**Legal Services Quick Guide: Legal and Regulatory Issues for Researchers**

**Introduction**

In accordance with [*The Concordat to Support Research Integrity*](https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity#:~:text=The%20concordat%20to%20support%20research%20integrity%20asks%20universities%2C%20research%20institutes,standards%20of%20rigour%20and%20integrity.) (Universities UK, 2019), researchers must comply with ‘ethical, legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities’ and have a responsibility to keep their knowledge of such obligations up-to-date.

This Guide aims to highlight the key legal and regulatory issues that may affect research, and to signpost further resources.

Bournemouth University’s Code of Good Research Practice provides guiding principles and standards of good practice for research at the University. All those involved in research at the University are required to abide by the Code, which provides further guidance on some of the issues highlighted in this Guide:

<https://intranetsp.bournemouth.ac.uk/policy/BU%20Code%20of%20Good%20Research%20Practice.pdf>.

Bournemouth University’s Research Ethics Code of Practice provides guidance about conducting ethical research, and also touches on some of the issues raised here:

<https://intranetsp.bournemouth.ac.uk/pandptest/8B-research-ethics-code-of-practice.pdf>.

**Examples of key legislation and regulations affecting research**

**Data Protection Act 2018**

*Key points*

* The UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA) provide a legal framework to ensure that personal information is handled properly.
* All research must comply with the UK GDPR and DPA and the data protection principles set out under these provisions, which govern the collection, use, retention and transmission of personal information; please see the University’s [Data Protection Policy](http://intranetsp.bournemouth.ac.uk/policy/Data%20Protection%20Policy%20for%20Staff%20and%20BU%20Representatives.docx) and the [Outputs and data](https://staffintranet.bournemouth.ac.uk/aboutbu/policiesprocedures/) section (under Policies and Procedures - Research) of the University’s intranet for further guidance.
* A Data Management Plan, as detailed in the University’s [Research Data Policy](https://intranetsp.bournemouth.ac.uk/documentsrep/Research%20Data%20Policy.pdf) is fundamental to achieving data protection compliance.
* All funded, contractual or collaborative research must comply with the specified requirements for personal information storage and retention. The University’s [Research Data Policy](https://intranetsp.bournemouth.ac.uk/documentsrep/Research%20Data%20Policy.pdf) sets out requirements on data storage and retention and detailed guidance can be found at the University’s [Data protection and privacy](https://www.bournemouth.ac.uk/about/governance/access-information/data-protection-privacy) webpage.
* Funders are increasingly stipulating retention periods linked to their awards, so researchers should ensure they are aware of any retention periods specified by project funders.
* The protection of personal information includes the need for secure storage, as well as the requirement for proper consent to access and use personal information. Note that personal information may include photographs, audio clips and film clips.
* One key aspect of compliance under the UK GDPR and DPA is privacy notices – i.e. the statements used when collecting personal data – which need to include information explaining:
  + BU’s legal basis for processing data;
  + individuals’ data rights;
  + how long BU will keep the data; and
  + that individuals have a right to complain to the ICO if they think there is a problem with the way their data is being handled.

Note that the UK GDPR requires the information to be provided in concise, easy to understand and clear language.

The University has a [Research Participant Privacy Notice](https://www.bournemouth.ac.uk/about/governance/access-information/data-protection-privacy/research-participant-privacy-notice) for people who are participating in, or have been invited to participate in, an academic research project being undertaken by BU researchers. A link to this Notice is provided within the University’s Participant Information Sheet provided to research participants by University researchers before they decide whether or not they wish to participate in the research.

* Where consent is used as the legal basis for processing of personal data, this consent must be freely given, specific, fully informed and unambiguous. Consent must also be revocable (i.e. people must be able to withdraw their consent) and you should have procedures in place to action and record it when this happens.
* Consent is not generally the legal basis under the data protection legislation for use of personal information for research. This is because the University can only rely on consent as the basis for processing data if the University would always be able to act on a withdrawal of consent, by removing data from its research project and outputs. Often the University would not be able to do this in the context of a research project, as this could affect the validity and integrity of the research process and/or the outputs from the research.
* In general, where the University is collecting and processing personal data for the purposes of an academic research projects, we rely on the following legal bases/conditions:
  + Article 6.1(e) of the UK GDPR, i.e. our processing is necessary for the performance of a task carried out in the public interest. Research is a task that the University performs in the public interest, as part of our core function as a university;
  + Article 9.2(j) of the GDPR, i.e. our processing is necessary for research purposes or statistical purposes (this condition applies as long as we are applying appropriate protections to keep the data secure and safeguard data subjects’ interests).
* Researchers should also be aware of the open access requirements associated with their research.

*Where can I find out more?*

* The University’s Data Protection Policy can be found in the Legal section of Policies and Procedures on the staff intranet:

<https://staffintranet.bournemouth.ac.uk/aboutbu/policiesprocedures/>.

* The Guide to Data Protection issued by the Information Commissioner’s Office can be found at: <https://ico.org.uk/for-organisations/guide-to-data-protection/>.
* The Information Commissioner’s Guidance to the UK GDPR can be found here:

[https://ico.org.uk/for-organisations/data-protection-reform/guidance-what-to-expect-and-when/?\_ga=1.1900017.151605751.1464189410](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/?_ga=1.1900017.151605751.1464189410)

* The University’s [Code of Good Research Practice](https://intranetsp.bournemouth.ac.uk/policy/BU%20Code%20of%20Good%20Research%20Practice.pdf) and its [Research Ethics Code of Practice](https://intranetsp.bournemouth.ac.uk/pandptest/8B-research-ethics-code-of-practice.pdf) contain further guidance on complying with certain aspects of data protection legislation.
* Information about HEFCE’s Open Access Policy is available on the University’s Research Blog: <http://blogs.bournemouth.ac.uk/research/2015/07/28/hefce-open-access-policy-adjustments-and-qualifications/>.

**Equality Act 2010**

*Key points*

* The Equality Act (EA) replaced all previous anti-discrimination laws with a single piece of legislation, which provides protection from unfair treatment and discrimination in the workplace and in wider society.
* The EA protects individuals against discrimination on the basis of nine protected characteristics: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.
* All staff have a responsibility to ensure that their conduct is in accordance with the University’s [Equality and Diversity Policy](http://intranetsp.bournemouth.ac.uk/policy/dignity-diversity-and-equality-policy.doc).

*Where can I find out more?*

* Information and guidance can be found at: <https://www.gov.uk/equality-act-2010-guidance>.
* See the University’s Equality and Diversity Policy under the People section of Policies and Procedures on the Staff Intranet: <https://staffintranet.bournemouth.ac.uk/aboutbu/policiesprocedures/>.

**Health and Safety legislation**

*Key points*

* There are various statutes and regulations covering health and safety at work. The Health and Safety at Work Etc. Act 1974 is the primary piece of legislation covering occupational health and safety in Great Britain.
* In accordance with the University’s [Code of Good Research Practice](https://intranetsp.bournemouth.ac.uk/policy/BU%20Code%20of%20Good%20Research%20Practice.pdf), all research undertaken must fulfill the requirements of health and safety legislation and good practice. Researchers will face a range of potential risks to their and others’ safety when conducting certain types of research, for example social research in a conflict zone or research using potentially harmful equipment or substances.
* Appropriate and thorough [risk assessment](http://staffintranet.bournemouth.ac.uk/workingatbu/healthsafetywellbeing/riskassessment/) must be undertaken when research is to be conducted in potentially hazardous conditions, involves potentially harmful material or might cause harm to the environment. Further information can be found in the University’s [Health & Safety in Research](http://intranetsp.bournemouth.ac.uk/policy/Health%20and%20Safety%20in%20Research%20Work.doc) policy.
* Those carrying out research activities, in common with all University staff, must follow all relevant parts of the University’s health and safety policies.

*Where can I find out more?*

* The University has a range of relevant policies which can be found in the ‘People’ section of Policies and Procedures on the staff intranet:

<https://staffintranet.bournemouth.ac.uk/aboutbu/policiesprocedures/>.

These include:

* COSHH Assessment Guidance on Hazardous Substances
* General Risk Assessment Guidance
* Health & Safety in Research
* Hazardous Substances Policy
* Risk Assessments Policy
* See also the University’s [Code of Good Research Practice](https://intranetsp.bournemouth.ac.uk/policy/BU%20Code%20of%20Good%20Research%20Practice.pdf).
* Further information about the Health and Safety at Work Etc. Act can be found at: <http://www.hse.gov.uk/legislation/hswa.htm>.
* A guide to Health and Safety regulation can be found at: <http://www.hse.gov.uk/pubns/hsc13.pdf>.

**Human Tissue Act 2004**

*Key points*

* The Human Tissue Act (HT Act) provides a legislative framework for regulating body donation and the removal, storage, and use of human organs and tissue. Human tissue is defined as material that has come from a human body and consists of, or includes, human cells.
* **Obtaining informed consent** is now the fundamental requirement underpinning the lawful removal, storage and use of human organs and tissue.
* The HT Act established an overarching Authority, the Human Tissue Authority (HTA), to regulate relevant activities through a system of licensing and the provision of directions and guidance.
* Researchers using human tissue must consult the guidance given on the HTA webpages and may be required to obtain a licence from the HTA.

*Where can I find out more?*

* The Human Tissue Authority’s website contains further information and guidance: <https://www.hta.gov.uk/guidance-professionals>.
* Also see guidance from the Medical Research Council: <http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/human-tissue/>.

**Intellectual property**

*Key points*

* Almost all research activity will involve some form of intellectual property. Intellectual property (IP) is the general term for intangible property rights which are a result of intellectual effort and includes: copyright, performance rights, database rights, patents, design rights, registered design rights, trademarks, know-how and confidential information.
* Some of the above IP rights, such as copyright, exist automatically on creation; others, such as patents and registered design rights, must be applied for to obtain protection.
* It is important that individuals do not infringe third party IP in their work; researchers must not use third party IP rights in research without appropriate permissions and licences from the owner(s) of that IP. Where licences or permissions are granted, they must be in writing and should be put in place with assistance from the Legal Services team ([legalservices@bournemouth.ac.uk](mailto:legalservices@bournemouth.ac.uk)).
* Researchers must take steps to manage and protect the University’s IP and should seek advice from Legal Services where necessary.

*Where can I find out more?*

* The Intellectual Property Office website contains useful information: <https://www.gov.uk/intellectual-property-an-overview>.
* The University’s Intellectual Property Policy and Intellectual Property Management Procedures can be found in the Legal section of Policies and Procedures on the Staff Intranet: <https://staffintranet.bournemouth.ac.uk/aboutbu/policiesprocedures/>.
* Legal Services Quick Guide to Intellectual Property Rights is available at:

<https://intranetsp.bournemouth.ac.uk/policy/Quick%20Guide%20to%20Intellectual%20Property%20Rights.docx>

and our Intellectual Property Guidance is available at: <http://intranetsp.bournemouth.ac.uk/policy/Intellectual%20Property%20Guidance.docx>

* Legal Services Legal Services Quick Guide to Contracting for Research and Enterprise is available here: <http://intranetsp.bournemouth.ac.uk/policy/Legal%20Services%20Quick%20Guide%20to%20Contracting%20for%20Research%20and%20Enterprise.docx>

**The Mental Capacity Act 2005**

*Key points*

* The Mental Capacity Act 2005 (MCA) provides a statutory framework for people who lack capacity to make decisions for themselves. It sets out who can take decisions, in which situations, and how they should go about this.
* The MCA sets out specific safeguards and controls for research involving, or in relation to, people lacking capacity to consent to their participation.
* All research involving those who lack capacity, or who during the research project come to lack capacity, must be approved by an ‘appropriate body’ operating under the MCA. An ‘appropriate body’ is defined in law. In England, an ‘appropriate body’ is a research ethics committee recognised by the Secretary of State.

*Where can I find out more?*

* The Government’s Mental Capacity Act Code of Practice can be found at: <https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice>.
* The University’s [Research Ethics Code of Practice](http://blogs.bournemouth.ac.uk/research/files/2012/09/8B-Research-Ethics-Code-of-Practice_February-20142.pdf) contains some further guidance on mental capacity issues.

**Disclosure and Barring Service requirements**

*Key points*

* The Criminal Records Bureau (CRB) and the Independent Safeguarding Authority (ISA) were merged in 2012 to become the Disclosure and Barring Service (DBS).
* A DBS check (previously CRB check) may be needed for staff undertaking certain activities and roles as part of their research, for example where they are working with children or vulnerable adults.

*Where can I find out more?*

* Further information can be found at: <https://www.gov.uk/disclosure-barring-service-check/overview>.
* BU Research Ethics ([researchethics@bournemouth.ac.uk](mailto:researchethics@bournemouth.ac.uk)).

**Animals (Scientific Procedures) Act 1986**

*Key points*

* The use of animals in experiments and testing is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA).
* Under the ASPA a ‘protected animal’ is ‘any living vertebrate, other than man, and any living cephalopod’. A protected animal is defined as ‘living’ until its circulation stops permanently or its brain is destroyed.
* Three licences are required by the ASPA before testing on animals is permitted:
  + a *personal* licence for each person carrying out procedures on animals;
  + a *project* licence for the programme of work; and
  + an *establishment* licence for the place at which the work is carried out.
* These licences are issued by the Home Office and will set out various conditions and requirements that must be complied with.

*Where can I find out more?*

* Further information and guidance is available at: <https://www.gov.uk/research-and-testing-using-animals>.
* Also see: <https://www.gov.uk/government/publications/operation-of-aspa>.

**Controlled drugs: Misuse of Drugs legislation**

*Key points*

* Certain drugs are subject to control under the Misuse of Drugs legislation: Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.
* The main purpose of the Misuse of Drugs Act 1971 is to prevent the misuse of particular named drugs and it achieves this by imposing a complete ban on the possession, supply, manufacture, import and export of controlled drugs except as allowed by regulations or by licence from the Secretary of State. A list of the most commonly encountered controlled drugs is set out on the Home Office website:

<https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation>

* Controlled drugs are grouped into schedules under the Misuse of Drugs Regulations 2001. University research departments generally do not require licences to possess and supply drugs in schedules 2, 3, 4 part I, 4 part II and schedule 5, but they do require licences to *produce* any of those drugs and to produce, possess and/or supply drugs in schedule 1.

*Where can I find out more?*

* Information is available from the Home Office: <https://www.gov.uk/controlled-drugs-licences-fees-and-returns>.
* Check the categorisation of any particular controlled drug by referring to the Schedules of the Misuse of Drugs Regulations 2001:

<http://www.legislation.gov.uk/uksi/2001/3998/contents/made>