



Ethics assessment and guidance in different types of organisations

Government and Government-Funded Organisations

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Annex 3.f

Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

Deliverable 1.1

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1 Introduction

The aim of this report is to analyse and compare how ethics assessment and ethical guidance of research and innovation is performed by Government and Government-Funded Organisations 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 were 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. An Italian organisation has been included as well, see Table 1). This report investigates how Government and Government-Funded Organisations are organised in these countries, China, the US and, if applicable, at the EU and global international level. The report also considers the situation in other EU member states and candidate countries. It studies 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.

Examples of Ethics Assessment and Guidance for research and innovation by government and government-funded organisations (Government organisations)¹ can probably be identified by a number of instances throughout the history of government funded research. The focus on ethical aspects has however definitely been intensified. An example of this is the focus on ethics in human subject's research following the Second World War and the atrocities committed in the concentration camps in Nazi Germany and the occupied countries. This led to the creation of the Nuremberg Code,² which among other principles, established the necessity of voluntary consent from the human subject.³

¹ The category of “government organisations” here intends to cover the organisations that have an advisory role to government or that are otherwise government-like.

² Nuremberg Code. http://tsubioethics.weebly.com/uploads/5/0/1/7/5017099/nuremberg_code.pdf

³ Hhs.gov, The Nuremberg Code, HHS.gov. <http://www.hhs.gov/ohrp/archive/nurcode.html>

Name or description ⁴	Sub-categorisation	Information table included in the Annex
Chinese Academy of Sciences (CAS)	Ethics Committee	No
The Convent of Disciplinary Officers, Poland	Ethics Committee	Yes
EUREKA, Europe	Networking organisation	Yes
The European and Developing Countries Clinical Trials Partnership (EDCTP), International	Funding organisation	Yes
A Federal Ministry in a Central European Country	Funding organisation	No
The Global Science Forum (GSF) at the OECD, International	Policy Advice organisation	Yes
A Governmental Agency in a EU member state	Networking organisation	No
Head Office for Clinical Research of the Public Paris Hospitals, France	Funding organisation	No
A National Agency Ensuring Compliance with Data Protection	Ethics Committee	No
National Center for Ethics in Health Care (NCEHC) at the U.S. Department of Veterans Affairs (VA), USA	Ethics Committee	Yes
National Committee for Biosecurity, Biotechnologies and Life Sciences, Italy	Ethics Committee	Yes
National Environment Advisory Committee, China	Policy Advice Organisation	Yes
The Netherlands Enterprise Agency (RVO)	Funding organisation	Yes
The Netherlands Ministry of Economic Affairs	Policy Advice organisation	Yes
A Parliamentary Office	Policy Advice organisation	No
An U.N. Agency, International	Ethics Committee	No
UK Biobank Ethics and Governance Council (EGC)	Ethics Committee	Yes
An Unit under an Intergovernmental Organisation	Ethics Committee	No

Table 1: Presentation of primary dataset

In China, the scientific community started to focus on research ethics in the 1980s, with a widening focus since at least the early 1990s.⁵

⁴ Due to the wish for anonymisation, some organisations are not indicated by name, but only by description.

⁵ According to a recent interview conducted for the SATORI project with members of the Chinese Academy of Science, 3 July 2014, Beijing. The interview was conducted by representatives from the University of Twente, The Netherlands.

Currently, government organisations that assess ethics and provide ethics guidelines for research and innovation can be identified in all ten countries on which this report focuses (see above), as well on an EU and international level.

The data for the report is primarily 18 interviews by members of the SATORI consortium. The interviewed organisations are presented in table 1, and the dataset is presented in a schematised form in section 8 (Annex). Some organisations wished for anonymity while other organisations have not been schematized, which is why only 10 tables are presented in the annex (see table 1). The organisations have further been categorized into four sub-categories, to ensure the best possible basis for making generalizations. These sub-categories are also presented in table 1. Further, has other available material been used for the report, including the country studies prepared by consortium partners for the SATORI project and the report *Materials for a Comparative report on practices of ethical assessment of research and innovation in Europe* for the MASIS project⁶.

For the anonymised organisations the description presented in table 1 will be used to ensure that an examination is possible internally in the report.

The report will start with an overview of basic characteristics of government 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. Finally, the primarily used dataset is presented in section 8 (Annex).

2 Government and Government-Funded Organisations: Basic Characteristics and Distribution

At the surface, the government organisations in the context of this report might show a strong commonality. The available dataset reveals how wide the difference between the organisations is. (see table 1 and the annex). The organisations analysed and compared in this report, spans from *The Convent of Disciplinary Officers*, an advisory body overseeing research ethics in Poland, to the *Ethics Consultation Department of the U.S. Department of Veteran Affairs*. A commonality between the organisations is a focus on how to strengthen and ensure ethically sound research and innovation in their respective institutions or in their respective countries.

A sub-categorization of the 18 organisations primarily examined in this report, indicates that four of them mainly engage with research and innovation through *funding* activities; four through governmental *policy advice*; two can be considered *network organisations*; and eight can be broadly considered as national or international *research ethics committees*.

The four governmental organisations considered funding agencies, represent two national (RVO and the Federal Ministry in a Central European Country) and one international (EDCTP) funding agency, while the fourth represents a group of public teaching hospitals (Head Office for Clinical Research of the Public Paris Hospitals). Of the four organisations, two are concerned with medical research, one with

⁶ The report *Materials for a Comparative report on practices of ethical assessment of research and innovation in Europe*, contains materials compiled by Ida Aagaard Larsen (The Danish Board of Technology), Copenhagen 2014 (Internal working document within the SATORI consortium, unpublished.)

sustainability issues, while the fourth focuses more broadly on technology development. Common for the organisations is a wish to support ethically sound research and innovation. All organisations in the category commit to ethics assessments, although focusing on different subjects.

Of the four organisations that can be sub-categorized as policy advisory organisations, three have a national focus (the parliamentary office, the Netherlands Ministry of Economic Affairs and the Chinese National Environment Advisory Committee) and the fourth is international in the form i.e. Global Science Forum (GSF) of the OECD.

Due to the differences in level (governmental, national, international) between the three organisations, commonalities in their missions are difficult to find, other than they seek to provide ethical advice to their respective organisations or governments.

One of the two network organisations is a governmental agency in an EU nation that creates network programs to stimulate research and innovation. The other network organisation is the intergovernmental open-platform organisation EUREKA. According to the mission of the organisations they both seek to promote and strengthen research and innovation by initiating networks that stimulate developments.

Of the eight governmental organisations that engages with research and innovation as research ethics committees (in a broad understanding of the term) two are international and six national. Of the six national organisations four represents national interests, while two (NCEHC and EGC) primarily focusses on departmental interests.

According to the above presented dataset and the previously mentioned publicly available SATORI Country Studies and the MASIS report, governmental ethics assessment and/or guidance organisations within research and innovation exists in all the case study countries, as well as in the EU and internationally. However some of the organisational sub-categories described above might not be represented in all case study countries. Especially within the area of human subject and animal research there is a prevalence of organisations. Most countries have organisations focusing on data protection and ethical assessing research and innovation in general.⁷ Furthermore, some of the organisations are very small, while others have hundreds of people on staff. Some of the organisations can be seen as institutional relatively independent e.g. with a focus area on the larger society, while some of the organisations are strictly embedded within a larger institution assessing or providing guidelines only for this.

3 Ethics Assessment by Government and Government-Funded Organisations: Prevalence and Aims

The following section will look at the prevalence and aims of governmental organisations. An overall categorization of the 18 government organisations primarily examined in this report (see annex and table 1) shows that while 15 of them either perform ethics assessment or provide

⁷ European Commission: http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm

guidance, three organisations do not. Ethics assessment seems to be mandated requirement for the majority of the organisations performing it. This includes e.g. the ethical requirements grant applicants have to follow under the EU research and innovation programme, Horizon2020.

The following goes through the sub-categories established above and assesses whether the organisations performs ethics assessment and/or guidance, and also examines aspects such as aims, and identifies beneficiaries of the performance.

Of the four organisations in the funding sub-category, three perform ethics assessment or guidance, while the fourth does not. Perhaps the most codified approach is found in the approach of the European and Developing Countries Clinical Trials Partnership (EDCTP). As part of the technical review process, a designated ethics expert performs the ethical review. At Netherlands Enterprise Agency (RVO) a top-down funding approach is applied within four focus areas: Sustainable, Agrarian, Innovative and International Business Enterprise. The aim of the ethics assessment of the three organisations is to ensure ethically sound research. The EDCTP further specifies compliance with the ethical requirements described in Horizon2020 grant procedures.

For the four organisations in the policy-advice, sub-category, the Netherlands Ministry of Economic Affairs (Min. EA), National Environment Advisory Committee (China) and the Global Science Forum (GSF) of the OECD engage directly with ethics assessment, while the parliamentary office does not. According to the Min. EA ethical considerations are included in every aspect of the ministry's work – the final decisions are however made on a political level. The beneficiaries of the assessments done by the Min. EA are dependent upon the area that the ministry works with.

The GSF focuses on defining higher level ethical principles, rather than looking at what might be considered details. One example is OECD's normative focus on ensuring that innovation has a green growth perspective.⁸ The beneficiaries of GSF's assessments are government science policy officials who bring issues to the GSF for analysis, deliberation and resolution in an intergovernmental setting.

Both of the network organisations perform ethics assessment; EUREKA by initiating ethics assessment when looking at the eligibility of participating organisations; the governmental agency by focusing on ethical issues when it initiates programs, even though this is not considered at a direct ethics assessment.

For the eight organisations broadly considered to be research ethics committees, seven of the organisations perform ethics assessments and/or provide guidance for research and innovation, while the sixth organisation primarily concerns itself with legal aspects concerning data protection legislation in a European country.

Only one of the five international organisations performing ethics assessment has outsourced the task, in this case to an agency conducting privacy impact assessments. Even though the organisations analysed are quite different, some commonalities can be found. This includes three organisations focusing on creating an ethical culture in the larger organisation they are part of. The beneficiaries of the assessments include

⁸ OECD: *About the OECD* : <http://www.oecd.org/about/>

the mother organisation, while also e.g. in the case of Polish Convent of Disciplinary Officers the beneficiaries must be considered to be the Polish scientific community in general and the patients of the hospitals of the U.S. Department of Veterans Affairs in the case of the NCEHC.

The NCEHC has further codified their ethical approach in a major program known as IntegratedEthics.⁹ (See Annex)

As evident from above and from the SATORI Country Studies, governmental agencies and organisations engage in ethics assessment differently. Some organisations have special ethics units, some have overall procedures, some mandated, some not. All in all it is clear that government and government-funded organisations that performs ethics assessment is a very heterogeneous group.

4 Institutional Setup of Ethics Assessment

The following section will describe the institutional setup of the ethics assessment organisations. More specifically it will look at aspects such as whether the institutions themselves undertake ethics assessment, or whether it is outsourced to an external organisation. Further the structure of the assessing unit will be described.

The sub-categorization of the organisations described above is provided in this section.

The four organisations performing ethics assessment in the funding sub-category have all internalized ethics assessment in the organisation. However, there are still differences between the organisations. In the case of the RVO, the organisation guides grant-seeking applicants to the various funding opportunities from national ministries or European Directorate-General departments. For the EDCTP, ethical assessment is done within technical reviews performed on all projects. These technical reviews include an ethics assessment. Experts can apply to the EDCTP to become an ethics reviewer. In the case of the governmental ministry, a designated person is directly responsible for ethics. None of the three organisations seems to follow a mandated methodology regarding ethics assessment.

The institutional setup of the four policy advisory organisations performing ethics assessment depicts two very different approaches. In relation to the Netherlands Ministry of Economic Affairs, the ethics assessment is as mentioned internalized; an interviewee mentioned, that for everything the Ministry does there are ethical considerations. Furthermore the Ministry might engage field experts, from e.g. universities, and also cooperate with external organisations which include companies or groups under other European governments. In the area of research and innovation there are two important agencies within the ministry, these are the above mentioned RVO and the Netherlands Bureau for Economic Policy Analysis, which carries out research on socio-economic issues for politicians and policymakers. The setup of the GSF is vastly different due to the intergovernmental nature of the OECD. Here ethics assessment is done through consultation of country representatives. The assessment is conducted by topic-focused expert groups, the members of which are primarily academics and experts nominated by the member countries of the OECD. For the Chinese National Environment Advisory Committee, the set-up is vastly different -

⁹ U.S. Department of Veteran Affairs, National Center for Ethics in Health Care
<http://www.ethics.va.gov/integratedethics/>

the organisation is embedded within the Ministry of Environmental Protection that seeks to ensure that experts contributes to the understanding of environmental challenges and environment protection.

The two networking organisations are quite similar in their institutional setup. Neither of them have a specifically designated ethics unit, while both have integrated at least parts of their ethics assessments into their internal procedures. This integration differs however due to the different work areas of the organisations. In the case of the governmental agency, this is done by initiating programs and debates on technology conflicts, while the EUREKA organisation does an “ethical check” when looking at the eligibility of organisations. This check is conducted by independent experts from a number of countries and by evaluators who are experts at the national level.

For seven of the eight research ethics committees that perform ethics assessment or provide guidelines, the assessment is done in-house. Probably the most substantial of these assessments is done by the NCEHC, where a relatively large center assesses systems, processes, environment and culture at the hospitals under the U.S. Department of Veterans Affairs. (See Annex for more details). At the time of the interview, NCEHC has 26 employees, including doctors, nurses, psychologists, social workers ethicists and philosophers. The center works collaboratively with the V.A. to accomplish their tasks. In general, NCEHC “[...] serves as VA’s authoritative resource for addressing the complex ethical [...]”.¹⁰ The anonymous Unit under an Intergovernmental Organisation is also an example of an organisation performing ethics assessment in-house. Here the assessing unit is seemingly integrated into the mother organisation. The main criteria for the persons performing the assessments include scientific expertise and ensuring geographical coverage. The representatives are further considered in their individual capacity and not as representatives of their respective countries, or organisations they might be affiliated with. An example of an organisation having outsourced ethics assessment could be the U.N. agency, where an external agency was hired to conduct a privacy impact assessment on its programs in certain countries.

As indicated from the above, there are large differences between the organisations in their respective institutional setups. Overall, the vast majority of organisations providing ethics guidelines or performing ethics assessments do this in-house, while only a very few have outsourced this.

5 Procedures for Ethics Assessment

The following section will focus on procedures for ethics assessment, prior, during and after the assessment in the 18 organisations presented in table 1. The sub-categorisation previously presented will also be followed in this section. Please be aware that the data-set available for this section is relatively limited and the results are very diverse which is why it was impossible to present more than very simplified generalisations.

Prior to assessment

¹⁰ U.S. Department of Veteran Affairs, National Center for Ethics in Health Care, <http://www.ethics.va.gov/about/index.asp>

The purpose of this subsection is to identify procedures prior to assessment that are followed to determine if a certain object of assessment should be assessed, and how it is then submitted for assessment.

The EDCTP (sub-categorized as a funding organisation), aims to accelerate the development of new clinical interventions against poverty-related diseases. The organisation supports clinical trials and capacity strengthening, and provides all necessary technical and administrative support to the calls and grants. As part of a technical review, the EDCTP has ethics experts as part of a committee, particularly for trials, to provide reviews from an ethical standpoint. Also, the organisation aims at compliance with the Horizon 2020 (European Framework Programme for Research and Innovation) procedures for ethics assessment. This type of formalized procedure is however not followed by the Head Office for Clinical Research of the Public Paris Hospitals, (another organisation considered to be in the funding sub-category) where according to a recent interview there were no official procedures for ethics assessment.

In the policy advice category, assessments at the GSF under the OECD, is initiated when GSF is contacted by e.g. ministries and science policy analysts, who request research on a particular area. The GSF then sets up a working group to define the best onward action, for instance, a comparative analysis of practices in different countries. On this basis, the Forum may develop basis principles such as transparency or engaging the public in the process. The Forum emphasizes that criteria such as specificity, commitment and inclusiveness are carefully considered.

In the ethics committee sub-category, a unit under an Intergovernmental Organisation, the unit is asked to perform risk assessment on a specific pertinent subject, by relevant authorities. The organisation then establishes a technical committee of international experts, to assess the subject at hand, in order to deliver the most scientific based assessment. The NECHC at the US Department of Veterans Affairs has an extensive program for managing ethics in health care organisations, known as IntegratedEthics (IE).

One core function in IE, is ‘ethics consultation’, which is based on the CASES-model: **C**larify the request, **A**ssemble relevant information, **S**ynthesize the Information, **E**xplain the analyses and **S**upport the consultation process.¹¹ Clarifying the request and assembling relevant information, are the first steps of the process, and can be regarded as prior to the assessment.

Another organisation considered to be in the sub-category ethics committee, is the National Committee for Biosecurity, Biotechnologies and Life Science. The committee addresses topics either chosen by the committee itself, or upon request raised in societal debates. All topics revolve around the scientific impact of R&I and its potential societal relevance. When a topic has been chosen for assessment, the committee organizes a series of plenary meetings, and in some cases, also special working groups.

¹¹ U.S. Department of Veteran Affairs, National Center for Ethics in Health Care
http://www.ethics.va.gov/docs/integratedethics/Ethics_Consultation_CASES_Pocket_Card--20070228.pdf

As evident from the above are procedures followed by the organisations prior to assessment are very diverse. From the relatively formalized process in the cases of e.g. NECH, GSF and an intergovernmental organisation, to the apparently more ad-hoc presented by Head Office for Clinical Research of the Public Paris Hospitals. Organisations with a specific ethics assessment office seem to have a more formalized process for ethics assessment.

During assessment

The purpose of this sub-section is to determine which procedures are followed during assessment.

Only one of the four organisations in the policy advice category, The Netherlands Ministry of Economic Affairs, has official procedures for ethics assessment during assessment. The Ministry closely cooperates with The Rathenau Institute, which provides frameworks and ideas for ethical frameworks. Also, the Ministry has engaged other external organisations in the process during assessment, for instance institutes of applied science. The steps taken by the above mentioned unit under an Intergovernmental Organisation during assessment, is to ensure the coordination of a technical committee of international experts. The organisation then investigates the subject, and provides a systematic and disciplined approach for making evidence-based decisions. The risk assessment, consisting of analysis and recommendations, is handed to a group of assigned delegates. They then process the risk assessment, reach agreement and provide a final recommendation.

The above mentioned CASES-model, outlines the procedures for ethics assessment at the NECHC of The U.S. Department of Veterans Affairs. After clarifying an issue relevant for ethics assessment and assembling relevant information, the last three steps in the CASES-model is executed: Synthesize the information, Explain the analyses and Support the consultation process.¹²

The working groups, established by the National Committee for Biosecurity, Biotechnologies and Life Science, discuss and assess the relevant subject, and compile documents and write a proposal for further evaluation. The committee then reviews the material in plenary meetings. Besides drawing on the proposal from the working group, the committee also takes European and international protocols on ethics assessment into account when performing the assessment.

The UK Biobank Ethics and Governance Council does not have formalized procedures for ethics assessment. However the council operates according to an Ethics and Governance Framework. The extensive framework is a description of standards, covering everything from recruitment of participants to research access to samples.

As evident from the above, the procedures followed during assessment, such as the steps taken prior to the assessment, are highly diverse.

¹²U.S. Department of Veteran Affairs, National Center for Ethics in Health Care
http://www.ethics.va.gov/docs/integratedethics/Ethics_Consultation_CASES_Pocket_Card--20070228.pdf

After assessment

The purpose of this sub-section is to establish which procedures are followed after assessment, e.g. how are the results of the assessment presented to the relevant target groups.

Of the four organisations in the funding sub-category, only the EDCTP has procedures for what is done following the assessment. As noted above, the technical review, performed by EDCTP, intended to ensure compliance with the Horizon 2020 procedures for ethics assessment. Approval for projects cannot be granted if they do not pass the review from an ethical standpoint. Since the target group encompasses individual scientists who are interested in approval of their projects, they make efforts to ensure that they pass the review.

At the unit under an intergovernmental organisation, the final recommendation is approved as an official decision, which is included in standards and guidelines, known by the professional community and all relevant stakeholders.

The NECHC at the US Department of Veterans Affairs evaluates their impact by an Integrated Ethics-staff survey, among employees at the health care facilities of the U.S. Department of Veterans Affairs. These surveys also reveal that some hospitals are more successful at implementing the IE-program than others. NECHC then follows up on the procedures and the ethical environment.

After assessment of a topic, the National Committee for Biosecurity, Biotechnologies and Life Science, publishes the assessment through official documents, and announces the position of the committee in audits. It is not necessarily converted into measures or regulations, but the viewpoint of the committee is taken into high consideration by the public, organs and bodies. (See annex)

To summarise the above, there are several procedures for ethics assessment. However, almost all of the organisations gather information and relevant expertise, and establish working groups and committees. The execution of the assessments, are typically done by these expert groups, and then reviewed by the specific organisation. After completing the ethics assessment, the assessments are either published or included in guidelines. Only a few of the organisations have procedures for following up on the impact of the assessment.

6 Principles and Issues for Ethics Assessment

This section will discuss the key ethical principles and issues in the ethics assessment practice of the governmental organisations included in this report.

As a tool for systematising and giving an overview over the ethical focus areas of the included organisations in the SATORI ethics Assessment reports, the project has defined 17 principles/issues and one open category marked as 'other'. The areas of concern to the organisations have been registered in the tables in the annex. The principles and issues found to be the most important for the organisations in the different sub-categories are shown in table 2. Of the 18 governmental organisations making up the primary data-set of this report, 13 organisations have focus on specific

principles or issues in ethics assessment. Some of the organisations have presented several principles and issues underlining their work, whereas some only focus on a few or one.

The ethical principles and issues are either part of a standard methodology or framework of the analysed organisations, or have been identified from deliberations with, and publicly available reports of the organisations.

As evident from table 2, all the issues and principles defined by the SATORI project were found to be relevant for at least two organisations.

Of the total of 18 principles and issues, four was found to of the greatest importance to the organisations that make up the primary data-set (see table 1). These are:

- ‘social impact’ (8 organisations)
- ‘professional integrity’ (7 organisations)
- ‘environmental impact’ (7 organisations)
- ‘social responsibility’ (6 organisations)

These four principles and issues are examined more in depth next.

Social impact

An important aspect for the majority of the organisations surveyed is ‘Social Impacts’ since it can be identified as an issue or principle for ethics assessment for eight out of the 13 organisations. The organisations which state that social impact is an important topic to take into consideration are quite evenly spread across the sub-categories. This indicates that many organisations are highly aware of the social impact of developments within research and innovation. It is furthermore noteworthy that all three organisations sub-categorized as funding organisations found the principle relevant and important for their assessments.

The Netherlands Ministry of Economic Affairs has further specified why the principle was found to be relevant to the organisation, due to a focus on robotics, machine learning and Big Data. Here social impact can be a central issue, as e.g. further automation will have a massive impact on the labour market. The Ministry further stresses that the technological development is important and should continue, but also calls for political decision making to tackle the expected social impact.

	Sub-categories				Total
	Funding organisations	Network organisation	Policy advice organisation	Ethics committees	
Organisations with identified principals and issues for ethics assessment	3	1	3	6	13
Social impacts	3	1	2	2	8
Professional integrity			2	5	7
Environmental impacts	1	1	2	3	7
Social responsibility	3	1	1	1	6
Scientific integrity			1	4	5
Equality / non-discrimination		1	1	3	5
Implications for health and/or safety	1			4	5
Implications for quality of life	1			4	5
‘Other’ (in total)					2
Implications for privacy			2	3	5
Human subject research			1	2	3
Treatment of animals in R&I	1		1	1	3
Human dignity				3	3
Autonomy / freedom	1			2	3
Implications for civil rights	1			2	3
Justice / fairness	1			2	3
Dual use (possible military uses) ¹³	1			2	3
Outsourcing of R&I to developing countries with lower ethical standards	1			1	2
Total number of organisations	4	2	4	8	18

Table 2: Principles and issues in assessment/guidance for 13 of the 18 organisations primarily examined in this report

¹³ In the case of National Committee for Biosecurity, Biotechnologies and Life Science, *dual use* has been marked as it was emphasised as a relevant issue, due to the commentary in the organisation table.

The eight organisations that found the issue of ‘social impact’ to be of importance for them are:

- An unit under an Intergovernmental organisation
- GSF
- A UN Agency
- The RVO
- The EDCTP
- A Federal Ministry in a Central European Country
- The Netherlands Ministry of Economic Affairs
- A Governmental Agency in European Country

Professional integrity

Of the seven organisations which state that professional integrity is an important principle, five of them are sub-categorized as ethics committees, and two provides policy advice, while neither the organisations of the organisations of the funding or network sub-category found the issue to be central.

The principle of professional integrity also covers topics such as research integrity, responsibility and transparency, which are important in the areas of research and innovation.

The seven organisations that found the issue of Professional Integrity important for them are:

- The Netherlands Ministry of Economic Affairs
- NCECH at the U.S. Department of Veteran Affairs (VA)
- National Committee for biosecurity, Biotechnologies and Life Science
- An unit under an Intergovernmental organisation
- An UN Agency
- GSF
- A Federal Ministry in a Central European Country

Environmental Impact

The organisations which state that environmental impact is an important topic to take into consideration are represented in all sub-categories.

- The National Committee for biosecurity, Biotechnologies and Life Science
- An unit under an Intergovernmental organisation
- A Governmental Agency in European Country
- The Netherlands Ministry of Economic Affairs
- An UN Agency
- The RVO
- Chinese national Environmental Advisory Committee

Social responsibility

Social responsibility is underlined by organisations in all sub-categories, but mostly by funding organisations. Social responsibility should be understood as the benefit for the society at large, including respect for gender, culture, equality.

The six organisations that found the issue of social responsibility important for them are:

- An UN Agency
- The RVO
- EDCTP
- A Federal Ministry in a Central European Country
- GSF
- A Federal Ministry in a Central European Country

Besides the above presented principles and issues found to be important, two organisations identified aspects not covered by the defined principles. These were noted in the 'Other' category and include:

- A Federal Ministry: The mutual impact of RRI and society.
- EDCTP: Legal compliance with ethical guidelines

Some of the organisations found that the principles and issues of importance depended upon the specific situation. In the case of the Netherlands Ministry of Economic Affairs, we find that the principle of integrity is underlying principle, as well as respecting national law and the national constitution. This legal focus can also be found in the case of the EDCTP. Here, care for health, safety and quality of life is crucial, but the organisation further stated that the issue of legal compliance with ethical guidelines is a matter of great concern for the organisation, especially the Horizon2020 procedures for ethics assessment.

7 Problems and Developments

When analysing the primary data-set, a number of strengths and weaknesses become either evident or were specifically identified by representatives of the organisations interviewed for the SATORI project. These are presented and discussed below.

While some organisations focus on evaluating the impact and importance of their work, others do little. The reasons for this are primarily the major differences in the focus point and institutional setup of the organisations. Examples of this are NCECH under the U.S. Department of Veteran Affairs and the EGC of the UK Biobank.

The evaluation procedures of the NCECH are highly developed. Every two years an external Seattle based evaluation service sends out a survey to all the employees of the hospitals under the U.S. Department of Veterans Affairs under the Integrated Ethics program. The survey was last conducted in 2013. The survey was split in two parts: one, on safety and the other, on ethics. For the ethics survey, the questions focused on the recipient's perception of the ethical environment, culture and organisational function. Staff members were randomly chosen to for each survey. From the surveys the NCECH found that the Integrated Ethics program had been well received by the staff.

Another example of a fairly developed evaluation program is the program of the Ethics and Governance Council under the UK Biobank.

On the other hand, other organisations might not have any formalised procedures, or perhaps only very rudimentary evaluation procedures to assess the impact and importance of their work.

A central weakness for at least some of the organisations is the lack of resources, including funding, manpower and specific knowledge on ethics and ethics assessment. This includes the EDCTP, where a lack of resources as well as the dependence on Horizon2020 produces, limits the reach of the organisation's activities. Another example where lack of resources is a constraining issue is an international organisation, where there is a lack of funding and time to evaluate specific solutions to ethics related problems. Further, the funders of the organisation might also present the challenge that solutions to a given situation should be found before sufficient time has been given to look at the ethical implications of the action.

Too few resources or too little focus on ethical aspects in the wider organisation might also be a problem when seeking to implement the findings of an assessment. One surveyed organisation found that the employees were highly responsive to the recommendations giving to the organisation on how to improve procedures. However, it took time to actually implement the new recommended procedures.

Several organisations have unclear ethical guidelines. An U.N. agency finds it important that there is clear ethical guidance to the wider organisation, while the government agency found it unproblematic with unclear guidelines. The agency noted further that there were no real weaknesses in the ethics assessment performed by the organisation, due to the assessment being multi-dimensional.

With regard to strengths of the ethics assessment process the network organisation EUREKA found that their organisational set-up worked well. This includes their bottom-up approach (as opposed to the top-down approach of Horizon2020 projects) and principle of business driven projects (an interviewee found that the closeness to the private sector, ensured that the organisation reflected the needs of the market).

Only a few surveyed organisations presented any thoughts on future developments. A Federal Ministry in a Central European country specifically focused on the notion of Responsible Research and Innovation (RRI); they found it important to have established a common ground on its inclusion in performance plans of universities. The agency especially found it puzzling why participatory elements of RRI were not included in thoughts on future developments, e.g. inclusion of civil society organisations. Another example of expected future developments comes from The Netherlands Ministry of Economic Affairs, which is in dialogue with The Rathenau Institute and the Dutch Parliament, on whether the need for a system to monitor ethical assessments and their impact.

8 Annex: Ethics Assessment and Guidance in Specific Government and government funded organisations

This Annex contains seven reports on particular surveyed Government and government funded organisations that were 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.

Name of organisation	National Environment Advisory Committee (国家环境咨询委员会)
Type of organisation	National ethics committee
Country	China, the People's Republic of
Website address	General: http://kjs.mep.gov.cn/zxkwjwzl/ Main page(s) on ethics assessment: same as general address
Basic description (organisation and mission)	The National Environment Advisory Committee is subordinated in the Ministry of Environmental Protection (MEP). It was built in 2006, based in the Division of General Affairs of the Department of Science, Technology and Standards. It is set up with the mission of implementing the Scientific Development Concept ¹⁴ and the Sustainable Development Strategy ¹⁵ which both are put forward by the State Council. The committee is instituted by the MEP as an expert-advisory organisation linking experts as the think tank with the national macroscopic and comprehensive decisions related to environmental protection of the country.
Interest in research and innovation	Interest in research and innovation related to the committee is mainly performed in the Ministry of Environmental Protection. Chinese Research Academy of Environmental Sciences ¹⁶ which is a research institute affiliated with the MEP works on scientific and technological search in environmental science, environmental planning and engineering design, and other related fields.
Ethics assessment and/or guidance	Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: The assessment work of the committee is basically about environmental protection issues in national plans for long-term development and implementation of important relevant technologies. In this case, the assessment and guidance is entangled. If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> None <input type="checkbox"/> Other <input type="checkbox"/> Commentary:
Terminology for ethics assessment / guidance	The committee's major work is advisory and the scope of work is limited in environmental protection. The initiative of the committee is to make the governmental decisions more scientific and environmental friendly so the development of the country can be sustainable. Its work is ethics related but the concept "ethics" is not explicitly expressed.
Name and description of ethics unit(s)	The National Environment Advisory Committee is itself the ethics unit. It is positioned in the Ministry of Environmental Protection. The committee is financed by the MEP.
Aims and motivation for ethics assessment	According to the <i>Constitution for the Work of National Environment Advisory Committee</i> ¹⁷ , major tasks of the committee include studying important issues

¹⁴ 科学发展观

¹⁵ 可持续发展战略

¹⁶ 中国环境科学研究院

¹⁷ 国家环境咨询委员会章程

	about the national environmental protection and environmental problems; advising on long-term development plans, regulations and laws on environmental protection, and economic and technological policies about environmental protection.																				
Objects and scope of assessment	The objects of the ethics assessment include: national problems in the development, national plans for long-term development, major laws and regulations on environmental protection, and major economic and technological policies related to environmental protection. The scope restrictions: the committee's scope of work is limited only within the issues related to environmental protection.																				
Beneficiaries of assessment	The government, the environment, the general public																				
Ethics assessment unit: appointment process	The National Environment Advisory Committee has one director, two to three deputy director and several committee members. The minister of MEP holds a concurrent post of the director. Famous experts and the deputy minister who is in charge of technological work in MEP hold the posts of deputy directors. Committee members are composed by academicians from Chinese Academy of Science and Chinese Academy of Engineering, influential professionals and officers. Directors, deputy directors and committee members are appointed by the MEP.																				
Procedure for ethics assessment: before																					
Procedure for ethics assessment: during																					
Procedure for ethics assessment: after																					
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input type="checkbox"/> professional integrity</td> <td><input type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input checked="" type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: The work of the committee is carried on mainly in accordance with two relevant regulations: the <i>Constitution for the Work of National Environment Advisory Committee</i> and the <i>Decision of the State Council on Implementing the Scientific View of Development and Strengthening Environmental Protection</i>¹⁸. The <i>constitution</i> is drafted and approved by the MEP, and the <i>decision</i> is drafted and approved by Chinese State Council.</p>	<input type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input type="checkbox"/> professional integrity	<input type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input checked="" type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input type="checkbox"/> implications for privacy	<input type="checkbox"/> other	<input type="checkbox"/> social responsibility	
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<input type="checkbox"/> social responsibility																					
Self-assessments, strengths and weaknesses																					
Other																					

¹⁸ 国务院关于落实科学发展观加强环境保护的决定

Name of organisation	The European and Developing Countries Clinical Trials Partnership (EDCTP)
Type of organisation	International funding organisation International government-funded agency
Country	International organisation (headquarters: The Netherlands – Europe office South Africa – Africa office)
Website address	<i>General:</i> http://www.edctp.org <i>Ethics assessment:</i> http://www.edctp.org/funding-opportunities/calls/ http://www.edctp.org/stay-up-to-date/meeting-reports/
Basic description (organisation and mission)	The European and Developing Countries Clinical Trials Partnership or EDCTP is a partnership between the European Union (EU), Norway, Switzerland and developing countries and other donors, as well as the pharmaceutical industry, to enable clinical trials and the development of new medicines and vaccines against HIV/AIDS, tuberculosis, and malaria. The first program envisioned the provision of €600 million for the period 2003-2007 in order to translate medical research results into clinical applications relevant to the needs of developing countries. The second EDCTP programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020. The European Union will provide a contribution of up to € 683 million for the 10-year programme (2014-2024), provided this is matched by contributions from the European Participating States.
Interest in research and innovation	As noted in the mission, the partnership is set up to help support collaborative research, which is therefore of complete interest and stake to EDCTP. In terms of social implications, EDCTP targets neglected infectious diseases, and works to ensure that collaboration functions as a partnership between the involved actors. In regard to ethical implications, EDCTP’s interest is both in ensuring ethical and legal compliance, but also in finding ways to ensure those standards can be met.
Ethics assessment and/or guidance	Assessment [] Guidance [] Other [x] None [] Commentary: The EDCTP does not engage directly in ethics assessment itself. However, it does provide for technical review of all projects. Pauline Beattie (Operations Manager) said, “As part of the technical review, we will always have ethics experts on the committee, particularly for trials, who would be present and give a review from an ethical standpoint. So that comes before we even see if they have approvals. Also, there’s a question about ethics for the scientists who are reviewed.” Again, the aim is to ensure compliance and comply with the Horizon 2020 procedures for ethics assessment. Additionally, EDCTP provides funding and support through its “Coordination and Support Actions” such as supporting sub-Saharan African countries in developing ethical and regulatory framework for conducting clinical trials, where there may be a focus on national ethics committees. If assessment/guidance is undertaken: In-house [x] Outsourced [] Other [] Commentary:
Terminology for ethics assessment / guidance	The EDCTP does not engage directly in ethics assessment itself. However, it does provide for technical review of all projects. The aim is to ensure compliance and comply with the Horizon 2020 procedures for ethics assessment. Additionally, EDCTP provides funding and support in developing ethical and regulatory framework for conducting clinical trials.

Name and description of ethics unit(s)	EDCTP does not have a specific unit within the organisation that deals with ethical issues; however it does provide Ethics grants for establishing committees, developing training programs, or chairing programs. Technical review of all projects is provided with an aim to ensure compliance and comply with the Horizon 2020 procedures for ethics assessment.
Aims and motivation for ethics assessment	EDCTP describes itself as, “a public-public partnership between countries in Europe and sub-Saharan Africa and the European union. It aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in sub-Saharan Africa. In line with the aforementioned, it provides Ethics grants for establishing committees, developing and chairing training programs, collaboration between organisations. Furthermore, it provides for technical review of all projects. The aim of all these activities is to ensure that the research done to enable clinical trials and the development of new medicines and vaccines, comply with the Horizon 2020 procedures for ethics assessment.
Objects and scope of assessment	EDCTP is a partnership between the European Union (EU), Norway, Switzerland and developing countries and other donors, as well as the pharmaceutical industry, to enable clinical trials and the development of new medicines and vaccines against HIV/AIDS, tuberculosis, and malaria. The EDCTP does not engage directly in ethics assessment itself. However, it does provide for technical review of all projects. Namely, all projects have to comply with the Horizon 2020 procedures for ethics assessment.
Beneficiaries of assessment	EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat diseases in sub-Saharan Africa. However, all projects EDCTP takes into account have to comply with the Horizon 2020 procedures for ethics assessment. Therefore, individual scientists are reviewed, but can be also singled out as beneficiaries.
Ethics assessment unit: appointment process	EDCTP does not have a specific unit within the organisation concerning ethical issues. However it does provide Ethics grants and it does provide for technical review of all projects. Potential reviewers can apply to become a reviewer. Reviewers do so in an advisory capacity with a written, technical review committee.
Procedure for ethics assessment: before	The EDCTP provides for technical review of all projects. The Operations Manager says, “As part of the technical review, we will always have ethics experts on the committee, particularly for trials, who would be present and give a review from an ethical standpoint. Also, there’s a question about ethics for the scientists who are reviewed.” From the provided list of ethical issues of concern to the organisation, care for health, safety, and quality of life are the ones singled out by the interviewees. The Operations Manager noted that they are most strongly concerned with legal compliance with ethical guidelines.” In all projects, there should be a compliance with the Horizon 2020 procedures for ethics assessment.
Procedure for ethics assessment: during	The EDCTP does not engage directly in ethics assessment itself. However, it does provide for technical review of all projects. The Operations Manager says, “As part of the technical review, we will always have ethics experts on the committee, particularly for trials, who would be present and give a review from an ethical standpoint. So that comes before we even see if they have approvals. Also, there’s a question about ethics for the scientists who are reviewed.” Again, the aim is to ensure compliance and comply with the Horizon 2020 procedures for ethics assessment. Potential reviewers can apply to become a reviewer. Reviewers do so in an

	<p>advisory capacity with a written, technical review committee. Additionally, EDCTP provides funding and support through its “Coordination and Support Actions” such as supporting sub-Saharan African countries in developing ethical and regulatory framework for conducting clinical trials, where there may be a focus on national ethics committees.</p>																				
Procedure for ethics assessment: after	<p>The aim of the technical review of all projects is to ensure compliance with the Horizon 2020 (European Framework Programme for Research and Innovation) procedures for ethics assessment. Approval for projects cannot be granted if they do not pass the review from an ethical standpoint. Since the target group encompasses individual scientists who are interested in approval of their projects, they will put efforts in ensuring they pass the review. Furthermore, there’s a separate question about ethics for the scientists who are reviewed. The EDCTP is a partnership between the European Union (EU), Norway, Switzerland and developing countries and other donors. Since the funding of EDCTP depends on them, they can be the ones considered to provide the ultimate oversight.</p>																				
Principles and issues in assessment / guidance	<table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input checked="" type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input type="checkbox"/> professional integrity</td> <td><input checked="" type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input checked="" type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input type="checkbox"/> implications for privacy</td> <td><input checked="" type="checkbox"/> other, specify:</td> </tr> <tr> <td><input checked="" type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: From the list provided list of ethical issues of concern to the organisation, care for health, safety, and quality of life were singled out as crucial. However, the Operations Manager noted that EDCTP is most strongly concerned with legal compliance with ethical guidelines. In all projects, they comply with the Horizon 2020 procedures for ethics assessment. In line with the aims of EDCTP, projects that are reviewed should enable clinical trials and the development of new medicines and vaccines against HIV/AIDS, tuberculosis, and malaria. In terms of social implications, EDCTP targets neglected infectious diseases, and works to ensure that collaboration is a partnership between the actors involved. In regard to ethical implications, EDCTP’s interest is both in ensuring ethical and legal compliance, but also finding ways to ensure those standards can be met.</p>	<input type="checkbox"/> scientific integrity	<input checked="" type="checkbox"/> justice / fairness	<input type="checkbox"/> professional integrity	<input checked="" type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input checked="" type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input type="checkbox"/> implications for privacy	<input checked="" type="checkbox"/> other, specify:	<input checked="" type="checkbox"/> social responsibility	
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<input checked="" type="checkbox"/> social responsibility																					
Self-assessments, strengths and weaknesses	<p>EDCTP describes itself as, “a public-public partnership between countries in Europe and sub-Saharan Africa and the European union. [It] aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in sub-Saharan Africa.”</p> <p>The countries participating in EDCTP as members of the EDCTP Association are:</p> <p>13 European countries – Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, UK; and</p> <p>13 African countries – Burkina Faso, Cameroon, Congo, The Gambia, Ghana,</p>																				

	<p>Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda and Zambia.</p> <p>EDCTP does not have a specific unit within the organisation concerning ethical issues; however it does provide Ethics grants for establishing committees, developing training programs, or chairing programs.</p> <p>EDCTP Operations Manager noted that the issues of care for health, safety, and quality of life are of special concern to the organisation, “but most strongly legal compliance with ethical guidelines.” In all projects, they comply with the Horizon 2020 procedures for ethics assessment.</p> <p>The EDCTP does not engage directly in ethics assessment itself. When it comes to Collaboration with organisations that systematically engage in ethics assessment/ethics guidance, this collaboration is more present in the area of capacity building than ethics assessment.</p> <p>Dependence on the Horizon 2020 procedures and financial contributions of countries somehow limits the reach of EDCTP activities.</p>
Other	<p>Speaking on the desirability of shared principles and protocols, interviewees noted that it could be desirable to have some common principles and protocols, but perhaps being too prescriptive would be difficult, as each country is different. Additionally, “There must be some convergence on procedures. Some countries are much stronger, particularly in research; some institutions do not have institutional ethics review for research to be carried out overseas, etc.”</p> <p>When it comes to benefit sharing and resources, it was again noted that “every country is unique, and so is the distribution of resources and training. If we use Africa as an example, they don’t have the capacity to build resources. Therefore, for compliance, you could get approval or you can get something that’s “approval” but that’s not actually been a true assessment.” This it to suggest there must be a focus on resources and training.</p> <p>When it comes to monetary protocols, some ethics committees require a certain proportional fee of the project, which can have negative connotations all around. However, situations where the ethics committee does not have a financial support of the institution and where the people are asked to volunteer, also pose problems.</p>

Name of organisation	EUREKA
Type of organisation	Non-assessor stakeholders - EU governmental, governmental organisations
Country	European Level
Website address	General: http://www.eurekanetwork.org/content/about-eureka Main page(s) on ethics assessment:
Basic description (organisation and mission)¹⁹	<p>EUREKA is a publicly-funded, intergovernmental network, being present in over 40 countries.</p> <p>EUREKA is a leading open platform for international cooperation in innovation. To this day, the organisation remains the only initiative of its kind committed to the ‘bottom-up’ principle - ensuring that any R&D project with a good business plan receives the relevant financial support, independent of its technological nature, or the type of organisations involved.</p>
Interest in research and innovation²⁰	The organisation strives for enhancement of European competitiveness by fostering innovation-driven entrepreneurship in Europe, between small and large industry,

¹⁹ Based on the EUREKA website, About Eureka, <http://www.eurekanetwork.org/content/about-eureka>

²⁰ Based on the EUREKA website, About Eureka, <http://www.eurekanetwork.org/content/about-eureka>

	<p>research institutes and universities. Therefore the network concentrates the existing potential of experts, of knowledge, research facilities and financial resources in a more efficient way. The organisation is constantly proving its value through a wealth of success stories – innovative products, processes and services that have been launched onto the market over the last 30 years, creating additional turnover and jobs for European companies, small and large – and by supporting the internationalization of businesses with innovative ideas.</p>																				
Ethics assessment and/or guidance	<p>Assessment <input type="checkbox"/> Guidance <input type="checkbox"/> Other <input type="checkbox"/> None <input checked="" type="checkbox"/></p> <p>Commentary: The assessment focuses on the eligibility criteria. Nevertheless, according to the interviewee, the organisation will be developing also ethical criteria to assess the project which should be introduced for the first time in March 2015. The interviewee referred to “ethical test” which would be the second step of the assessment, after the eligibility check of the project. The development is being executed by the Secretariat in Brussels. The ethical check will be conducted by independent experts from several countries, and at early stage by evaluators who are experts at the national level.</p> <p>If assessment/guidance is undertaken: In-house <input type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/></p> <p>Commentary:</p>																				
Terminology for ethics assessment / guidance	<p>The interviewee referred to “ethical test”.</p>																				
Name and description of ethics unit(s)	<p>The organisation does not have a specific ethics unit.</p>																				
Aims and motivation for ethics assessment																					
Objects and scope of assessment	<p>According to the description of the Eurostars, the program is open to all projects in all technology areas and market fields. The only requirement is that projects must have a civilian purpose. The organisation supports the rule “business knows best”, hence uses the ‘bottom-up’ approach according to which the SME running the project defines its nature.</p>																				
Beneficiaries of assessment																					
Ethics assessment unit: appointment process																					
Procedure for ethics assessment: before																					
Procedure for ethics assessment: during																					
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	Commentary:
Self-assessments, strengths and weaknesses	
Other	

Name of organisation	OECD - Science, Technology and Innovation section - Global Science Forum
Type of organisation	International governmental
Country	International organisation
Website address	<i>General:</i> http://www.oecd.org/science/sci-tech/oecdglobalscienceforum.htm <i>Main page(s) on ethics assessment:</i> n/a
Basic description (organisation and mission)	OECD's mission is better policies for a better life – helping governments develop better policies - its main focus is economics. Within that context, the <i>Science, Technology and Innovation</i> section has the <i>Science and Technology Policy division</i> and the <i>Global Science Forum</i> is nested within that division. The <i>Science and Technology Policy division</i> deals with ethics issues, but in the context of 'barriers' to, and promoting of innovation. Ethics as such is not at the forefront, and there are no dedicated ethicists in the division, but the focus is on public perception and concerns about new innovations, topics such as synthetic biology or nanotechnology. In terms of innovation, the division deals with all aspects of innovation, e.g. financial aspects, public engagement, entrepreneurship etc. But ethical issues come mainly in public engagements. In some area, OECD plays regulatory role, e.g. in areas such as nano-safety (safety of nanomaterials), where OECD works closely with European Commission and other regulatory bodies to define tests for nanomaterials. Occasionally, OECD comes out with Council recommendations, which countries are obligated to take on board (e.g. regulations for publicly funded clinical trials). But mainly, the role of OECD is advisory.
Interest in research and innovation	The Global Science Forum (GSF) provides a venue for consultations among senior science policy officials of OECD member countries. It produces findings and action recommendations on high-priority science policy issues requiring international consultations/co-operation, and identifies opportunities for collaboration on major scientific undertakings.
Ethics assessment and/or guidance	Assessment [] Guidance [x] Other [x] None [] Commentary: Science policy and regulation advice If assessment/guidance is undertaken: In-house [] Outsourced [] Other [x] Commentary: Consultation of country representatives.
Terminology for ethics assessment / guidance	Ethical issues, science policy and regulation.
Name and description of ethics unit(s)	Topic focused expert groups are set around individual projects and studies, with members of the group, mostly academics and experts, nominated from OECD member countries.
Aims and motivation for ethics assessment	The aim is to produce policy relevant/useful guidance, defining higher level principles, rather than detail. OECD's concern is about promoting innovation, increasingly inclusive innovation, innovation that has values and ethical issues attached to it.
Objects and scope of assessment	The aim is to consider what would be useful in terms of policy making globally.
Beneficiaries of assessment	The GSF's principal customers are the government science policy officials who bring issues to the GSF for analysis, deliberation and resolution in an

	intergovernmental setting.																				
Ethics assessment unit: appointment process	n/a																				
Procedure for ethics assessment: before	In practice, science policy analysts, ministries of science, innovation, business, would request from OECD the study for particular area. The <i>Global Science Forum</i> would then set up a working group to define what the Forum can usefully do, e.g. analysing practices in different countries, to set up basic principles (e.g. transparency, engaging public early in the process). Before any activity is undertaken, criteria such as specificity, relevance, workload, commitment and inclusiveness are carefully considered by the member countries.																				
Procedure for ethics assessment: during	(See above)																				
Procedure for ethics assessment: after	n/a																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input checked="" type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input checked="" type="checkbox"/> professional integrity</td> <td><input type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input checked="" type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input checked="" type="checkbox"/> social impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input checked="" type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary:</p>	<input checked="" type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input checked="" type="checkbox"/> professional integrity	<input type="checkbox"/> implications for health and/or safety	<input checked="" type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input checked="" type="checkbox"/> social impacts	<input checked="" type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input checked="" type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input checked="" type="checkbox"/> social responsibility	
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<input checked="" type="checkbox"/> social responsibility																					
Self-assessments, strengths and weaknesses	n/a																				
Other	The question is how to best engage the public, and how to effectively have multi-stakeholder discussions, because at the end, the political decision making depends on the public as well. This is a big challenge in innovation and technologies, particularly in life science, where you're manipulating life forms. The biggest obstacle is not regulatory, it has to do with public acceptance.																				

Name of organisation	National Committee for Biosecurity, Biotechnologies and Life Sciences
Type of organisation	National ethics committee
Country	Italy
Website address	<i>General:</i> http://www.governo.it/biotechnologie/eng/index.html <i>Main page(s) on ethics assessment:</i> http://www.governo.it/biotechnologie/documenti.html
Basic description (organisation and mission)	<p>The National Committee for Biosafety, Biotechnology and Life Sciences, originally called the “Scientific Committee for the risks arising from the use of biological agents,” was established at the Presidency of the Council of Ministers in 1992. The Committee performs the following functions:</p> <ul style="list-style-type: none"> assesses the risks arising from the use of biological agents, and to this end

	<p>identifies the risk factors and conditions for their classification;</p> <ul style="list-style-type: none"> • develops criteria for the definition of safety standards in relation to the applicative areas of biotechnology, biosafety and life sciences; • cooperates in drafting the regulations transposing European directives that in any way implicate the involvement of biotechnology, biosafety and life sciences; • as direct support of the President of the Council of Minister in the fields of biotechnology, biosafety and life sciences: <ul style="list-style-type: none"> ○ ensure coordination, harmonisation and integration of programs, initiatives and activities of ministries, institutions and organisations, both public and private ○ favours the knowability of the sector's initiatives and activities in order to allow national, uniform and homogeneous forms of intervention; ○ collaborates in establishing the Italian position in the European Community and internationally ○ disseminate knowledge and information ○ anticipates and validates the collection of data for the database of the National Observatory for Biosafety, Biotechnology and Life Sciences <p><i>Note:</i> <i>The activities of the “National Committee for Biosafety, Biotechnology and Life Sciences” are related to risks and safety issues in the Biosafety, Biotechnology and Life Sciences areas.</i> <i>In Italy the body acting as national ethical committee on bioethics issues is the National Bioethics Committee (http://www.governo.it/bioetica/eng/)</i></p>
Interest in research and innovation	The main issues addressed in recent years by its various working groups include: genetic testing, gene therapy, tissue engineering, development of biotechnology, cloning, legislation, clinical trials, GMOs, infrastructure, information, biobanks, and bio-nanotechnology
Ethics assessment and/or guidance	Assessment [] Guidance [x] Other [] None [] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [] Other [] Commentary:
Terminology for ethics assessment / guidance	Risk and safety assessment in the areas of Biosafety, Biotechnology and Life Sciences
Name and description of ethics unit(s)	National Committee for Biosecurity, Biotechnologies and Life Sciences
Aims and motivation for ethics assessment	Advising on the role and implications on research, development and innovation in Biosecurity, Biotechnologies and Life Sciences in various economic sectors.
Objects and scope of assessment	<p>Preparing opinions, guidance and proposals regarding ethical implications and risks of research and innovation in the areas of Biosafety, Biotechnology and Life Sciences.</p> <p>The assessment and guidance on risks in these areas, the drafting of national regulations (transposing EU directives), the coordination of programs and initiatives from both public and private players in these areas are amongst the duties of the Committee.</p>
Beneficiaries of assessment	Government, national legislators and regulators, public and private research players, and all other stakeholders including the general public.
Ethics assessment unit: appointment	The Committee is composed of acknowledged experts from public and private research and innovation organisations at national level, active in the different

process	scientific disciplines relevant with respect to Biosafety, Biotechnology and Life Sciences. Members of the Committee are appointed by the national Government. External experts might be appointed by the Committee to deal with specific topics.																				
Procedure for ethics assessment: before	The topics to address can be chosen by the Committee itself or upon a request raised by the society in consideration of the scientific impact of R&I and its potential societal relevance.																				
Procedure for ethics assessment: during	<p>The Committee organises its work in plenary meetings. Special working groups may be set up where required by the topic. Other experts on the issue under specific discussion can be aggregated to the Committee and to the Groups.</p> <p>Documents and proposals elaborated by the working Groups are reviewed by the Committee in plenary meetings and therefore subject to its approval.</p> <p>A key reference for the work of the Committee is given by guidance and strategies set at EU level (e.g. see the original 2002 EC Communication Life sciences and biotechnology - A Strategy for Europe).</p> <p>European and international protocols on ethics assessment are also taken in due account in the work of the Committee, in particular for basic ethical issues, such as, for example, those related to the respect of human dignity and integrity, biological diversity.</p>																				
Procedure for ethics assessment: after	The National Ethical Committee makes known its position through official documents and audits. The inputs are not necessarily automatically translated into measures or regulations, but given the high professional profile of the components of the Committee, its input, in any case, is taken in high consideration. The indications of the committees are public. There is a web site accessible to everybody and therefore its advices can influence also the action of nongovernmental bodies or the general public.																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input checked="" type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input checked="" type="checkbox"/> professional integrity</td> <td><input checked="" type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input checked="" type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input checked="" type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> human dignity</td> <td><input type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: Other relevant issues considered include: dual use, biological diversity, cloning, confidentiality and privacy.</p>	<input checked="" type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input checked="" type="checkbox"/> professional integrity	<input checked="" type="checkbox"/> implications for health and/or safety	<input checked="" type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input checked="" type="checkbox"/> environmental impacts	<input checked="" type="checkbox"/> human dignity	<input type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input type="checkbox"/> social responsibility	
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Self-assessments, strengths and weaknesses																					
Other																					

Name of organisation	The Ministry of Economic Affairs (Min. EZ), The Netherlands
Type of organisation	Government / government-funded agency
Country	The Netherlands
Website address	<p>General: http://www.algemenebestuursdienst.nl/</p> <p>Main page(s) on ethics assessment:</p> <ul style="list-style-type: none"> • Interviewee: drs. Jasper K. Wesseling, Deputy Director-General for enterprise and innovation, Ministry of Economic Affairs (<i>directeur Innovatie en Kennis bij Economische Zaken en plv. Directeur-generaal Bedrijfsleven en Innovatie</i>) http://www.algemenebestuursdienst.nl/organisatie/inhoud/wie-is-wie/w/wesseling-j-k • Netherlands Enterprise Agency (<i>Rijksdienst voor Ondernemend Nederland; RVO</i>) http://english.rvo.nl/home/about-rvonl/what-is-rvonl • Netherlands Bureau for Economic Policy Analysis (<i>Centraal Planbureau; CPB</i>) http://www.cpb.nl/en
Basic description (organisation and mission)	The Ministry of Economic Affairs is responsible for innovation policy in the Netherlands. Its mission is to foster knowledge development in companies and collaboration between research institutions and businesses.
Interest in research and innovation	The mission of the Ministry is to promote the Netherlands and Dutch enterprises as a strong international competitors with a focus on sustainability and paying attention to nature and the living environment. ²¹ The Ministry aims at creating an excellent entrepreneurial business climate, by creating the right conditions and giving entrepreneurs room to innovate and grow. ²² Furthermore, it fosters the cooperation between research institutes and businesses in order to enhance the Netherlands' leading positions in agriculture, industry, services and energy and invest in a powerful, sustainable country. ²³
Ethics assessment and/or guidance	<p>Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary:</p> <p>If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input checked="" type="checkbox"/> Other <input type="checkbox"/> Commentary: In the opinion of the interviewee, it is difficult for a government agency to say what kind of ethical assessment is conducted by the Ministry of Economic Affairs. For everything, that the Ministry does there are ethical considerations. However, the final decisions are made on a political level. This refers to every governmental action the Ministry undertakes. More practical social and environmental issues are included in the Ministry's considerations very rigorously. There are formats for environmental impact assessment and norms for social impacts. However, there is no format or standard for an ethical assessment.</p>
Terminology for ethics assessment/guidance	For everything, that the Ministry does there are ethical considerations. However, there is no format or standard for an ethical assessment. The interviewee referred to "ethical considerations" and the obligation of policy makers to include them in their daily work. He referred also to environmental impact assessment and norms for social impacts.
Name and description of ethics unit(s)	<p>The Ministry of Economic Affairs implements its programs through various directorates and agencies. In the area of Research and Innovation (R&I), there are two important agency within the Ministry:²⁴</p> <ul style="list-style-type: none"> • Netherlands Enterprise Agency (<i>Rijksdienst voor Ondernemend Nederland; RVO</i>), which seeks to stimulate sustainable, agrarian,

²¹ Government of the Netherlands, Ministry of Economic Affairs. <http://www.government.nl/ministries/ez>

²² Ibid.

²³ Ibid.

²⁴ Based on the SATORI D1.1 Country Report: The Netherlands.

	<p>innovative and international entrepreneurship, by helping businesses apply for grants, find business partners, obtain know-how, and comply with laws and regulations.</p> <ul style="list-style-type: none"> • Netherlands Bureau for Economic Policy Analysis (<i>Centraal Planbureau; CPB</i>), which carries out scientific research contributing to the decision-making process of politicians and policymakers on socioeconomic issues.
Aims and motivation for ethics assessment	<p>According to the Minister of Economic Affairs, Henk Kamp: Dutch businesses and knowledge institutions together constitute the engine of innovation, and they continually make major contribution to solutions for all sorts of societal challenges. The approach to these challenges goes hand in hand with the development of new products and services. In this context, societal challenges form key growth markets for the business community.²⁵</p>
Objects and scope of assessment	<p>Regarding the subject and a scope of the assessment, it is within the policy that the Ministry tries to assess the aforementioned issues. Sometimes policies have impact on the research community. Usually, policies have economic impact on the sectors that the Ministry is involved in. These are the cases, where the Ministry usually tries to assess the impact of its actions. The Ministry tries to include ethical aspects in considerations regarding the actions they undertake.</p>
Beneficiaries of assessment	<p>The interviewee did not indicate beneficiaries of the assessment, nevertheless it can be concluded that it depends on the area the Ministry deals with. The Ministry is not directly engaged in the innovation process, it does not innovate. The Ministry provides frameworks. The Ministry is constantly making decisions on the basis of questions e.g. what is the impact for that part of the country; for that group of people; for the environment etc.? The answer for these questions is not a blueprint. The Ministry needs to balance all the interests and issues.</p>
Ethics assessment unit: appointment process	<p>The policy makers have to include ethical considerations in their daily work. Sometimes, the Ministry engages external field-experts, usually from universities or institutes for applied research. Despite external experts, the Ministry cooperates with some knowledgeable partners, including institutes of applied sciences, companies, and in some cases teams up with another European government in order to learn from their experience.</p>
Procedure for ethics assessment: before	<p>Regarding the external expertise, there is a large set of general requirements. Most of them are financial, however some of them might deal with ethical issues. In the field of scientific studies, universities have their own general guidelines and the Ministry is confident that they will adhere to these guidelines. Therefore, these requirements are not included in specific grant decisions. The requirements for both private and public organisations are the same. Each organisation conducting research supported by the Ministry is required to adhere to the Dutch law and specific requirements that are included in general agreement.</p>
Procedure for ethics assessment: during	<p>The Dutch government is doing a lot of the assessment, however sometimes they engage external organisations, for instance institutes of applied science or Nano experts in universities. The Ministry closely cooperates with the Rathenau Institute²⁶ working on innovation and technology assessment. The Rathenau</p>

²⁵ The Ministry of Economic Affairs, “Global Challenges, Dutch Solutions”, p. 4. http://english.rvo.nl/sites/default/files/2014/01/Global%20Challenges-Dutch%20Solutions_ENG_2.pdf

²⁶ Note: The Rathenau Institute (Rathenau Instituut) is part of the Royal Dutch Academy of Sciences (KNAW). Its core aim is to study developments in science and technology, analyse their potential impact on society and policy, and to promote a dialogue on issues and dilemmas in science and technology. For further information see the report based on

	Institute provides the Ministry with new frameworks or ideas for frameworks. The Ministry very rarely consult the public in general. This however depends on the issue.																				
Procedure for ethics assessment: after	<p>In terms of the monitoring system of the ethical assessment and its impact, the Ministry does not have such system. Currently, the Ministry discusses with the Rathenau Institute and the parliament whether there is a need for this kind of system. The system, however, should lead to new ideas and new responses to ethical issues. He emphasized that, there is no misunderstanding that ethical issues should be and are taken into consideration. However, the question is how these issues can be monitored, because in most if the cases, you cannot say whether something is 100% ethical or unethical.</p> <p>The impact of assessment depends on the case. The assessment might lead to some kind of regulation, either on the national or the European level. It is quite rare that it will lead to a policy in the field of research. Nevertheless, the Ministry would stop research only rarely, in special cases.</p>																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input checked="" type="checkbox"/> professional integrity</td> <td><input type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input checked="" type="checkbox"/> treatment of animals in R&I</td> <td><input checked="" type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input checked="" type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: The Ministry does not have one shared framework of values and principles, because it is impossible to define beforehand all the issues that can be encountered; these are too broad. The basic point in the code is integrity and abiding the laws and constitution of the Netherlands. The interviewee explicitly referred to the principles and issues indicated above. Furthermore, according to the publication of the Ministry of Economic Affairs “Global Challenges Dutch Solutions” (January 2014), the Ministry recognizes its role in the following R&I areas: health, democratic change and well-being; food security, sustainable agriculture and forestry, marine, maritime and inland water research and the bio-economy; secure, clean and integrated transport; Climate Action, environment, resource efficiency and raw materials; inclusive, innovative and reflective societies; secure society.</p>	<input type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input checked="" type="checkbox"/> professional integrity	<input type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input type="checkbox"/> implications for quality of life	<input checked="" type="checkbox"/> treatment of animals in R&I	<input checked="" type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input checked="" type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input checked="" type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input type="checkbox"/> social responsibility	
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Self-assessments, strengths and weaknesses	According to the interviewee, there are no real weaknesses in ethics assessment performed by the Ministry, because the assessment is multi-dimensional. Even though there is not a clear guidebook on the procedure of ethical assessment, this is not a problem in real life – in the real performance of the organisation.																				
Other																					

Name of organisation	Netherlands Enterprise Agency (RVO) <i>Rijksdienst voor Ondernemend Nederland (RVO)</i>
Type of organisation	Non-assessor / Government
Country	The Netherlands
Website address	<i>General:</i> http://www.rvo.nl/
Basic description (organisation and mission)	Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland, RVO) encourages entrepreneurs in the Netherlands by providing grant schemes and support.
Interest in research and innovation	<p>The Netherlands Enterprise Agency focusses attention on four areas:</p> <ul style="list-style-type: none"> • Sustainable enterprise: People. Planet. Profit. Netherlands Enterprise Agency supports Dutch and international entrepreneurs and researchers in developing sustainable projects related to energy and climate and the environment in line with the 2020 and 2050 objectives for sustainable energy and reduced CO2 emissions. • Agrarian enterprise: The European Common Agricultural Policy (CAP) was developed to balance European agriculture. The CAP encourages farmers to make their businesses more sustainable and innovative. The Netherlands Enterprise Agency is responsible for realizing this policy in The Netherlands. • Innovative enterprise: The Netherlands Enterprise Agency supports and promotes international business, cooperation and development efforts, both private and public, and encourages knowledge institutes in knowledge valorization. <p>International business enterprise. The Netherlands Enterprise Agency supports and promotes international business, cooperation and development efforts, both private and public, and encourages knowledge institutes in knowledge valorization.</p>
Ethics assessment and/or guidance	<p>Assessment <input type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary:</p> <p>If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/></p> <p>Commentary:</p> <p>The Netherlands Enterprise agency does not have overall or general ‘moral principles’ to judge the desirable outcome of the project, research or innovation. The only overall principles might be that there is benefit for the Dutch economy and that the project is viable.</p> <p>All grant schemes and support programs are implementing the official policies of the different ministries, laws and European directives. All grant schemes and support programs are based on the Economic Affairs Subsidies Framework Act (Kaderwet EZ-subsidies (1996) (Ministry of Justice, 1996), provided in Annex 2, and Kaderwet Binnenlandse zaken. The Economic Affairs Subsidies Framework Act does not state the moral principles that the subsidy programs for research and</p>

	RVO is only the messenger.
Self-assessments, strengths and weaknesses	N.a.
Other	N.a.

Name of organisation	The Convent of Disciplinary Officers (Konwent Rzeczników Dyscyplinarnych)
Type of organisation	<i>Government agency interested in, and responsible for, overseeing research ethics (to be more precise a representative of advisory body overseeing cases of scientific misconduct)</i>
Country	Poland
Website address	<i>General: n/a Main page(s) on ethics assessment: n/a</i>
Basic description (organisation and mission)	The Convent is an advisory body, composed of <i>disciplinary officers</i> (rzecznicy dyscyplinarni) nominated by the Minister of Science and Higher Education. The Convent took over the work of the Panel of Good Scientific Practices (Zespół ds. Dobrych Praktyk Akademickich). The Convent currently composed of 16 members.
Interest in research and innovation	<p>The Convent oversees research ethics in the sense of scientific integrity and reliability. It intervenes in cases of scientific misconduct.</p> <p>The Convent is concerned with issues of scientific integrity and reliability (“<i>zasady rzetelności i uczciwości naukowej</i>”).</p> <p>The most common type of cases dealt with by the Panel and the Convent are the cases of plagiarism. Other problems include:</p> <ul style="list-style-type: none"> • nepotism; • writing negative reviews in order to hinder scientific careers of others; • conflicts of interest – the level of awareness among scientists of what constitutes a conflict of interest is very low. <p>A different type of problem is the fact that disciplinary officers (rzecznicy dyscyplinarni) function within the university and they are not fully independent. Moreover not all of them are lawyers. When parties to the conflict hire lawyers, the officer in fact becomes the weaker party.</p>
Ethics assessment and/or guidance	Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: If assessment/guidance is undertaken: In-house <input type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/> Commentary:
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	Conduct of scientists

Beneficiaries of assessment	Scientific community																				
Ethics assessment unit: appointment process	See “basic description”																				
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	<table border="0"> <tr> <td><input checked="" type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input checked="" type="checkbox"/> professional integrity</td> <td><input type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: the Convent is concerned with issues of scientific integrity and reliability</p>	<input checked="" type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input checked="" type="checkbox"/> professional integrity	<input type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input type="checkbox"/> social responsibility	
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Self-assessments, strengths and weaknesses	n/a																				
Other																					

Name of organisation	UK Biobank Ethics and Governance Council (EGC)
Type of organisation	Described as an “independent committee” (national)
Country	United Kingdom
Website address	<i>General:</i> http://egcukbiobank.org.uk/
Basic description (organisation and mission)	<p>UK Biobank operates according to an Ethics and Governance Framework. The project's conformity with the standards and commitments described in the framework is overseen by the Ethics and Governance Council. The Ethics and Governance Council (EGC) is an independent committee that acts as guardian of the Ethics and Governance Framework (EGF) under which UK Biobank operates. The EGC offers advice to UK Biobank, helping it to respond to changes in, for example, the law, and acts to safeguard the interests of research participants and the general public in relation to the project. The EGC also provides a monitoring role, checking UK Biobank's conformity to the commitments it has made in the EGF and reporting publicly on this conformity.</p> <p>The EGC functions as a “critical friend”. It is “with” the biobank in aspiring to put in place a world resource and to support Biobank’s attempt to build best practice on the technical side, the collection of materials and their storage and the scientific practice that goes with that. The “critical” side of their relationship centres on the EGC ensuring that participants’ interests are respected, as well as</p>

	<p>the public interest. If the EGC feels that the biobank is not acting in ways that are in the public interest or are consistent with the best interests of participants, they try to open up a conversation with them and encourage them to reflect on their protocols and practices to ensure that they are doing something that they can defend ethically. However, theirs is not only a bilateral relationship with the UK Biobank on one side and the EGC on the other - the funders (Wellcome Trust and the Medical Research Council) - are also an important third node in the governance network.</p>																				
Interest in research and innovation	<p>The purpose of UK Biobank is to provide a resource for research with the aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society for public benefit.</p>																				
Ethics assessment and/or guidance	<p>Assessment <input type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/> <u>Commentary:</u> please see Basic description section</p>																				
Terminology	N/A																				
Name and description of ethics unit(s)	N/A																				
Aims and motivation for ethics guidance	Please see “Basic description” above.																				
Objects and scope of guidance	Please see “Basic description” and “Principles and issues in guidance”.																				
Beneficiaries of guidance	UK Biobank, participants in the biobank, researchers and the public more generally																				
Ethics guidance unit: appointment process	<p>Appointments will be made by the Medical Research Council and the Wellcome Trust (“the Funders”) according to a process in keeping with the Nolan Principles of Public Life (the seven Nolan Principles include selflessness, integrity, objectivity, accountability, openness, honesty and leadership) and taking into account the views of the EGC Chair where appropriate. A broad range of experience and expertise will be sought across the membership. This may include the following: bioethics, philosophy, law, biomedical science, medical research, social science, health care, public health, public involvement, corporate social responsibility and public policy. The Council may, in due course, choose to include up to two UK Biobank participants in its membership.</p>																				
Procedure for ethics guidance: before	N/A																				
Procedure for ethics guidance: during	N/A																				
Procedure for ethics guidance: after	N/A																				
Principles and issues in guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input type="checkbox"/> professional integrity</td> <td><input type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input type="checkbox"/> human dignity</td> <td><input type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input type="checkbox"/> implications for privacy</td> <td><input checked="" type="checkbox"/> other, specify: please see below</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p><u>Commentary:</u> The Ethics and Governance Framework is a description of</p>	<input type="checkbox"/> scientific integrity	<input type="checkbox"/> justice / fairness	<input type="checkbox"/> professional integrity	<input type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input type="checkbox"/> human dignity	<input type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input type="checkbox"/> implications for privacy	<input checked="" type="checkbox"/> other, specify: please see below	<input type="checkbox"/> social responsibility	
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	<p>standards to which UK Biobank will operate during the creation, maintenance and use of the resource. The Framework also elaborates on the commitments that are involved, not only to those participating in the project but also to researchers and the public more broadly.</p> <p>“Relationship with participants” covers issues concerning recruitment, understanding and consent and confidentiality. “Relationship with research issues” includes stewardship of data and samples, research access to data and samples, relationship with society, management and accountability, external governance and benefit sharing.</p> <p>Specifically, principles include the following: relation between participants and biobank, consent, ownership of samples with biobank (commercial exploitation), right to withdraw, re-contact and confidentiality, to name some of the issues.</p>
Self-assessments, strengths and weaknesses	<p><u>Evaluation of the impact of EGC guidance on UK Biobank activities:</u> The respondents reported that the biobank is highly responsive to the EGC’s recommendations, although it does at times take time for the recommendations to be implemented. At times, their recommendations put a burden on biobank researchers’ time. Biobank is still quite a small operation - employing around 100 people - so anything that the EGC asks of it does have a cost in terms of time. There is an incentive for the biobank to comply with the EGC’s recommendations, particularly with regard to promoting its work on ethics. Indeed, good ethics is an important part of any application that the biobank makes to funders.</p> <p><u>Weaknesses or challenges in ethics guidance:</u> One challenge is getting the biobank to internalise ethics. The biobank is left to make its own decisions - this stance might be criticised from the outside. However, this is the best way for the EGC to operate as a critical friend.</p>
Other	

Name of organisation	U.S. department of Veterans Affairs (VA)
Type of organisation	National government agency
Country	USA
Website address	<i>General:</i> http://www.va.gov/ <i>Main page(s) on ethics assessment:</i> http://www.ethics.va.gov/
Basic description (organisation and mission)	<p>The VA is a government-run military veteran benefit system with a cabinet secretary as leader.</p> <p>The mission of VA is “[t]o fulfill President Lincoln’s promise “To care for him who shall have borne the battle, and for his widow, and his orphan” by serving and honoring the men and women who are America’s veterans.”²⁷ The core values of the organisation are according to secretary of VA Robert A. McDonald “[...] integrity, commitment, advocacy, respect and excellence [...]”²⁸.</p> <p>VA is split into three administrations: the National Cemetery, the Veterans Benefit and the Veterans’ Health Administration.</p> <p>U.S. veteran programs were first consolidated in 1921, when congress enacted legislation creating the Veterans Bureau. This organisation since been enlarged, especially following World War II.</p>
Interest in research and innovation	VA does in-house research, especially under the Veterans’ Health Administration where the Office of Research & Development “[...] aspires to

²⁷ http://www.va.gov/landing2_about.htm

²⁸ <http://www.va.gov/icare/>

	<i>discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for our Veterans and the nation.²⁹</i>
Ethics assessment and/or guidance	Assessment [] Guidance [x] Other [] None [] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [] Other [] Commentary:
Terminology for ethics assessment / guidance	The Ethics Consultation department under NCEHC has a program called integrated ethics. Integrated ethics is a comprehensible approach to managing ethics in health care organisations.
Name and description of ethics unit(s)	National Centre for Ethics in Health Care (NCEHC) “[...] serves as VA’s authoritative resource for addressing the complex ethical issues that arise in patient care, health care management, and research. ³⁰ ” “The mission of NCEHC is to establish, interpret, and communicate ethical standards in health care and promote practice consistent with those standards within VA and nationwide. ³¹ ” NCEHC works collaboratively with the VA in general to accomplish their task.
Aims and motivation for ethics assessment	NCEHCs work “[...]is aimed at clarifying and promoting ethical health care practices in VA and beyond, including ethics-related decisions, actions, systems, processes, environment, and culture. ³² ” The IntegratedEthics (IE) program is motivated by multiple factors. One factor was that that most ethics consultants do not have proper training or standards by which to perform ethics consultation. The NCEHC therefore decided to develop standards for ethics consultations.
Objects and scope of assessment	The object of assessment is health care practices, especially in the VA. The NCEHC does not do research ethics, but they sometimes answer questions related to research when asked but they do not assess research ethics. The whole research arm has its own structure and is not integrated in the integrated ethics program.
Beneficiaries of assessment	The primary beneficiaries must be seen as the patients at VA facilities, who NCEHC works to ensure are subject to ethically correct treatment.
Ethics assessment unit: appointment process	At the moment the NCEHCs office have 26 employees with various backgrounds including doctors, nurses, psychologists, social workers, ethicists and philosophers. Sometimes they also employ lawyers.
Procedure for ethics assessment: before	The ethical approach known as <i>IntegratedEthics</i> (IE) has been implemented in “[...] all of VA’s 152 medical centers and 21 regional networks. The model is continuously improved as new resource materials are added. ³³ ” The policies that the NCEHC develops and provide are binding, but it is impossible to monitor 30.000 staff members.
Procedure for ethics assessment: during	According to a recent interviewee, IE is a comprehensible approach to managing ethics in health care organisations. Previously did most medical centers only have the traditional ethics committees who focused on solving ethical concerns and conflicts around pertaining to their domains. The goal of integrated ethics is to improve the ethics quality throughout the whole organisation. The model is structured around three core functions, each of which targets a different level of ethics quality: <ul style="list-style-type: none"> • Ethics consultation – targets ethics quality at the level of decisions and actions;

²⁹ <http://www.research.va.gov/about/default.cfm>

³⁰ <http://www.ethics.va.gov/about/index.asp>

³¹ <http://www.ethics.va.gov/about/index.asp>

³² <http://www.ethics.va.gov/about/index.asp>

³³ <http://www.ethics.va.gov/integratedethics/index.asp>

	<ul style="list-style-type: none"> • Preventive ethics – targets the level of systems and processes; and • Ethical leadership – targets the level of environment and culture. <p>Ethics quality is the product of the interplay of factors at three levels:</p> <ul style="list-style-type: none"> • Decisions and actions, • Systems and processes, • Environment and culture <p>Together, these three levels define the ethics quality of an organisation.</p> <p>NCEHC has policies, procedures and expectations, which they use to monitor and assess each VA hospital on how they are doing with the implementation of the program. The approach NCEHC use for ethics consultation is called “CASES” Clarify the request, Assemble relevant information, Synthesize the information, Explain the analyses and Support the consultation process³⁴. The department takes on any question related to ethics including business, medication, and the consultants can be asked questions from everybody including patients, families, nurses, the doctor and the cleaning lady at the hospital.</p>																				
Procedure for ethics assessment: after	Assessments of policies etc. seems to be integrated into the work done at NCEHC																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input checked="" type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input checked="" type="checkbox"/> professional integrity</td> <td><input checked="" type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> human dignity</td> <td><input type="checkbox"/> social impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input checked="" type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: The above describes key principles and issues in IE. In the process of developing the NCEHC becomes aware of problems and then write guidance’s on how those situations ought to be handled. NCEHC have guidelines to describe the key-principles and values including ways to interpret them.</p>	<input type="checkbox"/> scientific integrity	<input checked="" type="checkbox"/> justice / fairness	<input checked="" type="checkbox"/> professional integrity	<input checked="" type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input checked="" type="checkbox"/> human dignity	<input type="checkbox"/> social impacts	<input checked="" type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input checked="" type="checkbox"/> autonomy / freedom		<input checked="" type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input checked="" type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input type="checkbox"/> social responsibility	
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Self-assessments, strengths and weaknesses	<p>NCEHC doing a few assessments to evaluate their impact. One assessment is called the IE staff survey. The survey is sent out every two years to all the employees. Last year they divided it up in two parts where half of the employees got a survey on safety and the other half were randomly selected to take an ethics survey. People/staff is asked for their perception on the ethical environment, culture and the organisational function.</p> <p>IE has generally been well received.</p> <p>Evaluation is done by the evaluation service in Seattle, Washington. The service also helps the NCEHC with assessing the impact of policies. For instance in</p>																				

³⁴ <http://www.ethics.va.gov/integratedethics/ecc.asp>

	<p>regards to an implementation of a new policy where the doctors have to retrieve orally consent before taking an HIV test. The evaluation staff made an assessment across all VA hospitals on how well the facility staff was complying with the new policy and making sure that a specific oral consent was obtained and documented. The results of the assessment were published and all the facilities, which did not meet a 95% threshold, were asked to do a quality improvement cycle around the quality gap.</p>
Other	<p>According to a recent interviewee does all the medical facilities at VA have their own culture. Some hospitals are more successful at implementing the IE program and using the policies than others. Some have more resources and the NCEHC know that when there is strong leadership there are strong programs. Each hospital is part of a network, which creates peer pressure and helps maintaining good processes.</p> <p>The IE program is a cultural and organisational change. NCEHC knows that all the rules are not followed at all times but they try to change the culture so that all the hospitals are working towards the same goal. Sometimes there is a problem with the system and a simple change can make it easier for all partners.</p>