



# **Ethical Principles for Teaching, Research, Consultancy, Knowledge Exchange and Related Activities**

**Effective from September 2024 to Present**

Student Regulations and Policies

[uclan.ac.uk/studentcontract](https://uclan.ac.uk/studentcontract)

<b>Purpose of Policy</b>	This policy contains the key principles which are intended to protect human, animal and other living subjects as well as the environment in all activities carried out in the University. The policy sets out the ethical principles for work with human participants, animals, micro-organisms, genetic modification, chemicals, radiation, the environment, art and military weapons, and artificial intelligence, and contains the key considerations that must be taken into account when undertaking research in respect in any of those areas, including the process for obtaining consent.
<b>Internal services involved</b>	Research and Enterprise Service
<b>Related UCLan regulations, policies and procedures</b>	Academic Regulations for Postgraduate Research Degrees Academic Regulations for Professional Doctorates Ethics Pack for Research Students
<b>Enquiries to</b>	Ethics, Integrity and Governance Unit <a href="mailto:EthicsInfo@uclan.ac.uk">EthicsInfo@uclan.ac.uk</a>
<b>Senior Managers responsible</b>	Head of Ethics, Integrity and Research Governance Unit
<b>VCG Lead</b>	Pro Vice Chancellor (Research and Enterprise)

<b>Version</b>	<b>Approved</b>	<b>Effective from</b>	<b>Revisions made</b>	<b>Next Review</b>
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2	May 2024	September 2024	Section 3: Ethical principles for work with human participants. Amended to include information about projects involving stakeholders, public participation, peer researchers, co-production and/or	May 2025

			participatory action research	

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# 1.0 Context of principles

- 1.1 The principles listed below are intended to protect human, animal and other living subjects as well as the environment in all activities carried out in the University.

## 2.0 General ethical principles

- 2.1 The University expects staff and students to adhere to the law and to be aware of the ways in which it affects their work. They should be aware of all relevant University policies and practices, including those relating to Data Protection and Freedom of Information. Work, particularly in the areas of Health, Science and Engineering, has health and safety implications. All such work must comply with the University's Health and Safety policies and practices including a full Risk Assessment. Researchers<sup>†</sup> should be aware of and adhere to the University's Code of Conduct for Research, while staff involved in Income Generating Activities (IGA) should adhere to University policy documents relating to contract work, financial management, investment and purchasing, including the current embargo on accepting funding from the tobacco industry.
- 2.2 Members of the University should consider the implications of their work in relation to:
- Respect for autonomy, which means respect for an individual's capacity for self-determination, bearing in mind specific needs and vulnerabilities of individuals;
  - Non-maleficence, which means avoidance of harm and potential harm, bearing in mind the specific vulnerabilities of those affected;
  - Beneficence, which means, wherever possible, promoting benefit;
  - Justice, which means the fair and appropriate treatment of those affected by the work.
- 2.3 Members of the University should be aware of and address any ethical issues relating to their work. Staff should be aware that the University has adopted ethical principles for teaching, research, income-generating activities and other work, and established an ethics procedure to ensure that the ethical guidelines are adhered to. Additionally, ensuring the principles of the **TRUST Code - A Global Code of Conduct for Equitable Research Partnerships** (formerly known as the Global Code of Conduct in Resource Poor Settings) for any research being conducted in low and lower-middle income countries as defined by the World Bank are applied. The way by which this is done will vary depending on the nature of the work, but they should consult with their appropriate Ethics Review Panel where ethical issues have been identified, and all such research, income-generating and teaching activities should be approved by an Ethics Review Panel. Students may not initially be aware of the University's ethical principles, but by the time they work on their final year dissertation/project they

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<sup>†</sup> Footnote: "Research" in this document is defined as a systematic investigation into a topic involving original data or original thought applied to existing information. It therefore covers some work within the teaching programme as well as some commercial work and non-academic research carried out by administrative staff. "Researchers" is defined as any member of staff, student or other worker at the University who is carrying out the research.

should be aware of them and of the role of School/Faculty and central ethics processes in overseeing such work.

- 2.4 The University will make reasonable adjustments whenever possible to enable individual staff or students to carry out their work without compromising their ethical principles.

## **Conflicts of Interest**

- 2.5 The conduct of research must be fair, honest and transparent. Researchers should consider any conflicts of interest (personal, professional, economic and political) between the researcher, funder/s, and/or participants and the wider community. Researchers should identify and inform the relevant stakeholders if there are any conflicts of interest which may harm participants, the researchers and the wider community, and which may influence or bias the research process and research findings.

## **Encryption**

- 2.6 When sensitive data is likely to be held on multiple and inaccessible backups encryption may be the only effective means of complying with an agreement to delete data. By deleting the encryption key, the encrypted copies remain on the backups but are irreversibly encrypted (and hence effectively deleted).
- 2.7 The following sections outline ethical principles and guidelines for work in areas which raise particular ethical issues.

## **3.0 Ethical principles for work with human participants<sup>‡</sup>**

- 3.1 Researchers should consider the ethical implications of their work in all circumstances. In doing so, they should strive to consider the viewpoints of all who may be affected by the work: participants, colleagues, members of the public, potential end-users, funding agencies and the researchers themselves. They should also be aware of any additional ethical guidelines relevant to their area of work and of any requirements for ethical approval external to the University.

## **Consent**

- 3.2 Participants should give their informed consent before any research is undertaken. The researcher should make every effort to provide sufficient information about the purpose and methods of the study and make participants aware of any aspects of the research that might reasonably be expected to influence willingness to participate.

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<sup>‡</sup> Footnote: Whilst this section relates primarily to research, other activities which raise similar issues should be considered and addressed in like manner.

This information should include details of the form in which the results of the study will be made available to them after taking part, i.e. whether they will be able to obtain individual results, or only a summary of the results of the study. If individual results are to be made available, this should be done cautiously, in a manner that takes account of any potential distress that may be caused (e.g. if the research relates to health problems or other sensitive issues). Potential participants should also be provided with details of how long the study will last, whether, and for how long, some or all the information they provide may be stored for potential future research. If future research might occur, they should also be informed as to whether, or in what circumstances, they will be approached for consent and whether further ethical approval will be sought prior to its commencement. Researchers should also bear in mind their own qualifications or competence to give advice on the relevant issues and should refer participants to appropriate sources of professional advice when necessary. If the nature of the research is such that fully informed consent is not possible, additional safeguards are required to protect the welfare; dignity and privacy of participants (see sections 3.5, 3.12 and 3.13).

- 3.3 Consent may be written or verbal, and must be well-informed, voluntary and specific. Whichever form of consent is used, a record should be kept for audit purposes.
- 3.4 In research with infants and children under the age of 16, informed consent should normally be obtained from their parents, defined as those holding "parental responsibility" for the child, including any other carer or local authority as specified in the Children Act 1989. Young people aged between 16 and 18, while not legally fully adult, are usually presumed to be competent to give consent. Children under 16 may be considered competent to give consent if they have sufficient intelligence and understanding of the proposed research (sometimes referred to as "Gillick Competence"). Whether or not parental consent is a legal necessity, however, it is considered good practice to involve parents as much as possible unless it is not in the child's best interests to do so. Whether or not parental consent is being obtained, researchers should remember that children of all ages have the right to be informed, to express an opinion, and to influence any decisions about their participation in research, and that this process should be facilitated in a way that is appropriate for the age and understanding of the child. Reliance on the consent of a head teacher acting "in loco parentis" should be reserved for the least contentious or intrusive studies, or those that are indistinguishable from normal school activities. It should not be relied upon where there is the possibility of a child being identified from the study results, or where the study is personal or relates to sensitive issues. Even when head teacher consent is being obtained, it is still considered good practice to advise the parents of the fact that the study is being undertaken, and to offer the option of withdrawal.
- 3.5 Where informed consent cannot be obtained from adults with impairments in understanding or communication, or if the research involves those in vulnerable situations or dependent relationships (e.g. the elderly in care), then special care should be exercised. Researchers should consult with, and obtain assent from, those well-placed to appreciate the participants' likely reactions, such as family members, professional carers, charitable organizations, other experts in the relevant field, or a supervising authority (e.g. Official Solicitor or The Court of Protection). Only in trials of

pharmaceutical products can consent for an adult's participation legally be obtained from another person, referred to as their 'legal representative'.

- 3.6 It is important for researchers to realise that they may sometimes be in a position of authority over participants who may, for example, be students, employees, clients or prisoners. They should not use this authority to pressurise individuals to participate in research.
- 3.7 Where research is carried out in a country other than the UK the researcher should generally follow the basic principles outlined here but should consider variations as may apply in that country.
- 3.8 Volunteers may be paid for their inconvenience and time, but such payment should not be so large as to induce them to risk harm beyond that which they risk without payment in their normal lifestyle.

### **Withholding Information or Misleading of Participants**

- 3.9 Withholding information from or misleading of participants is unacceptable except where this forms an essential part of the research. It is the responsibility of the researchers to determine whether alternative procedures are available. Participants in such research should be provided with additional information as soon as possible. They should then be asked to confirm their consent, and if they do not do so they should be removed from the study sample and their data destroyed. All Ethics Review Panels should pay attention to such research which should be avoided whenever possible. If, in the Ethics Review Panel's judgement, the participants are likely to object after debriefing, then the research should not be approved.

### **Feedback to Participants**

- 3.10 In studies where participants are aware that they have taken part in an investigation, once the data has been collected the researchers should provide participants with sufficient information at an appropriate level to enable them to understand the nature of the research. The researchers should, where possible, discuss with participants their experience of the research to monitor any unforeseen negative effects or misconceptions.

### **Withdrawal from the Research**

- 3.11 At the beginning of the investigation, researchers should make clear to participants that they have the right not to participate or to withdraw from the research at any time during data collection, irrespective of whether payment has been offered. Researchers should check throughout the investigation that the participants are not showing signs of distress and are still willing to continue. Procedures should be in place to provide care and support for participants if they do show signs of distress. Participants have the right, following their experience of research or debriefing, to withdraw their



consent, and require that their own data be destroyed. Where destruction of data is not possible participants should have been informed of this and given their consent at the outset.

## **Confidentiality and anonymity**

- 3.12 Subject to the requirements of the Data Protection and Freedom of Information Acts, all information collected about a participant during an investigation is confidential unless otherwise agreed in advance. If confidentiality cannot be guaranteed for any reason, participants must be warned of this in advance and should consent explicitly to the release of their information. Audio, video, photographic and other recordings can only be made with the express consent of those being recorded (except for recordings of public behaviour) as to both the making of the recording and subsequent uses of it. In open group discussion, such as used in focus groups, participants should be asked to agree to maintain the confidentiality of any information provided by others during the discussions.
- 3.13 Data on (or samples from) human participants should be coded or fully anonymised as soon as possible. Any codes linking names to data should be stored in a secure manner in a separate location from the coded data. When it is unnecessary to preserve the link between people's names and the data (or samples), the names should be removed from the data (or samples). Additionally, during the design of a study, researchers should always consider whether, even if people's names are not included, data might contain information from which others could deduce the identity of at least some of the participants. Should there be the potential for such identification, participants should be warned of this and consent in advance. Otherwise information which might lead to identification should either be removed or stored in a secure manner and (where appropriate) encrypted (see 2.6).

## **Consideration of Participants**

- 3.14 Researchers have a primary responsibility to protect participants from any unnecessary harm arising from the investigation. They should always comply with the Risk Assessment and Health and Safety procedures of the University (see 2.1).

## **Observational Research**

- 3.15 Studies based upon observation must respect the privacy and psychological well-being of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in situations where those observed would expect to be observed by strangers. Additionally, account should be taken of local cultural values.

## **Projects Involving Stakeholders / Public Participation / Peer Researchers / Co-Production and/or Participatory Action Research**

- 3.16 There are several ways in which stakeholder groups, community members, including children and young people, or patients may be involved in research projects in addition to being research participants in the conventional sense.
- 3.17 Methodologies and the terms used for those involved in research projects in different ways vary across different disciplines. Terms such as 'Participatory Research', 'Co-Production' and the involvement of 'Peer Researchers' are all terms which may be used in different ways in different fields, but they all may relate to:
- A greater level of public and community involvement in the research process
  - Working in partnerships
  - Inclusive approaches
  - Challenging of the traditional distinctions between the 'researcher' and the 'researched'
  - The democratisation of research
  - Acknowledging the value of local knowledge and questioning how we understand the ownership of knowledge
  - The empowerment of communities and traditionally marginalised groups
- 3.18 Across such projects, the same ethical principles apply as they would for any research project, but it is especially important within the context of these kinds of activities to consider the following:
- The understanding of 'research' may vary across different groups. From a university ethics point of view, this is defined as an activity which generates new knowledge which will be disseminated to a wider audience e.g., through publication in journals.
  - Who are the research participants? (Members of a community group who take part in a stakeholder advisory group are not research participants, unless some other kind of research is carried out with them)
  - This about who the research 'belongs' to and how ownership is defined.
  - Projects such as these can involve or be affected by complex sets of power relations between different groups which already may already exist in an organisational context. These power relations should be considered carefully within the specific context of the activity.
  - Be clear about whether discussions or ideas/insights from PPE, stakeholders, or advisory group members will be used, whether as quotes, verbatim, or merely key words and be explicit with participants about what they will inform and whether they will be published and make sure informed consent is obtained.
- 3.19 The sections below summarise the different ways in which individuals or groups may be

involved in research. Examples are provided and the implications for ethics review are outlined.

### **Advisory roles**

- 3.20 Stakeholders with knowledge and/or experience in a particular field are asked to join a steering group which advises UCLan researchers about the design or implementation of a research project.
- 3.21 It can also refer to members of public, including children, or patients with relevant lived experience who can contribute to how research is designed, conducted and disseminated. These advisory groups are often termed Public Patient Involvement (PPI), or lay members. The following issues should be considered:
- Ethical approval is not required for this activity, although it is worthwhile to provide an account of such work as context within an ethics application.
  - It is worth noting that if the activity becomes something more than merely advice to the research team and it is felt that there are insights from the stakeholder group that researchers wish to publish to a wider audience, then the activity becomes research and ethics review is required. Researchers should continue to consider ethical implications of a project throughout and if it looks like advisory activities are turning into something more, please contact the Ethics, Integrity and Governance Unit for advice, as you may be required to submit an ethics application for review.

### **Peer researcher role**

- 3.22 Members of a community which is the subject of the research carry out specific tasks such as interviewing their peers, translating for participants designing a survey or analysing data. The following issues should be considered:
- The potential impact on the peer researcher of carrying out peer research and on the community itself needs to be carefully considered. Is there any potential for harm? What might happen if peers learn things about each other that they might not have been aware of previously?
  - Consider how peer researchers will be acknowledged in any publications and what rights they should have over the data collected and how it is disseminated
  - Peer researchers must be competent to carry out the research and training must be provided. If there is an initial 'training phase' for the peer researchers, ethics review is not required for that training phase. However, if any data is being gathered during the training phase (e.g., evaluating the training which will then be published as research) then ethics review is needed as the peer researchers will also be participants.
  - The nature of the training needs to be considered carefully and details about the training needs to be included in an ethics application submitted for any data collection phase by the peer researchers.
  - The code of conduct for carrying out research needs to be explained and agreed with peer researchers. Matters such as confidentiality need to be highlighted.
  - Risk assessments will need to be in place for the peer research activities
  - Insurance cover will also need to be in place.
  - If peer researchers are collecting data which is also personal data from a GDPR

perspective, then it is possible that a data processor and/or a data sharing agreement will need to be place. You will need to liaise with Information Governance to ensure that adequate provisions are made.

- Particular care needs to be taken when groups such as peer researchers with experiences of trauma, survivors and children are involved. There must be a clear rationale for the involvement of vulnerable groups which is based on the project research questions.
- In a similar way to involving children as participants, when children are peer researchers they must assent to the activity and parental/ carer/ guardian consent must also be in place.

### **Research co-production role**

3.23 Community members design and carry out their own research with some assistance from UCLan staff. The following issues should be considered:

- Think carefully about power imbalances, the potential for conflicting agendas, differing understandings of what constitutes 'research', language use and terminology, inclusiveness, contrasting local, organisational or group cultures, and the potential for conflicts of interests.
- The potential impact of the collaboration needs to be considered, including any potential long-term impact after the project has completed. What support may be required? Is the impact too great? How can you be sure? Are the potential support needs too much?
- As with research participants, those involved in co-production need to be aware of the potential risks, harms and benefits of the collaboration. Think about how you will identify what these risks, harms and benefits might be and monitor them throughout the lifespan of the project.
- Think about who has a final say on the direction of the project and who has a claim (and in what way) on the project outcomes. Consider how such matters can be agreed upon from the outset.
- What framework will you use for governance and accountability?
- Is there a local ethics review process within the organisation or some other relevant body? An ethics review at UCLan may require that the outcome of this local ethics review also takes place and that it is submitted to the Ethics, Integrity and Governance Unit.
- When working in an international context, consult The TRUST Code - A Global Code of Conduct for Equitable Research Partnerships (<https://www.globalcodeofconduct.org/the-code/>)
- It is possible that a Collaboration Agreement would need to be set up before the start of the research which will cover the expectations upon each party and would outline who owns the IP arising from the project. You should check with Legal if this is required.
- If personal data is also involved, a Joint Controller Agreement (JCA) may be necessary (contact Information Governance).
- Again, it is important to identify whether those co-producing research are also participants in your research - for example if you wish to disseminate findings about the process of the activity, the co-producers are also participants and, as for any research

projects, information sheets, consent etc will need to be in place and ethical approval given before the start of the activity.

- Research which is co-produced often evolves during the course of the programme of activities. Consider whether a phased ethics application would be appropriate.

## **Participatory Action Research**

3.24 This is an approach to research in communities that emphasises participation and action. The key emphasis is an understanding of the problems and then changing it, collaboratively, following phased reflection and negotiation. The following issues should be considered:

- The focus is production of knowledge to be used for action and change, which are the main drivers for this style of research.
- In PAR, communities are involved at all stages of the research cycle from identifying a problem to the outputs.
- PAR groups can often be involved in research on themselves and their own understandings of the world, before they engage in research with others. For this reason, an early ethics application to enable inclusion of this knowledge in any future research publications is sometimes advisable.
- For academic researchers and funding bodies, a key output of the research process is publication, in PAR local communities may consider academic publication a low priority and instead want to focus on problem solving and action.
- PAR adopts a reflective approach in collaboration with all partners and works towards identifying solutions to problems. It is a cycle of evaluation to ensure the actions are delivering results. There is a strong focus of negotiation between research partners. In light of this, it is worth considering a phased ethical review process at different stages as the PAR evolves and develops.
- It may be worthwhile to consider consent in a phased approach too. With participatory action, research develops in phases, and this can make it difficult when to obtain consent. It may be worth considering a consensus agreement in the form of group minutes, where the group as a whole agrees to set rules around participation (and withdrawal) that all will adhere to within a particular phase or the research. Individual informed consent may be more appropriate when research participants are providing information/data which is specifically about them.
- Notes and issues as outlined above for research co-production will be relevant here
- In the case of insider action research, the researcher themselves is a member of the organisation, group or community where the research is taking place. This can present a number of unique challenges due to complex existing power relations between the researcher and potential participants, pre-existing and ongoing working relationships and the existence of insider knowledge about participants or the research site. There is a perception that access to participants is easier for insider research, but this presents challenges around ensuring informed consent and ensuring that individuals are not coerced to participate.

Appropriate procedures for acquiring data and securing gatekeeper permissions even within your own organisation must be in place. Researchers need to consider the impact of the research on their ongoing professional relationships and any possible negative consequences of participation in the research for themselves or for participants.

Confidentiality can also be difficult as the researcher's knowledge of the context may allow them to identify participants from their responses. Researchers must be aware of the potential for bias in insider research as participants may change their responses (e.g. in interviews) if they know the researcher. Where researchers are teaching staff, they need to reassure students about why they are being included (or not included) in the research. Consideration will also need to be given to how students who refuse to participate will be reassured they will not be affected and whether it is appropriate to carry out research with students whose work you are also assessing.

## **Additional Sources**

Durham Community Research Team, Durham University (2012) 'Community-based Participatory Research: Ethical Challenges', <https://www.durham.ac.uk/media/durham-university/departments-/sociology/Research-Briefing-9---CBPR-Ethical-Challenges.pdf> (Accessed 1 November 2023)

NIHR (National Institute for Health and Care Research) (2021) 'NIHR Guidance on co-producing a research project', <https://www.learningforinvolvement.org.uk/content/resource/nihr-guidance-on-co-producing-a-research-project> (Accessed 1 November 2023)

UKDS (UK Data Service) (nd) 'Anonymising qualitative data', <https://ukdataservice.ac.uk/learning-hub/research-data-management/anonymisation/anonymising-qualitative-data> (Accessed 15 January 2024)

UKRI (UK Research and Innovation) (2023) 'Co-Production in Research', <https://www.ukri.org/manage-your-award/good-research-resource-hub/research-co-production> (Accessed 1 November 2023)

UKRIO (UK Research Integrity Office) (2023) 'Co-production: participant and stakeholder involvement in research Seminar', <https://ukrio.org/events/webinar-series/co-production-participant-and-stakeholder-involvement-in-research> (Accessed 1 November 2023)

## **Medical Research with Humans and Clinical Trials**

3.25 Medical Research requires additional considerations; researchers should consult appropriate references (e.g. World Medical Association Declaration of Helsinki, 2000; Directive 2001/20/EC of the European Parliament and of the Council, 4 April 2001; The Medicines for Human use (Clinical Trials) Regulations 2004; Medical Research Council guidelines on <http://www.mrc.ac.uk>).

## **Teaching and Research using Human Tissue Samples**

3.26 Human material may be used in both teaching and research, e.g. preserved organs

which may be normal or pathological, tissues for biochemical analysis or slides prepared from tissues for microscopical examination. Any use of such material must comply with the Human Tissue Act 2004 and should follow Medical Research Council Operational and Ethical Guidelines, 2005. Advice must be sought from the Persons Designate of your Faculty, before any human tissue is brought onto UCLan premises. Detail of the Persons Designates for the Faculties can be found on the [ethics intranet page](#) (staff access only) or by contacting [EthicsInfo@uclan.ac.uk](mailto:EthicsInfo@uclan.ac.uk).

## 4.0 Ethical principles for work using animals

### General

- 4.1 The University of Central Lancashire conducts high quality research and teaching that addresses today's challenges. This includes some studies involving animals aimed at understanding disease and developing new medicines to treat chronic and debilitating conditions like Alzheimer's disease and cancer. UCLan is actively engaged in the development of a number of alternative methods such as computer modelling, tissue culture, cell and molecular biology and research with human participants. Therefore, alternative methods to the use of animals for research and teaching will be used wherever possible. However, if animals need to be used the University is committed to refine techniques and use the minimum number of animals to allow for research and teaching objectives to be met.
- 4.2 The principles apply to all University staff and students who are engaged in animal research and teaching. The use of animals in research and teaching includes the use of live animals, biological materials (tissues, blood, organs, cells) derived from animals, or animal-derived data. Ethical issues concerning the use of animals (including invertebrates) must be considered, irrespective of legislative requirements and where the activity is being undertaken (at UCLan, within the UK or overseas). **All activities by staff and students involving animals should undergo appropriate ethical review.**

### Guiding Principles

- 4.3 The University is committed to the principles of reduction, refinement and replacement (the 3Rs). The University has a 3Rs Strategy which outlines the long-term vision for embedding 3Rs into all stages of the research process and wider engagement across the University. 3Rs must be demonstrated in all project applications and teaching activities to ensure that the number of animals used is minimised and/or whether animal use is needed at all and that any activities/procedures taken are refined to maximise care and welfare of the animals.

**Reduction:** appropriately designed and analysed animal experiments that are robust and reproducible, and truly add to the knowledge base.

**Refinement:** Advancing research animal welfare by exploiting the latest in vivo technologies and by improving understanding of the impact of welfare on scientific outcomes.

**Replacement:** Accelerating the development and use of predictive and robust models and tools, based on the latest science and technologies, to address important scientific questions without the use of animals.

- 4.4 The University is committed to the development of alternative methods. Animal procedures are replaced with non-animal techniques wherever possible.
- 4.5 All staff and students involved in animal research and/or teaching must treat animals with care, respect and be appropriately trained.
- 4.6 Staff and students who use animals and/or animal derived material must keep detailed records of where animals/tissue were sourced (this must have been sourced ethically) and the number of animals used.
- 4.7 Please be aware that a Material Transfer Agreement (MTA) is required by UCLan for all incoming and outgoing material transfers from other institutions. The provider of the materials will provide an agreement. UCLan's legal team will provide the template if UCLan are the provider, or they will review agreements from other providers. In either circumstance researchers or students are not authorised to sign the MTA's on UCLan's behalf, UCLan's legal team will advise on the who the authorised signatory is.
- 4.8 Researchers should disseminate findings from their research in accordance with the ARRIVE guidelines including any limitations and report on 3Rs impact.

## **Legislation Overview**

### **Animals (Scientific Procedures) Act 1986 (amended 2012)**

- 4.9 In the UK, research and education activities involving scientific procedures on non-human vertebrates and cephalopods species (defined as 'protected animals') must comply with the requirements of the Animals (Scientific Procedures) Act 1986 (amended 2012) (incorporating changes brought in by the European Directive 2010/63/EU) or 'ASPA' which regulates procedures, carried out for scientific or educational purposes, that may cause pain, suffering, distress or lasting harm.
- 4.10 Research involving animals regulated under ASPA can only be undertaken when three licenses have been granted:
  - **Establishment Licence:** Animal research can only take place on premises which hold an Establishment Licence.
  - **Project Licence:** Research can only be done as part of an approved project and are only granted after appropriate training has been undertaken.
  - **Personal Licence:** Research can only be carried out by people with a Personal Licence who have sufficient training, skills and experience.

### **Other**

- 4.11 Not all research and teaching activities involving animals is regulated under ASPA. Animal activities may fall within other UK legislation. In the UK wild species are protected under the Wildlife and Countryside Act (1981), and specific licences may be required if a project affects wildlife/and or its habitat. In the case of teaching veterinary students, the Veterinary Surgeons Act (1966) applies. Staff and



students should be aware that they have a general duty of care towards any protected animal under the Animal Welfare Act (2006).

### **Animal By Products**

4.12 There is also provision under the Animal By Products (Enforcement) (England) Regulations 2013 for animal by-products (ABPs) not intended for human consumption to be used in research (this is not applicable for ABPs used for education purposes). Under this regulation the site where animal by products is used for research must be approved or registered with the Animal and Plant Health Authority (APHA).

UCLan has two sites registered (detailed below) with APHA for use of ABPs which fall under Category 2 ABPs and Category 3 ABPs.

- 1) Taphonomic Research in Anthropology: Centre for Experimental Studies (TRACES)
- 2) UCLan Preston Campus

### **Veterinary Research**

4.13 There are certain types of veterinary research that are exempt from ASPA regulations (noted below), but if proposed veterinary research does not fall within one of the listed exemptions this activity may then require to be regulated under ASPA.

Veterinary research subject to ASPA exemption include:

1. Clinical veterinary research and routine veterinary practice (also known as non-experimental clinical veterinary practices);
2. Non-experimental agricultural practices and practices undertaken for the purpose of recognised animal husbandry;
3. The administration of a medicine for research purposes in accordance with an Animal Test Certificate (veterinary clinical trials); and
4. Certain procedures done for the purpose of identifying animals.

4.14 As of September 2022 the Royal College of Veterinary Surgeons note that all clinical veterinary research should be subject to ethics review. This includes projects where consent from the owner/keeper of the animal is required before enrolment or when consent is needed for use of previously collected samples or the use of data from an animal. For further information on veterinary research please see the Royal College of Veterinary Surgeons guidance on routine veterinary practice and clinical veterinary research.

### **Overseas**

- 4.15 Research and teaching, if undertaken outside the UK must comply with any local regulations in that country and be conducted in accordance with legislation that would apply in the UK and UCLan's ethical principles (including the TRUST Code - A Global Code of Conduct for Equitable Research Partnerships, formerly known as the Global Code of Conduct in Resource Poor Settings).
- 4.16 Researchers need to be aware of the Nagoya Protocol on access and benefit sharing (ABS) which is an international agreement that intends to prevent unfair exploitation of foreign countries when accessing and using their genetic resources (any plant, animal and/or microbial materials). In line with UK ABS legislation, researchers accessing material from a country that is Party to the Protocol will need to gather evidence to

help demonstrate compliance, including that the material has been accessed in line with the legislation of the providing country.

### **Ethical Review Process**

4.17 The University considers all proposals that involve animals in any way, including proposals which are not governed by legislation. Proposals are reviewed by either the Animal Welfare and Ethical Review Body (AWERB) established in accordance with ASPA guidance or the AWERB sub-group.

### **Animal Welfare and Ethical Review Body (AWERB)**

4.18 An AWERB is a legal requirement under ASPA, any projects governed by ASPA must be considered by UCLan's AWERB which meets four times a year. All project licence applications, amendments and progress reports are reviewed by AWERB before they can be recommended to be submitted to the Home Office.

4.19 The AWERB committee membership comprises of veterinary surgeons, researchers, lay members, animal facility staff and other staff members to provide scientific and ethical scrutiny of projects and amendments in relation to scientific and ethical justification of animal use.

4.20 The tasks of AWERB are outlined in ASPA regulations but the group has wider responsibilities than advising on the suitability of project proposals, amendments and subsequent review. The AWERB provides advice on 3Rs, matters relating to the welfare and care of animals, management and operational processes, provide a forum for discussion and development of ethical advice and help to promote a 'culture of care' within the University, and as appropriate, in the wider community.

### **Animal Welfare and Ethical Review Body Sub-Group**

4.21 The AWERB sub-group reviews all project and teaching applications which are not regulated by ASPA. The group meet on an ongoing basis all year round and examples of such applications reviewed by the group are noted below (please note this is not an exhaustive list):

- The use of tissue in research harvested from vertebrates and cephalopods (*please note if material is collected whilst an animal is under general anaesthesia then this is a scientific procedure regulated under ASPA. If material is collected from an animal after it has been humanely killed, then this is not regulated*).
- Research conducted outside of the UK (*this will also include research that if took place in the UK would fall under ASPA, these projects may be referred to the main AWERB for review*).
- All collaborative projects with another institution which include animals, whether or not they are carried out by UCLan staff or students.
- Studies that may involve researcher interaction with both human and animals, including veterinary research (*this may require approval from AWERB and one of the Central Ethics Review Panels*).
- Pilot Projects
- Observational projects (in the wild and captivity)
- Research with invertebrates
- Teaching activities and practical's involving the use of animals should be submitted to the AWERB sub-group on an annual basis.
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## **Broadcasting / Film**

- 4.22 Under ASPA it is an offence to perform procedures as an exhibition to the general public or to be shown live on television. Filming of procedures for later editing or broadcast is not an offence. However, conducting a procedure for the sole purpose of broadcast is not permitted (Home Office, 2014).
- 4.23 At UCLan this also applies for projects not regulated under ASPA, whereby any public display / broadcast must be for a valid research purpose and not for the sole purpose of a broadcast.

## **Concordat on Openness on Animal Research in the UK**

- 4.24 At UCLan we take our responsibility in relation to the use of animals in research seriously. Therefore, we have become a signatory of the [Concordat on Openness on Animal Research in the UK](#) which is promoted by the organisation [Understanding Animal Research](#) for which UCLan is a member. Signing the Concordat illustrates our commitment to undertaking animal research in an ethical and responsible manner.

## **External Guidelines**

- 4.25 The University strongly supports and endorses the use of guidelines and resources available from external organisations including (but not limited to):
- The [PREPARE](#) (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence). Guidelines by the Norwegian Centre Norecopa which provide a checklist for planning and conducting animal studies. These guidelines should be used when preparing applications.
  - National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs):
    - [Resources on the 3Rs](#) (replacement, refinement and reduction).
    - The [Experimental Design Assistant](#). The NC3Rs have introduced this free tool which aims to help researchers design robust experiments by providing bespoke feedback on the study design and statistical analysis. This will help ensure researchers use the minimum number of animals consistent with their research objectives.
    - The [ARRIVE](#) (Animal Research: Reporting of In Vivo Experiments) guidelines by the NC3Rs provide a checklist to improve the reporting of research using animals. It is expected that these guidelines are followed by researchers during project planning and in the preparation of publications and other outputs - [Responsibility in the use of animals in bioscience research](#). This resource by the NC3Rs sets out the expectations of funding bodies for the use of such animals in research.
  - The [Laboratory Animal Science Association \(LASA\)](#) seeks to ensure the provision and best use of the appropriate animal models and has produced various guidance notes which should be referred to by everyone involved in animal research and be adhered to.

- The Royal College of Veterinary Surgeons Code of Professional Conduct for Veterinary Surgeons, which includes guidance on veterinary research and teaching.
- The Royal Society of the Prevention of Cruelty to Animals (RSPCA) Animals in Science resources covering a wide range of topics including welfare and severity assessment, culture of care, housing and refining procedures.

### **Failure to comply**

- 4.26 All staff and students are expected to comply with the provisions of this policy, and are expected to conform to external guidelines and resources as far as possible, as well as taking into account specific editorial policies of relevant journals or funding bodies.
- 4.27 Failure to comply with the provisions of this Policy may result in an internal investigation by the PEL holder / AWERB Operational Group (for ASPA regulated research), followed by appropriate action being taken in line with the University's Policy for Misconduct in Research (applicable to staff and post graduate research students), or the Academic Misconduct Policy (applicable to undergraduate and post graduate taught students).
- 4.28 Staff and students must act at all times in a manner that is consistent with relevant legislative requirements and the principles of the 3Rs. Any non-compliance is subject to internal and external investigation and may lead to suspension or in the case of ASPA regulated research revocation of the relevant licence(s), and criminal prosecution.

### **References and Further Information**

The Animals (Scientific Procedures) Act 1986 (ASPAs) Amendment Regulations 2012 (online) <https://www.legislation.gov.uk/ukxi/2012/3039/contents/made> [accessed 05.01.2023].

The British Psychological Society (2020) Guidelines for psychologists working with animals (online) <https://cms.bps.org.uk/sites/default/files/2022-07/Guidelines%20for%20Psychologists%20Working%20With%20Animals.pdf> [accessed 05.01.2023]

Home Office (2014) Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (online) [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/662364/Guidance\\_on\\_the\\_Operation\\_of\\_ASPA.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662364/Guidance_on_the_Operation_of_ASPA.pdf) [accessed 05.01.2023].  
Hubrecht R, Kirkwood J (Eds) (2010). *UFAW Handbook on the Care and Management of Laboratory and other Research Animals*, 8<sup>th</sup> Edition, Wiley-Blackwell.

NC3Rs/BBSRC/Defra/MRC/NERC/Royal Society/Wellcome Trust (2019) *Responsibility in the use of animals in bioscience research: expectations of the major research councils and charitable funding bodies*, 3<sup>rd</sup> Edition. London: NC3Rs.

Percie du Sert N, Ahluwalia A, Alam S, Avey MT, Baker M, Browne WJ, et al. (2020) *Reporting animal research: Explanation and elaboration for the ARRIVE guidelines 2.0*. PLOS Biology 18(7).

RCVS (2022) Code of Professional Conduct for Veterinary Surgeons: 25. Routine veterinary practice and clinical veterinary practice (online) <https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/routine-veterinary-practice/> [Accessed 05.01.2023]

RSPCA (2022) Animals in Science (online) <https://science.rspca.org.uk/sciencegroup/researchanimals> [accessed 05.01.2023]

UK Research Integrity Office (2020) Research Integrity: A primer on research involving animals 2.0 (online) <https://ukrio.org/wp-content/uploads/UKRIO-Research-Integrity-A-primer-on-research-involving-animals-V2.0.pdf> [accessed 05.01.2023]

## 5.0 Ethical principles for work with micro-organisms

### Background

5.1 Microbiology is the study of small (micro-) organisms including viruses, bacteria, protozoa, algae, fungi, yeasts and moulds. These are ubiquitous in nature and while some are harmful pathogens causing diseases such as meningitis and influenza, others are beneficial e.g. in recycling nutrients in the soil or can be used to human benefit e.g. production of vaccines or of antibiotics.

### Health and Safety

5.2 Work with micro-organisms on University premises should comply with relevant regulations and should only be carried out in laboratories with containment measures appropriate for the organisms likely to be encountered. The risk of escape of micro-organisms to the environment should be minimal.

Health and safety risks in microbiological work should be minimised e.g. by using attenuated or disabled laboratory strains of pathogens or by choice of culture media or experimental design to minimise the chances of culturing undesirable pathogens.

Special care should be given to ensure safe working practice for at-risk groups such as pregnant women or those who are immunologically compromised.

### References

Health and Safety at Work Act, 1974  
Report of Advisory Committee on Dangerous Pathogens, 2003  
Food Safety Act, 1990  
Control of Substances Hazardous to Health Regulations, 1999

## Ethical issues

- 5.3 The degree of risk accepted in work with micro-organisms should be balanced and justified by the actual or potential benefits (e.g. to humankind, to other animals, or to the environment).

## 6.0 Principles relating to genetic modification (GM)

### Background

- 6.1 Advances in molecular biology over the last 30 years, have resulted in the development of a wide variety of techniques, which are often grouped together and referred to as genetic modification. GM techniques have been applied to a wide range of micro-organisms, plants and animals, resulting in increased scientific understanding, as well as allowing the commercial production of enzymes, complex therapeutic agents and genetically modified crops. Some recent research has attempted to correct genetic disorders in humans by a process called gene therapy e.g. severe combined immuno-deficiency and type A haemophilia.

### Definitions

- 6.2 Genetic Modification (GM) is the alteration of the genetic material of an organism (either DNA or RNA) by use of a variety of techniques that do not occur in nature such that the modification can be replicated and/or transferred to other cells or organisms. Typically, GM involves the removal of DNA, its manipulation outside the cell and its reinsertion into the same or another organism. The aim of GM is often to introduce a new or altered characteristic to the target organism.
- 6.3 Genetically Modified Organisms (GMOs) are the organisms which have been genetically modified. GMOs may be plants, animals or (most commonly) micro-organisms. If the GMO is a micro-organism it is often called a genetically modified micro-organism (GMM).

### Health and Safety

- 6.4 GM work should comply with the Health & Safety Commission's contained use<sup>§</sup> regulations and should only be carried out in registered laboratories, animal houses, plant growth facilities (including growth rooms in buildings and suitable glasshouses) and large-scale production facilities on industrial sites.
- 6.5 Wherever possible GM work should use micro-organisms that have been disabled with mutations preventing their growth outside the controlled environment of a laboratory test tube. Where GMMs that are not disabled and still capable of growth

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<sup>§</sup> Footnote: 'Contained use' means that control measures are in place to minimise the chances of contact between GMOs and humans and/or the environment.

outside the laboratory are used, extra control measures should be in place before the work can commence.

- 6.6 Risk assessments and containment measures should comply with GMO(CU) (2000) and GMO(CU) Amendment (2005).
- 6.7 The University is a registered site (GM 239) and currently has two laboratories which operate at Containment Level 1 (the lowest of four Levels). All proposed GM work should be approved by the Genetic Modification Safety Committee (GMSC).

## **Ethical Issues**

- 6.8 The degree of risk accepted in GM work should be balanced and justified by the actual or potential benefits (e.g. to humankind, to other animals, or to the environment).

## **References**

Genetically Modified Organisms (Contained Use) Regulations (GMO[CU]), Health & Safety Commission, 2000. Genetically Modified Organisms (Contained Use) Regulations (GMO[CU] Amendment), Health & Safety Commission, 2005.

## **7.0 Ethical principles for work with chemicals**

- 7.1 All work using chemicals should comply with University health and safety regulations, procedures and practices, and appropriate disposal methods should be employed. This does not necessarily mean that no harm will be caused by an aspect of chemical work, e.g. particular chemicals may have high toxicity, they may be carcinogenic, mutagenic or teratogenic, or be so resistant to degradation that they will persist in the environment for a very long time. In all such cases the risk of any harmful effects should be weighed against the benefits of doing the work.

## **8.0 Ethical principles for work with radiation**

- 8.1 All forms of ionising radiation have the potential to damage living cells, and some radioactive materials will continue to emit radiation for hundreds, thousands or millions of years. The basic framework for radiological protection has been developed by the International Commission for Radiological Protection and the International Atomic Energy Agency which advocate an approach based on three principles, justification, optimisation and dose limitation.
- 8.2 All work at the University involving radiation should comply with University health and safety regulations, procedures and practices, and the risk of any harmful effects should be justified by weighing them against the benefits of doing the work.

## **9.0 Ethical principles for work in the environment**

## General

- 9.1 Work in the environment includes traditional fieldwork in geography and biology, but also all other work carried out in natural or human-made environments which focus on the environment and/or the people who live and work there. Thus, it also covers archaeology, conservation and environmental management (including agriculture, forestry, and waste management).

All environmental work should comply with relevant University Health & Safety policies and procedures including those relating to fieldwork and to hazardous equipment (e.g. in forestry).

## Ethical Issues

- 9.2 The main ethical issues in environmental work relate to the interaction between people and the environment:

- 9.3 *Biodiversity and Conservation*. Researchers should aim to disrupt the natural environment as little as possible except where alterations to the environment can be justified (e.g. to reduce pollution, to grow more food or to enhance biodiversity).

Studies of rare animals and plants protected by law must have the prior approval of the appropriate organization (e.g. in England this is Natural England). Collection of non-pest species that are not protected by law should only occur if it can be established that collection poses no threat to the population. Collection and study of animals should be approved by AWERB (see Section 4).

- 9.4 *Landownership*. Whilst extensive areas of the UK and other countries form open landscapes, legislation related to landownership and property rights should be complied with. Access to private land as well as the removal of material should always be agreed with the landowner prior to entry.

- 9.5 *People*. Ethical guidelines relating to work with people are given in Section 3.

- 9.6 *Archaeological Remains and Artefacts*. Artefacts found on excavation remain the property of the landowner. Human remains will always be treated with respect. Excavation and study of human remains should follow the guidelines established for the British Archaeological Jobs Resource (available at <http://www.bajr.org/documents/HumanRemainsGuide.pdf>).

## References

Wildlife & Countryside Act, 1981, amended 1984  
Countryside & Rights of Way Act, 2000

## 10.0 Ethical principles relating to art



- 10.1 Art will sometimes have a legitimate aim to challenge, shock, or even offend. In such cases consideration should be given as to whether precautions are needed to avoid access by those who might not be a suitable audience – for example, by warning notices or age restrictions.

## **11.0 Ethical principles for work with military weapons**

- 11.1 Research and consultancy work related to military weapons and the Defence Industry may raise ethical issues that conflict with the ethical principles of non-maleficence and beneficence (see 2.2 above). The appropriate University Senior Management Team member (normally the Executive Dean) should be involved in the evaluation of such proposals.

## **12.0 Guiding principles for self-experimentation**

- 12.1 Self-experimentation in research is a data-driven approach in which the experimenter conducts the experiment on themselves, using a single case, i.e.  $n = 1$ , where the experimenter is also the subject.

Approval for self-experimentation is required following normal University process for ethical approval. When applying for approval to undertake self-experimentation, a proposal should address the following questions:

- Q1. Is there a conflict of interest in the proposal?
- Q2. Is there a mechanism by which the experiment can be observed by a peer researcher?
- Q3. Is there a mechanism by which the results are confirmed by a peer researcher?
- Q4. Are there any restrictions imposed by any future publisher which would suggest the results could not be disseminated?
- Q5. Is there any potential harm to the experimenter or others who are involved?
- Q6. Is there a legitimate reason for the study?

Prior to submitting their application for ethical approval, the researcher must identify the journals they intend to publish their results in and address the author guidelines regarding self-experimentation. All safeguards must be in place to mitigate any risks to the participant and data.

## **13.0 Guiding principles internet mediated research**

- 13.1 Research involving the use of online surveys, questionnaires, social media, data processing, data analysis and storage etc. In addition to completing your application for ethical approval you should consult with your supervisor.

Internet-mediated research is research involving online activities to acquire data on participants, e.g. social networks, web-based surveys, video communications. When applying for approval to undertake internet mediated research, a proposal should consider the following points:

- Identity and location of participants.
- Inability to accurately locate participants, restricting the ability of researchers to intervene should participants disclose intentions to cause harm to themselves or others, or harmful behaviour viewed on Skype.
- Consent ensuring parents are involved in research involving children as would happen in face to face research.
- Assessing mental capacity of participants.
- Anonymity and compliance with data protection laws as IP addresses can be collected.
- The provision of online support links and organisations.
- Indemnity arrangements for the researchers.

13.2 Additional information regarding internet mediated research can be found in the UCLan document [Internet Mediated Research](#)

## **14.0 Ethical principles for autonomous and intelligent systems (A/IS)**

14.1 Research involving autonomous and intelligent systems (A/IS) should be conducted in accordance with professional and legal requirements. All research, including research which does not directly involve human participants, should consider the wellbeing, rights and dignity of humans. Any research involving the creation or testing of A/IS should be conducted in accordance with the ethical principles of the IEEE Ethically Aligned Design (IEEE, 2019) guidance document, as outlined below:

- *Human Rights* - A/IS shall be created and operated to respect, promote, and protect internationally recognised human rights.
- *Well-being* - A/IS creators shall adopt increased human well-being as a primary success criterion for development.
- *Data Agency* - A/IS creators shall empower individuals with the ability to access and securely share their data, to maintain people's capacity to have control over their identity.
- *Effectiveness* - A/IS creators and operators shall provide evidence of the effectiveness and fitness for purpose of A/IS.
- *Transparency* - The basis of a particular A/IS decision should always be discoverable. The term "transparency" in the context of A/IS also addresses the concepts of traceability, explainability, and interpretability.
- *Accountability* - A/IS shall be created and operated to provide an unambiguous rationale for all decisions made. People and institutions responsible for the design and production of A/IS need clarity around the manufacture and deployment of these systems to establish responsibility and accountability, and to avoid potential harm.

- *Awareness of Misuse* - A/IS creators shall guard against all potential misuses and risks of A/IS in operation.
- *Competence* - A/IS creators shall specify and operators shall adhere to the knowledge and skill required for safe and effective operation.