Ethics Assessment in Different Countries

United Kingdom

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

1. Introduction

This report offers an analysis of the existing structures and agents for the ethical assessment of research and innovation in the UK, both for the public and the private sector. It sets out 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).

The report has been compiled using data gathered from public sources such as organisational websites, books, and articles. The discussion section draws some insights from some of the SATORI stakeholder interviews.

1.1. Basic information about the UK

The United Kingdom (UK) is made up of Scotland, England, and Wales, together with Northern Ireland. Scotland, England, and Wales are also jointly referred to as Great Britain. London is the capital city and is one of the world's leading commercial, financial, and cultural centres.[1] Other major cities include Birmingham, Liverpool, Manchester in England, Belfast and Londonderry in Northern Ireland, Edinburgh and Glasgow in Scotland, and Swansea and Cardiff in Wales. The UK is a constitutional monarchy with two legislative houses (House of Lords) and the House of Commons. Queen Elizabeth II is the head of the State and the head of government is the Prime Minister.

According to the UK Office for National Statistics (ONS), the population of the UK grew to 64.1 million in mid-2013.[2] The estimated populations of the four constituent countries of the UK in mid-2013 were 53.9 million (growth of 0.70%) in England, 5.3 million (growth of 0.27%) in Scotland, 3.1 million (growth of 0.27%) in Wales and 1.8 million (growth of 0.33%) in Northern Ireland.[3] The UK Office for National Statistics (ONS) reports that in March 2011 "the Census showed that 49.8 million (92.3 per cent) of people aged three and over reported English (English or Welsh in Wales) as their main language".[4] 4.2 million people (7.7 per cent) reported another main language. Polish was the most popular 'Other' main language with 546,000 people reporting this as their main language (1.0 per cent of the total population). Welsh is an officially recognised language in Wales. Scottish Gaelic, sometimes referred to as Gaelic, is a Celtic language native to Scotland.

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[1] Chaney, William A., "United Kingdom", *Encyclopaedia Britannica,* Last Updated 23 March 2015. http://www.britannica.com/EBchecked/topic/615557/United-Kingdom

[2] Office for National Statistics, "Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2013", 26 June 2014. http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html

[3] Growth relative to 2012. Ibid.

[4] Office for National Statistics, "Language in England and Wales, 2011", 4 March 2013. http://www.ons.gov.uk/ons/rel/census/2011-census-analysis/language-in-england-and-wales-2011/rpt---language-in-england-and-wales--2011.html

1.2. Major economic sectors and industrial development

According to the World Fact Book, "The UK, a leading trading power and financial center, is the third largest economy in Europe after Germany and France. Over the past two decades, the government has greatly reduced public ownership".[5] The World Fact Book also reports,

> Agriculture is intensive, highly mechanized, and efficient by European standards, producing about 60% of food needs with less than 2% of the labor force. The UK has large coal, natural gas, and oil resources, but its oil and natural gas reserves are declining and the UK became a net importer of energy in 2005. Services, particularly banking, insurance, and business services, are key drivers of British GDP growth. Manufacturing, meanwhile, has declined in importance but still accounts for about 10% of economic output.[6]

1.3. R&D expenditure

According to the UK Office for National Statistics (ONS),[7]

- In 2013, total expenditure on Research and Development (R&D) performed in UK businesses, in current prices, increased by 8% to £18.4 billion compared with 2012. In constant prices, R&D expenditure increased by 6% compared with 2012.
- Civil R&D expenditure increased by 8% in 2013 to £16.7 billion while Defence R&D expenditure increased by 7% in 2013 to £1.7 billion.
- In 2013, expenditure on R&D performed in UK foreign owned businesses increased by 11% and constituted 54% of total expenditure.
- Business R&D expenditure in 2013 represented 1.1% of Gross Domestic Product (GDP).
- In 2013, total business employment in R&D in the UK increased by 11% to 178,000 Full Time Equivalents (FTE), the largest annual increase since 1985.

The UK is one of the five permanent members of the UN Security Council and a founding member of NATO and the Commonwealth. It pursues a global approach to foreign policy. The UK is an active member of the EU, although is not part of the Economic and Monetary Union.[8]

1.4. General picture of ethics assessment of R&I in the country

As regards ethics assessment of R&I, there is no single coordinated approach. Instead, the UK system tends to be rather *ad hoc* in nature, in the sense that there is no national bioethics commission that people can turn to, rather there are committees for distinct areas such as gene therapy where people can request advice and a wide, distributed set of organisations that give their opinion and provide advice on work. The most systematic approach is that of the Health Research Authority[9] which coordinates research ethics committees for the purposes of health research. Notwithstanding this *ad hoc* approach, the UK has a very well developed sensibility around ethics and science and medicine. Most universities have their own ethical

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[5] Central Intelligence Agency (CIA), "UK, The World Factbook". https://www.cia.gov/library/publications/the-world-factbook/geos/uk.html

[6] Ibid.

[7] Office for National Statistics, "Business Enterprise Research and Development, 2013", 20 November 2014. http://www.ons.gov.uk/ons/rel/rdit1/bus-ent-res-and-dev/2013/index.html. For 2012 figures see: http://www.ons.gov.uk/ons/rel/rdit1/gross-domestic-expenditure-on-research-and-development/2012/stb-gerd-2012.html

[8] CIA, UK, "The World Factbook". https://www.cia.gov/library/publications/the-world-factbook/geos/uk.html

[9] http://www.hra.nhs.uk/

approval system and while they will have some features in common, they can all operate independently. Moreover, the *Concordat to Support Research Integrity*[10] facilitates sector-wide guidance for universities and commits institutions funded by the UK higher education funding councils to comply with the commitments set out in the concordat. Socio-ethical analysis is a well-established component of most official processes of science and technology (S&T) decision-making.[11] Departments in the government that deal with S&T developments (the majority) will normally have an advisory structure dedicated to socio-ethical analysis.[12] There is no single institution in the S&T governance structure that could be considered a National Ethics Committee.[13] Instead, there are a number of organisations that are concerned with the ethics of specific S&T fields, e.g. the Gene Therapy Advisory Committee (GTAC)[14] and the former Human Genetics Commission,[15] a non-departmental body which advised the UK government on the social and ethical aspects of genetics. The closest equivalent to a national ethics committee is the Nuffield Council on Bioethics[16]; indeed Nuffield Council participates as the UK representative in the Forum of National Ethics Councils (NEC Forum) of the European Union.[17]

Major R&D companies in the UK engage in ethics assessment in a variety of ways encompassing corporate social responsibility, 'responsible business', 'open innovation' and environmental policies. Civil society organisations (CSOs) vary in the degree to which they are involved in ethics assessment; some organisations carry out some form of ethics assessment or implement ethics considerations in their research programmes, while others encounter ethics in the course of carrying out their mandate, and associated work. Some CSOs also provide ethical guidance and input into ethical reviews by other organisations.

From 2000, initiatives to involve the public in discussions about the future of science and technology were implemented in the UK following controversies around Bovine spongiform encephalopathy (BSE) or "mad cow disease" and genetically modified (GM) foods[18]. Notwithstanding early (and persistent) criticism of public dialogue initiatives, particularly regarding the widespread view that many important decisions had already been made prior to getting publics involved,[19] these moves led to an enhanced role for public engagement exercises in the governance of science and technology in the UK. More recently, the notion of 'responsible innovation' has gained increasing attention and includes societal actors and publics as key stakeholders in a 'responsible' approach to research and innovation. In the last few years, UK academics and funders have played an important role in advancing this notion by elaborating on the components of a framework for responsible innovation[20] and

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[10] http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

[11] http://www.uclan.ac.uk/research/explore/projects/assets/cpe_gest_D1_1.pdf

[12] Ibid.

[13] http://www.uclan.ac.uk/research/explore/projects/assets/cpe_gest_D1_1.pd

[14] http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/

[15] http://webarchive.nationalarchives.gov.uk/20100419143351/http://hgc.gov.uk/client/content.asp?contentid=5

[16] Systems in other countries tend to be more centralised, e.g. the French have a national consultative committee on ethics, which is very structured and driven from the centre.

[17] https://www.bka.gv.at/site/6806/default.aspx

[18] Sykes, K., and P. Macnaghten, "Responsible Innovation - Opening Up Dialogue and Debate", in Richard Owen, John Bessant and Maggy Heintz (eds.), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, John Wiley & Sons Ltd., 2013, pp. 85-104.

[19] Ibid.

[20] Stilgoe, J., R. Owen, and P. Macnaghten, "Developing a framework for responsible innovation", *Research Policy,* Vol. 42, No. 9, 2013, pp. 1568-1580.

incorporating responsible innovation as a component in funding requirements, as the Engineering and Physical Sciences Research Council has done. [21]

1.5. A brief history of ethics assessment in the country

The history of ethics assessment in the UK is not straightforward (and is difficult to elaborate as it has not been formally documented). One university suggests the changes in the ethical review landscape in academic social science have been driven by "broad social changes, including increased public expectation of transparency and accountability from institutions".[22]

There are a number of events/landmarks in the ethical assessment landscape in the UK that are significant from a historical perspective. One of the first significant events was the formal establishment of research ethics committees (RECs) in the National Health Service (NHS) in England in 1991, following the publication of Department of Health guidance HSG(91)5 (or the 'The Red Book').[23] Multi-centre research ethics committees were established in 1997, following publication of the Department of Health guidance HSG (97)23.[24] The adoption of the Human Rights Act in 1998 gave further effect to rights and freedoms guaranteed under the European Convention on Human Rights. The Central Office for Research Ethics Committees (COREC) was established in 2000. The Governance Arrangements for NHS Research Ethics Committees (GAfREC) were published in July 2001.

In 2004, The National Research Ethics Service (NRES) provided a single UK-wide ethical opinion, following the implementation of version 1.0 of the Standard Operating Procedures for RECs in the UK on 1 March 2004. The EU Clinical Trials Directive 2001/20/EC was adopted on 1 May 2004 through the regulations on clinical trials, which stimulated debate on good practice and risk based regulatory processes.

In 2005, the Department of Health revised the 'Research Governance Framework for Health and Social Care'. In the same year, the ESRC published the 'Research Ethics Framework'; this was revised in 2010, updated in 2012 and is now called the ESRC Framework for Research Ethics (FRE). The UK Research Integrity Office (UKRIO) was established in 2006 and the NRES on 1 April 2007 (incorporating the COREC and the NHS RECs in England).

In September 2011, GAfREC were revised and published to take account of legal, policy and operational developments since 2001. The Health Research Authority (HRA) was established on 1 December 2011 as a Special Health Authority, with NRES at the core of this NHS organisation.

In 2012, the UK government, Universities UK, Research Councils UK, the National Institute for Health Research, the Wellcome Trust and other key stakeholders developed the

[21] http://www.epsrc.ac.uk/index.cfm/research/framework/

[22] University of Lancaster, "Ethical Review Processes". https://www.lancaster.ac.uk/researchethics/2-2-background.html

[23] http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandguidance/Browsable/DH_088297

[24] Department of Health, HSG (97)23: Ethics Committee Review of Multi-Centre Research Establishment of multi-centre research ethics committee, 1997.
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018331

Concordat to support research integrity which seeks to provide a comprehensive national framework for good research conduct and its governance.[25]

2. National and regional government institutions and policies

This section focuses on the national and regional government institutions and policies in the UK. It looks at the institutional structure of government including the government organisations relevant to research and innovation. This section offers a discussion of the Governmental institutions for ethics assessment. It also outlines some of the major national laws, policies and regulations relating to ethics assessment and related activities. Finally, it discusses regional institutions and policies.

2.1. Institutional structure of government

The UK is a unitary democracy governed within the framework of a constitutional monarchy; this includes a Monarch who is head of State (currently Queen Elizabeth II) and the Prime Minister who is the head of government.[26] Executive power is exercised by Her Majesty's Government, on behalf of, and by consent of the Monarch, as well as by the devolved national governments.[27] Legislative power is vested in the two chambers of the Parliament of the United Kingdom, the House of Commons (democratically elected house of Parliament) and the House of Lords (independent from, and complementary to the House that comprises appointed members),[28] as well as in the Scottish parliament and Welsh and Northern Ireland assemblies. The judiciary is independent of the executive and the legislature. The highest court is the Supreme Court.[29] The UK has an uncodified constitution comprising constitutional conventions, statutes and other elements such as EU law. The UK is also responsible for several dependencies, which fall into two categories: the Crown dependencies, in the immediate vicinity of the UK, and British Overseas Territories, which originated as colonies of the British Empire.

The UK does not have a single legal system due to it being created by the political union of previously independent countries with the terms of the Treaty of Union guaranteeing the continued existence of Scotland's separate legal system. The UK has three distinct systems of law: English law, Northern Ireland law and Scots law. Constitutional changes led to the establishment of a new Supreme Court of the United Kingdom in October 2009. The Supreme Court is the final court of appeal for all UK civil cases, and criminal cases from England, Wales and Northern Ireland. It hears appeals on arguable points of law of general public importance and concentrates on cases of the greatest public and constitutional

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[25]http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

[26] Wikipedia: The Free Encyclopedia, "Politics of the United Kingdom". http://en.wikipedia.org/wiki/Politics_of_the_United_Kingdom

[27] Devolved national authorities are the Scottish Government, the Welsh Assembly Government and the Northern Ireland Executive.

[28] http://www.parliament.uk/about/how/role/system/

[29] The Supreme Court. https://www.supremecourt.uk/index.html

importance. It also maintains and develops the role of the highest court in the UK as a leader in the common law world.[30]

Government organisations relevant to research and innovation

There are a number of government departments and agencies that are relevant to research and innovation and exemplify the role of the government in R&I (regulatory, policy-making, guidance, funding). The following ministerial departments are relevant: The Department for Business, Innovation & Skills (BIS), Department for Culture, Media & Sport (DCMS) Department for Education, Department for Environment, Food & Rural Affairs, Department of Energy & Climate Change (DECC), and the Ministry of Defence. Non-ministerial departments relevant to research and innovation include: Food Standards Agency, Office for Standards in Education (Ofsted), Children's Services and Skills, The Office of Qualifications and Examinations Regulation (Ofqual) which regulates qualifications, examinations and assessments in England and vocational qualifications in Northern Ireland. There are also a number of other R&I relevant government agencies and public bodies,[31] 'high-profile' groups[32] and public corporations such as the BBC, Channel 4 and the Office for Nuclear Regulation.

2.2. Governmental institutions for ethics assessment

This section examines key governmental institutions with a role in the ethical review of research, in relation to: animals in research & testing, environment, food safety, health, defence, other (includes an organisation that examines and reports on ethical issues), and impact assessment.

Animals in research & testing

The Home Office issues licences under the Animals (Scientific Procedures) Act 1986 and authorises (a) projects involving the use of animals in research and testing, (b) those who carry out scientific procedures on animals and (c) the places where scientific procedures are carried out.[33]

The Home Office **Animals in Science Regulation Unit (ASRU)** plays an "essential role in overseeing the rigorous and proper regulation of animals involved in science".[34] ASRU is responsible for regulating the operation of the Animals (Scientific Procedures) Act 1986 (ASPA). **The Animals in Science Committee (ASC)** is an independent, non-executive, non-departmental public body convened by sections 19 and 20 of ASPA (as amended).[35] It was established by the Home Office on 1 January 2013 and replaced the Animals in Procedures Committee (APC). The ASC is responsible for providing impartial, balanced and objective

[30] The Supreme Court, "Role of the Supreme Court". https://www.supremecourt.uk/about/role-of-the-supreme-court.html

[31] For a comprehensive listing see: https://www.gov.uk/government/organisations

[32] E.g. Defence Infrastructure Organisation, Infrastructure UK, Office for Life Sciences, UK Trade & Investment Defence & Security Organisation, UKTI Education and the UKTI Life Sciences Organisation.

[33] Home Office, *Ensuring research and testing using animals is safe and reasonable*, Policy, 26 March 2013. https://www.gov.uk/government/policies/ensuring-research-and-testing-using-animals-is-safe-and-reasonable

[34] Home Office, Animals in Science Regulation Unit Annual Report 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328607/asru-annual-report-2013.pdf [quote by Norman Baker MP Minister of State]

[35] Ibid.

advice to Ministers on issues relating to the 1986 Act. The ASC also reviews project licence applications received by ASRU that involve the highest level of permissible harm (severe procedures) and involve one or more of the specially protected species.

Environment

Animal and Plant Health Agency (APHA)

The APHA, an executive agency, sponsored by the Department for Environment, Food & Rural Affairs, works to safeguard animal and plant health for the benefit of people, the environment and the economy.[36] The APHA is the result of the merging of the former Animal Health and Veterinary Laboratories Agency (AHVLA) with parts of the Food and Environment Research Agency (FERA)[37] responsible for plant and bee health to create a single agency responsible for animal, plant and bee health.

Food safety and hygiene

The Food Standards Agency (FSA)

The FSA is an independent government department responsible for food safety and hygiene across the UK that works with businesses to help them produce safe food, and with local authorities to enforce food safety regulations.[38] It values are: putting the consumer first, openness and transparency, science and evidence-based, acting independently and enforcing food law fairly.[39] The FSA is led by a Board appointed to act in the public interest. It does not represent particular sectors. The FSA represents the UK Government on food safety and standards issues in the European Union

Health

The key agencies operating in this area are briefly introduced.

The **Human Fertilisation and Embryology Authority (HFEA)** is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research.[40] The **Human Tissue Authority (HTA)** is a regulator created by Parliament in 2005 as an executive agency of the Department of Health, and is overseen by an Authority of lay and professional members appointed by the Government.[41] It regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public and also gives approval for organ and bone marrow donations from living people. The **Medicines and Healthcare products Regulatory Agency (MHRA)** (an executive agency of the Department of Health) regulates medicines and medical devices in the UK.[42] The **National Health Service (NHS) Health Research Authority (HRA)** protects and promotes the interests of patients and the public in health

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[36] https://www.gov.uk/government/organisations/animal-and-plant-health-agency/about
[37] On 1 April 2015 the business and operations of the Food and Environment Research Agency (Fera), an Executive Agency of Defra, transferred to Fera Science Limited (FSL), a Joint Venture (JV) between Defra and Capita. Their website is at www.fera.co.uk.
[38] http://www.food.gov.uk/about-us
[39] http://www.food.gov.uk/about-us/about-the-fsa
[40] HFEA. http://www.hfea.gov.uk/index.html
[41] HTA, "About us". https://www.hta.gov.uk/about-us
[42] MHRA. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

research, streamlines the regulation of research and is responsible for a wide range of projects to streamline research, and provides Integrated Research Application System (IRAS)[43] on behalf of IRAS partners.[44] It is also responsible for Research Ethics Committees (RECs),[45] the Gene Therapy Advisory Committee[46] and the Confidentiality Advisory Group (CAG),[47] which advises on Section 251 of the NHS Act (2006).[48]

According to the HRA, NHS Research Ethics Committees consist of up to 18 members (lay and professional)[49] who safeguard the rights, safety, dignity and well-being of research participants, independently of research sponsors. They "review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical"[50]. RECs are entirely independent of research sponsors, funders and investigators. Each year, RECs review around 6,000 research applications. There are currently more than 80 RECs across the UK.[51] RECs review a wide range of research, including research that falls into one or more of the following categories:[52]

- clinical trials of investigational medicinal products (CTIMPs), apart from phase 1 CTIMPs in healthy volunteers. (Selected RECs can review Phase 1 trials in healthy volunteers; our Central Booking Service (CBS) can identify agenda slots at meetings of these NHS Type 1 RECs)
- research involving medical devices;
- research involving prisoners;
- research involving adults lacking capacity;
- establishment of research tissue banks;
- projects funded by the US Department of Health and Human Services (DHHS);
- establishment of research databases.

The **United Kingdom Ethics Committee Authority (UKECA),** as outlined in the Medicines of Human Use (Clinical Trials) Regulations 2004, is responsible for establishing, recognising and monitoring ethics committees in the UK, in accordance with the Regulations. The UKECA consists of: (a) the Secretary of State for Health; (b) the National Assembly for Wales; (c) the Scottish Ministers; and (d) the Department for Health, Social Services and

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[43] The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. See https://www.myresearchproject.org.uk/

[44] HRA, "About the HRA". http://www.hra.nhs.uk/about-the-hra/

[45] HRA, "Research Ethics Committees". http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/

[46] HRA, "Gene Therapy Advisory Committee (GTAC)". http://www.hra.nhs.uk/about-the-hra/our-committees/gtac/

[47] CAG provides independent expert advice to the HRA (for research applications) and the Secretary of State for Health (for non-research applications) on whether applications to access patient information without consent should or should not be approved. Using CAG advice as a basis, the HRA or Secretary of State takes the final approval decision. See http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/

[48] Section 251 was created to enable the common law duty of confidentiality to be overridden to enable disclosure of confidential patient information for medical purposes, where it was not possible to use anonymised information and where seeking consent was not practical, having regard to the cost and technology available. See:http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/what-is-section-251/#sthash.OxVgdEQu.dpuf

[49] HRA, "Research Ethics Committees". http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/#sthash.SX2Euoef.dpuf

[50] Ibid.

[51] HRA, "Research Ethics Committees". http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/#sthash.SX2Euoef.dpuf

[52] Ibid

Public Safety for Northern Ireland.[53] The Authority may establish ethics committees to act for the entire UK or for designated areas; and in relation to such descriptions or classes of clinical trials, as it considers appropriate.[54] It may also by a notice in writing, recognise a committee as an ethics committee[55] and revoke recognition of an ethics committee if prescribed conditions are not met.[56]

Defence

In the defence sector, the **Ministry of Defence Research Ethics Committee (MODREC)** ensures that all research involving human participants undertaken, funded or sponsored by the Ministry of Defence (MOD) meets nationally and internationally accepted ethical standards.[57] The *Ministry of Defence Research Ethics Committees (MODREC) Terms of Reference* state that MODREC "should scrutinise the ethical implications of all submitted protocols for all research involving human participants, undertaken, funded or sponsored by the MOD".[58] It "should ensure that all policies, considerations, standards and safeguards as described or intended by JSP 536 and associated guidelines are applied appropriately, for the purpose of safeguarding the rights, dignity and welfare of people participating in research".[59] The MOD Joint Service Publication 536 details the instructions for the ethical conduct and treatment of human participants in MOD research (both clinical and non- clinical) and the process of achieving ethical approval for research.[60]

Other

The Nuffield Council on Bioethics[61] is an independent body that examines and reports on ethical issues in biology and medicine. In response to concerns that there was no government-sponsored national body responsible for overseeing developments in biomedicine and biotechnology, it was established by the Trustees of the Nuffield Foundation in 1991 and has been funded jointly by the Foundation, the Wellcome Trust and the Medical Research Council since 1994.[62] Its terms of reference include: identifying and defining ethical questions raised by advances in biological and medical research in order to respond to and anticipate them; making arrangements for examining and reporting on such questions, and publishing reports and representations. The Council meets regularly with the UK Department of Health to exchange information about current and future work.[63]

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[53] Section 5 (1) of the Medicines of Human Use (Clinical Trials) Regulations 2004.
[54] See section 6 of the Regulations.
[55] Section 7 of the Regulations.
[56] Section 8 of the Regulations.
[57] https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees
[58] Ministry of Defence, *MODREC Terms of Reference: Research Ethics Committees*, 2006. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/325461/modrec_tors.pdf
[59] Ibid.
[60] Ministry of Defence, *Joint Service Publication 536 Ministry of Defence Policy for Research Involving Human Participants*, Version 2.0, May 2014.
[61] Nuffield Council on Bioethics. http://nuffieldbioethics.org/
[62] Nuffield Council on Bioethics, "What is the Council's position in the UK policy framework". http://nuffieldbioethics.org/about/how-council-works/councils-position-uk-policy-framework/
[63] Ibid.

Impact assessment

Information Commissioner's Office (ICO)

The ICO is the UK's independent authority whose mission is to "uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals".[64] The legislation it covers includes the Data Protection Act 1998, Freedom of information Act 2000, the Privacy and Electronic Communications Regulations, Environmental Information Regulations, and the INSPIRE Regulations 2009.[65] The ICO maintains a register of data controllers; handles concerns relating to areas within its remit; takes various actions to enforce data protection,[66] privacy of electronic communications, freedom of information; and performs international duties. The ICO works with organisations to improve their processing of personal data in a number of ways. The ICO does not perform privacy impact assessment (PIA), rather provides guidance for organisations to perform privacy impact assessments.

2.3. National laws and policies for ethics assessment

This section outlines some of the major national laws, policies and regulations relating to ethics assessment and related activities.

The *ESRC Research Ethics Guidebook*, designed as a resource for social science researchers, highlights a number of UK laws as relevant.[67] Notable amongst these are the: Data Protection Act 1998, Human Rights Act 1998, Mental Capacity Act 2005, National Health Service Act 2006, Protection of Vulnerable Groups (Scotland) Act 2007, Safeguarding Vulnerable Groups Act 2006 and the Adults with Incapacity (Scotland) Act 2008.

The use of laboratory animals in the UK has been subject to special controls in the UK since 1876;[68] the Animals (Scientific Procedures) Act 1986 (ASPA)[69] expanded these and now along with the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 regulate the use of animals used for research in the UK. UK animal welfare controls are deemed to be the "strictest in the world".[70]

In relation to clinical trials, the Medicines for Human Use (Clinical Trials) Regulations 2004 aim to protect the rights, safety and well-being of research participants and to simplify and harmonise regulatory processes, and applies to trials designed to generate information on the efficacy or safety of medicines.

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[64] https://ico.org.uk/about-the-ico/our-information/mission-and-vision/

[65] https://ico.org.uk/about-the-ico/what-we-do/

[66] e.g. information notices, issuing undertakings, serving enforcement notices and 'stop now' orders, conducting consensual assessments (audits) to check organisations are complying, serving assessment notices to conduct compulsory audits to assess whether organisations processing of personal data follows good practice, issuing monetary penalty notices, prosecuting those who commit criminal offences under the Act; and reporting to Parliament on issues of concern. See https://ico.org.uk/about-the-ico/what-we-do/taking-action-data-protection/

[67] ESRC, *The Research Ethics Guidebook: A Resource for Social Scientists*, http://www.ethicsguidebook.ac.uk/

[68] 1876 Cruelty to Animals Act and the 1911 Protection of Animals Act. See UK House of Lords, *Select Committee on Animals In Scientific Procedures Report*, 2002. http://www.publications.parliament.uk/pa/ld200102/ldselect/ldanimal/150/15004.htm

[69] It has been revised to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes.

[70] http://www.understandinganimalresearch.org.uk/how/regulation/

The use of human samples is regulated by the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006.

Other important statutory instruments applicable to ethics in the medical and healthcare sector include: Health Service (Control of Patient Information) Regulations 2002, Ionising Radiation (Medical Exposure) Regulations 2002, Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010, Independent Health Care Regulations (Northern Ireland) 2005, Nursing and Midwifery Council (Midwives) Rules Order of Council 2004[71], Residential Care Homes Regulations (Northern Ireland) 2005[72], the Medical Devices Regulations 2002, and the Independent Health Care (Wales) Regulations 2011.

The law in the UK prescribes a review by an NHS Research Ethics Committee in certain situations e.g. adults lacking capacity to consent for themselves, disclosure of protected information from HFEA register, exposure to ionising radiation, human tissue, investigational medical devices, investigational medicinal products, practising midwives, private and voluntary health care, processing confidential patient information without consent, residential care homes, nursing homes, independent health care clinics.[73]

Laws and frameworks governing research ethics committees

In the UK, there is not one specific item of legislation governing research ethics committees. The UK Health Department's *Governance arrangements for research ethics committees* (GAfREC)[74] policy document describes what is expected from the research ethics committees that review research proposals relating to areas of the UK Health Departments' responsibility. It also elaborates on the need for review by these committees. Further, the policy covers the principles, requirements and standards for research ethics committees, including their remit, composition, functions, management and accountability. It also describes the Research Ethics Service in which the research ethics committees operate and the review they provide. Where a research study does not require review by a research ethics committee within the Research Ethics Service under the policy, review may be undertaken by research ethics committees established by universities or other institutions. The *ESRC's Framework for Research Ethics* sets out principles, requirements and standards for university committees that are compatible with those set out in GAfREC.

Laws and policies for higher education

The Higher Education Act 2004 makes provision for the setting up of the Arts and Humanities Research Council, and the funding of arts and humanities research. The Act also deals with the review of student complaints.[75] Further, it permits institutions to charge

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[71] Clinical trials involving practicing midwives anywhere in the UK require ethical approval by a REC.

[72] Ethical approval is required for any research involving residents (or information about residents) at a residential care home in Northern Ireland).

[73] http://www.hra.nhs.uk/resources/research-legislation-and-governance/legal-requirements-for-research-ethics-review/#sthash.fVKjYtu6.dpuf

[74] Department of Health, *Governance arrangements for research ethics committees, A harmonised edition*, May 2011. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf

[75] Section 13 of the Act gives the Secretary of State and the National Assembly for Wales the power to designate a body corporate that operates a student complaints scheme for England or Wales respectively. The scheme must provide for the review of qualifying complaints as defined by section 12. These are complaints against qualifying institutions which are made by individuals as students or former students at those institutions

variable fees and, providing they have an approved plan, fees above a basic rate. It also provides for the appointment of a Director of Fair Access to Higher Education.

Laws and policies for industry

The Companies Act 2006 regulates companies and other forms of business organisation. In particular, it prescribes the fundamentals of what a company is, how it can be formed and what it can be called, how companies can make decisions, safeguards for ensuring that the officers of a company are accountable to its members, company reconstructions, mergers and takeovers, overseas disqualification of directors, business names and statutory auditors, transparency obligations etc.

The Enterprise Act 2002, inter alia, creates offences for those entering into certain anti-competitive agreements and provides for the disqualification of directors of companies engaging in certain anti-competitive practices etc. The UK Bribery Act 2010 reformed the UK's anti-corruption laws and includes provisions about offences relating to bribery (both in the public and private sectors).

Consumer protection legislation is also relevant to industry. Consumer rights are protected by the Consumer Rights Act 2015. The Consumer Protection (Amendment) Regulations 2014 enable consumers to take action to seek redress when they have been victim of a misleading or aggressive commercial practice by a trader. The instrument introduces standard remedies and an entitlement to seek damages on falling victim to these practices.

Various pieces of legislation regulate the environmental impacts of industries. For example, the Clean Air Act 1993 regulates smoke emissions and commercial furnaces. Moreover, the Environmental Permitting (England and Wales) Regulations 2010 provide industry, regulators and others with a single extended permitting and compliance system, called the Environmental Permitting System, and a single regulatory framework streamlining waste management licensing, pollution prevention and control, water discharge consenting, groundwater authorisations and radioactive substances regulation.[76]

Private organisations, public bodies and sole traders have to comply with the Data Protection Act 1998 which regulates the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information.

The UK also has a designated National Contact Point (NCP) (based in the Department for Business, Innovation and Skills (BIS), tasked with raising awareness of the OECD Guidelines for Multinational Enterprises[77] for businesses, trade unions and non-governmental organisations and with implementing the OECD guidelines' complaint mechanism.[78]

(or students studying towards an award from a qualifying institution), except those which relate to matters of academic judgement. The complaint must relate to the acts or omissions of the qualifying institution. Qualifying institutions include all universities in England and Wales, constituent colleges of universities, higher education corporations and institutions designated by the Secretary of State, or the National Assembly for Wales as eligible to receive funds administered by a higher education funding council.

[76] Department for Environment Food & Rural Affairs, "2010 to 2015 government policy: Environmental quality", *Policy Paper,* 7 May 2015. https://www.gov.uk/government/publications/2010-to-2015-government-policy-environmental-quality/2010-to-2015-government-policy-environmental-quality

[77] http://www.oecd.org/investment/mne/oecdguidelinesformultinationalenterprises.htm

[78] https://www.gov.uk/uk-national-contact-point-for-the-organisation-for-economic-co-operation-and-development-oecd-guidelines-for-multinational-enterprises

2.4. Regional institutions and policies

Some ethical requirements apply differently across the regions of the UK as there are some differences evident in laws. For example, in Wales and Northern Ireland, research requires ethical review if it involves patients (or information relating to patients) receiving treatment in or for the purposes of an independent hospital or independent clinic. In Northern Ireland only, research requires ethical review if it involves patients (or information about patients) receiving treatment in or for the purposes of an independent medical agency.[79] Another example showing variance in ethical review requirements relates to the ethical review of research involving human tissue. The NHS Health Research Authority highlights different circumstances applicable to England, Wales and Northern Ireland on one hand, and Scotland on the other.[80]

The Four Nations' meeting is a discussion forum between the Health Research Authority (HRA), the Department of Health, the Health and Social Care in Northern Ireland (HSC), the Chief Scientists Office in Scotland (CSO) and the National Institute for Social Care and Health Research in Wales (NISCHR).[81] A standing item at each Four Nations' meeting is the review of any United Kingdom Ethics Committee Authority (UKECA) business.[82] The Four Nations' group is also responsible for considering ways to ensure compatibility in procedures and processes, where possible, across the four nations, including collaboration and development programme of work.[83]

3. Public research and innovation systems

This section focusses on public research and innovation systems in the UK. First, it examines the general structure and role of the government. Second, it covers some national research and university associations and standard-setting bodies that have a role in representing public R&I institutions. Third, it looks at research funding organisations and their role in ethics assessment. Fourth, it looks research performing organisations and their role in ethics assessment.

3.1. General structure and role of the government

The budget for science and research funding is allocated by the Department for Business, Innovation and Skills (BIS). Public research funding in the UK operates under the long-standing 'Haldane principle', according to which the Government identifies strategic priorities, and the scientific community selects projects within relevant fields on the basis of

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[79] http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/requirements-for-ethical-review-under-legislation/private-and-voluntary-health-care/
[80] For further details, see HRA, "Ethical review of research involving human tissue". http://www.hra.nhs.uk/resources/before-you-apply/types-of-ethical-review/ethical-review-of-research-involving-human-tissue/
[81] HRA, "Four Nations and UKECA". http://www.hra.nhs.uk/resources/research-legislation-and-governance/four-nations/#sthash.DCvJq5jo.dpuf
[82] Ibid.
[83] HRA, "Four Nations and UKECA". http://www.hra.nhs.uk/resources/research-legislation-and-governance/four-nations/#sthash.DCvJq5jo.dpuf

scientific merit, as assessed by peer review. The Research Councils are a central mechanism for the operation of this principle.[84]

Public sector funding for science and research in the UK is organised via the Dual Support system into two main channels:[85]

- The Research Councils provide grants for specific projects and programmes to both Universities and Research Council Institutes. The Research Councils define strategic priorities and allocate funds to research performers via peer review of research proposals. The funds under the Councils stream may go to individual projects or large-scale programmes of work around priority topics, in addition to funding Research Council Institutes.[86]
- The higher education funding bodies provide block grant funding to universities linked to quality research performance over 5 years as portrayed in the Research Assessment Exercise.[87]

The seven research councils are the main public investors in fundamental research in the UK covering a wide range of disciplines: [88]

- Arts and Humanities Research Council (AHRC)
- Biotechnology and Biological Sciences Research Council (BBSRC)
- Engineering and Physical Sciences Research Council (EPSRC)
- Economic and Social Research Council (ESRC)
- Medical Research Council (MRC)
- Natural Environment Research Council (NERC)
- Science and Technology Facilities Council (STFC)

Research Councils UK (RCUK) is a strategic partnership of the seven UK Research Councils. RCUK work scientifically, strategically and operationally alongside BIS to promote research, training and innovation in the UK.[89]

The Research Councils are non-departmental public bodies. They are independent legal bodies outside of government, accountable to Parliament and established by Royal Charter under the Science and Technology Act 1965 (or in the case of AHRC, the Higher Education Act 2004).[90]

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[84] https://www.gov.uk/government/policies/investing-in-research-development-and-innovation/supporting-pages/science-and-research-funding
[85] Ibid.
[86] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32477/10-917-economic-impacts-uk-research-council-system.pdf
[87] Ibid. The aim of the Research Assessment Exercise (RAE) was to produce quality profiles for each submission of research activity made by institutions. These quality profiles were used by the higher education funding bodies to determine grants for research. The RAE has been replaced by the Research Excellence Framework (REF).
[88] https://www.gov.uk/government/policies/investing-in-research-development-and-innovation/supporting-pages/science-and-research-funding
[89] Ibid.
[90] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32478/10-1356-allocation-of-science-and-research-funding-2011-2015.pdf

Four higher education funding bodies in the UK provide block grant funding to support the research infrastructure and enable institutions to undertake ground-breaking research of their choosing:[91]

- Higher Education Funding Council for England (HEFCE)
- Higher Education Funding Council for Wales (HEFCW)
- Scottish Funding Council (SFC)
- Department for Employment and Learning, Northern Ireland (DELNI)

The Higher Education Funding Council for England (HEFCE) is a non-departmental public body of the BIS. Most universities are charities and HEFCE is their principal regulator. The HEFCE has the duty to promote compliance with charity law by the universities for which they are responsible.[92]

The UK Space Agency[93] was established as an executive agency of BIS on 1 April 2011. It consolidated funding for space programmes from across government, the Research Councils and non-departmental public bodies, to encourage the continued growth of the UK space sector.

BIS is responsible for Government funding of key programmes at three of the UK's independent National Academies: the Royal Society (the UK's national academy of science), the British Academy (which promotes and champions the humanities and social sciences) and the Royal Academy of Engineering.[94]

3.2. National research associations and standard-setting bodies

This section covers some national research and university associations and standard-setting bodies that have a role in representing public R&I institutions.

Universities UK (UUK)

UUK aims "to be the definitive voice for universities in the UK".[95] UUK members are the executive heads (vice-chancellors/principals) of UK university institutions which have met the criteria for membership agreed by the board of UUK. UUK currently has 133 members.[96] According to its Strategic Plan 2013-2018, UUK's primary role is to support its members achieve their aims and objectives, and help maintain the world-leading strength of the university sector as a whole.[97] To this effect, it engages in lobbying and policy development, advocacy and campaigning, coordinating sector wide efforts on major issues and facilitates relationships between government, private sector, professions and sector agencies.

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[91] https://www.gov.uk/government/policies/investing-in-research-development-and-innovation/supporting-pages/science-and-research-funding
[92] https://www.hefce.ac.uk/
[93] https://www.gov.uk/government/policies/investing-in-research-development-and-innovation/supporting-pages/science-and-research-funding
[94] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32478/10-1356-allocation-of-science-and-research-funding-2011-2015.pdf
[95] http://www.universitiesuk.ac.uk/aboutus/whatwedo/Pages/VisionMission.aspx
[96] Universities UK, "Universities UK Members".
http://www.universitiesuk.ac.uk/aboutus/members/Pages/default.aspx
[97] Universities UK, *Strategic Plan 2013-2018*, September 2013.
http://www.universitiesuk.ac.uk/aboutus/whatwedo/Documents/UUKStrategicPlan2013_2018.pdf

The UK Research Integrity Office (UKRIO)

Another organisation that is relevant here (although, not a regulatory body) is the UKRIO. The UKRIO states that it "fills gaps between jurisdictions, where no overall regulation might apply, and helps to direct researchers, organisations and the public to regulatory bodies when issues fall within their jurisdiction".[98] The UKRIO (established in 2006) is an independent charity, offering support to the public, researchers and organisations to further good practice in academic, scientific and medical research.[99] It promotes "integrity and high ethical standards in research, as well as robust and fair methods to address poor practice and misconduct".[100] UKRIO reports on its website that many leading research organisations, including over 50 universities, use their published guidance, which is endorsed by funding and professional bodies.[101] The UKRIO is an advisory body not a statutory regulator.[102]

The Quality Assurance Agency for Higher Education (QAA)

The QAA, an independent body, monitors and advises on standards and quality in UK higher education.[103] The Agency publishes and maintains the UK Quality Code for Higher Education, conducts evidence-based external reviews of higher education providers and reports its findings publicly. It investigates concerns about academic quality and standards, conducts research and shares information about good practice. It consults and works with those who have an interest in the quality of UK higher education locally and internationally, including on common criteria for standards and quality. It also provides training to help higher education providers develop and improve their quality assurance processes.[104]

3.3. Research funding organisations

This section draws from, and builds upon the 'Ethics in funding organisations in the UK' report,[105] but only gives a few examples to illustrate differences in approaches to ethics assessment in the UK. More detailed information about research funding organisations has been provided in section 3.1 above.

As mentioned in section 3.1, university research is publicly funded through the dual support system.

Research funding bodies in the UK include the research councils listed in section 3.1. Research academies include the British Academy for the Humanities and Social Sciences, and the Royal Society (see section 3.1). Research charities include the Wellcome Trust (biomedical and medical humanities research), Arthritis Research UK (scientific and medical research on arthritis), The British Heart Foundation (cardiovascular research), and the Joseph Rowntree Foundation (JRF) (development and social research).

Ethics evaluation

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[98] UKRIO. http://www.ukrio.org/wp-content/uploads/UKRIO-leaflet-2013-web-version.pdf
[99] http://www.ukrio.org/about-us/
[100] Ibid.
[101] UKRIO, "Our work". http://www.ukrio.org/our-work/
[102] Ibid.
[103] http://www.qaa.ac.uk/
[104] http://www.qaa.ac.uk/about-us
[105] SATORI project, "Ethics in Funding Organisations in the UK", 2014.

Of the research councils, only the BBSRC provides for in-house ethics evaluation while the others rely on ethics clearance by competent national bodies. Research funding bodies that rely on ethics clearance by competent national bodies include AHRC, EPSRC, ESRC, RCUK, MRC, and the NERC. Academies such as the British Academy and the Royal Society largely rely on applicant organisations and awardees ensuring that they adhere to ethical requirements (and where necessary providing documentary evidence of the same).

The research charities (i.e. Wellcome Trust,[106] Arthritis Research,[107] The British Heart Foundation,[108] Joseph Rowntree Foundation[109]) also have provisions on and requirements for ethics evaluation/review but do not provide such services in-house.

The BBSRC requires that ethical issues must be resolved before a successful grant is announced and the award will not be made until applicants have satisfactorily addressed queries from the Panel.[110]

Proposals submitted to the ESRC must provide a full statement that proper consideration has been given to any ethics issues which the proposal raises. Where an ethics review is yet to be undertaken, this should be stated. All ESRC-funded grants must be approved by at least a light touch ethics review.[111]

The EPSRC requires applicants to consider the ethical issues regarding the material they intend to use, in addition to current public perceptions and attitudes towards the subject matter or research areas.[112] The EPSRC will not fund a project if it believes that there are ethical concerns that have been overlooked or not appropriately accounted for.[113] Specific requirements concern human participation, animal research, genetic and biological risk, approvals and broader societal issues and public interest concerns.[114] If approval is required for the research, this must be sought and granted before commencing.

The EPSRC has adapted its requirements to include responsible innovation and commissioned the development of a framework for responsible innovation to support research policy development at EPSRC, while also being generally applicable. Richard Owen and colleagues have developed a framework comprising four integrated dimensions of anticipation, reflection, deliberation and responsiveness and anchored in future-oriented concepts of collective responsibility including care and responsiveness.[115] EPSRC

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[106] http://www.wellcome.ac.uk/Funding/Biomedical-science/Application-information/index.htm
[107] http://www.arthritisresearchuk.org/research/information-for-applicants/applying-for-a-grant/essential-information.aspx
[108] https://www.bhf.org.uk/research/information-for-researchers/frequently-asked-questions
[109] http://www.jrf.org.uk/sites/files/jrf/JRF-application-for-funding_0.doc
[110] See BBSRC, "Ethical Monitoring Process". http://www.bbsrc.ac.uk/engagement/accountability/ethical-monitoring-process/
[111] http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf. Light touch reviews identify projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases, this is the only ethics review necessary, and can be undertaken using a pre-defined checklist.
[112] https://je-s.rcuk.ac.uk/Handbook/pages/GuidanceonCompletingaStandardG/EthicalInformation.htm
[113] Ibid.
[114] https://je-s.rcuk.ac.uk/Handbook/pages/GuidanceonCompletingaStandardG/EthicalInformation.htm
[115] Owen, R., P. Macnaghten, & J. Stilgoe, "Responsible research and innovation: From science in society, to science for society, with society", *Science and Public Policy*, 39, 2012, pp. 751–760.

recommends that all researchers demonstrate awareness of and commitment to, the principles of Responsible Innovation.[116]

The ESRC does not require that ethics approval is obtained before the submission of a research proposal, however all proposals must set out the kind of ethics approval the applicant(s) considers will be needed for the proposed research, and why.[117] The Royal Society requires host organisations to have formal written procedures for the handling of allegation of scientific fraud or research misconduct. Failure to comply with the terms and conditions leads to termination of the Award and the Society reserves the right to recover grant monies in part or full.

3.4. Research performing organisations

Research funders in the UK generally place responsibility for meeting ethical requirements and standards in the hands of the applicants i.e. research performing institutions.

Most higher education institutions (HEIs) such as universities, academies, colleges have their own ethics policies and procedures. Many require that funded, and PhD research in particular, is ethically sound and approved. For instance, The London School of Economics and Political Science (LSE) Research Ethics Policy (which sets out the procedure for obtaining independent ethical scrutiny of research proposals by the LSE Research Ethics Committee)[118], is a part of the School's over-arching Ethics Code.[119] The University of Edinburgh has formally adopted the UK Research Integrity Office's Code of Practice for Research (2009) in place of its Code of Good Practice in Research (November 2002).[120]

Universities have established procedures for ethical review. The process generally depends upon the nature of the research, and there might be one or more applicable. For example, for studies involving NHS patients, participants with mental incapacity, studies which involve storing human tissue, clinical trials, etc., ethical approval is to be gained via the National Research Ethics Service (NRES). Universities have internal committees with the overall responsibility for implementing a University's ethics policy and procedures. These committees provide ethical review and approval as required.

Other independent research organisations (or IROs) such as the British Institute of International and Comparative Law (BIICL) (which conducts research across the broad range of public international law, private international law, comparative law and European law), state that they maintain "the highest standards of research integrity and supports the commitments set out in the *Concordat to support research integrity* and *"*ensure that all research proposals undergo an ethics review at an appropriate level, depending on the type of research to be undertaken".[121] The National Museums Scotland (another IRO) has a framework for the ethical conduct of research guided by principles of dignity, respect,

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[116] http://www.epsrc.ac.uk/index.cfm/research/framework/

[117] ESRC, "Framework for Research Ethics (FRE)", 2010, Updated September 2012.
http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf

[118] LSE, "Research Ethics Policy and Procedures".
http://www.lse.ac.uk/intranet/researchAndDevelopment/researchDivision/policyAndEthics/ethicsGuidanceAndForms.aspx

[119] LSE, "Ethics Code". http://www.lse.ac.uk/intranet/LSEServices/ethics/home.aspx

[120] University of Edinburgh, "Research Ethics Framework". http://www.ed.ac.uk/schools-departments/humanities-soc-sci/research-ke/support-for-staff/college-research/ethics-framework

[121] BIICL, "Research". http://www.biicl.org/research

selflessness, honesty, integrity, objectivity, accountability, openness, and leadership which apply equally to staff and external researchers. The code forms part of the National Museums Scotland policies on staff conduct and research.[122]

Hospitals offer specialist ethics services to help professionals engaged in research within their organisations to consult upon or deal with ethical issues.[123]

Research performing organisations also provide ethics guidance and carry out ethical awareness-raising activities, as evidenced in the above two paragraphs. Universities offer expert advice, provide training and guidance at various levels and topics in research ethics[124] for their staff and students and organise collaborative events such as fora, face to face workshops and individual drop-in sessions, to discuss research ethics and developments.[125] The University of Sheffield offers (inter alia) case studies for expanding understanding and to spark discussion of different ethical perspectives – the case studies cover different aspects such as use of social media, human environment interactions, men and violence.[126]

4. Private research and innovation systems

This section focuses on private research and innovation systems. It examines the general structure and the role of government. It focuses in on industry associations, accreditation, certification and standard setting organisations. Finally, the section offers a description of some of the ways in which industry in the UK engages in CSR (to the extent that it relates to R&I) and ethics assessment of R&I.

4.1. General structure and the role of government

The BIS Innovation Report 2014 highlights that "The UK innovation system is a range of interacting elements. It is delivered by a range of different institutions, firms and individuals working in collaboration".[127] According to the report, the innovation infrastructure in the UK covers: the institutions supporting the development and management of intellectual property, standards, measurement, accreditation and design including the Intellectual Property Office, Design Council, the National Measurement System and the British Standards Institution (BSI). The knowledge base comprises a range of organisations providing education, training and research including Higher Education Institutions (HEIs), and Public Sector Research Establishments (PSREs). The report also spotlights the "business community engaged in innovation across the economy and bodies supporting their commercialisation of innovation", including the Technology Strategy Board (TSB) - the UK's innovation agency, with the remit

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[122] National Museums Scotland, *Research ethics policy.*
http://www.nms.ac.uk/media/72194/nmsresearchethicspolicy.pdf
[123] See for instance, Great Ormond Street Hospital, "Clinical Ethics service information for health professionals". http://www.gosh.nhs.uk/health-professionals/clinical-specialties/clinical-ethics-service-information-for-health-professionals/
[124] For instance, see: King's College London, "Training & Guidance".
http://www.kcl.ac.uk/innovation/research/support/ethics/training/index.aspx
[125] See University of Leeds, "Research ethics training and guidance". http://www.sddu.leeds.ac.uk/sddu-research-ethics-courses.html
[126] The University of Sheffield, University Research Ethics Committee (UREC) Training Resources for Ethics and Integrity. https://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/educationresources/trainingresources
[127] Department for Business, Innovation and Skills, *Innovation Report 2014,* March 2014.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/293635/bis-14-p188-innovation-report-2014-revised.pdf

to accelerate economic growth by stimulating and supporting business-led innovation – and the intermediate sector organisations such as Research and Technology Organisations (RTOs).[128] The UK also provides an attractive tax environment for companies carrying out R&D.

The previous section on *laws and policies for industry* covers some of the legislation and initiatives that support ethics assessment in private industry. Others include: the Government Buying Standards (GBS) for sustainable procurement which are a set of easy to use product specifications for public procurers and are set at 'mandatory' and 'best practice' levels.[129] Under the 'Greening Government Commitments' all central government departments and their related organisations must ensure that they meet the mandatory levels of the GBS.[130] Another relevant document is DEFRA's Ethical Procurement Policy Statement.[131]

CSR is voluntary and business-led in the UK; this means it is diverse and constantly evolving to meet changing circumstances.[132] The Department for Business, Innovation & Skills defines corporate responsibility or corporate social responsibility as "the responsibility of an organisation for the impacts of its decisions on society and the environment above and beyond its legal obligations, through transparent and ethical behaviour".[133] It ran a public consultation on corporate responsibility from 27 June 2013 to 27 September 2013.[134]

4.2. Industry associations, accreditation, certification and standard setting organisations

This section examines the role of industry associations, industry network organisations and accreditation, certification, evaluation and standard setting organisations for industry that play a role in the setting and enforcement or promotion of standards and practices with regard to ethics assessment and CSR in industry.

With a few exceptions, industry associations and networks in the UK do not play a very hands-on approach in setting and enforcing ethical standards and practices for their member organisations. The **Confederation of British Industry (CBI),** a large business lobbying organisation has developed a Statement of reporting principles (corporate reporting).[135] The **Market Research Society (MRS)** (a large research association comprising of member

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[128] Ibid.

[129] https://www.gov.uk/government/collections/sustainable-procurement-the-government-buying-standards-gbs

[130] https://www.gov.uk/government/publications/greening-government-commitments-targets

[131] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69421/ethical-procurement-policy-statement.pdf

[132] See Department for Business, Innovation and Skills, *Corporate Responsibility*, Department for Business, Innovation and Skills, April 2014.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300265/bis-14-651-good-for-business-and-society-government-response-to-call-for-views-on-corporate-responsibility.pdf

[133] Department for Business, Innovation and Skills, *Corporate responsibility: call for views*. 27 June 2013.
https://www.gov.uk/government/consultations/corporate-responsibility-call-for-views

[134] Results are documented in: Department for Business, Innovation and Skills, *Corporate Responsibility*,
Department for Business, Innovation and Skills, April 2014.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300265/bis-14-651-good-for-business-and-society-government-response-to-call-for-views-on-corporate-responsibility.pdf

[135] CBI, "Shaping the Future of Corporate Reporting Statement of reporting principles".
http://www.cbi.org.uk/media/2604458/cbi_reporting_principles.pdf

organisations that provide and use market, social and opinion research, business intelligence, market analysis, customer insight and consultancy) has a Code of Conduct[136] that sets out the professional standards that research practitioners must maintain. MRS members must adhere to the MRS Code of Conduct, Regulations[137] and associated disciplinary procedures. The **British Standards Institution (BSI)** has issued BS ISO 26000:2010 Guidance on social responsibility.[138] BS ISO 26000:2010 outlines international recommendations for social responsibility and covers organisational governance, human rights, working practices, environmental policies, sustainable development and community involvement. The BSI also has a consumer's guide to BS ISO 26000:2010.[139] The **United Kingdom Accreditation Service (UKAS)** is the sole national accreditation[140] body recognised by government, to assess, against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services.[141] UKAS has accredited the Food and Environment Research Agency (FERA) for plant health inspection.[142]

4.3. Industry

This section offers a description of some ways in which industry in the UK engages in CSR (to the extent that it relates to R&I) and ethics assessment of R&I. It also discusses ethics assessment in large corporations versus SMEs, and the role of stakeholders in CSR and ethics assessment.

Leading R&D companies in various sectors have different positions, policies and take different actions related to CSR. Some companies specify commitments to the UN Universal Declaration of Human Rights, the OECD Guidelines for Multinational Enterprises, core labour standards set out by the International Labour Organization (ILO), UN Global Compact[143] and the UN Guiding Principles on Business and Human Rights.[144] Companies have codes of conduct[145] supported by ethics and compliance teams or ethics advisory groups. Where deemed necessary, companies may consult external ethics and impact assessment experts on new and emerging issues.

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[136] MRS, *Code of conduct*, September 2014.
https://www.mrs.org.uk/pdf/mrs%20code%20of%20conduct%202014.pdf
[137] E.g. MRS Regulations for the use of predictive diallers, MRS Regulations for using research techniques for non-research purposes, MRS Regulations for administering incentives and free prize draws, Code of Conduct for Elections
[138] BSI, "BS ISO 26000:2010". http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030140726
[139] BSI, *Ethical business: protecting our planet and the people on it. A consumer's guide to the social responsibility standard – BS ISO 26000:2010.* http://shop.bsigroup.com/ProductDetail/?pid=000000000030140726
[140] According to UKAS, accreditation is a formal, third party recognition of competence to perform specific tasks.
[141] UKAS, "About UKAS". http://www.ukas.com/about-accreditation/about-ukas/
[142] UKAS, "First Seeds of Accreditation for Plant Health Inspection Bear Fruit". http://www.ukas.com/media-centre/press-releases/First_accreditation_plant_health_inspection.asp
[143] GSK, "Ethical conduct and supply chain". http://www.gsk.com/en-gb/responsibility/our-behaviour/ethical-conduct-and-supply-chain/
[144] E.g. see Unilever, "Inclusive Business". http://www.unilever.co.uk/sustainable-living-2014/inclusive-business/
[145] E.g. See BT plc, "The Way We Work: BT's Business Practices", October 2013.
http://btplc.com/TheWayWeWork/Businesspractice/TWWW_Policy_UK.pdf; Shell, "General Business Principles". http://www.shell.com/global/aboutshell/who-we-are/our-values/sgbp.html

Leading research companies also practice CSR to varying degrees. For instance, TNS International has contributed to setting and donating to a charity fundraising initiative.[146] Dunnhumby encourages staff to volunteer time on community betterment projects.[147] Ipsos MORI has a *Responding Responsibly* programme focused on reducing environmental impact and contributing to local communities.[148] It also states that it double-checks its research using a senior director from its *Polls for Publication* panel, to ensure that the findings and their interpretation is accurate and unbiased.[149]

CSR in large corporations versus SMEs

A working paper on *'Corporate Social Responsibility: Engaging Small and Medium Sized Enterprises in the Debate'* explores CSR from the perspectives of SMEs in the UK.[150] The paper highlights that there is some growth in the engagement of SMEs in the CSR agenda,[151] along with a growing recognition that the issues that are important for CSR are as relevant for small companies as they are for large companies, but the motivational pressures that may engage SMEs in CSR are not the same as for large companies. The paper also underlines how "the motivational pressures that may engage SMEs in CSR are not the same as for large companies. While the growing visibility and global impact of large companies and brands has heralded calls for greater transparency and accountability, SMEs remain largely invisible and unlikely to see CSR in terms of risk to brand image or reputation. For SMEs, issues closer to home are far more likely to hold their attention such as employee motivation and retention and community involvement".[152]

Role of stakeholders in CSR

There are a wide range of stakeholders in CSR, including regulators, businesses of all sizes, charities, representative bodies, educational bodies and individuals. Each of these play different roles. A BIS document summarising the views of stakeholders on corporate responsibility, highlights what some stakeholders (such business of all sizes, charities, representative bodies, educational bodies and individuals) see as the role of the government.[153] According to it, a "majority of respondents said that Government should have the equivalent of a 'light touch' role, particularly as there were already many organisations occupying this space".[154] Respondents saw "Government's role as chiefly one of an intermediary, bringing business, regulators and other stakeholders together to facilitate, in particular, a dialogue between all sides and agreeing action on ways forward."[155]

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[146] TNS, "Corporate and social responsibility". http://www.tnsglobal.com/who-we-are/corporate-social-responsibility

[147] Dunnhumby, "In the Community". http://www.dunnhumby.com/uk/community

[148] Ipsos MORI, "Corporate Responsibility". https://www.ipsos-mori.com/aboutus/corporateresponsibility.aspx

[149] Ibid.

[150] Jenkins, Heledd, *Corporate Social Responsibility: Engaging Small and Medium Sized Enterprises in the Debate*, The Centre For Business Relationships, Accountability, Sustainability and Society, Working Paper No. 18, 2004.

[151] Ibid, p. 7.

[152] Jenkins, op. cit, 2004, p. 6.

[153] Department for Business, Innovation and Skills (BIS), *Good for Business & Society: Government response to call for views on corporate responsibility,* Department for Business, Innovation and Skills, London, 2014. BIS/14/651

[154] Ibid.

[155] BIS, *Good for Business & Society*, op. cit. 2014.

The BIS document also highlights how a significant majority of respondents pointed to differences between business (e.g. size, sector, communities in which they operate and the varying complexity of their operations) and noted this had implications for how corporate responsibility is practiced.[156] Respondents commented that collaboration, in a number of forms, was seen to be an increasingly important aspect of corporate responsibility (it was also noted that collaboration between SMEs and large companies rarely happened).[157] A significant number of respondents suggested that a more supportive and collaborative approach through the supply chain and sectors was important to advance the sustainability agenda.[158] Examples of such support: mentoring, providing guidance, knowledge and training, setting expectations and making available resources such as expertise and funding. Respondents identified a disconnection between business and society, particularly at a local level. On the one hand, businesses did not know or understand the social issues that existed and how they might help. On the other hand, local communities, and in particular charities, did not articulate the issues relative to them well enough for businesses to at least consider getting involved.[159]

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

This section discusses associations of professionals in research and innovation or in ethics assessment (and related fields) and their role in ethical assessment of R&I.

5.1. National associations for R&D professions (for public and/or private R&D)

National associations for R&D professions play a part in upholding and promoting ethical standards in the UK. We examine a few examples here.

Royal Society of Chemistry (RSC)

The RSC is the UK's professional body for chemical scientists.[160] The RSC has provisions for 'Ethical Guidelines and Conflict of Interest' for RSC publications. Where guidelines are breached or appear to be so, the RSC consults its Code of Conduct and Best Practice Guidelines of the Committee On Publication Ethics (COPE) and acts accordingly.[161] As part of its ethical policy, the RSC is a member of CrossCheck (a multi-publisher initiative to screen published and submitted content for originality).[162] It also has a publications related policy on Experiments Involving Live Subjects.[163]

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[156] BIS, *Good for Business & Society*, op. cit. 2014, p. 4.
[157] BIS, *Good for Business & Society*, op. cit. 2014, p. 5.
[158] BIS, *Good for Business & Society*, op. cit. 2014, p. 6.
[159] BIS, *Good for Business & Society*, op. cit. 2014, p. 6.
[160] RSC, "About us". http://www.rsc.org/about-us/
[161] RSC, "Ethical Guidelines for Publication in Journals and Reviews".
http://www.rsc.org/Publishing/Journals/guidelines/EthicalGuidelines/EthicalGuidelinesandConflictofInterest/sect1.asp
[162] RSC, "CrossCheck".
http://www.rsc.org/Publishing/Journals/guidelines/EthicalGuidelines/CrossCheck/CrossCheck.asp
[163] Ibid.

The British Psychological Society

The British Psychological Society provides ethics guidance to its members who are engaged in research. The BPS also works to encourage other researchers engaged in human research. The Code of Ethics and Conduct - which is the overarching code - deals with professional roles in providing therapeutic interventions and deals with issues regarding working with clients and patients.[164] The Code of Human Research Ethics provides a set of general principles that are applicable to all research contexts and cover research with human participants.

Two other examples of national associations for R&D professions are the British Association for Counselling & Psychotherapy (BACP), a professional body representing counselling and psychotherapy in the UK, and the Association of Research Managers and Administrators (ARMA), a professional association for research managers and administrators in the UK.

5.2. National organisations for (ethics) assessors

This section offers a description of three national organisations for professionals working in ethics assessment and related areas.

The National Research Ethics Advisors' Panel (NREAP)[165] is an independent, multidisciplinary expert panel hosted by the Health Research Authority and is a resource available to all research ethics committees (RECs) funded by the UK Health Departments within England and the devolved nations[166]. The main objective of the panel is to help research ethics committees (RECs) to deliver robust, consistent and fair decisions through engagement and consultation with stakeholders with an interest in health research. NREAP also informs and deliver appropriate ethics guidance and training to the RECs and the wider research community. The panel also advises the HRA Board on ethical matters.

The Association for Research Ethics (AfRE)[167] seeks to promote excellence in ethical research on human beings and acts as a representative body for university research ethics committees (RECs). The AfRE promotes proper standards of research involving human participants by fostering high standards of ethical review. The association provides information, support and training to its membership and works to encourage co-operation amongst its membership.

The Scottish Council on Human Bioethics[168] is an independent, non-partisan, non-religious Scottish charity composed of doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics. In addition to engaging, assisting and advising legislators, fellow professionals and other interested parties with ethical analysis and commentary on issues, the Council contributes to informing public

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[164] The British Psychological Society, "Ethics & Standards". http://www.bps.org.uk/what-we-do/ethics-standards/ethics-standards

[165] http://www.hra.nhs.uk/about-the-hra/our-committees/panels-and-advisory-groups/

[166] These are Scotland, Wales and Northern Ireland.

[167] http://www.arec.org.uk/index.asp

[168] http://www.schb.org.uk/about/

debate on ethical issues and provides media with relevant and reliable information and comment.

6. CSOs

6.1. The CSO landscape

A UK Cabinet Office document on *Supporting a Stronger Civil Society (2010)* includes charities, social enterprises and voluntary groups within its scope.[169]The NCVO UK Civil society Almanac 2014 definition of civil society "seeks to include all of the organisations that are variously labelled as the third sector, the voluntary sector, the non-profit sector, the community sector, and so on."[170]

There are different bodies at the national level that regulate/govern CSOs. In the Cabinet Office, the Minister for Civil Society leads on the civil society agenda and is responsible for: the Big Society agenda, National Citizen Service and youth policy, social action, civil society sector support and social enterprise and social investment.[171] The Commission on Civil Society and Democratic Engagement is responsible for advising Parliament about the appropriate regulation of civil society during election periods.[172] The Independent Commission for Aid Impact (ICAI) is the independent body (reports to Parliament) responsible for scrutiny of UK aid and focuses on maximising the impact and effectiveness of the UK aid budget for intended beneficiaries and the delivery of value for money for the UK taxpayer.

The Charity Commission registers and regulates charities in England and Wales,[173] and is responsible, inter alia, for registering eligible organisations in England and Wales which are established for only charitable purposes and taking enforcement action when there is malpractice or misconduct. The Charity Commission has a risk framework that sets out the Charity Commission's regulatory approach and how it assesses risk when deciding individual cases.[174]

The Charities Act 2011, alongside other devolved Acts and relevant statutory instruments, provide the legal and regulatory framework for charities in England and Wales and combines previous charity legislation. The Charity Commission follows the better regulation requirements in the Charities Act 2011, namely: proportionate, accountable, consistent, transparent and targeted (only at cases where action is needed).[175]

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[169] Cabinet Office for Civil Society, *Supporting a Stronger Civil Society*, Cabinet Office, 2010. http://www.cpa.org.uk/cpa_documents/support_stronger_civil_society_consultation.pdf

[170] NCVO UK Civil Society Almanac, "What is civil society", 2014. http://data.ncvo.org.uk/a/almanac14/what-is-civil-society-2/

[171] See Cabinet Office, "Parliamentary Secretary (Minister for Civil Society)". https://www.gov.uk/government/ministers/parliamentary-secretary-minister-for-civil-society

[172] The Commission on Civil Society and Democratic Engagement. http://civilsocietycommission.info/terms-of-reference/

[173] The Charity Commission. https://www.gov.uk/government/organisations/charity-commission/about

[174] The Charity Commission, "Setting up and running a charity – guidance: How to manage risks in your charity", 23 May 2013. https://www.gov.uk/how-to-manage-risks-in-your-charity

[175] The Charity Commission, "Risk Framework". https://www.gov.uk/government/publications/risk-framework-charity-commission

6.2. The role of CSOs in ethics assessment

Civil society organisations play various roles related to ethics (and ethical assessment or ethical review of research and innovation).

As part of their research funding mandates, charity organisations[176] such as Cancer Research UK support the Universities UK's Concordat to Support Research Integrity, and "expects research to be conducted according to the highest standards of rigour and integrity, with the core elements of research integrity; honesty, rigour, transparency & open communication and duty of care to participants, to be upheld at all times".[177] Further, it requires all funded research and tissue sample collections to be carried out in compliance with the law.[178]

GeneWatch UK is a not-for-profit group that monitors developments in genetic technologies from public interest, human rights, environmental protection and animal welfare perspectives. One of GeneWatch UK's principles is that the "consideration of the impacts of genetic technologies on the environment, health, animal welfare and human rights should be at the heart of decision-making".[179]

Other CSOs investigate ethical issues as part of their investigative and critical research work. For example, Privacy International, a London-based charity, conducts research into, and investigates government surveillance and the companies facilitating it.[180] Statewatch has an Observatory on the European Security Research Programme (ESRP)[181] and has published alongside the Transnational Institute a couple of critical reports.[182]

CSOs also organise information sharing and educational activities, about the ethical implications of research and innovation. They are in a unique position to facilitate the discussion of the ethical issues arising out of both publicly and privately funded research and innovation actions. The Joseph Rowntree Foundation for instance has published a manual for ethical research practice, from the perspective of mental health service users and survivors.[183]

CSOs may provide input for ethics policies and guidance by collaborating with, organisations that develop ethics policies, guidance and standards or engage in ethics assessment. For

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[176] The section on ethics in funding organisations discusses some other charity organisations.

[177] Cancer research UK, "Research integrity". http://www.cancerresearchuk.org/funding-for-researchers/applying-for-funding/conditions-of-your-grant/research-integrity. See also See CRUK's Guidelines for Scientific Conduct. Cancer Research UK, Guidelines for Scientific Conduct, Version 01, 1 July 2013. http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@fre/@gen/documents/generalcontent/scientific-conduct-guidelines.pdf

[178] CRUK, "Human biological samples". http://www.cancerresearchuk.org/funding-for-researchers/applying-for-funding/conditions-of-your-grant/human-biological-samples

[179] http://www.genewatch.org/sub-396416

[180] Privacy International. https://www.privacyinternational.org/

[181] http://www.statewatch.org/Targeted-issues/ESRP/security-research.html

[182] Hayes, Ben, *Neoconopticon: The EU security-industrial complex,* TNI/Statewatch, 2009; Töpfer, Eric, *The German Security Research Programme. Transferring military technology–securitising civil research,* 2006. http://www.statewatch. org/analyses/no-124-german-security-research-programme.pdf; Hayes, Ben, *Arming big brother: The EU's security research programme*, TNI Briefing series 2006/1, TNI/Statewatch, Amsterdam, 2006. http://www.statewatch.org/analyses/bigbrother.pdf

[183] Faulkner, Alison, *The ethics of survivor research. Guidelines for the ethical conduct of research carried out by mental health service users and survivors,* Published for the Joseph Rowntree Foundation, Policy Press, 2004. http://www.jrf.org.uk/publications/ethics-survivor-research-guidelines-ethical-conduct-research-carried-out-mental-health-

instance, The Universities Federation for Animal Welfare, the Humane Slaughter Association, RSPCA and People for the Ethical Treatment of Animals (PETA) are members of the Animals in Science Committee.[184] GeneWatch UK made a submission to the UK House of Lords Science and Technology Committee's inquiry into setting funding priorities for scientific and technological research.[185]

CSOs often run campaigns, and highlight ethical issues in R&D that foster a need for the consideration and evaluation of such issues. For example, the Open Rights Group (ORG) works on, and lobbies policy-makers and other activists on issues such as mass surveillance, to copyright, censorship, data protection and open data and privacy.[186]

7. Discussion[187]

While there is no single, coordinated approach to ethics assessment, the UK has a very well developed system of ethics assessment with a wide variety of organisations engaging in ethics assessment or ethics guidance. Ethics assessment and guidance of R&I in the UK include the following issues: research integrity, ethical standards in human subjects' research and animal experimentation, clinical research and regulation of medicines and medical devices. Ethical analysis is well-established within S&T decision-making as reflected in the incorporation of advisory structures in governmental departments.

The UK has a very dense, populous higher education establishment compared to many other countries and autonomy in the university sectors is important. Most universities will have their own ethical approval system and while universities will have some things in common, they can all operate independently. At the same time, the UK has a distinct approach to the regulation and governance of research integrity with, for example, the Concordat to Support Research Integrity which facilitates sector-wide guidance for universities and commits institutions funded by the UK higher education funding councils to comply with the commitments set out in the concordat. In addition, the UKRIO functions as an independent source of advice regarding matters of research integrity. The vast majority of research councils outsource ethics requirements, with only one - the BBSRC - having its own procedures. Ethics assessment at the national level tends to be field-specific with committees dedicated to the analysis of particular areas of science and technology. The Nuffield Council on Bioethics is the closest equivalent to a national ethics committee and is widely acknowledged as a proxy-national body providing guidance on ethical issues that are likely to arise in the context of new developments in biological and medical research.

Major R&D companies in the UK engage in ethics assessment in a variety of ways, encompassing corporate social responsibility (largely voluntary and business-led), 'responsible business', 'open innovation' and environmental policies. Industry associations and networks, with a few exceptions, do not play a very hands-on approach in setting and

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[184] See Animals in Science Committee, "Membership", https://www.gov.uk/government/organisations/animals-in-science-committee/about/membership. The Committee is responsible for providing impartial, balanced and objective advice to Ministers on issues relating to the Animals (Scientific Procedures) Act 1986.
[185] GeneWatch UK, "GeneWatch UK submission to the House of Lords Science and Technology Committee's inquiry into setting funding priorities for scientific and technological research", September 2009. http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GWsub_fin.doc
[186] ORG, "Our work". https://www.openrightsgroup.org/ourwork/
[187] This section includes insights from interviewees.

enforcing ethical standards and practices for their member organisations. National associations for R&D professions play some part in upholding and promoting ethical standards in the UK.

Public engagement plays an important role in the governance of science and technology in the UK. UK academics and research funders have played, and continue to play, a central role in advancing the theory and practical application of responsible innovation.

CSOs play various roles related to ethics assessment such as investigation of ethical issues, information sharing, provide input into ethics policies and guidance, and run campaigns and lobbying activities.