Annex 7: Some key legislation and regulation affecting research

(i) Legislation relating to Children

Significant legislation governs the protection of children in the UK. Whilst much of this is not research specific, it sets the context for research with children. The NSPCC have produced a factsheet which provides an introduction to legislation which protects children and young people in the UK. This can be found at:
http://www.nspcc.org.uk/Inform/policyandpublicaffairs/uk-legislation_wda100749.html

Images of children should be used with greatest of care. Use of images of children involve significant ethical issues must be fully considered (see the UREC Guide on working with children). There are also clear legislative requirements. The following link provides further information about legislation in relation to indecent photographs of children:
http://www.cps.gov.uk/legal/h_to_k/indecent_photographs_of_children/#a02

The following link gives advice in relation to publication of images of children:
http://www.nspcc.org.uk/Inform/research/briefings/Photographing-children_wda96007.html

The Medical Research Council have produced guidance on medical research involving children, which covers some legislation requirements concerned with legal informed consent. The Guidance can be found at:
http://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/

(ii) Clinical trials legislation

- Information about legislation relating to clinical trials can be found on the MHRA website:
  http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Legislation/Legislation/index.htm

- In order to obtain a favourable opinion from a Research Ethics Committee through the NRES system, it is a requirement that clinical trials should 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. The following guidance is taken from the NRES web pages.

  'What types of research does this apply to?

  This requirement will apply to clinical trials which, for the purposes of registration, are defined as the first four categories on the Integrated Research Application System (IRAS) question 2:

  - *Clinical trial of an investigational medicinal product (CTIMP),*
  - *Clinical investigation or other study of a medical device,*

- *Combined trial of an investigational medicinal product and an investigational medical device,*
- *Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.'*

'Accepted registers

These include:

- *EU Clinical Trials Register (http://www.clinicaltrialsregister.eu). This register is linked to the EudraCT register, which is mandatory for all CTIMPs in patients authorised on or after 1 May 2004.*
- *International Standard Randomised Controlled Trials Number (ISRCTN) Register. This register accepts registration of randomised controlled trials and any other research study designed to assess the efficacy of health interventions in the human population.*
- *ClinicalTrials.gov. This is a register of studies in the United States and around the world.'*

Further guidance can also be found at:
http://www.hra.nhs.uk/documents/2013/10/clinical-trial-regulation-guidance.pdf

- In addition to such external registration, all UWE Bristol clinical trials, including non CTIMP trials of interventions, must be registered on the UWE Bristol Clinical Trials Register via the Research Governance Manager.

- Additional guidance about good research practice in clinical trials is provided in the MRC's 'Guidelines for Good Clinical Practice in Clinical Trials', which can be found at: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416

It should be noted that there is new EU Clinical Trials regulation that will apply from 28 May 2016. This is intended to streamline the authorisation process. Further information can be found at:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1401366187088&uri=OJ:JOL_2014_158_R_0001

(iii) Data Protection Act 1998

- The University requires those conducting research to comply with the Data Protection Act.

- The University's data protection policy can be found at:
http://www1.uwe.ac.uk/aboutus/policies

and further guidance can be found at**:** http://www.uwe.ac.uk/finance/sec/dp/

- 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.

- Guidance about data protection in relation to filming in public spaces can be found at: http://www.jisclegal.ac.uk/ManageContent/ViewDetail/ID/3217/Is-it-okay-to-film-people-in-public-places-21-August-2013.aspx

(iv) Dual use research

A definition of dual use research from McLeish and Paul (2004) is given as follows:

'Dual use is a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications'.

Dual use technology is subject to a range of National and transnational controls, and researchers should ensure that they are compliant with the relevant legislation and regulation. Information about the requirements for the UK, Europe and the USA can be found at the links below:

http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls/

https://www.gov.uk/uk-strategic-export-control-lists-the-consolidated-list-of-strategic-military-and-dual-use-items

(v) Equality Act 2010

The following is taken from: https://www.gov.uk/equality-act-2010-guidance:

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.

(vi) The Freedom of Information Act 2000

The following is taken from the Information Commissioner's Office Website (http://ico.org.uk):

The Freedom of Information Act 2000 provides public access to information held by public authorities. It does this in two ways:

- public authorities are obliged to publish certain information about their activities; and
- members of the public are entitled to request information from public authorities.

The Act covers any recorded information that is held by a public authority in England, Wales and Northern Ireland, and by UK-wide public authorities based in Scotland.

Further information can be found on the Information Commissioner's Office Website: http://ico.org.uk/for_organisations/sector_guides/~/media/documents/library/Freedom_of_Information/Detailed_specialist_guides/definition_document_for_universities_and_higher_education_institutions.pdf

(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
- Information about the requirements with which UWE Bristol researchers must comply can be found on the 'standards' page of the University health and safety web pages (HSS22). Also more specifically 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 Officer. Their details can be accessed via the HAS Health and Safety intranet pages, using the link given above.

(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)…

- Further details can be found at: http://www.hse.gov.uk/legislation/hswa.htm

(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 Research Governance Manager in relation to any research involving human tissue. All human tissue projects must be logged on the UWE Bristol Human Tissue Register. Material containing human cells can be held without a license for a period of a few days, specifically and solely for the purpose of rendering it acellular, 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 Research Governance Manager.

- General Guidance about the Human Tissue Act can be found at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm

  The University's human tissue research procedures can be found at: http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx

- Research using human tissue must be registered on the UWE Bristol Human Tissue Register, via the Research Governance Manager. 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 currently have a site license for human tissue research. It is therefore necessary to obtain permission from an NHS REC via the NRES system on a project by project basis. Some uses are not licensable via this mechanism, such as

tissue banks, which cannot currently be held at UWE Bristol. This also 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 at:

  http://www.ipo.gov.uk

(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, which can be found at: https://www.justice.gov.uk/downloads/protecting-the-vulnerable/mca/mca-code-practice-0509.pdf

(xiii) Radiation legislation

Health and Safety Standard HSS18 on Radiation Safety provides information about relevant legislation, and the UWE Bristol regulatory regime, which must be complied with. Advice can also be sought from the University's Health and Safety Manager.

(xiv) Safeguarding/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: https://intranet.uwe.ac.uk/ou/hr/Pages/Safeguarding-guidance.aspx (in relation to staff) and http://www1.uwe.ac.uk/aboutus/policies.aspx (in relation to students).

- There are significant ethical issues involved in working with children and young people. Researchers should ensure that they have carefully considered the issues, drawing where appropriate on the expertise of colleagues in the University with specific expertise in the research area, and/or FREC members. Research involving children includes contact with children themselves, either face to face or by other means, their data, and their images. The University has produced guidance for research with children and young people which can be found at: http://www1.uwe.ac.uk/research/researchethics/guidance.aspx

- 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. http://www1.uwe.ac.uk/aboutus/departmentsandservices/professionalservices/humanresources/hrpoliciesandprocedures.aspx

  The University has a separate policy which relates to students, the Policy Statement On The Recruitment And Placement Of Students Who Are Ex-Offenders (http://www1.uwe.ac.uk/aboutus/policies). 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.