Ethics assessment and guidance in different types of organisations

Research Funding Organisations

Author: Doris Wolfslehner, Secretariat of the Austrian Bioethics Commission

Interview Contributors: C Martín Arribas & Leyre de Sola Perea, Instituto de Salud Carlos III
Marlou Bijlsma, Nederlands Normalisatie Instituut (NEN)
Lise Bitsch, The Danish Board of Technology Foundation
Erich Grießler, National Correspondent Austria, Res-AGorA
Agata Gurzawska, Xin Ming, University of Twente
Clare Shelley-Egan & Rowena Rodrigues, Trilateral Research & Consulting
Zuzanna Warso, Helsinki Foundation for Human Rights
Dubravka Vejnović and Dalibor Petrovic, Centre for the Promotion of Science (CPN)

June 2015

Annex 3.c
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
Deliverable 1.1

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI* - which received funding from the European Commission's Seventh Framework Programme *(FP7/2007-2013)* under grant agreement n° 612231

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 funding organisations in Europe, China, and the United States (US). The report is based on online and offline documentation, previous published reports, and interviews with representatives of organisations in nine different countries (seven European countries, China, and the US) and Institutions of the European Union (EU). Seven representative European countries have been singled out for in-depth study, including six EU member states (Austria, Germany, the Netherlands, Poland, Spain, United Kingdom) and one candidate for EU membership (Serbia). In the report, it will be studied how Research Funding Organisations are institutionally embedded, how they perform ethics assessment and with what aims, and what the perceived strengths and weaknesses are.

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 which state that harms to individuals and society should be avoided and benefits for them should be promoted. Ethical guidance is different from ethics assessment in so far, as 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.

Research Funding Organisations play an important role, as they add to the regular funds available at Universities and public or private research performing institutions. In relation to society, Research Funding Organisations play an important role through thematic programmes, which can and very often do focus on grand societal challenges, which can be tackled by researchers through the available funds.

The report will start with an overview of basic characteristics of the analysed Research Funding Organisations and will then analyse the prevalence and aims of ethics assessment in these institutions. The report will continue with an overview of the institutional set-up of ethics assessment and the respective procedures and will end with an overview of principles and issues for ethics assessment and reported problems and developments.

2 Research Funding Organisations: Basic Characteristics and Distribution

Research Funding Organisations support research activities through top-down or bottom-up programmes. In order to do so, they usually rely on the institutional set-up and infrastructure of universities or research performing institutions in the particular country. The funds are either public or private. Research funding is either managed by Ministries, usually the Ministry of Research, Economy, or Technology, agencies charged by the government, international institutions or private trusts.

Research Funding Organisations in Europe and the US have several categories of funding instruments for researchers. On the one hand they provide large-scale, long-term research

programmes focussed on specific targets or themes (top-down programmes). On the other hand they provide for collaboration between researchers or between researchers and other partners e.g. from the industry (bottom-up programmes).

Top-down programmes include e.g. the inclusion of society into research procedures,[1] knowledge dissemination and open access publication of research results,[2] covering of research themes tackling major societal issues identified through a consultation process between the government, civil society organisations and industry usually laid down in research programmes, or the realisation and use of large-scale infrastructure.[3] The added value of top-down research relates to the possibility of meeting needs of the society by implementing national research plans focussing, inter alia, on the collaboration between research and industry supporting competitiveness of the European economy.[4]

Bottom-up programmes cover curiosity driven research, support of individual researchers, or international collaboration and exchange.[5] Bottom-up programmes are usually steered by excellence, which can only be guaranteed by open calls.[6] Open calls allow a good insight into different research areas and can draw on the innovative potential of researchers.[7] Thus new lines of research emerge only when innovative research is encouraged.[8]

The aim of research funding in Europe, China, and the US relates to supporting ongoing developments of science and basic research at a high international level and to strengthening international performance and capabilities in science and research as well as the country's attractiveness as a location for high-level scientific activities, primarily by funding top-quality research projects for individuals and teams and by enhancing the competitiveness of the innovation systems and their research facilities.[9,10] One US organisation points to the fact that they have supported 145 researchers that have been sole or shared recipients of 85 Nobel Prizes.[11] Another key objective of research funding relates to contributing to regional development by ensuring access of the scientific and technological community to scientific-technological equipment necessary for the development of its research activities to ensure short and long-term stability and create the necessary synergies to optimise the transfer of research results to the productive sector.[12]

As regards areas of funding, priority areas cannot be identified within Europe, and the US. The areas covered range from agriculture and food security, industrial biotechnology and bioenergy, bioscience for health,[13] biomedical research, both basic and clinical research,

[1] Interview, 15.1.2015
[2] Interview, 3.2.2015
[3] Interview, 3.2.2015
[4] Interview, 3.2.2015
[5] Interview, 3.2.2015
[6] Interview, 15.1.2015
[7] Interview, 9.12.2014
[8] Interview, 3.2.2015
[9] Interview, 15.1.2015
[10] Interview, 23.1.201
[11] Interview, 10.3.2015
[12] Interview, 23.1.2015
[13] Interview, 31.10.2014

including research conducted with animals or chemicals,[14] research related to health-science and the wider humanities, and society and ethics, i.e. supporting research that explores the social and ethical aspects of health and biomedical science,[15] as well as to research in areas provided for by national research innovation policy, such as the Dutch research and innovation policy encouraging research in the following areas: Agro, Food and Horticulture, Connecting Sustainable Cities, Creative Industry, Cultural and Societal Dynamics, Healthy Living and High Tech Systems and Materials (e.g. in the fields of Scarcity, Sustainable Energy, Water and Climate).[16] Priority areas of funding in China could not be researched in the framework of this report.

3 Ethics Assessment by Research Funding Organisations: Prevalence and Aims

Ethics assessment is perceived as a pertinent question in all analysed funding organisations and has become an integral part of the project selection process.

The prevalence of ethics assessment in its various forms is high in Europe, China, and the US. The necessity of research being "perfectly clean" ethically-speaking[17] is recognised by funding organisations in order to achieve real research excellence.[18]

The focus within ethics assessment can however differ between organisations. One organisation, which does not carry out an impact assessment *per se*, is taking more of an interest in how the external ethics review process is being carried out and whether it is an impediment to research in some areas. The organisation has a new policy focusing on training of research ethics committees (RECs). The aim is to ensure that the RECs themselves are aware of the issues and know how to deal with them.[19] One organisation reports on its strategy of supporting researchers to include considerations in regard to thinking widely about ethical issues at an early stage.[20]

Those organisations, which report that ethics assessment can be foreseen depending on possible recommendations by the scientific experts in cases in which ethics assessment is not required for by law, point to the advantage of this system, as ethical issues in their broadest sense can be reviewed. This situation arises on the one hand in regard to the inclusion of research fields, in which ethics assessment is not mandatory, e.g. psychology,[21] and on the other hand in regard to new ethical issues e.g. evaluation of adverse effects (negative social impacts) of research that significantly outweigh the benefits.[22]

[14] Interview, 10.12.2014
[15] Interview, 25.11.2014
[16] Interview, 3.2.2015
[17] Interview, 18.12.2014
[18] Interview, 23.10.2014
[19] Interview, 25.11.2014
[20] Interview, 31.10.2014
[21] Interview, 15.1.2015
[22] Interview, 15.12.2014

One European organisation, which does not yet engage in ethics assessment itself, indicates plans to establish a permanent body on ethics assessment.[23]

Ethics assessment in the National Science Foundation of China (NSFC) is undertaken by a supervision committee in accordance with two relevant regulations: the *Constitution of the Supervision Committee*, and the *Methods Dealing with Misconduct in the Work of Science Foundation (Trail)*[24].

The term "ethics assessment" is used by all analysed organisations. This includes the notions of ethics review and ethics appraisal.[25] Ethics assessment has been integrated to a very large extend into the regulatory framework of the analysed European countries and the US. In case the European Commission/European Research Council provides for funding, the respect of the regulatory framework of the country in which the research is carried out is a precondition.

As regards China ethics assessment does not seem to be provided for by legislation, but depends on internal regulations of NSFC.

The aims of ethics assessment in Europe and the US relate to the protection of research subjects, to enhancing ethical conduct of research staff,[26] to justifying the research funded by the organisation vis-à-vis the public,[27] and to complying with national legislation. In addition, those organisations which provide for in-house ethics assessment[28] have in principle the possibility to refuse a project on ethical grounds, although this rarely happens in practice. The model relying on external ethics approval by a competent body does not give a funding organisation an independent possibility to reject a project on ethical grounds. The project selection committee only verifies that there are ethics approvals by a competent body in place. This means that the funding organisation does not have an influence on the ethics approval decision. The funding organisation is satisfied as long as a competent body has provided a positive ethical review. Organisations relying on a mixed-model (an approach in between relying on external ethics assessment and having an in-house procedure) give room for discussion on ethical grounds; there are no legally binding consequences, as ethics review in this case is not provided for by law.

Ethics assessment at NSFC guarantees the implementation of the principles for evaluation, safeguards the fairness and scientific value of the funding system and the interests and rights of scientists, and promotes scientific integrity and ethics in research.[29]

All analysed funding organisations specify the organisation itself and the applicants as the possible beneficiaries of ethics assessment.[30]

[23] Interview, 25.12.2014
[24] See annex.
[25] Interview, 23.10.2014
[26] Interview, 10.3.2015
[27] Interview, 14.11.2014
[28] For further information in regard to the different procedures in ethics assessment see below.
[29] See Annex.
[30] Interview, 31.10.2014; Interview, 15.12.2014; Interview, 17.10.2014.

4 Institutional Set-up of Ethics Assessment

The difference in the ethics assessment procedures mainly lies in the institutional set-up. The majority of the funding organisations rely on external ethics assessment provided for by the competent national body. During the selection process, the services of the funding organisation (or the selection committee) verify whether the relevant ethics approvals from the competent national body or other certifications provided for by law are annexed to the project proposal.[31]

Some organisations provide for ethics assessment by independent experts assisting the services of the funding organisation with the task of ethics assessment (in-house ethics assessment). In the case of the EU Horizon 2020 programme, independent experts can submit their profile in order to become an expert in ethics assessment on the participant portal.[32] For recruitment for ethics assessment in the Horizon 2020 programme, persons need to have expertise in ethics in research in e.g. the following fields: Human protection, involvement of children/vulnerable populations, data protection, animal welfare, environmental protection, international cooperation, misuse/malevolent use or research integrity. Ethics review panels consist of two to five experts. During the pre-screening and screening phase the panels comprise of two independent ethics experts of which one serves as rapporteur. In the phase of ethics assessment, the panel comprises of five independent ethics experts of which one serves as rapporteur. The experts and the rapporteurs are appointed by the European Commission.[33]

The phases of the screening in the case of the Horizon 2020 programme can be described as follows:[34]

- During proposal submission the applicant is asked to fill in an ethics self-assessment of their research proposal and an ethical issues table.
- Ethics pre-screening is done on any application with the help of independent experts. In case no ethical issues have been declared or ethical issues have been adequately addressed, this is confirmed through "ethics clearance". In case additional ethical issues are identified in the pre-screening phase, the project will undergo ethics screening.
- The ethics screening with the help of independent experts confirms and checks all ethical issues which have not been adequately addressed. The independent experts can give "conditional ethics clearance", recommend an "ethics assessment", or "refuse ethics clearance".

Other organisations doing in-house ethics assessment have a very similar process not always divided as clearly into different phases. For NSFC, who is doing in-house ethics assessment,

[31] Interview, 9.12.2014; Interview, 15.1.2015; Interview, 25.12.2014; Interview, 10.12.2014; Interview, 25.11.2014; Interview, 23.01.2015; Interview, 20. 11.2014; Interview, 13.1.2015.
[32] European Commission, Participant Portal. http://ec.europa.eu/research/participants/portal/desktop/en/experts/index.html
[33] European Commission, *Grants Manual - Section on: Proposal submission and evaluation (sections III.5, III.6, IV.1, IV.2). Version 1.4*. 28 May 2015. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf
[34] Ibid.

no clear distinction between scientific evaluation and ethics evaluation can be reported. The different phases of ethics assessment remain unclear.

Three organisations studied take an approach in between relying on external ethics assessment and having an in-house procedure (mixed model). One European organisation does not have a formal ethics assessment process, but installed a light ethical monitoring process where it asks researchers who apply for funding, referees and the committees who review grant applications to flag any applications that are likely to raise social or ethical issues. Any such applications are sent to members of a panel, who then discuss solutions in regard to ethically problematic parts of the project.[35]

In one European organisation an agreement was made to organise a Standing Committee to take ethical issues into account. The committee is responsible for formulating guidelines on conflict of interest, fraud and ethical matters related to any aspect of their competences, clarifying criteria and considering any particular instances or situations in which ethical concerns may arise. Consensus is reached through discussion of individual projects.[36]

Another European organisation indicated that for those proposals where an ethics review is not a lawful necessity, ethics assessment is carried out by independent experts appointed by the organisation on a case by case basis.[37]

As regards the institutional set-up of ethics panels external, in-house, and mixed models of ethics assessment rely on independent experts coming from different fields of research. The independence and inter-disciplinarity of competent national bodies in ethics assessment in the external-model is usually provided for by law, although this aspect was not specifically analysed in this report. As regards ethics clearance by internal ethics bodies, the interviews showed that they also follow the respect for independence and inter-disciplinarity.

The ethics assessment framework used by organisations with in-house ethics assessment and in the mixed model is developed by the individual institution. The Horizon 2020 programme has a standardised reference for ethics evaluation,[38] which does however not prevent ethics evaluators to take into account any additional point which he or she finds appropriate.[39] Others, especially in the mixed model, rely on experts pointing out critical aspects of certain proposals without relying on a standardised framework.

5 Procedures for Ethics Assessment

This section analyses procedures for ethics assessment and divides these procedures in the following three categories: Before the start of a particular research project, during the implementation of the research project, and after the implementation of the research project.

[35] Interview, 31.10.2014
[36] Interview, 18.12.2014
[37] Interview, 15.12.2014
[38] European Commission, *Ethics Issues Table Template.* Version 1.1. 11 July 2014. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/ethics-eit_en.pdf
[39] This information is based on personal experience of the author of the report.

As regards the phase before the start of a particular research project, the NWO, for instance, on the one hand verifies compliance with national legislation on ethics review. On the other hand, the NWO consults with civil society panels representing the business community and NGOs in regard to evaluation of the projects' societal relevance.[40] Other organisations exclusively verify compliance with national legislation in regard to ethics review and check respective compliance of the projects.[41,42] One organisation looks into ethical implications of the research and has developed an application form including questions in this regard which have to be addressed by the applicants.[43] Another organisation asks evaluators to assess in addition to compliance with national legislation on ethics review, both the scientific-technical aspects and ethical issues. If ethical issues are detected which cannot be solved, the research project would not receive funding.[44,45]

One European organisation consults on the application with a large number of experts to provide their view on the proposal including persons with non-scientific backgrounds in order to evaluate societal impacts, and to guarantee the adequate coverage of social issues, for example to determine whether the scientists have adequately considered the beneficiaries and those who might be adversely affected. In addition, research institutions and grant holders have to ensure that all appropriate personal and project licences required, as well as the ethical review body approval, have been granted. Applicants are also expected to have developed their proposals in accordance with the organisation's cross-funder guidance, the organisation's data sharing policy (including a data management plan), and the organisation's principles of good scientific practice.[46]

Another European organisation indicates that in principle ethical issues are not evaluated, but at times, particularly in the case of controversial sociological or psychological research, where experiments on humans are carried out, applicants might – in the course of evaluation – be asked detailed questions about the ethical aspects of their research. In the case of experiments on animals for instance, even though the competent committee has to grant the necessary permission, applicants can be questioned on the necessity of carrying out experiments with animals. This is however not a rule and depends on the panellists.[47]

As regards the phase during the implementation of the project, one European organisation has procedures to take action when there is sufficient evidence that scientific misconduct has taken place. The organisation's strategy is based on the assumption that host institutions of applicants and grant holders have primary responsibility for the detection of scientific misconduct and for the investigation and adjudication of any breaches of research integrity. Notwithstanding this, all concerns about potential scientific misconduct or suspected breaches

[40] Interview, 15.1.2015
[41] Interview, 10.12.2014
[42] Interview, 17.10.2014
[43] Interview, 31.10.2014
[44] Interview, 23.1.2015
[45] Interview, 15.12.2014
[46] Interview, 31.10.2014
[47] Interview, 17.10.2014

of research integrity regarding an applicant or project will be addressed within the appropriate legal and procedural framework.[48]

Another European organisation verifies that work on a particular part of a project requiring ethics approval is started only after this approval has been granted. This applies to research involving human subjects, genetically modified organisms, or any other sensitive or dangerous materials.[49] One European organisation verifies compliance with the organisation's policy in regard to confidentiality and conflict of interest.[50]

As regards the phase after the implementation of the project, one European organisation indicates that in general applicants address the issues by themselves and there is high compliance with the recommendations made during the selection process. In practice most issues are addressed early on, so that no subsequent follow-up is necessary. If further ethical issues arise, it is the applicants' responsibility to address them and to make the funding organisation aware of such issues.[51]

The research shows that ethics assessment in the phase before the start of the research projects is more developed than ethics assessment in the phases during or after project implementation. Most organisations, which do not provide for in-house ethics assessment, have developed a light non-standardised procedure (mixed model) to go beyond ethics assessment provided for by law during this initial phase. Ethics assessment in this initial phase mainly relates to ethical issues related to research specific questions including their societal impact.

The phase during project implementation is characterised by ethics assessment in regard to "the making of research" and mostly relates to questions of research integrity or scientific misconduct.

The phase after the implementation of the project is the weakest and is reported by only one organisation which addresses compliance with issues which have come up during previous phases of ethics assessment.

6 Principles and Issues for Ethics Assessment

Principles and issues used by funding organisations in Europe and the US for ethics assessment are not easily to grasp, as ethics assessment is not always formalised. The minimal standard of ethics assessment relates to ethical principles provided by law. These principles usually relate to human subject research, animal research, and data protection.

The Horizon 2020 programme is a good example of a programme doing comprehensive ethics assessment going beyond human subject research, animal research, and data protection.[52] In

[48] Interview, 18.12.2014
[49] Interview, 31.10.2014
[50] Interview, 23.1.2015/3.2.2015.
[51] Interview, 31.10.2014
[52] European Commission, *Ethics Issues Table Template.* Version 1.1. 11 July 2014. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/ethics-eit_en.pdf

order to illustrate ethical principles and related ethical issues by individual research fields the Horizon 2020 programme is used as an example.

The ethical principles and ethical issues in relation to topics can be summarised as follows:[53]

Ethical principles	**Ethical issues**
Human embryos/ foetuses	• Origin of cells • Informed consent for the use of donated embryos for the derivation of cell lines • Protection of personal data and privacy of donors • Prohibition of financial inducement
Humans	• Free and informed consent • Risks/benefits evaluation, particular in case of invasive techniques • Inclusion of vulnerable populations
Human cells/ tissues	• Source of human biological samples and personal data and respective informed consent
Protection of personal data	• Privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention, and destruction • Right to be forgotten • Security by design
Animals	• Issues on reduction, replacement and refinement ("three Rs principle")
Third countries	• Potential exploitation of research participants and/or local resources • Non-compliance with Horizon 2020 ethical rules • Health and safety risks for researchers and staff
Environmental protection and safety	• Harm to the environment can occur as part of the experimental design of the research and as the result of undesirable side-effects of the technologies
Misuse	• Potential misuse of materials, technologies and information (research that involves information on, or the use of, biological, chemical, radiological, explosive and nuclear security sensitive materials and the means of their delivery; research and the development of technologies that could have severe negative impacts on human rights standards if misapplied) • Research that has the potential for terrorist or criminal abuse
Dual use	• Impact of research beyond civilian application • Impact on current standards in military ethics (global ban on weapons of mass destruction, issues of proportionality, discrimination of combatants, accountability in drone and robots development, incendiary or laser weapons)

[53] European Commission, *Guidance How to complete your ethics self-assessment.* Version 3.0. 3 February 2015. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

Table 1: Table on ethical principles by field of research

In addition, organisations report on awareness for principles within the programmes, which relate to "the making of science", such as conflict of interest, plagiarism, self-plagiarism and misuse of resources. These principles are overarching and apply to all research fields.[54,55] One European organisation reports on its "Scientific Misconduct Strategy" which provides for enforcement of cases of misconduct through the applicable legal and procedural framework.[56]

As regards China, the NSFC only refers to principles related to "the making of science" such as scientific integrity, and professional integrity.[57].

In addition, there are organisations in Europe which introduced the gender aspect, open-access strategies, quality of the research team, and scientific impact, the usefulness of science as principles which apply to all programmes.[58,59,60,61]

One European organisation reports that the most important ethical issues assessed include the balance of benefits and harms when doing research, making sure the appropriate consent is in place, respecting autonomy and ensuring benefit sharing of research capacity and results. In addition genomics, data sharing and sample sharing raise ethical issues related to privacy and confidentiality. Much of the organisation's activities are framed around good governance both in terms of policy and the research that is funded. External governance is also important, i.e. proceedings in RECs and the regulatory environment in which the organisation operates.[62]

Another European organisation reports that integrity, protection of human beings, promotion of the social good, informed consent, beneficence, and justice are examples of basic principles, without which one cannot talk about research integrity and are therefore assessed for project selection in all fields of research going beyond those fields in which ethics assessment is mandatory.[63]

One European organisation reports that if a number of similar projects raise the same ethical questions, guidelines or statements are formulated on the issue.[64]

Soft criteria which are used in ethics assessment by the analysed funding organisations in the "making of research" can be summarised as follows:

[54] Interview, 18.12.2014
[55] Interview, 9.12.2014
[56] Interview, 18.12.2014
[57] Reference is also made to justice and fairness, but it remains unclear how this principle is applied and in which context.
[58] Interview, 9.12.2014
[59] Interview, 15.1.2015
[60] Interview, 23.1.2015
[61] Interview, 17.10.2014
[62] Interview, 25.11.2014
[63] Interview, 15.12.2014
[64] Interview, 13.1.2015

Making of research	Principles
Research Integrity	• Quality of research according to scientific standards • Quality of the research team • Scientific impact
Scientific misconduct	• Plagiarism • Conflict of interest • Misuse of resources
Additional criteria in relation to individuals[65]	• Autonomy / integrity • Protection of human beings • Informed consent • Beneficence • Justice • Balance of benefits and harms in doing research
Additional policy criteria	• Usefulness of science • Open-access strategies • Gender issues • Transparent communication on topics which are researched and the Respective consortia • Ensuring benefit sharing of research capacity and results • Promotion of the social good

Table 2: Additional principles related to the "making of research"

7 Problems and Developments

Problems in relation to ethics assessment in Research Funding Organisations in Europe and the US are reported in relation to the scope of the existing ethics assessment, which is considered as too narrow and the relation between hard law and the inclusion of "soft criteria" into ethics assessment.[66]

One European organisation reports that the scope of existing ethics assessment, which is limited to the assessment of compliance with national legislation (review by the national competent body), is too narrow. In addition, data on proposals which have been refused on the basis of non-compliance with legal requirements are missing.[67]

[65] These criteria may also be covered by procedures carried out in ethics review by the competent national body, but are reported by one organisation as a precondition for research integrity.
[66] This section does not apply to China, as data on China has only been gathered through desk research. Reliable data for an analysis of problems and developments have to be based on interviews.
[67] Interview, 10.12.2014

The finding that the scope of ethics assessment often is too narrow is supported by another organisation, as it reports to not having the procedural tools for assessing the consequences of research in regard to its beneficence/maleficence. The representative of that organisation states that it is a paradox that all research on animals has to obtain ethics clearance, while not everybody who conducts research on human beings (e.g. engineers who are testing a new type of a wheelchair) has to consult an ethics committee. In addition, RECs themselves do not know whether they should issue opinions beyond their competence (medical research or clinical trials). As regards the existing procedures their main weakness is that they are fragmentary and apply only to some types of projects, while in fact all projects should undergo ethics assessment.[68]

One European organisation reports on the challenge of identifying critical new problems, such as the definition of a "new" application, and to develop respective solutions.[69]

Another European organisation reports that ethical issues in their broadest sense (e.g. the issue of responsibility for research) play a major role, especially in situations when carrying out research might have adverse effects (negative social impacts for instance) that significantly outweigh the benefits. In those cases ethics shall determine, that it is not possible to conduct research, whose results might be ambiguous or whose social impacts (matters regarding nation, race etc.) might be hard to foresee. The organisation however points out that in some projects it is hard to determine during the application phase potential ethical threats and dangers. The organisation sees a key problem in the lack of detailed regulations as well as thinking in categories that, if something is not prohibited, it is allowed. The representative of the organisation therefore militates for the education of young researchers in regard to their awareness of ethical responsibility for their studies. The representative of the organisation further states that it is important to raise awareness among researchers that concentrating only on legal regulations is not enough to establish whether their actions are right or wrong.[70]

One European organisation reports that that the phases of ethics assessment which are not determined by legislation depend on the personal ethics of the reviewer. Possible solutions in relation to the project are in this situation case based. The exchange of problematic ethical cases in annual meetings between the various funding agencies is reported as very helpful.[71]

Another European organisation reports that they have been trying to bring in new experts to sit on ethics panels. The focus was put on experts from the natural sciences, as the majority of proposals that go through the ethics review come from the natural sciences. Another advantage of having natural scientists as part of the ethics review would be that they would see that ethics review is not about potentially prohibiting research but on how to improve the research. In addition, the organisation would like to increase civil society organisations access to review panels, but has only had limited success when inviting NGOs – the organisation

[68] Interview, 20.11.2014
[69] Interview, 3.10.2015
[70] Interview, 15.12.2014
[71] Interview, 23.1.2015

found that these bodies are reluctant to participate in the process as they want to keep an independent position.[72]

As regards ethical assessment beyond criteria provided for by the legislation, one European organisation reports additional transparency as an added value. In regard to the inclusion of stakeholders in priority setting during programming, the organisation regards the inclusion of stakeholders in applied research, which is close to the market, as challenging in relation to compliance with EU state-aid rules.[73]

The same organisation reports its difficulties in including gender aspects as an ethical principal, as the principle was first received as superfluous, hindering research. Respective benefit was only seen in regard to user interests in connection with market acceptance. The introduction of gender aspects as a principle which applies for all programmes was a major challenge, as consensus had to be built on how gender aspects relate to the programmes, 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 evaluators were necessary to raise understanding for gender aspects and to find common understanding on implementation.[74]

One US organisation reports on complaints with regard to becoming overly bureaucratic. The challenge relates to developing user friendly policies for ethics review, as policies can sometime be interpreted in different ways, which leads to confusion among researchers taking time away from research. The organisation also reports that the bigger picture at times gets lost in organisational rules. The organisation has experimented with translating regulatory requirements into regular questions on paper. Reviewers preparing for a review might then explicitly ask themselves these questions. Although it worked well, it did not completely eliminate the space for interpretation. An additional challenge is related to inconsistency in the reviews between different review boards.[75]

The organisations on the one hand call for more certainty in regard to ethics evaluation, on the other hand they also report on complaints with regard to becoming overly bureaucratic in case norms have been established. As ethics in regard to new technologies will always remain a moving target, it is to be expected that legislation will always lag behind scientific developments. The reported case by case approach for ethical issues which arise during project selection and a structured exchange on these issues between different Research Funding Organisations seems to be a viable approach to this problem besides awareness raising among researchers and respective education that ethics is an integral part of science.

As regards the acceptance of ethical criteria in the research community beyond what is provided for by law, the findings suggest that Research Funding Organisations may have difficulties in convincing the research community of their added value. In the long run the research community has however accepted the respect for new criteria called for by Research Funding Organisations if they have been well introduced to the community and have been accompanied by training measures. The reports also show that not all measures, e.g. inclusion

[72] Interview, 23.10.2014
[73] Interview, 9.12.2014
[74] Interview, 9.12.2014
[75] Interview, 14.11.2014

of stakeholders in research can be implemented in all cases, as a conflict with other provisions may arise.

As regards the composition of ethics' panels there have been efforts to include participation of NGOs and civil society organisations, which have not been successful as these bodies want to keep an independent position.

It can be summarised that developments in ethics assessment might bring a broadening of the scope of ethics assessment not just in terms of disciplines, but also in regard to the perception of the "making of research". These are already considered by the Research Funding Organisations which give room for soft criteria. These criteria relate to research integrity, scientific misconduct, and additional policy criteria, such as usefulness of science, open-access strategies, gender issues, transparent communication on topics which are researched and the respective consortia, ensuring benefit sharing of research capacity and results, and promotion of the social good.

8 Annex: Ethics Assessment and Guidance Research funding organisations

This Annex contains only three reports on particular surveyed funding organisations, as the other organisations asked for full anonymity. For each funding organisation that was surveyed and did not ask for anonymity, 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.

The following organisations were surveyed either through desk research and / or interviews:

- European Union: two organisations, anonymous
- Austria: two organisations, anonymous
- China: National Natural Science Foundation of China (based on desk research)
- Germany: German Research Foundation
- The Netherlands: Netherlands Organisation for Scientific Research
- Poland: National Science Centre and two other organisations, anonymous
- Serbia: Ministry of Education, Science and Technological Development, National Agency for the Regional Development
- Spain: two organisations, anonymous
- United Kingdom: two organisations, anonymous
- USA: two organisations, anonymous

The findings of the interviews are integrated in an anonymised form into the report for those organisations which asked for full anonymity.

Name of organisation	**National Natural Science Foundation of China** **(国家自然科学基金委)**
Type of organisation	Funding organisation
Country	China, the People's Republic of
Website address	General: http://www.nsfc.gov.cn/ ; http://www.nsfc.gov.cn/publish/portal1/ Main page(s) on ethics assessment: http://www.nsfc.gov.cn/nsfc/cen/00/its/jiandu991013/jiandu2.html
Basic description (organisation and mission)	The National Natural Science Foundation of China (NSFC) is directly under the jurisdiction of the State Council. It administrates the National Natural Science Fund and coordinates the fund to support basic research and promote free exploration.
Interest in research and innovation	Since its establishment, NSFC has comprehensively introduced and implemented a rigorous and objective merit-review system to fulfil its mission of supporting basic research, fostering talented researchers, developing international cooperation and promoting socioeconomic development.
Ethics assessment and/or guidance	Assessment ☒ Guidance ☐ Other ☐ None ☐ Commentary: the work is basically supervision and investigation into integrity-related issues. If assessment/guidance is undertaken: In-house ☒ Outsourced ☐ None ☐ Other ☐ Commentary: The assessment is undertaken by a supervision committee in the NSFC.
Terminology for ethics assessment / guidance	Supervision. The supervision covers different aspects: developing regulations for the supervision; dealing with complaints and reports about the fund; supervising the application, reviewing, administrating and implementing of the fund.
Name and description of ethics unit(s)	Supervision Committee. The supervision committee is the supervising sector in NSFC. It independently conducts supervision function and reports to the plenary session of NSFC Council its work. An office of supervision committee is responsible for the daily work of the committee.
Aims and motivation for ethics assessment	The supervision guarantees the implementation of the principles for evaluation, safeguards the fairness and scientific value of the funding system and the interests and rights of scientists, and promotes scientific integrity and ethics in research. The assessment is carried on for the sake of scientific and research integrity. This supervision committee is also a part of the Chinese inter-agency mechanism for

	building R&D integrity.
Objects and scope of assessment	The supervision covers all the misconduct during all the processes of the work of the fund, including applying, reviewing, implementing, including and other managing activities. The fund management organ takes a sample survey on the implementation of the funded projects and the performance of duties by the supporting institutions. In addition, the supervision committee also deals with complaints and reports about the fund.
Beneficiaries of assessment	Research integrity, individual scientists
Ethics assessment unit: appointment process	The Supervision Committee is composed of scientists and administrative experts engaged with the NSFC. A standing committee is formed within the Supervision Committee. The committee members are assigned following the request of the Constitution of the Supervision Committee[76], according to which the members should have good scientific ethics and good academic achievement and also dedication to the work of supervision for NSFC.
Procedure for ethics assessment: before	1. The supervision committee carries on a sample survey on the funded projects. 2. In addition, the office of the supervision committee receives complaints and reports and informs the reporters about the working progress. The reports which are not within the jurisdiction will be archived after the approval of the deputy director of the supervision committee. The reports which are within the jurisdiction will be reported in meetings or to deputy directors to decide if they need to be put on record. If not, the report will be archived. The reports concerning the use of the funds will be handed over to the audit department.
Procedure for ethics assessment: during	1. The fund management organ takes a sample survey on the implementation of the funded projects and the performance of duties by the supporting institutions, and checks the original records on the implementation of the funded projects at the time of survey. 2. The complaints and reports that are put on record will be investigated by a specially assembled investigating team.
Procedure for ethics assessment: after	1. Results of the sample survey will be recorded and publicised to the general public. The fund management organ will set up archives on the credits of project principals and supporting institution. At the end of each accounting year, the fund management organ publishes the funded projects and the punishments to those acts against the regulations in this year. 2. About the complaints and reports, the investigating team will write investigating reports and the supervision committee will review the report and give corresponding judgments. The audit department will give judgments for the cases concerning the misuse of the fund.

[76] 监督委员会章程

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 ☐ social responsibility Commentary: The work of the supervision committee of NSFC is carried on mainly in accordance with two relevant regulations: the *Constitution of the Supervision Committee*, and the *Methods Dealing with Misconduct in the Work of Science Foundation (Trail)*[77]. The *constitution* is drafted and approved by the NSFC, and the methods is drafted and approved by the supervision committee of NSFC.
Self-assessments, strengths and weaknesses	
Other	

Name of organisation	The German Research Foundation (Deutsche Forschungsgemeinschaft, DFG)
Type of organisation	Funding organisation
Country	Germany
Website address	*General:* http://www.dfg.de/en/ *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	The German Research Foundation (*Deutsche Forschungsgemeinschaft*, DFG) is the self-governing organisation for science and research in Germany. The main role of DFG is to fund knowledge-oriented research without stipulation of topics and utilise competition to select the best projects in terms of scientific quality.[78]

[77] 对科学基金资助工作中不端行为的处理办法（试行）
[78] DFG, Mission Statement, http://www.dfg.de/en/dfg_profile/mission/index.html.

	The DFG supports scientists and academics, with a particular attention to the promotion of young researchers and equal opportunities in the German research system.[79] The DFG promotes networking and cooperation in the field of research, especially interdisciplinary and international cooperation – as well as the interaction of science with industry and society.[80] One of the role of the DFG is providing policy advice to parliaments, governments and public institutions as well as the general public on scientific issues.[81] The DFG is the largest funder for competitive (third-party) funding in basic research. Legally it is structured as an association under private law. Its member organisations include most German universities, non-university research institutions, scientific associations and the Academies of Sciences and Humanities.[82]
Interest in research and innovation	The DFG supports all scientific disciplines and areas of research, facilitates cooperation among researchers, advances early career researchers and promotes equal opportunity in science and the humanities.[83] The Clinical Trials Programme – one of the programmes within the DFG's funding portfolio - enables individuals who have completed their academic training to conduct at any time patient-oriented clinical research within a temporary project.[84] This programme entails specific requirements and includes therapeutic trials, e.g. pharmacological trials, prognostic and diagnostic trials, which all have to be carried out at multiple centres.[85]
Ethics assessment and/or guidance	The DFG's evaluation procedure focuses on the evaluation of a proposal of research, and the decision is whether the DFG should fund it or not. A proposal is being checked taking into consideration certain parameters including formal requirements. There is no specific instant in the process that only looks at the ethical assessment. However, a positive ethics assessment of the university ethics board is a requirement for proposals involving humans or human material.
Terminology for ethics assessment / guidance	The DFG does not explicitly do ethics assessment. The interviewee referred to the assessment of a research proposal, ethical aspects are not the main focus of the assessment.
Name and description of ethics unit(s)	There is no specific instant in the process that only looks at the ethical assessment.
Aims and motivation for ethics assessment	The main role of DFG is to fund knowledge-oriented research without stipulation of topics and utilise competition to select the best projects in terms of scientific quality.[86]
Objects and scope of assessment	The DFG funds research projects in all the fields, but only basic research. In terms of the money flows, about 15 percent goes to humanities and social sciences, 45 percent to life science, 25 percent goes to natural science and 20 to engineering.
Beneficiaries of assessment	The beneficiaries of the assessment are the researchers whose projects applying for funds. The DFR provides funding only for public universities and public

[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] http://www.dfg.de/download/pdf/dfg_im_profil/evaluation_statistik/foerderatlas/dfg_funding_atlas_2012.pdf
[83] Based on the document provided by the interviewee on ethical evaluation in Germany.
[84] Based on the document provided by the interviewee on ethical evaluation in Germany.
[85] Based on the document provided by the interviewee on ethical evaluation in Germany.
[86] DFG, Mission Statement, http://www.dfg.de/en/dfg_profile/mission/index.html.

	research institutes, and sometimes private people, e.g. retired researchers. The DFG never funds research conducted by private companies. The interviewee referred also to specific stakeholders, who are representatives of various scientific disciplines - all scientists.
Ethics assessment unit: appointment process	The reviewers are chosen on the basis of their expertise in the field. In most cases they are experienced researchers of the same field as the reviewed proposal, but who are not in any way related to the applicant. The review boards consist of scientists from different disciplines, who are elected for the review boards by the whole German scientific community. They assess the quality and validity of the reviews and propose proposals for funding. Regarding the selection process for the review board, the members are scientists, and they are chosen on the base of their expertise. All scientists in Germany are engaged in the election process which takes place every four years at all research institutions. The main decision making body, that finally decides about the funding, is composed of scientists and people from the government. Scientists are in the majority, nevertheless it is a mix of scientists and politicians. The scientists in the joint committee are elected by the members of the DFG, which are the German universities.
Procedure for ethics assessment: before	The DFG's ethics evaluation is restricted to experiments involving human beings or/and human materials.[87] In these cases, a positive votum of a university's ethics committee is mandatory. It relies 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),[88] - Helsinki Declaration, - Directive on the protection of animals used for scientific purposes (2010/63/EU). The DFG does not have a specific institutional set up for ethics clearance, as it relies on a review by the competent national body for human subject research and animal research.
Procedure for ethics assessment: during	The DFG's evaluation procedure focuses on the evaluation of a proposal of research, and the decision is whether the DFG should fund it or not. A proposal is being checked taking into consideration certain parameters including formal requirements (whether it is complete or not, whether it is based on plagiarism, whether it is in line with the laws of the country). This part of the assessment is more a formal check, and not content-wise. If the proposal fulfills all the formal requirements, it is sent to reviewers who state their opinion on the proposal (originality, quality, novelty etc.). Normally, the proposal is being reviewed by two or three individual reviewers. After receiving the reviews, the DFG's review board discusses the proposal and decides whether a proposal should be funded or not. This is sent to the decision-making bodies that decide on the funding. The DFG has different disciplinary units in the head office. The review board system is organized by discipline. In most cases the main decision-making body follows the review board opinion. The interviewee noted that in most of the cases, there would not be very explicit

[87] Based on the document provided by the interviewee on ethical evaluation in Germany.
[88] The Directive is subject to reform.

	ethical considerations there. The DFG funds basic research, for which there are only very specific situations where ethical issues would arise. However, there are different aspects where ethical considerations take place. First of all, this concerns scientific integrity, e.g. it is the DFG's task to make sure that the reviewer is not coming from the same university as the applicant. The reviewers are anonymous for the applicant. Concerning the scientific review, in the Clinical Trials Programme draft proposals are evaluated by expert reviewers and then undergo comparative review by the "Clinical Trials" review panel, which is primarily composed of members of DFG review boards.[89] If the review is positive, a full proposal can be submitted, which is also evaluated by expert reviewers and then assessed by comparative review.[90] The final funding decision is made by the DFG's Joint Committee on the basis of the recommendation made by the review panel.[91] Regarding ethics clearance, the DFG asks for copies of the positive ethics review by the competent national body.[92] The DFG works with the ethics committees. Without their consent the DFG would not process the proposals.
Procedure for ethics assessment: after	The DFG decides whether to fund a project or not. The applicant can improve, change the application and write a new one, the proposal needs, however, to go through the whole process from the beginning. There is no specific instant in the process that only looks at the ethical assessment. Since the DFG does not specifically do ethics assessment, this does not really apply them. However, for ethical and political question, the DFG may issue recommendations. In the opinion of the interviewee, these kinds of recommendations had an impact on the way the government deals with several issues. As an association that is the general voice of the science. The DFG issues general statements about what to do in a certain field. This is not binding, but might feed into legislative debates. For example, the stem cell research regulation is a legal issue. In this legislative process, the DFG issued an opinion. The opinions are addresses to the public. However, if the opinion is about a legislative process, it would be mostly targeted at the parliament. Furthermore, it could also be targeted at disciplinary associations or any other actors in a certain field. In most cases, the opinions are non-binding, but sometimes guidelines have been developed with these kind of statements as background documents, e.g. the DFG made a statement on survey techniques some years ago.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [x] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [x] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [x] environmental impacts [x] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [x] dual use (possible military uses) [ ] other, specify:

[89] Based on the document provided by the interviewee on ethical evaluation in Germany.
[90] Based on the document provided by the interviewee on ethical evaluation in Germany.
[91] Based on the document provided by the interviewee on ethical evaluation in Germany.
[92] Based on the document provided by the interviewee on ethical evaluation in Germany.

	Commentary: Please find below a broader description of principles that DFG takes into consideration while making a decision on funding a project.
Self-assessments, strengths and weaknesses	Self-assessment is mostly done on a meta-level. If a number of similar projects raise the same questions, then at some point the review board might conclude that guidelines or statements should be formulated on the issue. The review board members might decide to apply the same standards in the future. Since ethical considerations, apart from scientific integrity, are not the prime concern of the DFG, the potential weakness might be that these issues are only discussed within a certain community, a review board on a specific discipline. There would not be a discussion between those review boards, therefore there could be more interaction between them. This does not however necessarily cause a problem. Furthermore, the interviewee suggested, that there could be a better debate in Germany about scientific integrity. The DFG is a driving force with the Research Ombudsman system, but it is not binding for the whole German research community. The DFG is taking up this role, but at a certain point it does not have a position of an official office for scientific integrity.
Other	

Name of organisation	**Netherlands Organisation for scientific Research (NWO)** ***Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO)***
Type of organisation	Assessor
Country	The Netherlands
Website address	*General:* www.nwo.nl. Other NWO websites are www.zonmw.nl and www.stw.nl and www.fom.nl *Main page(s) on ethics assessment:* http://www.nwo.nl/actueel/dossiers/wetenschappelijke+integriteit
Basic description (organisation and mission)	The core task of NWO remains stimulating quality and innovation in non-programmatic and thematic scientific research within all disciplines. The NWO strategy will build further on this basis with a focus that strengthens the connections researchers have with the business community and society. As a research council, NWO's task is to advance the quality of scientific research in the Netherlands: from literature to astronomy and from earth sciences to sociology. NWO encourages the outcomes of scientific progress being used for society's benefit. NWO effects this through clear ambitions for science policy based on its strategy for 2011-2014. The policy 2015-2018 will be presented on

	13 April 2015. NWO seeks to realise its ambitions in two ways: by funding scientific research on a competitive basis, and through the efforts and facilities of the strong national institutes it manages. Scientific research and innovation form the basis of our wealth and well-being in the Netherlands. NWO determines its policy in consultation with social partners, government and scientists. NWO's vision is to work together with these stakeholders on the growth of scientific knowledge, knowledge that will genuinely benefit society both now and in the future. NWO has the following ambitions: • Investing in talent and curiosity-driven research • Curiosity-driven research leads to many scientific breakthroughs. NWO therefore gives talented scientists the opportunity to carry out innovative research. • Through a process of peer review, scientists from around the world select the best research proposals submitted to NWO. New lines of research emerge when innovative research is encouraged. Research sometimes leads to surprising and even pioneering results. NWO is an advocate of competitive funding, and invests in research driven by the curiosity of researchers. Collaboration in themes: In consultation with the scientific field, government, civil society organisations and industry, NWO identified major social issues for the period 2011-2014 as research themes. The Dutch government is encouraging research investment in nine designated priority areas. Linked to the national research and innovation policy, NWO has adjusted its themes in response to the economic priority areas policy (topsectoren beleid). Researchers and industry are brought together to realise innovative scientific research. Particular attention is paid to research carried out in partnership with industry. The themes are the following • Agro, Food and Horticulture • Connecting Sustainable Cities • Creative Industry • Cultural and Societal Dynamics • Healthy Living • High Tech Systems and Materials • Materials - Solutions for Scarcity • Sustainable Energy • Water and Climate • Facilitating knowledge utilisation Industry, government bodies and public organisations can benefit from scientific

	research. NWO facilitates this knowledge utilisation as much as possible. Scientific research yields knowledge and skills that can be used by others, for example to develop software or to draw up policy recommendations. NWO strengthens the link between knowledge producers and knowledge users, for example by investing in research into issues relevant to society. NWO also encourages knowledge utilisation by always asking researchers about the possible applications of their research. Furthermore, NWO supports knowledge utilisation with start-up funding and matchmaking events. International collaboration: NWO collaborates with many countries to strengthen research and to maintain the Netherlands' top global position in science. Making high-quality facilities accessible NWO offers scientists access to high-quality facilities that are usually too expensive for a single university. Examples are supercomputers, particle accelerators or a large database.
Interest in research and innovation	NWO funds scientific research at Dutch universities and research institutes. NWO does this through a range of 150 funding instruments linked to its ambitions. (http://www.nwo.nl/en/funding/research+funding) NWO has several categories of funding instruments for researchers: large-scale, long-term research programmes focussed on a specific target or theme, or collaboration between researchers, partly set up in close consultation with other partners • For individual researchers focussed on encouraging talent • For the realisation and use of large-scale infrastructure • For curiosity-driven, non-programmed research • For research programmes focussed on international collaboration and exchange • For knowledge dissemination and open access publication of research results The funding instruments cover the entire spectrum of fundamental and applied research. Knowledge utilisation (societal and scientific applicability of the results) is increasingly a criterion in the assessment of funding instruments . The frequency of funding rounds varies per instrument, from one per year, or several rounds per year, to submission on a continuous basis. Funding instruments can be specific to an NWO division or a group of NWO divisions. Other instruments are NWO wide. An overview of all NWO funding instruments is given under Our funding instruments. The description of the instruments, and the associated calls for

	proposals, contain all relevant information about how to submit research proposals, and how submitted proposals are assessed.
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [x] Other [ ] Commentary: NWO holds the 'scientific integrity desk'; violations of scientific integrity can be reported.
Terminology for ethics assessment / guidance	The Netherlands code (VSNU Association of Universities the Netherlands, 2014) provides the principles and the best practices, on the following six principles: • Honesty and scrupulousness: Scientific activities are performed scrupulously, unaffected by mounting pressure to achieve; • Reliability: Science's reputation of reliability is confirmed and enhanced through the conduct of every scientific practitioner. A scientific practitioner is reliable in the performance of his research and in the reporting, and equally in the transfer of knowledge through teaching and publication; • Verifiability: Presented information is verifiable. Whenever research results are publicised, it is made clear what the data and the conclusions are based on, where they were derived from and how they can be verified • Impartiality: In his scientific activities, the scientific practitioner heeds no other interest than the scientific interest. In this respect, he is always prepared to account for his actions; • Independence: Scientific practitioners operate in a context of academic liberty and independence. Insofar as restrictions of that liberty are inevitable, these are clearly stated. • Responsibility: Academic practitioners acknowledge their responsibility for the societal implications of their work. They are willing to discuss and explain their choice of research themes. NWO defines knowledge utilisation as: Knowledge utilisation is a process that facilitates the use of scientific knowledge outside of academia and/or by other scientific disciplines. The process often requires interaction between the researcher and the intended knowledge user, and this contact can take place in all phases of the research: from formulating the research question through to disseminating the research results.
Name and description of ethics unit(s)	Research with humans and research with animals should have permission from the respective ethics committees. A civil society panel representing the business community and NGOs evaluates the research proposals for their social relevance. Violations of scientific integrity can be reported at the 'scientific integrity desk'. (http://www.nwo.nl/actueel/dossiers/wetenschappelijke+integriteit)
Aims and motivation	NWO's scientific integrity policy is aimed at preventing and detecting scientific

for ethics assessment	misconduct and is in line with the policy of the universities, the Association of Universities in the Netherlands (VSNU) and the Netherlands Academy of Arts and Sciences (KNAW). The NWO policy applies to both the application phase and the phase after research proposals have been awarded funding, and concerns: • Awareness: Netherlands Code of Conduct for Scientific Practice • The possibility to report violations via the Scientific Integrity Desk • Possible measures from NWO after a violation of integrity has been established The Netherlands Code of Conduct for Scientific Practice (VSNU, 2012) forms the guiding principle for NWO's integrity policy. Everybody who submits an application to NWO must state that they are familiar with the code and that they are complying with it. Also after an application has been awarded funding, NWO requires researchers to state in the progress reports that they are adhering to the code. The Netherlands Code of Conduct for Scientific Practice contains rules for academic education and research at Dutch universities. Key points from the Netherlands Code of Conduct for Scientific Practice are: • Scrupulousness • Reliability • Verifiability • Impartiality • Independence • Responsibility Two NWO programmes specifically focus ethical issues: The Responsible Innovation program funds and encourages research in which the ethical and social aspects of new technology are considered right from the design phase. This prevents expensive adjustments having to be made in retrospect or society rejecting the new technology. What are the legislative and ethical consequences of using video equipment in the operating theatre? What went wrong with the electronic patient record and what is needed to gain support? Does the number of hooligans in nightlife areas decrease with increased and more advanced camera supervision or are there other effects? The Responsible Innovation programme funds and encourages research into such questions. The 2012 funding round focussed on the top sectors Energy, Life Sciences & Health, Agri & Food, and Horticulture. The New technology and systems in transition programme. Research within this program focuses on the ethical and social aspects of new technologies such as ICT, nanotechnology, biotechnology and neurosciences, and on technological systems in transition such as energy, transportation, agriculture and water. The Responsible Innovation program approach has five pillars:

	• Interdisciplinary: researchers from all relevant scientific disciplines collaborate closely to come up with socially responsible innovation pathways. • Valorisation: stakeholders are closely involved with the research via a valorisation panel so that the results can be implemented directly. • Proactive: ethical and social aspects are involved right from the start and incorporated into the design process. • Social relevance: a civil society panel representing the business community and NGOs evaluates the research proposals for their social relevance. • International orientation: explicit attention is paid to the global nature of the research questions, including their relevance to developing countries.
Objects and scope of assessment	Each funding instrument has its own assessment criteria. The objectives of the funding instrument need to be reached with the proposed research.
Beneficiaries of assessment	NWO assesses research applications for funding. Our funding instruments states the instruments to which a research proposal can be submitted. Detailed information and the criteria for each NWO grant are presented in the 'calls for proposals'. Who can apply is stated for each instrument. These are usually researchers employed at a Dutch university or a research institute recognised by NWO. The strictness of these criteria can differ per instrument.
Ethics assessment unit: appointment process	NWO appoints a selection committee or jury for each funding instrument. Referees must be experts in the scientific area of proposal they assess. Referees are sought using international databases such as Web of Science, MEDLINE, ReviewerFinder and Scopus, as well as NWO data. The list of chosen referees can be submitted for advice to a subject specialist who is not involved in the proposals or the assessment process. In principle, referees are not paid for their contribution. A referee usually has three to four weeks to give his or her written assessment of a research proposal. Usually a referee only assesses one of the proposals. NWO asks referees and members of the selection committee to sign the NWO Code of Conduct on Conflicts of Interest and to act in accordance with this. The code of conduct also applies to board members who take funding decisions, and NWO staff involved in the procedure. If a conflict of interest arises, then the code states how NWO will deal with this.
Procedure for (ethics) assessment: before	NWO first determines whether the research proposals satisfy the admissibility criteria for the funding instrument concerned. Admissible proposals are assessed against the selection criteria described in the call for proposals. For most instruments, NWO consults external specialists for the research proposals submitted. The research proposals are first sent to these experts for peer review. NWO values the assessment of these external specialists.

	A pre-selection of the proposals may take place to minimise the burden for referees. The aim of this is to ensure that referees receive only proposals that NWO thinks have a good chance of being granted. Pre-selection takes place if a large number of proposals are submitted. That is, more than four times as many proposals as can be granted funding. The referees' assessments are collated in a referees' report. The applicant is given the opportunity to respond to the referees' assessment. This rebuttal plays an important role in the assessment process. If referees do not play a role in the assessment process then the proposals are submitted directly to the selection committee.
Procedure for ethics assessment: during	NWO appoints a selection committee or jury for each funding instrument. Its task is to compare and assess the research proposals. The committee or jury has access to all the research proposals as well as the referees' reports and applicants' rebuttals. An interview or site visit can also form part of the assessment procedure. Based on this information, the selection committee issues a funding advice to the NWO board that takes the funding decision.
Procedure for (ethics) assessment: after	The board that takes the funding decision is usually NWO's Governing Board, an NWO divisional board or a body mandated by an NWO board. Firstly, the board assesses whether the selection committee worked according to the procedure and selection criteria described in the call for proposals. Board members have access to all relevant information such as research proposals, referees' reports, applicants' rebuttals, the description of the assessment procedure, the composition of the committee, and the assessment of the conflict of interest code. The board then takes a funding decision. Usually the board adopts the selection committee's advice. It may, however, deviate from this if it states its reasons for doing so. Applicants are sent a formal letter informing them of the board's decision and the reasons underlying this. When applicants do not agree with the decision, they can lodge an objection within six weeks of receiving the formal letter. NWO has an independent Appeals and Objections Committee that considers the appeals submitted.
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 [x] treatment of animals in R&I[x] environmental impacts [x] human dignity [x] social impacts [x] equality / non-discrimination [x] outsourcing of R&I to developing [x] autonomy / freedom countries with lower ethics standards

	[x] implications for civil rights [x] dual use (possible military uses) [x] implications for privacy [x] other, specify: valorisation, inter-disciplinarity, [x] social responsibility social relevance, proactive, international orientation Commentary: Each finding instrument has its own objectives. The research proposal is assessed
Other	VSNU (2014) *the Netherlands code of conduct for scientific practice. Principles of good scientific teaching an research.*

Name of organisation	**National Science Centre (NCN)** **(Narodowe Centrum Nauki)**
Type of organisation	National funding organisation
Country	Poland
Website address	*General:* http://www.ncn.gov.pl/ *Main page(s) on ethics assessment:* same as the general address
Basic description (organisation and mission)	NCN is an agency supervised by the Ministry of Science and Higher Education. It was set up in 2011 with the aim of supporting basic research. NCN funds projects in Arts, Humanities and Social Sciences, Life Sciences and Physical Sciences and Engineering. The NCN created 10 types of funding schemes. They are dedicated to researchers at different stages of their career.[93]
Interest in research and innovation	NCN funds research projects.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [x] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ]
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	For some of the proposals it is required by law to obtain the consent of a competent (bio)ethics committee. There are certain fields, which are not sufficiently regulated. In such cases, ethical assessment of research is conducted by experts who review the proposal.
Aims and motivation for ethics assessment	The applicant has to declare that the required consent will be provided. Apart from that, experts who assess the project pay attention to ethical aspects.
Objects and scope of assessment	Research proposals, research projects
Beneficiaries of assessment	Applicants

[93] http://www.ncn.gov.pl/o-ncn/zadania-ncn?language=en

Ethics assessment unit: appointment process	When required by the law, ethics assessment is done by (bio)ethics commissions. In other cases, when there are no strict legal requirements (e.g. in the case of psychological or sociological studies) assessment may be provided by an ethics commission established at a research institute or university. Ethical aspects are taken into consideration when a project is assessed by experts at NCN. Applications are assessed by distinguished experts from Poland and abroad. Due to lack of appropriate funding, NCN does not have a special unit for ethics/research integrity.
Procedure for ethics assessment: before	While bioethics committees are regulated by the executive act of the Minister of Health and Social Care[94], there are no appropriate provisions for research involving humans in social sciences. In practice evaluations are performed by special committees (sometimes bioethics committees), which are established at particular institution or research facility.
Procedure for ethics assessment: during	If an applicant did not receive a consent, which was required according to experts, his or her application would not be taken to the next stage of the assessment with an express remark that the consent should have been obtained. When a project is assessed by experts at National Science Centre, ethical aspects are also taken into consideration. If experts find that it raises ethical doubts, the project will not receive funding even if the consent is not formally required.
Procedure for ethics assessment: after	
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 [x] other, specify: see commentary [ ] social responsibility

[94] Minister of Health and Social Care (Minister Zdrowia i Opieki Społecznej), Executive act of the Minister of Health and Social Care of 11 May 1999 on specific regulations regarding constituting, funding and operating of bioethics committees (Rozporządzenie Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. w sprawie szczegółowych zasad powoływania i finansowania oraz trybu działania komisji bioetycznych), 11.05.1999. http://isap.sejm.gov.pl/DetailsServlet?id=WDU19990470480

	Commentary: Most of the enumerated principles do play a role in the course of assessment. Integrity, protection of human beings, promotion of the social good, informed consent, beneficence, and justice are examples of basic principles, without which one cannot talk about research integrity. Experts, when conducting assessments, often discuss the issue of informed consent.
Self-assessments, strengths and weaknesses	Ethical issues in their broadest sense (e.g. the issue of responsibility for research) play a major role, especially in situations when carrying out research might have adverse effects (negative social impacts for instance) that significantly outweigh the benefits. In those cases ethics shall determine, that it is not possible to conduct research, whose results might be ambiguous or whose social impacts (matters regarding nation, race etc.) might be hard to foresee. Due to the fact that at NCN research is funded in the form of projects it is hard to determine during the application phase what are all the possible ethical threats and dangers. A key problem is the lack of detailed regulations as well as thinking in categories that, if something is not prohibited it is allowed. It is important to educate young researchers, that they are ethically responsible for their studies. The point is to make them aware, that concentrating only on legal regulations is not enough to establish, whether theirs actions are right or wrong.
Other	

Name of organisation	**Ministry of Education, Science and Technological Development**
Type of organisation	National funding organisation – non-assessor
Country	Serbia
Website address	*General:* http://www.mpn.gov.rs/ *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	The Ministry of Education, Science and Technological Development of the Republic of Serbia carries out public administration activities related to: the system, development and promotion of scientific and research activities for the purposes of scientific, technological and economic development; defining and implementing the policies and strategies of scientific and technological development; defining and implementing the programs of scientific, technological and development research; training scientific research staff; defining and implementing innovation policies; fostering techno-entrepreneurship and the transfer of know-how to the economy; developing and improving the innovation system in the Republic of Serbia; developing the scientific and research information system and scientific and IT infrastructure; defining the policies and strategy for building the information society; preparing laws, other regulations, standards and measures in the field of e-business; investigating the application of IT and the internet; providing IT services; developing and

	improving the academic computer network; coordinating the preparation of strategic and development documents at the national level; research in the field of nuclear energy; ensuring the safety of nuclear facilities; producing and disposing of radioactive materials, except in nuclear power plants, as well as other activities stipulated by the law.
Interest in research and innovation	MESTD has huge interest in research and innovation. It is practically the only government body that funds research and innovation in Serbia in such a great scale.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [x] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ]
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	There is no special body in Ministry of Education, Science and Technological Development (MESTD) that deals with ethical evaluation of research and innovation. Ethical evaluation is done only when it comes to funding of research projects for which the call is announced every four years and it is done only in fields of natural science and biomedicine. This is new practice and it was applied in previous call for the first time, for current projects (2011-2015). Anonymous ethics commission was established ad hoc for that purpose, so it is not known who were the members and what were the criteria. MESTD has plan to establish permanent body which will work continuously and do ethical assessment of projects in next call for funding (2016-2020). Also, it would supervise the process of research planned by projects.
Aims and motivation for ethics assessment	
Objects and scope of assessment	
Beneficiaries of assessment	
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	

Procedure for ethics assessment: after	
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
Self-assessments, strengths and weaknesses	Interviewee thinks that ethical issues have mostly been neglected. New members of MESTD are willing to deal with this problem in more serious way. They wish to set ethics as one of top priorities because it belongs there and it should not be brought up only when some ethical problem emerges. In future, ethics will be of the same importance as other key elements of research and innovation and it will be evaluated in that manner.
Other	