Ethics assessment and Guidance in Different Types of Organisations

Universities

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Annex 3.e
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
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Contents

1   Introduction

The aim of this report is to analyse and compare how ethics assessment and ethical guidance of research and innovation is performed by universities in the European Union, the United States and China. The report is based on online and offline documentation, previous published reports, and interviews with representatives of organisations in ten different countries and at the EU and global international level. Eight representative European countries have been singled out for in-depth study, including seven EU members and one candidate for EU membership: Austria, France, Germany, the Netherlands, Poland, Serbia (EU candidate country), Spain and the United Kingdom. In the report, it will be investigated how universities are organised in these countries, in China, the US and at the EU and global international level. The situation in other EU member states and candidate countries will be considered as well. It will be studied how organisations of this type are institutionally embedded, how they perform ethics assessment and guidance and with what aims, and what are the perceived strengths and weaknesses of their participation in ethics assessment and guidance.

Ethics assessment, in the context of this report, is any kind of assessment, evaluation, review, appraisal or valuation of research or innovation that makes use of ethical principles and criteria. Ethical principles are criteria that aim to determine whether certain actions or developments are right or wrong. They define individual rights like rights to freedom and privacy, and include principles of justice and principles that say that harms to individuals and society should be avoided and benefits for them should be promoted. Ethical guidance is different from ethics assessment in that it does not concern an evaluation of practices and products of research and innovation that have already occurred, but rather presents rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere.

Globally, universities are arguably the most important research institutions and educators of new researchers. Their importance for society cannot be overstated: universities "play a central role in the development of society, the economy and culture, at every level – global, regional, national and local".[1] According to the European University Association, universities in Europe are

> key stakeholders in building the European Research Area: they play the major role in supplying trained researchers; they encompass diverse missions in basic and collaborative research; they have the capacity to foster interdisciplinary research skills and expertise; they are embedded in cities and regions as key components of social and economic development; and, not least importantly, they are focal points for dialogue and knowledge exchange with citizens and society.[2]

Certain types of research at universities are subjected to national ethics regulation procedures (depending on the scope of these regulations in a particular country). Furthermore, many universities consider ethical assessment as a part of research and educational excellence. For these reasons, they establish ethical policies, codes and committees and provide ethical

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[1] http://www.iau-aiu.net/sites/all/files/Bucharest_Dec_0.pdf.
[2] http://www.eua.be/eua-work-and-policy-area/research-and-innovation.aspx.

courses and trainings. In many countries, as will be discussed in Section 3, legally recognised research ethics committees are affiliated with universities.

This report begins with brief description of institutional characteristics of universities, associations of universities and accreditation agencies. Section 3 then discusses the aims of ethics assessment and ethical guidance at universities and related institutions. Sections 4 and 5 present institutional setups and procedures for ethics assessment. Section 6 discusses ethical principles upheld and ethical issues addressed by universities. The final section gives an account of problems faced by ethics assessors at universities and their expectations for future developments. The Annex provides detailed information on specific surveyed institutions.

2 Universities: basic characteristics and distribution

Universities are higher education and research institutions. First universities appeared in medieval Europe with the University of Bologna, founded in 1088, considered to be oldest. The university was established as "a community of teachers and taught, accorded certain rights, such as administrative autonomy and the determination of curricula (courses of study) and of the objectives of research as well as the award of publicly recognised degrees."[3] Its European origins aside, the university has developed into a global institution, present all over the world. The number of universities varies according to the size of the country and its population, e. g. there are nearly 400 universities in Germany compared to four universities in Slovenia.

Most universities combine education with research, although the so-called "research universities" place special emphasis on research and innovation. Typically, universities cover a wide range of fields and disciplines and are divided into faculties, departments or similar units accordingly. However, some universities focus on specific fields only. Many universities establish specialised institutes for research in particular disciplines. Some universities are public, while others are privately funded; some are free for students, while others charge tuition fees – these characteristics depend largely on the legislation, regulations and policy in individual countries.

For the purposes of mutual cooperation, universities have established associations at the regional, national and international levels. Some examples:

- Association of Universities in the Netherlands (VSNU)
- German Rectors' Conference (HRK)
- Association of Commonwealth Universities (ACU)
- Federation of Universities of the Islamic World (FUIW)
- Association of African Universities (AAU)
- European University Association (EUA)
- International Association of Universities (IAU)

Associations represent the interests of universities in relation to governments, formulating common positions and campaigning for higher education and research policy solutions. A more comprehensive list with links to organisations' websites can be found on the IAU's website.[4]

Universities all over the world require accreditation for its education programmes. Regulations and types of institutions that provide such accreditation vary greatly in different countries.

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[3] Walter Rüegg, "Foreword. The University as a European Institution", in: A History of the University in Europe. Vol. 1, Cambridge University Press, Cambridge 2012, p. xix.
[4] http://www.iau-aiu.net/content/university-associations.

3   Ethics Assessment by Universities: prevalence and aims

Motivations for ethical considerations of research and innovation at universities come from external and internal sources. On the one hand, external obligations under national and international regulations, and to funders and academic publishers might mean ethical approvals of research projects is required. On the other hand, many universities believe ethical awareness can enhance the excellence of their research.

While it is common for universities to include research ethics or at least research integrity-related provisions in their general codes of conduct, more and more universities are establishing more specific codes of ethics or even more integrated ethics policies. This entails the establishment of research ethics offices, providing guidance for students and researchers, and research ethics committees, assessing individual project proposals. Ethics is also being integrated into the educational process through courses and trainings. Ethics committees are becoming the central organisational form of ethical activities at universities. These committees are often in charge of developing and implementing ethical guidelines, assessment protocols and training programmes for staff and students.

As research institutions, universities are subject to the general ethical assessment system and regulation in a country. In some countries this entails that some university research projects are reviewed by external ethical committees, depending on research regulation in each county. Nevertheless, many universities establish their own research ethics committees (RECs), guidelines and protocols to complement external review. These committees often have a guidance role and their advice is non-binding. In fields not covered by a national review system (as is often the case in non-medical research), university committees may act as replacements for the external review and have the power to stop ethically inappropriate research from being carried out. In some countries, however, ethical assessment is officially assigned to research ethics committees at the institutions where research takes place. In these cases, internal assessment by a university's research ethics committee is obligatory and binding.

In Germany, 33 out of 53 officially recognised research ethics committees are attached to faculties of medicine and universities.[5] These RECs are responsible for ethical review of research involving humans at the university under *Länder* laws. Similar system is in place in Austria, where there are 3 university RECs at medical faculties. For example, the Ethics Committee of the Medical University of Vienna approves clinical research projects carried out at the university and the Vienna General Hospital. All publicly or privately funded research projects (involving human subjects) have to be submitted to the Ethics Committee.[6] In Poland, the Medical Profession Act assigns ethical assessment of biomedical research projects to biomedical committees at the institution where the research is taking place.[7] Binding assessments are also provided in some other fields, as in the case of the Ethics Commission at the Department of Social Psychology of the Faculty of Psychology at Warsaw University.[8] There is a similar situation in Spain: research ethics committees, conducting ethical

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[5] http://www.eurecnet.org/information/germany.html.
[6] SATORI interview with a Committee member.
[7] http://www.eurecnet.org/information/poland.html.
[8] SATORI interview with a Committee member. See Annex.

assessment of human subject research at universities are associated in the Network of Ethics Committees in universities and public research centres.[9] In Serbia, ethical assessment is also taking place at research institutions, including universities. Some committees, like the Professional Ethics Committee at the University of Belgrade, mostly deals with integrity issues, such as plagiarism.[10] In the United States, Institutional Review Boards are established at universities to assess research projects under licence and regulations by the Food and Drug Administration and Department of Health and Human Services. Many of these committees also provide ethical training and advice at their universities. Medical universities in China started establishing ethics committees at the start of this century, following new clinical practice regulations issued in 1998.[11]

In other countries, the role of university ethics committees is dependent on universities' own regulations. In universities across the UK, externally assessed projects do not require additional internal assessment, which is nevertheless frequent. As stated on the website of the Central University Research Ethics Committee (CUREC) at the University of Oxford:

> The University does not wish to duplicate the machinery that already exists for review of such research and will accept as properly sanctioned all research that has received approval from the National Research Ethics Service […] The University has, however, established machinery to deal with other research involving human participants [...] It is now the expectation – and in some cases formal requirement – of funding bodies that all research involving human participants is subject to an ethical review process.[12]

At King's College London, the College Research Ethics Committees reviews all research involving human participant (including social sciences, humanities and arts), except for those that are legally subject to external review. "Research, involving human participants, is increasingly affected by governance and regulation. The ethics application process is designed to help researchers navigate these requirements. The College is committed to ensuring its researchers adhere to high ethical standards. This is to protect both participants and researchers."[13]

University RECs play a similar role in the Netherlands, where they review research not legally needing external review – which is especially the case in social sciences.[14] For example, the ethics committee at the Faculty of Behavioural, Management and Social Sciences at the University of Twente provides non-binding assessments on request by the researchers.[15] In some cases, university RECs review projects prior to being submitted for external review. University RECs in Austria – other than the above-mentioned ones at major medical faculties – provide ethical assessment on a voluntary basis. Members of such RECs have claimed in interviews for SATORI that some researchers acknowledge that considering ethical issues in an interdisciplinary debate has added value in comparison to scientific peer review and makes research projects better. Their aim is also to improve awareness of ethical issues at their

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[9] http://www.ub.edu/rceue/index2.htm.
[10] SATORI interview with a Committee member. See Annex.
[11] SATORI China country study.
[12] http://www.admin.ox.ac.uk/curec/introduction/
[13] http://www.kcl.ac.uk/innovation/research/support/ethics/about/index.aspx.
[14] SATORI case study on ethical assessment in the Netherlands.
[15] SATORI interview with a Committee member.

faculties and provide ethical assessment if requested by funders and academic publishers. Such a guidance and advisory role is also taken up by university committees in France. Ethics Committee at the Aix-Marseille Université has a mission to respond to questions by researchers and others on ethical issues they face at research work. The Committee offers a platform for interdisciplinary discussion and reflexion on these issues.[16]

National universities associations often take on the role of ethical guidance. The Association of Universities in the Netherlands (VSNU) has published four codes of conduct: on personal data, scientific integrity, animal experiments, and good governance. VSNU also ensures that institutions come together to agree common regulations of ethics assessment, for example the appointment of an ombudsperson to deal with issues of scientific integrity.[17] Universities UK was, along with the UK government and research funding agencies, responsible for the development of the Concordat to Support Research Integrity that provides a single framework to underpin the integrity of research in all disciplines and helps coordinate activities to support it.[18]

International associations of universities have a similar role. The League of European Research Universities (LERU) participates in ethics discussions on the EU level and has a working group on ethics.[19] LERU published "Agenda for Ethics Research in Horizon 2020".[20] The document claims that ethics is essential to responsible R&I and presents proposals for its implementation. LERU promotes the integration of ethical considerations and awareness at an early stage of the research process and advocates for a multidisciplinary approach. The International Association of Universities (IAU) established a Working Group for Ethics in Higher Education in association with Magna Charta Observatory (MCO). The group developed the Guidelines for an Institutional Code of Ethics in Higher Education. The Working Group advises on

> overall strategic directions to be pursued to increase the visibility and use of the Guidelines by institutions of higher education. It is also invited to propose new and alternative actions that IAU could undertake to support its Members in this policy area or to continue the discussion of ethics-related issues. More specifically, the Working Group provides recommendations on how IAU could assist its Member institutions make the best use of the Guidelines to develop, improve or strengthen their policies. The Working Group is also expected to make recommendations on other, related activities that might be undertaken to promote ethical conduct and to improve understanding the ethical challenges[.][21]

In general, the aims of ethical assessment and guidance at universities and university associations are the following:

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[16] http://recherche.univ-amu.fr/public_content/comite-dethique-daix-marseille-universite.
[17] See SATORI case study on ethical assessment in the Netherlands.
[18] http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx#.VVyRQPmqqko.
[19] http://www.leru.org/index.php/public/activities/working-groups/.
[20] http://www.leru.org/index.php/public/news/leru-publishes-an-agenda-for-ethics-research-in-horizon-2020/.
[21] http://www.iau-aiu.net/content/working-group-1.

- To ensure that research, conducted at a university, is in line with national and international standards and regulations, as well as with publishers' and funders' requirements by providing in-house ethical assessment of research projects;
- To provide internal ethics assessment in fields and disciplines (especially in non-medical research), where the assessment is not fully institutionalised and there are no obligatory external assessing procedures;
- To offer ethical guidance in the form of general ethical codes or advice on requests made by the institution or individual researchers;
- To promote high ethical standards and ethical debate among their employees and to integrate it in the educational process through courses or trainings.

Accreditation agencies may consider ethics-related activities as a part of higher education programs evaluation frameworks. For example, the European Qualification Framework (the so called Dublin Descriptors) require attention in the curriculum to training in reflection on ethical and social issues and responsibilities of knowledge, gained at education programs.[22]

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[22] SATORI Interview with NVAO representative.

4   Institutional Setup of Ethics Assessment

The level of institutionalisation of ethics assessment at universities varies greatly across different countries and particular universities. While it is common for universities to adopt codes of conduct with provisions referring to research integrity and defining misconduct, a significant number of universities are yet to establish research ethics policies (defining aims, values and procedures of ethics assessment at the university e.g. Oxford University's "Policy on the Ethical Conduct Of Research"[23] or London School of Economics' "Ethics Code"[24]) and committees.

Institutional forms of assessment range from independent ethics committees at individual faculties and departments to central university-wide committees and research ethics offices. Central ethics committees are responsible for designing ethics policies and procedures as well as managing ethics assessment at the university. Central committees usually delegate assessment to faculty committees, sub-committees or panels in order to properly address discipline-specific issues.

E.g.: Subcommittees and panels of College Research Ethics Committee (CREC) at King's College London:[25]

- Psychiatry, Nursing & Midwifery
- Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences
- Social Science & Public Policy, Law, Arts & Humanities and KLI
- Arts & Humanities Research Ethics Panel
- Law Research Ethics Panel
- Education & Management Research Ethics Panel
- Geography, Social Science, Health & Medicine Research Ethics Panel
- War Studies Group Research Ethics Panel

Research ethics offices (e.g. at King's College London[26]) are established to provide expert advice on application procedures to researchers and students, applying for ethics assessment of their research-project proposals.

Members of university research ethics committees are usually appointed by the universities' governance bodies and include professors and researchers at the university, chosen for their knowledge in the field and/or experience with ethical issues. A variety of disciplines within the field of the research being assessed may be represented in committee membership, alongside lawyers, philosophers/ethicists and theologians. Lay members or patient representatives (in the case of university hospitals) are often included to ensure independence. Some universities also include student representatives. Some examples of university RECs' memberships are listed below.

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[23] http://www.admin.ox.ac.uk/curec/policystatement/
[24] http://www.lse.ac.uk/intranet/LSEServices/ethics/home.aspx.
[25] http://www.kcl.ac.uk/innovation/research/support/ethics/committees/index.aspx
[26] http://www.kcl.ac.uk/innovation/research/support/ethics/about/office.aspx

CREC at King's College London:[27]

Members (appointed by or on behalf of the Academic Board):

- Chairman
- 7 academic members
- 2-3 lay members
- Student Member
- Chairs of CREC's subcommittees (Ex-officio members)

Permanent Invitee:

- Director of Research Management
- Director of Research Grants & Contracts
- Senior Assistant Registrar Research and Graduate School Support

In attendance:

- Research Ethics Team Leader (Secretary)
- Officers of the CREC's subcommittees

Medical University of Vienna's Ethics Committee:

Members are chosen by the Chair of the Committee and have to be nominated by the Senate of the Medical University. The Ethics Committee of the Medical University of Vienna consists of specialists and of various medical disciplines and of lawyers, pharmacists, statisticians, and representatives of nursing, patient advocacy, disability representation and pastoral care.[28]

University of the Basque Country: Committee on Ethics in Research and Teaching, comprising three subcommittees: Research Involving Humans; Animal Experimentation; Research with Biological Agents and Genetically Modified Organisms

The committee's members are Teaching and Research Staff and Administration and Services Staff. The election system has been recently changed and the committee's composition follows the relevant laws. The committee for human research includes teachers, jurists, experts in data protection, geneticists and other specialists. The committee for GMOs includes microbiologists, neuroscientist and other specialists. The secretary is common for all three committees. The renovation of members is made through an open call. From all candidates the committee selects three, with a recommendation, to the rector.[29]

Apart from ethics assessment itself, universities often include faculty departments (deontology departments at medical faculties, ethics departments etc.) or found research centres devoted to research ethics and offer courses on research ethics within various study programmes. For example, the Centre for Advanced Study in Bioethics, at the University of Münster, was set up to provide "in-depth discussion on the basic principles of plausible norm foundation in

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[27] CREC Constitution.
http://www.kcl.ac.uk/innovation/research/support/ethics/storeddocs/2Committees/1CREC/1CURRENTCRECTermsofReferenceJan2012.pdf
[28] Interview for SATORI.
[29] Interview for SATORI.

bioethics".[30] The International Centre for Ethics in the Sciences and Humanities (IZEW) was established at the University of Tübingen.[31]Another example is the Centre for Research Ethics & Bioethics at the University of Uppsala, Finland. The Centre investigates "ethical, philosophical and legal aspects of biomedical research and clinical practice within the format of multi-disciplinary research projects" and offers research ethics-related courses.[32] The Centre for Bioethics at Harvard Medical School has designed a platform for integrating ethics and scientific discovery, and for generating collaboration among students, scientists, clinicians and bioethicists, which enables a collaborative exchange of disciplinary perspectives on ethical challenges.[33] The Centre comprises several ethics boards and committees, evaluating protocols for research ethics assessment, institutional guidelines and policies. A community ethics committee, consisting of members of the informed public allows for inclusion of a wider array of stakeholders in the ethics discussion. The Centre also provides ethics courses for all medical students of the School.

National cooperation between universities can take the form of national associations or rectors' conferences. National associations of universities do not assess individual projects, but they often take on the important standard setting and ethical guidance role. Associations usually form steering committees or working groups – members are representatives of member universities – to work on ethical codes and guidelines. VSNU, the Dutch association, represents universities vis-à-vis the Dutch government and formulates policies and standards for several issues, common to the universities.[34] VSNU has developed 4 codes that discuss ethical issues: the codes for use of personal data, scientific integrity, animal experiments and good governance.[35] Most of these issues are taken up by the Steering Committee on Research and Valorisation. Ethical issues are discusses by the VSNU when there is a bottom-up need address the issues or upon request by the government.[36] Another example is the Universities UK (UUK), a representative organisation for universities in the UK that aims to provide "high quality leadership and support to our members, to promote a successful and diverse higher education sector".[37] Working with a range of stakeholders, UUK develops higher education policies and strives to influence the government policy.[38]

Cooperation between universities at the national level can also take place at an informal level. King's College London hosts the UK University Research Ethics Committees Forum, a platform for debate and experience exchange. Regular meetings are organised to encourage debate and spread new knowledge.[39] In Ireland, different stakeholders have organised a joint working group to draft a national approach to research integrity and ethics.[40] The working

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[30] http://www.uni-muenster.de/KFG-Normenbegruendung/en/.
[31] http://www.uni-tuebingen.de/en/facilities/zentrale-einrichtungen/international-centre-for-ethics-in-the-sciences-and-humanities.html.
[32] http://www.crb.uu.se/presentation.html
[33] SATORI interview with the executive director of the Center. All views are her own.
[34] http://www.vsnu.nl/
[35] http://www.vsnu.nl/gedragscodes.
[36] SATORI interview with a representative of the VSNU.
[37] http://www.universitiesuk.ac.uk/aboutus/whatwedo/Pages/VisionMission.aspx.
[38] http://www.universitiesuk.ac.uk/ABOUTUS/WHATWEDO/POLICYANALYSIS/Pages/default.aspx.
[39] http://www.kcl.ac.uk/innovation/research/support/ethics/training/ukurecforum.aspx
[40] "Draft Policy Statement on Ensuring Research Integrity in Ireland". http://www.iua.ie/wp-content/uploads/2013/01/Ireland-Research-Integrity-statement-Draft-2-03.pdf

group contains members from Irish Universities Association, Royal Irish Academy, Health Research Board, Science Foundation Ireland, Enterprise Ireland, Higher Education Authority, the Irish Research Council, and Quality and Qualifications Ireland.[41]

At the international level, the European University Association has a membership of around 750 universities. EUA gathers and disseminates information to members regarding best practices and facilitates mutual learning activities.[42] Research ethics has not emerged as a topic for EUA, although it has founded, together with the University of Bologna, the Magna Charta Observatory of Fundamental University Values and Rights (MCO). This body was established to defend the values and rights, set out in the Magna Charta of the European Universities, drafted in 1988. Its Council consists of "members, chosen among those playing a leading role in the defence of the fundamental university values".[43] As mentioned above, MCO collaborates with the International Association of Universities (IAU), which brings together 630 institutions from around the world. Established as an UNESCO-based organisation in 1950, it facilitates reflection and action on common concerns of its members.[44] The MCO and the IAU have established the Joint IAU-MCO Working Group on Ethics in Higher Education. Members include experts, representatives of member institutions and organisations.[45] Some associations, such as the League of European Universities (LERU), accept their members (and therefore members of the ethics working group) by invitation only. LERU's principle mission is to promote basic research at universities as an essential part of the innovation process and progress in society.[46] The association draws on its academic potential to impact research policy in Europe.

Accreditation agencies accredit higher education programs and most often operate at the national level. The Accreditation Organisation of the Netherlands and Flanders (NVAO) is an exception in this regard as it is a bi-national organisation. Nevertheless, university programs are evaluated and accredited according to national legislation and regulations. International frameworks, like the already mentioned Dublin indicators, can also be applied (as is the case with NVAO).[47]

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[41] http://www.iua.ie/research-innovation/research-integrity/#
[42] SATORI interview with a representative of EUA.
[43] http://www.magna-charta.org/default.aspx?lang=en
[44] http://www.iau-aiu.net.
[45] http://www.iau-aiu.net/content/working-group-1.
[46] http://www.leru.org.
[47] SATORI interview with a representative of the NVAO.

5   Procedures for Ethics Assessment

Many universities assess their own research projects and organise ethical guidance and training at their institution. Associations of universities provide national and international ethical guidance and strive to influence (inter)national research policies.

At some universities, an ethical approval is obligatory for certain kinds of research. Universities' research ethics offices provide application forms and checklists, and general guidelines and advice to help their researchers and students. In some countries, it is important to first ascertain whether the assessment is by a university committee's authority, or whether an external review is obligatory. The review procedure then depends on the identified level of risk. Low-risk projects do not usually require a full review.

In some countries, such as Germany and Austria, the law prescribes the establishment of a university REC for review of biomedical research. The Medical University of Vienna's Ethics Committee takes into account the European directives regarding ethical review, national laws, and the soft laws.[48] The submitted documents are sent anonymously to external evaluators for assessment according to criteria of the Helsinki Declaration. Decisions are then made at the committee meetings and are obligatory. Before becoming an independent university, the Medical University of Vienna was a faculty at the University of Vienna. The faculty's ethics committee served as an ethics committee for the university as a whole. After the separation, the University of Vienna established a new ethics committee.[49] This committee – which does not assess biomedical research – was established based on the University's Statute rather than the law. Ethics assessment is not obligatory, but researchers can ask for ethics review of individual projects when ethically relevant aspects are touched upon in their work and they wish to ensure that their research projects adequately respect the fundamental values of human dignity, liberty and health and do not violate legal provisions. The decision of this Ethics Committee is non-binding. The comparison of these two committees is indicative of the two types of ethical committees usually found at universities: the ones authorised by national regulations on biomedical research and the ones established by universities on their own initiative, assessing research in other fields.

Associations of universities do not perform ethical assessment of particular projects. Their role is, rather, a guiding one. They provide voluntary ethical codes and guidelines, advise on procedures, issue statements on current issues, or organise awareness campaigns.

In the Netherlands, VSNU formulates policies and standards for issues that universities can agree on.[50] VSNU works to find out what are the areas with sufficient commonalities for actual representation and scientific integrity is typically seen as a common concern. In general, they look for a common denominator that is sufficiently shared by the members. The members of the steering committees assume responsibility for agreeing frameworks and approaches upon which each university can base its policies. The codes of conduct and guidelines prepared by the steering committee need the approval of the general assembly. The rectors meet and discuss their policies and try to find common grounds. Scientific integrity

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[48] SATORI interview with a Committee representative.
[49] SATORI interview with a Committee representative.
[50] SATORI interview report with a VSNU representative.

policy was first discussed at local universities; however, when it was deemed necessary to revisit the procedure at a higher level, it was transferred to the VSNU.

The Joint IAU-MCO Working Group on Ethics in Higher Education acted upon the fact that "there exists no international code or guidelines on ethical conduct for higher education institutions that articulates how, as institutions, they promote academic and scientific integrity and prevent academic dishonesty and unethical behaviour by actors and stakeholders that form the academic community".[51] The working group drafted the Guidelines for an Institutional Code of Ethics in Higher Education[52] at its meetings and then set out to provide assistance to universities to implement such guidelines at the local level.

From "IAU-MCO Guidelines for an Institutional Code of Ethics in Higher Education":

§ 4.1 It is necessary but insufficient for higher education institutions to elaborate and adopt an Institutional Code of Ethics. Higher education institutions need to go beyond declaring the values and principles they protect and promote by integrating these fully into their institutional strategies, curriculum, management processes and relations with outside stakeholders including international partner institutions, while continuously updating their Code and monitoring its application to ensure relevance and currency.[53]

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[51] http://www.iau-aiu.net/content/background.
[52] International Association of Universities and Magna Charta Observatory, *Guidelines for an Institutional Code of Ethics in Higher Education*, December 2012.
[53] Ibid., p. 6.

6   Principles and Issues for Ethics Assessment

The most universally accepted principles, considered to be fundamental to the "vocation of universities", can be found in the Magna Charta Universitatum,[54] first drafted by rectors of European universities in 1988 and currently signed by nearly 800 universities from around the world.[55] The document emphasises:

- the autonomy and freedom of universities;
- their social responsibility and cultural importance;
- the inseparability of teaching and research;
- rejection of intolerance and openness to dialogue.

The *IAU-MCO Guidelines for an Institutional Code of Ethics in Higher Education* refers to the following documents for the "universal core values that define higher education": the Constitution of the International Association of Universities,[56] the IAU's Policy Statement Academic Freedom, University Autonomy and Social Responsibility,[57] the Magna Charta Universitatum and UNESCO's Recommendation concerning the Status of Higher Education Teaching Personnel[58].[59]

While accepting cultural differences, the IAU-MCO Guidelines outline the following universal principles:

- Academic integrity and ethical conduct of research;
- Equity, justice and non-discrimination;
- Accountability, transparency and independence;
- Critical analysis and respect for reasoned opinions;
- Responsibility for the stewardship of assets, resources and the environment;
- Free and open dissemination of knowledge and information;
- Solidarity with and fair treatment of international partners.[60]

VSNU's "The Netherlands code of Conduct for Scientific Practice" is based on six principles:

- Scrupulousness
- Reliability
- Verifiability
- Impartiality
- Independence
- Responsibility[61]

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[54] Magna Charta Universitatum. http://www.magna-charta.org/library/userfiles/file/mc_english.pdf.

[55] http://www.magna-charta.org/magna-charta-universitatum/the-magna-charta-1/the-magna-charta

[56] http://www.iau-aiu.net/content/iau-statutory-documents.

[57] http://archive.www.iau-aiu.net/p_statements/af_statement.html

[58] http://portal.unesco.org/en/ev.php-URL_ID=13144&URL_DO=DO_TOPIC&URL_SECTION=201.html.

[59] International Association of Universities and Magna Charta Observatory, *Guidelines for an Institutional Code of Ethics in Higher Education*, December 2012, p. 2.

[60] *Ibid*.

[61] Association of Universities in the Netherlands VSNU, *The Netherlands Code of Conduct for Scientific Practice*, 2004 (2014), p. 4.

Individual universities often draft their own ethical codes and guidelines as they consider high ethical standards to be important for the excellence of their research and for the reputation of the institution. In some countries, state-accredited university RECs, usually established at faculties of medicine, follow national and international biomedical research legislation and regulation, based on the Helsinki Declaration, the Oviedo Convention etc. The scope of ethical issues tackled by ethical assessment and guidelines depends on the spectrum of scientific disciplines covered by an ethics committee. It can hardly be argued that university RECs follow a specific set of principles. These are rather dependant on discipline-specific standards and the general state of ethics assessment in a particular country.

http://www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The%20Netherlands%20Code%20of%20Conduct%20for%20Academic%20Practice%202004%20%28version%202014%29.pdf.

7   Problems and Developments

In SATORI interviews with university RECs' members a number of concerns were brought up.[62] This section briefly discusses the expressed opinions.

Universities and university associations, trying to establish a common ethics assessment framework across a variety of fields may face difficulties due to the differences between disciplines in relation to the same ethical issue or principle. This is why many universities establish different ethics assessment protocols in different faculties. Differences between countries also come into play in international projects. Calls have been made to establish an international ethics framework for universities, e.g. by IAU.

While ethicists at universities want to discuss research ethics in all its complexity, researchers feel ethics assessment is merely a yet another administrative burden. This is why some SATORI interviewees feel ethics should be embedded from the start of research projects and also be a part of a researchers' education. Ethical awareness should be raised and efforts made by universities not to reduce ethics to its restrictive dimension. In faculties and departments where ethics policies were recently established, researchers may be unfamiliar with ethics principles and assessment protocols.

In countries where ethics regulation is not established to a sufficient degree, university RECs risk resistance to their judgments. Some interview respondents complained of a lack of financial resources and allocated time to properly assess research proposals and monitor compliance.

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[62] More information on these interviews can be found in SATORI report on research ethics committees.

8   Annex: Ethics Assessment and Guidance in Specific Universities

This Annex contains five reports on particular surveyed organisations. For each organisation that was surveyed, basic data is provided about the organisation, its mission, structure, and role in ethics assessment and/or ethical guidance, and its procedures for assessment and guidance.

Two national and two international university organisations were interviewed, along with two accreditation organisations and an ethics centre at a university. Findings from 13 interviews with university RECs' representatives are included in this report, although reports on these institutions are included in the chapter on research ethics committees.

Country/Region	Name in English	Organisation type
The Netherlands	Association of universities in the Netherlands (VSNU)	National association of universities
European	European University Association	International association of universities
The Netherlands	The Accreditation Organisation of the Netherlands and Flanders	Accreditation organisation
Serbia	Commission for Accreditation and Quality Assurance	Accreditation organisation
USA	Harvard Medical School, Center for Bioethics	University

Table 1: Surveyed organisations

Name of organisation	**VSNU - Association of universities in the Netherlands** (VSNU - Vereniging van Samenwerkende Nederlandse Universiteiten
Type of organisation	Association of universities
Country	Netherlands
Website address	General: http://www.vsnu.nl/home-english.html Main page(s) on ethics assessment: http://www.vsnu.nl/codes-of-conduct-en.html http://www.vsnu.nl/gedragscodes (page in Dutch on codes of conduct; more elaborate than English version) http://www.vsnu.nl/wetenschappelijke_integriteit.html (Page in Dutch on scientific integrity)
Basic description (organisation and mission)	The VSNU is the organisation of Dutch research universities. Its core aim is to represent the universities as a whole vis-à-vis the Dutch government, the ministry and other societal organisations. Its governing board is called the general board. The VSNU formulates policies and standards for issues that universities can agree on; for example on common standards on the labour policy. It is part of the work of the VSNU to find out what are the areas with sufficient commonalities for actual representation. In practice the VSNU is an important partner in national discussions on research agendas and educational policies. Nevertheless, in many domains the universities have independent positions. There is a fair body of issues that most universities agree with and in this respect they are represented by the VSNU.
Interest in research and innovation	The VSNU, representing Dutch research universities, has a strong focus on research and innovation.
Ethics assessment and/or guidance	Assessment [ ] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [x] Commentary: The focus of the VSNU is on ethical guidance, not assessment. Policies, directives, codes, reports and evaluations relating to ethical guidance can be developed by the VSNU itself or delegated to committees, after which the VSNU board has to approve.
Terminology for ethics assessment / guidance	The VSNU does not much refer to "ethics" or "ethical guidance", but does refer to "scientific integrity" and "codes of conduct".

Name and description of ethics unit(s)	Most ethical issues relating to research and innovation are taken up by the Committee on Research and Valorisation ("Stuurgroep Onderzoek & Valorisatie"), http://www.vsnu.nl/srv-en.html. This steering committee advises the general board on research and knowledge transfer issues and policies.
	The steering committee has several tasks: to promote quality and integrity of scientific research and contribution of research for social and economic development. Dealing with ethical issues (common good, social integrity, codes of conduct of various kinds) is part of its task.
Aims and motivation for ethics assessment	Ethical guidance is undertaken when there is a bottom-up need to address such issues, or when government puts pressure on VSNU to address them. There is no specific mission statement or protocol that dictates that ethical issues should be addressed by the VSNU.
Objects and scope of assessment	Ethical issues that the VSNU has dealt with in the past include scientific integrity, the use of personal data in scientific research, and ethical issues in relation to good governance of universities and animal testing.
Beneficiaries of assessment	The codes and policies of the VSNU regarding ethical guidance are meant for university boards and research groups and individual researchers at universities. Sometimes the beneficiaries can also include the government which has requested a certain issue to be addressed by VSNU.
Ethics assessment unit: appointment process	The formal task of the steering committees of the VSNU, including the Committee on Research and Valorisation, is to prepare advice for the general board. Members of steering committees are members of the boards of the member universities (in theory there is a standing invitation for all university representatives, but in practice only the members of the committee meet and prepare advices and decisions for the general board). On the level of the general board, all universities are represented, either by the university chair or the rector. It is the institution that has a membership and can be represented by any of the members.
Procedure for ethics assessment: before	Usually the VSNU will only tackle questions of which the need of the issue has been clear in overall university matters – mostly in a reactive way. This approach reflects the "organisational personality" of the VSNU, while it is not seen as a joint resource for universities to develop policy up front but to raise local issues to the level of the common interest. If a local issue is recognised as common interest, the steering committee is asked to prepare an advice on it; such a process proceeds bottom-up. That is, unless issues are raised at the political arena. If the minister has a question, that might incite the other way for the VSNU to be set in motion.
Procedure for ethics assessment: during	The steering committees, Committee on Research and Valorisation, prepare guidelines that are focused on, or include, ethical guidance when the need for such guidelines arises. There is no set procedure for this. The members of the steering committees assume responsibility, be it that the decisions are made at the level of the general board meetings. This responsibility should not be situated on

	a practical or organisational level; rather in agreeing on frameworks and approaches on which each university can base its policies. This translates into the structure by which each university takes care of these things (ethical issues, scientific integrity). With regards to the decision-making procedures of the VSNU, sometimes issues are voted upon (e.g. labour policy). With most issues, however, one aims at consensus; which is a very "Dutch" approach. Organisations shy away for making decisions by means of shared majority rules. In general, one looks for a common denominator that is sufficiently shared by the members. The codes of conduct and guidelines prepared by the steering committee only come into existence on the approval of the general assembly. And the way they come into existence is by rectors coming together, bringing their local policies on the table and finding common grounds. Sometimes you have a "green field" approach, but then still the policy is to select opinion leaders, put them in a committee and let them write a set of recommendations.
Procedure for ethics assessment: after	After a decision has been made and guidelines or codes are published, universities should in theory act on them. In practice you can see that sometimes this does not happen. In such case, the mismatch is generally represented as "a matter of interpretation". However, this does not hold for very straightforward issues, as for example the issue of scientific integrity.
Principles and issues in assessment / guidance	[x] scientific integrity [ ] justice / fairness [ ] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [x] treatment of animals in R&I [ ] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [x] social responsibility Commentary: There are 4 codes of the VSNU that discuss ethical issues: the code for use of personal data, scientific integrity, animal experiments, and good governance. The code for scientific integrity also includes a paragraph on social responsibility. Having an independent ombudsperson dealing with questions of scientific integrity is part of the codes. The VSNU has stipulated that research ethics in the broader sense are included in educational systems as general guideline.

Self-assessments, strengths and weaknesses	One current point under development is research data policy; a topic under development that all universities should address. But they are intimidated by the complexity of the issue because of the different role of data in different disciplines. There are issues on how long research data should be available. But this does not take into account the volume of data (e.g. astronomers get a lot of data. What data can they get rid of; what should they keep?). This is also a matter of technology, dealing with what is technologically feasible.
	This is why everybody is a bit at loss with the issue of research data. Some things are straightforward, like the data from surveys with people (this is data you can keep; you can decide on how long and how to keep data anonymous – a lot of that is fixed by laws on personal data). Unlike social sciences, experimental sciences have data logs. Some of them are old-fashioned notebooks – so we need to translate it into a question: what is an electronic log? It's a difficult discussion.
	Even within a university, we can discern huge differences between communities. It seems to be the case that we either should make policy on very abstract principles, but then it is very weak, or policies with operational implications but then it's very local what you stipulate. All of these policies cost considerable resource to establish and maintain.
	Data research policies will require substantial administration, by researchers themselves. But also maintaining it will be a very challenging task. It is one of the areas where we can at some level of abstraction say what is desirable but at the level of practicality and elaboration it might be very difficult to implement it.
Other	(From interview with prof. dr. Ed Brinksma, former head of the Committee for Research and Valorisation)
	As said, there are 4 codes of the VSNU that discuss ethical issues: the code for use of personal data, scientific integrity, animal experiments, and good governance. For the everyday practice such codes might not be very useful documents. The current discussion revolves around the question how this should evolve. A list of laudable attitudes can be listed but either they are very obvious or too vague; at a sufficient level of abstraction everybody tends to agree with the principles.
	Having an independent ombudsperson dealing with questions of scientific integrity is part of the codes; all Universities should have such a body. It settles quite some things. There should be an ombudsperson whom can be approached and it is stipulated that this person cannot be the chairman of the central committee. There are also softer sides to this policy; it is advisable that the ombudsperson has senior experience in research but is not too much attached (e.g. professors emeriti). A local choice that is made here, as elaboration on the VSNU guidelines is to have an independent ombudsman for someone who is accused of scientific infringement. The Dutch national code does not stipulate anything in this respect.
	An important recent observation is that we should focus on some unification at the international level. We have observed that if we have international projects going on, there is no code in the case of infringement against scientific integrity.

In some parts of international agreements, like in legal documents, the court to go to is defined; but these documents also points out the necessity to align the codes. At the international level, there are quite a few procedures that need to be aligned. In the Netherlands these policies are defined by VSNU, in Denmark it has the character of a law. In some other countries there is nothing at all. We should aim for international convergence because we currently face a difficult situation. In the context of such discussions, we should also ask whether more complicated documents result in actual improvement.

Next to deciding on the codes of conduct, the committee spends most of its time on discussing and advising on research policies. Depending on the actual situation, research integrity has been a topic that has attracted attention, also because of scandals that were widely present in the media. There was a need for universities to respond on these scandals. Other ethical questions are dealt with if they occur. Animal experiments are a good example. There are guidelines in this respect, but activist movements sometimes necessitate discussions about these things.

Indirectly, when talking about scientific impacts, we are in a period during which we need to include social impact as one of the dimensions on which research is assessed. This research impact includes the quality control of PhD dissertations in which scientific integrity has become an important aspect. The VSNU has developed a set of performance indicators and there has been quite some discussion on how to broaden this apart from economic impact. This concern been a discussion in the steering committee, and we have been looking at the question how to accommodate and evaluate that? The results of this discussion are a good example of something that has become a framework; within the framework adopted by the VSNU the technical universities have adopted a more refined standard. Some research policies on the social impact of research are part of special domains. For example, in certain branches of research we should consult medical ethical committees.

With respect to ethical and research integrity issues there is a close link between the steering committee and the national conference of rectors – formally independent of the VSNU. This is a semi-formal organisation where the rectors of the Dutch universities meet and discuss important policy issues. There has been a period in which this conference was an integral part of the VSNU. This created some ambiguity in the governance structure, while it incorporated two important advisory bodies (if they did not agree, things became unclear). Consequently, the conference of rectors has been placed at a distance of the VSNU. In the ethical issues that are discussed there is a lot of synergy or synchronisation between the rectors' conference and the steering committee on research and valorisation.

Name of organisation	**European Universities Association (EUA) Council for Doctoral Education**
Type of organisation	European organisation representing universities (EU and international ethics assessment organisations)
Country	Pan-European
Website address	*General:* http://www.eua.be/cde/Home.aspx *Main page(s) on ethics assessment:* N/A
Basic description (organisation and mission)	The EUA has a wide membership base of around 750 universities across Europe and countries including Russia, Turkey and Kazakhstan. They use their wide membership base to gather evidence about topics that are important for universities and to disseminate information to members regarding best practice activities and other mutual learning activities, in addition to European developments which impact on members' activities. The EUA interacts with Science Europe and the Global Research Council, amongst other organisations. The EUA is different from other university networks as it represents the entire sector. However, the EUA is involved in dialogue with university networks. Moreover, the EUA spends time on building global networks and holds a biannual event with leaders of doctoral education. Research ethics hasn't emerged as a topic at these events. The respondent feels that this is a thorny issue (e.g. case of medical research and informed consent). The EUA does not offer its own set of guidelines regarding ethics but does facilitate events and opportunities to be more specific about the sharing of best practices. Work of the EUA Council for Doctoral Education: The EUA Council for Doctoral Education aims to contribute to the development, advancement and improvement of doctoral education and research training, in addition to internationalisation issues and the tracking of students and graduates. Currently, the Council is preparing a round of consultations on university trends such as monitoring the Bologna process, university-business collaboration, open access the mobility process and so on.
Interest in research and innovation	The EUA Council for Doctoral Education pursues the development, advancement and improvement of doctoral education and research training in Europe.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [ ] Commentary: N/A If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary: N/A As the EUA Council for Doctoral Education does not provide ethics guidance or

	carry out ethics assessment, it was not possible to go into any great depth on the topic of ethics.
Terminology for ethics assessment / guidance	N/A
Name and description of ethics unit(s)	N/A
Aims and motivation for ethics assessment	N/A
Objects and scope of assessment	N/A
Beneficiaries of assessment	N/A
Ethics assessment unit: appointment process	N/A
Procedure for ethics assessment: before	N/A
Procedure for ethics assessment: during	N/A
Procedure for ethics assessment: after	N/A
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [ ] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [ ] other, specify:

	[ ] social responsibility
	Commentary: N/A
	Ethical issues in doctoral education and research training: Ethics issues vary from plagiarism to data management, informed consent and animal welfare. Regarding ethics and research ethics in doctoral education and research training, the Council sees these issues "more and more". Institutions set standards and guidelines. Universities feel that they have a responsibility to inform researchers about ethics and researchers should apply advice/guidelines. High capacity universities also have high levels of awareness of research ethics.
Self-assessments, strengths and weaknesses	N/A
Other	N/A

Name of organisation	**NVAO - The Accreditation Organisation of the Netherlands and Flanders** (NVAO – De Nederlands-Vlaamse Accreditatie Organisatie)
Type of organisation	University or public research institute; standardisation, certification or accreditation organisation
Country	Netherlands
Website address	General: http://nvao.com/ (NL: http://www.nvao.net/) Main page(s) on ethics assessment: N/A
Basic description (organisation and mission)	The NVAO is a bi-national organisation, established by the Dutch and Flemish governments by treaty in 2005. It is charged with evaluating all educational programs in higher education in the Netherlands and Flanders. It has the formal power to accredit programs, which means to assess whether degrees in programs of public institutions are considered to have their supposed effects. It has as a consequence that the students in the programs are entitled to funding as well as the program as well. It has an important meaning for institutions in higher education. NVAO also does institutional audits in which it assesses the institutional quality system for educational programs, and it does assessment of distinctive (quality) features of programmes and institutions at the request of the relevant institution.
Interest in research	The organisation is focused on accrediting institutes and programs (bachelor, master) of higher education, many of which prepare for training for research

and innovation	and/or innovation.
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary: The NVAO does not normally evaluate whether institutes or programs act ethically, nor does it develop guidelines for this. It evaluates whether ethics training or attention to ethical issues is included in educational programs and institutions, if such inclusion of ethics is dictated by existing quality protocols. NVAO is not involved in formulating such protocols; they come from the professional field, from government, and from the European qualification framework for bachelor and master programs. In some cases the government thinks it is proper to set certain criteria; mostly within the notion of public trust, safety and health. For the rest one could generally say, the stronger the organisation of professionals is, the more influence they have on the programs.
Terminology for ethics assessment / guidance	Reference is made to "ethics" and "social and ethical issues/responsibilities" in evaluation frameworks.
Name and description of ethics unit(s)	No specific ethics unit. Assessment of inclusion of ethics training is undertaken as part of more general evaluations of program quality by visiting committees, panels of experts who review programs and institutions. The NVAO provides guidelines for the composition and operation of these committees, receives and assesses the reports of these committees. These reports are the basis of the final accreditation reports of the NVAO.
Aims and motivation for ethics assessment	Accreditation processes take inclusion of ethics training or attention to ethical issues by programs and institutions into account to the extent that protocols prescribe that they have to be included. The most general set of criteria for evaluating educational programs consists of the EU-level "Dublin Descriptors". These specify that bachelor students "have the ability to gather and interpret relevant data (usually within their field of study) to inform judgments that include reflection on relevant social, scientific or ethical issues" and that master students "have the ability to integrate knowledge and handle complexity, and formulate judgments with incomplete or limited information, but that include reflecting on social and ethical responsibilities linked to the application of their knowledge and judgments". In addition, individual protocols for particular disciplines that are used in accreditation may contain specific guidelines for inclusion of ethical issues in educational programs. Also, Dutch on higher education specifies that programs of public institutions should teach students to be aware of their environment and the social impact of their profession.
Objects and scope of assessment	Assessed are educational programs and institutions for their inclusion of ethics training and attention to ethical issues. This includes bachelors, masters and research masters. PhD programs are not considered education but as part of research career. The discussion on whether this should be changed is going on in

	the Netherlands though.
Beneficiaries of assessment	Programs and institutions of higher education; indirectly, the government who funds public institutions, or funders or privately funded programs, as well as the students at these institutions.
Ethics assessment unit: appointment process	The VSNU accredits institutions by means of peer-review. In collaboration with the institution and program, it assigns a committee of relevant experts that makes a report. Based on this report NVAO make its own decision on accreditation.
Procedure for ethics assessment: before	Programs and institutions are periodically accredited by Dutch law. The procedure begins with a self-assessment by the program or institution. The basic idea is that a program describes its own intentions and curriculum. It aims to show that the curriculum has good quality and that it is in line with the European qualification framework (Dublin descriptors) and with any individual disciplinary protocol that has been agreed on. This will include reference to ethics training.
Procedure for ethics assessment: during	The visiting committee checks whether programs meet their own ambitions and goals, based on the self-evaluation report and possibly an on-site visit. The committee is guided by the European qualification framework (Dublin Descriptors) and Dutch law on higher education, and by any individual disciplinary protocol that has been agreed on. This includes ethics training. The NVAO then considers the report of the committee, makes its own judgment, and then decides whether accreditation occurs or not.
Procedure for ethics assessment: after	If the accreditation is positive, the program or institution can continue its work. If it is negative, the program or institution is no longer accredited; it will have to make serious efforts to improve and win back accreditation, or it may lose funding or be closed down. The most important ethical problems at stake are violations of the principles in the Dublin Descriptors. It could be that if the committee visiting the program see that these elements are insufficiently represented. That would lead to a discussion between the program, the institutions and the committee to see that a more impropriate inclusion of these aspects can be included in the program.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [ ] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [X] environmental impacts [ ] human dignity [X] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing

	[ ] autonomy / freedom countries with lower ethics standards
	[ ] implications for civil rights [ ] dual use (possible military uses)
	[ ] implications for privacy [X] other, specify: see comment below.
	[ ] social responsibility
	Commentary: The Dublin Descriptors require attention in the curriculum to training in reflection on ethical and social issues or responsibilities (see "Aims and motivation for ethics assessment". Disciplinary protocols may specify additional requirements for ethics training. In addition, Dutch educational programs can ask for a special evaluation on the quality mark of "sustainability"; programs will then be evaluated on how well they pay attention to sustainability issues in their program.
Self-assessments, strengths and weaknesses	From interview with dr. Anne Flierman, chairman of NVAO: The accreditation committees can in practice neglect some of the criteria in the established protocols during the accreditation process. There is little assessment on whether or not the committees stick to these criteria; which might be a point for improvement of the accreditation process. Normally, committee members come from the education's field; it is not their first reaction to question the domain specific framework with respect to social and ethical concerns. In the domain specific frameworks in the science and engineering disciplines I'm afraid that social elements are not always included. But the committee that discusses this framework is in the first place focused on the content. Nevertheless, for the engineering sciences, committees are aware that engineering is not only a technical science any more but has to take into account the social and ethical concerns. With regards to ethics assessment, formally speaking, committees have to check the criteria in the Dublin descriptive. The question is whether they do take it into account sufficiently. In the Dutch law on higher education, it is mentioned that programs should teach students to be aware of their environment and the social impact of their profession. The interesting point is that this only applies to public institutions. For example, Islamic universities have an accredited program; and currently there is a discussion about whether these programs pay sufficient attention to the role of Imams in Western society. The minister considers including also non-public institutions in the law. They are subjected to the Dublin descriptive, but not in the law on higher education in the Netherlands. I look very critically at the rules concerning the attribution of distinctive criteria to programs. Legislation in the Netherlands gives institutions the ability to give a distinctive criterion, like a sustainability mark. When they ask for it, we ask the panel to look at the program and pay attention to this criterion in a sufficient manner. There is a standard for which criteria have to be met, if they do so they can call themselves a program with a distinction. The problem is that it is a bit of a fashion article. Quite a few institutions want to have this criterion and then I ask what does it mean. I don't think it indicates real differences between programs. I

	would advise the minister to abolish it. Elaborating on it would mean more bureaucracy and more paperwork. We are looking at the process in terms of how we can make it easier, getting rid of regulations.

In the Dublin Descriptors, sustainability is a form of social responsibility. It should be more explicitly included and it should say that sustainability should be a part of all programs. Some elements of sustainability should be part of the programs. The same goes for basic human rights; you cannot conceive of a program that completely neglects those. Not all European countries are already on the same level. |
| **Other** | N/A |

Name of organisation	Commission for Accreditation and Quality Assurance
Type of organisation	Accreditation organisation for universities – non-assessor
Country	Serbia
Website address	*General:* http://www.kapk.org
Basic description (organisation and mission)	The National council of higher education to deal with accreditation, quality assurance of higher education institutions and evaluation of study programs have set CAQA. The Commission is independent and functions on the principle of professionalism. Besides the implementation of the accreditation procedure and issue of licenses the Commission is proposing the following standards and procedures determined by the National council: standards and procedure of accreditation of higher education institutions; accreditation of study programs; self-assessment and quality evaluation of the higher education institutions. The Mission of Commission is to contribute to the maintenance and enhancement of the quality of Serbian HE, to comply with internationally accepted quality standards, to create a pool of trained reviewers for process of accreditation and external quality control and to act as a main driving force for the development of quality assurance in HE of WB countries by fostering cooperation between agencies in the region.
Interest in research and innovation	Check of scientific verification of PhD theses.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [x] Commentary:

If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ]

Commentary: |
| **Terminology for ethics** | N/A |

assessment / guidance	
Name and description of ethics unit(s)	The Commission doesn't have separate unit that deals with ethical issues.
Aims and motivation for ethics assessment	N/A
Objects and scope of assessment	N/A
Beneficiaries of assessment	N/A
Ethics assessment unit: appointment process	N/A
Procedure for ethics assessment: before	N/A
Procedure for ethics assessment: during	N/A
Procedure for ethics assessment: after	N/A
Principles and issues in assessment / guidance	[x] scientific integrity [ ] justice / fairness [x] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [x] other, specify: transparency [ ] social responsibility

	Commentary:
Self-assessments, strengths and weaknesses	N/A
Other	N/A

Name of organisation	**Harvard Medical School (HMS)**
Type of organisation	National university or public research institute
Country	USA
Website address	*General:* http://hms.harvard.edu/ *Main page(s) on ethics assessment:* http://bioethics.hms.harvard.edu/
Basic description (organisation and mission)	HMS is the graduate medical school of Harvard University and is one of the leading medical schools in the world. The faculty consists of over 12.000 persons. In the fiscal year 2014 HMS had revenue of $617 million.[63] HMS has had a long and distinguished history since being established in 1782.
Interest in research and innovation	HMS focuses on research in a great number of initiatives, programs and centres[64]. 15 researchers have shared in nine Nobel Prizes for work done while at HMS[65].
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: CfB provides both ethical commentary and states ethical guidelines for research and practices. If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	N/A
Name and description of ethics unit(s)	Centre for Bioethics (CfB) is a centre at and funded by HMS. The authority of the centre can be great, e.g. does research projects has to be approved by CfB.

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[63] http://hms.harvard.edu/about-hms/facts-figures
[64] http://hms.harvard.edu/research/initiatives-programs-centers-and-institutes
[65] http://hms.harvard.edu/about-hms/facts-figures

Aims and motivation for ethics assessment	The aims of CfB is to: • Teach ethics to medical students across the 4-year curriculum. • Support and strengthen the ethics programs at HMS teaching hospitals and affiliated facilities. • Prepare the next generation of practitioners and leaders in bioethics. • Address contemporary ethical issues in the biosciences and health care. • Engage the public in understanding and addressing ethical aspects of health care and new biotechnologies.[66]
Objects and scope of assessment	The objects of the assessments are proposed research projects, clinical practices and institutional practices, guidelines, policies and behaviour of researchers within HMS. CfB only teaches practitioners related to natural science, engineering, social science and humanities aspects of ethics related to their field.
Beneficiaries of assessment	The users of the ethical advise depends on the focus of CfB. They include medical researchers and students, hospital staff and other organisations (organisational ethics).
Ethics assessment unit: appointment process	CfB chooses their own staff. Employees typically have a professional degree in medicine or nursing, while also having some experience with regards to ethics. 68 people are associated with CfB[67].
Procedure for ethics assessment: before	CfB chooses their own research topics, but the recommendation of their "Research Ethics Committee" is mandatory for proposed research projects. This leads to proposed research protocols and designs are often adapted to reflect the advice of the research ethics committee.
Procedure for ethics assessment: during	CfB is designed as a platform for integrating ethics and scientific discovery, and for generating collaboration among students, bench scientists, clinical researchers, clinicians, practicing bioethicists, academic philosophers, humanities scholars and others. The purpose for each discipline is to collaboratively bring their diverse disciplinary perspectives to work, whereby CfB relies on their previous experiences instead of a fixed set of principles. Staff from the CfB goes on rounds in the ICU, whereby they are part of on-going ethical discussions regarding patients. CfB has consultations with stakeholders of the public. A "Community Ethics Committee" (CEC)[68], consisting of a diverse voluntary group of people, is in place. The committee meets once a month and consists of 18 members, who CfB corresponds with by email between their meetings. All teaching hospitals ethics committees can ask the CEC for input. The committee

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[66] http://bioethics.hms.harvard.edu/about-us
[67] http://bioethics.hms.harvard.edu/people
[68] See http://www.medicalethicsandme.org/ for more information on CEC.

	works on one particular subject at a time. The members receive readings from CfB regarding a subject. This leads to a survey of opinions, where the members can voice their understandings. The outcome of the survey is discussed in the group. The members can send to friends on Facebook in order to get an uninformed public opinion. The CEC are considered "informed public" as they get information before their survey, while the Facebook friends do not get any additional information.
Procedure for ethics assessment: after	The output of the work of CEC is a report on the subject of the survey. The reports are available online[69]. According to an interviewee, is a monitoring system of the recommendations and advice of CfB in place. While their clinical ethics advice is almost always followed, CfB have examples of policy recommendations within organisational ethics not being followed. The reason for the policy recommendations not being followed, are stated as lack of resources and the inertia of the existing institutional routines.
Principles and issues in assessment / guidance	[x] scientific integrity [x] justice / fairness [x] professional integrity [x] implications for health and/or safety [x] human subjects research [x] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [x] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [x] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [ ] social responsibility Commentary: CfB does not have a fixed set of principles but takes point of departure in their diverse group of employees' values and the values of the CEC. The above is found to be the key values of the CfB.
Self-assessments, strengths and weaknesses	Strengths: The strong integration of CfB into HMS must be seen as a strength of the center. An example of this is CfB participating at rounds in the ICU. Weaknesses: Ethical aspects are seen by the practitioners as something they have outsourced to CfB. The interviewee states the reason for this, is the workload and time pressure the practitioners face. The interviewee finds that moral decision-making is not easily efficient if conventional thinking is challenged. CfB is addressing this problem through capacity building by having ethics courses at

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[69] http://www.medicalethicsandme.org/p/publications-of-cec.html

	HMS. The interviewee notes that a general problem for research ethicists is to keep up with scientific developments (e.g. Neuroscience). The interviewee finds it impossible to give good ethical advice without understanding the science.
Other	The centre for Bioethics has interactions/collaborations with: • The Catalyst program (an institutional structure that covers all research ethics committees) • The Petrie-Flom centre for Health Law Policy, Biotechnology, and Bioethics at Harvard law school. • The Edmond J. Safra Centre for Ethics and the Professions, which "seeks to advance teaching and research on ethical issues in public life.[70]" • PRIM&R, Public Responsibility in Health and Medicine

[70] http://ethics.harvard.edu/pages/about