scientific practice most universities have elaborated individual guidelines. There is no common system for how implementation of guidelines of good scientific practice is secured, as this depends on the legal quality of these guidelines, which differ between the different universities due to their autonomy. As regards ethics the latest three-year performance agreements between universities and the Federal Ministry contain the obligation of setting up non-statutory Ethics Committees at universities.

The qualitative research performed in the framework of this report based in interviews shows that the non-statutory Ethics Committees are regarded as an additional track to peer review. The difference in regard to peer-review is that the Ethics Committees evaluate projects from different angles. The impact of the Ethics Committees relate on the one hand to awareness raising and on the other hand to making the projects better through interdisciplinary dialogue. In case research is concerned in which it is not totally clear form a legal point of view whether it is ethically problematic or not, the view of the



Ethics Committee adds to its "legalization" respectively "acceptability". As regards procedures a shared ethics approach enshrined in the legal system is not regarded as desirable. The legal system could provide for some procedural issues such as the fixing of quotas within the Committees.

The major policy advisory bodies for research and innovation are the *Austria Science Board* providing guidance to the respective Minister and the universities relating to matters of universities and the Austrian R&D system and the *Austrian Council for Research and Development*, which is the central advisory body for research, technology and innovation of the federal government. It can be considered as a standard setting body for research, technology and innovation.

In addition policy makers, implementing institutions and other actors of the Austrian Science and Innovation System have taken joint initiatives to encourage better and more transparent strategic planning and evaluation of research and innovation policies in Austria and to develop a culture of evaluation. The respective initiatives are the *Platform for Research and Technology Policy Evaluation* and *Technology – Innovation – Policy Consulting*. Ethics assessment has however not been a particular focus in this field.

Research funding is provided for by the Austrian Research Promotion Agency, and the Austrian Science Fund. Besides that, individual ministries fund high level research on project level, such as the Federal Ministry of Science, Research and Economy, and the Federal Ministry of Transport, Innovation and Technology.

The Austrian Research Promotion Agency and the Austrian Science Fund do not have individual Ethics Committees for project selection, as they rely on ethics clearance of universities, where the projects are implemented.

Ethical issues at the Austrian Research Promotion Agency are taken into account at programme level rather than at project level. The gender aspect was e.g. introduced into all programmes in 2011. As regards open-access strategies the Austrian Research Promotion Agency is more hesitant than other organisations, as the projects are closer to the market than projects of other funding organisations. Innovations which are to have success on the market cannot be made public without any restrictions. As regards the inclusion of stakeholders in research itself the Austrian Research Promotion Agency is also very cautious, as in applied research, which is close to the market, there is potential conflict with EU state-aid rules. The question of compliance with EU state-aid rules is a permanent challenge for the Agency.

The Austrian Science Fund tackles ethical issues, such as the inclusion of society through individual programmes, such as the existing programme for science communication. In addition there are ideas about initiating a citizens' science programme. As regards gender aspects the Austrian Science Fund does not intervene in the recruiting practice of universities. As regards open access, the Austrian Science Fund has an existing strategy, which is being implemented at present encouraging and supporting leading Scientific Austrian Journals to provide open access to their publications.

As regards funding of the Austrian Federal Ministry of Science, Research and Economy ethics clearance is provided for by an expert committee in its Seedfinancing Programme in the framework of the Austrian Economic Service. The Ethics Committee of the Seedfinancing-Programme was established in 2012. The Ethics Committee can give ethics clearance, formulate ethics requirements, or can reject the proposal on ethical grounds.

In addition to universities, where a governance system was introduced comprising of three-year performance agreements and global budgets between the universities and the federal authorities, Austria has several research performing institutions. The major research performing institutions are the Ludwig Boltzmann Gesellschaft (LBG), the Research Institute of Molecular Pathology (IMP), Christian Doppler Society (CDG), Austrian Academy of Sciences / the Institute of Technology



Assessment, Austrian Institute of Technology, the Institute of Science and Technology Austria, the National Foundation for Research, Technology and Development.

On the basis of qualitative research based on interviews performed in the framework of this report, it can be summarised that research performing institutions in Austria perceive ethics as an integral part of research which is to be respected by the researchers. As basic research is often perceived as neutral, the question of responsibility becomes relevant when scientific findings are transformed into applications. As regards the inclusion of society into setting the research agenda, there are different approaches depending on whether the concept is a bottom-up or a top-down concept. Bottom-up concepts, as practiced by the IMP do not allow for participation of citizens, whereas top-down concepts relate to the need of the society militating for the inclusion of citizens in priority setting. The added value of open innovation processes relate to meeting and tackling of needs and problems of society. Other issues such as gender, open access, diversity, opens science or participation are usually not an issue.

Policies and initiatives to support ethics practices in private industry mostly concern *corporate social* responsibility (CSR). Austria transposed the Directive 2003/51 on the annual and consolidated accounts of certain types of companies, banks and other financial institutions and insurance undertakings into national legislation obliging joint stock companies and groups of companies to report on environmental and employee issues in their annual status reports. Austria has not elaborated an Action Plan on Business and Human Rights as advised by the UN Working Group on the issue of human rights and transnational corporations and other business enterprises. Neither has Austria committed to elaborating such an Action Plan.

The Austrian business council for sustainable development is Austria's leading platform for CSR and Sustainable Development. The council's most important activities are related to leadership on CSR and sustainability, exchange of best practices, knowledge transfer and education as well as the establishment and administration of a national CSR network. The council comprises about 300 Austrian companies, which have all adopted an internal branch specific CSR policy.

As an example the report presents the CSR strategies of three large Austrian companies: The OMV-Group, Borealis-AG, and voestalpina-AG. The section on the OMV-Group is also based on interviews, as an example for ethics assessment in industry. The research shows the OMV- Group has long been actively involved in sustainability management taking responsibility for the environment and the society and have now elaborated the resourcefulness strategy relating to education and development (skills to succeed-programme), environmental management (eco-efficiency-programme), new technologies (eco-innovation-programme), engagement for resourcefulness, sustainability controlling (development of indicators for resourcefulness and their evaluation), and diversity (internationality and gender-programme). The strategy of resourcefulness was elaborated to install sustainability in the shared value chain of the OMV-Group focussing on human resources and natural resources and to mark a new approach in contrast to CSR, which is strongly connected to charity in public perception. The resourcefulness strategy is implemented through Management by Objectives. One target per employee has to relate to the resourcefulness strategy. Targets are evaluated and are connected to a financial bonus system. It has to be noted however that the resourcefulness strategy only relates to the internal functioning of the OMV-Group. The principles of the resourcefulness strategy do not manifest themselves in the industry's position on ethics/CSR on a more global level e.g. emission trading, as repeatedly taken by the Austrian Chamber of Commerce.

There are a number of Austrian associations for the various research and innovation professions, which vary in their level of involvement in ethics assessment. Some associations are merely focusing on enhancing their members' career opportunities within the profession. Other organisations, especially in the field of medicine, also engage in the elaboration of guidelines or recommendations e.g. the Austrian Association for Internal and General Intensive Care and Emergency, the Federation of Austrian Societies for Intensive Care Medicine, the Austrian Association for Anaesthesia, Reanimation and Intensive Medicine, the Austrian Association for Reproductive Medicine and



Endocrinology. The guidelines do per se not have a legal status, but they are helpful in determining national standards; in case of court proceedings, they can play a decisive role in order to determine the "lege artis" criteria.

Austrian CSOs are very active in engaging in public discussion, particularly in the field of environmental protection, animal rights, human rights, and patient / disabled organisations. Due to the fact that Austria has a tradition of consensus politics, governmental policies are usually pre-discussed with CSOs. Stakeholders can therefore actively participate in the forming of governmental action.

In summary, ethics assessment in its various forms including policies in the fields of human subject and animal research, environmental impact assessment, data protection, dual use, GMOs, research integrity, or corporate social responsibility, are well developed in Austria.

A clear institutional and procedural set-up is present in all those fields, which are covered by legislation (human subject and animal research, environmental impact assessment, data protection, dual use, GMOs), based on common rules of the European Union.

As regards research integrity, ethics assessment in the humanities and corporate social responsibility, the approach is less homogeneous manifesting itself in the fact that there is a soft law approach towards these issues. At present the respective institutions, as the qualitative research has shown, do not support the idea of institutionalising/legalising ethics assessment. In can however be expected that in the future common procedures will be established for ethics assessment in those areas.