# Ethics Assessment in Different Countries

## United States of America

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**Annex 4.k**

**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 the existing structures and agents for the ethical assessment of research and innovation in the United States of America (U.S.), both for the public and private sector. It will analyse how national and regional governments have put into place organisational structures, laws, policies and procedures for ethical assessment, how both publicly funded and private research and innovation systems address ethical issues in research and innovation, and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs). We will begin by providing some basic information about the U.S. and the historical development of ethics assessment institutions in the country.

The U.S. is, by a wide range of parameters, the most dominant country in the world. The country is large and diverse and with 319 million inhabitants (2014), the third largest in the world by population and fourth largest by total area. Washington DC in the District of Columbia is the capital. The U.S. consists of 50 states and a unified federal component that includes Washington, DC. The 48 contiguous states and Washington, D.C., are in central North America between Canada and Mexico. The state of Alaska is located in the north western part of North America and the state of Hawaii is an archipelago in the mid-Pacific. The country also has five populated and numerous unpopulated territories in the Pacific and the Caribbean. The U.S. is one of the world's most ethnically diverse and multicultural nations, the product of large-scale immigration from many countries. The geography and climate of the United States are also extremely diverse, and the country is home to a wide variety of wildlife. [1,2] There is no official national language in the U.S., but English is the *de facto* official language. Recognised regional languages include: Spanish, French, Hawaiian, Samoan, Chamorro, Carolinian and 19 native Alaskan languages. English is the dominant language, and 80 per cent of the population speaks English as their sole language.[3] The United States is the world's oldest surviving federation. It is a constitutional republic and representative democracy.[4,5]

The U.S. economy is the largest in the world with a GDP of $16,72 trillion (2013 estimate).[6] The U.S. dollar is the most used currency in international transactions and is the world's foremost reserve currency.[7] The United States has a mixed economy and has maintained a stable overall GDP growth rate, a moderate unemployment rate, and high levels of research

[1] Adams, J.Q., Pearlie Strother-Adams, *Dealing with Diversity*, Kendall/Hunt, Chicago, 2010.
[2] National Wildlife Federation, "Wildlife Library". http://www.nwf.org/wildlife.aspx
[3] Feder, Jody, *English as the Official Language of the United States: Legal Background and Analysis of Legislation in the 110th Congress*, 25 January 2007.
[4] Scheb, John M., John M. II Scheb, *An Introduction to the American Legal System*, KY: Delmar, Florence, 2002, p. 6.
[5] Killian, Johnny H., "Constitution of the United States", The Office of the Secretary of the Senate. http://www.senate.gov/civics/constitution_item/constitution.htm
[6] The World Factbook, CIA.gov, The World Factbook, 2015. https://www.cia.gov/library/publications/the-world-factbook/geos/us.html
[7] The Implementation of Monetary Policy – The Federal Reserve in the International Sphere. http://www.federalreserve.gov/pf/pdf/pf_4.pdf

and capital investment.[8] The US has abundant natural resources, a well-developed infrastructure, and high productivity. It has been the world's largest national economy (not including colonial empires) since at least the 1890s.[9] The United States is the largest producer of oil in the world, as well as its second largest importer.[10] Leading American corporations and brands include: Wal-Mart, Exxon Mobile, Chevron, Berkshire Hathaway, Apple, Phillips 66, General Motors, Ford Motors, General Electric, Amazon, Microsoft, and Coca Cola.[11] Table 1: A breakdown of the GERD by financing sector (2011)[12] and Table 2: A breakdown of the GERD by performing sector (2011)[13] shows a breakdown of the Gross Domestic Expenditure on Research and Development (GERD), in terms of percentages, by financing sector and performing sector. Figure 1[12] shows the composition of the GDP per sector.

| Government | Industry | Other domestic sources | Sources abroad |
|---|---|---|---|
| 31,17% | 58,58% | 6,46% | 3,79% |

**Table 1: A breakdown of the GERD by financing sector (2011).**

| Business enterprise sector | Higher education sector | Government sector | Private non-profit sector |
|---|---|---|---|
| 68,53% | 14,55% | 12,66% | 4,26% |

**Table 2: A breakdown of the GERD by performing sector (2011)**

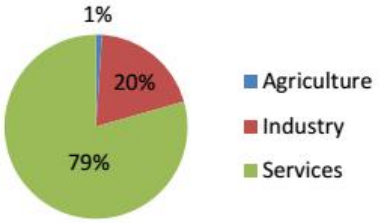


**Figure 1: GDP composition by sector**

The practice of ethics assessment takes place both in governmental organisations and non-governmental settings (including private industry and CSOs) and is spread over many U.S. institutions and organisations. The United States is one of the only developed countries without a permanent bioethics committee. However, in 1974 and 1978 the U.S. Congress appointed two separate term-limited committees to address issues related to research ethics.

[8] U.S. Diplomatic Mission to Germany, "Basic Conditions and Resources". http://usa.usembassy.de/economy-conditions.htm
[9] International Monetary Fund, "List of Countries by GDP PPP per capita", International Monetary Fund. http://goo.gl/OOz6tG
[10] Reuters, "U.S. surges past Saudis to become world's top oil supplier –PIRA", 15 Oct 2013. http://www.reuters.com/article/2013/10/15/us-oil-pira-idUSL1N0I51IX20131015
[11] Fortune, "Fortune 500 2014", http://fortune.com/fortune500/
[12] https://www.cia.gov/library/publications/the-world-factbook/geos/us.html

Since then, each sitting U.S. President has appointed a temporary bioethics committee that coincided with the President's term. While each committee's presidential charge has varied, most, including the current commission, have been created to advise the president on bioethical issues related to medicine, science, and technology. The President appoints the committee, and its composition, terms, and way of working is closely linked to the term of any sitting president.

To address specific concerns related to research ethics, the U.S has an extensive system for Institutional Review Boards (IRBs)[13] in place to oversee human subjects' research. IRBs are responsible for critical oversight functions for research conducted on human subjects. In the United States, the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)—both in the Department of Health, and the Human Services-- regulate IRBs. The IRBs are subject to federal regulation, which defines the rules and responsibilities for institutional review, which, in turn, is required for all research that receives support, directly or indirectly, from the United States federal government.[14] Additional requirements apply to IRBs that oversee clinical trials of drugs involved in new drug applications, or to studies that are supported by the United States Department of Defence. In addition to registering its IRB with the OHRP, an institution is also required to obtain and maintain a *Federal wide Assurance* (FWA), before undertaking federally funded human research.[15] The FWA is an assurance of compliance with the "Common Rule" (see below and section 2.3), including establishing and maintaining an IRB. The FWA must be renewed every five years.[16]

The history leading to the U.S tradition of IRBs includes previous problems with human subjects' research. A famous example is the Tuskegee syphilis experiment. Here, beginning in 1932, 399 impoverished African-Americans were enrolled in an observational study of the natural history of syphilis and followed for 40 years, well after the common use of penicillin for treating the disease. While promised health-care, they were denied treatment for syphilis– further they were never informed that they had the disease.[17] Another factor was a famous essay by Henry K. Beecher (1966), addressing a number of ethical problems with a great number of research projects involving human subjects.[18] This led the U.S. Congress to enact the National Research Act (1974), and to the development of the Belmont Report, which outlined the primary ethical principles in human subjects review; these include "respect for

[13] Also sometimes referred to as Independent Ethics Review Committee (IEC), Ethical Review Board (ERB) and Research Ethics Board (REB).
[14] U.S. Department of Health and Human Services, "Title 45, Code of Federal Regulations". http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[15] U.S. Department of Health and Human Services, "IRBs and Assurances". http://www.hhs.gov/ohrp/assurances/index.html
[16] Hhs.gov., Federalwide Assurance (FWA) for the Protection of Human Subjects. http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html
[17] Katz, Ralph V., et al., "Willingness of minorities to participate in biomedical studies: confirmatory findings from a follow-up study using the Tuskegee Legacy Project Questionnaire", *Journal of the National Medical Association,* Vol. 99, Issue 9, 2007, pp. 1-19. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1780164/pdf/nihms15039.pdf
[18] Harkness, Jon, Susan E. Lederer, and Daniel Wikler, "Laying ethical foundations for clinical research", *Bulletin of the World Health Organisation*, Vol. 79, Issue 4, 2001, pp. 365-366. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2566394/pdf/11357216.pdf

persons", "beneficence", and "justice".[19] An IRB may only approve research for which there is a bona fide informed consent process for participants, for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants.[20]

Other important pieces of national legislation related to ethics assessment have been the Animal Welfare Act (1966) and the National Environmental Policy Act (1970) (see section 2.3). Furthermore, the Federal Sentencing Guidelines for Organisations (1991) has indirectly led to the creation of compliance and ethics programs in many U.S. organisations, including companies (see section 4.1).

Finally, the U.S. *Office of Technology Assessment* (OTA), played an important part in the development of (ethical) technology assessment in the U.S. and globally. From its establishment in 1972 to its closure in 1995, OTA "[…] *provide*[d] *objective analyses to inform policy decisions on technology matters"*[21] producing roughly 750 reports. While OTA has been a model for similar organisations in many nations,[22] funding was abolished as some Members of Congress saw the organisation as unnecessary.[23] The cessation of funding for the OTA has led to a decentralisation of technology assessment in the U.S. (see section 2.2).

# 2 National and regional government institutions and policies

This chapter will provide a discussion of U.S national government institutions and policies relating to research and innovation. In its sections, the following will be examined: the general institutional structure of U.S government and government-controlled institutions; governmental institutions with a role in ethics assessment; and national laws and policies for ethics assessment. Finally, regional institutions and policies are briefly presented.

## 2.1 General Institutional structure

In this section, the general institutional structure of U.S. government and government-controlled institutions, as it relates to research and innovation, will be laid out. The following topics will be included in the discussion: the form of government; the nature of and relations between executive, the legislative and judicial branches; the major ministries and government organisations; and the role of government in research and innovation in the private sector.

[19] U.S. Department of Health and Human Services, "Belmont report" http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[20] Ibid.
[21] Lin, Albert C., "Technology Assessment 2.0: Revamping Our Approach to Emerging Technologies", *Brooklyn Law Review*, Vol 76, Issue 4, 2010, pp. 1-62 [p. 22]. https://law.ucdavis.edu/faculty/lin/files/Technology-Assessment-2.0-Revamping-our-Approach-to-Emerging-Technologies.pdf
[22] Peha, Jon M., "Science and Technology Advice for Congress: Past, Present, and Future", *Renewable Resources Journal,* Vol. 24, Issue 2, Summer 2006, pp. 19-23. http://repository.cmu.edu/cgi/viewcontent.cgi?article=1054&context=epp
[23] Lin, op. cit., 2010, p. 24.

### 2.1.1 General structure of government

The United States is the world's oldest surviving federation. It is a constitutional republic and representative democracy.[24] The United States has operated under a two-party system for most of its history. Since the general election of 1856, the major parties have been the Democratic Party (described as centre-left or liberal), founded in 1824, and the Republican Party (described as centre-right or conservative), founded in 1854. The government is structured as a constitution-based federal republic, where power is shared between the federal government and state governments. The Declaration of Independence from July 4th 1776 is considered the founding document of the United States of America.

Under the tenth amendment to the U.S. Constitution, all governmental powers not delegated to the federal government are reserved for the U.S. states or people.[25] This can, however, be circumvented, e.g., through "Conditions of aid," where the federal Congress can cut off funds if the states do not implement a particular policy.[26] In general, the relationship between the federal government and the states can be considered as fluid and is dependent upon a number of factors, which have changed throughout U.S. history. These factors include the ideological standpoint of the President and the federal Congress, as well as the leanings of the U.S. Supreme Court. The federal government is organised according to a "checks and balances" system, where the executive (the presidency), legislative (U.S. congress) and the judicial (from the national Supreme Court down to district courts) branches of government can change acts of the other branches to ensure a government where no individual or group gains too much power.[27] The natures of the three branches of federal government are overall as follows:

The executive branch: "The […] branch carries out and enforces laws. It includes the president, vice president, the Cabinet, executive departments, independent agencies, and other boards, commissions, and committees."[28]

The legislative branch, which includes the Congress (split into The Senate and the House of Representatives), and various support agencies: "The legislative branch enacts legislation, confirms or rejects presidential appointments, and has the authority to declare war."[29]

The judicial branch, which includes the Supreme Court: "The judicial branch interprets the meaning of laws, applies laws to individual cases, and decides if laws violate the Constitution. The judicial branch is comprised of the Supreme Court and other federal courts."[30]

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[24] Scheb, John M.; John M. II Scheb, *An Introduction to the American Legal System*, KY: Delmar, Florence, 2002, p. 6; Killian, Johnny H., "Constitution of the United States", The Office of the Secretary of the Senate. http://www.senate.gov/civics/constitution_item/constitution.htm
[25] Law.cornell.edu, CRS/LII Annotated Constitution Tenth Amendment. https://www.law.cornell.edu/anncon/html/amdt10
[26] Caselaw.lp.findlaw.com. FindLaw | Cases and Codes. http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=CASE&court=US&vol=483&page=203
[27] Wikipedia, "Separation of powers under the United States Constitution". http://en.wikipedia.org/wiki/Separation_of_powers_
[28] U.S. Federal Government. http://www.usa.gov/Agencies/federal.shtml
[29] Ibid.
[30] U.S. Federal Government. http://www.usa.gov/Agencies/federal.shtml

### 2.1.2 Government organisations relevant to research and innovation

Many organisations throughout the federal and state governments are responsible for national science policy. Large-scale policy issues are primarily discussed under the federal budget process, although some scientific issues are directly legislated (see section 2.3). The main body advising the president on issues relevant to research and innovation is the *Office of Science and Technology Policy* (OSTP). Other important councils include the *President's Council of Advisors on Science and Technology* (PCAST) and the *National Science and Technology Council* (NSTC). In the U.S. Congress, a number of committees have jurisdiction over science policy, including the House Committee on Science and Technology and the Senate Committee on Commerce, Science and Transportation. These committees also oversee federal agencies that receive research funding.

The Office of Science and Technology Policy (OSTP) was established in 1976. The OSTP has as a mission to "provide the President and his senior staff with accurate, relevant, and timely scientific and technical advice on all matters of consequence; second, to ensure that the policies of the Executive Branch are informed by sound science; and third, to ensure that the scientific and technical work of the Executive Branch is properly coordinated so as to provide the greatest benefit to society."[31] An example of the work of the OSTP is the Federal Research Misconduct Policy (FRMP). The FRMP established a common definition of research misconduct and provided guidelines for how misconduct cases should be investigated and sanctioned[32]. FRMP was published in 2000 and required all federal institutions that support intra- or extramural research to implement it within one year. The actual implementation is, however, different from institution to institution.[33]

President Obama announced the present President's Council of Advisors on Science and Technology (PCAST) on April 27, 2009. PCAST is "an advisory group of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President. PCAST makes policy recommendations in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people."[34] Each president since Franklin D. Roosevelt has established an advisory council on science and technology.

[31] Office of Science and Technology Policy, "About OSTP"
https://www.whitehouse.gov/administration/eop/ostp/about

[32] Office of Science and Technology Policy (2000) "Federal Policy on Research Misconduct"
http://www.gpo.gov/fdsys/pkg/FR-2000-12-06/html/00-30852.htm
http://ora.research.ucla.edu/RPC/Documents/DOT-Research_Misconduct_Policy.pdf

[33] ORI - The Office of Research Integrity, Federal Policies. https://ori.hhs.gov/federal-policies

[34] Office of Science and Technology Policy, "About PCAST".
https://www.whitehouse.gov/administration/eop/ostp/pcast/about

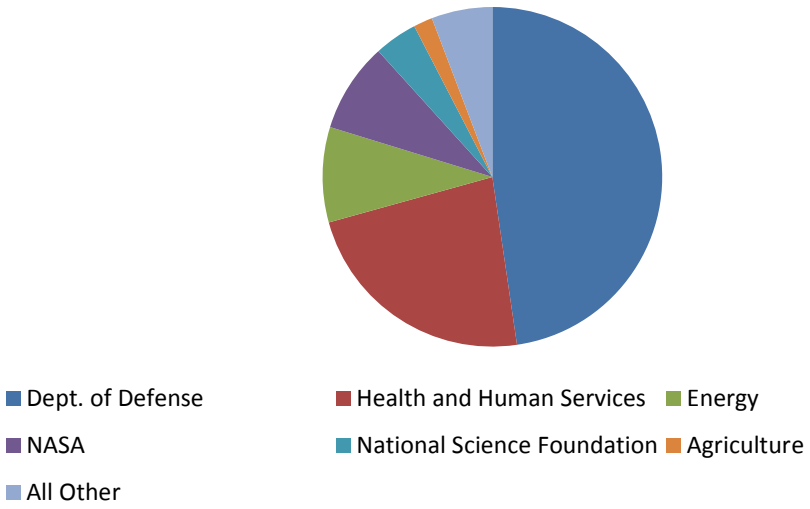


**Figure 2: R&D in the FY 2015, budget by Agency (budget authority in millions of dollars). Source: http://www.whitehouse.gov/sites/default/files/microsites/ostp/fy2015rdtables.pdf**

The National Science and Technology Council (NSTC), was established by Executive Order on November 23, 1993. This Cabinet-level Council is "the principal means within the executive branch to coordinate science and technology policy across the diverse entities that make up the Federal research and development enterprise. Chaired by the President, the membership of the NSTC is made up of the Vice President, the Director of the Office of Science and Technology Policy, Cabinet Secretaries and Agency Heads with significant science and technology responsibilities, and other White House officials."[35] The work of the Council is organised under five primary committees: Environment, Natural Resources and Sustainability; Homeland and National Security; Science, Technology, Engineering, and Math (STEM) Education; Science; and Technology. Each committee oversees a number of sub-committees and working groups focused on different aspects of science and technology and working to coordinate across the federal government.

The leadership of the *National Science Foundation (NSF)* includes the government-funded *National Science Board* (NSB) and a director. The NSB provides independent policy advice to the Executive Branch and Congress on science and engineering research. The NSB is made up of 25 members (from industry and universities) appointed by the President for six-year terms.[36]

A large number of organisations provide advice and input to the science policy of the federal government and the U.S. states, including corporations, CSOs and professional organisations.

[35] Office of Science and Technology Policy, "The National Science and Technology Council". https://www.whitehouse.gov/administration/eop/ostp/nstc
[36] National Science Board, http://www.nsf.gov/nsb/about/index.jsp

*The National Academies of Science* is a particularly important organisation in this regard (see also section 3.1).[37, 38]

To give an idea of the scope and spread of federal funding, the allocation of funds for R&D according to U.S. departments will briefly be presented. As evident from Figure 2 of the projected budget for R&D in U.S. agencies, the *Department of Defence* has budget authority over almost half (48% - $64,43 billion), while *Health and Human Services* has budget authority over 23% ($31,06 billion). The remaining 29% ($39,61billion) is split among a great number of government departments and agencies[39].

## 2.2 Governmental institutions for ethics assessment

A significant number of governmental institutions do work related to ethics assessment (e.g., advising the government) or related areas (e.g., technology or impact assessment). The following is a list of some of these institutions. While the list should not be seen as exhaustive, it offers an overview and understanding of the breadth of governmental organisations somewhat related to ethics assessment. Some of the organisations listed are not formally part of the U.S. government, but can still be considered to have a close relationship with the government (e.g., through funding or giving advice to the government as their primary task).

### 2.2.1 National ethics committees

The *Presidential Commission for the Study of Bioethical Issues* (PCSBI) (established by President Obama in 2009) advises the executive branch on bioethical issues arising from advances in biomedicine and associated areas of science and technology.[40] PCSBI is not a standing bioethics commission, but President Obama created the committee, as every president since the 1970s has done. PCSBI receives its assignments either through a request from the President or members of his Cabinet, or from their own deliberative process that brings to light important issues related to ethics and health.[41]

The *U.S. Office of Government Ethics* (OGE) is an independent agency in the Executive Branch that works with approximately 5,500 ethics officials throughout the federal government who are tasked with identifying and resolving potential conflicts of interest. OGE works together with federal agencies to create regulation and policy regarding avoidance of conflict of interest.[42] Among other things, OGE has established a standard for ethical conduct within the Executive Branch.[43]

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[37] Wikipedia, "Science policy of the United States". https://en.wikipedia.org/wiki/Science_policy_of_the_United_States

[38] Not included here are the United States House Committee on Science, Space and Technology and the United States Senate Commerce Subcommittee on Science and Space, since their role does not seem to be primary advisory but rather policy-making.

[39] See http://www.usa.gov/directory/federal/index.shtml, for a complete listing of government agencies and departments

[40] Presidential Commission for the Study of Bioethical Issues, "FAQs". http://bioethics.gov/node/242

[41] Interview with Lisa M. Lee of the Presidential Commission for the Study of Bioethical Issues.

[42] U.S. Office of Government Ethics, "About". http://www.oge.gov/About/About/

[43] U.S. Office of Government Ethics, "Employee Standards of Conduct". http://www.oge.gov/Laws-and-Regulations/Employee-Standards-of-Conduct/Employee-Standards-of-Conduct/

On behalf of the Secretary of Health and Human Services, the *U.S. Office of Research Integrity* (ORI) oversees and directs the Public Health Service's (PHS) research integrity undertakings. ORI develops policies and regulations related to the avoidance of research misconduct within the PHS and help to develop educational initiatives for the research community.

The *Office for Human Research Protections* (OHRP) provides ethical oversight for research conducted by more than 20 federal departments that fund research,, primarily related to title 45, part 46 of the Code of Federal Regulations (Protection of Human Subjects), including IRBs.

Within the *U.S. Department of Veterans Affairs* (VA), the *National Center for Ethics in Health Care* (NCEHC) "[…] serves as VA's authoritative resource for addressing the complex ethical issues that arise in patient care, health care management, and research."[1] "The mission of NCEHC is to establish, interpret, and communicate ethical standards in health care and promote practice consistent with those standards within VA and nationwide."[2] NCEHC implements ethics-related policy and manages IntegratedEthics® Programs (formerly ethics committees) at all VA health care facilities.[44]

### 2.2.2 Impact assessment bodies

*Technology assessment agencies*

Following the abolition of the OTA (see chapter 1), a number of governmental institutions have carried out technology assessments on an *ad hoc* basis. None of these institutions has technology assessment as a primary area of expertise or work.

*The Government Accountability Office* (GAO) has conducted a few technology assessment pilot projects under the auspices of the U.S. Congress. These reports have primarily been related to counterterrorism (e.g. use of biometric technologies or cybersecurity measures).

The *Office of Science and Technology Policy* (OSTP) has the authority to initiate, among other studies, technology assessments to resolve critical and emerging problems. The office has, however, fairly limited resources and has primarily focused on acting as a communication channel between the president and the scientific community and on coordinating science and technology policy across the federal government.[45]

The *National Research Council* (NRC – see further section 3.2) issues reports on science and technology topics in response to the requests of congress and agencies. These reports are "[…]

[44] National Center for Ethics in Health Care, "Integrated Ethics". http://www.ethics.va.gov/integratedethics/index.asp

[45] Lin, Albert C., "Technology Assessment 2.0: Revamping Our Approach to Emerging Technologies", *Brooklyn Law Review*, Vol 76, Issue 4 2010, pp: 1-62 [p. 24-26]. https://law.ucdavis.edu/faculty/lin/files/Technology-Assessment-2.0-Revamping-our-Approach-to-Emerging-Technologies.pdf

designed to generate expert recommendations in response to specific questions rather than to raise issues independently, address broader policy questions, or foster public debate". [46]

*Health and environmental impact assessment agencies*

A number of governmental and non-governmental organisations conduct health and environmentally related impact assessments.[47] The following provides a brief overview of two organisations chosen to illustrate the wide variety of issues on which organisations focus.

The *Health Effects Institute* (HEI) is an independent, public-private partnership research organisation, which receives half of its funding from the U.S. Environmental Protection Agency (EPA) and the other half from the automobile industry. HEI seeks to identify and, in some cases, fund priority areas for health effects research and communicate their research to policy makers, industry and the public. In addition to other areas of work, HEI conducts health impact assessments of air pollutant emission.

*The National Health and Environmental Effects Research Laboratory* (NHEERL) is a research laboratory under the EPA. NHEERL is the "[…] focal point for scientific research on the effects of contaminants and environmental stressors on human health and ecosystem integrity." [48]

The wide variety of organisations might be accounted for by federal regulation since The National Environmental Policy Act (NEPA) requires U.S. governmental agencies to consider the impacts of major federal actions on the human environment[49] (see section 2.3).

*Social impact assessment agencies*

A number of governmental agencies work with social impact assessments, including the National Marine Fisheries Services (NOAA)[50] and the U.S Environmental Protection Agency (EPA).[51] The EPA has a 'Sustainable Practices Program', directed at communities, technologies, transportation and chemicals. The EPA also has educational activities directed at children. One can, for example, 'follow the Lorax' to learn about climate change and the environment.[52]

## 2.3 National laws and policies for ethics and impact assessment

This section gives an overview of major U.S. national laws, policies and regulations on ethics assessment and related activities. In addition, a number of relevant policies and guidelines

[46] Lin, op. cit. 2010, p. 26.
[47] US EPA, "Health and Environmental Assessment - Resources: Organisations and Agencies", Air Quality Management (AQM) Portal.
http://www.epa.gov/oaqps001/aqmportal/management/links/assessment_resources_org.htm
[48] US EPA, "Basic Information - Health and Environmental Effects Research"
http://www.epa.gov/nheerl/basic_information.html
[49] Department of Commerce, National Oceanic and Atmospheric administration, national marine fisheries service instruction, Adopted 24 December 2007. http://www.nmfs.noaa.gov/sfa/reg_svcs/NMFSI_01-111-02.pdf
[50] http://www.nmfs.noaa.gov/sfa/reg_svcs/NMFSI_01-111-02.pdf
[51] US EPA, "Social Impact Assessment". http://www.epa.gov/sustainability/analytics/social-impact.htm
[52] http://www.energystar.gov/ia/partners/publications/pubdocs/LoraxActivityBook-webPrint_041615_508v2.pdf?5577-ff8b

from governmental agencies are included. As noted in section 3.1 the federal government has only limited authority over the higher education system; hence. The legislation presented below must be seen as only indirectly influencing educational institutions. The legislation for ethics assessment in relation to private industry is presented in section 4.1.

### 2.3.1 Human subject research

As a result of a number of incidents where human subjects research was found to be unethical (with the *Tuskegee Syphilis Experiment* probably the most infamous),[53] Congress enacted the National Research Act in 1974. This created the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. This Commission was charged with identifying "[…] the basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles."[54] This led to 17 reports including the *Institutional Review Board Report* and the *Belmont Report*, as well as the congressional enactment (in 1976) of title 45, part 46 of the Code of Federal Regulations (also known as the Common Rule) that requires institutional review boards (IRBs) to oversee federally funded research involving human subjects, and a requirement for obtaining informed consent from the subjects.[55] [56] An IRB is an "[…] appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research."[57]

### 2.3.2 Research using animals

The *Animal Welfare Act* was enacted by Congress in 1966 and has since been modified several times. Currently, the Act covers "[…] all warm-blooded animals except rats, mice and birds, and farm animals used in food and fiber research."[58] The Act makes it mandatory for research conducted in federally funded research institutions[59] to comply with *The Guide for the Care and Use of Laboratory Animals,*[60] to have an *Institutional Animal Care and Use*

[53] Centers for Disease Control and Prevention, "Tuskegee Study and Health Benefit Program". http://www.cdc.gov/tuskegee/index.html
[54] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[55] U.S. Department of Health & Human Services, "Code of Federal Regulations". Revised 15 January 2009. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[56] There are a number of exemptions from the mandatory IRB review; e.g., research conducted in educational settings. http://irb.ucsd.edu/Exemption_fact_sheet.pdf
[57] FDA, "Institutional Review Boards Frequently Asked Questions - Information Sheet". http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#IRBMember
[58] AAALAC, "Resources". http://www.aaalac.org/resources/usregs.cfm
[59] Research using animals are primarily conducted at research institutions receiving federal funding. http://www.aboutanimaltesting.co.uk/who-performs-animal-testing.html
[60] http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-Use-of-Laboratory-Animals.pdf

*Committee* (IACUC)[61, 62] and to follow the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia.[63] [64]

### 2.3.3 Stem cell research regulation

While stem cell research has not been entirely prohibited under U.S. law,[65] it has been a highly contentious issue in political debate.[66] There is no federal legislation that bans institutions receiving federal funding from performing stem cell research. In the current situation, federal funding is only unavailable if if human embryos are created for research purposes or "[…] research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on foetuses in utero […]."[67]

### 2.3.4 Discrimination in Federal employment based on genetic information

In February 2000, President Clinton prohibited discrimination (executive order 13145) in federal employment based on genetic information.[68] At the signing of the order President Clinton said "[…] people's medical records, their financial records and their genetic records are among the most important things that we have to protect.[69]" On May 2nd 2008, the U.S. Congress also passed the Genetic Information Nondiscrimination Act (GINA), which is meant to prevent discrimination for employment or health insurance based on a person's genetic information.[70]

### 2.3.5 Federal Acquisition Requirements (FAR)

A number of ethically related restrictions also exist under the Federal Acquisition Regulation (FAR). While this primarily focuses on other aspects related to federal acquisitions, e.g., providing standard contracts and requirements for market research, requirements for *Contractor Code of Business Ethics and Conduct* are also present.[71] Contractors to U.S.

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[61] An IACUC can be considered as equal to an IRB.
[62] It is perhaps interesting to note that IACUCs were a legal requirement before IRBs.
[63] Leary, Steven. et al, *AVMA Guidelines for the Euthanasia of Animals,* American Veterinary Medical Association, 2013. https://www.avma.org/KB/Policies/Documents/euthanasia.pdf
[64] Office of Laboratory Animal Welfare, "Public Health Service Policy on Humane Care and Use of Laboratory Animals". http://grants.nih.gov/grants/olaw/references/phspol.htm#AnimalWelfareAssurance
[65] Pew Research Center's Religion & Public Life Project, *Stem Cell Research at the Crossroads of Religion and Politics*, 2008. http://www.pewforum.org/2008/07/17/stem-cell-research-at-the-crossroads-of-religion-and-politics/
[66] CNN, "Obama overturns Bush policy on stem cells", *CNN,* 9 March 2009. http://edition.cnn.com/2009/POLITICS/03/09/obama.stem.cells/index.html
[67] Kearl, Megan, "Dickey-Wicker Amendment, 1996", *The Embryo Project Encyclopedia*. http://embryo.asu.edu/pages/dickey-wicker-amendment-1996
[68] The White House, Executive Order 13145 to Prohibit Discrimination in Federal Employment Based on Genetic Information, Adopted 08-02-2000, Genome.gov, 2000 Release: Barring Genetic Discrimination. http://www.genome.gov/10002084
[69] The National Human Genome Research Institute, "President Clinton's Comments on the Signing of Executive Order 13145". http://www.genome.gov/10002346
[70] U.S. National Library of Medicine "The Genetic Information Nondiscrimination Act (GINA)", http://ghr.nlm.nih.gov/spotlight=thegeneticinformationnondiscriminationactgina
[71] Federal Acquisition Regulation (FAR), FAC Number/Effective Date: 2005-82/06-08-2015. https://www.acquisition.gov/?q=browsefar

federal institutions must generally "[…] conduct themselves with the highest degree of integrity and honesty"[72] and "[…] promote an organisational culture that encourages ethical conduct and a commitment to compliance with the law." While not specified, one might reasonably assume that this must also be the case with regards to research and innovation.[73]

### 2.3.6 National Environmental Policy Act (NEPA)

NEPA (1969) requires federal agencies to conduct environmental impact assessments of major federal actions and to ensure that the government considers the environment when addressing legislation. The preamble of the Act states that the purpose of the act is "[t]o declare a national policy which will encourage productive and enjoyable harmony between man and his environment [and] to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare or man […]."[74] The process agencies must go through when taking an action that could lead to environmental impacts involves determining whether an action is exempt from NEPA; if not, agencies must prepare an Environmental Impact Statement (EIS). An EIS is a "[…] technical document that describes and comparatively evaluates [a] proposal and its alternatives."[75] The process of an EIS is federally mandated and described in detail.[76] The meaning and impact of NEPA will further be expanded in the Discussion (chapter 7).

## 2.4 Regional institutions and policies

The federalism and decentralised nature of U.S. government means generally that much of the legislation is left up to the state or local legislators. This is also the case in areas pertaining to ethics assessment. Due to the scope of this report, this sub-part can only be seen as a brief introduction to regional institutions and policies.

### 2.4.1 Ethics commissions

42 U.S. states have at least one ethics commission.[77,78] While the regulation of ethics commissions differs among states, in general commissions oversee governmental employees' and public officials' compliance with ethically related state laws (e.g., Conflict of Interest Laws[79]), present regulations that pertain to their work, and investigate and determines penalties for offenders.[80]

[72] Federal Acquisition Regulation (FAR), Clause 3.1002. https://www.acquisition.gov/?q=browsefar
[73] Federal Acquisition Regulation (FAR), Clause 3.1002. https://www.acquisition.gov/?q=browsefar
[74] National Environmental Policy Act of 1969, 31 December 2000. http://www.epw.senate.gov/nepa69.pdf
[75] Felleman, J. and S. Draggan, *Environmental Impact Assessment*, 2013. http://www.eoearth.org/view/article/152590/
[76] FHWA, Environmental Review Toolkit, Section 4(f), NEPA Implementation - Guidance for Preparing and Processing Environmental and Section 4(f) Documents. http://environment.fhwa.dot.gov/projdev/impta6640.asp
[77] NCSL, State Ethics Commissions. http://www.ncsl.org/research/ethics/state-ethics-commissions.aspx#ethics
[78] A number of cities have an equivalent commission for the governance of the city.
[79] State of New Jersey State Ethics Commission, "New Jersey Conflicts of Interest Law". http://www.state.nj.us/ethics/statutes/conflicts/
[80] NCSL, "Committees & Commissions: What's the Difference?". http://www.ncsl.org/research/ethics/committees-amp-commissions-whats-the-differenc.aspx

### 2.4.2 State and local regulation

In addition to national regulation, research institutions might also be subject to additional state and local legislation, e.g., with regard to animal testing,[81] IRBs[82] or stem cell research.[83] Moreover, areas with no nationwide legislation, e.g. nanotechnology,[84] might have local or state legislation.[85]

[81] AAALAC, "Resources". http://www.aaalac.org/resources/usregs.cfm?printPage=1&
[82] Yale University, "IRBs". http://www.yale.edu/hrpp/policies/documents/100GD7otherlaws-FINAL-1-7-13--KLM.pdf
[83] Mansnerus, Laura, "In Stem-Cell Law, Supporters See Opportunity for New Jersey", *Nytimes.com*, 6 January 2004. http://www.nytimes.com/2004/01/06/nyregion/06STEM.html
[84] Dixon, Kim, "FDA says no new labelling for nanotech products", *Reuters.com*, 25 July 2007. http://www.reuters.com/article/2007/07/25/us-fda-nanotechnology-idUSN2514226320070725
[85] The New York Times, "Berkeley to be first city to regulate nanotechnology", *The New York Times*, 12 November 2006. http://www.nytimes.com/2006/12/12/technology/12iht-nano.3870331.html?_r=1&

# 3 Public research and innovation systems

This chapter will provide a discussion of the public research and innovation systems. In the section below, the following will be discussed, respectively: the general structure of government, national research associations and standard-setting bodies, research funding organisations and research performing organisations.

## 3.1 General structure and the role of government

This section provides an overview of the general structure of the publicly funded and controlled R&I and higher education system and the role of the government within this structure. A description of the different organisations and their interrelations is provided, in addition to an outline of the executive and regulatory powers of the government.

### 3.1.1 Systems of higher education and research institutions

The U.S. system of higher education and government-funded research is highly decentralised. This is based upon the Constitution "[…] which reserves power over education to the states and local authorities, as well as to individual schools and higher education institutions."[86] The following will provide an overview of the general structure of the U.S. system of higher education, with a particular emphasis on the role of government.

*Universities*

As of 2010, there was 4599 degree granting institutions in the U.S. The vast majority of these institutions are private.[87] Even though private universities are licensed by the state, universities are independent of state control. Some of the universities might receive funding from the state governments to provide public services.[88] A number of public universities also exist. State authorities appoint government boards to public universities. These universities typically receive an annual allocation from the state budget funds and are expected to adhere to state regulations. This, however, depends on the relationship between the state and the university. It is, however, of importance to note that "[p]ublic institutions are internally self-governing and autonomous with respect to academic decision-making." [89]

*Federal government*

The federal government only has limited direct authority over institutions of higher education and research in the U.S. The authority includes areas pertaining to, for example, promotion of educational policies, administration of federal assistance programs and enforcing educational related civil rights law.

[86] U.S. Department of Education, "Organisation of U.S. Education". https://www2.ed.gov/about/offices/list/ous/international/usnei/us/edlite-org-us.html
[87] NCES, "Number of educational institutions, by level and control of institution: Selected years, 1980-81 through 2010-11". http://nces.ed.gov/programs/digest/d12/tables/dt12_005.asp
[88] USNEI, "Organisation of U.S. Education: Tertiary Institutions". https://www2.ed.gov/about/offices/list/ous/international/usnei/us/postsec-inst.doc
[89] USNEI, "Organisation of U.S. Education: Tertiary Institutions". https://www2.ed.gov/about/offices/list/ous/international/usnei/us/postsec-inst.doc

The federal government does however not "own, control or oversee U.S. schools or postsecondary institutions." [90] The indirect authority of the federal government is greater. An example of this was mentioned in section 2.1 regarding requirements for receiving federal research funding, where federal funding may not be issued to institutions that do not abide by certain animal testing requirements.

*State government*

The direct authority of state governments over higher education is far more substantial than that of the federal government: "[…] [S]tate governments exercise oversight and coordinating authority over higher education within their jurisdictions, issue corporate charters to institutions, regulate standards and quality to varying degrees, and may have regulatory authority over various aspects of the operation of public institutions." [91]

The authority of state governments is even greater as far as public and state universities are concerned - these institutions are directly affiliated with the state government.[92] Each state supports at least one state university, coordinated by state commissions on higher education.

A university can be more directly affiliated with the U.S. government through University Affiliated Research Centres (UARC), whereby the U.S. Department of Defence directs a research centre associated with a university. 14 such centres exist.[93] Another example of a direct link between the federal government and universities is Federally Funded Research and Development Centres (FFRDCs): a FFRDC "[…] is a hybrid organisation designed to meet a federal need through the use of private organisations".[94] There are 39 of these organisations, a third of which are administered by universities or colleges, with the remaining two-thirds administered by industrial firms or non-profit organisations.[95]

In addition to collaboration with universities, the federal government invests directly in research through approximately 40 research and development agencies, where 11 out of 15 departments are affiliated with a research agency.[96] Finally a number of number of associations and consortia are involved with represent various groups with important structural and organisational functions. [97] One example is the American Council on Education

[90] USNEI, "Organisation of U.S. Education: The Federal Role".
https://www2.ed.gov/about/offices/list/ous/international/usnei/us/edlite-org-us.html
[91] USNEI, "Organisation of U.S. Education: State Role II - Tertiary Education".
https://www2.ed.gov/about/offices/list/ous/international/usnei/us/postsec.doc
[92] USNEI, "Organisation of U.S. Education: State Role II - Tertiary Education".
https://www2.ed.gov/about/offices/list/ous/international/usnei/us/postsec.doc
[93] Defense Innovation Marketplace. http://www.defenseinnovationmarketplace.mil/UARC_FFRDC.html
[94] Kosar, Kevin R., "The Quasi Government: Hybrid Organisations with Both Government and Private Sector Legal Characteristics", Congressional Research Service, 22 June 2011.
http://www.fas.org/sgp/crs/misc/RL30533.pdf
[95] National Science Foundation, "NCSES FFRDC Research and Development Expenditures: Fiscal Year 2009 - US National Science Foundation (NSF)".
http://www.nsf.gov/statistics/nsf11314/content.cfm?pub_id=4067&id=4
[96] Wikipedia, "United States research agencies".
http://en.wikipedia.org/wiki/Template:United_States_research_agencies
[97] Wikipedia, "College and university associations and consortia in the United States".
http://en.wikipedia.org/wiki/Category:College_and_university_associations_and_consortia_in_the_United_States

(ACE). ACE is an advocacy group representing the presidents of degree-granting institutions.[98] [99]

This section provides an overview of the research associations and standard-setting bodies in the U.S., in addition to an analysis of their role in ethics assessment. First, we discuss the role of the National Academies and the National Research Council, before moving on to a discussion of the field specific organisations involved in ethics assessment.

***The National Academies***

The U.S. National Academies (NA) consists of the National Academy of Science, the National Academy of Engineering, the Institute of Medicine and the National Research Council, which serves collectively as the national scientific academy of the U.S. While not receiving direct appropriations from the federal government, the academies receive funding for individual activities. In addition, the academies receive funding from other sources, including states, industry and foundations.[100]

NA can trace its history back to the American Civil War during which time the National Academy of Science was established by a federal act approved by President Lincoln in 1863[101]. The federal charter of the NA states that "On request of the United States Government, the corporation [NA] shall investigate, examine, experiment, and report on any subject of science or art."[102] The scientific members of the NA are elected at an annual meeting and "[…] serve pro bono to address critical national issues and give advice to the federal government and the public."[103]

With regards to ethics assessment, the primary role of NA seems to be agenda and standard setting. Examples of NA's publications are presented below:

- *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct* (2002) is a report that focuses on fostering a research environment that promotes integrity.[104]
- *On Being a Scientist: A Guide to Responsible Conduct in Science* (first edition in 1989, third in 2009) "describes the ethical foundations of scientific practices and some of the personal and professional issues that researchers encounter in their work."[105]

[98] http://www.acenet.edu/about-ace/Pages/default.aspx
[99] USNEI, "Organisation of U.S. Education: Tertiary Institutions". https://www2.ed.gov/about/offices/list/ous/international/usnei/us/postsec-inst.doc
[100] http://www.nationalacademies.org/about/whoweare/index.html
[101] http://www.nasonline.org/about-nas/leadership/governing-documents/act-of-incorporation.html
[102] 36 U.S. Code § 150303 - Services to United States Government. https://www.law.cornell.edu/uscode/text/36/150303
[103] Brandeis University. http://www.brandeis.edu/about/faculty/national.html
[104] Rubenstein, Arthur H. et al., *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct*, The National Academic Press, Washington, 2002. http://iao.sinica.edu.tw/RI/doc/Educational/Integrity.pdf
[105] Bertozzi, Carolyn et al., *On Being a Scientist: A Guide to Responsible Conduct in Research*, Third edition, The National Academic Press, Washington, 2009. http://biblioteca.ucv.cl/site/colecciones/manuales_u/12192.pdf

- *Ethical Considerations for Research Involving Prisoners* (2006) presents how prisoners can be protected during research.[106]

- *Onlineethics.org* is an "[…] electronic repository of resources on science, engineering, and research ethics, for engineers, scientists, scholars, educators, students, and interested citizens."[107] The homepage provides a great diversity of material, including case-studies, ethics codes and teaching material within a number of different sciences.

***The National Research Council* (NRC)**

The National Research Council is a council under NA and functions as its working arm. The mission of the council "[…] is to improve government decision making and public policy, increase public understanding, and promote the acquisition and dissemination of knowledge in matters involving science, engineering, technology, and health".[108] Advice from NRC has led, for example, to legislative acts facilitating the enhancement of U.S. competiveness[109] and changes to U.S. drug safety regulation. Another example of NRC's work is on climate change, a contested issue in U.S. scientific debate. The Council has stated that the work of the Intergovernmental Panel on Climate Change represented the view of the established scientific community well.[110]

The individual national academies have advisory boards, e.g., U.S. National Academy of Sciences' Board on Science, Technology, and Economic Policy[111] that assist the academies in producing advisory reports.

***Accreditation bodies of U.S. universities***

While the U.S. government does not accredit universities they do have an important say in the matter, as the Department of Education publishes a list of nationally recognised reliable accrediting agencies. These agencies establish which institutions of higher education meet a number of quality criteria determined by the agency.[112] While some of these accreditation agencies are national, others are regional and some only focus on a specific type of institution.[113]

[106] Gostin, Lawrence, et al. *Ethical considerations for research involving prisoners*, National Academies Press (US), 2007. http://www.ncbi.nlm.nih.gov/books/NBK19882/?report=reader#!po=25.0000
[107] http://onlineethics.org/
[108] http://www.nationalacademies.org/nrc/
[109] The National Academies, "Our Advice in Action". http://www.nationalacademies.org/about/advice/index.html
[110] Cicerone, Ralph J. et al, *Climate Change Science: An Analysis of Some Key Questions,* The National Academic Press, Washington, 2001. http://www.nap.edu/openbook.php?record_id=10139
[111] The National Academies, Board on Science, Technology, and Economic Policy (STEP). http://sites.nationalacademies.org/pga/step/index.htm
[112] U.S. Department of Education, "Database of Accredited Postsecondary Institutions and Programs". http://ope.ed.gov/accreditation/
[113] U.S. Department of Education, "Accreditation in the United States". http://www2.ed.gov/admins/finaid/accred/index.html

***Research associations and standard setting bodies***

In general, there are relatively few research associations in the U.S., seemingly due to strong anti-trust legislation, which makes it difficult to organise private company research associations.[114] There are however some examples of research associations with (some) participation by companies. Examples include:

- *United States Council for Automotive Research* – An association of government agencies and private companies seeking […] to advance important, socially responsible automotive issues related to energy, the environment and safety."[115]
- *The Semiconductor Research Corporation* - An association of government agencies, private companies and universities seeking to create synergy between members.[116]
- *Rare Diseases Clinical Research Network* – a number of programs under the National Institutes of Health "[…] designed to advance medical research on rare diseases by facilitating collaboration, study enrolment and data sharing."[117]
- *Engineering Research Centres* – Under the auspices of the National Science Foundation, the centres are "[…] interdisciplinary, multi-institutional centres that join academia, industry, and government in partnership to produce transformational engineered systems […]."[118]

## 3.2 Research funding organisations

This section will provide a discussion of how organisations funding research include ethics assessment in determining how to spend their resources. We will give a few examples of the way in which ethics assessment plays a role in the allocation of funding. Please note however that the overview cannot be considered complete coverage of the role of ethics assessment in U.S. funding allocations, due to the multitude of both private and public funding organisations.

Almost half of the federal funding of research is under the authority of the *Department of Defence* (see Figure 2). Much of the defence related research is conducted by industry. Therefore, the ethical requirements presented in the FAR (see section 2.3) also apply here.

The department with the second largest budgetary authority is the *Department of Health and Human Services*, where the majority of funding is allocated through the *National Institute of Health* (NIH). Competition between individual researchers for funds from NIH is fierce, with approximately 80.000 grant applications submitted each year. The allocation process comprises two steps:

[114] Henry, Jane & David Mayle (eds.), *Managing innovation and change*, Sage, 2002, pp.172-173.
[115] USCAR, "Partners & Collaborators". http://www.uscar.org/guest/members-and-partners/
[116] SRC, "SRC Vision, Mission, Charter and Values – SRC". https://www.src.org/about/mission/
[117] Office of Rare Diseases Research (ORDR-NCATS). http://rarediseases.info.nih.gov/research/pages/41/rare-diseases-clinical-research-network
[118] NSF ERC, "Welcome to the ERC Program". http://erc-assoc.org/

1. *The initial peer review* is an assessment of scientific and technical merit, by approximately 16,000 NIH affiliated reviewers from the scientific community. The reviewers review applications from their area of expertise according to five criteria, evaluating the importance and likelihood of success of a proposed project. Besides these criteria, applications are also assessed according to ethical principles. Such assessment might require redrafting of the application or even rejection of the application. These include ethical problems related to the protection of human subjects from research risks and in the use of vertebrate animals, as well as ethical problems related to the selection of human subjects. The explicit inclusion of these parameters seems to follow national legislation (see section 2.3).

2. Following the initial peer review, a *second level of review* is carried out. This review takes as its point of departure the initial peer review, while also taking into consideration the mission and research priorities of the different centres and councils that make up the NIH.[119, 120]

This means that successful applications are required to have both technical and scientific merit, while the research subject should also be relevant to the funding institution.

The NIH has further presented guidelines for human stem cell research, as an implementation of changes in government policy. These guidelines include aspects such Informed Consent from donors.[121]

Further, the department of Health and Human Services oversees the *Office of Research Integrity* (ORI). ORI oversees and directs research integrity activities, on behalf of the secretary of Health and Human Services[122]. The office is in charge of educating researchers on the responsible conduct of research. It also develops policies and procedures for dealing with cases of misconduct, and it reviews, monitors, and recommends misconduct findings and actions to the secretary of the department of Health and Human Services. ORI is comprised of a number of offices and agencies: Office of Public Health and Science, The National Institutes of Health, The Centers for Disease Control and Prevention, The Food and Drug Administration, The Substance Abuse and Mental Health Services Administration, The Health Resources and Services Administration, The Agency for Healthcare Research and Quality, The Agency for Toxic Substances and Disease Registry, The Indian Health Service, and Office of Regional Health Administers.[123]

Another example of ethical requirements for funding can be found in the requirements of the National Science Foundation (NSF) that require institutions that receive funding from NSF to

[119] Department of Health and Human Services, "Overview Information". http://grants1.nih.gov/grants/guide/rfa-files/RFA-HL-14-024.html
[120] National Institutes of Health (NIH), "NIH Peer Review: Grants and Cooperative Agreements". https://grants.nih.gov/grants/peerreview22713webv2.pdf
[121] NIH, "2009 Guidelines on Stem Cell Research". http://stemcells.nih.gov/policy/pages/2009guidelines.aspx
[122] The regulatory and research integrity activities of the Food and Drug Administration are excluded.
[123] The Office of Research Integrity 'About ORI', https://ori.hhs.gov/about-ori

"[…] describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research […]."[124]

The Gordon and Betty Moore Foundation appear to be the largest private U.S. foundation awarding grants for public research.[125] [126] The grants are given to a broad spectrum of scientific disciplines.[127] The foundation applies four criteria when evaluating potential grants. These are "(1) Importance, (2) Potential to make a difference and lead to an enduring impact, (3) Measureable outcomes and (4) Portfolio effect." [128]

The second largest private foundation is the Simons Foundation. The foundation is an initiative set up by James and Marilyn Simons as part of fulfilling the 'Giving Pledge'[129]. The Foundation's supported Autism research, Mathematics and Science. The activities of the Foundation ended in 2013.

The third largest private foundation funding scientific research, the David and Lucile Packard Foundation,[130] is more explicit in its inclusion of ethical aspects. According to the core values of the organisation the Foundation works to "[…] encourage the highest possible standards of conduct and ethics." [131]

To ensure that the staff conducting the assessments is well informed about ethically sound research, the private company Informing Change has been involved. The company has "[…] developed a set of resource documents that provide information on what human subjects protection is and include flowcharts and guidelines on how to spot and address potential ethical issues in proposed projects."[132]

As presented in section 2.1, a number of ethical issues comprise a part of the conditions for research funding. Please note that the issues mentioned here are most likely not exhaustive.

### 3.3 Research performing organisations

Overall research performing organisations, and the researchers performing research within them are governed by the policies and procedures set out by the Office for Research Integrity (described in the previous section). All universities have research integrity officers (or offices)

[124] NSF, "US NSF – About". http://www.nsf.gov/bfa/dias/policy/rcr.jsp
[125] Foundation Center, "Aggregate Fiscal Data for Top 50 FC 1000 Foundations Awarding Grants for Science and Technology, 2012". http://data.foundationcenter.org/#/fc1000/subject:science/all/top:foundations/list/2012
[126] Please note we are using 2012 numbers. At the time of writing this report they were the most resent numbers available.
[127] Gordon and Betty Moore Foundation. http://www.moore.org/programs/science
[128] Gordon and Betty Moore Foundation. http://www.moore.org/docs/default-source/Annual-Reports/five-year-report.pdf?sfvrsn=0
[129] The Giving Pledge in an initiative by Bill and Melinda Gates. The idea resulted from conversations with Warren Buffet and other U.S. as well as non U.S. philanthropists around the World. Participants pledge to give away half or more of their wealth.
[130] Foundation Center, "Aggregate Fiscal Data for Top 50 FC 1000 Foundations Awarding Grants for Science and Technology, 2012". http://data.foundationcenter.org/#/fc1000/subject:science/all/top:foundations/list/2012
[131] The David and Lucile Packard Foundation, "Our Values - The David and Lucile Packard Foundation". http://www.packard.org/about-the-foundation/values/
[132] Informing change, "The David & Lucile Packard Foundation". http://informingchange.com/areas-of-expertise/philanthropy/the-david-lucile-packard-foundation

on staff, to guide researchers on responsible conduct, and to monitor and check for misconduct cases. A large number of research performing institutions have therefore developed internal ethical standards, typically through codes of conduct.[133] The following section sets out examples of research performing institutions.

*Stanford University* is one of the most prestigious universities in the U.S.[134] The university sets out a code of conduct on its homepage. This code applies to people associated with the university, including students, staff and contractors. The code states, among other things, "[…] rules of fairness, honesty, and respect for the rights of others will govern our conduct at all times." The code further states "No unethical practice can be tolerated because it is "customary" outside of Stanford or that it serves other worthy goals."

The code also sets out expectations related to confidentiality and privacy, conflict of interest/conflict of commitment, human resources, financial reporting, compliance with laws, use of university resources and reporting suspected violations.[135]

Suspected violations of the code should be reported to the internal Compliance and Ethics Helpline, so that appropriate resolutions will be found.[136]

Many universities, including Stanford[137] offer ethics training and education to university staff and researchers. This may include training in the responsible conduct of research, moral reflection and general research ethics. Furthermore, training may be offered with regard to complex regulation relating to, for example, human subjects research and animal testing.

These types of codes of conduct can be found at a great number of universities.

Hospitals comprise another example of research performing organisations in which codes of conduct have become the norm in recent years. The codes of conduct seek to make clear expectations regarding professional behaviour and describe a process for the handling of breaches of such behaviour.

Some commentators are however critical of these codes, as they are seen as contributing to diminishing the role of employees and reflecting a lack of trust on the part of leadership.[138]

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[133] A great number of codes of conduct/ethics can be found at http://ethics.iit.edu/ecodes/
[134] Business Insider, "The 50 Best Colleges in America". http://www.businessinsider.com/best-colleges-in-the-us-2014-9?op=1&IR=T
[135] Stanford University, "1.1.1 University Code of Conduct". https://adminguide.stanford.edu/chapter-1/subchapter-1/policy-1-1-1
[136] Stanford University, "Compliance and Ethics Helpline". https://acp.stanford.edu/compliance/compliance-and-ethics-helpline
[137] Stanford University, "Responsible Conduct of Research". https://doresearch.stanford.edu/training/responsible-conduct-research
[138] Collier, Ryan, "Physician codes of conduct becoming a norm", *CMAJ : Canadian Medical Association Journal*, Vol. 183, Issue 8, 2011, pp. 892-893; Komesaroff, Paul A. & Ian H. Kerridge, "The Australian Medical Council draft code of professional conduct: good practice or creeping authoritarianism?", *The Medical Journal of Australia*. Vol. 190, Issue 4, 6 February 2009. https://www.mja.com.au/system/files/issues/190_04_160209/kom11209_fm.pdf

Besides codes of conduct, a primary ethical focus in research performing organisations is, as earlier noted, on human subject research and animal testing.

# 4 Private research and innovation systems

This chapter will focus on ethics assessment and, in particular, corporate social responsibility (CSR) in private research and innovation systems. First, a brief description of the U.S. industry landscape and a number of industry organisations is provided. Then, governmental policies for ethics assessment are set out. Finally, relevant industry associations and the engagement of industry in ethics assessment comprise the focal point of the remaining parts of this chapter.

## 4.1 General structure and the role of government

In this section, the U.S. industry landscape, major U.S. organisations that represent industry and U.S. policies that support ethics assessment will be described.

### 4.1.1 U.S. industry landscape

The U.S. has the world's highest GDP[139] and almost 150 million people employed[140] in the public and private sector. The vast majority of employment is in the service-providing sector (80% as of 2012)[141]. 139 of the world's 500 largest companies are based in the U.S., including the largest company by revenue; Wal-Mart Stores, with companies such as Exxon Mobile, Chevron, ConocoPhillips and Fannie Mae following on the Fortune 500 list of world's largest companies.[142] These are all included in the approximately 10 million companies that existed in the U.S. as of 2007.[143]

### 4.1.2 Major organisations that represents industry

There exist at least 7,800 associations, professional societies and labour unions in the U.S.[144] The following section sets out some of the major associations, along with associations of special interest to ethics assessment.

Many of the organisations include major lobbying efforts, both on national and state levels.

- *The National Association of Manufacturers* (NAM) is, according to its website, the largest manufacturing association in the U.S., and represents "[…] small and large manufacturers in every industrial sector and in all 50 states."[145]
- *The Biotechnology Industry Organisation* (BIO) is the largest organisation to represent biotechnology organisations in the U.S. and globally. Corporations,

[139] CIA, *The World Factbook*. https://www.cia.gov/library/publications/the-world-factbook/fields/2195.html
[140] As of February 2015, http://data.bls.gov/cgi-bin/surveymost
[141] U.S. Department of Labour, "Employment by major industry sector". http://www.bls.gov/emp/ep_table_201.htm
[142] Fortune, Global 500 2014. http://fortune.com/global500/
[143] US Census Bureau, "American FactFinder – Results". http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_00A1&prodType=table
[144] Associationexecs.com, "National Trade and Professional Associations Directory". https://www.associationexecs.com/national-trade-and-professional-associations-directory
[145] http://www.nam.org/About/

academic institutions and related organisations are represented in the association[146].

- *The Pharmaceutical Research and Manufacturers of America* (PhRMA) also represents U.S. pharmaceutical and biotech companies.
- *The American Iron and Steel Institute* (AISI) is a major organisation representing the North American steel producers.[147]
- *The American Council for Technology and Industry Advisory Council* (ACT-IAC) is a "[…] public-private partnership dedicated to improving government through the application of information technology."[148] The organisation was established in 1979 by governmental employees.
- *The Association for Manufacturing Excellence* (AME) is a knowledge exchange organisation that represents 4000 members, sharing best practices and approaches.

### 4.1.3 Government policies and initiatives to support ethics assessment in private industry

While no U.S. regulations exists requiring companies to produce CSR reports or to follow certain guidelines,[149] some policies can be found concerning ethical business conduct and behaviour.

The following examples are just two, and must therefore not be seen as exhaustive:

- *The Federal Sentencing Guidelines for Organisations* (FSGO) exist to bring about consistency in the conviction of organisations and corporations violating U.S. law. Under FSGO, convicted organisations receive reduced sentences if they establish compliance and ethics programs, which a great number of organisations have done. This has led to "[…] FSGO's "seven-step" standards for compliance/ethics programs have become the de facto framework for U.S. corporations and also serve as a reference point for many U.S. regulatory and enforcement agencies.[150]" The "seven-steps" seems to refer to the seven requirements presented in chapter eight of FSGO.[151]

[146] https://www.bio.org/node/3089
[147] American Iron and Steel Institute. http://www.steel.org/About%20AISI.aspx
[148] ACT-IAC. https://actiac.org/content/about-act-iac
[149] Cecil, Lianna, "Corporate social responsibility reporting in the United States," *McNair Scholars Research Journal*, Vol. 1, Iss. 1, Article 6, 2010. http://commons.emich.edu/cgi/viewcontent.cgi?article=1006&context=mcnair
[150] Ethics Resource Center, "The Federal Sentencing Guidelines for Organisations at Twenty Years", ERC Ethics Resource Center, 2012 [p. 2]. http://www.ethics.org/files/u5/fsgo-report2012.pdf
[151] US Sentencing Commission, "Guidelines Manual. Chapter Eight – Sentencing of Organisations". http://www.ussc.gov/guidelines-manual/2012/2012-8b21

- The Foreign Corrupt Practices Act (FCPA) was enacted in 1977 to make it illegal to bribe foreign officials, among other concerns.[152]

Over 50 programs, policies and activities at 12 U.S. agencies focus upon supporting U.S. businesses' CSR programs. In general, government activities can be split into four categories: Endorsing, facilitating, mandating or partnering[153] (i.e., public-private partnerships). The following provides some examples:

- [Endorsing] The CSR team under the U.S. Department of State seeks to promote CSR initiatives and provide guidance to companies that engage with CSR[154]. This includes the Award for Corporate Excellence (ACE). Companies are nominated by local State Department representatives.[155]

- [Facilitating] The U.S. official credit agency, *the Export-Import Bank of the United States* (Ex-Im Bank), has an Environmental Exports Program which "[…] enhances the Ex-Im Bank's financing package for such U.S. goods and services [e.g. renewable energy or water treatment projects], thereby encouraging foreign buyers to purchase U.S. exports that are beneficial to the environment."[156]

- [Mandating] *The Overseas Private Investment Corporation* (OPIC), "the U.S. Government's development finance institution"[157] mandates that beneficiaries comply with some CSR criteria. These criteria include environmental protection, human rights and international labour rights.[158]

- [Public-private partnership] EPA's Centre for Corporate Climate Leadership has a voluntary government partnership where EPA seeks to encourage corporations to set goals for greenhouse gas emissions.[159] "Partners receive training and technical assistance in completing the greenhouse gas inventories, and EPA works with each partner to develop standard Inventory Management Plans."[160]

[152] The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq. ("FCPA"). http://www.justice.gov/criminal/fraud/fcpa/
[153] GAO, "Report to Congressional Requesters – Globalisation - Numerous Federal Activities Complement U.S. Business's Global Corporate Social Responsibility Efforts", August 2005. http://www.gao.gov/assets/250/247363.pdf
[154] U.S. Department of State, "Corporate Social Responsibility". http://www.state.gov/e/eb/eppd/csr/
[155] U.S. Department of State, "Secretary of State's Award for Corporate Excellence". http://www.state.gov/e/eb/ace/index.htm
[156] GAO, op. cit., 2005.
[157] OPIC, "OPIC mobilises private capital to help solve critical development challenges | OPIC: Overseas Private Investment Corporation". https://www.opic.gov/who-we-are/overview
[158] GAO, op. cit., 2005.
[159] Epa.gov. Center for Corporate Climate Leadership | US Environmental Protection Agency. http://www.epa.gov/climateleadership/
[160] GAO, op. cit., 2005.

- [Public-private partnership] In 2000, the governments of U.S. and U.K., together with CSO's and "[…] companies in the extractive and energy sectors […]"[161] created the Voluntary Principles on Security and Human Rights. These principles seek to "[…] guide companies in maintaining the safety and security of their operations within an operating framework that encourages respect for human rights".[162] Apparently, almost every major oil and mining company in the U.S. has become part of the program.[163]

In general, the initiatives above seem to be uncoordinated. This might however change, since the U.S. government in September 2014 presented plans for a "[…] National Action Plan to promote and incentivise responsible business conduct, including with respect to transparency and anticorruption, consistent with the UN Guiding Principles on Business and Human Rights and the OECD Guidelines on Multinational Enterprises."[164]

## 4.2 Industry associations, accreditation, certification & standard setting organisations

This section offers a discussion of the role of industry associations and networks, certification, evaluation and standard setting organisations for industry in the setting and enforcement or promotion of standards and practices with regards to ethics assessment and CSR in industry. The extent of the use by industry of independent, external ethics committees when evaluating R&D is also discussed.

### 4.2.1 Industry associations

Due to the large number of industry associations in place, it is not feasible to give a complete analysis of their approaches to CSR. For this reason, a number of relevant examples are provided. The two associations below, while both are major associations, were chosen to give an indication of the great difference in approach to CSR reporting there is among different associations in the U.S.

- NAM does not appear to focus on CSR related activities for its members, rather focusing on "[…] help[ing] manufacturers do what they do best: create economic strength and jobs."[165] In fact, NAM seems to work against at least some policies related to CSR, including opposition to rules on using conflict minerals from the DR Congo[166] and working openly against EPA regulation of greenhouse gas emissions. [167]

[161] "The Voluntary Principles on Security and Human Rights", *Foley Hoag LLP, the Secretariat for the Voluntary Principles on Security and Human Rights*. http://www.voluntaryprinciples.org/what-are-the-voluntary-principles/
[162] Ibid.
[163] GAO, op. cit., 2005.
[164] The Whitehouse, "FACT SHEET: The U.S. Global Anticorruption Agenda". https://www.whitehouse.gov/the-press-office/2014/09/24/fact-sheet-us-global-anticorruption-agenda
[165] NAM. http://www.nam.org/About/
[166] Altschuller, Sarah, "Business Groups File Petition for Review of the SEC's Conflict Minerals Rule", *Corporate Social Responsibility and the Law*, 22 October 2012. http://www.csrandthelaw.com/2012/10/22/business-groups-file-petition-for-review-of-the-secs-conflict-minerals-rule/
[167] NAM, "Capital Briefing". 31 March 2011. http://www.nam.org/Communications/Publications/Capital-Briefing/Archive/033111.aspx

- *PhRMA* has developed a number of policies in areas related to CSR, while it appears not to have published guidelines for CSR or promotion of CSR reporting. Examples of PhRMA's work include its Principles for Responsible Clinical Trial Data Sharing[168] and a Code on Interactions With Health Care Professionals.[169]

### 4.2.2 Network organisations

A notable example of an industry network organisation is the *Defence Industry Initiative* (DII) on *Business Ethics and Conduct*. This is a nonpartisan and non-profit organisation which seeks to ensure "[…] promotion and advancement of a culture of ethical conduct in every company that provides products and services to the United States Armed Forces."[170] This is done through making resources available[171] and requiring companies to sign a standard list of five principles. These include aspects such as honest business dealings, promotion of the highest level of ethical values and nurturing of an ethical culture, the establishment of effective business ethics and compliance programs and sharing of best practices in relation to business ethics and accountability to the public.[172]

### 4.2.3 Certification, evaluation and standard-setting organisations

Certification, evaluation and standard-setting organisations for industry focus primarily on CSR related activities and less so on other forms of ethics assessment. The most important standard setting organisation in the U.S., is the *American National Standards Institute* (ANSI), members of which include "[…] Government agencies, Organisations, Companies, Academic and International bodies, and individuals […]"[173] ANSI contributes to certification, evaluation and standard-setting within a great number of areas, including ISO standards (e.g., ISO 26000 on Social responsibility).

Another example is ANSI approval of other organisations or companies' proposals for standards. An example is the *Sustainable Management Standard* produced by *The American Society of Plumbing Engineers* (ASPE) and the *Water Quality Association* (WQA).[174]

Labelling activities by organisations, for example, for fair-trade or ecological concerns, also provides examples of certification, evaluation or standard-setting activities by organisations, examples of this are the around 200 ecological labels found in the U.S. These include the labels *Animal Welfare Approved*, *BASF Eco-Efficiency* and *USDA Organic*. [175]

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[168] PhRMA, "Principles on Conduct of Clinical Trials – Communication of Clinical Trial Results". http://www.phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final_0.pdf
[169] PhRMA, "Code on Interactions With Health Care Professionals". http://www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals
[170] Defense Industry Initiative, "About us". http://www.dii.org/about-us
[171] Defense Industry Initiative, "Resources". http://www.dii.org/resources
[172] Defense Industry Initiative, "DII Principles". http://www.dii.org/dii-principles
[173] ANSI, "ANSI Membership". http://www.ansi.org/membership/overview/overview.aspx?menuid=2www.ansi.org/membership
[174] American Society of Plumbing Engineers, "Sustainable Management Standard Receives ANSI Approval". https://www.aspe.org/content/sustainable-management-standard-receives-ansi-approval
[175] Ecolabel Index, "All ecolabels in United States". http://www.ecolabelindex.com/ecolabels/?st=country,us

### 4.3 Industry

This section offers a discussion as to how U.S. industry engages in CSR and ethics assessment to the extent that these relate to R&I.

Although more than 99% of U.S. companies can be considered small or medium-sized and have almost 50% of private sector employment[176,177], only few small and medium sized enterprises (SMEs) engage with CSR [178, 179].

The fact that U.S. SMEs only engage in CSR to a limited extent might also be inferred from the results presented by Cecil (2010), where Cecil sought to identify the state and trend of CSR reporting in general in U.S. companies. This is done through the homepage CorporateRegister.com, "[*a*]*ccording to their website, the organisation estimates to have captured over 90% of the world's published CSR reports*". Searches on the website found that while in 1991 two companies issued CSR reports, 154 companies did this in 2001 and in 2006, 230 issued CSR reports. The industry sectors for which most CSR reports were published were found to be *electricity*, *chemicals* and *oil & gas*.

A general conclusion from Cecil (2010) is that "[t]he United States appears to lag behind other countries in issuing CSR reports." The reason for this is primarily found to be the lack of formal requirements in the U.S. for companies to issue CSR reports.[180]

While Cecil (2010) does not investigate the size of companies doing the CSR reporting, the relatively few reports might be seen as underlining the point that primarily major corporations issue CSR reports.

[176] SBA, "Frequently Asked Questions". https://www.sba.gov/sites/default/files/FAQ_Sept_2012.pdf
[177] Companies with fewer than 100 employees are usually considered small, while companies with 100-999 employees are medium-sized http://whatis.techtarget.com/definition/SMB-small-and-medium-sized-business-or-small-and-midsized-business
[178] Adapa, Sujana, and Jennifer Rindfleish, "Corporate Social Responsibility in Small and Medium Sized Accountancy Firms", *International Journal of Humanities and Management Sciences*, Vol. 1, Iss. 1, 2013. http://www.isaet.org/images/extraimages/IJHMS%200101220.pdf
[179] Cecil, Lianna, "Corporate social responsibility reporting in the United States" *McNair Scholars Research Journal*, Vol. 1, Iss. 1, 2010. http://commons.emich.edu/cgi/viewcontent.cgi?article=1006&context=mcnair
[180] Ibid.

# 5 Professional groups and associations in the R&I field

This chapter will provide a brief discussion of the role that professional associations play in R&I or the ethics assessment thereof.

## 5.1 National associations for R&D professions

A large number of national associations for R&D professions exist in the U.S., within a wide range of research oriented professions.[181] While some organisations focus on improving the career options of their members, others have a more integrative focus. These organisations are often larger and seek to, among other concerns, engage members in professional ethical issues. In addition, some associations develop codes of conduct. The following sets out some examples of associations for R&D professions that engage in ethics assessment.

- The *American Veterinary Medical Association* (AVMA) is an organisation representing more than 86,500 veterinarians. While seeking to advocate for its members, AVMA also plays an important role in ethics assessment with regard to animal research in the U.S. The members include professionals "[…] working in private and corporate practice, government, industry, academia, and uniformed services."[182] AVMA has a number of professional policies[183], including the *Principles of Veterinary Medical Ethics of the AVMA,* which all veterinarians are expected to follow[184].

For research, the AVMA has published the *AVMA Guidelines for the Euthanasia of Animals: 2013 Edition,*[185] which has been adopted widely in research environments (see section 2.3).

- The *American Society for Biochemistry and Molecular Biology* (ASBMB) is a scientific and educational organisation with more than 12,000 members. The organisation publishes three journals, carries out advocacy activities, as well as providing general support for professionals in biochemistry and molecular biology[186].

Among their other activities, ASBMB has also published a code of ethics which it expects its members to follow in order to ensure responsible practice of research. The code of ethics lists three groups to whom professionals are obligated - the public, other investigators and trainees - and specifies how these obligations are to be understood[187].

- The *American Society for Bioethics and Humanities* (ASBH) […] promotes the exchange of ideas and fosters multidisciplinary, interdisciplinary, and inter-professional scholarship, research, teaching, policy development, professional

[181] Wikipedia, "Medical associations based in the United States". http://en.wikipedia.org/wiki/Category:Medical_associations_based_in_the_United_States
[182] AVMA, "Who We Are". https://www.avma.org/About/WhoWeAre/Pages/default.aspx
[183] AVMA, "AVMA Policies". https://www.avma.org/KB/Policies/Pages/default.aspx
[184] AVMA, "Principles of Veterinary Medical Ethics of the AVMA". https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx
[185] Leary, Steven, et al, "AVMA Guidelines for the Euthanasia of Animals", American Veterinary Medical Association, 2013. https://www.avma.org/KB/Policies/Documents/euthanasia.pdf
[186] ASBMB, "About Us". http://www.asbmb.org/AboutUs/
[187] ASBMB, "Code of Ethics". http://www.asbmb.org/Page.aspx?id=70

development and collegiality among people engaged in clinical and academic bioethics and the medical humanities[188]."

- *Public Responsibility in Medicine and Research* (PRIM&R) is a non-profit organisation with more than 4,000 members. The mission of the organisation is to "[…] advance the highest ethical standards in the conduct of biomedical, behavioural, and social science research".[189]

PRIM&R accomplishes this by, for example, providing education to professionals who oversee research on human subjects and animals. They offer conferences and other sorts of programs to the professionals that staff IRBs, ethics committees and IACUCs.

- The *American Psychological Association* (APA) is a major organisation with nearly 130,000 members[190]. "The mission of the APA is to advance the creation, communication and application of psychological knowledge to benefit society and improve people's lives.[191]"Among other activities, APA has published the very comprehensive *Ethical Principles of Psychologists and Code of Conduct*. Membership of APA commits individuals to live up to the ethics code.[192] An amendment from 2010 stressed that the standards put forward should never be used to justify violations of human rights.[193]

- The *American Academy of Arts and Sciences* (AmAcad) is an honorary society in which peers nominate and elect members. AmAcad was established in 1780 and currently has a focus on four broad programs: Humanities, Art and Education; Science, Engineering and Technology; Global Security and International Affairs and American Institutions and the Public Good. Employing these programs AmAcad "[…] provides authoritative and nonpartisan policy advice to decision-makers in government, academia, and the private sector."[194]

## 5.2 National organisations for ethics assessors

A number of organisations can be identified as being exclusively for ethics assessors in a professional context. The following offers a brief description of three of these organisations.

- *The Health Care Compliance Association* (HCCA) is an association for compliance officers in healthcare, which provides training, certification and networking opportunities for its more than 10,000 members. This is also reflected in the mission of the association: "HCCA exists to champion ethical practice and compliance standards

[188] ASBH, "Purpose of ASBH". http://www.asbh.org/about/content/purpose-of-asbh.html
[189] PRIM&R, "Mission, Vision, & Values, Public Responsibility in Medicine and Research". http://www.primr.org/about/mission/
[190] APA, "Who We Are". http://www.apa.org/about/apa/index.aspx
[191] APA, "APA Strategic Plan". http://www.apa.org/about/apa/strategic-plan/default.aspx
[192] APA, "Ethical Principles of Psychologists and Code of Conduct". http://www.apa.org/ethics/code/index.aspx
[193] APA, "APA Amends Ethics Code to Address Potential Conflicts Among Professional Ethics, Legal Authority and Organisational Demands". http://www.apa.org/news/press/releases/2010/02/ethics-code.aspx
[194] - American Academy of Arts & Sciences, "About the Academy". https://www.amacad.org/content.aspx?i=104

and to provide the necessary resources for ethics and compliance professionals and others who share these principles."[195]

- The *Society of Corporate Compliance and Ethics* (SCCE) is a more broadly focused offspring of HCCA with nearly 5,000 compliance officers from a wide range of industries.[196] The mission of SCCE is "[…] to champion ethical practice and compliance standards and to provide the necessary resources for ethics and compliance professionals and others who share these principles."[197] Furthermore, SCCE provides certification, training materials and organises events for their members. In addition to other material, SCCE publishes a *Code of Professional Ethics for Compliance and Ethics Professionals*. This includes the minimum standard of conduct for compliance and ethics professionals.[198]

- The *Ethics & Compliance Association* (ECA) is exclusively "[…] for individuals responsible for their organisation's ethics, compliance, and business conduct programs."[199] Like SCCE, ECA has published *Standards of Conduct for Ethics and Compliance Professionals.*[200]

[195] HCCA - Health Care Compliance Association. http://www.hcca-info.org/
[196] SCCE. http://www.corporatecompliance.org/AboutSCCE/AboutSCCE.aspx
[197] Ibid.
[198] SCCE, "Code of Professional Ethics for Compliance and Ethics Professionals". http://www.corporatecompliance.org/Portals/1/PDF/Resources/SCCECodeOfEthics_English.pdf
[199] The Ethics and Compliance Officer Association. http://www.theecoa.org/imis15/ECOAPublic/ABOUT/ECOAPublic/AboutContent/ABOUT_THE_ECOA.aspx?hkey=e446751b-96ae-49ae-8b9d-aa387ef8a83b
[200] The Ethics and Compliance Officer Association, "Standards of Conduct for Ethics and Compliance Professionals". http://www.theecoa.org/iMIS15/Documents/Standards_of_Conduct.pdf?hkey=da9eee43-d890-4ab6-8fb9-c264e2ec5d8c

# 6 Civil Society Organisations

This chapter offers a discussion of the role in ethics assessment of R&I by civil society organisations (CSOs). First, the CSO landscape is discussed, and then the role of CSOs in ethics assessment is reviewed.

## 6.1 The CSO landscape

The following section provides a brief overview of the CSO landscape in the U.S., including examples of major CSOs and their societal role, with a special emphasis on possible research activities.

While the organisations have their headquarters in the U.S., many have activities in a great number of other countries as well. According to the U.S. Department of State, there are 1.5 million NGOs in the U.S.[201]; for this reason, it is not possible to create a complete picture of the activities of these organisations in this brief report.

### 6.1.1 National legislation and regulation for CSOs

Any group of individuals can form an NGO in the U.S., but to enjoy legal benefits, e.g., tax exemption, it has to be formally incorporated and registered according to the law of the relevant state.

Below we present major CSOs and outline their societal roles.

**Religious organisations**

The three largest religious congregations (according to membership) in the U.S. are Christian:

- *The Catholic Church*
- *The Southern Baptist Church*
- *The United Methodist Church*[202]

**Environmental organisations**

The following lists the three largest environmental organisations according to revenue.[203]

- *Nature Conservancy* – more than 600 scientists are on its staff and the organisation works "[…] to conserve the lands and waters on which all life depends."[204]

- *Wildlife Conservation Society* – 200 Ph.D. scientists are on staff,[205] who work "[…] to save wildlife and wild places across the globe."[206]

[201] U.S. Department of State, "Fact Sheet: Non-Governmental Organisations (NGOs) in the United States". http://www.humanrights.gov/wp-content/uploads/2012/01/factsheet-ngosintheus.pdf
[202] National Council of Churches USA. http://www.ncccusa.org/news/110210yearbook2011.html
[203] Forbes, "The 200 Largest U.S. Charities List: Environment/Animal – Forbes". http://www.forbes.com/lists/2011/14/200-largest-us-charities-11_rank-environment-animal.html
[204] The Nature Conservancy, "Vision & Mission". http://www.nature.org/about-us/vision-mission/index.htm?intc=nature.tnav.about.list

- *WWF United States* – WWF U.S. has scientists on staff [207] and funding external scientific research.[208]

**Civil liberties/human rights organisations**

- The *American Civil Liberties Union* (ACLU) – A major civil rights organisation with a focus on challenging suspected breaches of civil rights through the court system and creating new legislation.[209]

- *Human Rights First* – This organisation seeks to protect refugees, combat torture and defend persecuted minorities.[210]

**Consumer organisations**

- *The Consumer Federation of America* (CFA) – an overarching organisation for the advancement of consumer interests. This organisation seeks to meet its mission through research, advocacy and educational activities.[211]

- *Centre for Science in the Public Interest* (CSPI) – the goals of the organisation include providing objective information to the public and policymakers, by conducting "[…] *research on food, alcohol, health, the environment, and other issues related to science and technology."* [212]

- *Public Interest Research Group* (PIRG) – A consumer group whose methods include investigative research to counter "[…] the influence of big banks, insurers, chemical manufacturers and other powerful special interests."[213]

**Development (aid) organisations**

- *Food for the Poor, Inc.* (FFP) – The largest international relief and development organisation based in the U.S. The organisation is based on ecumenical Christianity.[214]

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[205] Wildlife Conservation Society, "Testimony of Kelly Keenan Aylward Washington Office Director, Wildlife Conservation Society Before the House Appropriations Subcommittee on Interior, Environment & Related Agencies March 18, 2015". http://docs.house.gov/meetings/AP/AP06/20150318/102895/HHRG-114-AP06-Wstate-AylwardK-20150318.pdf
[206] Wildlife Conservation Society. http://www.wcs.org/about-us.aspx
[207] World Wildlife Fund, "WWF Scientists and Science Staff". http://www.worldwildlife.org/pages/conservation-science-staff?_ga=1.245989252.1617900589.1427209165
[208] World Wildlife Fund, Inc., "Financial Statements and Independent Auditor's Report – Years Ended June 30, 2014 and 2013". http://assets.worldwildlife.org/financial_reports/23/reports/original/WWF_Non-A133_FS_-_June_03__2014_(S).pdf?1418328169&_ga=1.242496002.1617900589.1427209165
[209] American Civil Liberties Union. https://www.aclu.org/about-aclu
[210] Human Rights First, "About Us". http://www.humanrightsfirst.org/about
[211] The Consumer Federation of America, "Overview". http://www.consumerfed.org/about-cfa/overview
[212] Centre for Science in the Public Interest, "Mission Statement". http://www.cspinet.org/about/mission.html
[213] U.S. PIRG, "About Us". http://www.uspirg.org/page/usp/about-us
[214] Food For The Poor, "About Us". http://www.foodforthepoor.org/about/

**Animal rights organisations**

- *The Humane Society of the United States* (HSUS) – The largest animal protection organisation in the U.S. with a large number of employed scientists.[215]

**Science organisations**

- *The American Association for the Advancement of Science* (AAAS) – The work of the association includes the promotion of responsible science, increasing public engagement with science and protecting the integrity of science.[216]AAAS further publishes the renowned scientific journal *Science.*[217]

**Health organisations**

- *American Cancer Society* (ACS) – This organisation works towards eradicating cancer.[218]

**Minority organisations**

- *National Association for the Advancement of Colored People* (NAACP) – The focus of this organisation is the elimination of racism in the U.S.[219]

- *National Congress of American Indians* (NCAI) – This organisation seeks to protect and enhance the sovereign rights of native communities.[220]

### 6.1.2 CSOs as performers of R&I

As indicated above, many, but not all, CSOs fund or are otherwise involved with R&I. These organisations include environmental, consumer and science organisations, as well as patient disease groups that perform R&I, e.g., the American Cancer Society (ACS) that has spent more than $4 billion since 1946 on finding cures for cancer. This makes them, according to themselves, "[…] the largest nongovernmental funder of cancer research in the United States […]."[221]

**Funding sources for CSOs**

Funding for CSOs can stem from many sources. Some are either partly or entirely funded by the government. Examples of U.S. organisations that have received or are receiving funding

[215] The Humane Society of the United States, "About Us: Overview". http://www.humanesociety.org/about/overview/?credit=web_id93480558
[216] AAAS. http://www.aaas.org/about-aaas
[217] AAAS, "Science Journals". http://www.aaas.org/science-journals
[218] ACS, "ACS Fact Sheet". http://www.cancer.org/aboutus/whoweare/acs-fact-sheet
[219] NAACP, "Our Mission". http://www.naacp.org/pages/our-mission
[220] NCAI, "Mission and History". http://www.ncai.org/about-ncai/mission-history
[221] ACS, "How the American Cancer Society fights back through research". http://www.cancer.org/aboutus/howwehelpyou/about-us-research

from the government, include the American Association of Retired Persons[222], World Vision[223] and World Wildlife Fund.[224]

## 6.2 The role of CSOs in ethics assessment

This section will briefly discuss the roles of CSOs as stakeholders in public discussion, as participants in ethics assessment panels and procedures, and as agents who engage in ethics assessment.

### 6.2.1 CSOs as stakeholders in public discussion

The vast majority of the organisations presented above participate in public discussion as stakeholders. This includes specific debates relevant to the topic of this report, such as religious congregations' stand on stem cell research[225] or animal rights organisations positions on animal testing.[226] Their role in the public debate can be seen as mediator, conveying public concern to other stakeholders. Furthermore, CSOs seek to influence and change public opinion through publicity, information campaigns, and other activities. CSOs are therefore important in promoting certain value and moral stances, that can indirectly guide and influence assessment of R&I.

### 6.2.2 CSOs as participants in ethics assessment panels and procedures

American CSOs often participate in public hearings. More specifically, CSOs can be invited to participate directly in governmental assessments done through the NEPA legislation. This participation helps to facilitate open governmental decision-making, aimed at ensuring that "[…] agencies now operate under strong internal and external pressures to select and design projects from the start with an eye toward reducing their adverse environmental consequence."[227] Even though CSO participation in IRBs is possible, e.g., as specified in the IRB Resource Manual at the University of Southern California[228], no such instances have been identified in the empirical research carried out for this report.

### 6.2.3 CSOs as agents who engage in ethics assessment

In addition to the general legislative requirements already described (see section 2.3), CSOs can also engage in ethics assessment by developing specific requirements for scientific

[222] AARP, "Consolidated Financial Statements Together with Report of Independent Certified Public Accountants – AARP – December 31, 2013 and 2012". http://www.aarp.org/content/dam/aarp/about_aarp/annual_reports/2014-06/2013-Consolidated-Financial-Statements-AARP.pdf
[223] World Vision, Inc. and Affiliates, "Consolidated Financial Statements – September 30 2013 and 2014". http://www.worldvision.org/sites/default/files/pdf/2014-consolidated-financial-statements.pdf
[224] Folger, J., "Does the federal government fund any NGOs? Which ones?", *Investopedia*. http://www.investopedia.com/ask/answers/13/federal-government-fund-ngos.asp
[225] Pew Research Centre's Religion & Public Life Project, "Religious Groups' Official Positions on Stem Cell Research". http://www.pewforum.org/2008/07/17/religious-groups-official-positions-on-stem-cell-research/
[226] Humane Society International, "About Animal Testing". http://www.hsi.org/campaigns/end_animal_testing/qa/about.html
[227] Karkkainen, Bradley C., "Toward a smarter NEPA: monitoring and managing government's environmental performance", *Columbia Law Review*, 2002. p. 913.
[228] University of Southern California Office for the Protection of Research Subjects, "What it Takes to be an IRB Community Member". https://oprs.usc.edu/files/2013/05/Community-Member-Booklet-5.1.13.pdf

research. A specific example is the *American Association for the Advancement of Science* (AAAS). Within its Scientific Responsibility, Human Rights and Law Program (SRHRL) the association conducts a number of research projects that investigate social, ethical and legal issues of research. Other topics addressed by the SRHRL programme include stem cell research, inheritable human genetic modification and ethical issues associated with the advancement of information technology. The assessments done by SRHRL are primarily based on existing ethical principles or directives, for example, the Universal Declaration of Human Rights, and must advance the overall mission of the AAAS, to "Advance science, engineering, and innovation throughout the world for the benefit of all people."[229]

In general, the results of projects can be used by a wide variety of stakeholders, including universities, industry organisations, and government. A recent interviewee stated that the organisation, on occasion, also has assisted in the development of legislation. According to the SRHRL's homepage, this involvement is primarily indirect, e.g., through seminars for Members of Congress and judges[230].

Another important CSO in the U.S. involved with ethics assessment of research and innovation is the Hastings Centre. The Centre is an "independent, nonpartisan, and non-profit bioethics research institute founded in 1969. The Centre's mission is to address fundamental ethical issues in the areas of health, medicine, and the environment as they affect individuals, communities, and societies."[231]

Finally, the Wilson Centre is a prominent U.S. CSO involved in ethics assessment in relation to science and technology (although not its primary mission). The Wilson Centre was set up as a memorial to President Woodrow Wilson. It is a key non-partisan policy forum in the U.S. for tackling global issues through independent research and open dialogue. It has as its mission to form and inform actionable ideas for Congress, the Administration and the broader policy community.[232]

[229] AAAS, "About AAAS". http://www.aaas.org/about-aaas
[230] AAAS, The homepage for SRHRL is http://www.aaas.org/program/scientific-responsibility-human-rights-law "SRHRL Past Projects: Genetics. http://www.aaas.org/page/srhrl-past-projects-genetics
[231] The Hastings Center, "About us". http://www.thehastingscenter.org/About/Default.aspx?id=5009#ixzz3Yni2tpPn
[232] Wilson Center, "Mission and Vision Statement". http://www.wilsoncenter.org/mission-and-vision-statement

# 7 Discussion

The following chapter provides a discussion of findings concerning ethics assessment in the U.S. The chapter takes as it point of departure the report itself, while also incorporating points from a number of interviews carried out for the country study.

In 2011, the Office of Science and Technology Policy and the Department of Health and Human Services proposed changes to the Common Rule[233]. These changes are as follows: no requirement for annual review of research only presenting minimal risks to the subjects; one IRB is sufficient for a study conducted at multiple locations; and a requirement for informed consent if specimens are used from a non-research procedure (i.e., discarded tissue)[234]. Overall, these changes are focused upon modernising human subject research requirements[235].

Interesting aspects of the U.S. case are also visible in areas other than research concerning human subjects. Federally prescribed environmental and technology assessments also require particular attention. NEPA (see section 2.3), often described as a Magna Carta of environmental legislation[236], prescribes environmental impact assessment of major federal actions (e.g., building of bridges, major roads and other infrastructure projects). However, Lin (2010) finds the impact of NEPA small when compared with the lofty ambitions presented in the preamble of the Act (see section 2.3); it is only mandatory for major federal actions and the EIS is only seen as a procedural duty as opposed to creating a clear mandate for whether or not to commit to an action. These constraints in the importance of the Act are primarily due to juridical decisions of the Supreme Court.[237] Some see NEPA as a legislative result of the public outcry triggered by the Santa Barbara oil spill. [238]

While the Office of Technology Assessment (OTA) has been a model for similar organisations all over the world, the office was closed in 1995 (see chapter 1). This has led to the decentralisation of technology assessment in the U.S. The GAO, OSTP and NRC have partly taken over the responsibilities (see section 2.2). While a number of suggestions have been made for re-establishing OTA none has gained sufficient traction in Congress[239].

The U.S. has a tradition of free private enterprise, whereby companies should not be subjected to "too much" regulation. This is also evident for ethics assessment, where governmental ethical requirements can be considered as indirect – nonetheless the impact of legislation has

[233] See the Federal Register, Vol. 76 Iss. 143, 26 July 2011. http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm
[234] UCSF, "UCSF Human Research Protection Program". http://research.ucsf.edu/chr/Fed/OHRP_ANPRM.asp
[235] See the Federal Register, Vol. 76 Iss. 143, 26 July 2011. http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm
[236] Mandelker, Daniel R., "National Environmental Policy Act: A Review of Its Experience and Problems", *The Washington University Journal of Law & Policy*, Vol. 32, 2010. pp 293-312. http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1082&context=law_journal_law_policy
[237] Lin, Albert C., "Technology Assessment 2.0: Revamping Our Approach to Emerging Technologies", *Brooklyn Law Review*, Vol 76, Issue 4 2010, pp. 1-62. https://law.ucdavis.edu/faculty/lin/files/Technology-Assessment-2.0-Revamping-our-Approach-to-Emerging-Technologies.pdf
[238] Manheim, Frank T., *The Conflict over Environmental Regulation in the United States*, Springer, 2008, p. 44.
[239] Lin, op. cit., 2010.

been significant. This is the case for the Federal Sentencing Guidelines for Organisations (see section 4.1), which have led to the creation of ethics programs whereby companies receive lower penalties for violating the law. This carrot-and-stick methodology has meant that the guidelines have become the *de facto* standard for ethics programs, and are used in thousands of companies [240] (this is also evident in the number of corporate ethics assessors in the U.S., see section 5.2). According to Chandler (2014), "[…] the bulk of evidence to date indicates that the guidelines have had an influence on ethics programs that appear to lead to improved ethical behaviour in organisations." [241] Since their introduction in 1991, the guidelines have been revised a number of times, seemingly in order to strengthen the requirements for companies following the guidelines. [242] For universities, guidelines for ethics adopted by the NSF and the NIH, together with policies and procedures of the Office for Research Integrity (ORI), have been, and continue to be very influential.

Another example of federal legislation can be found in the Federal Acquisition Requirements, which stipulate ethical requirements for contractors to the U.S. Federal Institutions (see section 2.3). Lin (2010) suggests that companies in general have a strong incentive to further conduct health and safety assessments for technologies they develop, since they have a legal liability. In general, companies go beyond the legal requirements explicitly required by the law, for example, by being extra careful when assessing potential social environmental consequences. [243]

While some advances have been made in recent years to ensure that scientists look at the social desirability of their research, there is still a difference in this regard between Europe and the U.S.[244] In the interviews we conducted for this report, we also found that thinking of broader societal and environmental impacts as part of evaluating research and innovation has not yet become an integral part of the U.S. system. The term 'Responsible Research and Innovation' (RRI) is the EU umbrella term for approaching the evaluation and process of research with a mind to outcomes understood broadly (including environmental and societal concerns). In the U.S., RRI type research and thinking is mainly restricted to specific research centres, like the Centre for Nanotechnology in Society at Arizona State University or the Science, Technology Innovation Programme at the Wilson Centre, as well as scholars with the American Association for the Advancement of Science.

There is a wide variety of organisations in the U.S. that engage in activities that can be seen as ethics assessment of research and innovation. This is evident for institutions receiving government funding, for example, in the ethical requirements for conduct of primarily medical research involving human subjects. This includes the Common Rule mandating informed consent of the participants of research projects and the creation of IRBs. It is further evident in

[240] Schwartz, Mark S. "Federal Sentencing Guidelines for Organisations" "Business and Corporate Integrity", in Robert C. Chandler (ed.), *Business and Corporate Integrity*, Praeger, 2014, pp. 157-180.
[241] Ibid, p. 171.
[242] Schwartz, op. cit., 2014, pp. 157-180.
[243] Lin, op. cit., 2010,
[244] See also this exploratory study by Wyndham et al. (2015), which confirms the difference in emphasis on 'social responsibility' between Europe and North America. 'http://www.aaas.org/sites/default/files/AAAS%20Social%20Responsibility%20Questionnaire%20Report_A%20Preliminary%20Inquiry.pdf

the number of requirements stipulated by the NIH in their highly developed procedures for giving research grants: a careful balancing is carried out between the public good that can be gained from a project and the risks to which research participants are exposed. The legislative requirements for human subject research are in general seen as the outcome of a number of ethically questionable research projects, including the Tuskegee syphilis experiment (1932-1972), the Milgram Experiment (1961) and a number of radiation experiments.[245] We also learned from the interviews that the U.S. generally follows a reactive approach to ethical issue on science and technology. This attitude seems to be a cultural characteristic of the U.S., where there is a strong belief in the autonomous development of science and technology. In general, Americans are strongly opposed to state intervention, in general, and in research and developmental activities specifically, and treasure individual and property rights. According to an interviewee, individual rights are often considered as superior compared to other rights, especially concerning social justice issues. The particular cultural characteristic of the U.S has historic roots, and is particularly evident in the U.S. Bill of Rights[246]. Another particular characteristic of the U.S. debate on science and technology is the role of and controversy surrounding religion and religious values in (public) debates. One example is the discussion surrounding the regulation of stem cell research.

In ethics assessment, the Belmont report and its principles are highly influential. Apart from that, assessors primarily focus on their own experience when doing ethical assessments. This is also evident in number of the interviews in which the interviewees reported that they did not have a standardised method for conducting assessments. The U.S. places great emphasis on ethical aspects of human subjects' research. However, the U.S. is one of the few developed countries that do not have a standing bioethics commission. The intertwined nature of governmental bioethics assessment with political developments is also a defining characteristic of ethics assessment in the U.S. Finally, the landscape of large, influential CSOs like the AAAS, the Hastings Centre, and influential private university centres like the Kennedy Institute of Ethics at Georgetown University, the department of Bioethics as Harvard Medical School, and the John Hopkins Berman Institute of Bioethics are a defining feature of the U.S landscape. These are centres that sit apart from government, but exercise considerable influence on public and political opinion.

[245] Subcommittee on Energy Conservation and Power of the Committee on Energy and Commerce U.S. House of Representatives, "American nuclear guinea pigs: three decades of radiation experiments on U.S. citizens", Congressional Hearings. http://contentdm.library.unr.edu/cdm/singleitem/collection/conghear/id/102#metajump
[246] US Congress, "The U.S. Constitution & Amendments: The Bill of Rights". https://www.constitutionfacts.com/content/constitution/files/Constitution_BillOfRights.pdf