Ethics assessment and guidance in different types of organisations

Research Ethics Committees

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

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Contents

1. Introduction

The aim of this report is to analyse and compare how ethics assessment of research and innovation is performed by Research Ethics Committees (RECs) in the European Union, Norway, Serbia, the United States and China. This report is based on online and offline documentation, previously published reports, and interviews with representatives of organisations in eleven countries.[1] Nine representative European countries were selected for in-depth study, including seven EU members and one candidate for EU membership, and one non-EU (non-candidate) member: Austria, France, Germany, the Netherlands, Norway (non-EU member), Poland, Serbia (an EU candidate country), Spain and the United Kingdom. The main source for the in-depth study is interviews. Based on these interviews, we have compiled tables for all interviewed organizations, that are included as an annex to this report.[2]

In this report, the aims, organisation and procedures of RECs will be investigated. It will be studied how RECs are institutionally embedded, how they perform ethics assessment, what their aims are in performing this assessment, and what are the perceived strengths and weaknesses of their participation in ethics assessment.

Ethics assessment, in the context of this report, is any kind of formal assessment, evaluation, review, appraisal or valuation of research or innovation that centrally 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 such as the 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 differs from ethics assessment in that it does not evaluate practices and products of research and innovation that have already occurred, but rather presents rules, codes, and recommendations that future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere. In this report we distinguish between committees that conduct ethics assessment and committees or associations that perform ethics guidance. RECs are defined here as ethics committees doing ethical assessment of research as stipulated in the beginning of this paragraph. Such committees may also have a guiding function, but it is not a defining characteristic of a REC.

RECs have been initiated for the purpose of preventing harm that research may cause to research subjects and/or the environment. The history of how the first RECs were created has been debated. However, it is evident that a number of atrocities related to research on human beings created a need for ethics assessment of research. Among the most infamous examples are the experiments on Jews during the Nazi regime and the Japanese biological and chemical warfare experiments on Chinese people during the 1930s and 40s. The Nuremberg Code of ethics (1947) and the Helsinki Declaration (1962 and on) were some of the responses. The Nuremberg Code and the Helsinki Declaration formulated ethical principles including the need for voluntary consent, avoiding harm of research subjects, and weighing up the risks against potential benefits. Before this, scientists paid little or no attention to the protection of research subjects.

[1] Austria, China, France, Germany, the Netherlands, Norway, Poland, Serbia, Spain, Sweden, and United Kingdom.
[2] Due to lack of consent to public use of the contents the interviews of the representatives from the US that were contacted for this study, the REC activities in the US will only be described in general terms, and will be based on desk research on the US from elsewhere in the SATORI project.

Requirements to have research proposals reviewed by an independent body were formulated to more effectively prevent unethical research practices. The first documented requirement of an ethical review of clinical research is the 1953 US Federal Government document "Group Consideration for Clinical Procedures Deviating from Accepted Medical Practice or Involving Unusual Hazard". This document was followed by other initiatives, and in 1975, in the Tokyo revision of the Helsinki Declaration, the requirement of ethical review of experimental research procedures involving human subjects by an independent ethical committee was implemented.[3] This was the beginning of the institutionalization of RECs. In the last few years, ethical assessment has included the protection of animals used for scientific purposes and environmental research as long it can directly affect human beings.

In this report we will review interviews of 30 representatives of different types of RECs from nine countries: Austria (8)[4], China (2), France (3), The Netherlands (2), Norway (1), Poland (3), Serbia (5), Spain (4) and Sweden (2).

Five associations of RECs are also included in this study: the Association for Research Ethics, (AfRE) in the United Kingdom, the National Association of Research Ethics Committees (Asociación Nacional de Comités de Ética de la investigación, or ANCEI) in Spain, the Pharmaceutical Companies/Les enterprises du médicament (LEEM), in France, the Permanent Working Party of Research Ethics Committees in the Federal Republic of Germany Inc. (AMEK) in Germany and a fifth anonymised association from a Western European country. Associations of RECs are organisations that promote research ethics and make recommendations and provide guidance for RECs. The interviews with the representatives of the associations contribute to a deeper understanding of the institutional landscape of RECs.

In section 2 we will present the basic characteristics of the RECs included in this study. Here we will also describe the different types of RECs and how they are distributed across the countries chosen for this study. In section 3 we will describe and discuss the aims of the different RECs presented. Section 4 will describe the institutional arrangements chosen for the RECs included in this study. In section 5 we will describe the procedures for ethics assessment, and section 6 will identify and discuss the ethical framework, the ethical principles and issues that play a role in the ethics assessment practice. Section 7 discusses the perceived strengths and weaknesses that the representatives of the RECs have reported in their work.

2. Research Ethics Committees: Basic Characteristics and Distribution

This section will present the basic characteristics of RECs in general, and introduce the characteristics of different types of RECs.

RECs can be described as multidisciplinary, independent groups of individuals appointed to consider ethical issues in research. As we saw in the introduction, RECs were initially instituted to deal with pressing ethical issues related to biomedical and behavioural research involving human research subjects. Today there are RECs assessing a wider range of ethical issues. Ethical assessment by research ethics committees also covers research and experimentation on animals, the assessment of the environmental and social impact of research, and scientific and professional

[3] Borovecki, Ana, "Committees: Research Ethics Committees" in *Encyclopedia of Global Bioethics*, Springer International Publishing, 2014.
[4] The Austrian university research ethics committees are not presented by name due to requests for anonymisation.

integrity. Moreover, ethical assessment of research in the social sciences and the humanities are becoming more common.

The RECs included in this report are constituted on different levels: local, regional and national. What is characteristic of a local REC, and thus distinguishes it from a regional REC, is not made clear in the literature. However, in general, local RECs are considered to be RECs that are linked to universities, hospitals or research centres, while regional RECs assess research ethical issues within a particular geographic area. National RECs are, as the term clearly indicates, research ethics assessment committees that operate on a national level. In this report we will adhere to this distinction between RECs operating on different levels.[5]

National RECs must be distinguished from national ethics committees (NECs). While national RECs assess research on a national level, NECs are committees that mainly offer ethics guidance (as the term is defined in the introduction section) and policy advice. However, sometimes there is not a clear distinction between a national REC and a NEC since some national RECs actually do both (the National Committee for Research Ethics in the Social Sciences and the Humanities, NESH, in Norway, for example).

RECs on different levels can differ in scope. They are often restricted by discipline (e.g., medicine, social sciences, behavioral sciences), or by focus on a particular topic or issue (e.g., human subjects, animal experimentation, or other specific issues). The scope of RECs also varies between countries: some countries differentiate between RECs that assess clinical trials and those that do not, establishing different requirements for each.[6] For example, in Serbia, the Ethics Committee of Clinical Centre Nis (ECCC) includes research on assisted fertilization and organ transplantations,[7] while in Spain such matters are the focus of ad hoc committees.[8]

30 RECs and 5 associations from 12 different countries and of different types are included in this report. Their distribution in terms of what level they operate at is illustrated in table 1 below.

The distribution in the table is broadly made. Some of the RECs extend over several categories. For example, Bioethics Committee of Children's Memorial Health Institute (KBpCZD) and ECCCC are RECs at hospitals, but are also university committees.

Let us take a closer look at table of RECs, starting at the local level. 15 of the 35 RECs and associations of RECs studied are university committees. This is representative of the fact that research ethics committees are often local bodies within the organisations that perform research.[9] They review research conducted at the universities and are thus local bodies for ethics assessment of research. Austria, with eight represented university ethics committees, dominates in terms of the number of represented university RECs. This may be a result of how research assessment is organized in the studied countries as they differ in what types of organisations and committees perform ethics assessment. In Austria the legal provisions for ethical assessment are mainly included in the University Act, and so are international provisions such as the Regulation

[5] There is also a European network for RECs, EUREC. Its aim is to coordinate action between RECs and to interlink them with other organisations of research involving human participants. It aims to meet new challenges and ethical problems. EUREC does not make assessments and is not part of the study.
[6] In Spain: Royal Decree 223/2004 on clinical trials on medicines. BOE. http://www.boe.es/buscar/doc.php?id=BOE-A-2004-2316
[7] Prof. dr Miroslava Živković, Deputy of the Director of Clinical Centre in Niš, personal interview, 20 Nov 2014.
[8] Law 14/2007 on Biomedical Research. BOE. http://www.boe.es/buscar/act.php?id=BOE-A-2007-12945&tn=1&p=20110602&vd=#tviii
[9] SATORI, Annex 1 "Description of work", p. 4.

on clinical trials on medicinal products for human use (2014/536/EU), the Council Directive concerning medical devices (93/42/EEC), and the Directive on the protection of animals used for scientific purposes (2010/63/EU).[10]. This may explain the large number of university committees in Austria. In comparison, although many Swedish universities have ethical boards or ethics councils, ethics approval there is not dealt with at a university committee level. Instead there are regional boards responsible for vetting research in their regions. For example, the Linköping Regional Board of Vetting Research Involving Humans (LRB) is one of six such regional boards in Sweden. The decision to have regional boards vetting research is stipulated in the Swedish Ethical Review Act. The Swedish law regulating ethics assessment of research involving humans was introduced as a requirement for Sweden joining the European Council's Convention on Human Rights and Biomedicine. To be able to ratify the convention, Sweden had to implement a legally enforced regulation regarding ethical vetting of research involving human research subjects.

	Local	Regional	National	Industry
University	- Anonymised university research ethics committee 1, AT - Anonymised university research ethics committee 2, AT - Anonymised university research ethics committee 3, AT - Anonymised university research ethics committee 4, AT - Anonymised university research ethics committee 5, AT - Anonymised university research ethics committee 6, AT - Anonymised university research ethics committee 7, AT - Anonymised university research ethics committee 8, AT - Peking University Health Science Center (PUHSC), CN			

[10] See University Act 2002 (Universitätsgesetz) § 30.

	Local	Regional	National	Industry
	- Shanghai Institute for Biological Science (SIBIS), CN - Ethics Committee of the Faculty of Behavioural, Management and Social Sciences of the University of Twente (REC-BSUT), NL - Ethics Commission, Department of Social Psychology of the Faculty of Psychology at Warzaw University (ECW), PL - Professional Ethics Committee, University of Belgrade (PEC), SRB - National Distance Education University (UNED), ES - University of the Basque Country (UVP/EHU), ES			
Hospital	- Bioethics Committee of Children's Memorial Health Institute, (KBpCZD), PL - Ethics Committee of Military Academy (ECMMA), SRB - Ethics Committee of Clinical Centre Nis (ECCC), SRB			
Association			-National Association of Research Ethics Committees (ANCEI), ES - Association for Research Ethics (AfRE), UK - (Anonymised) Western European association of RECs - Permanent Working Party of Research Ethics Committees in the Federal Republic of Germany Inc. (AMEK)	- The Pharmaceutical Companies (LEEM), FR

	Local	Regional	National	Industry
Research Institute	- French Ethics Committee for Animal Experimentation n°89/ The Institut Pasteur Committee for Ethics in Animal Experimentation (CETEA), FR		- Ethics Committee of the French Institute of Health and Medical Research (IMSERM), FR	
Other (administrative body, appeal body, supervising committee, etc.)		- Linköping Regional Board of Vetting Research Involving Humans (LRB), SE - Ethics Committee for Clinical Research of Aragon (CEICA), ES - Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country (CEIC-E), ES	- Central Committee on Research Involving Human Subjects (CCMO), NL - The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH), NO - Appeal Bioethics Committee (ABC), PL - Ethics Board of Serbia (EOS), SRB - Ethics Council for Protection of Experimental Animal's Welfare (ECPEAW), SRB - Central Ethical Review Board (CEPN), SE	

Table 1. Levels and organisation of RECs represented in the report

All countries represented in this report have legal provisions for ethics assessment of research stating that research of a certain type must undergo ethical assessment before research begins. There is a general requirement to gain approval for research involving human beings. Despite this, research ethics is still applied in different ways among the studied countries, both regarding the assessment procedure and the type of research assessed (research involving humans and/or animals, vulnerable research subjects, medical and/or drug trials, etc.). In some countries, there are general legal provisions regulating ethical review of research (for example, the Ethical Review Act (Act 2003:460) in Sweden and the National Research Act in US), while other countries (e.g. Austria and the UK) do not have a general legal framework regulating ethical review, but rather have specific acts that are relevant for ethics assessment of research, such as acts on human rights, animal welfare, clinical trials, data protection, endangered species, environment, and so on.

Let us turn to the regional RECs. The Linköping Regional Board of Vetting Research Involving Humans (LRB) has already been mentioned. In the table above, we can see that besides the LRB, the only regional RECs represented are two Spanish regional RECs: the Ethics Committee for Clinical Research of Aragon (CEICA), and the Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country (CEIC-E). The two Spanish regional RECs are

assigned by the government of their respective region (Aragon and Basque Country) to assess research proposals. In the case of Spain, the existence of regional boards can be explained by the Spanish constitution's division of the country into autonomous communities that have their own executive power.

It is difficult to draw any conclusion from the available material as to why regional RECs are underrepresented in the report. Sweden and Spain have regional RECs for two very different reasons. The division of a country into autonomous regions cannot be the single explanation: first of all, this explanation does not apply to Sweden. Moreover, Austria, which is divided into autonomous regions, has a completely different set-up than Spain. It would nevertheless to be interesting to see if there are more countries than Sweden and Spain that have regional RECs or if it is an uncommon method for countries to organise ethics assessment.

The national RECs, as indicated in the table above, is a category of RECs where we can find diverse types of organisations with different functions that all operate on a national level. In the table they are represented by the Central Committee on Research Involving Human Subjects (CCMO), the National Committee for Research Ethics in the Social Sciences and the Humanities (NESH), the Appeal Bioethics Committee (ABC), the Ethics Board of Serbia (EOS), the Ethics Council for Protection of Experimental Animal's Welfare (ECPEAW), the Central Ethical Review Board (CEPN), and the Ethics Committee of the French Institute of Health and Medical Research (IMSERM). The various aims of the RECs will be discussed in the next section.

Let us turn to the associations of RECs. The purpose of associations of research ethics committees is largely to harmonise and standardise procedures for ethics committees, to provide education for members of research ethics committees, and other related tasks. The associations of RECs studied here all operate on a national level. Nevertheless they differ from each other in various aspects. ANCEI, AfRE and the anonymised Western European association of RECs are administrative national bodies. The German association, the Permanent Working Party of Research Ethics Committees in Germany (AMEK) is a national forum for harmonizing the work of individual RECs in Germany that began in the 1980s. Unlike ANCEI, AfRE and the anonymised association, AMEK lacks the official status of an administrative national body. However, since there is no national REC in Germany, in practice AMEK does perform this function and thus serves as a consultancy for the public, government and parliaments.[11]

Besides the three administrative levels (local, regional and national), we can also add a fourth category for RECs and associations of RECs that operate in the industrial sector. This category is represented in this study by The Pharmaceutical companies/Les Enterprises du Médicamente (LEEM). LEEM is a trade association representing the pharmaceutical industry in France. It is an association of RECs belonging to the industry sector. LEEM also has its own institutional ethics committee, the Comité de déontovigilance des entreprises du medicament (CODEEM).

The number of RECs in each country varies, in most cases according to the country's size. There are 24 accredited RECs in the Netherlands, 27 in Austria and 104 in the UK. However, in some countries, the number of committees does not seem to be correlated with the country's size:

[11] Based on the information available at European Network for Research Ethics Committees, "National Information: Germany". http://www.eurecnet.org/information/germany.html. Retrieved 2015-06-21.

Germany has 53 ethics committees, while Belgium has 215.[12] Instead it may be a question of how ethics assessment is organised in different countries, where some countries focus on having many local boards dealing with ethics assessment of research, while others instead have fewer regional research ethical committees (such as Sweden, for example). It may also depend on what role ethics assessment of research plays: for instance, if ethical approval by an independent ethics committee is required prior to performing a certain type of research, or if the committees only have an advisory role.

3. Ethics Assessment by Research Ethics Committee: Aims

In this section, we will describe the mission and aims of RECs and associations of RECs, their objects of assessment (what do they assess?), and the beneficiaries of assessment (who will use the assessments?). The organisations represented in the tables in the appendix to this report have different profiles. These differences should be taken into account to understand the variety of objects of research, beneficiaries and aims.

3.1 The aims and beneficiaries of local and regional RECs

Let us turn to a description of the aims, objects of assessment, and beneficiaries of RECs. RECs generally evaluate research proposals, and their aim is usually to assess the ethical acceptability of these research proposals and to give recommendations for a better consideration of ethical issues in the performance of the research. As mentioned in the previous section, RECs are often restricted by discipline (e.g., medicine, social sciences, behavioral sciences), or by focus on a particular topic or issue (e.g., human subjects, animal experimentation, or other specific issues). Their beneficiaries are usually the researchers who have submitted the research proposal, but other beneficiaries may also be involved.

As seen in the previous section, 15 of the represented local RECs are university committees. We will begin by discussing the aims and beneficiaries of these RECs, and then turn to local RECs at research institutes and to regional RECs. The aim of the university RECs is to review projects which are conducted at the university, and which do not fall under the competence of other assessment bodies. In many countries it is regulated by law to submit certain types of research for ethical assessment to a REC. Therefore, one of the aims of RECs are to enforce the law. This is the case for several local and regional RECs studied in this report (PUHSC, SIBS, the Austrian University Committees, and several more).

The university RECs in some cases also have the role of supporting the rectorate in ethical matters and to prepare written statements regarding ethical issues. The scope and object of assessment depends on the faculties of the university. The medical universities represented here mainly assess issues related to biomedicine and related human subject research issues, technology universities largely assess studies related to technical research, and so on.

Among the university RECs, faculty committees are also represented: for example, the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences of the University of Twente (REC-BSUT) is a university REC that considers research proposals in the social and behavioral sciences performed at the University by students or staff. It has a strong focus on issues concerning human subjects.

[12] Based on the information available at http://www.eurecnet.org/information/index.html#.

The hospital RECs have similar aims, but focus on biomedical and clinical research and clinical trials. Two interviewees have reported assessing transplantation practices. Both of them are in Serbia, the Ethical Committee of Clinical Centre in Niš (ECCC) and the Ethics Committee of the Military Medical Academy (ECMMA). The ECCC is the only committee in the study that also decides about issues on biomedical-assisted fertilisation.

The regional boards basically perform the same types of assessments as the university committees, but on a regional level. The Linköping Regional Board of Vetting Research Involving Humans is one of six regional committees in Sweden assessing research proposals concerning human beings. The regional boards assess research proposals of two kinds: (i) projects that according to the Ethical Review Act (2003:460) are required to be vetted, and (ii) research proposals where the researcher wants ethical advice due to requirements for publication, or wants ethical advice for other reasons.

The Ethics Committee for Clinical research of Euskadi (CEIC-E) and the Ethics Committee for Clinical Research of Aragon (CEICA) are Spanish regional RECs that assess all clinical trials involving human beings, their data or samples, trials with drugs and health products carried out in Euskadi and Aragon. They also serve as external ethics committees of biobanks.

3.2 The aims and beneficiaries of national RECs, associations of RECs and RECs within the industry sector

As described in section 2, the national RECs can have various aims and functions. Here we will examine these aims further, as well as the aims of associations of RECs and RECs within the industry.

Let us start with the associations of RECs. The aim of these associations is to harmonise and standardise the work of individual RECs within a specific area, such as a particular country. For example, ANCEI has relations with all RECs in Spain that assess biomedical research, which can be regarded as their beneficiaries because its main aim is to promote training of their members. The main function of AfRE in the 1990s was the coordination of all the RECs in the UK's National Health Service (NHS). Today the coordination is managed by the NHS, and AfRE is a representative body of university Committees. It also organises training sessions, and their beneficiaries are the Health Research Authority, sponsors and universities where they provide external training assistance in research ethics. AfRE has also edited guidelines for policies and procedures for clinical research, social sciences and humanities. The Spanish government must consult ANCEI, as the representative of the national RECs, when a new regulation on ethical evaluation is being debated, although its opinion is nonbinding. For the values that guide their evaluations, ANCEI mentions the most important international documents regarding biomedical research. In their guidelines, AfRE considers that independence, competence, facilitation and openness should guide the ethical evaluation. As previously mentioned, AMEK is a national forum for harmonizing the work of individual RECs in Germany. It discusses emerging issues of medical research and the ethical review process with the aim to improve the assessment of biomedical research on human beings performed by the members of AMEK. AMEK elaborates (non-binding) recommendations regarding pressing ethical issues related to ethics assessments.

The beneficiaries of associations of RECs are individual research ethics committees in universities and researchers in general through the organisations for which they work.

The role of the national RECs are: (1) to supervise local and/or regional RECs, (2) to assess specific types of research ethical issues, and (3) to serve as appeal bodies. Not all of the national RECs are involved in all of these activities.

CEPN, CCMO and EOS serve as supervisors of local and/or national RECs, ensuring that they act in accordance with the national provisions that regulate ethics assessment of research in their respective country. ABC, CEPN, CCMO and EOS serve as appeal bodies when a researcher wishes to object to a decision made by a REC.

Some national RECs are assigned specific ethical assessment tasks that are not assigned to local or regional RECs: CCMO has limited reviewing tasks that are laid down in the Medical Research Involving Human Subjects Act (WMO) and the Embryo Act. CEPN assess issues in connection with the inauguration of biobanks in accordance with the Biobanks in Medical Care Act (2002:297).

IMSERM is a public scientific and technological institute which operates under the joint authority of the French Ministry of Health and the French Ministry of Research, and is the only French public research institute that focuses entirely on human health. It performs translational research in addition to fundamental or clinical research. It has several different committees managing different issues (reflection-guidance, assessment and scientific integrity). The committees reflect upon ethical issues such as the socio-ethical implication of incidental findings in genomic research, gender as bias in research, the consent concept within the scientific community, emerging technologies that may have an impact on the functioning of our societies, and ethical challenges of health research in countries with limited resources.

The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH) in Norway has a quite different role than the other national RECs in this study. NESH is an administrative body under the Ministry of Education and Research in Norway. It develops and administrates ethical guidelines for research within the social sciences, humanities, law and theology. The Norwegian system is divided into three national committees which together cover all research fields, and NESH is one of these three committees. NESH is an interesting case related to ethical assessment of social science research and research within the humanistic disciplines. They are, to our knowledge, the only national ethics committee that has a well-elaborated ethical framework for assessment research within social science and the humanities (that is, that goes beyond the ethical assessment of research involving humans). One of NESH's primary tasks is to engage in policy-oriented assessment in cases where it is unclear if or how the ethical guidelines on research ethics provided by NESH are adequate or relevant because of research raises new issues, perhaps due to new types of problems or methodologies, or when the research involves vulnerable research subjects. This type of assessment may result in recommendations of how to interpret and apply the guidelines, and in some cases recommend a revision of the guidelines. The beneficiaries are individual researchers, doctoral and master students, the authorities, and the public.

The Serbian Ethics Council for Protection of Experimental Animal's Welfare, ECPEAW, also has a different role from the other national RECs in this study. It only focuses on ethics assessment of research involving animal experimentation. ECPEAW is a special working group that provides expert opinions and participates in the implementation of terms of reference in the field of animal welfare.

A specific aim of the RECs on all levels is also to make ethics reviews of research to allow the researcher to publish the results in academic journals that require ethics approval of the research before publication.

4. Institutional Setup of Ethics Assessment

In this section we will describe the institutional setup of ethical assessment in the RECs represented in this study. We will discuss how the committees are constituted and appointed, how the committees are composed, and what type of expertise is required of its members. We will begin by first giving an account of the institutional framework that most RECs have to address.

4.1 The 'juridification' of ethical reflection of ethical issues related to research

Ethical assessment of research by committees has become an increasingly widespread practice. The countries referred to in this study have – at least in some form, and for at least some type of research (usually clinical trials and research involving human subjects and animals) – legal provisions requiring ethics assessment of research. In medicine, biomedical research, clinical trials and in experiments involving animals, there are clear legalistic institutional setups for all countries involved in this study. The reason for this is that most of the studied RECs have been initiated due to legal requirements, such as the clinical trials Directive (2001/20/EG) and the Directive 2010/63/EU on the protection of animals used for scientific purposes. To be able to ratify these directives, the countries had to have legal provisions regarding the ethical evaluation of research involving human subjects research and research that use animals for scientific purposes. Similar legal requirements are also found outside of a European context. The Chinese RECs are the result of a similar process. In September 1999, the Chinese State Drug Administration (SDA) introduced the Drug Good Clinical Practice regulation. The purpose of this regulation was, among other things, to ensure the rights and safety of human research subjects.[13] It stipulated that drugs promoted in China must be vetted and that research protocols must be reviewed by ethics review committees.

Thus, the approach to ethics by the committees regarding ethical assessment of research tends in varying degrees to be about the implementation of legal rules. A Swedish ethics assessment expert in social science research and education, argues in an interview that the legal implementation of ethics assessment in research is moving towards the "juridification of ethics assessment".[14] The degree of juridification of ethics assessment of research varies among the countries referred to in this study. Sweden is a clear example of a country that has taken the juridification of ethics assessment quite far. The Swedish legal act regulating vetting of all research involving human beings stipulates not only that research involving human beings must undergo ethics assessment by a committee and how that committee is to be composed, but also stipulates the ethical principles that are to be applied by the committee. The legalistic setting for the committee's work is emphasized by the condition that the work of the committee must be led by a judge.[15]

[13] Based on the information available at http://www.bioon.com/drug/chemdrug/243155.shtml
[14] Interview with an anonymised ethics assessment expert in social science and education.
[15] There has not been enough time to go through all the relevant countries, but it would be an interesting task to see to what degree ethics assessment of research is implemented in the legal framework. That is, not only the

What has been described is true mostly for biomedical research, clinical trials, drug testing, experimental on animals, and related research. In the social science and the humanities the tendency is a soft-law approach, with the exception of research collecting and storing personal data where, for the European Union countries, the EU Data Protection Directive (95/46/EC) is applicable.

4.2. The composition of the RECs and the appointment of its members

The individual committee members of the RECs are often appointed by the centre to which they are attached or by the regional or national government. The members of university committees are appointed by the rector or the University. The committees consist of both academic experts in the relevant disciplines and sometimes also people from outside of the University (politicians and/or laypersons). The number of members varies between different countries, ranging from 5 in the Austrian university committees to 26 in CETEA.

The differing composition of committees can be illustrated by a few examples:

- ECCC's members are selected according to the Law on Health Care and appointed by the Director of the Clinical Centre.

- The Regional Minister of Health of the Government of Aragon appoints members of CEICA. CEICA is composed of a physician, a nurse, a representative of the Research Commission of the Aragon Institute of Health Sciences (IACS), a representative of Clinical Ethics Committee of Aragon, a Clinical pharmacologist, a hospital Pharmacist, a Primary Care Pharmacist, an expert in Clinical Epidemiology, a representative of the Aragon Institute of Health Sciences, a law graduate, a representative of the Consumer Organisations registered in the Register of Consumers Associations of Aragon, someone from outside the health profession, a Bachelor of Biomedical Sciences hired by the IACS, who acts as Secretary of the Committee, as well as experts appointed on an "ad hoc" basis when necessary. In total CEICA consists of 16 members. The BMS' ethics committee is composed of senior researchers from the faculty of BMS of the university, including ethics specialists from the philosophy department. With regard to composition, the main rule is that each individual department of the faculty has representation in the committee; each department delegates a member to the committee.

- The IMSERM Ethics Committee includes about 15 members appointed for a period of 3 years with the possibility of renewal. At least half of the members do not belong directly to INSERM. The fields of expertise of the members cover biomedical research in humans, animal testing, regulations on health products and processes, and the economics and sociology of health.

- NESH in Norway has twelve members: two lay representatives and ten members with different professional backgrounds. The scientific members are appointed by the Norwegian Research Council, and they are chosen based on research performance. The

requirement to assess certain types of research, but also to what degree the framework that the committee is to apply is implemented in the regulations.

final decision is made by the Ministry of Education and Research in Norway.

- LRB and the other five Swedish regional committees are headed by a judge, which emphasizes the legalistic approach on the ethical assessment procedure. Each board has ten members with scientific qualifications, and five persons representing the public. One of the scientific members is also the scientific secretary and is appointed by the chairman.

- The Shanghai Institutes for Biological Science (SIBS) ethics committee consist of one director and 20-25 members. The members are professionals and experts in life sciences, biotechnology, basic and clinical medicine, drugs and medical equipment, society, ethics and law. For special or unusual research subjects, related experts will be invited to participate in the ethics assessment when necessary. The director and the members in committee are employed by SIBS. The term of employment is four years and employees can be reappointed consecutively. The study interview does not reveal what body is responsible for appointing committee members. There is no consultation of the public.

- CCMO in the Netherlands has very specific legal requirements regarding the composition of the board. A general condition is that all members must be independent. They cannot have a personal interest in the research being assessed. Membership should be refused when independence cannot be assured. In the medical board there must be a physician who must have adequate practical and scientific experience regarding medical-scientific research involving humans. There must also be a legal specialist, a methodologist, an ethical specialist, as well as a researcher with experience of research on human subjects from the subject's point of view. There must also be a hospital pharmacist and a clinical pharmacologist.

- CETEA is composed of 26 persons, predominantly of persons involved in animal testing. The Institut Pasteur appoints the members. Besides researchers, the committee must be composed by at least an individual undertaking experiments, an individual involved in housing and caring for animals, a veterinary surgeon, and an individual external to animal experimentation establishments who demonstrates a real interest in animals. In addition, two of the members of the committee must be laypersons.

The composition of RECs greatly depends on the individual committee's aims and includes a wide range of disciplines, such as biomedicine, ethics, social sciences, psychology and law. Ethics assessment procedures may vary on each committee, although biomedical research ethics are generally harmonised due to international agreements and guidelines.

5. Procedures for Ethics Assessment

5.1 Procedures prior to assessment, during assessment, and after assessment

In this section we will describe the procedures for ethical assessment made by the RECs analysed in this report. They are assumed to have specific roles before, during, and after a research project is authorised and conducted, and the research results are evaluated and reported. Their responsibilities therefore encompass the entire spectrum of research. The associations of RECs do

not perform assessment themselves, but in their role as providers of ethics training, harmonisation and standardisation of ethics assessment, they indirectly and/or directly have a role both before and after the assessment and will therefore be described in this context.

5.2 Procedure for ethics assessment: before

Ethical review procedures for research can vary from country to country depending on whether the evaluation is voluntary, recommended or mandatory, or the type of projects to be evaluated. Committees have established SOP (Standard Operating Procedures) for evaluating different types of projects (e.g., biomedical research projects, clinical trials with drugs and health products or post-authorization observational studies with drugs).

When the law requires ethical assessment of research proposals, or when the researcher wants advice or needs ethical approval for journal publication, researchers will send their research proposals for REC ethics evaluation prior to the start of the research project. There is also in most cases a standard application form that the researcher has to complete. The application should in most cases include information on the person responsible for the experiment, what qualifications this person has, a description of the experiment, and the expected benefits achieved by the experiment. The application should also include the project plan and documentation ensuring the consent of the participants.

The RECs have regular meetings; some as often as every sixth weeks or up to two times per year. Before the meeting each case submitted to the board will be prepared by one or several members of the committee. In the LRB one member has the responsible to prepare the case and make a pre-assessment, also suggesting if the application should be approved, rejected or if there is a need to make revisions. The process before ethics assessment is the same for the Swedish appeal body, CEPN, the Polish RECs considered in this study (KBpCZD and ABC), and the NESH (and probably for most other RECs).

Procedures taking place before the assessment could also include assessing whether the research that will be conducted requires ethics assessment.[16] The Swedish RECs will not deal with cases that are not considered research according to the Ethical Review Act. This is the case even if the person who submits the project for ethical vetting is seeking approval to be able to publish the result of his or her study.

5.3 Procedure for ethics assessment: during

The decision procedure varies between the different RECs. Some RECs discuss the proposal until a consensus is reached (ECMMA and NESH), while other RECs will make their decisions by voting (KBpCZD). The RECs will only consider the ethical acceptability of the project. However, sometimes the scientific quality of the proposal will also affect the decision (CCMO).

[16] E.g. in the case of Sweden, the law applies to research that includes the handling certain types of sensitive personal data, personal data regarding violations of law that include crimes, judgments in criminal cases, penal law sanctions, or administrative deprivation of liberty, research that subjects a research subject to a physical intervention, that is performed according to a method with the purpose of affecting a research person physically or mentally, and which includes an apparent risk of injuring the research subject either physically or mentally, research that relates to studies of biological material that has been taken from a living person, and can be traced to that person, and research that constitutes a physical intervention on a deceased person, or relates to studies of biological material that has been taken from a deceased person for medical purposes, and can be traced to that person.

Experiments and research that are at risk of harming humans and animals will only be approved if the expected benefit of the research exceeds the expected risk of harm caused. If the scientific quality is poor, it is unlikely that the research will benefit the research subjects. The process is described by several interview subjects as a weighing process where justification for the use of human research subjects or the use of animals and the level of risk of damage inflicted are weighed against the scientific value of the study (CETEA, LRB, CEPN).

After the decision, the submitter will receive a written judgment regarding the ethical issues. If serious ethical issues are found and no approval can be given, the committee may ask the submitter to submit a revised proposal. When in the opinion of the Committee the project meets the ethical and legal requirements, a favourable report is issued.

The ethical review of clinical trials must follow the procedures established by the European regulation and the guidance of Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH).[17] In the Netherlands non-medical research is initially assessed on ethical permissibility by the EC. In both standardized (research that contains normal research practices for a particular field) and non-standardized cases, the submitter will receive a written judgment regarding ethical permissibility, and advice for addressing ethical issues. As with medical research, the submitter may be asked to revise the proposal and resubmit it if the committee finds serious ethical issues with the proposal.

5.4 Procedure for ethics assessment: after

After approval, the researcher can begin his/her research. If no approval is given, he/she can revise and resubmit or send it to an appeal body (CEPN, ABC, EOS, CCMO). When the ethical reports are not binding, the researcher also has the option of ignoring the judgment and going ahead with the research (e.g., BMS, Netherlands and NESH). In these cases there is no monitoring of compliance with the committee's recommendations.

ECPEAW-Serbia only states opinions, but the minister makes a decision through the Directorate for veterinary medicine. Appeals are submitted to the Directorate for veterinary medicine.

Rarely do RECs perform monitoring of the results of the research. In some countries, there is an administrative follow-up and in-situ monitoring that involves randomly reviewing logs, medical records, and similar practices. In clinical trials, inspectors perform trial monitoring and control visits. Other RECS have no follow-up procedures even though their decisions in most cases are binding (LRB, CEPN).

6. Principles and Issues for Ethics Assessment

6.1 Values and principles of Research Ethics Committees

In this section we will discuss which ethical principles and issues play a role in ethics assessment practices, and how prominently they feature. We will begin by giving an account of general

[17] European Parliament and the Council, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *OJ L* 158, 27.5.2014, pp. 1–76.

ethical frameworks that the RECs consider and then move on to identify and discuss the principles and issues for ethical assessment that the RECs take into consideration in the ethical assessment of research.

Let us begin by looking at the general frameworks that the RECs consider implicitly and explicitly. All RECs have to follow national and international laws and regulations. In some countries (e.g. China and US) international regulations are explicitly referred to in the legal and guiding documents regulating ethics assessment. The Chinese ethical frameworks of ethics assessment are, to take one example, explicitly based on Declaration of Helsinki and CIOMS.[18] However, as is pointed out in CIOMS, the principles can be interpreted in regard to cultural values, as long as it does not violate any universally applicable standards.[19] Therefore, in the case of China, the non-collectivistic principles (such as informed consent, which in general is thought to relate to the principle of autonomy) are interpreted in a Chinese collectivistic context.[20] Whether the outcomes of the assessment are affected by cultural sensitive interpretations is not clear but it would be an interesting and important issue to scrutinise further.

As stated earlier, all countries examined in this study have ratified international declarations relevant for ethics assessment. Therefore, many of the interviewed representatives of the RECs studied here mention that they base their ethical assessment on codes such as the Declaration of Helsinki (SIBS, PUSHSC, CEICA), the Oviedo convention (CEIC-E, UNED), the Nuremberg Code (ECCC, SIBS), the EU Charter of Human Rights (ABC), etc., at least for RECs assessing biomedical issues. European Directives such as the clinical trials Directive (2001/20/EG), the Directive 2010/63/EU on the protection of animals used for scientific purposes, and the Data Protection Directive (95/46/EC) are also mentioned. RECs involved in the ethics assessment of research involving animals refer to the principle of the Three Rs (CETEA). The Three Rs stands for Replacement, Reduction and Refinement, and the principle was developed in the 1960s as a framework for animal research. The principle has been implemented in EU adopted directives. Directive 2010/63/EU on the protection of animals used for scientific purposes firmly anchors the principle of the Three Rs in EU legislation.[21] When it comes to identifying specific frameworks and principles, it shows that several RECs have their own frameworks or codes for ethics

[18] The Drug Good Clinical Practice, promulgated by the Chinese State Drug Administration (SDA), stipulates that all research involving human subjects should be conducted in accordance with the ethical principles of the Declaration of Helsinki (principles of justice, respect for persons, beneficence and non-maleficence). The Good Clinical Practice Guidelines (GCP), which is a regulation for the standardisation of clinical trials, ensures standardisation by demanding that all research involving human research subjects conform to the Declaration of Helsinki (to the principles of fairness, respect of human integrity, maximisation of benefits and minimisation of the harm to the human subject) (Article 4). GCP makes repeatedly references to the ethical principles in the Declaration of Helsinki, that is, the protection of the life, health, privacy and dignity of the human subject; that medical research conforms to generally accepted scientific principles; that caution is exercised when the research may affect the environment, and the welfare of animals; the demand for a free and informed consent; the rights of the human subjects; and protection of specially vulnerable research subjects. Chinese Good Clinical Practice, (2003). http://www.bioon.com/drug/chemdrug/243155.shtml; Appendix: The Declaration of Helsinki", Article 10-27.

[19] Based on the information available at http://www.cioms.ch/publications/layout_guide2002.pdf. Retrieved 2015-06-21.

[20] Renzong, Qiu, "Reflections on Bioethics in China. The Interaction Between Bioethics and Society" in Catherine Myser (ed.), *Bioethics Around the Globe*, Oxford University Press, Oxford, 2011, p. 181.

[21] The European Commission. Based on the information available at http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm. Retrieved 2015-06-21

assessment of research (NESH, LEEM, AfRE, PEC, CEID, as well as some of the Austrian university RECs).

Let us now turn to the principles and issues that have been identified as important for the RECs assessment of research (table 2).

The most important aspects evaluated are those related to (1) human subjects research, (2) the autonomy of participants (which includes informed consent), (3) implications for health and / or safety (non-maleficence), (4) scientific integrity, (5) implications for privacy, and (5) human dignity.

That human subjects research scores high is not surprisingly since the majority of the RECs studied explicitly assess research involving human subjects.

One issue that is deemed important is how informed consent can be secured. The RECs (e.g., LRB, CEPN, NESH) pay special attention to information sheets and consent forms presented to potential participants. This is considered especially important when the research subject is vulnerable. This correlates with the indication in table 2 that autonomy is an important guiding principle for RECs.

Scientific integrity scores high in the study. This is perhaps surprising since several of the committees (CEPN, LRB (insert more)) do not evaluate issues regarding scientific integrity. However, the large number of Austrian RECs represented in the study can to some degree explain the high value. Austria has a specific agency, The Agency for Research Integrity, with the purpose to promote of good scientific practice and research integrity. The Agency was founded due to acute pressure after the "Strasser scandal", that is, to address a specific problem in the Austrian research community.

The principle of human dignity has its background in both religious and humanistic moral traditions (Collste 2002). Among the studied RECs, human dignity is shown to be important especially in Catholic countries such as Spain and Poland.

Principles and issues in assessment / guidance	[18] scientific integrity [14] professional integrity [22] human subjects research [9] treatment of animals in R&I [17] human dignity [13] equality / non-discrimination [21] autonomy / freedom [10] implications for civil rights [17] implications for privacy [4] social responsibility [7] justice / fairness [19] implications for health and /or safety[22]	[8] implications for quality of life [5] environmental impacts [4] social impacts [0] outsourcing of R&I to developing countries with lower ethics standards [1] dual use (possible military uses) [7] informed consent [2] Protection of data [1] research in other cultures [1] protection of cultural heritage [1] confidentiality

Table 2. The distribution of principles and issues addressed by the RECs

[22]In one case the principle was not specified as a principle regarding implications for health and/or safety. The representative for Ethics Commission, Department of Social Psychology of the Faculty of Psychology at Warsaw University, Poland, mentions "wellbeing of research participants as an important principle. Here this has been interpreted as a specification of "implications for health and/or safety".

6.2 Animal welfare principles and values

The Directive 2010/63/EU on the protection of animals used for scientific purposes offers a common approach for the ethical review of research involving animals. However, in some countries the REC has only an advisory role.[23]

The assessment framework relates to the principles of replacement, reduction and refinement as laid down by the European Directive on the protection of animals used for scientific purposes. The criteria for the competence of the personnel involved is another relevant issue for ethics assessment in the field.

CETEA bases its core assessment on the 3Rs of the European Directive 2010/63/EU, supplemented by a cost-benefit analysis:

- Replacement: use animals only when absolutely necessary
- Reduce: use the appropriate number of animals
- Refine: design the research in order to minimize the harm inflicted to animals

According to the interview with the representative from CETEA, RECs that consider animal welfare generally rule that only when the benefits of the research outweighs the harm can the research be justified.

6.3 Vulnerable subjects

Research involving children and other vulnerable research subjects is one of the issues that raises more concerns for ethics assessment due to the increased risk of participants being harmed or exploited. Examples of vulnerable research subjects are children, prisoners, pregnant women, and research subjects that are unable to give informed consent. Such participants must receive extra protections. The EU adopted a new Regulation on clinical trials in 2014 to face the challenge of how to include vulnerable research subjects in research and in clinical trials. Even though there is an increased risk to the research subjects who belong to this category, excluding them from participating in research and clinical trials is not an option when they would benefit from the research.[24] Examples of important ethical problems in research and innovation that are assessed by the committee are, for example, research in schools with (young) children or in clinical trials, which involves informed consent.

7. Problems and Developments

7.1 The main strength and weaknesses of existing institutional setups

RECs differ in their perception of their own strengths and weaknesses, and those of RECs in general. Some REC spokespersons believe there are no major weaknesses in their REC or the REC systems, whereas others see significant issues. The representative of the studied REC from the Netherlands thinks that there are no major weaknesses or problems in how ethics assessment

[23] Prof. Dr. Zoran Todorović, President of Ethics council for protection of experimental animal's welfare, personal interview, 17 Nov 2014.
[24] Interview with Åsa Nilsson Dahlström, member of Linköping Regional Board for Vetting Research Involving Humans, Sweden; Gennet, Èlois, Roberto Adorno & Bernice Elger, "Does the new EU Regulation on clinical trials adequately protect vulnerable research participants?", *Health Policy*, Vol 119, Issue 7, 2015, pp. 925-931.

takes place in their committee. The representative from KBpZCD argues that there are no weaknesses in the ethical assessment procedures, but that there are certain areas in which such assessments are not legally required, even though that would be highly beneficial. Ethics committees should according to the interviewee not only operate in the field of medicine, but also in psychology and sociology, where research is often based on questionnaires and interviews.

The representatives from the Austrian university RECs are unanimous in their view that the existing setup has led to major improvements. Among researchers a tendency towards an ethics of responsibility has been noted and the general sensibility for the importance of ethics has increased. One interviewee reveals that in former days it was not seen as an ethical problem to use bone chippings of deceased persons for research without consent. This has changed considerably in recent years. The committees are not seen as an obstacle to research. At the beginning there was a certain hesitation towards the committees regarding implications of ethics review on the freedom of research. Although, one interviewee argues that there is still some hesitation towards ethics review, as the "culture" of deliberations regarding ethics has not yet been fully accepted. Furthermore, increased dialogue with the public could be useful.

As we have seen in section 5, the assessment procedures differ between different RECs. The decision procedure also varies, from voting to a consensus-based approach. The interviewed representative from the anonymised association from a Western European country argues that the weakness of their RECs practices are that the discussion will vary from committee to committee "because there is a human factor" involved, implying that ethical assessments relying on personal opinion are less justifiable than assessments performed through purely procedural arrangements.

The interviewed representatives of NESH in Norway differ in their opinions regarding weaknesses of the existing institutional setup and assessment procedure. One representative found their consensus-based assessment procedure wanting, arguing that it gives a picture of the issues dealt with being easily solved, which, the interviewee adds, is not the case. Another interviewee saw instead the consensus-based procedure as the strength of the Norwegian system. The interviewees had also different opinions on how well the guidelines are institutionalised in the research community. One argued that the guidelines were deeply rooted in the research community, while another argued that the weakness of NESH is that NESH and its guidelines are quite unknown to several groups of researchers, especially within the humanities.

Other RECS, such as ECMMA in Serbia and LRB and CEPN in Sweden, inform us that they do not have clear procedures (standards, protocols, guidelines) on how to perform ethics assessment. The view of the Swedish review system is that it is functional but with room for improvement. One Swedish interview subject argues that there are too many committee members in the boards (15 members and a judge) for the discussions to be fruitful. Another issue is that the law regulating that research involving human subjects must be vetted remains unknown among many researchers. There is a great awareness among medical researchers, psychologists, etc., but among social scientists and researchers within education and the humanities, many researchers lack awareness of these regulations and therefore do not apply for ethics assessment. The lack of monitoring is also considered problematic.

The representative for KBpCZD argues that the ethical assessment procedure is working, but that there are certain areas (psychology and social science) in which ethics assessments are not legally required even though there are good reasons to assess the research that is about to be conducted.

Other common problems concern the ethics training of the members, especially new members who can be wholly unfamiliar with ethics assessment, and the updating of REC protocols for new ethical issues or regulations. Moreover, there is a clear idea in biomedical ethical committees specifically that they evaluate too much in terms of compliance with existing regulations.

As strengths, some RECs, for example the CEIC-E in Spain, report that the number of registered incidents is very low, however the committees believe that there is room for improvement, as mentioned by CEIC-E and ECCC in Serbia. The only weakness mentioned by the University of Twente Ethics Committee is due to an expansion of the committee, and that the new members would need some training in ethical issues.

In addition to the development of guidelines and recommendations, some committees mention as strengths that they organise and give courses in health centres about ELSI (Ethical, Legal and Social Issues) and best practices. This is relevant for the REC Associations, AfRE in the UK and ANCEI in Spain.

In Spain, assessments by RECs of research projects are binding if they are negative, and RECs have not detected cases where their opinion has not been followed, but there is no monitoring due to a lack of resources. Some RECs, CEIC-E and CEICA, have a Quality Committee responsible for making decisions on quality and the overall supervision of the implemented quality management system. Within its quality plan the satisfaction of the Committee's users (developers and researchers) is evaluated annually. The Committee also participates in the review of the program of Good Scientific Practice Guide.

In the opinion of the representative from ANCEI-Spain, one weakness in the committee's operation is that the ethical evaluation is not recognized as important as the methodological evaluation. It is not understood that they are different levels of evaluation. Methodologically proper research could present problems in the ethical evaluation. The Association is working on training through working groups, conducting sessions, preparing and publishing documents of interest on the web. It is necessary to increase the number of associates and increase the participation of existing ones, and to access and make connections with RECs from universities conducting ethical review in other disciplines (social sciences, humanities, engineering, etc.). New technologies are creating new challenges (neuroscience, big data, use of social networks, etc.) and it is necessary to be aware of the risks that they may generate, debate them, agree on procedures, and training assessors on these issues.

7.2 Self-assessments

In general, no self-assessments have been performed of the effectiveness and impact of their ethics assessment practices by the RECs that were studied.

7.3 Weaknesses in Animal welfare Assessment

Regarding animal welfare ECPEAW-Serbia informs us that there are no data on the number of animals sacrificed annually. Removal of produced waste is not regulated and currently it is done by the city sanitation service. There should also be a detailed register of anesthetics used. A register of research institutions that use animals has been made, but many institutions refuse or

fail to register. The problem is that institutions need to fulfill numerous criteria and as a result the REC has chosen a more liberal approach. The legal framework for animal testing is good in the opinion of the representative, but it nevertheless needs improvement. Some education and training of the people who conduct research has been done, but it is insufficient, and training programs need to be improved. The biggest problem, however, is that some researchers do not follow the law.

Annex: Ethics Assessment and Guidance in Specific Research Ethics Committees

This Annex contains 30 reports on surveyed Research Ethics Committees and 5 RECs associations. For each organisation that was surveyed, basic data is provided about the organisation, its mission, structure, and role in ethics assessment and/or ethical guidance, and its procedures for assessment and guidance.

The following organisations were surveyed:

COUNTRY / REGION	NAME	ORGANISATION TYPE
Austria	Anonymised university research ethics committee 1	REC
Austria	Anonymised university research ethics committee 2	REC
Austria	Anonymised university research ethics committee 3	REC
Austria	Anonymised university research ethics committee 4	REC
Austria	Anonymised university research ethics committee 5	REC
Austria	Anonymised university research ethics committee 6	REC
Austria	Anonymised university research ethics committee 7	REC
Austria	Anonymised university research ethics committee 8	REC
China	Peking University Health Science Center (PUHSC)	REC
China	Shanghai Institutes for Biological Science, CAS (SIBS)	REC
France	Ethics Committee of the French Institute of Health and Medical Research (IMSERM)	REC
France	French Ethics Committee for Animal Experimentation n°89 (CETEA)	REC
France	The Pharmaceutical Companies, LEEM	Association
Germany	Permanent Working Party of Research Ethics Committees in the Federal Republic of Germany Inc. (AMEK)	Network
The Netherlands	Central Committee on Research Involving Human Subjects (CCMO)	REC

COUNTRY / REGION	NAME	ORGANISATION TYPE
The Netherlands	Ethics Committee of the Faculty of Behavioural, Management and Social Sciences of the University of Twente	REC
Norway	The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)	REC
Poland	Appeal Bioethics Committee (ABC/OKB)	REC
Poland	Bioethics Committee of Children's Memorial Health Institute (KBpCZD)	REC
Poland	Ethics Commission, Department of Social Psychology of the Faculty of Psychology at Warsaw University	REC
Serbia	Ethics Board of Serbia (EOS)	REC
Serbia	Ethics Committee of Clinical Centre Nis (ECCC)	REC
Serbia	Ethics Committee of Military Medical Academy (MMA)	REC
Serbia	Ethics Council for Protection of Experimental Animal's Welfare (ECPEAW)	REC
Serbia	Professional Ethics Committee, University of Belgrade (PEC)	REC
Spain	Ethics Committee for Clinical Research of Aragon (CEICA)	REC
Spain	Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country (CEIC-E)	REC
Spain	National Association of Research Ethics Committees (ANCEI)	Association
Spain	National Distance Education University (UNED)	REC
Spain	University of the Basque Country (UPV/EHU)	REC
Sweden	Central Ethical Review Board, CEPN	REC
Sweden	Linköping Regional Board of Vetting Research Involving Humans (LRB)	REC
United Kingdom	Association for Research Ethics (AfRE)	Association
Western European country	Name anonymised (table not included below)	Association

Name of organisation	**Peking University Health Science Center (PUHSC)**

	(北京大学医学部)
Type of organisation	University
Country	China
Website address	*General:* http://english.bjmu.edu.cn/index.htm *Main page(s) on ethics assessment:* http://research.bjmu.edu.cn/zl/llwyk/index.htm
Basic description (organisation and mission)	The Highest goal of PUHSC is, with all its heart and all its might, to create an internationally recognized medical institute of excellence and to offer first-class medical education for the health of all human beings. PUHSC offers a full range of courses for 8 specialties including basic medical sciences, clinical medicine, preventive medicine, stomatology, pharmacy, nursing, medical laboratory diagnosis and biomedical English. It has 47 accredited doctoral programs and 59 master programs. In addition to offering undergraduate and graduate programs, it also plays an active role in continuing education. PUHSC hosts 6 postdoctoral programs.
Interest in research and innovation	PUHSC has adopted the education model of 8-year program for medicine (leading to MD or Ph.D degrees), 7-year program for preventive medicine (leading to MS degrees), established Biomedicine Cross-discipline Research Centers, devoted efforts for the integration of Medical disciplines , Sciences and Humanities, and established many inter-disciplinary research centers that combine Basic Medical Sciences with Clinical Medicine.
Ethics assessment and/or guidance	Assessment ☒ Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house ☒ Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	Human Research Protection Program, which was founded in 2010 in PUHSC. On the purpose of all-round protection of interests of participants through providing researchers with high-quality and multi-channel training, conducting an independent study program, timely and efficient ethics review, supervising ethical issues in the research process and so on.
Name and description of ethics unit(s)	Peking University Biomedical Ethics Committee
Aims and motivation for ethics assessment	Improve the human research protection system well-ordered operation in Peking University, enhance biomedical research quality and effectively protect the rights and welfare of research participants.
Objects and scope of assessment	Biomedical research involving human and related technology in Peking University. Typically, studies involving people include the following : 1. Interventions for individuals to obtain the relevant safety and / or effectiveness of information : such as drug / medical devices / surgical treatment / health education , and so on ; 2. Direct contact with the individual , the collection of personal information through the blood or tissue samples , interviews or questionnaires and other forms ; 3. Collect personal information previously saved involve identifiable personal privacy and identity. All research involving human subjects must be submitted to the ethics committee for review. When the researchers could not confirm whether they are engaged in activities " involving human research" , please consult the Office of the Ethics Committee
Beneficiaries of assessment	Through the protection of research human subjects to achieve the protection of researchers and research organisation.

Ethics assessment unit: appointment process	1. Submit documents in digital version. According to the documents list to prepare the documents: Research proposal, informed consent, questionnaires, research records and / or case report forms, diary cards and so on. 2. Ethics Committee office check if the materials are complete within five working days after receiving the material. If the documents are incomplete or file elements are flawed, send "supplement / modify submittal material," which told missing items file, defect elements. 3. Acceptance notification: After passing the documents format review, the office sent acceptance notification to prepare paper documents for review and to inform the review scheduled date and place. 4. After the Ethics Commission Office accepted, project-related materials will be sent to the Review Committee. When necessary, the Office of the Ethics Committee will inform the researchers to answer questions about the contents of the Ethics Committee on the proposed project. Researchers need to be familiar with and understand the whole research program, and to be prepared, arrived at the place 15 minutes in advance.
Procedure for ethics assessment: before	The content of the ethic assessment form is issued by Peking University Biomedical Ethics Committee, the content includes: 1. Project overview 2. Source of funds 3. Conflict of interest 4. Main researchers 5. Special audit requirements 6. Research abstract 7. Participant recruitment , costs and compensation 8. Submittal documents 9. Project leader declared : I will follow the requirements of laws and regulations and international ethics guidelines and ethics committee to undertake this study
Procedure for ethics assessment: during	Ethic review committee is responsible for the assessment. Researchers need to be familiar with and understand the whole research program, and to be prepared, arrived at the scheduled place 15 minutes in advance on the scheduled day. When necessary, the Office of the Ethics Committee will inform the researchers to answer questions about the contents of the Ethics Committee on the proposed project.
Procedure for ethics assessment: after	Ethics Committee Office is responsible for receiving and summarizing reviewed comments, finally generating the decision after chairman / leader confirmed. Inform the applicant by e-mail within five working days, while completing the issue of "ethics review document" or "ethical review comments" in public.
Principles and issues in assessment / guidance	☒ scientific integrity [ ] professional integrity [ ] treatment of animals in R&I ☒ human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness ☒ implications for health and/or safety human subjects research [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: Biomedical research involving human subjects : ethics review of relevant laws and regulations: 1. Federal Regulations 45CFR46 2. ICH-GCP 3. Standards and Operational Guidance for Ethics Review （WHO） 4. International ethical guidelines for biomedical research involving human subjects

	5. Biomedical research involving human ethics review (Trial) 6. Ethical review of drug clinical trials guidelines 7. Good Clinical Practice (GCP)
Self-assessments, strengths and weaknesses	
Other	

Name of organisation	**Shanghai Institutes for Biological Science, CAS (SIBS)** (中国科学院上海生命科学研究所)
Type of organisation	Academy of sciences
Country	China
Website address	*General:* http://english.sibs.cas.cn/ *Main page(s) on ethics assessment:* http://www.sibs.ac.cn/iec/index.asp
Basic description (organisation and mission)	Shanghai Institutes for Biological Sciences (SIBS) of Chinese Academy of Sciences (CAS) is a leading research institution for life sciences in China. It was established on July 3, 1999, through structural reorganisation and institutional reform of 8 former CAS institutes of biological sciences in Shanghai. SIBS have a strong commitment to training young researchers as evidenced by its well-designed graduate programs. SIBS offer a master's-doctoral program, which takes five to six years. As of December 2014, SIBS had an enrollment of 1,835 graduate students, including 1,165 Ph.D. students and 670 M.Sc. students, all of whom will be assessed for transfer into the Ph. D. program.
Interest in research and innovation	SIBS focus on human health and the frontiers of biology, and encourage collaboration and a multidisciplinary approach as a means of pursuing research excellence. Institute scientists have received a wide array of science and technology awards for original achievements in neuroscience, molecular cell biology, genomics, genetics, immunology, tumor biology, nutrition and metabolism, and biotechnology between 2000 and 2014.
Ethics assessment and/or guidance	Assessment [☒] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [☒] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	The ethic assessment conducted by SIBS mainly focus on the area of life science and biomedical research, e.g. drug clinical trial, clinical application of medical technology, medical research involving human life.
Name and description of ethics unit(s)	Biomedical Research ethics Committee, SIBS, CAS (中国科学院上海生命科学研究院生命科学伦理委员) Biomedical Research ethics Committee is a permanent department which is responsible for the ethic assessment of life science research in SIBS and is authorized and funded by SIBS. The cost of ethical assessment of research projects undertaken by submitted organisation.
Aims and motivation for ethics assessment	The purpose of the ethics assessment is to protect the security, rights and well-being of research participants, promote the vigorous development of life science research in the context of ethical principles. Ethic committee provides guidance and help on the projects carried out on humans and animals involves the ethical and procedural issues, which in the light of the basic internationally accepted ethical principles, the status quo and trends of biomedical science and technology development.
Objects and scope of assessment	Objects of assessment: 1. The research activities that use modern physics, chemistry and biology research methods on human to investigate human physiology and pathological phenomena and diagnosis, treatment and prevention of disease. 2. The experimental application of medical technology or product formed through biomedical research activities on humans. Except that the application in clinical practice has

	been more than two years, or the clinical application of technology have been approved by health administrative departments. Scope of assessment: 1. Projects are funded by the SIBS. 2. Scientific research that are conducted by employees in SIBS, or conducted with the property and facilities in SIBS. 3. Scientific research are not conducted in SIBS, but is related with employees in SIBS and responsibility of SIBS. 4.Scientific research that involving the employment of private information, e.g. identifying and contacting with human subjects or potential human subjects
Beneficiaries of assessment	The main beneficiaries are research participants; however scientists and SIBS will also be protected via the protection of the research participants.
Ethics assessment unit: appointment process	Ethic committee consist of 1 director and 20-25 members, the members are experts on the aspect of life sciences, biotechnology, basic and clinical medicine, drugs and medical equipment, society, ethic and law. When research projects are special in term of research subjects, related experts will be invited to participate in the ethics assessment when necessary. Director and members in ethic committee are employed by SIBS. The term of employment is four years and employees can be reappointed consecutively. To maintain the continuity of the work, the number of transition should not more than one-third.
Procedure for ethics assessment: before	The research projects that need to be assessed by ethics committee should submit the following materials: (A) Ethical Assessment Application Form; (B) Research or related technology applications; (C) Subject Informed Consent.
Procedure for ethics assessment: during	1. Working conference convened by the director of the ethics committee. Project assessment meeting was convened by the director or person in charge of the project assessment who is commissioned by the director. 2. The Ethics Committee should provide objective assessment comments in serious and fair altitude in the assessment process. 3. For projects submitted for assessment, formal assessment has to be done within one week of receipt of materials, and ethical assessment should be finished within three weeks after the completion of formal assessment. 4. The result of the ethical assessment is subject to the comments of the ethic committee members, approval of ethic assessment under the circumstance of two-thirds committee members' consent. 5. The ethical assessment result which is signed by the director of Ethic Committee will be informed to the research project leader and SIBS.
Procedure for ethics assessment: after	1. SIBS and related research project leader have the right to appeal the assessment result. 2. For approved projects, if the research project leader confirms that this project does not meet rules and regulations of related organisation or SIIBS, this project will be suspended or terminated in name of the organisation. However, once the Ethic Committee veto the research project, the unit cannot approve it again. 3. Ethic committee members are not allowed to participate in the assessment if there is a conflict of interest between ethic committee members and submitted research project. Committee members have the duty of confidentiality on the relevant documents and submittals project materials, and the relevant information are not allowed to be referenced or be informed to the third party without permission.
Principles and issues in assessment /	[ ] scientific integrity [ ] professional integrity ☒ human subjects research ☒ justice / fairness ☒ implications for health and/or safety [ ] implications for quality of life

guidance	[ ] treatment of animals in R&I ☒ human dignity [ ] equality / non-discrimination [ ] autonomy / freedom ☒ implications for civil rights [ ] implications for privacy ☒ social responsibility [ ] environmental impacts ☒ social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: Ethics assessment of relevant laws and regulations: 1. Nuremberg Code 2. Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 2008, World Medical Association 3. The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979. 4. "Ethical assessment of drug clinical trials guidelines" issued by State Food and Drug Administration in 2010. 5. "Administrative Measures for the clinical application of medical technology" Issued by the Ministry of Health in 2009. 6. "Human international ethical guidelines for biomedical research" issued by WHO in 2002. 7. "People's Republic of China Drug Administration Law" issued by the State Council formulated in 2001.
Self-assessments, strengths and weaknesses	
Other	

Name of organisation	**The French Institute of Health and Medical Research (IMSERM)** (Institut national de la santé et de la recherche médicale)
Type of organisation	Public research institute
Country	France
Website address	*General:* http://www.imserm.fr/ *Ethics assessment:* http://www.imserm.fr/qu-est-ce-que-l-imserm/l-ethique-a-l-imserm
Basic description (organisation and mission)	The IMSERM is a public scientific and technological institute which operates under the joint authority of the French Ministry of Health and the French Ministry of Research, the only French public research institute that focuses entirely on human health. IMSERM teams carry out fundamental research or clinical research but also translational research.
Interest in research and innovation	IMSERM carries out research.
Ethics assessment and/or guidance	Ethics assessment (in-house): done by the IMSERM Ethics Committee (Comité d'éthique de l'IMSERM) and the Ethics Review Committee of the IMSERM (Comité d'évaluation éthique de l'IMSERM or CEEI). The IMSERM Ethics Committee issues publically available opinions on the ethical issues addressed. On the other hand, the Ethics Review Committee of the IMSERM issues ethical clearance on specific research projects. It is registered as an IRB with the OHRP in the USA.
Terminology for ethics	Information not provided.

assessment / guidance	
Name and description of ethics unit(s)	The IMSERM Ethics Committee mission is to manage reflection on ethical issues raised by medical scientific research and health research as it is implemented within the Institute. Its mission is a general one in regard to ethics; the committee does not address individual research projects. However, the Ethics Review Committee of the IMSERM, the Institutional Review Board reviews individual research projects which need an ethical clearance but are outside the scope of the Committees for the Protection of Persons (Comités de Protection des Personnes or CPP)'s statutory tasks .
Aims and motivation for ethics assessment	Information not provided.
Objects and scope of assessment	Information not provided.
Beneficiaries of assessment	The research institute IMSERM and CNRS following an agreement between the two institutes) and participants in the research project.
Ethics assessment unit: appointment process	The IMSERM Ethics Committee includes about fifteen members appointed for a period of 3 years, with renewal possible for its most active members, as certain skills are rare, especially when they are solicited on a voluntary basis. At least half of the members do not belong directly to IMSERM, and at least half are not biologists or doctors. Gender parity is respected. The fields of expertise of the members are complementary and cover biomedical research in humans, animal testing, regulations on health products and processes, and the economics and sociology of health.
Procedure for ethics assessment: before	/
Procedure for ethics assessment: during	/
Procedure for ethics assessment: after	/
Principles and issues in assessment / guidance	[ ] scientific integrity [x] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [ ] human dignity [x] equality / non-discrimination [ ] autonomy / freedom [x] implications for civil rights [ ] implications for privacy [ ] social responsibility [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: ethical questions around the use of animals in research. Commentary: Information not provided.
Self-assessments, strengths and weaknesses	Information not provided.
Other	/

Name of organisation	**French Ethics Committee for Animal Experimentation n°89** or Institut Pasteur (Paris, France) Committee for Ethics in Animal Experimentation (CETEA)
Country	France
Website address	General: none Main page(s) on ethics assessment:
Basic description (organisation and mission)	Currently in France there are 125 Ethics Committees for Animal Experimentation. The Institut Pasteur Committee for Ethics in Animal Experimentation (CETEA) is one of them. The Ethics Committees for Animal Experimentation, set up by the regulation (Article R214-117 of the Rural and Maritime Fisheries Code), assess research projects using animals for scientific purposes.
Interest in research and innovation	A research project using animals for scientific purposes is conducted in an experimentation establishment (*établissement utilisateur*) (e.g. an animal housing facility). Each experimentation establishment is under the "jurisdiction" of one Ethics Committee for Animal Experimentation. There are three experimentation establishments at the Institut Pasteur. All three are under the jurisdiction of CETEA. As it is the case with IRBs in the United States of America, the Ethics Committees for Animal Experimentation are institutional or multi-institutional committees.
Ethics assessment: yes/no	Assessment ☒ In-house ☒ Outsourced ☐ None ☐ Other ☐ Commentary:
Terminology for ethics assessment	The official terminology for the work carried by the Ethics Committees for Animal Experimentation is "ethics assessment".
Name and description of ethics unit(s)	The Ethics Committees for Animal Experimentation declare themselves spontaneously to the Ministry of Research and are approved on criteria set by a national charter originally drawn up by the National Committee for Consideration of Ethics in Animal Experimentation (*Comité National de Réflexion Ethique sur l'Expérimentation Animale* or CNREEA). This charter, the National Charter on the Ethics of Animal Experimentation (*charte nationale portant sur l'éthique de l'expérimentation animale*), was also used as guidelines when committees have been set up. The Ethics Committees for Animal Experimentation also interact with the Regional Delegations for Research and Technology (*délégations régionales à la recherche et à la technologie* or DRRT) whose mission is to validate the committees' composition and operating mode. The Ethics Committees for Animal Experimentation are independent but the DRRT are somehow their certification or quality control body.
Aims and motivation for ethics assessment	The authorization of the competent authority - the Ministry of Higher Education and Research (*Ministère de l'Enseignement supérieur et de la Recherche* or MESR) - is required for a research project using animals for scientific purposes to start (Article R214-122 of the Rural and Maritime Fisheries Code). The Ministry bases its decision on ethics assessment which it entrusts to an Ethics Committee for Animal Experimentation (Article R214-124 of the Rural and Maritime Fisheries Code). The authorization can't be granted without ethical clearance (Article R214-123 of the Rural and Maritime Fisheries Code).
Objects and scope of assessment	The ethics assessment of the project is limited exclusively to the field of animal experimentation. Keeping in mind this context, ethics assessment performed by CETEA covers two cross-fertilizing fields: natural science (*recherche en biologie du vivant*) and medical science (*recherche biomédicale*) with the aim of knowledge advancement for human or animal health. The ethics assessment of the project is restricted to its ethical aspects. Furthermore, the ethics assessment pertains only to the part of the project comprising manipulations on animals.
Beneficiaries of	The users (consumers) of the ethics assessment are the scientists carrying the research

assessment	project.
Ethics assessment unit: appointment process	According to the regulation, the ethical committee must be composed of, at least: - A researcher, - An individual undertaking experiments, - An individual involved in housing and caring for animals, - A veterinary surgeon, - An individual external to the animal experimentation establishment(s) and who demonstrates real interest in animal protection." CETEA is composed of twenty-six people, predominantly of people involved in animal testing. Nevertheless, there are also two "naïve" members in the committee. Members are chosen by the institution. The CETEA members were chosen by the Institut Pasteur. For now, the composition of committees is merely registered by the Ministry that verifies the compliance with the regulation.
Procedure for ethics assessment: before	All research projects including experimentation on animals must undergo an ethical assessment by one Ethics Committee for Animal Experimentation (Article R214-117 of the Rural and Maritime Fisheries Code). However, all procedures on animals are not considered as experimentation on animals (Article R214-88 of the Rural and Maritime Fisheries Code). Acts below a particular threshold (the pain, suffering, anxiety or lasting harm induced by the penetration of a needle, Article 1 of the decree No. 2013-118 of February 1st 2013 on the protection of animals used for scientific purposes) are not considered as experimentation on animals and thus don't require an ethics assessment. In its application to Ministry, the principal investigator specifies in which experimentation establishment the experiments on animals will be conducted. The Ministry then sends the file to the Ethics Committees for Animal Experimentation specific to this experimentation establishment. The committee assesses the project and gives an opinion to the Ministry which then delivers or not the authorization accordingly. During the assessment process, the committee is free to get in touch with the researcher.
Procedure for ethics assessment: during	This general reference for the work of the Ethics Committees for Animal Experimentation is the National Charter on the Ethics of Animal Experimentation (*charte nationale portant sur l'éthique de l'expérimentation animale*). The details are left to the discretion of each committee. According to the interviewee, The ethics assessment addresses the justification for i) the use of animals, ii) the number of animals used and iii) the level of damage inflicted to the animals. However, for the ethics assessment, the soundness / validity / appropriateness of scientific questioning is absolutely irrelevant. Therefore, ethics assessment and science assessment of the project are strictly separate.
Procedure for ethics assessment: after	Once an authorization is granted by the Ministry, the Ethics Committee for Animal Experimentation is no longer involved. Its opinion is binding and implementation is under the responsibility of the experimentation establishment. However, the Ethics Committee can also ask for a retrospective review of the research project. This retrospective review is required by the regulation in case of research primates as well as projects including "severe" procedures. According to the interviewee, two actors are also involved in the achievement and could do a sort of on-going ethical review: - The Person responsible of the Implementation (*Responsable de la Mise en Œuvre* or RMO) verifies that the project is conducted in accordance with what the Ethics Committee for Animal Experimentation and the Ministry of Research authorized (i.e. quality control). - The Animal Welfare Body (*structure chargée du suivi du bien être animal* or SBEA) verifies that the animals live in good conditions (i.e. whistleblower role).
Principles and issues in	☐ scientific integrity ☐ justice / fairness ☐ professional integrity ☐ implications for health and/or safety

assessment	☐ human subjects research ☒ treatment of animals in R&I ☐ human dignity ☐ equality / non-discrimination ☐ autonomy / freedom ☐ implications for civil rights ☐ implications for privacy ☐ social responsibility ☐ implications for quality of life ☐ environmental impacts ☐ social impacts ☐ outsourcing of R&I to developing countries with lower ethics standards ☐ dual use (possible military uses) ☐ other Commentary: There is a shared framework of ethical values and principles used in ethics assessment conducted by the CETEA. The core assessment is based on the three Rs principle: - Replace: use animals only when absolutely necessary, - Reduce: use the appropriate number of animals, - Refine: design the experiments in order to minimize damages inflicted to animals. This approach is supplemented by a cost–benefit analysis in order to determine whether the cost to the animal is compensated by the expected benefit to society. Thus, individual assessors also bring their own values to the table. In the ethics assessment there is a component of subjectivity, a component of affect. Faced with the same procedure, individuals may have very different reactions. Cost and benefit are precisely two subjective concepts bound by personal appreciation, almost philosophical. Conversely, the cost–benefit analysis is not based on the scientific quality of the project. According to the interviewee, the CETEA only explicitly requires proof of the scientific quality of the project given by the science assessors of the process. This doesn't mean that the scientific aspects of the project are ignored by ethics assessors. Assessors need to know the protocol but they do not have to express themselves from a scientific point of view ("about science").
Self-assessments, strengths and weaknesses	• According to the interviewee, the fact that the authorization procedure does not apply to all experiments on animals raises issues. Some practices are considered common practices that are covered by the accreditation of the experimentation establishment and are not submitted to the Ministry of Research or to the Ethics Committees for Animal Experimentation. Moreover, without an ethics committee approval, it is impossible to publish results in scientific peer reviewed literature. Therefore, a parallel circuit bypassing the Ministry of Research has been set up. It allows an ethics assessment of projects excluded from the main circuit on a self-regulatory basis of the institution which makes it mandatory for the researchers of said institution. According to the interviewee, this parallel circuit provides for a certificate which in particular allows a researcher to order animals, but ideally all recorded animals should be related to a specific project. • According to the interviewee, one of the challenges in the implementation of ethics assessment is to make clear that ethics assessment and science assessment are separate / unrelated processes. • According to the interviewee, it is possible to better attune procedures and argumentation approaches by Ethics Committees for Animal Experimentation. • According to the interviewee, there is no impact study of assessment performed by the CETEA.
Other	

Name of organisation	**The pharmaceutical companies (LEEM)** (Les entreprises du médicament)
Type of	Professional organisation

organisation	
Country	France
Website address	*General:* http://www.leem.org/ *Ethics assessment:* http://www.leem.org/article/codeem-comite-de-deontovigilance
Basic description (organisation and mission)	LEEM is a professional organisation (trade association) representing the pharmaceutical industry in France.
Interest in research and innovation	Some members (pharmaceutical companies) of the Leem are involved in fundamental or translational research on vaccines, drugs or medical devices (they are not represented by Leem for this last activity). Moreover, the Leem also coordinates the CSR (Corporate Social Responsibility) strategies of its members but this is not part of the Codeem's duties.
Ethics assessment and/or guidance	Ethics assessment (in-house): The Codeem mission includes drafting reports, making recommendations to the Board of Leem as to ethical issues in the field of the pharmaceutical industry. Ethics guidance (in-house): Leem has a Code of Deontology (i.e. Code of Conduct).
Terminology for ethics assessment / guidance	Information not provided.
Name and description of ethics unit(s)	The Leem has its own institutional ethics committee: the Codeem, a committee in charge of deontological vigilance ("Comité de déontovigilance des entreprises du medicament"). The Codeem is composed of two sections: a "Commission de déontologie" (Section of ethics) and a "Section des litiges et des sanctions" (Section in charge of litigation and sanctions). The scope of the Section in charge of litigation and sanctions is strictly limited to violations of the Leem Code of Conduct and does not assess research projects in themselves but only complaints as to violations of the Code of Conduct.
Aims and motivation for ethics assessment	The main motivation of Leem is to assure product safety. Self-regulation, as Leem produced a Code of Deontology (i.e. Code of Conduct) which is an operational and up to date synthesis of international and French self-regulations is another motivation in engaging in ethics considered to be the foundation of an approach by the pharmaceutical industry.
Objects and scope of assessment	The objective being to assure the safety of the drug, of the supply, of the research or of the drug intake, the Codeem can draft reports making recommendations to the board of Leem as to ethical issues in the field of the pharmaceutical industry, related to the issue of safety for instance.
Beneficiaries of assessment	The ethics assessment is intended for the pharmaceutical industries as well as the consumer of health products they supply.
Ethics assessment unit: appointment process	The Commission de déontologie of the Codeem is composed of: three persons qualified in the field of ethics, three stakeholders and three representatives of the industry. The Section des litiges et des sanctions is composed of two magistrates and three other members, one from each of the colleges composing the Commission.
Procedure for ethics assessment: before	Information not provided.
Procedure for ethics assessment: during	Information not provided.
Procedure for ethics assessment: after	Information not provided.
Principles and issues in	[ ] scientific integrity [ ] justice / fairness

assessment / guidance	[ ] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [ ] human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [x] implications for health and/or safety [ ] implications for quality of life [x] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: Commentary: Environmental impacts considered through CSR.
Self-assessments, strengths and weaknesses	Information not provided.
Other	/

Name of organisation	Permanent Working Party of Research Ethics Committees in the Federal Republic of Germany Inc. (*Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e. V.*)
Type of organisation	National network of Research Ethics Committees at Universities, Medical Associations and States authorities. (Note: In Germany, there is no National Ethics Committee for medical research, therefore the Working Party is accepted as an important consultancy for the public, governments and parliaments)
Country	Germany
Website address	*General:* http://www.ak-med-ethik-komm.de/ *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	The Permanent Working Party of Research Ethics Committees (RECs) in the Federal Republic of Germany Inc. (hereinafter: The Working Party) is a forum for exchange of information and harmonization for the work of ethics committees discussing emerging issues of medical research and the ethical review process.[25] The Working Party organizes semiannual meetings to enhance the cooperation between the RECs.[26] At these meetings the whole of medical research is considered, regarding issues of scientific, legal and ethical interest are discussed with experts coming from the membership or coming from outside.[27] Specific examples are research in emergency situations, research on persons not able to consent, deep brain stimulation.[28] In addition, practical questions are discussed with the aim to propose a uniform procedure.[29]
Interest in research and innovation	The Working Party aims to improve the assessment of biomedical research on man including identifiable data and removed tissues, carried out only by its members, by offering a forum for exchange of experience and elaborating recommendations.
Ethics assessment and/or guidance	Assessment [] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	The interviewee emphasized that the Working Party does not assess research projects. Serving as a forum of its members for exchange of experience and for discussion of scientific, legal and ethical questions it may elaborate recommendations as a guidance for the member RECs. These RECs are free in the decision to follow or not to follow this

[25] Based on the information available at European Network for Research Ethics Committees, *National Information: Germany*, http://www.eurecnet.org/information/germany.html.
[26] Ibid.
[27] Ibid.
[28] Ibid.
[29] Ibid.

	guidance.
Name and description of ethics unit(s)	Regarding the fields that are covered by the ethical committee, this is medical science, and this is only medical science. In Germany, on the one hand there is the academic field with 33 RECs at Universities, and on the other hand there are medical associations (17 RECs), institutions of public rights, which are entitled to establish RECs. The medical associations have the status of authorities in Germany and they are supervised by the government of the States. Furthermore, the procedures of the function and work of research ethics committees have to be approved by the States government.
Aims and motivation for ethics assessment	The Working Party does not any kind of ethical assessment. The ethical assessment is done by the members of the Working Party, the local Research Ethics Committees. The RECs do the assessment on the basis of the protocol of research: intention, aim, methods etc. Furthermore, the REC assess the quality of the researcher and the quality of the study site. This includes 33 ethics committees at the universities, 17 at medical associations, and 3 attached to States governments in Germany.
Objects and scope of assessment	Regarding the fields that are covered by RECs, this is medical science. The Working Party addresses by its recommendations to its members the whole field of biomedical research on man including identifiable data and stored biological material of human origin. These recommendations should enable the member of RECs to assess submitted projects of the mentioned type.
Beneficiaries of assessment	The users of the assessment are physicians as researchers. The assessment is carried out also for the benefit of involved persons. Furthermore, for the moment as established in Germany, the REC may also accept non-physicians as applicants. In clinical trials on drugs or on medical devices the sponsor is the applicant as introduced by the Federal law. The procedure looks as follows: a physician or the sponsor presents his or her research protocol to the legally competent REC, which gives an opinion on that protocol.
Ethics assessment unit: appointment process	The RECs in Germany are composed of experts in several disciplines. The composition is therefore multi-disciplinary and the expertise of members is different, e.g. ethicists, lawyers, physicians. All RECs have "experienced physicians", duly qualified in their disciplines and in medical research, and physicians who are experienced in theoretical research or basic research. Furthermore, there are also experts in statistics and always lay persons. This however depends on States law regulations, as there are 53 research ethics committees in Germany. The relevant regulations are on the States level. These regulations require multi-disciplinary composition and duly qualified persons as members. There is no federal legislation concerning Research Ethics Committees. As far as the selection procedure of the members of RECs is concerned, it follows the States law and therefore it varies. Normally, they are chosen by the faculty of medicine at universities, and then they have to be confirmed by the academic authorities (a president or a senate of the university). The members of RECs at the medical association are chosen by the board of the medical association. There are no consultation of stakeholders or the public engaged in the selection process.
Procedure for ethics assessment: before	The research ethics committees in Germany are only entitled to assess biomedical research as pointed out already, and they are free to do so in the legal framework. Regarding interaction with other organisations, the interviewee emphasized that they discuss with other organisations, but it is not an interaction.
Procedure for ethics assessment: during	The procedure looks as follows: a physician or the sponsor presents his or her research protocol to the research ethics committee, legally competent for him or her. The REC is asked to issue an opinion on that research project. All physicians, who are researchers are obliged to apply for an ethics assessment by the Code of Deontology (legally binding in Germany) or by the internal right of the Universities. For clinical trials on drugs or on medical devices the sponsor is obliged by the federal drug law or by the federal law on medical devices to seek the opinion of the REC, which is legally competent for the physician as the principle investigator. The ethical values used for the assessment include:

	informed consent, the respect of autonomy, integrity, protection of human rights and fundamental freedoms, beneficence, non-malfeasance, justice, and promotion of the social good. The promotion of social good is a value, however research must be independent on the question, whether or not it brings a social good. Research may also be done only for the purpose to improve knowledge, the justification is that an enhancement of basic knowledge may lead in the future to an improvement of healthcare. Regarding the shared framework of values and principles, the framework is shared, but during a discussion individual members of the REC may bring into the discussion their own values and principles.
Procedure for ethics assessment: after	In Germany there are two legal situations. A part of the decisions or opinions of research ethics committees are binding and the others are not binding. Opinions given for drug research and for research on medical devices are binding by law, so called favorable opinions (if favorable of course). Votes in all other fields of research are, legally spoken, an advice to the researcher. The decisions and opinions in medical research are followed in the cases where the decision are legally binding. If a binding decision is not followed, the applicant will undergo sanctions. According to the federal law, a drug research project or a research project on medical devices can start only with the approval of the federal authority, and with the favorable opinion of the competent REC. The Working Party is composed by the RECs in the States, which are represented by authorized members. The Working Party discusses with the relevant ministries of the Federal government proposals for new legislation and is asked for comments e.g. by the Federal Parliament. The Working Party has an influence on the legislation. In addition there discussions with non-governmental organisations (NGOs), the German faculties of medicine or the pharmaceutical companies. Twice a year at its semiannual meetings, the Working Party exchanges opinions and discusses points and several opinions, from theoretical and practical points of view, for instance data protection.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [x] environmental impacts [x] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [x] dual use (possible military uses) [ ] other, specify: Commentary: Please find attached the comments of the interviewee on particular principles (Attachment 1).
Self-assessments, strengths and weaknesses	In terms of the monitoring system, it is difficult for RECs to monitor a project or the complaints. There is a need for a very big infrastructure. Most of the monitoring is done in drug research, but it is also done in the other fields of research. The interviewee addressed some weaknesses regarding the assessment. First of all, the interviewee emphasized that the members of RECs fulfil their duty. That means they read protocols, even if they are not experts in the field of the protocol. In the opinion of the interviewee this is a point of discussion. Secondly, being a member of RECs is a challenging position, requiring knowledge and experience, so it is difficult to find persons willing to adapt to specific situations. It is preferable that an older member shares his/her experience with the younger one. Thirdly, there is a need for infrastructure – e.g. internet/intranet, which is a practical problem.
Other	In the opinion of the interviewee, the importance of ethics assessment is the transparency as such in the country and the trust in research that everything is done to assure good qualified research, which is in line with legislation, with ethics, and which has scientific quality. Assessment helps to prevent unqualified research, in terms of methodology but also of

	qualifications of researchers. The most important ethical problems in research in Germany is research on persons who are not able to consent, and this comprises minors, and persons who have lost their ability to consent; e.g. Alzheimer disease or other kind of dementia, or young person who had an accident. This problem is linked to legislation. A major point of discussion addresses the question to what extent a person is in reality able to consent. In 80 to 90 percent of applications complaints of the REC are not about the method of research, biostatistics etc., but it is the insufficient information for the person invited to participate at a research project. The information should be provided in the language understandable for a lay person ("plain language") and not be too long. The information prior the informed consent should be given by a qualified researcher who is able to answer questions of the invited participant.

Name of organisation	**Central Committee on Research Involving Human Subjects (CCMO)** Centrale Commissie Mensgebonden Onderzoek (CCMO)
Type of organisation	Assessor
Country	Netherlands
Website address	*General:* www.ccmo.nl http://www.ccmo.nl/en/ *Main page(s) on ethics assessment:* http://www.ccmo.nl/en/review-procedure
Basic description (organisation and mission)	The Central Committee on Research Involving Human Subjects (CCMO) protects subjects taking part in medical research by reviewing the research on the basis of the statutory provisions laid down for them and taking into account the interests of medical progress
Interest in research and innovation	Before research with human subjects can commence in the Netherlands the research file must first be approved by an independent committee of experts. This is laid down in the Medical Research Involving Human Subjects Act (WMO).
Ethics assessment and/or guidance	Assessment [X] Guidance [X] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [X] Outsourced [X] Other [ ] Commentary: The review system is a de-central one, whereby accredited reviewing committees spread throughout the country are responsible for the review. Research that falls under the Medical Research Involving Human Subjects Act (WMO) must be reviewed by an independent committee of experts. The research may not begin without a positive decision by this committee (CCMO, 2015). There are two types of reviewing committees: – the Central Committee on Research Involving Human Subjects (CCMO) – the de-central accredited Medical Research Ethical Committees (MRECs)
Terminology for ethics assessment / guidance	The CCMO directive on assessment (http://www.ccmo.nl/attachments/files/revised-ccmo-directive-on-the-assessment-of-clinical-trial-agreements-dated-30-08-2011.pdf) provides the following definitions: a. WMO: Medical Research Involving Human Subjects Act; b. research study: a study covered by the scope of section 1, letter b, of the WMO; c. sponsor: the party conducting the research study, d. investigator: the party performing the research study,; e. funder: the party providing the study's sponsor with the funding required to conduct the study; f. participating centre: participating centre as referred to in article 1.1 of the CCMO directive pursuant to section 24 of the WMO, concerning the review procedure for multicentre research and the external review of monocentre research (CCMO External Review Directive); g. a research study conducted at different locations by different researchers: research as

	referred to in section 1, letter m, of the WMO; h. agreement: the written undertakings entered into by the funder with the sponsor and by the sponsor with the investigator, participating centre or principal investigator, concerning the funding or performance of a research study, as well as written undertakings between investigators concerning that performance.
Name and description of ethics unit(s)	There are two types of reviewing committees: – the Central Committee on Research Involving Human Subjects (CCMO) – the de-central accredited Medical Research Ethical Committees (MRECs) 24 accredited MRECs in the Netherlands review medical/scientific research proposals. The majority are linked to an institution such as an academic medical center or a hospital. An accredited MREC determines the region it covers with regards to reviewing research. This is known as the working environment. In practice, the majority of MRECs review for the whole of the Netherlands. The MRECs also review the research proposals of private companies. For instance the MREC of Wageningen University reviews the research proposals of Unilever, as far as this research is done in the Netherlands (CCMO, 2015).
Aims and motivation for ethics assessment	Before research with human subjects can commence in the Netherlands the research file must first be approved by an independent committee of experts. This is laid down in the Medical Research Involving Human Subjects Act (WMO).
Objects and scope of assessment	The ethical issues of concern are laid down in the WMO. Most important are proportionality of risks for subjects and scientific interest. Additionally it is important that the research proposal has a sound methodology and the research will answer the research questions. The Research involving Human Subjects Act Medical (WMO) sets the following requirements for research involving humans (CCMO, 2013): **Division 2. Rules on research involving human subjects (Section 3)** The committee competent pursuant to section 2, subsection 2 is only empowered to approve a research protocol if: a. it is reasonable to expect that the trial will lead to the advancement of medical science; b. it is reasonable to expect that the advancement referred to under a could not be achieved without the participation of human subjects or by less radical means; c. it is reasonable to expect that the anticipated benefit to individual subjects and other present or future patients will be proportionate to the risks and burden for subjects; d. the methodology of the trial is to be of the requisite standard; e. the trial is to be performed at suitable institutions and by or under the supervision of persons possessing research expertise, at least one of whom possesses expertise of direct relevance to the procedures involved in the trial in which the subject is to participate; f. it is reasonable to expect that any payment offered to the subject would not be of undue influence upon the decision as to whether consent should be given for the subject's participation in the trial; g. any payments to be received by the investigator and the institution at which the trial takes place are reasonably commensurate with the nature, scale and purpose of the clinical trial; h. the research protocol clearly indicates the extent of the potential benefits of the clinical trial to the subjects involved in it; i. the research protocol includes suitable criteria for the recruitment of subjects; j. the trial satisfies all other criteria which may reasonably be set for it.
Beneficiaries of	Research proposals that include research on human subjects

assessment	
Ethics assessment unit: appointment process	**WMO EXPERTISE REQUIREMENTS FOR MEMBERS OF MRECs** Directive of the Central Committee on Medical Research Involving Human Subjects, the CCMO, under article 24 of the Medical Research Involving Human Subjects Act (WMO), specifying in more detail the provisions of article 16, clause two, point b of the WMO on the requirements relating to the expertise and suitability of members of Medical Research Ethics Committees as defined in article 16, clause one, of the WMO. 1. All members of a medical research ethics committee must meet the suitability requirements laid down in part A of the appendix to this directive. 2. Members of a medical research ethics committee who sit on the committee because they work in one of the disciplines referred to in article 16, clause two, point a of the WMO must also meet the expertise requirements applicable to them that are laid down in part B of the appendix to this directive. 3. In order for the requirements laid down in parts A and B of the appendix to be assessed, a curriculum vitae, a statement of interests and (subsidiary) roles, a declaration of confidentiality and the relevant CCMO update form, all signed and dated, must be submitted to the CCMO. **A. GENERAL CONDITIONS** Independence is a requirement that applies to all members of medical research ethics committees. Membership should be refused in cases where independence is not assured. All members represent a single discipline during a meeting of a medical research ethics committee.*1* **B. CONDITIONS APPLYING TO DISCIPLINES, ART. 16, CLAUSE TWO, POINT a OF THE WMO** **1. PHYSICIAN** Have graduated from a university course in medicine; Be registered as a physician on the basis of the Individual Healthcare Professions Act (BIG); Have demonstrable experience with medical-scientific research involving human subjects, which can be shown from publications and/or dissertation; Have at least three years' experience working as a physician within the five years preceding application for recognition as an MREC member with the expertise required under the WMO. **2. LEGAL SPECIALIST** Have graduated from a university course in Dutch law; Have demonstrable knowledge of and affinity with medical law; Have at least three years experience working as a lawyer within the five years preceding application for recognition as an MREC member with the expertise required under the WMO. **3. METHODOLOGIST** Be registered as an epidemiologist by the SMBWO*2* (PhD level) or by the Netherlands Epidemiological Society (MSc level), as a biostatistician by the VVS*3*, or be a graduate statistician having majored in an exact science, or a graduate social scientist having majored in a relevant subject; 1 This condition does not apply to hospital pharmacists and clinical pharmacologists.

	One individual may represent both disciplines. 2 Registration in the records of the Foundation for Training in Medical-Biological Scientific Investigation (*Stichting voor opleiding tot Medisch-Biologisch Wetenschappelijk Onderzoeker;* SMBWO) 3 Registration in the records of the Netherlands Society for Statistics and Operations Research (VVS) Have demonstrable research experience with methods and techniques involved in medical-scientific research involving human subjects, which can be shown from publications and/or dissertation; Have at least three years' experience working as a methodologist in the field of medical-scientific research involving human subjects within the five years preceding application for recognition as an MREC member with the expertise required under the WMO. **4. ETHICAL SPECIALIST** Have graduated from a university course in theology, philosophy, humanistics or a (university) masters' course in ethics; Have demonstrable knowledge of medical ethics, which can be shown from scientific publications and/or dissertation; Have at least three years experience working in the field of medical or health ethics within the five years preceding application for recognition as an MREC member with the expertise required under the WMO. **5. MEMBER ASSESSING THE STUDY FROM THE SUBJECT'S POINT OF VIEW** Have at least five years social experience obtained by performing (paid or unpaid) work; Have the ability to give an independent assessment of medical-scientific research from the subject's perspective.*4* **6. HOSPITAL PHARMACIST** Be registered as a hospital pharmacist on the basis of the *Individual Healthcare Professions Act* (BIG); Have demonstrable experience with medical-scientific research involving human subjects, which can be shown from a CV, publications and/or dissertation; Have demonstrable experience with the assessment of the substantive pharmaceutical aspects of drugs research; Have at least three years experience working as a hospital pharmacist within the five years preceding application for recognition as an MREC member with the expertise required under the WMO. **7. CLINICAL PHARMACOLOGIST** Be registered as a clinical pharmacologists (internists category, hospital pharmacists category or other category) by the Dutch Society of Clinical Pharmacology and Biopharmacy; Have demonstrable experience with clinical pharmacological research (experimental and/or observational drugs trials involving human subjects), which can be shown from publications and/or dissertation; Have at least three years experience working in the field of clinical pharmacology within the five years preceding application for recognition as an MREC member with the expertise required under the WMO.

Procedure for ethics assessment: before	First assess whether the study protocol requires assessment by CCMO or MREC If a study falls under the scope of the Medical Research Involving Human Subjects Act (WMO) then is must be undergo a prior review by an accredited MREC or the CCMO. Research falls under the WMO if the following criteria are met: **1. It concerns medical/scientific research and** **2. Participants are subject to procedures or are required to follow rules of behaviour** **3. It concerns medical-scientific research** The WMO does not offer a definition of the term medical-scientific research. As a result, it is not always clear if the research protocol must be submitted for review by law. A comparable matter is the case with studies with (leftover) embryos and the Embryo Act. The CCMO assists in this by offering the following definition: *'Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.' (Non-official translation)* Research with a medicinal product is also categorised as medical-scientific research. And behavioural-scientific research can in certain cases also be deemed medical-scientific. Furthermore, nursing, physiotherapy and psychology research can in some cases fall under the WMO. The kinds of studies that do not fall under the WMO are, for example, studies relating to quality analysis of two different laboratory instruments with the aim of researching the possibility of switching to a cheaper instrument or research on the improvement of existing techniques for new applications. An example is research on the configurations and conditions of MRI to visualize certain organs, or on fMRI to be able to measure brain activity during certain tasks. However, as soon as such research is aimed at improving *diagnostic* possibilities of (f)MRI, it does fall within the definition of medical-scientific research. Another type of research which is not considered as medical-scientific research is a student practical during which they carry out certain procedures on one another. Such a study does not contribute to new insights in the field of medicine and does not lead to the publication of scientific articles. **2. Participants are subjected to procedures or are required to follow rules of behaviour** In general, research with human subjects only falls under the WMO if there is an infringement of the physical and/or psychological integrity of the subject. The subject himself/herself must be physically involved in the research for the research to fall under the WMO. Therefore retrospective research/file research does not fall under the WMO. In that case the data are already available and not collected specifically for a medical-scientific research. The subject does not have to do or abstain from something on behalf of the research. A blood sample being taken from the participant for the purpose of scientific research: this always falls under the WMO as the participant is subjected to a procedure. If additional blood is taken for the research as part of a planned vene puncture or from an existing line, then the research also falls under the WMO.

	Research during which a participant must provide one urine sample once, generally does not fall under the WMO. However, research during which urine samples must be provided over the course of a three-week period does.
Procedure for ethics assessment: during	The committee jointly review the study and come with a judgment. The committee follows the directives in http://www.ccmo.nl/attachments/files/revised-ccmo-directive-on-the-assessment-of-clinical-trial-agreements-dated-30-08-2011.pdf
Procedure for ethics assessment: after	The research may not begin without a positive decision by this committee (CCMO, 2015).
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [X] human subjects research [ ] treatment of animals in R&I [X] human dignity [x] equality / non-discrimination [X] autonomy / freedom [ ] implications for civil rights [x] implications for privacy [ ] social responsibility [X] justice / fairness [X] implications for health and/or safety [X] implications for quality of life [ ] environmental impacts [x] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: [X} sound methodology to assure that the study will answer the research questions [X] public disclosure of results Commentary:
Self-assessments, strengths and weaknesses	The investigators make a self-assessment to assess whether the study requires assessment by the CCMO or MREC.
Other	Additional information in the interview report (WP1_NL_report on CCMO)

Name of organisation	**Ethics committee of the Faculty of Behavioural, Management and Social Sciences of the University of Twente** (Commissie Ethiek van de Faculty of Behavioural, Management and Social Sciences van de Universiteit Twente)
Type of organisation	Research ethics committee
Country	Netherlands
Website address	http://www.utwente.nl/bms/en/research/research-ethics/
Basic description (organisation and mission)	The Ethics Committee (EC) of the faculty of Behavioral Sciences is a committee consisting of scientists from the faculty that has been established to pass its judgment on research that is carried out by students and employees.
Interest in research and innovation	The EC is entirely focused on the evaluation of research in the social and behavioral sciences
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	The EC considers itself to pass judgment on and approve research proposals. It explicitly does so from the point of view of (research) ethics, and aims to evaluate ethical permissibility.
Name and description of	Identical to above (Ethics committee)

ethics unit(s)	
Aims and motivation for ethics assessment	The aim of the Ethics Committee is to ensure that research that is carried out by students and employees has been screened for ethical issues. It aims to judge whether planned research is in accordance with the regulations and standards that were stated in the faculties' Protocol about Ethics and Research and to make recommendations to researchers for better adhering to ethical standards.
Objects and scope of assessment	The aim of the ethics committee is to ethically assess the research proposals of students and research staff of the faculty of Behavioural, Management and Social Sciences (BMS). Sometimes research that has already been performed is evaluated, if the proposals for the research have not been assessed beforehand. Only research involving human test subjects and/or personal data requires ethics assessment. Researchers can themselves determine whether this is the case.
Beneficiaries of assessment	The beneficiaries are the students and research staff of the faculty who submit research proposals to the committee; they receive comments from the committee.
Ethics assessment unit: appointment process	The ethics committee has been instituted by the dean of the faculty of BMS. The ethics committee is composed of senior researchers from faculty of BMS of the university. Their expertise stems from their experience of being in the ethics committee. In the committee, there are ethics specialists from the philosophy department of the faculty of BMS, but this not so by design. Regarding composition, the main rule is that each individual department of the faculty has representation in the committee; each department delegates a member to the committee. There is no involvement of stakeholders other than the academics and there is no discussion on whether that should happen.
Procedure for ethics assessment: before	Researchers are made aware by the committee and the dean's office that they are recommended to have their research proposals assessed by the EC. Researchers are not forced to have their proposals assessed; it is only strongly recommended that they do so. Most in fact do so. If and when researchers choose to submit their proposal, they go to the website of the committee and fill out the appropriate form which provides information about their proposal and potential ethical issues in it.
Procedure for ethics assessment: during	After receiving a form with a request for ethical assessment (see above), it is first determined, by the secretary of the committee, whether the research is medical-scientific in nature. If so, it goes to a special medical ethical committee outside the faculty. If not, then it is determined, on the basis of checked boxes, whether the research qualifies as standardized research. This is research that contains research practices that are normal for a particular field. It then goes to a member of the committee from the same department as the submitter, who provides feedback on the request concerning the ethical permissibility of the research – within 10 working days. If the proposal covers non-standardized research, then the procedure is that the submitter will be asked to give a justification of the deviation of the standard research and give other special particulars that can be relevant for the ethics committee; the whole committee will debate the proposal in a special session. Individual committee members can also request that a particular standardized proposal is nevertheless decided on by the entire committee. In both standardized and non-standardized cases, the submitter will receive a written judgment regarding ethical permissibility, and advice for addressing ethical issues. If serious ethical issues are found and no approval can be given, the committee may ask the submitter to submit a revised proposal.
Procedure for ethics assessment: after	After approval, the researcher can start his/her researcher. If no approval is given, he/she can revise and resubmit. The researcher also has the option of ignoring the judgment and go ahead with the research.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards

	[x] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [ ] social responsibility Commentary: Not considered are scientific fraud, animal experimentation, social or environmental impacts of the research, and potential negative use of data (dual use). Justice and fairness are considered in relation to research participants only. Examples of important ethical problems in research and innovation that are assessed by the committee are research in schools with (young) children, which involves informed consent (How often should it be asked or given? And when is parental supervision necessary?), and research with mystery shopping experiments, which involves the problem of how to obtain informed consent without compromising the experiment. One major ethical problem that occurred related to a questionnaire on bullying filled out by children without parental supervision.
Self-assessments, strengths and weaknesses	The interviewee, Ms. Janke Rademaker, secretary of the committee, thinks there are no major weaknesses or problems in how ethics assessment takes place in the committee. There is only one thing: The committee has to be enlarged due to a recent departmental merger. This might cause some temporary problems. The new members of the committee would be wholly unfamiliar with ethics assessment (as at their former departments ethics assessment was not practiced), so they may need some ethics education and training. Current members do not need further ethics training, unless perhaps there is a new European framework or something for ethics assessment.
Other	The committee does not interact much with other organisations in relation to ethics assessment. It does get in touch every once in a while with a medical research ethics committee (MREC) at a local hospital (Medisch Spectrum Twente)—which may ask for its opinion on some particular issue. All ethical issues relating to medical procedures and animal experiments are directly delegated to this MREC.

Name of organisation	**The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)** (Den nasjonale forskningsetiske komité for sammfunnsvitenskap og humaniora)
Type of organisation	National ethics committee
Country	Norway
Website address	General: www.etikomm.no Main page(s) on ethics assessment: https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-in-the-social-sciences-and-the-humanities-nesh/
Basic description (organisation and mission)	NESH is an administrative body under The Ministry of Education and Research. It develops and administrates ethical guidelines for research within the social sciences, humanities, law and theology. The Norwegian system is divided into three national committees together covering all research fields. NESH consists of ten scientific members and two laypersons. The guidelines comprise 47 principles and were first written in 1993. The guidelines are institutionalized in the Norwegian research system. The researchers ought to take the guidelines into consideration by doing a self-evaluation of their research. If they do not find the guidelines to be guiding for their case they will ask NESH for advice. If the case is of principal interest the researcher can bring the case to the committee. The committee has four annual meetings. There is also an ongoing administrative procedure where researchers and students can get advice by phone or email.

	NESH has an advisory role only. The users of the assessment are individual researchers, doctoral and master students, the authorities, and the public.
Interest in research and innovation	NESH deals with ethics evaluation and formulates advisory statements in regard to of research projects. NESH develops ethical guidelines for research within the social sciences, humanities, law and theology.
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [x] None [ ] Commentary: Develops guidelines for research ethics. If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	----
Name and description of ethics unit(s)	----
Aims and motivation for ethics assessment	
Objects and scope of assessment	NESH has two main goals: (1) To provide advice on research ethics and quality assurance of research projects. The projects NESH give advice on are either contract research or projects where the researcher wants to get access to and to use sensitive data. In some cases the holder of the information requires an ethical approval from NESH before the researcher can get access to the information. (2) To give advice in cases where it is unclear if or how the ethical guidelines on research ethics provided by NESH are adequate or relevant because of the research raising new issues, e.g. due to new types of problems or methodologies, or when the research involves vulnerable research subjects.
Beneficiaries of assessment	Researchers, doctoral and master students, authorities, politicians, the public
Ethics assessment unit: appointment process	The scientific members are appointed by the Norwegian Research Counsil. They are chosen based on research performance. The final decision is made by the Ministry of Education and Research in Norway.
Procedure for ethics assessment: before	NESH conducts two different types of ethics assessment. The first type of assessment is an ongoing administrative procedure where researchers and students can get ethical advice on their research project by phone or email. This procedure is for minor issues, e.g. interpretation of ethical principles. The second type is evaluation of more problematic cases where the principles do not give guidance or if the ethical issues are of principal interest. In the latter case the researcher can bring their case to the committee for evaluation. The procedure for the latter case: The researcher will make a formal inquiry to NESH. The inquiry should contain a specification of what ethical aspects/challenges in the project that he/she primarily wants NESH to consider. When specifying the ethical aspects/challenges the researcher should relate to what he/she believes to be the most relevant ethical principles in the guidelines. The formal inquiry should also contain a description of the research project, necessary attachments, e.g. if the project has been previously evaluated by another relevant research ethics committee, these evaluations should be added.

	One of the committee members will undertake a more thorough assessment of the case and will also prepare a statement.
Procedure for ethics assessment: during	The Guidelines provide a framework of ethical principles for assessing research. The actual assessment consists in applying normative ethical principles to a specific case. The case is discussed during a meeting until the committee has reached consensus. The outcome (the advice to the researcher) of the evaluation as casuistic and based on consensus. In cases where consensus is not possible, the advice to the researcher can be communicated in terms of "pro and cons". An evaluation/assessment is never precedent for subsequent cases.
Procedure for ethics assessment: after	The secretary will write a statement and inform the researcher about the decision.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [x] social responsibility [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [x] environmental impacts [x] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: research in other cultures; protection of cultural heritage Commentary: The NESH guidelines comprise 47 principles.
Self-assessments, strengths and weaknesses	There is no self-evaluation practice and procedure in NESH. The three representatives were asked about the strengths and weaknesses of the system form ethics assessment of research. Three representatives interviewed presented rather different views regarding strengths and weaknesses. R1: Strengths: The Norwegian system is functional by being institutionalized in the research community. The guidelines should be embedded in the research community. The committee is continuously evaluating the ethical principles in the guidelines and their applicability. Weaknesses: None R2: Weaknesses: The interviewee finds the consensus-based assessment procedure wanting. There is an idea that the statement made by the committee should reflect unanimity. This gives a picture of the issues dealt with being easily solved, which is not the case. The procedure, the discussion leading to consensus is often very extensive, which should reflect the formulations in the statement to the researcher. The relation between NESH and other ethical committees (e.g. universities ethical committees) could be made clearer. R3: Strengths: The guidelines are useful as a framework for discussion about research ethical issues. Nevertheless, without discussion the principles in the guidelines will not provide any answers for particular cases. Weaknesses: The weakness of is that NESH and its guidelines are quite unknown to several groups of researchers, especially within the humanities. A lot of the questions that NESH deals with are therefore perennial ones. Another weakness, according to the interviewee, is that there is no impact assessment. The effect has never been "measured".
Other	----

Name of organisation	**Appeal Bioethics Committee (ABC)** (Odwoławcza Komisja Bioetyczna)
Type of organisation	(Appeal) Research ethics committee
Country	Poland
Website address	*General:* www.mz.gov.pl/rozwoj-i-inwestycje/nauka/komisje-bioetyczne/odwolawcza-komisja-bioetyczna *Main page(s) on ethics assessment:* same as general address
Basic description (organisation and mission)	The Appeal Bioethics Committee (ABC) handles appeals to decisions issued by local Bioethics Committees (BCs) that concern research involving human beings. ABC assesses the ethical aspects of research proposals. It evaluates the potential harm done to human beings. The assessment done by ABC is addressed to parties who applied for the ethical review It is a subject of discussion whether other, non-medical, types of research on human beings should be subject to ethical review by a bioethics committee. In general the answer is "yes", however the opinions vary even among the members of ABC. In practice, however, this is not a major issue, since most problems concern clinical trials.
Interest in research and innovation	The Committee assesses research on human beings.
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	The words "bioethics" and "ethics are explicitly used.
Name and description of ethics unit(s)	N/A
Aims and motivation for ethics assessment	Ethics assessmnet is mandated by national law
Objects and scope of assessment	proposals for medical research involving humans and clinical trials (after an appeal to a decision of a local bioethics committee)
Beneficiaries of assessment	The assessment done by ABC is addressed to parties who applied for the ethical review.
Ethics assessment unit: appointment process	Members of ABC are nominated by the Minister of Health. ABC operates pro-bono, its members do not receive any kind of remuneration, even though the amount of work is vast. ABC operates at the Ministry of Health; however at the Ministry there are no staff members who would focus solely on managing the work of ABC. Rules on how members of ABC are appointed have been specified in act on medical profession (1996). The term of ABC is not fixed. The current ABC has been operating for the longest period of time, i.e. 14 years.
Procedure for ethics assessment: before	Research who plan to perform research on humans are required to submit proposals for review. They fill out standardized forms. It is a subject of discussion whether other, non-medical, types of research on human beings should be subject to ethical review by a bioethics committee. In general the answer is "yes", however the opinions vary even among the members of ABC. In practice, however, this is not a major issue, since most problems concern clinical trials.
Procedure for ethics	ABC does not issue recommendations, but decisions that have a status similar to that of administrative decisions. ABC relies in its activities on international instruments, such as,

assessment: during	for example, the rules of Good Clinical Practice, as well as the national legislation, the Code of Medical Ethics, the Ethical Code of Researchers (ECR). Moreover a number of other international instruments and conventions are referred to, such as the European Convention on Human Rights, Oviedo Convention, Charter of Fundamental Right, UNESCO declaration on human genome.
Procedure for ethics assessment: after	The decisions of ABC are final and binding. "Regrettably, due to limited resources, ABC is not cooperating with other institutions to the extent it should be."
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [x] human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [x] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: see commentary Commentary: *"Key values that form the basis for ABC's activities are listed in the EU Charter of Fundamental Rights. They include: dignity, privacy, security, right to health, right to work, etc. In the case of clinical trials the crucial principle is the protection of health of the participant, as well as his or her privacy. Recently the need to protect privacy has become more pressing."*
Self-assessments, strengths and weaknesses	The lack of financial resources is one of the basic problems faced by ABC. Important members of ABC, e.g. lawyers, resign due to lack of time. Another serious obstacle is the lack of permanent staff. All administrative staff that were assigned by the Ministry of Health to assist ABC have other duties. *"This is a paradox, since the regional bioethics committees do employ supporting staff."*
Other	

Name of organisation	Bioethics Committee of Children's Memorial Health Institute *(Komisja Bioetyczna przy Centrum Zdrowia Dziecka)*
Type of organisation	Research ethics committee
Country	Poland
Website address	*General:* http://www.czd.pl/ (website of the Children's Memorial Health Institute) *Main page(s) on ethics assessment:* http://epn.czd.pl/Strony/KomisjaBioetyczna.aspx
Basic description (organisation and mission)	The Bioethics Committee was established in 1984 and operates at Children's Memorial Health Institute, which is one of the biggest children's hospital in Poland and in the same time a research institute. The Committee's work is regulated by the executive act of the Minister of Health and Social Care of 11 May 1999 on specific regulations regarding constituting, funding and operating of bioethics committees[30]. The Committee assesses clinical trials taking into consideration the ethical as well as scientific context. It also

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

	supervises how the trials are carried out. Its main objective is to ensure the safety of research subjects and the high quality of research[31].
Interest in research and innovation	The Bioethics Committee of Children's Memorial Health Institute is interested especially in the assessment of drug trials, genetic research and new therapeutic methods.
Ethics assessment and/or guidance	Assessment [X] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [X] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	Ethical norms are only auxiliary and the matter of accessibility of certain scientific methods or experiments should be regulated by legal norms, both national and international. Ethical norms may be formulated as rules of good scientific practice adopted and accepted by a scientific community or they may be regarded as the proposal for legislative improvements.
Name and description of ethics unit(s)	The Committee is a body at Children's Memorial Health Institute and it does not consist of any specific units.
Aims and motivation for ethics assessment	The main purpose of carrying out ethic assessments is to ensure the safety of research subjects and the high quality of research. According to the act of 5 December 1996 on medical profession[32], a medical experiment can only be conducted, if an independent Bioethics Committee have issued a positive opinion.
Objects and scope of assessment	The assessment of the Bioethics Committee takes into consideration the ethical criteria as well as the purposefulness and feasibility of a research project (with regard to article 29 of the Act on Medical profession).
Beneficiaries of assessment	Anyone, who intends to carry out medical experiments (mostly scientists).
Ethics assessment unit: appointment process	The Committee's members (in the number of 11-15) are appointed for a 3-year term by the director of the institution. According to the executive act they shall be specialist physicians and representatives of other professions, in particular clerics, philosophers, lawyer, pharmacists and nurses and should have at least 10 years of experience in their field.
Procedure for ethics assessment: before	According to the executive act on bioethics committees a person, who is planning to carry out a medical experiment should file an application, which would in particular include information on: • person responsible for carrying out the experiment (his or her name, qualification etc.); • description of the experiment; • expected benefits; To the application one shall annex the project of the experiment as well as the consent of the participant.
Procedure for ethics assessment: during	The procedure is stipulated in the executive act on the bioethics committees as well as in the rules of proceedings of Bioethics Committee of Children's Memorial Health Institute. The chairperson of the Committee selects members, who are responsible for issuing the opinion. The person, who intends to conduct the experiment should present the project and provide them with any necessary explanations. To issue an opinion, half of the committee's members plus one person shall vote in favour of it. The written opinion should be issued within 3 months.
Procedure for ethics assessment: after	The opinion of the Bioethics Committee is not final. The following parties may appeal: • the applicant; • director of the Health Centre, where the experiment is to be conducted; • competent Bioethics Committee. The appeal should be delivered to the Committee, which later passed it on to the Appeal Bioethics Committee. The appeal shall be considered within 2 months.

[31] http://epn.czd.pl/Strony/KomisjaBioetyczna.aspx
[32] The Act of 5 December 1996 on Medical Profession (Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty).
http://isap.sejm.gov.pl/DetailsServlet?id=WDU20081360857

Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [X] human subjects research [ ] treatment of animals in R&I [ ] human dignity [ ] equality / non-discrimination [X] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [X] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [X] other, specify: informed consent, involvement of non-professionals in the assessment procedure Commentary: The range of information to be given is very important. It should be detailed, but in the same time it should not cause unnecessary concern. As far as the involvement of non-professionals are concerned, their participation in the ethics assessment procedure is essential, for it provides for an outside point of view (philosophical, moral etc.).
Self-assessments, strengths and weaknesses	There are no weaknesses in the ethical assessment procedures. However, there are certain areas, in which such assessments are not legally required, even though that would be highly beneficial. Ethics committees should not only operate in the field of medicine, but also psychology and sociology, where research is often based on questionnaires and interviews. Committees shall asses: what kind of questions can be asked?; how to formulate questions?; what are the lines of privacy, which shall not be crossed? In legal studies, especially in criminology, such committees would also be useful. They would assess the accessibility of certain research methods.
Other	The issue of informed consent is important especially with regard to research involving minors. If the person on whom the experiment shall be carried out is under 16, the consent should be granted by his or her legal guardian. Should the minor be over 16, his or her consent is also required. In the event of any discrepancies, permission (or lack of it) of the person concerned outweighs.

Name of organisation	Ethics Commission, Department of Social Psychology of the Faculty of Psychology at Warsaw University (Komisja ds. Etyki Badań Naukowych Katedra Psychologii Społecznej Wydziału Psychologii UW)
Type of organisation	National university
Country	Poland
Website address	*General:* http://www.psych.uw.edu.pl/o_nas.php?id=1&sub_id=2.24 *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	According to the rules of procedure[33] the role of the Ethics Commission ("Commission") is to ensure that research conducted at the Faculty of Psychology ("Faculty") is ethical. The Commission shall achieve this goal by giving opinions on research projects, as well as by preparing and promoting ethical standards concerning psychological research.
Interest in research and innovation	The Commission shall ensure that research conducted at the Faculty is ethical.
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for	n/a

[33] http://www.psych.uw.edu.pl/files/o_nas/wladze/komisje/regulamin_komisji_ds_etyki_badan_naukowych.pdf

ethics assessment / guidance	
Name and description of ethics unit(s)	n/a
Aims and motivation for ethics assessment	The Commission was created with the purpose of assessing research proposals.
Objects and scope of assessment	Research proposals
Beneficiaries of assessment	Individual researchers, the Commission assesses research proposals by researchers from the Faculty.
Ethics assessment unit: appointment process	Members of the Commission are appointed by the Faculty's Council. They are researchers from the Faculty, PhD candidates and one representative of the student community. Members do not receive remuneration for the work in the Commission. There are no formal guidelines on who should be the member, or what kind of experience they should have.
Procedure for ethics assessment: before	Scientists are to submit proposals for review. They filled out the forms supplied by the Commission.
Procedure for ethics assessment: during	The Commission is currently composed of 11 members – there are three working groups composed of three members each, and two additional members who are responsible for administrative tasks. The Committee meets at least three times per year (usually four or five times). Members of the working groups read proposals and present them at the plenary where they are discussed by all the members.
Procedure for ethics assessment: after	The opinion of the Commission is binding. It is either positive or negative. In some cases, if the proposal has only minor flaws, the Commission may decide to give a conditionally positive opinion. It contains a set of recommendations for the applicant who is obliged to amend his or her proposal, and submit it once again.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [ ] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: well-being of research participants Commentary: The major principle guiding the work of the Commission is the obligation to protect participants – the Committee should make sure that the well-being of research participants' is safeguarded.
Self-assessments, strengths and weaknesses	The majority of opinions are positive or conditionally positive. For example between October 2012 and November 2014, during 12 sessions, from among 160 opinions 77 (48.1%) were positive, 23 (24.4%) were negative and 60 (37.5%) conditionally positive. Due to limited resources, there has been no monitoring of compliance with the opinions. Evaluations of the impact of ethics assessment have not been conducted. Unfortunately, in most cases, researchers perceive ethics assessment as a yet another administrative burden and a formality they have to take care of.

	It would be desirable for proposals to be assessed by experts from a given discipline, which currently is not always the case.
Other	

Name of organisation	**Ethics Board of Serbia** Etički odbor Srbije (EOS)
Type of organisation	National ethics committee
Country	Serbia
Website address	*General:* No website. *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	EOS was established by the Ministry of Health in 2008 to formulate guidelines of professional ethics for medical workers, supervise ethics assessment of medical research and clinical trials and to advise on ethical issues concerning professional and research ethics in medicine. EOS does not assess individual research proposals, programs nor results and innovations. These assessments are within the competence of ethics committees of individual research institutions. The role of EOS is to oversee and control the work of these committees, which can request advice and opinions from EOS. EOS also acts as court of appeal and can intervene in contentious situations. The 9 members of the EOS are appointed by the Ministry of Health. Ethical values and principles of EOS are defined by the Basic Principles of Medical Workers' Professional Ethics, a document developed by EOS. EOS interacts with individual ethics committees at medical institutions, as well as the Medicines and Medical Devices Agency and the Ministry of Health. It has strong ties with the ethics committee of the Pharmaceutical Chamber of Serbia and also collaborates with the Bioethical Society in organising public tribunes with the view to raise awareness on ethical issues related to medicine.
Interest in research and innovation	EOS supervises ethics assessment of medical research and clinical trials.
Ethics assessment and/or guidance	Assessment [ ] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	Ethical terminology is used.
Name and description of ethics unit(s)	The members of the EOS are appointed by the Ministry of Health for a mandate of 5 years. There are no specific regulations according to which members are chosen. EOS consists of 9 members, mostly medical professors and one law professor.
Aims and motivation for ethics assessment	The Board's tasks are defined by the law on medical care and include: formulating guidelines of professional ethics for medical workers and supervising their implementation; to coordinate the work of ethics committees in medical (research) institutions; to supervise medical research and clinical trials of drugs and medical procedures in medical institutions; to advise and give opinions on ethical issues concerning medical research and clinical trials; to supervise the procedures and advise on issues concerning organ donations for health and research purposes; to supervise the procedures and advise on issues concerning the fertility treatment and medically assisted reproduction.
Objects and scope of assessment	The ethical problems assessed by EOS are problems linked with professional integrity (of medical workers, including researchers), human subjects research, fertility treatments and organ donation. EOS can help solve these problems by providing ethical guidelines, opinions, advice and mediation in case in conflicts.
Beneficiaries of assessment	The users of assessments are individual researchers and ethics committees, as well as the government.
Ethics assessment unit:	The members of the EOS are appointed by the Ministry of Health for a mandate of 5 years. There are no specific regulations according to which members are chosen. EOS consists of 9

appointment process	members, mostly medical professors and one law professor.
Procedure for ethics assessment: before	EOS does not assess individual research proposals, programs nor results and innovations. These assessments are within the competence of ethics committees of individual research institutions. The role of EOS is to oversee and control the work of these committees, which can request advice and opinions from EOS. EOS also acts as court of appeal and can intervene in contentious situations, e. g. when an individual committee does not respond to an assessment request or in cases of research cooperation between several institutions when the committees in those institutions do not agree in their assessments. Individual researchers can also request advice on their research practice. The government can request EOS advice on policies related to medicine and medical research, e. g. on fertility treatment and organ donation legislation.
Procedure for ethics assessment: during	Ethical values and principles of EOS are defined by the Basic Principles of Medical Workers' Professional Ethics. The values and principles stated in the document include freedom and autonomy of medical professions, their duty to serve the public health and wellbeing of patients, acting consciously with respect for human dignity, the principle of non-discrimination, not using their expertise for non-humane goals, etc. The document also provides basic guidance for EOS in its assessments. It is, however, supplemented by personal opinions of individual EOS members. The members meet once a month to discuss all issues and vote on decisions. So far, all decisions were taken unanimously.
Procedure for ethics assessment: after	Recommendations of EOS are nonbinding – EOS only has an advisory role – and are not always followed. EOS can as a mediator in case of conflict (e.g. between individual researchers and ethics committees or between several ethics committees) but has no power to enforce a decision or impose a penalty – it can only report the unresolved issues to the Ministry. There is no special procedure for monitoring of compliance.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [ ] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: organ donation; fertility treatment Commentary:
Self-assessments, strengths and weaknesses	One big obstacle for EOS to fulfill its goals is the lack of administrative and financial support provided. So far, the functioning of EOS was made possible more by the enthusiasm of its members then by sound material conditions. EOS currently has no premises of its own and no administrative personnel. On the first change of mandate, the ministry appointed new members without consultation with the previous members, thereby jeopardizing its continuity. Due to these problems, in its second mandate, EOS has yet to resume its full activities. The proper functioning of EOS is also made harder by the dispersed nature of ethics assessment in the country. Ethics assessment is done at individual institutions with no central database containing contact information on particular committees, which makes communication and the supervising activities of EOS more difficult. Committees at some institutions are hard to reach. In the future, individual committees should report on their activities to EOS.
Other	n/a

Name of organisation	Ethics Committee of Clinical Centre Nis (ECCC)

Type of organisation	Research ethics committee - assessor
Country	Serbia
Website address	*General:* http://www.kcnis.rs/index.php/uprava-kc/eticki-odbor *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	ECCC deals with the issues related to the clinical trials of drugs tested on humans, gives approvals for summary protocols and CRF protocols and all things that make a proper research. Ethics Committee also decides about the issues on biomedical assisted fertilization, organ transplantations. Furthermore, they make assessments of medical devices and provide results for sponsors, patients and the Agency for Medicines and Medical Devices. ECCC consists of medical doctors, jurists and one laic (a professor, poet, priest..). All members of ECCC are selected according to a Law on Health Care and appointed by Director of Clinical Centre. The ECCC closely collaborates with Ethics Committee of Niš Medical faculty as well as with other EC on the institutional level. They also collaborate with Ethics Board of Serbia and with the Medicine and Medical Devices Agency of Serbia and with Ministry of Healthcare.
Interest in research and innovation	ECCC is specially interested in clinical trials and R&I in the fields of biomedical assisted fertilization and organ transplantation.
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	To make sure that procedures recommended by Good research practice and Good clinical practice are respected and to preserve patent's rights.
Objects and scope of assessment	Biomedical assisted fertilization, clinical trials, organ transplantation, medical devices.
Beneficiaries of assessment	Patients, doctors, researchers.
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and	[x] scientific integrity [ ] justice / fairness

issues in assessment / guidance	[x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary:
Self-assessments, strengths and weaknesses	There is no self-evaluations practice and procedure in ECCC. There is no training for members. Public consultations are very rare when it comes to delicate issues such is transplantation, cloning, IVF, transhumanism.
Other	

Name of organisation	Ethics Committee of Military Medical Academy (ECMMA)
Type of organisation	assessor
Country	Serbia
Website address	General: http://www.vma.mod.gov.rs/eng/ Main page(s) on ethics assessment: http://www.vma.mod.gov.rs/en/about-mma/MMA-Ethics-Committee#.VR5hWdzN6Nk
Basic description (organisation and mission)	The Military Medical Academy (MMA) is a medical, educational and scientific-research institution with an internationally acknowledged reputation. As a military hospital with centralized care, the MMA can ensure that a consultation meeting of the most skilled medical experts can be called up in 10 minutes to respond to any kind of medical problems. It was established in 1844, and today, within its framework, it has the Medical School committed to creating new generations of military doctors. It is also recognized as a scientific research center of excellence. MMA has 27 clinics and 17 institutes, the Specialist Outpatient Clinic, the Poison Control Center, the Emergency Department and the Solid Organ Transplantation Center performing more than 5000 diverse diagnostic and therapeutic procedures. The MMA operates as a part of the Ministry of Defense. Thanks to its military organisational structure and commitment to providing the best, most comprehensive quality medical care, it has been rewarded and recognized as a medical institution meeting the highest world standards. The MMA has always been opened to all our citizens, and since its recent full integration in the National Health System, it serves 40 percents of civilian patient population. Each year, it has more than 230.000 civilian outpatient visits, of which more than 20.000 result in hospital admissions. Furthermore, on Wednesdays, its Emergency Department operates round the clock providing comprehensive emergency response services to the whole population of Serbia.
Interest in research and innovation	Institute of Medical Research is a part of MMA. The scientific-research work in the field of biomedicine represents the Institute's principal activity aimed at resolving actual issues of concern to the Serbian Armed Forces Medical Services. The Institute carries out diagnostic and consulting activity concerning immunology, molecular medicine and neurobiochemistry issues. Four departments operate within its framework: Department of Clinical and Experimental Physiopathology, Department of Clinical and Experimental Immunology, Molecule Medicine Department and Department of Laboratory and Experimental Care and Use of Animals.
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:

Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	ECMMA is formed based on resolution given by chief commander of MMA. Its work is in accordance with laws that apply to all other medical and healthcare institutions. Also, there is a board that oversees animal welfare. Members of ECMMA are medical doctors, jurists (judges from Serbia and sometimes from abroad), journalist and priest. Medical doctors are experts in different fields of medicine, but there is always one clinical pharmacologist present and usually surgeon internist as well as scientific researcher. In most cases decisions are the result of consensus. Their work is fully independent, but in accordance with laws and rulebooks. Most decisions are routine one. ECMMA works in accordance with its own rulebook. Annual report (only formal, without detailed data) is submitted to chief commander of MMA, but the members also decided to submit it to Ethics Committee of Serbia. Their aim was to have all documents at one place in order to be able to track if some institution refuse to conduct clinical trial, but other accept it and why this has happened. This enables the researcher to ask the permission from different ethics committees until one of them gives approval.
Aims and motivation for ethics assessment	Protecting patient's rights and providing recommendations regarding scientific justification of biomedical research.
Objects and scope of assessment	There are three fields of interest that are dealt by Ethics Committee of Military Medical Academy (ECMMA): clinical trials, cells and tissues transplantation and scientific and research activities. Clinical trials have been conducted in accordance with law since 2007 and this was done (procedures defined by new Law on Health Care) on demand of pharmaceutical companies. When it comes to transplantation, the cells are not the problem, but organs related issues are. It is possible to come across all kinds of situations there. There have been the cases that people got married in order to obtain the needed organ and it was clear that behind this is pure trade. The aim of the ECMMA in that matter is to protect both the donor and the recipient of the organ. Scientific research projects and PhD studies conducted at MMA is the third field in which ECMMA plays important role. When it comes to scientifically justification of candidates ECMMA usually gives recommendations, not prohibitions. There is separate commission for evaluation of projects, which should give its opinion whether the project is justified scientifically. No one's project has been evaluated if they didn't obtain approval from ethics committee first.
Beneficiaries of assessment	Researchers, medical doctors, patients, pharmaceutical companies.
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment:	

after	
Principles and issues in assessment / guidance	[x] scientific integrity [x] justice / fairness [ ] professional integrity [x] implications for health and/or safety [x] human subjects research [x] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [x] human dignity [ ] social impacts [x] equality / non-discrimination [ ] outsourcing of R&I to developing [x] autonomy / freedom countries with lower ethics standards [x] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [ ] social responsibility Commentary:
Self-assessments, strengths and weaknesses	There is no self-evaluations practice and procedure in ECMMA and no clear procedure (standards, protocols, guidelines) how to perform ethics assessment. These are main thing that should be change in the future.
Other	

Name of organisation	Ethics council for protection of experimental animal's welfare (ECPEAW)
Type of organisation	Assessor
Country	Serbia
Website address	*General:* *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	ECPEAW is a special working group established by the Minister with the regulations governing the civil service, in order to discuss professional issues, providing expert opinions and participating in the implementation of terms of reference in the field of animal welfare. This Council has only advisory role and no binding power of so ever. It consists of 13 members who are elected every three years and proposed by Minster. Idea is that all research institutions in Serbia should be represented and then from proposed institution professionals with best qualifications are elected.
Interest in research and innovation	
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	
Objects and scope of assessment	1) providing advices in the area of Ethics and Animal Welfare in conducting experiments and genetic modification and manipulation of animals; 2) providing experts opinion on the ethical and scientific justification of the experiments, as well as the cessation of animal testing;

	3) providing advices in order to harmonize the work of ethics commissions for protection of welfare of animals used in animal testing; 4) providing expert opinion on the execution of specific and invasive experiments; 5) participating in development and promotion of alternative methods of conducting the experiments; 6) reporting to the minister annually on its work and the status of welfare of animals used in animal testing
Beneficiaries of assessment	Researchers and institutions using experimental animals.
Ethics assessment unit: appointment process	Each time there is a new experiment planned approval of minister should be obtained. Application form should be filled in and submitted to local ethics commission (EC of institution, faculty, institute). In case of most invasive experiments (which is strictly defined) local EC needs to forward the application to ECPEAW and they are obliged to set up a meeting to discuss the particular issue. Members of ECPEAW do not meet on regular bases, but only when specific request should be discussed.
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	Decisions are reached after brainstorming and in 99% of cases by consensus.
Procedure for ethics assessment: after	ECPEAW only states opinion, but the minister makes a decision trough Directorate for veterinary medicine. Appeal is to be submitted to Directorate for veterinary medicine.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [ ] human subjects research [x] treatment of animals in R&I [ ] human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary:
Self-assessments, strengths and weaknesses	There is no self-evaluations practice and procedure in ECPEAW. There is no data on number of animals scarified annually. Removal of produced waste is not regulated and currently it is done by city sanitation service. There should also be the detailed register of anesthetics used. Register of research institutions that use animals have been made, but many institutions refused to register. Problem is that institutions need to fulfill numerous criteria and that's why EC has chosen more liberal approach. Legal framework is good, but it needs improvement. Education and training of people who conduct research have been done, but not enough, training programs need to be improved, but the biggest problem is that the law is not obeyed.

Other	

Name of organisation	Professional Ethics Committee, University of Belgrade (PEC)
Type of organisation	assessor
Country	Serbia
Website address	*General:* http://www.bg.ac.rs/en/bodies/professional-ethics-committee.php *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	PEC makes sure that the Code of Ethics is being honored by teachers, associates and students of the University. The Code of Ethics is passed by the University Council at the proposal of the PEC. The Council also adopts the PEC Book of Rules, which closely defines the composition and the function of the Committee. PEC has nine members. Each Faculty Group, as well as student representatives and founders, are represented in the PEC. Members' term of office is three years, except for the student representatives, whose term of office is one year. The PEC decisions are binding but there is possibility of compliance. For example, when it comes to judging whether the appeal for plagiarism is justified, members of the PEC forward this cases to qualified commissions which are specialized for that particular field of science, because they do not consider themselves to be competent enough to make the decision on their own, due to the lack of knowledge. These commissions are usually at faculties and PEC expect them to discuss the appeal, especially if it is about plagiarism
Interest in research and innovation	PEC is interested in the research and innovation activities performed by universities.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	Maintaining the dignity of the University of Belgrade and further developing moral values of the academic community.
Objects and scope of assessment	There are two key documents for the work adopted by Council: Code of Professional ethics of University of Belgrade and Rulebook of Council for Professional Ethics. Code of Professional Ethics stipulates these basic principles: - The equality of all citizens before the law - Prohibition of discrimination - The inviolability of human life and dignity - Autonomy of universities - Freedom of scientific and artistic creativity - Developing a spirit of tolerance Just recently, the PEC has initiated the process of creating framework regarding plagiarism

	and auto plagiarism issues, but this document is in early stage and Senate of University should give an opinion on that in following months. The idea is to distribute this to all faculties so they can adopt it and act in accordingly.
Beneficiaries of assessment	Academic community
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [x] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary:
Self-assessments, strengths and weaknesses	There is no self-evaluations practice and procedure in PEC. PEC was not working efficiently in previous years, it was put under many pressures, there was resistance when resolving about appeals should be done and practically speaking for one and a half year the work of council was blocked. Quote: "Big problem exists due to many unclear issues which are not clearly and strictly defined and in accordance with laws, regulations and rulebooks, so there is constant fear not to make judgments too early which then could lead to lawsuits in court of justice."
Other	

Name of organisation	Ethics Committee for Clinical Research of Aragon (Comité Ético de Investigación Clínica de Aragón, CEICA)
Type of organisation	Research Ethics Committee (Regional)
Country	Spain
Website address	*General:* http://www.iacs.aragon.es/awgc/inicio.estaticas.do?app=investigacion/ofrecemos/ceica/&file

	=/index.html *Main page(s) on ethics assessment:* Procedures: http://www.iacs.aragon.es/awgc/inicio.estaticas.do?app=/investigacion/ofrecemos/ceica&file=documentos.html
Basic description (organisation and mission)	The Ethics Committee for Clinical Research of Aragon (CEICA) is a deliberative, consultative independent collegial body composed of medical and non-medical members, assigned to the department in the Government of Aragon competent in health matters. The Committee is responsible for ensuring the correct application of the methodological, ethical and legal principles of all clinical trials with drugs and health products that are made in Aragon, either in public centres or public sector activities, and those made in private institutions and centres. Any biomedical research projects involving people, personal data or biological samples of human origin. The CEICA also serves as external ethics committee of the Biobank of Aragon. The Committee has also evaluated the screening program for colon cancer and evaluates the actions of technological innovation in which the research subject is a human being, including those with bodies. The Committee does not evaluate the results of investigations of approved projects or aspects of the scientific conduct of researchers.
Interest in research and innovation	See above
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	-
Aims and motivation for ethics assessment	Ethical assessment of biomedical research is required by law (Law 14/2007 on biomedical research).
Objects and scope of assessment	The ethical evaluation is performed on projects on biomedical sciences, humanities and social sciences. Other fields, such as engineering, are assessed if they involve human subjects, e.g. software evaluation projects in orthopaedics, home automation...). Projects with animals, environment, transgenic, biosafety ... are evaluated by the Advisory Committee on Animal Research.
Beneficiaries of assessment	
Ethics assessment unit: appointment process	The CEICA consists of 16 members. Among its members it must at least include: A physician, a nurse, a representative of the Research Commission of the Aragon Institute of Health Sciences (IACS), a representative of Clinical Ethics Committee of Aragon, a Clinical pharmacologist, a hospital Pharmacist, a Primary Care Pharmacist, an expert in Clinical Epidemiology, A representative of the Aragon Institute of Health Sciences, a law graduate, a representative of the Consumer Organisations registered in the Register of Consumers Associations of Aragon, outside the health profession, a Bachelor of Biomedical Sciences hired by the IACS, who acts as Secretary of the Committee, as well as experts "ad hoc" when necessary. They are elected at the proposal of the CEICA and appointed by the Minister of Health.
Procedure for ethics assessment:	Standard operating procedures of CEICA:

before	~ presentation of biomedical research projects ~ presentation of clinical trials with drugs and health products ~ presentation of post- authorization observational studies with drugs SOPs include assessing the implications for individual and civil rights, distributive justice, health and safety, quality of life. As for dual use or outsourcing of research procedures there are not assessment procedures.
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	CEICA, as other RECs, does not participate in the evaluation of the results; the results are not contrasted with the objectives of the protocol.
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [ ] social responsibility [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: The evaluation framework is based on the principles outlined in the Declaration of Helsinki, the principialist theory, human rights, the common good, as well as the laws and regulations in Spain (Law on Biomedical Research, Law on Data Protection, Law on patient autonomy, specific rules of clinical drug trials) and the guidance of Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH). The most important aspects evaluated are those related to the autonomy of participants; they pay special attention to information sheets and consent presented to potential participants.
Self-assessments, strengths and weaknesses	The CEICA has a Quality Committee responsible for making decisions on quality and the overall supervision of the implemented Quality management system. Within its quality plan the satisfaction of the Committee's users (developers and researchers) is evaluated annually. The Committee also participates in the review of the program of Good Scientific Practice Guide. The CEICA's assessments on research projects are binding if they are negative and they have not detected cases where their opinion has not been followed, but there is no monitoring due to a lack of resources.
Other	Interviewee considers that training is important, it would be necessary an important work of training aimed at changing attitudes.

Name of organisation	Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country (Comité Ético de Investigación Clínica de la Comunidad Autónoma del País Vasco, CEIC-E).
Type of organisation	Research Ethics Committee (Regional)
Country	Spain
Website address	*General:* http://www.osakidetza.euskadi.eus/r85-pkfarm03/es/contenidos/informacion/ceic_ensayos_clinicos/es_ceic/ensayos_clinicos.html *Main page(s) on ethics assessment:* ~ Quality Management (Gestión de Calidad)

	http://www.osakidetza.euskadi.eus/r85-pkfarm03/es/contenidos/informacion/ceic_calidad/es_ceic/calidad.html. ~ Evaluation of clinical trials http://www.osakidetza.euskadi.eus/r85-pkfarm03/es/contenidos/informacion/ceic_ensayos_clinicos/es_ceic/ensayos_clinicos.html ~ Acting as an external ethics committee for approved Biobank in Euskadi http://www.osakidetza.euskadi.eus/r85-pkfarm03/es/contenidos/informacion/ceic_biobancos/es_ceic/biobancos.html
Basic description (organisation and mission)	The Ethics Committee for Clinical Research of Euskadi (CEIC-E) does the ethical evaluation of all proposals for research projects carried out in the Basque Country (Euskadi) on human beings, their data and samples. This includes clinical drug trials, prospective observational studies with drugs and health products to take place both in Osakidetza (Basque Health Service) centres and in private centres. The CEIC-E also serves as external ethics committee of the biobanks authorized in Euskadi. As such, it performs the function of advice to biobanks and approves or denies, if appropriate, the samples requests received in biobanks. It has also evaluated the neonatal screening programs.
Interest in research and innovation	
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	Ethical evaluation/assessment
Name and description of ethics unit(s)	-
Aims and motivation for ethics assessment	Ethical assessment of biomedical research is required by law (Law 14/2007 on biomedical research).
Objects and scope of assessment	See description Fields primarily covered by the evaluation is the field of biomedical and clinical research, but also research into behavioural sciences (psychology) carried out in health centres.
Beneficiaries of assessment	Mainly research promoters, either from public or private institutions. The CEIC-E also makes reports for management of the centres where research is conducted and performs the tutelage of local ethics committees of the three Basque provinces. Also the participants of the research who can ask their doubts and are contacted when the monitoring of projects is being done.
Ethics assessment unit: appointment process	The CEIC-E is made according to the Spanish legislation (RD 223/2004 of clinical trials and the Law 14/2007 on biomedical research). The CEIC-E is attached and is accredited by the Department of Pharmacy the Basque Government. Generally, local ethics committees propose new members who are appointed by the Deputy minister of Health of the Basque Government. Given the voluntary and altruistic character of the members, for the election of members it must be considered their ethics training or commitment to acquire it as well as their experience and knowledge of research methodology. To renew the accreditation of the Committee, it shall justify continuing education courses conducted by the Committee members. According to PNT established by the quality standards the CEIC-E organizes four courses per year.
Procedure for ethics	The Committee's ethics evaluation is performed prior to the start of the research project.

assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	To monitor studies there is an administrative follow-up and in situ monitoring randomly reviewing logs, medical records... In clinical trials inspectors perform trial monitoring and control visits.
Principles and issues in assessment / guidance	[ ] scientific integrity [x] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [ ] social responsibility [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: There is no consensual document on good scientific practices. In relation to professional integrity, it only has procedures for assessing the professional qualifications and not of professional integrity. With regard to research with children there are no specific procedures. In the general evaluation procedure in addition to the principles and guarantees laid down in the Oviedo Convention and its additional protocols and LIB, valuation is required by a paediatrician or neurologist in the case of projects whose participants are adults with difficulty to consent. Regarding the assessment of social or environmental impact, use of animals in research the CEIC-E requests the reports required by law (the Committee of animal welfare, safety of workers handling biological materials, biosecurity...). The assessment of the implications for individual and civil rights and distributive justice are included in the standard procedures of ethical review in accordance with the principles mentioned in paragraph f). As for dual use or outsourcing of research there are no known evaluation procedures.
Self-assessments, strengths and weaknesses	The Quality Commission is responsible for carrying out impact assessment. In order to standardize the processes carried out by the secretariat of CEIC-E, this Commission stablished a system of quality management based on a process approach for the CEIC-E based on ISO 9001: 2008. The number of reported incidents is very low, however the Committee believes that there is room for improvement. In general methodological evaluation of projects is exhaustive. Ethical deliberation mainly discusses the principle of autonomy, the information given to the patient and informed consent document. However, there is a clear idea that the Committee evaluates more in terms of compliance with existing regulations. Ethical deliberation can be improved. According to the law, REC's reports are binding. The recommendations issued by the CEIC-E are observed at 100%. A monitoring committee reviews the Committee's decisions and the compliance with them in the projects undertaken in the Basque Health Service. The main difficulties arise from the lack of resources and lack of time for reports. They have few resources to ensure attendance of all evaluators (volunteers) to the Committee's meetings or the delivery of reports in time. This leads to the fact that sometimes a quorum for decision is not reached.
Other	The Committee participates in courses, workshops on ELSI, best practices in health centres. In addition to the development of guidelines and recommendations.

Name of organisation	National Association of Research Ethics Committees (Asociación Nacional de Comités de Ética de la investigación – ANCEI)
Type of organisation	REC association
Country	Spain
Website address	*General:* www.ancei.es *Main page(s) on ethics assessment:*
Basic description (organisation and mission)	The purposes ANCEI pursues include: promoting basic and further training of those who will form part of the REC or part of the REC, and be the meeting place for ANCEI's members and other associations formed for similar purposes, both nationally and internationally. The National Association of Committees for Research Ethics has among its objectives: organising training activities and conferences open to the scientific community, to enhance the knowledge of the activities of the RECs; establishing partnerships, both national and international, with other associations of such committees and bioethics societies or associations with common goals; promoting studies, projects and publications related to the activities of the RECs, and their dissemination; helping improve the information and training on biomedical research and ethical safeguards that must exist for studies in humans; any other activity, in various formats and media, to disseminate the responsibility and duties of these committees. The National Association of Research Ethics Committees does not have among its purposes to conduct ethical review of research. Its aims are directed to promote basic and further training of people to be part or part of the RECs, as evaluators of biomedical research.
Interest in research and innovation	
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [x] Commentary: The association does not perform ethical evaluation. It contributes to the training of members of ethics committees that evaluate research projects involving human subjects, their samples or data. If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] 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	N/A
Beneficiaries of assessment	N/A
Ethics assessment unit: appointment process	N/A
Procedure for ethics assessment:	N/A

before	
Procedure for ethics assessment: during	N/A
Procedure for ethics assessment: after	N/A
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [ ] human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary:
Self-assessments, strengths and weaknesses	One weakness is that the ethical evaluation is not recognized as important as the methodological evaluation. It is not understood that are different levels of evaluation. Methodologically proper research could present problems in the ethical evaluation. The Association is working on training through working groups, conducting sessions, preparing and publishing on the web documents of interest. It is necessary to increase the number of associates and increase the participation of existing ones, and access and make connections with RECs from universities conducting ethical review in other disciplines (social sciences, humanities, engineering...). New technologies are creating new challenges (neuroscience, big data, use of social networks...) and it is necessary to be aware of the risks that they may generate, debate them, agree on procedures and training assessors on these issues.
Other	The association has relations with all RECs in the country, as well as the Spanish Coordinator Centre of RECs and the Spanish Agency for Medicines and Health Products in relation to assessment and monitoring of the clinical trials with medicines and clinical research with medical devices. Also with research funding agencies, both public and private, biobanks and, in general, state or regional public authorities. With those organisations, institutions or associations requesting advice on ethics in clinical, epidemiological and public health research, or for the development of studies with biological samples or medical records containing personal health information.

Name of organisation	National Distance Education University (Universidad Nacional de Educación a Distancia. UNED)
Type of organisation	University
Country	Spain
Website address	*General:* http://portal.uned.es/portal/page?_pageid=93,1&_dad=portal&_schema=PORTAL *Main page(s) on ethics assessment:* http://portal.uned.es/portal/page?_pageid=93,559463,93_20546176&_dad=portal&_schema=PORTAL
Basic description (organisation and mission)	The National Distance Education University (UNED) has as its mission the public service of higher education through the modality of distance education. Facts and data about UNED: • At more than 205,000 students, UNED has the largest student population in Spain and is one of the largest universities in Europe.

	• Since 1972, UNED has sought to translate into action the principle of equal opportunity in access to higher education through a methodology based on the principles of distance learning and focused on the needs of the student. • UNED is the leader in the implementation of cutting edge technologies applied to learning, with the largest offer of virtual courses in Spain.
Interest in research and innovation	Research is for the UNED a priority. From the beginning, the University has had professors and researchers from prestigious and relevant trajectories.
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	The UNED has a Bioethics Committee whose role is to assess and issue a report on: • research projects involving human beings, utilization of personal data, biological samples of human origin, animal experimentation, biological agents or using genetically modified organisms, environment when there are implications for health. • The suitability, in accordance with ethical standards, of the results of the work that is sent to impact journals for publication. • the student papers (dissertations, end of masters papers).
Aims and motivation for ethics assessment	
Objects and scope of assessment	See above. The Committee usually receives consultations on procedures for requesting reports, modifications to projects that are underway ... They receive inquiries from researchers or directors of the papers that are evaluated.
Beneficiaries of assessment	researchers of the University Colleges: psychology, Sociology, Political Sciences, Law, Life Sciences
Ethics assessment unit: appointment process	The Committee is a collegial body attached to the Office of Research, consists of members from all faculties, persons responsible for the animal facility of the University, representative of the administrative staff and the Research Results Transfer Office (OTRI). Its members are elected at the proposal of the dean of the faculty.
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	When problems arise in the ethical assessment the Committee transmits to the researcher the recommendations needed to address them and guides on solutions to the problems the project raises.
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[x] scientific integrity [x] professional integrity [x] human subjects research [x] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [x] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing

	[x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [x] social responsibility countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: The framework of values and ethical principles for research involving human beings is what is contained in the Oviedo Convention. Animal research must be faced trying to minimize the damage and suffering inflicted on animals, and produce these damages only when there is a proportioned cause, where the rule of the three Rs (3 R) is derived. Revise and approve procedures for research or teaching practice involving the use of biological agents (AB) and genetically modified organisms (GMOs), toxic and radioactive agents and conducted under the rules of good laboratory practice and biosafety. There are policies that are being put up on the implementation of the scientific integrity of researchers in which issues of professional integrity are included. The UNED has an occupational health service and assessment of environmental impact and these issues are also evaluated in the ethical assessment, especially when there is involvement of human rights.
Self-assessments, strengths and weaknesses	According to the Spanish legislation favourable report from the REC is required for the completion of any project to be done with humans, their samples or data and reports from the REC are binding. The report is requested because it is required by the norm or by the publishers of scientific journals. The university also requires the report of the REC for end of master papers. In all cases they are binding. There is no direct monitoring of compliance with the recommendations, except through the evaluation of publications. The main reason for not performing a closer monitoring is the lack of resources at Committee. Although it is not quantified the Committee appreciates that its work has contributed to an improvement in the presentation of projects and to instil in researchers a 'culture' of ethical evaluation. The assessment of the impact of ethical evaluation and the recommendations made by the Committee regarding animal research, for example, are more easily measured and can be evaluated. However, in disciplines such as psychology it is more difficult to assess the risk-benefit, participant involvement in studies (e.g. assessing the number of exploratory sessions necessary to carry out the studies). There are also difficulties with studies conducted with children, in schools.... In these cases the Bioethics Committee has an important educational work to do with researchers to also convince them that the Committee is the most effective contributor to the researcher. One of the challenges is the lack of time the Committee has to do the assessment. The Report Requests arrive a few days before the closing of the calls and this can cause problems with projects that have unfavourable reports. The Committees should work for researchers to be active agents who are interested in the ethical evaluation. The ethical assessment is a force and Committees should contribute information to train on the importance of it.
Other	The UNED is considering expanding the scope of the activity of ethics assessment to the field of scientific integrity and good scientific practice. Possibly the Bioethics Committee will also address those functions.

Name of organisation	University of the Basque Country (Universidad del País Vasco/Euskal Herriko Unibertsitatea, UPV/EHU)
Type of organisation	University
Country	Spain

Website address	*General:* http://www.ehu.eus/es/ *Main page(s) on ethics assessment:* https://www.ehu.eus/es/web/ceid/presentacion https://www.euskadi.eus/r48-bopv2/es/bopv2/datos/2014/02/1400732a.shtml
Basic description (organisation and mission)	The University of the Basque Country (UPV / EHU) is composed of more than 50,000 people, is responsible for 70% of the research carried out in the Basque Country and has already generated a quarter of a million graduates in diverse areas of knowledge. It is distributed in three campus, one for each of the provinces of the Basque Autonomous Community - bringing together 32 faculties and schools.
Interest in research and innovation	See above
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	Committee on Ethics in Research and Teaching at the University of the Basque Country (Comisión de Ética en la Investigación y la Docencia de la Universidad del País Vasco, CEID). It is divided in three subcommittees: • Committee on Ethics in Research Involving Humans (Comité de ética en la investigación con seres humanos, CEISH); • Committee on Ethics in Animal Experimentation (Comité de Ética en la Experimentación Animal, CEEA); • Committee on Ethics in Research with Biological Agents and Genetically Modified Organisms (Comité de Ética en la Investigación con Agentes Biológicos y Organismos Genéticamente Modificados, CEIAB).
Aims and motivation for ethics assessment	The Committee uses a model based on five points of assessment: • Social and scientific value • Team training: only standardized for animal research, but some training is required also for humans and modified organism research. • Methodology • Ethical aspects, with different requirements for human research (informed consent, confidentiality, insurance, traceability…), animal research (replacement, reduction and refinement), biological agents and GMO (mainly biosecurity, prevention, precaution and information). Legislation and regulatory issues, including agreements and authorizations, especially in projects in the fields of education, sports or sociology; also for certain types of animal research.
Objects and scope of assessment	The Committee evaluates research projects and teaching practices that use human subjects, animals or biological agents and Genetically Modified Organisms (GMO). It has also received some questions about plagiarism and has acted as a mediator in conflicts, but this is not included in the competencies of the committee. There is a defender of the student that acts in case of conflict and can consult with the committee if necessary. The main fields covered are, by category: • In human research, biology, biomedicine, social sciences: Medicine, dentistry, nursing, physiotherapy; sports science, teaching, pedagogy, psychology, sociology, social work, criminology, law, engineering (telecommunications, replication of human voice, vulnerable groups, location bracelets), biology,

	biochemistry, genetics. • In animal research: biology, biomedicine, biochemistry • GMOs: biology, biomedicine, genetics. Many projects need the evaluation of all three committees.
Beneficiaries of assessment	Mainly researchers and teachers, also research groups related to the university and, in some cases, private universities (Deusto and Mondragón).
Ethics assessment unit: appointment process	The committee's members are Teaching and Research Staff and Administration and Services Staff. The election system has been recently changed and the committee's composition follows the relevant laws. The committee for human research includes teachers, jurists, experts in data protection, geneticists and other specialists. The committee for GMOs includes microbiologists, neuroscientist and other specialists. The secretary is common for all three committees. The renovation of members is made through an open call. From all candidates the committee selects three, with a recommendation, to the rector. There has never been a shortage of candidates.
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [x] human subjects research [x] treatment of animals in R&I [x] human dignity [x] equality / non-discrimination [x] autonomy / freedom [x] implications for civil rights [x] implications for privacy [x] social responsibility [x] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [x] environmental impacts [x] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [ ] other, specify: Commentary: There are no policies for fraud and research misconduct. During some time the Committee collaborated in the analysis, but it is not one of its functions. They have SOP to resolve conflicts of interests and they use the good practices code of the Institute of health Carlos III (ISCIII). The University made a theoretical statement on cooperation with the army, and research groups collaborate, but these issues do not go to the committee.
Self-assessments, strengths and weaknesses	The committee conducted an impact assessment four years ago, by doing a survey among the researchers that had been subject to ethical assessment. The evaluation was positive, although bureaucratic problems were noted, as well as the time the assessment takes. There is not enough monitoring, due to the lack of resources. They have made three models to do the monitoring, but it has been impossible to do it.
Other	In human and animal research the committee's recommendations are binding: if the law does not make them so, the university regulation does; the university's insurance covers the research projects only if they have been assessed by the committee. Around 70% of the research projects carried out in the university are evaluated by the committee, but there is no

	monitoring of compliance.

Name of organisation	**Central Ethical Review Board (CEPN)** (Centrala etikprövningsnämnden)
Type of organisation	Research ethics committee
Country	Sweden
Website address	General: www.epn.se
Basic description (organisation and mission)	The Central Ethical Review Board assesses research proposals that involves individual human beings, under the following conditions: (i) appeals of decisions taken in the RECs, (ii) cases where a REC is not in agreement about the outcome of an ethical vetting, and (iii) certain issues in connection with the inauguration of biobanks in accordance with the Biobanks in Medical Care Act (2002:297). The Central Ethical Review Board consists of four members with scientific qualifications and two members are laypersons. A chairman who is a judge heads the Board. The scientific members are recruited from relevant disciplines (medicine, psychology, sociology, etc.).
Interest in research and innovation	CEPN deals with ethics assessment based on the Swedish research ethics review system (Lagen (2003:460) om etikprövning av forskning som avser människor /The Ethical Review Act (2003:460))
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ]
Terminology for ethics assessment / guidance	----
Name and description of ethics unit(s)	----
Aims and motivation for ethics assessment	"One reason is that people who participate in research as the subjects of such research, or something similar, should be protected against the risk of physical injury, mental injury or the violation of their integrity. To the extent that certain research can involve risks for the subjects of the research, there should be an investigation that includes, among other things, a weighing-up of the risks involved against the knowledge gained. High standards should be insisted upon with respect to the quality of the research and to ensure that the subjects involved have understood and accepted the conditions that apply to their participation. It is also legitimate for the general public to be given both insight into and influence upon the ethical vetting of research, since it is of general interest that human dignity should be protected and human integrity should be safeguarded. Regulation that is enforced by law and guarantees the participation of representatives of the general public in the process of ethical vetting should, in the long term, increase the confidence of the general public in research." http://www.epn.se/en/start/background-and-regulations/
Objects and scope of assessment	The Central Ethical Review Board is having the following goals: - Supervision of the law that regulates the Swedish research ethics review system (Lagen (2003:460) om etikprövning av forskning som avser människor /The Ethical Review Act (2003:460)), except for the supervision provided by the Medicinal Products Agency and the National Board of Health and Welfare and the Swedish Data Inspection Board. The Ethical Review Act (2003:460) regulates

	research that involves individual human beings. - Assessing appeals of decisions taken in the regional boards (RECs). - Assessing cases where a REC is not in agreement about the outcome of an ethical vetting.
Beneficiaries of assessment	Researchers, the public, individual human research subjects
Ethics assessment unit: appointment process	The Swedish National Research Council (Vetenskapsrådet) suggests candidates for the board. The Central Ethical Review Board is consists of four members with scientific qualifications and two members are laypersons. A chairman who is a judge heads the Board. The scientific members are recruited from relevant disciplines (medicine, psychology, sociology, etc.).
Procedure for ethics assessment: before	The cases are prepared and pre-assessed before the meeting. The scientific members are assigned one or two applications each, which they will assess more carefully and report on to the board.
Procedure for ethics assessment: during	The cases are presented to the board. After the presentation the board discusses the ethical aspects that may exist. When there is a need for interpretation of the Act to assess the case, the interpretations of the legally trained members of the board will often get more weight due to their expertise. The evaluative nature of the ethical principles stated in the Act opens up for a number of interpretations in relation to the case being assessed.
Procedure for ethics assessment: after	The secretary will write a statement and inform the researcher about the decision.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [ ] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [x] implications for privacy [ ] social responsibility [x] other, specify (confidentiality) [ ] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) Comment: The Ethical Review Act provides a framework of ethical principles for vetting research. The Act states that research must be conducted with respect for human dignity. This is the most important ethical principle stated in the law. The Act also states other ethical principles such as the principle of non-maleficence, the principle of confidentiality, and the principle of autonomy. The Personal Data Act provides principles concerning confidentiality and privacy and specifies what kind of research that should be vetted according to the law.
Self-assessments, strengths and weaknesses	There is no self-evaluation practice and procedure in CEPN. The interviewed representative believes the Swedish ethics assessment system to be functional. The weak point is that the system is constructed with the ethical vetting of medical research in mind. Especially the application form could be improved to better fit non-medical research.
Other	CEPN has also the task of investigation misconduct in research. This task is separated from the ethical vetting of research conducted by CEPN. The investigation is conducted by the Expert group for misconduct in research at the Central Ethical Review Board. “The expert group shall, at the request of a university or other Higher Education Institute that has the State as principle (…) issue a statement on cases concerning investigation of suspected misconduct in research, artistic research and developing work”.

	http://www.epn.se/en/start/expert-group-for-misconduct-in-research-at-the-central-ethical-review-boardstar/

Name of organisation	**Linköping Regional Board of Vetting Research Involving Humans** (Regionala etikprövningsnämnden i Linköping)
Type of organisation	Reasearch ethics committee
Country	Sweden
Website address	General: www.epn.se
Basic description (organisation and mission)	Linköping Regional Board for Vetting Research Involving Humans is one of six regional boards in Sweden with responsibility to assess research in their regions. There is also a central (national) board mandated to assess appeals of decisions taken in the regional boards. The regional boards assess research projects of two kinds: (i) Projects which according to the act is required, and (ii) when the researcher wants an ethical advice from the regional board, due to requirement for publication, need of ethical advice etc. The regional boards are divided in sections for vetting of medical research and sections for vetting of non-medical research involving humans. The interviewees providing information for this summary are representatives from the latter section, which vets research projects within mainly behavioral sciences, for example, psychology, sociology, and, social work. The board has the power to assess research and make recommendations, but also to constrain or to prohibit certain projects or research activities. The ethics assessment is carried out before the research takes place.
Interest in research and innovation	Linköping Regional Board of Vetting Research Involving Humans deals with ethics assessment based on the Swedish research ethics review system (Lagen (2003:460) om etikprövning av forskning som avser människor /The Ethical Review Act (2003:460))
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: Develops guidelines for research ethics. If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	----
Name and description of ethics unit(s)	----
Aims and motivation for ethics assessment	"One reason is that people who participate in research as the subjects of such research, or something similar, should be protected against the risk of physical injury, mental injury or the violation of their integrity. To the extent that certain research can involve risks for the subjects of the research, there should be an investigation that includes, among other things, a weighing-up of the risks involved against the knowledge gained. High standards should be insisted upon with respect to the quality of the research and to ensure that the subjects involved have understood and accepted the conditions that apply to their participation. It is also legitimate for the general public to be given both insight into and influence upon the ethical vetting of research, since it is of general interest that human dignity should be protected and human integrity should be safeguarded. Regulation that is enforced by law and guarantees the participation of representatives of the general public in the process of ethical vetting should, in the long term, increase the confidence of the general public in research."

	http://www.epn.se/en/start/background-and-regulations/
Objects and scope of assessment	The board assesses research projects before the research is taking place. People who participate in research as the subject of research should be protected against the risk of physical or mental injury, or the violation of their integrity. Research that involves a risk for the subjects of the research is required by law to be submitted to ethical vetting. e.g. if there is a weighing-up of the risks involved against the knowledge gained.
Beneficiaries of assessment	Researchers, the public, individual human research subjects
Ethics assessment unit: appointment process	The board is headed by a chairman (a judge). The board has ten members with scientific qualifications and five representing the general public. One of the scientific members is also scientific secretary appointed by the chairman. All members have personal substitutes. The scientific members are mainly recruited from the relevant disciplines, medicine for the medical and psychology etc. for the other section. The members representing the general public are mainly politicians.
Procedure for ethics assessment: before	Project applications are submitted to the Regional Board by the researcher responsible for a research project. The applications are then sent out to the members of the board around two weeks before the board meeting. The cases are prepared and pre-assessed before the meeting. The scientific members are assigned one or two applications each, which they will assess more carefully and report on to the board.
Procedure for ethics assessment: during	At the meeting, all members are expected to have read all applications. The appointed scientific representative gives his or her report and suggests a decision. After the report the board discusses the ethical aspects that may exist. The discussion is followed by decision: to approve, to demand completions or to reject a proposal.
Procedure for ethics assessment: after	The scientific secretary will write a statement informing the researcher about the decision.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] professional integrity [x] human subjects research [ ] treatment of animals in R&I [x] human dignity [ ] equality / non-discrimination [x] autonomy / freedom [ ] implications for civil rights [x] implications for privacy [ ] social responsibility [x] other, specify (confidentiality) [ ] justice / fairness [x] implications for health and/or safety [x] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) Comment: The Ethical Review Act provides a framework of ethical principles for vetting research. The Act states that research must be conducted with respect for human dignity. This is the most important ethical principle stated in the law. The Act also states other ethical principles such as the principle of non-maleficence, the principle of confidentiality, and the principle of autonomy. The Personal Data Act provides principles concerning confidentiality and privacy and specifies what kind of research that should be vetted according to the law.
Self-assessments, strengths and weaknesses	There is no self-evaluation practice and procedure. Identified strengths and weaknesses by interviewees: The ethics assessment system is perceived to be functional but with room for improvement: Many researchers within the humanities and social science are not aware of the fact that some of their research must be vetted. Information to researchers about the work of the vetting board's as well as the need of ethical vetting is wanting. One of the interviewees says that monitoring is wanting; at least it should be done occasionally for the

	board to know if the ethical vetting fulfills its purpose.
Other	The regional boards do not deal with issues related to scientific integrity. There is a separate expert group for misconduct in research appointed at the Central Ethical Review Board. The expert group consists of four members with academic expertise in different fields of research and one chairperson who is a judge. One of the members must be an ethics expert. All members of the expert group have personal substitutes. The members and their personal substitutes are appointed by the Government. The expert group does not monitoring compliance, but at the request of a university or another Higher Education Institute (HEI), covered by the Higher Education Act (1992:1434), they shall make statements on cases concerning investigations of suspected misconduct in research, artistic research and development work (SFS 2013:507). The expert group for misconduct in research is a member of the European Network of Research Integrity Offices, ENRIO. http://www.epn.se/en/start/expert-group-for-misconduct-in-research-at-the-central-ethical-review-boardstar/

Name of organisation	**Association for Research Ethics (AfRE)**
Type of organisation	National association promoting research ethics in human subjects research and representing university research ethics committees *Their main focus is on promoting research ethics.*
Country	United Kingdom
Website address	*General:* http://www.arec.org.uk/index.asp?pageid=525597
Basic description (organisation and mission)	AfRE has the following mission: • The Association for Research Ethics seeks to promote excellence in ethical research in human beings. • The protection and maintenance of the health and safety of the community by promoting proper standards of research involving human participants by fostering high standards of ethical review. • To provide information, support and training to its membership, to establish national, European and regional networks for the discussion of topics of mutual interests and to encourage co-operation amongst its membership to enable the collection and collation of information and opinions from them. • To work in partnership with external agencies in order to better promote sound ethical standards The association has been transformed over the last six or seven years. Universities began to join around 2007 – they are now the only organisations represented by the association, so it's more of a university representative body for RECs. The role of AfRE – as it is now – is to promote research ethics as a subject in its own right rather than just as a representative organisation for the committees – this is why they changed their name from the Association for Research Ethics Committees (AREC). In the last year, AfRE has cooperated with the Health Research Authority in providing workshops – about 12 in the year for students, supervisors and representatives of sponsors (the institutions that are legally responsible for the conduct of the research and those that have to approve protocols). AfRE continues to provide training – there will be a series of workshops held this year, based on the requirements of universities. AfRE is informally recognised by the research councils, Universities UK and the UK Research Integrity Office (UKRIO) and they work in cooperation with the latter.
Interest in research and innovation	Focus on human subjects research

Ethics assessment and/or guidance	Assessment [ ] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary: Please see "Principles and issues in guidance"
Terminology	Please see previous box.
Name and description of ethics unit(s)	N/A
Aims and motivation for ethics guidance	Please see "Basic description"
Objects and scope of guidance	Please see "Basic description"
Beneficiaries of guidance	Research ethics committees in universities
Ethics assessment unit: appointment process	N/A
Procedure for ethics assessment: before	N/A
Procedure for ethics assessment: during	N/A
Procedure for ethics assessment: after	N/A
Principles and issues in guidance	[ ] scientific integrity [ ] professional integrity [ ] human subjects research [ ] treatment of animals in R&I [ ] human dignity [ ] equality / non-discrimination [ ] autonomy / freedom [ ] implications for civil rights [ ] implications for privacy [ ] social responsibility [ ] justice / fairness [ ] implications for health and/or safety [ ] implications for quality of life [ ] environmental impacts [ ] social impacts [ ] outsourcing of R&I to developing countries with lower ethics standards [ ] dual use (possible military uses) [x] other, specify: social media and informed consent Commentary: AfRE has produced a document called "A Framework for Policies and Procedures" for university RECs. The framework is a suggested model for research ethics which they offer to universities. The framework starts with basic principles and then works through how these basic principles might be put into practice. The set of guidelines covers different discipline areas from clinical research to social sciences and the humanities. The general principles advanced in the document come under the headings of 'independence' (an ethics committee must be independent of its institution, so that its judgements can only be questioned by another ethics committee), 'competence' (the members of the committee must be trained and competent to make these judgements), 'facilitation' (their role is not to create hurdles for research but rather to find a way forward for the research) and openness. The most important ethical issues in R&I in ethics guidance provided by the organisation:

	Currently, the most difficult issue is social media and the extent to which what one picks up in social media can be used in research without obtaining the consent of the participant. Those who are using social media may not be aware that researchers may use it for research purposes. This presents an ethical dilemma, i.e. how do you consult with the person when often there is no means of getting in contact with people to ask them. AfRE held a very popular workshop on this topic last year and will repeat it as there is such a demand for it.
Self-assessments, strengths and weaknesses	While AfRE does not carry out auditing or compliance checks regarding their framework, if a university wants external auditing of their research ethics arrangement, AfRE can provide that based on their framework. AfRE is planning a meeting in 2015 to which they will invite principal stakeholders to learn about how the framework is being received and whether any amendments need to be made to the framework. They know that quite a few universities have used it. It offers a self-assessment tool which a number of universities are trying out against their own practices and policies. Universities have reported that the document is very useful.
Other	