Annex 6: Some key legislation and regulation affecting research

i) Animals and Animal By-Products

The University expects all staff and students engaged in research and educational activities to comply with both the letter and the spirit of legislation, regulation and best practice and professional guidelines. UWE Bristol will always encourage, as part of research or teaching, the development of new understandings, methods, techniques or equipment to improve ethical practice, including animal welfare. As part of the process of evaluation of research and teaching activities with animals, the University will take into consideration any potential reputational harm to the University, and the extent to which the clearly set out cost-benefit analysis, ethical practice, and risk mitigations render the research or teaching activity to be acceptable and appropriate for approval.

All research with animals or animal by-products must be considered and approved by the Animal Welfare and Ethics Sub-Committee (AWESC) and, thus, registered on the UWE Animal and Animal By-Products Research Register before research activities begin or samples are brought onto UWE premises. Further information on how to apply can be obtained from the Research Governance Team (researchgovernance@uwe.ac.uk).

Key legislation relating to research with animals and animal by-products is listed below:

a) Animal Scientific Procedures Act (ASPA) 1986

- The Animals (Scientific Procedures) Act 1986 (ASPA) regulates procedures that are carried out on 'protected animals' for scientific or educational purposes that may cause pain, suffering, distress or lasting harm. "A protected animal" for the purposes of this Act means any living vertebrate other than humans, and any living cephalopod. Research with these animals (either with live animals or the killing of such) is only permitted under licence.
- UWE does not hold a Home Office Licence, so such research cannot be conducted on UWE premises.

b) The Veterinary Surgeons Act 1966

The following is not covered by ASPA but by the Veterinary Surgeons Act:

- Non-experimental clinical veterinary practices: The clinical investigation and management of the health or welfare of animals is generally considered to be non-experimental clinical veterinary practice when it involves an intervention which is of direct benefit to the animal or its immediate peer group.
- Veterinary clinical trials: Veterinary clinical trials required to be carried out for marketing authorisations of veterinary medicinal products are a requirement of the Veterinary Medicines Regulations 2011 (et seq).

c) The Wildlife and Countryside Act 1981

The Act (www.legislation.gov.uk/ukpga/1981/69/contents) covers protection of wildlife (birds, and some animals and plants), the countryside, National Parks, and the designation of protected areas, and public rights of way. For example, under the Act it is an offence to (with the exception of certain species) intentionally:

- kill, injure, or take any wild bird; take, damage or destroy the nest of any wild bird while that nest is in use or being built; or take or destroy an egg of any wild bird.
- kill, injure or take certain listed wild animals; and prohibits interference with places used for shelter or protection, or intentionally disturbing animals occupying such places. The Act also prohibits certain methods of killing, injuring, or taking wild animals.
- pick, uproot or destroy certain listed wild plants, or any seed or spore attached to any such wild plant.

d) Animal Welfare (Sentience) Act 2022

https://www.legislation.gov.uk/ukpga/2022/22/enacted

This Act (https://www.legislation.gov.uk/ukpga/2022/22/enacted) makes provision for an Animal Sentience Committee with functions relating to the effect of government policy on the welfare of animals as sentient beings. This Act broadens the range of animals now covered by welfare legislation, including decapod crustaceans.

e) Wildlife and habitat regulations in the UK

There are licensing requirements in the UK relating to birds, fish and shellfish, invertebrates, mammals, reptiles and amphibians, and other licensing requirements relating to categories such as keeping European protected species and releasing non-native species. The relevant licence will always need to be obtained before commencing any research or teaching activity that requires one. Government guidance can be found at: Environmental management : Wildlife and habitat conservation - detailed information - GOV.UK (www.gov.uk).

f) There are specific requirements related to the import and export of animals or animal derived material: Guidance on importing and exporting live animals or animal products - GOV.UK (www.gov.uk).

g) DEFRA regulation relating to the use of Animal by-products can be found at: Guidance for the animal by-product industry - GOV.UK (www.gov.uk). UWE must register our use of ABPs with DEFRA, and researchers must register their use with UWE (NB this also applies to teaching).N.B. Registration is required to be based on a physical location, not in a UWE-wide basis, so researchers should check that their work location is registered (researchgovernance@uwe.ac.uk).

h) Other legislation and regulation:

- The Conservation of Habitats and Species Regulations 2017

- Wild Mammals Protection Act 1996
- Animal welfare legislation including the Animal Welfare Act 2006. Current animal welfare legislation in the UK is set out at: www.gov.uk/guidance/animal-welfare
- The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- The Protection of Badgers Act 1992
- Countryside and Rights of Way Act 2000
- The Protection of Animals Act 1911 is now mostly repealed, but an unrepealed section imposes an obligation on anyone setting spring snares to check them at least once a day.
- The Whaling Industry (Regulation) Act 1934
- The Conservation of Seals Act 1970
- The Salmon and Freshwater Fisheries Act 1975
- The Dangerous Wild Animals Act 1976
- Animal Health Act 1981 gives ministers strong powers to remove a threat to agriculture, except in the case of badgers or European Protected Species.
- The Deer Act 1991
- Natural Environment and Rural Communities Act 2006 puts a legal duty on public bodies to take biodiversity into account when exercising their functions.
- Wildlife and Environment (Scotland) Act 2011
- The Nagoya Protocol (Access and Benefit Sharing regulation)

Legislation relating to Children (Safeguarding)

- NSPCC website provides guidance on the legislation which protects children and young people in the UK. A UK Parliament briefing provides an overview of child protection legislation in England.
- There is guidance available to researchers to help them understand how to comply with the law and avoid harm. The NSPCC provides guidance on Research with children: ethics, safety and avoiding harm. The MRC/ESRC provide joint guidance on Involving children in research. HRA guidance can be found at: Research involving children - Health Research Authority (hra.nhs.uk).
- Images of children should be used with the greatest of care. Use of images of children involve significant legal and ethical issues, which must be fully considered. The NSPCC also provides guidance on photography and sharing images of children.
- There are also clear legislative requirements. Further information about legislation in relation to indecent and prohibited images of children can be found in the CPS guidance on Indecent and Prohibited Images of Children.
- There is statutory guidance for schools and colleges related to keeping children safe in education so any researchers whose activities would fall under this guidance must ensure their activities are compliant.

ii) DBS requirements

- All researchers working with children and/or vulnerable adults (which includes data not just personal interaction) are required by the University to undergo safeguarding training. This includes supervisors of students working with children and young people. The University's safeguarding policies can be found at: Safeguarding - Stay safe on and off campus | UWE Bristol.
- The University is registered with the Disclosure and Barring Services (DBS) and is required to obtain a disclosure for staff undertaking certain activities and roles within or on behalf of the University. The University's Disclosure and Barring Checks policy for staff sets out those roles where a disclosure is or may be required depending on the level and nature of the contact with vulnerable individuals or for another reason. The Policy aims to ensure the University fulfils its responsibilities and obligations for the safeguarding of children, young people and adults with whom University staff and students are in contact as part of their work and also for the assurance of the individual, external agencies and the University itself.
- The University also has a in place a policy statement on the recruitment of ex-offenders.
- As an organisation using the Disclosure and Barring Service (DBS) to assess applicants' suitability for places on university programmes related to the Child and Adult Workforce, UWE Bristol complies fully with the DBS Code of Practice. Where students are not assessed at the application stage, but later wish to work with children or vulnerable adults, the necessity for a DBS check must be considered prior to such research commencing. It is the responsibility of the Director of Studies or the Student Research Supervisor to identify such cases and ensure checks are completed where necessary.

iii) Clinical trials legislation

- Government Guidance can be found at: Good clinical practice for clinical trials - GOV.UK (www.gov.uk).
- UWE Researchers must comply with the UK Department of Health Research Governance Framework requirement that **all clinical trials research** be in compliance with Good Clinical Practice (GCP). All researchers involved in the project should therefore complete GCP Training.
- UKRI/MRC guidance about clinical research governance, including clinical trials, can be found at: Clinical research governance – UKRI.
- In order to obtain a favourable opinion from a Research Ethics Committee through the Health Research Authority Approval System, it is a requirement that clinical trials be registered in a publicly accessible database, and failure to register will be regarded as a serious breach of good research practice. It should also be noted that a failure to register would significantly impede the ability to publish. Health Research Authority guidance on research registration can be found at: Research registration and research project identifiers - Health Research Authority (hra.nhs.uk).

- In addition to such external registration, all UWE Bristol clinical trials, including non-CTIMP trials of interventions, must be recorded on the relevant UWE system, including PIMs and the Research Governance Record, or equivalent.
- There is additional, specific legislation relating to clinical trials of **medicinal products**, and details can be found at: Clinical Trials of Investigational Medicinal Products (CTIMPs) - Health Research Authority (hra.nhs.uk).
- There is additional, specific legislation relating to clinical trials of medical devices, and further details can be found at: Clinical Trials of Investigational Medicinal Products (CTIMPs) - Health Research Authority (hra.nhs.uk).
- Information about when software applications are considered to be a medical device, and how they are regulated, can be found at: Medical devices: software applications (apps) - GOV.UK (www.gov.uk).

iv) Data Protection Act 2018

The University requires those conducting research to comply with the Data Protection Act. The Data Protection Act relates to the protection and use of personal information. In terms of research, this is most likely to be personal information about external research subjects. However, it should be noted that information held as part of the University's formal record about students and staff is also covered by the Act, and any proposed research use must be carefully considered in terms of legal probity, as well as ethical approval. The protection of personal data includes the need for secure storage, as well as proper consent for access and use.

Relevant guidance is available at:

- University guidance on UK GDPR
- The University's data protection and information security policies and data protection guide
- Third party survey tools used to collect research data must be fully compliant with data protection legislation. The University currently has only approved Qualtrics for this purpose. Details regarding recommended online forms and survey tools (can be found here. Advice must be sought before using any other tool (particularly where personal data will be processed outside the European Economic Area).
- There are specific provisions for journalism, for guidance contact the UWE Data Protection Office.
- Information about the list of transcription companies with which UWE has an up-to-date Data Processing Agreement (necessary for compliance with the law) can be obtained from the RBI Hub (res.admin@uwe.ac.uk)

v) Dual-use research technology and Export Controls

Dual-use refers to technologies which can be used for both good and harm. Such technologies are controlled under UK and international legislation and regulation. UK export

controls are intended to restrict the flow of such technology outside of the UK. This may include physical materials/goods, software and technology. Government guidance on exporting military or dual-use technology defines the purpose of UK Export Controls as:
'*Export controls for technology aim to prevent transfers that can lead to developing or producing weapons or goods which:*

- *could be used against the UK and allied forces*
- *cause national security concerns.*'

This guidance also explains that:
'*UK export controls:*

- *apply to anyone or any entity in the UK and, in limited circumstances, to UK persons overseas*
- *are not based on nationality of an individual, except where they apply to UK persons overseas*
- *are based on a concept of exports or transfers to a person or destination overseas, including access to controlled technology by persons located overseas'*

and

> '*Any transfer, permanent or temporary, of controlled technology overseas requires an export licence. This applies to a variety of circumstances. It includes for the purposes of demonstration, bidding or tendering for an overseas contract through to contract fulfilment and training material for maintenance and servicing.*
>
> *The location of the exporter is the country from which they are transferring controlled technology, or the location of a person who makes available controlled technology being accessed from overseas. The destination of transfers of technology is dependent upon the location of the intended recipient. For export control, the routing or storage of the controlled technology does not determine the destination.*
>
> *All foreign or UK persons based in the UK need a licence if they wish to transfer controlled technology overseas which they have created or acquired in the UK, or brought in to the UK from overseas. This is irrespective of the origin of the technology, for example US origin.'*

Research activities that may bring you within the scope of dual use and export control legislation include:

- physical exports of 'technology' (e.g. laboratory equipment or samples, even small quantities)
- research agreements with overseas partners (which may involve the transfer or controlled technology or software)
- International travel (e.g. data or presentations on lap-tops, meetings with non-UK nationals, remotely accessing electronic files from overseas)
- Teaching or supervising the research of international students.

Researchers are responsible for obtaining licenses and for compliance with export controls law. Failure to obtain a license when one is needed may be a criminal offence.
Government Guidance about exporting controlled goods can be found at: Exporting controlled goods - GOV.UK (www.gov.uk).

Export controls can apply to varied items, including blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions. There are ten broad categories set out in the Government guidance: nuclear materials; materials, chemicals, micro-organisms and toxins; materials processing; electronics; computers; telecommunications and information security; sensors and lasers; navigation and avionics; marine; aerospace and propulsion
Each category is then divided again into: systems equipment and component; test, inspection and production equipment; materials; software; technology.

A further useful indicative example of what may constitute Dual-use technology is provided by the WHO in relation to dual use research of concern (DURC):

> *'Dual-use research of concern (DURC) describes research that is intended to provide a clear benefit, but which could easily be misapplied to do harm. It usually refers to work in the life sciences, but the principles are also applicable to other fields including engineering and information technology. It encompasses everything from information to specific products that have the potential to create negative consequences for health and safety, agriculture, the environment or national security.*
>
> *The possibility that research might be misused, either intentionally or accidentally, is a long-standing concern of science. It can have implications in ethics and wider societal issues, and involves not only research communities and public health, but also donors, scientific publishing and public communication.*
>
> *One example is research into viruses and other pathogens. Scientists often create modified versions of dangerous viruses in laboratories to study how they behave in humans and animals, and ultimately how to fight them. While this is a necessary step in biological research, the modified viruses also pose safety concerns and have the potential to cause great harm if not controlled correctly or used to intentionally infect people or animals.*
>
> *Another example is pharmaceutical research and development. Scientists researching asthma have developed aerosol methods that help deliver drugs deeper into the lungs. While this research may hold great benefits for people with asthma and other respiratory issues, they could also be used to increase the damage of biological weapons such as anthrax.'*

The above demonstrates that this is an area of international concern. In some instances, controls from other territories may apply in additions to UK-administered control. For

example, **US Export controls are extraterritorial**, and attached to US products, software and technical data wherever they go, even after the incorporation into other articles.

Where 're-export' clauses apply, 'viewing' of US-controlled technical data by foreign nationals within the UK can be considered re-export, and so may not be permitted.

Further information about US Export Control legislation is given at:
https://www.trade.gov/us-export-controls

A breach of US Export Control laws could lead to significant potential penalties, including imprisonment for individual researchers, and the inclusion of UWE on the US "Denied 38 Parties" list, which would have very severe consequences for the University.

vi) Equality Act 2010

The Equality Act 2010 legally protects people from discrimination in the workplace and in wider society.

It replaced previous anti-discrimination laws with a single Act, making the law easier to understand and strengthening protection in some situations. It sets out the different ways in which it's unlawful to treat someone.

vii) The Freedom of Information Act 2000

UWE must comply with the FOI Act. Guidance can be found on the Information Commissioner's Office site.

viii) Genetic modification legislation

- UWE Bristol is not involved in the release or marketing of GMOs or GM products. We do, however, undertake research which involves the contained use of genetically modified organisms. This is regulated under the Genetically Modified Organisms (Contained Use) Regulations 2014. This is the primary piece of legislation that applies to the use of genetically modified organisms in the workplace. Links to this legislation can be found at: http://www.hse.gov.uk/biosafety/gmo/index.htm.
- The University's Genetically modified organisms policy (HSS22) provides information about the requirements with which UWE Bristol researchers must comply. More specific guidance is set out on the HAS Health and Safety intranet pages: https://intranet.uwe.ac.uk/sites/hlshas/Pages/Genetically-Modified-Organisms.aspx.
- GM research at the University is governed by the Genetic Modification Safety Committee. Further details and guidance on conducting GM research at UWE Bristol can be obtained from the committee chair or the Biological Safety Adviser in the University's Health and Safety Team.

ix) Health and Safety at Work Act 1974

- The Health and Safety at Work Act 1974 imposes a general duty on the University to ensure that by the manner in which it conducts its activities, there is an absence of risks to the health and safety of its staff and others (students, visitors, contractors, etc.) *so far as is reasonably practicable.*
- "So far as is reasonably practicable" means that the degree of risk in a particular activity or circumstance must be balanced against the time, trouble, cost and physical difficulty of taking measures to avoid the risk. The appropriate efforts to counterbalance the risk are the control measures – the preventative and protective measures.
- The *Management of Health and Safety at Work Regulations* (MHSW) specifically requires the University to make a "suitable and sufficient" assessment of the risks to the health and safety of its staff and others (students, visitors, contractors, etc.) who are exposed to risks arising out of the University's activities… "for the purposes of identifying the measures (it) needs to take to comply with the requirements and prohibitions imposed upon (it)…"
- UWE's policies and procedures health and safety standards with regards to Health and Safety have been dealt with extensively in Annex 5 of this Code.
- The University has also set in place a 'Legal register' of legislation relevant to health and safety which can be found on the UWE intranet pages: https://intranet.uwe.ac.uk/tasks-guides/Policy/legal-register.

x) Human Tissue Act 2004

The Human Tissue Act 2004 '*regulates the removal, storage and use of human tissue. This is defined as material that has come from a human body and consists of, or includes, human cells'*.

The Human Tissue Act regulations can be complex to interpret. A decision will need to be made firstly as to whether the tissue is 'relevant material' under the Act (and the Act does relate to less obvious tissue, such as the residual cells in urine and faeces, even where the research will not use these cells). A decision will also need to be made about whether the research is for a 'scheduled purpose'. Such decisions are not always clear cut. Researchers (including Student Research Supervisors) are therefore expected to consult for advice with the Officer to the Human Tissue Sub-Committee (HTSC) in relation to any research involving human tissue. All human tissue projects must be logged on the UWE Bristol Human Tissue Register, prior to any tissue being brought onto UWE premises. Material containing human cells can be held without a license for a period of a few days and never more than a week, specifically and solely for the purpose of rendering it acellular **by recognised means**, but no research whatsoever can occur on those samples, even if that research would itself render the samples acellular, or can be done within a few days. Human Tissue research at UWE Bristol is governed by the Human Tissue Sub-Committee, and advice is also available from its members, via the Officer (researchgovernance@uwe.ac.uk).

The UWE Human Tissue Quality Management System (QMS) sets out the University's requirements for the conduct and management of human tissue research. The QMS can be found at:
http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

Research using human tissue must be registered on the UWE Bristol Human Tissue Register, via the Officer to the HTSC. It is the responsibility of Project Managers to ensure that the entry in the human tissue register for their research is kept up to date.

The University does not have a license for the storage of human tissue for research purposes. It is therefore necessary to obtain NHS REC approval for the storage and use of human tissue in individual research projects, on a project-by-project basis (via the HRA approval process).

This means that tissue cannot be stored after the project NHS REC approval has expired, without an approved amendment of the end date. The tissue can only be used for the purposes set out in the NHS REC application, without a further application or an application for an amendment (and only then if this is in line with participant consent).

It is the Project Manager's responsibility to ensure that NHS REC permission is up to date and conditions adhered to, and that tissue is not retained by the University past the expiry date of the permission. At the end of the project the tissue either needs to be destroyed, moved to another site which has a site license, or a further NHS REC project application for new work completed before the end date of the existing approval. Any such further permissions must be in place in advance – tissue cannot be stored at UWE Bristol for any time period without permission, as this would be unlawful.

It should be noted that a lack of compliance with the legislation can result in a prison sentence.

xi) Intellectual Property Legislation

The University requires those conducting research to comply with Intellectual Property legislation.

Information about intellectual property legislation can be found on the Intellectual Property Office website.

xii) The Mental Capacity Act 2005

- The Mental Capacity Act 2005, covering England and Wales, provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they may lack capacity in the future. It sets out who can take decisions, in which situations, and how they

should go about this. Because the Act is intended to assist and support people who may lack capacity, the Act protects people who take part in research projects but lack capacity to make decisions about their involvement. It makes sure that researchers respect their wishes and feelings. UWE Bristol research involving people who lack capacity must comply with the requirements of the Act.

- Guidance and information, including guidance in relation to research, is provided in the Mental Capacity Act 2005 Code of Practice. UKRI/ESRC have also produced guidance on research with potentially vulnerable people, which sets out some of the legislative and ethical issues.
- Note: Under the Mental Capacity Act 2005, 'intrusive' research requires approval from an NHS or Social Care REC if it will at any stage involve people unable to consent for themselves because of an impairing condition. Intrusive procedures are those requiring consent in law, including use of identifiable tissue samples or personal information.

xiii) Working with Offenders, HMP Services and Probation Trusts

- All applications to conduct research requiring access to data, staff or offenders are managed by the National Offender Management Service. Applications should be submitted through the Integrated Research Application System (IRAS) and the pdf emailed to national.research@noms.gsi.gov.uk.
- Further information on making research applications to the National Offender Management Service can be found at: https://www.gov.uk/government/organisations/national-offender-management-service/about/research#research-application-process.

xiv) PREVENT Duty (radicalisation of vulnerable individuals) **New Government legislation has placed a statutory duty on Higher Education Institutions to have "*due regard to the need to prevent people from being drawn into terrorism*".**

The legislation, known as Prevent Duty, applies to all kinds of extremism, for example the Far Right, Islamist groups and animal rights groups.

The objective of the Prevent Duty is to safeguard individuals from being radicalised and drawn into terrorism.

UWE needs to be aware of any research that may potentially have an influence on radicalisation and ensure that it is appropriately reviewed. The University must also be aware of all research using security sensitive information. The University will need to assure itself through the ethical review process that the research is appropriate per se and that researchers are supported and protected in relation to their research, and appropriate for the level and experience of the researcher.

Further information on UWE Bristol's response to the Prevent Duty can be found at: Safeguarding - Stay safe on and off campus | UWE Bristol

UWE also provides guidance for security sensitive research, within the Research Ethics Handbook.

xv) Ionising Radiation Regulations and The Environmental Permitting Regulations

HSS18 Radiation Safety Policy sets out the University's requirements. Advice can also be sought from the University's Head of Health and Safety at safety@uwe.ac.uk.

Non-Ionising Radiation

For work involving non-ionising radiation there is a Health and Safety Standard HSS20. This covers all non-ionising radiation to include artificial optical and electromagnetic fields. In support of this Health and Safety Standard, the Guidance on the Safe Use of Lasers in Education and Research, published by the Association of University Radiation Protection Officers, is adopted by the University as representing good practice. The Standard also ensures compliance with The Control of Electromagnetic Fields at Work (EMF) Regulations 2016.