Ethics Assessment and Guidance at the Global Level

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June 2015

Annex 5.b
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

Deliverable 1.1

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

CONTENTS

1 INTRODUCTION

The aim of this report is to analyse the existing structures and agents for the ethical assessment and guidance of research and innovation at the global international level. This chapter offers an analysis of the ways in which organisational structures, laws, policies and procedures for ethical assessment and guidance have been put in place at the global level; the ways in which both publicly funded and private research and innovation systems address ethical issues in research and innovation; and the role of ethical assessment in the activities of professional groups and associations for research and innovation.

Ethics assessment of research and innovation on the global level is a complex nexus ranging from private and public research funding and performing organizations to civil and non-profit societies and associations all overseen by local, regional, national and international governmental laws, policies, and recommendations. Research and innovation is assessed differently according to the type of research that takes place. For example, certain areas such as biomedical and human subjects' research areas have much stricter global oversight and assessment capacities than others which rely on more *laissez-faire* approaches, such as evaluating scientific misconduct or the use of animals of research, both of which the oversight and assessment capacities vary greatly depending upon the region and context.

Modern global ethics assessment practices trace their origin to the post-World War II era.[1] The creation of the Nuremberg Code, which aimed to provide the basic tenets of ethical human subject research at the conclusion of World War II in response to the atrocities of Nazi human experimentation, signalled the rise of international attention to the consideration of ethical research conduct, especially those related to human subjects' research.[2] This code would later be augmented by the Declaration of Helsinki in 1964, guided by the World Medical Association, an international and independent confederation of free professional Medical Associations, also borne in the post-World War II climate.[3] It was in the same environment that the World Health Organisation (1948) and United Nations Educational, Scientific and Cultural Organisation (1945) were created. These two organisations would jointly establish the Council for International Organisations of Medical Sciences (CIOMS) in 1949, whose 1993 *International Ethical Guidelines for Biomedical Research Involving Human Subjects* serves as an elaboration and guiding text cited by institutions from regional to international levels.[4]

The creation of international and inter-governmental agencies provides the framework in which international efforts addressing ethics assessment takes place. The increased presence of global ethics assessment bodies, discussions, and standards have facilitated increasing harmonization and debates over proper and viable ethics assessment practices. For example, the Declaration of Helsinki has provided a benchmark for the creation of regional policies. Similarly, UNESCO's Assisting Bioethics Committee programme creates a model of bioethics committees across different countries with differing social climates grounded in similar ethical principles. More recently, global discussions and actions within ethics

[1] Plomer, Aurora, *The law and ethics of medical research: international bioethics and human rights*, Routledge, 2013.
[2] Annas, George J., and Michael A. Grodin, "The Nazi doctors and the Nuremberg code," *J. Pharmacy & Law*, 4 1995, pp. 167-245.
[3] http://www.wma.net
[4] These are but a few of many international efforts, which are considered in greater detail below, which helped establish the current global level ethics assessment environment.

assessment align with the rise of multinational corporations and actors, necessitating even greater global reflection. That is to say, the discussions and actions of global bodies are a part of the globalization process and the scope of their activities must be self-reflective as well, and not simply commenting on practices of regional actors. For example, the increased cooperation between governments facilitating research within and beyond its borders has hastened the pace of research activity, raising the questions about research and innovation as an enterprise. Consequently, the oversight of ethics assessment of these practices is a source of lively debate by participants, local actors, academic centres, governments, and inter-governmental organisations.

2 GLOBAL GOVERNMENTAL INSTITUTIONS AND POLICIES

2.1.1 GLOBAL GOVERNMENTAL INSTITUTIONS AND POLICIES FOR ETHICS ASSESSMENT

This section highlights the kinds of global governmental institutions which engage in ethics assessment and the methods by which they do so.

Global governmental and government-funded controlled organs and institutions help provide the conditions for ethics assessments and ethics reviews to take place. To create these conditions, global governmental institutions' activities range from the establishment of internationally recognized standards, codes, declarations, and other soft-law instruments; capacity-building for regional ethics assessment; providing forums for international collaboration and reflection; or serving in an advisory capacity to governments. Ethics assessment in the form of ethics review, such as done by an ethics review committee, takes place more limitedly on the global level and generally only when the governmental organisation is providing funding for research or performs research as a part of its functions, such as with the World Health Organization (WHO). In these cases, the organisation may also engage in ethics review of research project proposals.[5] The ethics review may either be done in-house by members of an internal committee or assessed by an external reviewer.

The creation process of internationally recognized soft-law and legal provisions addressing ethics assessment takes various forms. Most notably, they can be created by member states of inter-governmental organisations or by multi-stakeholder forums created for the reflection of such issues, which are often connected to each other. The most prominent role of such organisations is to first create a global platform on which discussion of current and relevant bioethics principles can take place, engaging all parties with vested interest. This leads to the production of international benchmark documents such as the *Universal Declaration on Bioethics and Human Rights*[6]. The adoption of the Declaration by UNESCO Member States intends to provides ethical guidance to States,

> 1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
>
> 2. This Declaration is addressed to States. As appropriate and relevant, it also provides

[5] Interview with Najeeb al-Shorbaji, Director of Knowledge, Ethics and Research at World Health Organization, 5 February 2015
[6] http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.[7]

The Declaration also charges UNESCO "to promote and disseminate the principles set out in this Declaration."[8] To that end, UNESCO houses three consultative organs: the International Bioethics Committee (IBC)[9], the Intergovernmental Bioethics Committee (IGBC)[10], and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)[11]. UNESCO also acts as the Secretariat of the United Nations Inter-Agency Committee on Bioethics. In addition, ethics assessment is facilitated by UNESCO actions in institutional capacity building, such as its activities in helping establish national bioethics committees and training committee members in the field[12]. An example of this is the UNESCO Global Ethics OBservatory (GEObs) which is involved in worldwide coverage of bioethics issues and other applied ethics in science and technology. By providing freely accessible information online, the initiative acts as a "crucial platform for supporting and advancing ethics activities by assisting Member States and other interested parties to identify experts, establish ethics committees, construct informed policies in the area of ethics, and design ethics teaching curricula."[13]It furthers ethics assessment capacities by providing Ethics Teacher Training Courses and the development of a Core Curriculum on Bioethics.[14]

The World Health Organization (WHO)[15] engages in ethics assessment in various capacities. It helps set standards and norms, oversees the ethical review of research being conducted, and capacity building. Notably, it also has a process for ethics committee accreditation. According to its literature, the WHO Secretariat states "Research Ethics in WHO is overseen by the WHO Research Ethics Review Committee known as the WHO ERC and its Secretariat, housed within the RPC Department. The ERC secretariat manages the committee, provides initial review of research projects, facilitates ethics review, and liaises with technical units."[16]

According to the WHO, "The ERC secretariat also supports capacity strengthening, through the ethics review process, and through the development of checklists, templates and other guidance documents that support research proposal development. Capacity building workshops are also organized at regional, country and HQ level. In addition, a Casebook on Ethical Issues in International Health Research soon to be published by the Secretariat is a compilation of more than 50 case studies relating to research ethics, which can be used as a resource by professionals interested in running workshops or courses in research ethics."[17]

[7] http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
[8] Ibid.
[9] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/
[10] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/intergovernmental-bioethics-committee/
[11] http://www.unesco.org/new/en/social-and-human-sciences/themes/comest/
[12] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/assisting-bioethics-committees/
[13] http://www.unesco.org/new/en/social-and-human-sciences/themes/global-ethics-observatory/about-the-geobs/
[14] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/ethics-education-programme/
[15] http://www.who.int
[16] http://www.who.int/rpc/research_ethics/en/
[17] Ibid.

Both literature and interviewees indicated respect, beneficence, and justice as principles of concern to the WHO ERC. Additionally, they cite the Declaration of Helsinki and CIOMS Guidelines and guiding documents.[18]

The Organisation for Economic Co-operation and Development (OECD)[19] sets international standards that align with its objectives of enhancing global productivity and growth[20]. OECD recommendations address the economic implications of R&I on populations and seek to maintain the well-being of citizens in this regard. These recommendations are aimed at both governmental institutions and the private sector. Relevant instruments include the following:

- C(2010)16 Recommendation of the Council on Principles for Transparency and Integrity in Lobbying
- C(2008)105 Recommendation of the Council on Enhancing Integrity in Public Procurement
- C(2003)107 Recommendation of the Council on OECD Guidelines for Managing Conflict of Interest in the Public Service
- C(1998)70 Recommendation of the Council on Improving Ethical Conduct in the Public Service Including Principles for Managing Ethics in the Public Service.

These recommendations are outlined in further detail in section 3 of the literature review.

The Council of Europe, Bioethics committee (DH-BIO)[21], is an intergovernmental body which is made up of delegations of the 47 Members States with expertise in various aspects of bioethics. By scope, it evaluates the ethical and legal issues of developments in the biomedical field. More recently, in regards to emerging technologies their mandate specifies that in 2014 the DH-BIO is in charge of studying the scientific and ethical implications of emerging technologies and their convergence, discussed at a conference and in 2015 priority challenges for human rights must be brought forward on this topic and examined for the development of a white paper.

The Council for International Organisations of Medical Sciences (CIOMS)[22] through its membership represents a substantial proportion of the biomedical scientific community. In 2013, the membership of CIOMS included 49 international, national and associate member organisations, representing many of the biomedical disciplines, national academies of sciences and medical research councils. As the current head said in an interview for SATORI, "CIOMS is a body of bodies" which sets the agenda for the organisation. [23] The main objectives of CIOMS are:

1. To facilitate and promote international activities in the field of biomedical sciences, especially when the participation of several international associations and national institutions is deemed necessary;
2. To maintain collaborative relations with the United Nations and its specialized agencies, in particular with WHO and UNESCO; and

[18] Interview with Najeeb al-Shorbaji, Director of Knowledge, Ethics and Research at World Health Organization, 5 February 2015.
[19] http://www.oecd.org/
[20] Adapted from Deliverable 3.3 and Deliverable 1.1 Chapter 7
[21] http://www.coe.int/t/dg3/healthbioethic/cdbi/default_en.asp
[22] http://www.cioms.ch/
[23] Interview with Johannes JM van Delden, President, CIOMS, February 2015.

3. To serve the scientific interests of the international biomedical community in general.

To achieve its objectives, CIOMS has initiated and coordinates the following main long-term programmes:" To do so, it carries out programs in Bioethics, Health Policy, Ethics and Human Values - An International Dialogue, Drug Development and Use, International Nomenclature of Diseases. As previously discussed, it is most notable for the CIOMS guidelines which expand upon the principles found in the WMA Declaration of Helsinki. The Guidelines are currently under revision. The President indicated, "The CIOMS does not engage directly in ethics assessment itself. However, through its guidelines and publications, it provides a basis for ethical guidance and practices." He continues, "All the ethical issues from the list are included as issues of concern to the organisation. There is no particular focus on a single set of ethical issues. However, professional ethics and integrity are considered as ethical issues of special concern due to the orientation of CIOMS. There are some very controversial issues in research ethics, sharing of benefits, post-trial arrangements [regarding access to successful clinical trials pharmaceutics], area of informed consent – whether to have broad consent or explicit consent. Improving the climate for researchers is of equal importance - for instance ludicrous timeframes in which REC have to do reviews and in which there has to be one reporting nation, while other nations have to be fed into that and compiled."[24]

Alongside institutions, there has been an accompanying rise in collaborative efforts between ethics committees in different regions. The "Global Summit of National Ethics/Bioethics Committees" is a good example of such efforts. The summit states, "The Global Summit is a unique platform for the exchange of information about the on-going work of national ethics Advisory Boards or commissions, and thus represents an opportunity for open, quality dialogue. The aims of the Summit are:

- to encourage the inclusion of bioethics in the national agendas of the nations and organisations in attendance
- to strengthen the activities developed by the commissions, as well as the guides, recommendations and guidelines issued by different organisations
- to understand the impact of the national commissions on the societies of their respective countries
- to exchange strategies and information in order to consolidate National Bioethics Commissions
- to provide the opportunity for an open debate, focusing on specific issues such as the protection of human participants in health research, biobanking, end of life choices, public health and aging, among others. The quality of this discussion has been identified by participants as the most valuable outcome
- to contribute to updating information regarding the status and functions of national commissions."[25]

[24] Ibid
[25] http://bioethicsummit.mx/en/summit.html

2.1.2 PUBLIC RESEARCH AND INNOVATION SYSTEMS

2.1.2.1 GLOBAL RESEARCH ASSOCIATIONS AND STANDARD-SETTING BODIES

In terms of associations and standard-setting bodies for research and innovation systems and ethics assessment strictly for the non-private organisations, there are few in existence on the international level. However, there are university associations, associations of science academics, and accreditation, certification, and standard-setting organisations whose activities directly affect public research and innovation systems and ethics assessment, even if the scope of their activities is not limited to public research and innovation. Below is a selection of these associations and bodies.

The International Association of Universities (IAU) brings together 630 academic institutions from around the world.[26] Established as an UNESCO-based organisation in 1950, it facilitates reflection and action on common concerns of its members.[27] The Magna Charter Observatory and the IAU have established the Joint IAU-MCO Working Group on Ethics in Higher Education. Members include experts, representatives of member institutions and organisations.[28]

The Magna Charta Universitatum,[29] was first drafted by rectors of European universities in 1988 and now signed by nearly 800 universities from around the world.[30] The document outlines, as the most universally accepted principles as:

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

The "IAU-MCO Guidelines for an Institutional Code of Ethics in Higher Education" refers to the following documents for the "universal core values that define higher education": the Constitution of the International Association of Universities, the IAU's Policy Statement Academic Freedom, University Autonomy and Social Responsibility, the Magna Charta Universitatum and UNESCO's Recommendation concerning the Status of Higher Education Teaching Personnel.[31]

In addition to referencing the above documents, the "Guidelines" state the following universal principles:

- academic integrity and ethical conduct of research;
- equity, justice and non-discrimination;
- accountability, transparency and independence;
- critical analysis and respect for reasoned opinions;
- responsibility for the stewardship of assets, resources and the environment;
- free and open dissemination of knowledge and information;

[26] Adapted from Deliverable 1 Universities chapter
[27] http://www.iau-aiu.net.
[28] http://www.iau-aiu.net/content/working-group-1.
[29] Magna Charta Universitatum. http://www.magna-charta.org/library/userfiles/file/mc_english.pdf.
[30] http://www.magna-charta.org/cms/cmspage.aspx?pageUid={8e9114fe-86db-4d26-b9d7-167c03d479aa}
[31] International Association of Universities and Magna Charta Observatory, *Guidelines for an Institutional Code of Ethics in Higher Education*, December 2012, p. 2.

- solidarity with and fair treatment of international partners.[32]

The International Council for Science (ICSU) is a non-governmental organisation with a global membership of national scientific bodies (121 Members, representing 141 countries) and International Scientific Unions (32 Members) whose mission is to strengthen international science for the benefit of society. ICSU was founded in 1931 "to promote international scientific activity in the different branches of science and its application for the benefit of humanity." ICSU seeks to: identify and address major issues of importance to science and society; facilitate interaction amongst scientists across all disciplines and from all countries; promote the participation of all scientists—regardless of race, citizenship, language, political stance, or gender—in the international scientific endeavour; provide independent, authoritative advice to stimulate constructive dialogue between the scientific community and governments, civil society, and the private sector.

While there are non-profit research systems, there are few purely government-funded global research and innovation systems. Current global activities in public research and innovation are exemplified by efforts such as the "Global Forum on Research and Innovation for Health 2015". The "Global Forum on Research and Innovation for Health 2015"[33] wants to find solutions for the world's unmet health needs by encouraging research and innovation by providing a platform where low- and middle-income countries can define the global research agenda together. This is a form of mobilization of stakeholders in in global research through the creation of a forum. These forums must take more steps to gain visibility as compared to broader-level structures in order to for their guidelines to be adopted by governments. To the author's knowledge there is no specification towards ethics assessment but this mobilization of stakeholders in developing countries helps reacting against an ethical issue, which is the one of justice in regards to research and innovation, even though this may not be expressed explicitly.

There are more specific global associations involved in research and innovation, such as the Association for Practical and Professional Ethics (APPE).[34] The APPE is an international organisation giving scholarships, encouraging education and, practice in practical and professional ethics. The APPE trains professionals to improve ethical conduct in the workplace and to encourage public dialogue in ethics and values.

Furthermore, there is the Global Research Alliance on Agricultural Greenhouse Gases, which brings countries together to find ways to grow more food without growing greenhouse gas emissions. The most important facet of such organisations is that they place concerns in both developing and developed countries on the same platform, in order to reach internationally acceptable policies which are still aligned with global environmental policy.[35]

Global research associations tend to be association rather than funding or research-conducting intuitions. For example, Community of Science (COS) is an international collaborative network of scientists and their institutions whose goal is to accelerate science and promote the visibility and funding of scientific research with a site containing searchable databases.

[32] *Ibid*.
[33] Global Forum on Research and Innovation for Health 2015. http://www.forum2015.org/index.php/about-us
[34] Association for Practical and Professional Ethics (APPE).) http://appe.indiana.edu/about/about-appe/
[35] Global Research Alliance on Agricultural Greenhouse Gases. http://www.globalresearchalliance.org/

International Research Ethics Education and Curriculum Development Program has provided grants for the development of training programs in international research ethics.[36]

The Society of Research Administrators International (SRA International) is a research management society providing education, professional development and the latest comprehensive information about research management to 4,500 members from over 40 countries. It claims to be the "only research management society in the world whose membership spans the entire spectrum of research institutions including: colleges and universities, research hospitals and institutes, government agencies, non-profit funders of research, and industry."[37]

The International Federation for Ethics Review (IFER) is an international non-governmental organisation, formed by a voluntary compact among countries, granting agencies, philanthropies, and healthcare, patient advocacy, and research organisations, that seeks to streamline and harmonise the ethics review process of specific types of research projects. [38]

The previous century also saw the emergence of large multinational public research organisations, such as the European Organisation for Nuclear Research, the European Molecular Biology Laboratory, the European Bioinformatics Institute, the Intergovernmental Panel on Climate Change, and the International Thermonuclear Experimental Reactor. However, there is little research on the patterns of multinational R&D within these organisations.

The discussion below is taken from the more comprehensive chapter discussing standards, organizations, and accreditations organizations for SATORI Deliverable 1.1.The organisations discussed in this section are identified primarily as private organisations since they operate independently of government funding. However, they interact closely with legislating bodies in order to share policy recommendations or serve in an advising capacity.

The World Certification Institute (WCI) is a global certifying body that grants credential awards to individuals as well as accredits courses of organisations. It provides a structured assessment system to assess and certify globally accepted experiential work practices, skills, competencies and professional management. The basic criteria for receiving credential awards are adequate years of experience and demonstration of competence in a specific field of occupation.[39] Its professional activities are coordinated through authorised and accredited centres in America, Europe, Asia, Oceania and Africa.[40]

Sedex (which provides a risk assessment tool to manage ethical risk in the supply chain) is "dedicated to driving improvements in ethical and responsible business practices in global supply chains".[41] Sedex Information Exchange (Sedex) is a not-for-profit membership association, incorporated in the UK as a company limited by guarantee. It is a membership

[36] http://www.cohred.org/wp-content/uploads/2012/09/FIC-Ethics-program-historical-context.pdf
[37] http://srainternational.org/about-sra-international
[38] http://jlb.oxfordjournals.org/content/1/1/3.full
[39] WCI, "About WCI". http://www.worldcertification.org/about-wci/
[40] Ibid.
[41] Sedex. http://www.sedexglobal.com/

association that operates for the mutual benefit of all its members.[42] Sedex is headquartered in London with regional offices in Shanghai, China and New York, USA.[43]

Clinical Research Society (CRS), responsible for the Emerging Clinical Research Professional (ECRP) Certification, is a registered, non-profit, independent membership organisation. CRS states it "is the primary resource for clinical and translational medicine providing leadership for ethical and meaningful innovations that leads to betterment of mankind". It seeks to provide an interdisciplinary platform for professionals working in contract research, pharmaceutical, biotechnology and medical device industries, and those in hospital, medical research institutes and physician clinics. CRS is comprised of a community of more than 23,000 professionals in over 160 countries dedicated to drug/device development and healthcare. CRS was founded in 2006 to address the knowledge sharing need of interdisciplinary professionals in the pharma-biotech industry and, in particular, to develop a common understanding of the ethical principles, necessary for research on human subjects.[44] CRS has Council Members and representation from professionals from across the globe. Executive Council Members provide necessary guidance and support various initiatives of the Society.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) International is a private, non-profit organisation promoting the humane treatment of animals in science through voluntary accreditation and assessment programs.[45] AAALAC is governed by a Board of Trustees which comprises more than 60 scientific, educational and professional organisations (or member organisations). Each member organisation appoints a representative to serve a three-year term on the AAALAC Board. AAALAC suggests that "by actively involving major organisations, AAALAC International remains responsive to the issues that members face, while making sure that members of the scientific community understand and support the AAALAC International accreditation program".[46] The Council on Accreditation (at the centre of AAALAC's mission and work) comprises highly accomplished animal care and use professionals from around the globe who conduct the program assessments that determine which institutions are awarded AAALAC accreditation. Their responsibilities include conducting site visits, reviewing site visit reports, evaluating information, reviewing yearly reports from accredited institutions, and conferring the accreditation status of institutions. The Council is divided into North American, European, and Pacific-rim sections. AAALAC maintains a worldwide pool of more than 300 ad hoc consultants/specialists who have expertise beyond the realm of traditional laboratory animal species as well as specific expertise (for example, in aquatics, or agricultural science). Many also have unique discipline competencies, such as applied neuroscience, behavioural science, toxicology, pharmacology or physiology.

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) promotes high-quality research through an accreditation process[47] that helps organisations worldwide strengthen their human research protection programs (HRPPs). The AAHRP is an independent, non-profit accrediting body and uses a voluntary, peer-driven,

[42] Sedex, "Corporate governance". http://www.sedexglobal.com/about-sedex/corporategovernance/
[43] Sedex. http://www.sedexglobal.com/about-sedex/corporategovernance/#sthash.KwMMQw2Y.dpuf
[44] Clinical Research Society. http://www.clinicalresearchsociety.org/welcome-to-crs/
[45] AAALAC. http://www.aaalac.org/about/index.cfm
[46] AAALAC, "Accreditation FAQs". http://www.aaalac.org/accreditation/faq_landing.cfm#F2
[47] Any public or private (non-profit or for-profit) organisation that is located in or outside the United States and engaged in human research may be accredited.

educational model to ensure that HRPPs meet rigorous standards for quality and protection. AAHRP's senior level staff provide strategic and substantive leadership and oversight on all aspects of AAHRPP's operations; assist organisations through all stages of the accreditation process, provide oversight of the review process and of educational programming for AAHRPP clients as well as the larger research community; undertake global business development and community relations. AAHRPP site visitors review applications and conduct their own comprehensive peer-review assessment, which includes an on-site evaluation.[48] AAHRPP's Board of Directors is responsible for overseeing the accreditation process. The Board is composed of individuals concerned with research involving humans as research participants. Five of AAHRPP's directors represent research participants or other community stakeholders.[49] AAHRPP's Council on Accreditation reviews applications and reports, and makes determinations regarding accreditation; it comprises of members appointed by the Board of Directors. Council members are experienced AAHRPP site visitors.[50]

The Ethisphere® Institute is a global organisation engaged in "defining and advancing the standards of ethical business practices that fuel corporate character, marketplace trust and business success".[51] Ethisphere began in 2007 as an online industry e-newsletter published by corporate compliance and ethics training and consulting firm, Corpedia. It evolved into a quarterly print Ethisphere Magazine publication with a large circulation of corporate, academic, legal and governmental subscribers.[52] It has a number of Advisory Boards.[53]

Social Accountability Accreditation Services (SAAS) is an accreditation agency that works to evaluate, accredit, and monitor organisations that demonstrate competency to audit and certify organisations that conform to social standards.[54] SAAS began work in 1997 as an accreditation department within Social Accountability International (SAI)[55] and was formally established as its own independent, not-for-profit organisation in 2007. SAAS has since expanded its scope to include accrediting bodies to audit against the InterAction PVO standard, conducting oversight of the BSCI verification code, development of the Magen Tzedek program, accreditation of the GoodWeave International system, and oversight and monitoring of the organisations delivering SA8000 Training.

The US-based Compliance Certification Board (CCB) develops criteria to determine competence in the practice of compliance and ethics across various industries and specialty areas, and recognizes individuals meeting these criteria through its compliance certification programs.[56] The Society of Corporate Compliance and Ethics and the Health Care Compliance Association (SCCE/HCCA) created an independent certification body called the Compliance Certification Board (CCB).[57] The CCB is an independent body made up of compliance and ethics professionals who determine what obligations needed to be fulfilled

[48] AAHRPP, "Site visitors". http://www.aahrpp.org/learn/about-aahrpp/site-visitors
[49] AAHRPP, "Board of Directors". http://www.aahrpp.org/learn/about-aahrpp/board-of-directors
[50] AAHRPP, "Council on Accreditation". http://www.aahrpp.org/learn/about-aahrpp/council-on-accreditation
[51] Ethisphere. http://ethisphere.com/about/#sthash.1v5JUopV.dpuf
[52] http://ethisphere.com/about/history/#sthash.uIiVW7I8.dpuf
[53] Further details at: http://ethisphere.com/about/advisory-boards/#sthash.4kC2xFUM.dpuf
[54] SAAS. http://www.saasaccreditation.org/about
[55] Social Accountability International. http://www.sa-intl.org/
[56] http://www.compliancecertification.org/
[57]Snell, Roy, "Compliance certification by the profession, for the profession, and of the profession", Undated. http://www.compliancecertification.org/portals/2/PDF/CCB/ceo-letter-certification-facts.pdf

prior to and after certification, including Continuing Education Units (CEUs).[58] Early on, CCB hired Applied Measurement Professionals (AMP), a testing organisation that employs doctorate-level (PhD/EdD) psychometricians and statisticians to facilitate all phases of CCB's examination development process, including job analysis/validation, construction, administration, and scoring.

At the EU regional level, there is one organisation that deals with quality assurance in higher education. The European Association for Quality Assurance in Higher Education (ENQA) is a membership association which represents its members at the European level and internationally. ENQA members are quality assurance organisations from the European Higher Education Area (EHEA) that operate in the field of higher education. The membership criteria of ENQA encompass Part III of the Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG)[59] and some additional requirements and guidelines. Bodies that do not wish to, or for whatever reason are unable to, apply to become members of ENQA may request affiliate status within ENQA. Affiliates are bona fide organisations or agencies with a demonstrable interest in the quality assurance of higher education.[60] ENQA consists of three entities: General Assembly, Board and Secretariat. The General Assembly, composed of the representatives of the ENQA member agencies, with representatives of respective European Ministries and stakeholders attending as observers, is the main decision-making body of the association.[61]

2.1.3 RESEARCH FUNDING ORGANISATIONS

One global research funding organisation demonstrating the interconnectivity of global efforts is the International Foundation for Science (IFS).[62] IFS was founded in 1972 as a Research Council and registered as a non-governmental organisation (NGO) in response to one of the principal recommendations of the 1965 Pugwash Conference in Venice 'in order to address the stultifying conditions under which younger faculty members in the universities of developing countries were attempting to do research'." [63] The IFS receives funds from donors such as development organisations and science academies. The IFS aims in encouraging young men and women scientists in developing countries to conduct relevant and high quality research that can be put into use. The IFS mainly provided opportunities to these scientists to propose research in biological and water resources in low-income countries. These research projects are assessed by international experts before that the IFS gives a grant to these scientists. Furthermore, IFS provides local training courses contributing towards strengthening the capability of developing country scientists.

The National Institutes of Health (NIH) is a biomedical research facility that is an agency of the United States Department of Health and Human Services. The NIH has a program called "Fogarty International Research Ethics Education and Curriculum Development Program" that provides grants for the development of training program in international research ethics

[58] Ibid.
[59] ENQA, *Standards and Guidelines for Quality Assurance in the European Higher Education Area*, European Association for Quality Assurance in Higher Education, 3rd Edition, Helsinki, 2009. http://www.enqa.eu/wp-content/uploads/2013/06/ESG_3edition-2.pdf
[60] ENQA. "ENQA in a Nutshell". http://www.enqa.eu/index.php/about-enqa/enqa-in-a-nutshell/
[61] ENQA. http://www.enqa.eu/index.php/about-enqa/enqa-organisation/
[62] International foundation for science. http://www.ifs.se/
[63] http://www.ifs.se/

for low- and middle-income countries (LMICs). It is not directly engaged in ethics assessment but in rather ethics guidance throughout encouraged the development of training program in international research ethics.[64]

There has been the idea of creating an International Federation for Ethics Review (IFER) expressed in different scientific journals, such as within the article of Edward S. Dove, Bartha M. Knoppers and Ma'n H. Wawati, "Toward an ethics safe harbour for global biomedical research", that mentions this international non-governmental organisation, made up of voluntary countries, that would grant agencies, patient advocacy, and research organisations, which aim to harmonise the ethics review process of specific types of research projects.[65]

The Global Innovation Fund[66] is a collaboration between Department of International Development (DFID), the United States Agency for International Development (USAID), the Omidyar Network, the Swedish International Development Cooperation Agency (Sida) and Department for Foreign Affairs and Trade in Australia (DFAT) launched in 2014 providing funding at 3 stages: pilot, test and scale in any sector and any country "provided that the innovation targets those living on under $5, or preferably, under $2 a day."[67] The Global Innovation Fund does not address ethics assessment directly in its application or policies, aside from a conflict of interest policy for its members.

The European and Developing Countries Clinical Trials Partnership (EDCTP) is a partnership between the European Union (EU), Norway, Switzerland and developing countries and other donors, as well as the pharmaceutical industry, to enable clinical trials and the development of new medicines and vaccines against HIV/AIDS, tuberculosis, and malaria. The first program envisioned the provision of €600 million for the period 2003-2007 in order to translate medical research results into clinical applications relevant to the needs of developing countries. The second EDCTP programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020. The European Union will provide a contribution of up to € 683 million for the 10-year programme (2014-2024), provided this is matched by contributions from the European Participating States.

As noted in the mission, the partnership is set up to help support collaborative research, which is therefore of complete interest and stake to EDCTP. In terms of social implications, EDCTP targets neglected infectious diseases, and works to ensure that collaboration functions as a partnership between the involved actors. In regard to ethical implications, EDCTP's interest is both in ensuring ethical and legal compliance, but also in finding ways to ensure those standards can be met.

The EDCTP does not engage directly in ethics assessment itself. However, it does provide for technical review of all projects. Pauline Beattie (Operations Manager) notes, "As part of the technical review, we will always have ethics experts on the committee, particularly for trials, who would be present and give a review from an ethical standpoint. So that comes before we even see if they have approvals. Also, there's a question about ethics for the scientists who are

[64] http://www.cohred.org/wp-content/uploads/2012/09/FIC-Ethics-program-historical-context.pdf
[65] Edward S. Dove, Bartha M. Knoppers and Ma'n H. Wawati, "Toward an ethics safe harbor for global biomedical research". http://jlb.oxfordjournals.org/content/1/1/3.full
[66] https://www.gov.uk/international-development-funding/global-innovation-fund
[67] ibid

reviewed."[68] Again, the aim is to ensure compliance and comply with the Horizon 2020 procedures for ethics assessment.

Additionally, EDCTP provides funding and support through its "Coordination and Support Actions" such as supporting sub-Saharan African countries in developing ethical and regulatory framework for conducting clinical trials, where there may be a focus on national ethics committees.

COHRED, the Council on Health Research for Development, describes itself as "a global, non-profit organisation whose singular goal is to maximize the potential of research and innovation(R&I) to deliver sustainable solutions to the health and development problems of people living in low and middle-income countries. Its mission is: To provide leadership and effective solutions to support low and middle income countries to build their own research and innovation systems for health and development."[69] In interviews, the executive director stated, the organisations interest in "ethical issues around partnerships and research collaborations for health (capacity building, transfer of skills, benefit sharing, transfer of technology)." COHRED currently aims at developing a Fairness Index, which is intended to be used to track measures of good practice in health care research and as a benchmarking tool for identifying partners in health care research. Additionally, COHRED has developed and been implemented a cloud-based ethics review system for ethics committees to use. The system has primarily been deployed in African nations, in which it can enhance communication between ethics reviewers and research actors. While COHRED does not engage it ethics assessment itself, it has held trainings directly targeting ethics committee administrators, for which is noted are hardly ever included in traditional ethics trainings.[70]

3 PRIVATE RESEARCH AND INNOVATION SYSTEMS

The development of private research and innovation systems has driven national and regional political agendas to adopt strategies for increasing the amount of research and innovation taking place within their boundaries. For example, the European Union has established in its Horizon 2020 project "To achieve the target of investing 3% of GDP in R&D in particular by improving the conditions for R&D investment by the private sector, and develop a new indicator to track innovation."[71] Similarly, India has launched a "Make in India" campaign in 2014 to increase international investment in manufacturing in India, including IT, pharmaceuticals, biotechnology, energy, and mining.[72] These efforts track the increasing leveraging of research and innovation systems in order to strengthen economic positions by incentivizing private research and innovation within domestic political boundaries.

Innovation and Growth: Rational for an Innovation Strategy, is an example of OECD policy that developed a reform agenda in order to better support new information and communication technologies (ICT) on a global level and make "regulatory frameworks more conducive to innovation in a range of policy areas."[73],[74] Examples include better management

[68] Interview with Pauline Beattie, Operations Manager, EDCTP; February 2015
[69] www.cohred.org
[70] Interview with Carel IJsselmuiden, Executive Director, COHRED; February 2015
[71] http://ec.europa.eu/eu2020/pdf/annex1.pdf
[72] www.makeinindia.com
[73]Organisation for Economic Co-operation and Development. *Innovation and Growth: Rationale for an Innovation Strategy*. Paris: OECD, 2007. Web.
[74] The following section on OECD strategy is adapted from SATORI Milestone 5

and public funding of science research, as well as tax credits or incentives for the private sector to encourage innovation. The system is intended to help resolve global challenges, including sustainable development and environmental problems. The document does not directly present ethical challenges, but refers to certain hurdles that have an ethical component, for example, support of entrepreneurs pursuing frontiers in science while maintaining rights for established corporations in similar industries. The OECD studies have determined that restrictive economic regulations in product and labour markets, and productivity growth are inversely linked, thus dissuading further innovation, and takes steps to prevent this from occurring on a global level[75]

Also in within scope of governance for R&I is the OECD Innovation Strategy. The policy suggests that governments can work to accommodate innovation by implementing "structural reforms in education and training policies, in entrepreneurship policies, in product and labour markets, in public research institutions, and [establishing policies such as pro-growth tax reform] to help develop networks and markets for knowledge."[76] The ethical component within the Innovation Strategy is the application of innovation to mitigation of global and social challenges. The most salient ethical points are related to parallel maintenance of flexibility to develop innovation by autonomous means and encouraging enterprises to promote valuable technologies that are cost-effective and applicable to current global challenges. The underpinning priorities are: "empowering people to innovate, unleashing innovation in forms, creating and applying knowledge, applying innovation to address global and social challenges, and improving the governance and measurement of policies for innovation."[77] Furthermore, the policy acknowledges that R&D is not the only mode of innovation in today's climate; firms are capitalizing on "a wide range of complementary technological and non-technological changes and innovations," coupled with international collaboration to achieve progress.

There also exist private research funding initiatives, which allocate resources to various subcomponents of the R&I process as a whole. Such private funders have established ethical codes of conduct or guidelines for internal use, which are generally aligned with globally accepted principles. Some private funders are charitable organisations such as the Bill and Melinda Gates Foundation, which provides support to both academic research institutions and independent companies undertaking R&I initiatives. The Foundation has an internal set of principles upon which they determine which causes are ethically conformant, and this evaluation procedure is made publicly available on their webpage. While ethicality of projects is not explicitly mentioned, there are specific measures that demonstrate commitment to funding ethical projects.[78] For example, the strategy mentions that key local stakeholders should be involved in projects carried out in developing regions to conduct an objective and systematic assessment. There are some challenges faced in this scheme; though private funders often make their ethical standards publicly available, some internal review processes, such as grant review and granting of funds may not always be as easily available. This is the case for foundations such as the World Cancer Research Fund International, which illustrates

[75]Organisation for Economic Co-operation and Development. *Economic Policy Reforms: Going for Growth 2007*. By Jean-Philippe Cotis. London: OECD, 2007.Web.
[76]Organisation for Economic Co-operation and Development. *Ministerial Report on the OECD Innovation Strategy*. Paris: OECD, 2010. Web.
[77]*The OECD Innovation Strategy: Getting a Head Start on Tomorrow*. Paris: OECD, 2010. Web.
[78] http://www.gatesfoundation.org/How-We-Work/General-Information/Evaluation-Policy

the types of research projects that the organisation is interested in funding, but does not publicise specifics on ethical evaluation of these projects.

Private organisations often collaborate with other private non-profit groups to develop ethical operation schemes and ensure that projects are conformant to their individual ethics policies. For example, the Shell Foundation has partnered with the global sustainability network Forum for the Future to develop an ethical marketing scheme, in which they "[connect] international retailers with [small-scale] producers in developing countries to supply goods to international markets." This is beneficial to both parties; individual proprietors can gain from the capital and market knowledge to expand business prospects in global markets, and international corporations can ensure that they are sourcing from high-quality retailers which are ethically vetted.[79]Corporate Social Responsibility (CSR) strategies are forms of corporate self-regulation, the adoption of which is often guided by national frameworks. CSR tools include standards, principles, codes of conduct and reporting initiatives on social responsibility performance. CSR is an internationally recognised concept and is acknowledged at international, regional and national levels. Key examples of global initiatives include the Universal Declaration on Human Rights[80] (and Charter of Fundamental Rights of the European Union[81] and the European Convention on Human Rights[82]); United Nations Guiding Principles on Business and Human Rights[83]; United Nations Global Compact[84]; and the OECD Guidelines for Multinational Enterprises (OECD Guidelines)[85]. Global international protocols set out overarching key principles for responsible and ethical behaviour. The International Organization for Standardisation (ISO) is an independent, non-governmental membership organisation comprising representatives of various national standards bodies. [86] ISO 26000 is a standard that provides guidance on how businesses and organisations can operate in a socially responsible way. [87]

Individual corporations can also help ensure ethical compliance and advisory services. For example, one of the leading positions among the providers of ethics and compliance advisory services belongs to the US-based company NAVEX Global. NAVEX Global presents itself as the largest ethics and compliance community in the world.[88] With more than 8,000 clients, it serves nearly 75% of the Fortune 100[89] and more than half of the Fortune 1000 companies. It is a merger of former industry leaders ELT, EthicsPoint, Global Compliance services and PolicyTech.NAVEX Global operates world-wide, providing services in over 200 countries. Thus, it represents a good example of work patterns of similar companies and can give insight in general tendencies in the global policies and initiatives to support ethics assessment in

[79] https://www.forumforthefuture.org/project/scaling-success/overview
[80] http://www.un.org/en/documents/udhr/
[81] http://ec.europa.eu/justice/fundamental-rights/charter/index_en.htm
[82] http://www.echr.coe.int/Documents/Convention_ENG.pdf
[83] http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf
[84] https://www.unglobalcompact.org/
[85] http://www.oecd.org/corporate/mne/
[86] http://www.iso.org/iso/home.html
[87] http://www.iso.org/iso/home/standards/iso26000.htm
[88] http://www.navexglobal.com/resources/videos/navex-global-approach-ethics-compliance
[89] An annual list of the 100 largest public and privately-held companies in the United States. The ranking is compiled using gross revenue figures, and is published by Fortune magazine.
The Fortune 100 list is more exclusive than both the Fortune 500 and Fortune 1000 lists, both of which rank more companies. Because it only covers U.S. companies, the list does not take foreign companies into consideration, though many of the listed companies do have international operations.
Read more: http://www.investopedia.com/terms/f/fortune-100.asp#ixzz3ckLZ4GXW

private industry. The Ethical Leadership Group (ELG), for example, is the advisory services division of NAVEX Global, with a mission to help companies develop and promote cultures of integrity. Their clients list encompasses important private sector stakeholders such as Toyota, McDonald's, Boeing, Honda, and Goldman Sachs. NAVEX Global also offers Ethics & Code of conduct training courses, policy management solutions and awareness campaign design and implementation services. It works along partners such as The Ethics & Compliance Officer Association (ECOA), The Association of Corporate Counsel (ACC), The Society of Corporate Compliance & Ethics (SCCE) or Open Compliance and Ethics Group (OCEG), who altogether form a comprehensive network of ethics and compliance expert organisations. Private stakeholders are interested to address such organisations primarily in order to increase their competitiveness. Links with the public sector cannot be avoided in the environment of globalized economies. The recent economic crisis only intensified the need for public-private sector cooperation. As can be seen from the example of European Union, contractual Public Private Partnerships also take place in the domain of research and innovation.[90] Public funding is expected to trigger additional investments to develop new technologies, products and services, all having beneficial effects for state's economies in general. In order to support ethics assessment and Corporate Social Responsibility, the public stakeholders tend to exclude partners that work in contradiction with favoured ethical practices. On the other, they actively seek to partner with socially responsible businesses which follow both nationally and internationally set standards. Private stakeholders practicing good governance and management that promote ethics principles; such as outlining clear tasks and responsibilities in a contractual agreement, engaging a risk management process and having in place provisions for monitoring and evaluation; are more likely to attract public investment and therefore improve their commercial success.

3.1.1 INDUSTRY ASSOCIATIONS AND ACCREDITATION, CERTIFICATION AND STANDARD SETTING ORGANISATIONS

The International Organisation for Standardization (ISO) is an independent, non-governmental membership organisation composed of representatives from various national standards bodies. With 163 member countries, it is the world's largest developer of voluntary International Standards.[91] Although its guidelines are not formally binding, they often become part of national legislations through treaties or the development of national standards.

ISO 26000 is a particular ISO standard that provides guidance on how businesses and organisations can operate in a socially responsible way. It elucidates the term of social responsibility, helps businesses and organisations translate principles into effective actions and shares best practices related to the subject. The standard was developed by representatives from government, NGOs, industry, consumer groups and labour organisations around the world. Such an international consensus in its creation guarantees a far-reaching, global effect. In the field of ethics assessment and CSR, compliance with ISO recommendations should reduce costs as well as promote international cooperation. The standards help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

[90] http://ec.europa.eu/research/industrial_technologies/ppp-in-research_en.html
[91] See more : http://www.iso.org/iso/home/about.htm

Industry's relationship to the society and environment is increasingly being used as a measure of its overall performance and ethics assessment (as well as impact assessment in general[92]) thus becomes essential in furthering its commercial appeal. Companies are ready to address independent, external organisations and networks that can help them to improve their practices on the topic. In this vein, it is critical to understand assessment or regulatory agencies and industry as partners in ethical practice, rather than antagonistic groups.

The International Association for Impact Assessment (IAIA), for example, is the leading global network on best practice in the use of impact assessment for informed decision-making regarding policies, programs, plans and projects. It is an international forum with members that include both individuals and organisations representing over 120 different nations. IAIA believes the assessment of the environmental, social, economic, cultural, and health implications of policy proposals represents a critical contribution to sound decision-making processes, and to equitable and sustainable development. Corporate members benefit from up-to-date industry information and easier access to impact assessment experts, which should altogether result in better environmental and social outcomes.

The voluntary basis on which companies approach such organisations can also be witnessed from the examples of Standard Ethics and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).[93] Standard Ethics is the first independent European Sustainability reporting and rating agency which aims at promoting corporate ethics, Corporate Social Responsibility (CSR), Socially responsible investing (SRI) and corporate governance according to the principles and guidelines of the UN, the OECD, and the EU. It issues only "solicited" ratings, namely the ones requested by nations and companies themselves.

On the other hand, AAALAC International is a private, non-profit organisation that promotes the humane treatment of animals in science through voluntary accreditation and assessment processes.[94]

The external committees that evaluate the compliance of companies' R&I practices to the established international standards are usually comprised of experts who are appointed on the basis of their merits by the governing bodies of the evaluating organisation.[95] There is a tendency for them to be highly specialized, not just in a particular theme, but also in a particular geographical setting[96], in order to give an assessment that best suits the company's individual needs.

[92] Impact assessment can be simply defined as the process of identifying the future consequences of a current or proposed action.
[93] Further examples of organisations that set up principles and initiatives serving to promote ethics assessment practices are the International fertilizer industry association (IFA) in the scope of fertilizer production, distribution and sales, and International Railway Industry Standard (IRIS), with a focus on the railway industry.
[94] More than 950 companies, universities, hospitals, government agencies and other research institutions in 40 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use.
[95] See example: *4.How does someone become a Council member?* (http://www.aaalac.org/accreditation/faq_landing.cfm#F4)
[96] See example: http://www.aaalac.org/about/council.cfm ("The Council includes North American, European and Pacific Rim sections which evaluate programs in their respective regions.")

4 PROFESSIONAL GROUPS AND ASSOCIATIONS IN THE R&I FIELD

International associations for R&I professions share certain similarities when it comes to their mission and objectives. They are mostly founded in order to promote interactions between its members, expedite the processes of taking scientific discoveries to practice, and facilitate the free exchange of information and ideas.

"The International Society for Medical Publication Professionals" (ISMPP) is an example of a non-profit, voluntary professional membership association dedicated to advancing medical publication planning and development, supporting medical publication professionals, and ensuring ethical medical publication practices. According to its Code of Ethics: "ISMPP promotes high standards for professional ethics and practices, and encourages members to meet such standards. Members should act in a manner that promotes integrity and reflects positively on the individual professional, ISMPP, and the medical publication profession, consistent with accepted ethical and legal principles."[97]

Such a statement probably best reflects the role of professional associations in upholding ethical standards in the R&I field. Organisations generally adopt voluntary ethics principles which serve as a professional resource to its members. Despite the fact that such provisions are not binding, the emphasized voluntary character of membership in professional associations provides a high certainty that the members will adhere to established rules.

Clinical Research Society (CRS) is a non-profit, independent membership organisation, similar to ISMPP. It provides an interdisciplinary platform for more than 23,000 professionals in over 160 countries working in the area of clinical and translational medicine. The Society's webpages state that it was founded "to address the knowledge sharing need of interdisciplinary professionals in the pharma-biotech industry and, in particular, to develop a common understanding of the ethical principles, necessary for research on human subjects."[98] Professional associations naturally demand that their members comply with the existing legal framework.[99] However, they also complement legal rules by providing up-to-date information and professional development through conferences and education initiatives. The professional authority and the appeal of other members' good practices should not only promote the importance of the established ethics assessment practices, but also give feedback on their possible weak points, serve to detect future problems and provide valuable advice for the policy-makers.

As opposed to associations that have mostly or exclusively individual members, and predominately influence professionals in their individual capacity; "The International Union of Psychological Science" (IUPsyS) is a professional association that consists of National Member organisations, not more than one National Member coming from any one country. Such membership enables a broader, more systematic impact on its target group and ensures a multiplier effect in the promotion of ethics assessment practices and the upholding of professional ethical standards in general.

[97] http://www.ismpp.org/ethics
[98] http://www.clinicalresearchsociety.org/welcome-to-crs/
[99] In some organisations, it is even demanded that the members oppose behaviour that violates accepted ethical or legal principles. See more: http://www.ismpp.org/ethics

5 DISCUSSION

The greater theme of global level ethics assessment is growing interconnectivity between regional actors. Though policies and soft-laws in ethics do exist on an international platform, ethics assessment takes place to a greater extent on the national and regional levels
One notable exception is research projects funded by the WHO.[100] However, the global dialogue provides the backdrop in which ethics assessment practices occur. International guidelines are frequently cited by regional level organisations, from ethics review committees to national level agencies such as the United States Food and Drug Administration to EU level Directives.

While global standards may exist, the implementation of them varies across countries. This can be for either philosophical or practical reasons. Different priorities by regional actors mean differential commitment to international standards. For example, the aforementioned United States Food and Drug Administration no longer cites the current WMA *Declaration of Helsinki* as a reference point to the use of placebos in clinical trials. Instead, it refers to a prior revision. The World Medical Association holds that the current version of the *Declaration of Helsinki* is the only version and that reference prior ones is inappropriate. There are also practical barriers to implementing global standards within ethics assessment. COHRED and EDCTP both identify lack of capacities to perform ethics reviews due to local deficiencies as practical barriers to international ethics assessment compliance. The practical barriers range from language barriers to timing issues, as some committees may still operate by post. Thus, in cases where approvals must be received in limited time window, the practicality of obtaining a positive ethics review by the local committee may be prohibitive.

With respect to harmonisation of ethical principles, all interviewees indicated a measure of approval. However, each identified issues to consider in the development of a harmonised system. Most frequently cited was the need for adaptability to local conditions.[101] Concerns about an excess of standards without focus the means for monitoring or implementing were recurrent. The increased attention to the ethical standards by which research and innovation should be evaluated without addressing practical issues that preclude ethics assessment standards being implemented has also been cited as detrimental to the aims of the development of ethics assessment standards.

Other critiques mention the scope of harmonisation across research and innovation practices and whether ethical principles scan the entirety of research and innovation. Similarly, one interviewee indicated that the focus should be on the future development of standards that may arise as the shift of research performing areas increases from the United States, Europe, and Japan, suggesting that new models may emerge to supplant current western dominant ethical systems.

All in all, the greater harmonisation of ethical assessment practices has already begun over the course of the last century as evidenced by the existence of the global actions cited in this report.

[100] This was evidenced when the WHO ERC issued a statement on the ethical permissibility of research being conducted during the 2014 Ebola outbreak.
[101] EDCTP & COHRED Interviews