University of Central Lancashire

Ethical Pack for Research Students
Effective from
January 2019 - August 2019

STUDENT REGULATIONS AND POLICIES

uclan.ac.uk/studentcontract

University of Central Lancashire

UCLan Ethics Pack

For Research Degree Students

V4 (2018)

UCLan Ethics Pack for Research Degree Students

This pack contains all relevant information you, as a UCLan Research Degree Student, will need for the Ethics process here at UCLan.

PLEASE NOTE THAT THIS PDF VERSION SHOULD NOT TO BE USED FOR COMPLETION OF THE INDIVIDUAL DOCUMENTS (CHECKLIST / FORM) – PLEASE USE THE LINK BELOW TO ACCESS, AND DOWNLOAD, FORM FORMAT VERSIONS.

Document A – Ethics Guidance notes for Research Degree Students
Please read these notes before completing any paperwork

Document B – Ethics Checklist
Use this form if you are seeking 'Ethical Clearance'

Document C – Ethics Application Form
Use this form if you are seeking 'Ethical Approval'[1]

Document D – Guidance Notes for completion of Ethics Application Form
Please refer to these notes for guidance on completion of the form

If you need any further information or advice either go to Ethics page on the student portal at https://www.uclan.ac.uk/students/research/ethics.php or email EthicsInfo@uclan.ac.uk.

Training sessions are also available throughout the year for research degree students to explain the ethics system and how to complete your ethics application – for the next available 'Obtaining Ethical Approval at UCLan' session go to Research Training Calendar (located at http://www.uclan.ac.uk/research/study/student_training.php) where you will be directed to Eventbrite to book a place.

[1] Where ethical approval has already been gained from another university or other external organisation, please see 'External approval' in Guidance notes.

DOCUMENT A

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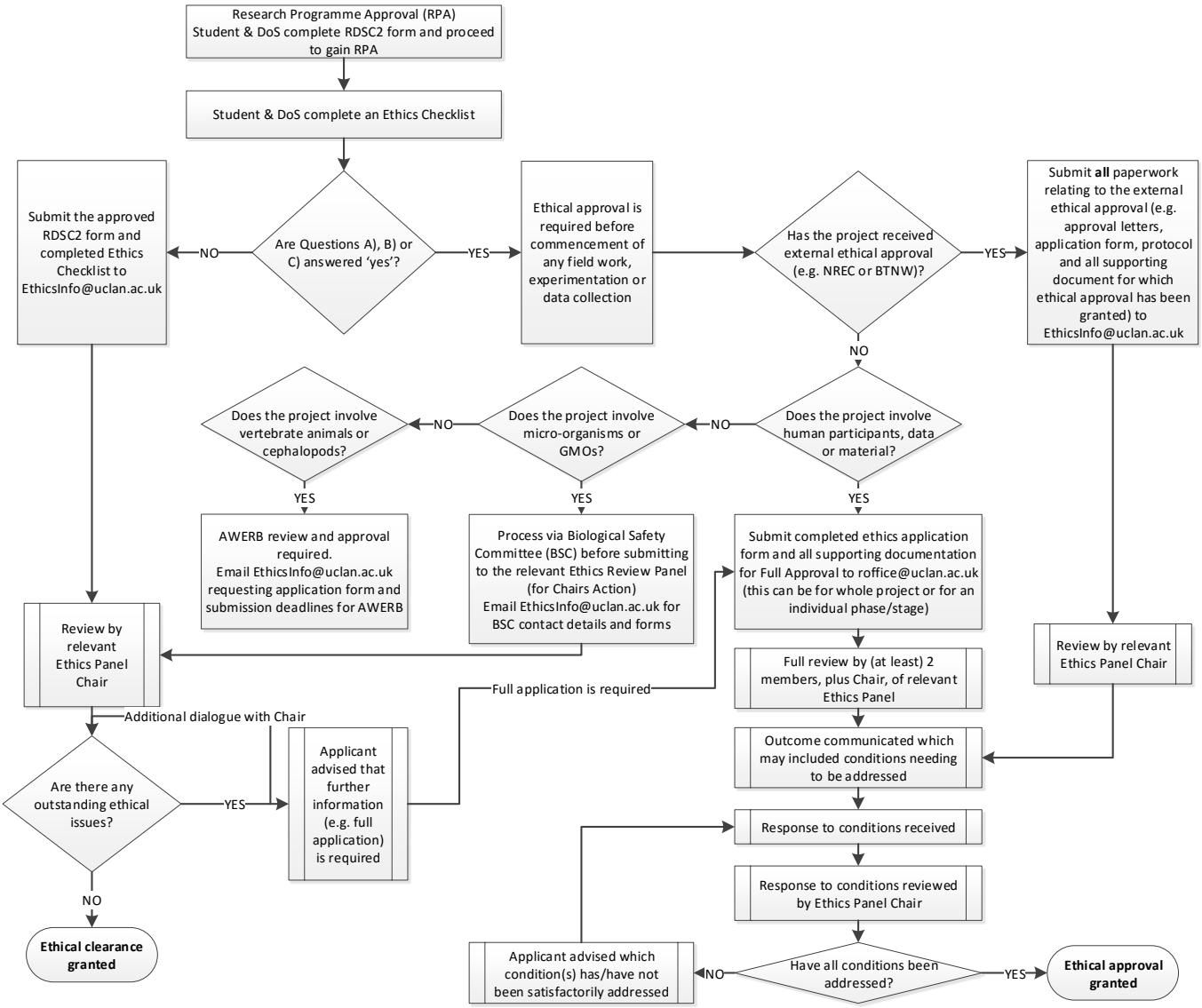
Ethics Guidance notes for Research Degree Students

Ethical Review

All research degree student projects, irrespective of the nature or activity involved, will need to be reviewed by their relevant Ethics Review Panel.

Process (Flow diagram)



Ethical clearance is distinctive from approval. Clearance is given as confirmation that ethical approval is not required.

Ethics Checklist

If, on completion of the Ethics Checklist, Questions A), B) or C) are answered '**Yes**' then refer to **Full Approval** notes below.

If, on completion of the Ethics Checklist, Questions A), B) and C) are answered '**No**' then a copy of the student's approved RDSC2 (Application to Research Programme Approval) form along with the completed Ethics Checklist should be emailed to EthicsInfo@uclan.ac.uk (please prefix the subject line of the email with the appropriate Ethics Review Panel acronym). Where Questions D) to G) have been answered 'Yes', please provide further details on the ethical implications specific to the proposed student project and submit along with the ethics checklist and a copy of the student's approved RDSC2 form.

The documentation will be reviewed and confirmation provided that the student's research programme approval proposal has received ethical clearance[1] and that a Full Approval application is not required (unless changes are subsequently made to the study and therefore the student/Director of Studies should revisit the Ethics Checklist and, if appropriate, submit an ethics application form).

The Ethics Panel Chair may however feel that there are ethical issues to be addressed and as such will advise the Director of Studies/student that an application for Full Approval (see below) will be required at the appropriate time and before commencing data collection.

External approval (e.g. HRA)

Where a student's project has already been approved by an external ethics committee, please submit all the paperwork relating to that approval (i.e. application form, supporting documents – final versions – and approval notification) to EthicsInfo@uclan.ac.uk to be reviewed by the Chair of the relevant Ethics Review Panel as opposed to completing UCLan ethics application form. E.g. if the project has received HRA approval (including NHS REC), then the paperwork to be submitted is the completed IRAS (Integrated Research Application System) application form; final versions of all supporting documentation – such as information sheet, consent forms, questionnaires, etc. – and all outcome letters, including the final favourable opinion letter. *N.B. Where only HRA approval is to be granted (e.g. the project is exempt from NHS REC review), then a full review will be required by the relevant UCLan Ethics Review Panel and this can be in parallel with the submission to HRA.
Other examples of external ethical approvals are BioBanks (such as BTNW), NOMS – National Offender Management Service (for projects involving prisons) – now called Her Majesty's Prison and Probation Service (HMPPS), County Councils and other universities.
External ethical approval **must** be obtained before submitting to UCLan Ethics*.

Full Approval

Where the need for Full Approval has been identified, either on completion of ethics checklist or notification from UCLan Ethics Review then, the student's fieldwork/data collection can only commence once full ethical approval has been granted. Due to the nature of project, it may be necessary to make separate proposal applications for different stages of the project, especially if the design of the later stages is highly dependent on the findings from the earlier stages.

[1] distinctive from approval. Clearance is given as confirmation that ethical approval is not required.

For projects involving micro-organisms, or genetically modified micro-organisms (GMOs), initial advice and/or review/approval by the Biological Safety Committee is required before submitting to the relevant Ethics Review Panel to be dealt with via Chairs Action.

For projects involving vertebrate animals (other than humans) or cephalopods[2], please contact the AWERB Reporting Officer, via EthicsInfo@uclan.ac.uk email address, for a copy of the relevant application form and submission deadlines.

For projects that involve human participants (including the use of their data or material), the process for an application for Full Approval requires a completed ethics application form. The completed ethics application form along with any supporting documentation (e.g. information sheet, consent form, questionnaire, etc.) should be emailed to EthicsInfo@uclan.ac.uk. A review by (at least) two members of the relevant Ethics Review Panel will then take place providing feedback on the application. It will then be passed to the Ethics Panel Chair. The Ethics Panel Chair, after reviewing the paperwork and the reviewers' feedback/comments, will then provide a decision on the application.

Outcome / Decision

The Ethics Review Panels can make five kinds of decisions on an application:-

1. Outline approval or approval in principle (may include exemption from full review) – *this is not normally applicable to postgraduate research student projects*
2. Approved either outright, or with suggested recommendations (recommendations are discretionary)
3. Approved subject to specified conditions being addressed (conditions are mandatory)
4. Re-submission required
5. Reject

All communications regarding research student ethics submissions will be sent to both the Director of Studies and the student.

Documentation

A copy of the ethics application form and ethics checklist can be downloaded from https://www.uclan.ac.uk/students/research/ethics.php

The RDSC2 (Application for Research Programme Approval or Application to Register) form is available to download, along with guidance notes, in the Research Document Library on the Student Portal.

Contacts

BAHSS (Business, Arts, Humanities and Social Science)
PSYSOC (Psychology and Social Work)
STEMH (Science, Technology, Engineering, Medicine and Health)
Administrators: Alison Naylor – 01772 892728; Sinead Baldwin – 01772 892397 & Chris Riley – 01772 894031
Email: EthicsInfo@uclan.ac.uk

[2] Cephalopods are an active predatory mollusc of the large class Cephalopoda, such as an octopus or squid

DOCUMENT B

University of Central Lancashire

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Ethics Checklist

All activities - undergraduate, postgraduate, research, commercial, knowledge transfer, evaluation, audit or teaching and learning - need ethical consideration.

This checklist will identify whether a project requires an application for ethics approval, and to which review panel/process it should be referred. No field work, experimentation or work with participants can start until approval is granted. The questions should be completed by the Principal Investigator or supervisor of the proposed project. Where projects involve students, the Principal Investigator is always the supervisor/Director of Studies and never the student.

Principal Investigators, or supervisors/Director of Studies, are responsible for ensuring that all activities fall within the principles set down in the University Code of Conduct for Research and the University Ethical Principles for Teaching, Research, Knowledge Transfer, Consultancy and Related Activities. They are also responsible for exercising appropriate professional judgment in undertaking this review and evaluating the activity according to the criteria laid down in this checklist. If you are uncertain about any sections of this document, or need further information and guidance, please contact the Ethics and Integrity Unit, in Research Services (EthicsInfo@uclan.ac.uk).

If, on completion of the checklist:

- ***any*** question is answered '***Yes***', then an application for ethical approval is required:-
    - For **undergraduate** and **postgraduate taught** projects, students should in the first instance discuss the project and ethical issues with their supervisor. Unless the project is considered to be ethically complex or of a sensitive nature (e.g. involves vulnerable populations) submission for ethical approval should be sought through the relevant School Ethics Committee or process.
    - For **research, commercial and other projects**, use the questions to help compile suitable evidence and submit an application to the relevant Ethics Review Panel.

- ***all*** questions are answered '***No***' and you (the Principal Investigator) are not concerned with the ethical nature of the activity, then it is unnecessary to apply for ethical approval. However, it is still incumbent on you to observe the University's Ethical Principles in the conduct of the activity and to record that:
    - a review has taken place of the ethical aspects of the activity; and that
    - *either* no ethical issues have been identified *or* ethical issues have been identified but that these have been addressed satisfactorily.

All **research student registration proposals**, irrespective of the outcome of the Ethics Checklist, need to be submitted to the relevant Ethics Review Panel to be dealt with either by Chair's Action or full review. See specific guidance for research degree students at https://www.uclan.ac.uk/students/research/files/2015_e-Ethics_guidance_notes_re_Research_Degree_Student_V6.docx

Further details on the Ethics process, including an electronic version of this checklist, are available at https://www.uclan.ac.uk/students/research/ethics.php

1 Project

1.1 Project Title										
1.2 Project type	Staff research		Research degree (including Prof Doc)		PG taught		UG taught		Commercial	
1.3 Short description in layman's terms [no acronyms or jargon]										
1.4 Dates	Start		End							
1.5 School of …..										
1.6 Project supervisor /principal investigator: name, position and original signature										
1.7 Co-workers/ Co-Researchers / Postgraduate Research Student: names and positions										
1.8 Declaration	I understand that personal data about me as a researcher in this checklist is required by the Ethics and Integrity Unit within Research Services, on behalf of the University, for the purpose of ethics review, and to evidence that the appropriate level of ethics review has been undertaken. Such data will be stored and managed in accordance with the principles established in the General Data Protection Regulations (GDPR) and the Data Protection Act 2018.									

Read any associated procedures and guidance or follow any associated checklist link, and delete, 'Yes' or 'No', for each characteristic.
If you respond 'No', then in your judgment you believe that the characteristic is irrelevant to the activity. You may only tick 'No' to the main question (i.e. A, B, etc) where none of the statements in that section apply to your activity.
If you are unsure whether to answer 'Yes' or 'No' to a question, you should answer 'Yes' and submit details to relevant Ethics Review Panel for initial review.

A)	**Does the activity involve human participants, data or material e.g. as research participants including the use of their data or using human tissue/fluid/DNA samples?**	**Yes/No**
	If Yes, and	
	Where the activity involves any external organisation for which separate and specific ethics clearance is required (e.g. NHS; school; any criminal justice agencies including the Police, Crown Prosecution Service, Prison Service, Probation Service or successor organisation) *seek and gain external ethics before submitting for UCLan ethical approval. Submission can be just the external organisation ethics application paperwork – email details to EthicsInfo@uclan.ac.uk to check.*	
	Where the activity involves the use of human tissue / DNA samples or body fluid *seek and gain relevant external ethics before submitting to relevant Ethics Review Panel. Submission can be just the external organisation ethics application paperwork (e.g. Brain Tissue North West) – email details to EthicsInfo@uclan.ac.uk to check.*	
	Continued/…	

	For all other activities involving human participants, their data or materials*, *complete and submit UCLan Ethics Application Form to relevant Ethics Review Panel – BAHSS; PSYSOC or STEMH.*	
	* such as :- requiring participants to give informed consent; potential imbalance of power and authority which might compromised the validity of participants' consent; researchers and/or participants in the potential disclosure of any information relating to illegal activities; the observation of illegal activities; or the possession, viewing or storage of any material (whether in hard copy or electronic format) which may be illegal potential risk of physical, social, emotional or psychological harm, distress or discomfort to the researchers or participants (*Please note also the University's Policy and procedures on Safeguarding and Prevent)*; deception of the participant be necessary during the activity; aim to shock or offend (e.g. art) invasion of privacy or access to confidential information about people without their permission excavation and study of human remains	
B)	**Does the activity involve isolation and culture of micro-organisms, orgenetically modified micro-organism or cell lines?**	**Yes/No**
	If so, process via UCLan Biological Safety Committee before submitting to the relevant Ethics Review Panel	
C)	**Does the activity involve scientific procedures[1] being applied to a vertebrate animal (other than humans) or cephalopods[2]?**	**Yes/No**
	If so, please email EthicsInfo@uclan.ac.uk requesting application form and submission deadlines for AWERB (Animal Welfare and Ethics Review Board)	
D)	**Does the activity involve collection of rare plants, endangered species or work in the natural environment?**	**Yes/No**
	If so, please submit this checklist together with outline details of the activity / UCLan's role to EthicsInfo@uclan.ac.uk	
E)	**Does activity relate to military/defence/weapons or the Defence industry, including excavation of battlefields, military installations, etc** (i.e. site with unexploded bomb)**?**	**Yes/No**
	If so please submit this checklist together with outline details of the activity / UCLan's role to EthicsInfo@uclan.ac.uk	
F)	**Does the activity involve or accessing Security-Sensitive Research Material or proscribed terrorist materials?** e.g. Will you be viewing or accessing data / prohibited material (digital or paper) that can be interpreted as contravening counter-terrorism legislation under the Terrorism Act (2006)**?**	**Yes/No**
	If so, please submit a copy of this checklist to the OfficerforEthics@uclan.ac.uk	
G)	**Are there any potential other ethical and political concerns?** **e.g.** Are you aware of any • potential ethical concerns or political concerns that may arise from either the conduct or dissemination of this activity, e.g. unethical practices of companies funding this research; results of research being used for political gain by others; potential for liability to the University from your research? • ethical concerns about collaborator company / organisation, e.g. its product has a harmful effect on humans, animals or the environment; it has a record of supporting repressive regimes; does it have ethical practices for its workers and for the safe disposal of products?	**Yes/No**
	If so please *submit this checklist together with outline details of the activity / UCLan's role to EthicsInfo@uclan.ac.uk*	

[1] Including interrupting an animal's natural environment (e.g. tracking or observing wild deer)

[2] Cephalopods are an active predatory mollusc of the large class Cephalopoda, such as an octopus or squid

UCLan Ethics Review Panels

The Ethics Review Panel for Business, Arts, Humanities, and Social Sciences (BAHSS) has responsibility for the following Schools:

- Art, Design and Fashion
- Journalism, Media and Performance
- Humanities and the Social Sciences
- Language and Global Studies
- Lancashire School of Business and Enterprise
- Lancashire Law School
- Forensic and Applied Sciences (Archaeology only)
- Engineering (Construction/Building/Surveying)
- Sport and Wellbeing (Coaching)
- Centre for Excellence in Learning and Teaching (CELT)

The Ethics Review Panel for Psychology and Social Work (PSYSOC) has responsibility for the following Schools:

- Psychology
- Social Work, Care and Community

The Ethics Review Panel for Science, Technology, Engineering, Medicine and Health (STEMH) has responsibility for the following Schools:

- Engineering (except Construction/Building/Surveying)
- Forensic and Applied Sciences (except Archaeology)
- Physical Sciences and Computing
- Dentistry
- Medicine
- Pharmacy and Biomedical Sciences
- Nursing
- Community Health and Midwifery
- Health Sciences
- Sport and Wellbeing (Allied Health Research Unit – AHRU; Sport Exercise and Nutritional Science – SENS and Centre for Applied Sport and Exercise Sciences - CASES)

Please contact Ethics and Integrity Unit in Research Services (EthicsInfo@uclan.ac.uk) regarding submission of applications involving animals or cephalopods.

Please contact Biological Safety Committee Chair (jasmith@uclan.ac.uk) regarding submission of applications involving Microbes & Genetically Modified Organisms

External Ethical Approval

Where the student's project involves NHS – either staff or patients – please email IRASSponsor@uclan.ac.uk to determine requirements for both IRAS Sponsor sign off and UCLan ethics review.

Where other external ethical approval is required, e.g. another university or organisation, the standard process is to gain the required external ethical approval, followed by submission for ethical approval at UCLan using the external ethics application documentation and approval notification. If in doubt, please email EthicsInfo@uclan.ac.uk for advice.

Helpful Tips :-
Where an activity involves collecting, obtaining, accessing, viewing, holding or any other kind of processing of personal data please refer to UCLan Data Protection Guidance/GDPR/Checklist
Where an activity involves fieldwork, travel (e.g. overseas) or lone working please refer to your School Risk Assessment procedures
Where Health and Safety clearance is a requirement of the activity (e.g. lab work) please check all relevant COSHH forms and/or Safety clearance/approval are in place
Please consider the University's requirements and procedures under Safeguarding and Prevent.
Please note the above are not approved by ethics. However Ethics will require evidence that relevant approvals have been gained where appropriate.

DOCUMENT C

University of Central Lancashire

UNIVERSITY OF CENTRAL LANCASHIRE
Ethics Application Form

PLEASE NOTE THAT ONLY ELECTRONIC SUBMISSION IS ACCEPTED

This application form is to be used to seek approval from one of the three University Ethics Review Panels (BAHSS; PSYSOC & STEMH). Where this document refers to 'Ethics Review Panel' this denotes BAHSS; PSYSOC & STEMH. These Ethics Review Panels deal with all staff and postgraduate research student project. Taught (undergraduate and MSc dissertation projects) will normally be dealt with via School/Faculty process / committee.

If you are unsure whether your activity requires ethical approval please complete a UCLan Ethics Checklist. If the proposed activity involves animals, you should not use this form. Please contact the Ethics and Integrity Unit within Research Services – EthicsInfo@uclan.ac.uk – for further details.

Please refer to the notes for guidance on completion of the form.

If this application relates to project/phase which has previously been approved by one of the UCLan Ethics Review Panels, please supply the corresponding reference number(s) from your decision letter(s). ONLY REQUIRED FOR PHASED PROJECT SUBMISSIONS		
Previous Ethics Approval Ref No		
1.1 **Project Type:**		
☐Staff Research ☐Commercial Project	☐Masters by Research ☐MPhil Research ☐PhD Research ☐Professional Doctorate	☐Taught MSc/MA Research ☐Undergrad Research ☐Internship
1.2 **Principal Investigator:**		
Name	School	Email
	Choose an item.	
1.3 **Other/Co- Researchers / Student:**		
Name	School	Email
	Choose an item.	
	Choose an item.	
	Choose an item.	
1.4 **Project Title:**		
1.5 **Proposed Start Date:**		
Click here to enter a date.		
1.6 **Proposed End Date:**		
Click here to enter a date.		

1.7 **Is this project in receipt of any external funding** (including donations of samples, equipment etc.)?

☐Yes ☐No

If Yes, please provide details of sources of the funding and what part it plays in the current proposal.

1.8 **Project Description** (in layman's terms) including the aim(s) and justification of the project (max 300 words)

Give a brief summary of the background, purpose and the possible benefits of the project. This should include a statement on the academic rationale, context of the activity and justification for conducting the project.

1.9 **Methodology** Please be specific

Provide an outline of the proposed method, include details of sample numbers, source of samples, type of data collected, equipment required and any modifications thereof, etc.

1.10 **Has the quality of the project been assessed**? (select all that apply)

☐Independent external review

☐Internal review (e.g. involving colleagues, academic supervisor, School process)

☐Research Programme Approval gained on Click here to enter a date. ***(Please that RPA is a prerequisite for Research Degree Student, including Prof Doc, projects to be able to submit for ethics)***

☐None

☐Other

If other please give details

1.11 **Please provide details as to the storage and protection of your physical / electronic data for the next 5 years** – as per UCLan requirements – **or whichever archive period is appropriate**

1.12 **How is it intended the results of the study will be reported and disseminated**? (select all that apply)

☐Peer reviewed journal – hard copy or online

☐Internal report

☐Conference presentation

☐Other publication

☐Written feedback to research participants

☐Presentation to participants or relevant community groups

☐Dissertation/Thesis

☐Other

If other, please give details

1.13 **Will the activity involve any external organisation for which separate and specific approval is required** (e.g. NHS; school; any criminal justice agencies including the Police, Crown Prosecution Service, Prison Service or Probation Service)?

☐Yes ☐No

*IF **YES**, BEFORE PROCEEDING WITH THIS FORM, click here to CHECK WHEN, HOW AND WHAT IS REQUIRED*

If Yes, please provided details of the external organisation and attached letter of approval

1.14 **The nature of this project is most appropriately described as research involving:-**
(more than one may apply)

☐Behavioural observation
☐Questionnaire(s) – *please provide a copy of the questionnaire /survey*
☐Interview(s) – *please provide a list of questions to be asked, or if semi-structured the topics*
☐Qualitative methodologies (e.g. focus groups) –*please provide the questions/topics to be covered*
☐Psychological experiments
☐Epidemiological studies
☐Data linkage studies
☐Psychiatric or clinical psychology studies
☐Human physiological investigation(s)
☐Biomechanical device(s)
☐Human tissue(s)*
☐Human genetic analysis
☐A clinical trial of drug(s) or device(s)
☐Lab-based experiment – *please provide relevant COHSS / RA forms*
☐Archaeological excavation/fieldwork
☐Re-analysis of archaeological finds/ancient artefacts
☐Human remains analysis
☐Lone working or travel to unfamiliar places (e.g. interviews in participants homes) – *please provide relevant risk assessment form*
☐Other (please specify in the box below)

If 'Other' please provide details

1.15 **Human Participants, Date or Material – the project will involve:**

Please select the appropriate box(es)

☐Participants [proceed to next question 1.16]
☐Data [proceed to question 2.20]
☐Tissues /Fluids / DNA Samples [proceed to question 2.21]
☐Remains [proceed to question 2.24]

1.16 **Will the participants be from any of the following groups:**
(tick as many as applicable)

☐Students or staff of this University†
☐Children/legal minors (anyone under the age of 18 years)
☐Patients or clients of professionals
☐Those with learning disability
☐Those who are unconscious, severely ill, or have a terminal illness
☐Those in emergency situations
☐Those with mental illness (particular if detained under Mental Health Legislation)
☐People with dementia
☐Prisoners
☐Young Offenders
☐Adults who are unable to consent for themselves

* Please email EthicsInfo@uclan.ac.uk if any project involves HT
† Where staff or students of the university are being used please explain how this is not a convenience sampling

☐Any other person whose capacity to consent may be compromised ☐A member of an organisation where another individual may also need to give consent ☐Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes ☐Other vulnerable groups (please list in box below)
If 'Other' please provide details
1.16a **Justify their inclusion**
*Ethics approval covers **all participants** but particular attention must be given to those in a vulnerable category. Therefore you need to fully justify their inclusion and give details of extra steps taken to assure their protection.*
1.16b **Is a DBS – Disclosure and Barring Service (formerly CRB – Criminal Records Bureau) check required?**
Certain activities and/or groups of individuals require DBS (formerly CRB) clearance. If unclear please seek advice.
☐Yes ☐No
If Yes, please advise status of DBS clearance (e.g. gained; in process; etc)
1.16c **All staff should be aware of UCLan's Policy and Procedures on Safeguarding and Prevent. Please confirm that, where relevant to your project, the appropriate training has been undertaken.**
Please refer to UCLan Safeguarding Children, Young people and Vulnerable Adults Policy and Prevent guidance
☐Yes ☐No ☐N/A
If Yes, please give details of relevant training session – external or internal - and when (e.g. within last 3 years)
1.17 **Please indicate exactly how participants in the study will be (i) identified, (ii) approached and (iii) recruited**?
If an advertisement and/or information sheet is being used, please attach
1.18 W**ill consent be sought from the participants and how will this be obtained**?
If a written consent form is being used, please attach
1.19 **How long will the participants have to decide whether to take part in the research**?
1.20 **What arrangements have been made for participants who might not adequately understand verbal explanations or written information, or who have special communication needs**?
Gives details of what arrangements have been made (e.g. translation, use of interpreters, etc).
1.21**Payment or incentives: Do you propose to pay or reward participants**?
☐Yes ☐No
If Yes, please provided details

1.22 **Will deception of the participant be necessary during the activity**?
☐Yes ☐No
If Yes, please provide justification, and complete Question 1.28
1.23 **Does your project involve the potential imbalance of power/authority/status, particularly those which might compromise a participant giving informed consent**?
☐Yes ☐No
If Yes, please detail including how this will mitigated *Describe the relationship and the steps to be taken by the investigator to ensure that participation is purely voluntary and not influenced by the relationship in any way.*
1.24 **Does the procedure involve <u>any</u> possible distress, discomfort or harm (or offense) to participants or researchers** (including physical, social, emotional, psychological and/or aims to shock / offed – e.g. Art)?
☐Yes ☐No
If Yes, please explain *Describe the potential for distress, discomfort, harm or offense and what measures are in place to protect the participants or researcher(s). Please consider all possible causes of distress carefully, including likely reaction to the subject matter, debriefing or participant upset.*
1.25 **Does the activity involve any information pertaining to illegal activities or materials or the disclosure thereof**?
☐Yes ☐No
If Yes, please detail *Describe involvement and explain what risk management procedures will be put in place.*
1.26 **What mechanism is there for participants to withdraw from the investigation and how is this communicated to the participants**?
1.27 **What are the potential benefits for the research**?
1.28 **Debriefing, Support and/or Feedback to participants**
Describe any debriefing, support or feedback that participants will received following the project and when.
1.29 **Will the project involve access to confidential information about people without their consent**?
☐Yes ☐No
If yes, please explain and justify *State what information will be sought, from which organisations and the requirement for this information.*

1.30 **Confidentiality/Anonymity** - Will the activity involve:		
	Yes	No
a. non-anonymisation of participants (i.e. researchers may or will know the identity of participants and be able to return responses)?	☐	☐
b. participants having the consented option of being identified in any publication arising from the research?	☐	☐
c. the use of personal data (i.e. anything that may identify them – e.g. institutional role – see DP checklist for further guidance)?	☐	☐
*If **yes to any** please attach completed Data Protection (DP) checklist*		
1.31 **Does the activity involve human tissue?**‡ See **Human Tissue Act (HTA) Supplementary list of Materials** to check what is classified as human tissue.		
☐Yes ☐No		
If no, please skip to question 1.32 If yes, please detail and answer questions 1.31a-c		
1.31a **Who will be sourcing the human tissue? (e.g. a tissue bank governed by its own HTA licence)**		
1.31b **Will the human tissue be stored at UCLan? (please note restrictions on storage)**		
☐Yes ☐No		
If yes, please state how long and in what form - cellular or acellular (DNA extracted) *Please note – if human tissue is only kept for the purpose of DNA extraction rendering it acellular the HTA storage regulations may not apply. If holding for DNA extraction, please state the length of time the tissue would be stored pre-extraction.*		
1.31c **Is the human tissue being used for an activity listed as a 'scheduled purpose' under Schedule 1 Parts 1 and 2 of the Human Tissue Act 2004?** *(click here to see list of HTA 'scheduled purpose' activities)*		
☐Yes ☐No		
1.32 **Does the project involve excavation and study of human remains**?		
☐Yes ☐No		
If yes, please give details *Discuss the provisions for examination of the remains and the management of any community/public concerns, legal requirement etc.*		

‡ Until such time as the University gains its own HTA Research License, human tissue that is for a 'scheduled purpose' and not sourced from a BioBank or part of an NREC approved project can only be stored for a maximum of 5 days

DECLARATION

This declaration needs to be signed by the Principal Investigator (PI), and the student where it relates to a student project (for research student projects PI is Director of Studies and for Taught or Undergrad project the PI is the Supervisor). Electronic submission of the form is required to EthicsInfo@uclan.ac.uk. Where available insert electronic signature – alternatively, provide an email in lieu from appropriate party.

Declaration of the:
☐Principal Investigator
OR
Director of Studies/Supervisor and Student Investigator
(please check as appropriate)
• The information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it.
• I have read and understand the University Ethical Principles for Teaching, Research, Knowledge Transfer, Consultancy and Related Activities.
• I have read and understand the University's policy and procedures on Safeguarding and Prevent.
• I undertake to abide by the ethical principles underlying the Declaration of Helsinki and the University Code of Conduct for Research, together with the codes of practice laid down by any relevant professional or learned society.
• If the activity is approved, I undertake to adhere to the study plan, the terms of the full application of which the Ethics Review Panel* has given a favourable opinion and any conditions of the Ethics Review Panel in giving its favourable opinion.
• I undertake to seek an ethical opinion from the Ethics Review Panel before implementing substantial amendments to the study plan or to the terms of the full application of which the Ethics Review Panel has given a favourable opinion.
• I understand that I am responsible for monitoring the research at all times.
• If there are any serious adverse events, I understand that I am responsible for immediately stopping the research and alerting the Ethics Review Panel within 24 hours of the occurrence, via EthicsInfo@uclan.ac.uk.
• I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
• I understand that research records/data may be subject to inspection for audit purposes if required in future.
• I understand that personal data about me as a researcher in this application is required by the Ethics and Integrity Unit within Research Services, on behalf of the University, for the purpose of ethics review, and to evidence that the appropriate level of ethics review has been undertaken. Such data will be stored and managed in accordance with the principles established in the General Data Protection Regulations (GDPR) and the Data Protection Act 2018.
• I understand that the information contained in this application, any supporting documentation and all correspondence with the Ethics Review relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
• I understand that all conditions apply to any co-applicants and researchers involved in the study, and that it is my responsibility to ensure that they abide by them.

* Ethics Review Panel refers to BAHSS, PSYSOC or STEMH

• **For Principal Investigator:** I understand my responsibilities to work within a set of ethical and other guidelines as set out by the University Policies and/or professional standards.
• **For Supervisor/Director of Studies:** I understand my responsibilities as Supervisor/Director of Studies, and will ensure, to the best of my abilities, that the student investigator abides by the University's Policy on Research Ethics at all times.
• **For the Student Investigator**: I understand my responsibilities to work within a set of ethical and other guidelines as agreed in advance with my Supervisor/Director of Studies and understand that I must comply with the University's regulations and any other applicable code of ethics at all times.

☐**Signature of Principal Investigator:** **or** ☐**Supervisor or Director of Studies**	
Print Name:	
Date:	Click here to enter a date.
Signature of Student Investigator:	
Print Name:	
Date:	Click here to enter a date.

DOCUMENT D

GUIDANCE NOTES FOR COMPLETION OF ETHICS APPLICATION FORM

HOW TO SUBMIT

Your application needs to be filled in electronically and emailed to EthicsInfo@uclan.ac.uk. Please insert in the subject line of your email the acronym of the Ethics Review Panel that needs to deal with your application. Ethics Review Panel acronyms are BAHSS, PSYSOC or STEMH – click here to see the list of Schools associated with each Ethics Review Panel.

PHASED SUBMISSION

Ethical approval can be granted in **phases**. If you have a project that is likely to evolve, or has subsequent phases determined by initial results – you can apply for Phase One approval, and then come back for Phases Two, Three or even more as your research progresses.
When submitting an application for a later phase of a project which has already received approval for an initial phase, please supply the corresponding Ethics reference number(s) for the approved phase.

GENERAL

Please provide all information requested and justify where appropriate. Use as much space as you need – the answer sections (denoted by a 'grey oblong shape') will expand as you type. Click on a box or circle to select the relevant option (e.g. type or Yes/No) and click on the 'grey oblong shape' to start typing for the free text entry questions.

The form should be completed in such a way as to be accessible to a lay person, i.e. in plain English with all parts of the protocol clearly outlined. Please explain any abbreviations or acronyms used in the application.

The application form contains some questions that depending on the nature of the project will require further sub-questions to be completed. This guidance mirrors the application form, providing instructions on how to answer each question and is designed to help you to complete the form to a high standard. Links to relevant documents (e.g. templates, professional body codes, national guidelines and legislation) are also provided. In order to grant ethical approval, the Ethics Review Panel needs sufficient detail to be able to judge the ethical issues presented by, and addressed in, the design of the study.

It is the applicant's responsibility to ensure that an English translation of any supporting documentation is a faithful translation of the copy being used with participants.

Previous Ethics Approval Ref No: This only needs to be completed if the application relates to a previously approved application (e.g. previous phase of a project). Please provide the approval ref number for the previous approved phase/project.

Question 1.1 Project Type: Please select whichever option applies to your project.

Question 1.2 Principal Investigator: This should be the name of the person who takes responsibility for the research from a UCLan perspective. It should therefore be a member of UCLan staff (not an hourly-paid lecturer). In the case of student research, their Main Supervisor or Director of Studies should be named here and the application will be viewed as a joint application and the responsibility of both the student and their principal supervisor (Director of Studies for a research student project and Main Supervisor for taught or undergrad student projects).

Question 1.3 Other Researchers / Student: For student applications, please provide the students details here as well as other members of the supervisor team. We strongly recommend that all supervisors review the documentation prior to submission for ethical approval.

Question 1.4 Project Title: Where your activity involves participants, the title provided should normally be the same title you use on study documentation for participants (information sheets, consent forms, etc).

Question 1.5 Proposed Start Date: This should be the anticipated start date for the part of the project involving data collection/ participants (not the date the student started).

Question 1.6 Proposed End Date: This should be when the project is completed. Please note that Ethics Review Panel approval is normally deemed to expire **five years** form the approval date unless otherwise requested.

Question 1.7 External Funding: If the project is externally funded i.e. not funded by UCLan, it should be stated here. Give details of the specific funding of the project - for example to buy equipment, pay participants, pay for a research assistant, etc.

Question 1.8 Project Description: The basic summary should indicate broadly what the project is about and what you are interested in finding out. There should be a short rationale for the validity of the project however extensive background and research literature is not necessary, neither are extensive reference lists, although one or two key relevant studies might be detailed (for example, if your project is following up another, or is perhaps testing a theory presented in another).

Question 1.9 Methodology: Indicate how the research question(s) outlined in the answer to Question 1.8 will be addressed. This section might include information about an experimental design for example, indicating the factors that will be investigated. If the project includes any procedure which is beyond established and accepted techniques please include a description of it.

Question 1.10 Review/Assessment: If relevant, describe the review process and outcome. If the review has been undertaken but not seen by the investigator, give details of the body which has undertaken the review.

Question 1.11 Data Storage: Please consider the format – electronic or physical - as well as whether the data being stored contains personal and/or anonymised details. Clarify what storage methods are being used – e.g. data, codes and all identifying information to be kept in separate locked filing cabinets for paper format; access to computer files to be available by password only; encrypted formats/devices; etc. Please note that personal data must be stored on a UCLan secure server. See UCLan Code of Conduct for Research; UCLan Data protection checklist, GDPR guidance and LIS IT Security Policy or refer to subject specific guidelines.

Question 1.12 Dissemination: As more than one may apply, select as many that are relevant to your project.

Question 1.13 External Organisation/Gatekeeper: Please note that an application to the Ethics Review Panel should only be submitted once external approval has been obtained.
Depending on the approval already granted – e.g. NREC via IRAS application or another university's ethics committee – the external ethics paperwork should be submitted rather a UCLan Ethics Application Form (see further guidance or contact the Ethics and Integrity Unit in Research Services EthicsInfo@uclan.ac.uk) for advice.
If you have been granted exemption from obtaining explicit patient consent for your research via the Department of Health Patient Information Advisory Group (PIAG) under Section 251 of the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001), please provide details and a copy of the notification with your application.
Please provide details of the external organisation / gatekeeper involved as well as any approval letter / communications (emails will suffice where the senders full contact details are included e.g. position, title, Company).

Question 1.14 Nature of the Project: Tick each box that correctly reflects the research being undertaken (more than one may apply). Please note the requirement to provide additional documentation – e.g. where 'Questionnaire(s)' is ticked, a copy of the questionnaire or survey being used should be submitted. For online surveys, this can be a link to the website, screen shots the online survey/webpages or word document which clearly outlines the survey details (e.g. questions, potential response options as well as any instructions). If such documentation (e.g. Questionnaires and/or interview schedules and/or focus group agendas) is to be developed as part of the project, highlight this under the Methodology (Question 1.9). In such cases, approval will only be granted subject to later approval of the questionnaire(s) and/or interview schedule(s) and/or focus group agenda. Such later approval will normally be considered by Chair's Action. For researchers undertaking qualitative interviews or focus groups where a predetermined schedule or agenda is inappropriate, the researcher should indicate the opening question (or topic) and where possible identify key areas that could be covered. If it is methodologically inappropriate to identify potential areas then the researcher should state this and provide a brief (a few sentences) explanation as to why this is the case (under Question 1.9 Methodology). If you are planning to use other data collection methods (e.g. observation, taking tissue/blood samples), please provide clear details of these, either within your response to Question 1.9 Methodology or in a separate document.

Question 1.15 Human Participants, Data or Material: Tick each box that applies (e.g. the project is recruiting participants to take blood samples, select both 'Participants' and 'Tissues / Fluids / DNA Samples'). The 'Data' option is where existing and/or third party data is being used (e.g. data from a third party organisation's database or case files). Please note that only certain questions apply to the 'Data', 'Tissues / Fluids / DNA Samples' and 'Remains' options.

Question 1.16 Participant Group/Category: Again, as more than one option may apply, tick all boxes that are relevant to the project.

Question 1.16a Justifying inclusion of a vulnerable group: For each group/category selected in Question 1.16 give the reason for their inclusion and any relevant exclusion factors, any equality and diversity factors must be explained here. Explain who the proposed participants will be (e.g. student population, members of the Preston Women's Institute, hospital out-patients, etc) and, if appropriate, what age ranges you anticipate they will have. One common error in providing information about participants is that extensive detail is provided about participants in an experimental condition, but detail about a control population is glossed over. If you are using people in the creation of research materials (e.g. video or audio recordings) then these people should be considered participants too, and given briefing/debriefing information accordingly. Where staff or students of the university are being used reassurance needs to be provided that their inclusion is not purely for convenience sampling.

Question 1.16b DBS Check: Certain activities and/or potential participant groups (e.g. children or vulnerable adults) may require the researcher(s) to gain a DBS (Disclosure and Barring Service) certificate. To see if a DBS check is required please see guidelines on the Disclosure and Barring Service (formerly Criminal Records Bureau – CRB) website.

Question 1.16c Safeguarding / Prevent: In all of our activities, UCLan is committed to safeguarding and promoting the welfare of children, young people and vulnerable adults as part of its common law duty of care and in response to specific legislation. UCLan has statutory responsibilities (placed on all HEIs) under the 'Counter Terrorism and Security Act (2015)' , the 'Prevent Duty Guidance for Higher Education Institutions in England and Wales' the 'Revised Prevent Duty Guidance' and the 'HEFCE Prevent duty monitoring framework'. The university is managing its Prevent responsibilities as part of a holistic approach to Safeguarding. Certain activities and/or potential participant groups (e.g. children or vulnerable adults) may require researcher(s) to have undertaken specific Safeguarding or Prevent training – details of such training (either internal or external) should be provided as appropriate, together with confirmation that the training has been undertaken in the last 3 years. Any queries regarding Safeguarding or Prevent should be raised with your College Safeguarding Lead or directly with the University Safeguarding Leads. See UClan's Staff Intranet site for full details of UClan's policy and procedures on Safeguarding and Prevent.

Question 1.17 Identify, Approach and Recruitment of the Proposed Participants: Indicate how participants will be approached and what sort of advertising will be used to get people interested. Particular attention should be paid to whether the approach is ethical in terms of enticements to participate or whether participants feel pressured to take part; this is of particular importance in such relationships as therapist/patient and student/tutor etc. In some circumstances some thought may be needed as to whether the approach method is appropriate given the topic of study. For example, approaching couples in the street and asking about partner violence would be considered unacceptable. If you are mailing to or phoning people, please explain how you have obtained or will obtain their names and contact details.

In virtually all studies with human participants, the participants should be given some kind of information sheet to keep, this could either be a briefing or debriefing sheet. Within the information sheet, it should be clear to the study participants what will be the potential risks and benefits to all involved in the research should they choose to participate in the research project. The Information Sheet will normally include: contact details for the researcher, some information about the purpose of the study and why they are being asked to take part, what taking part involves for them, any risks or benefits to taking part, information about confidentiality/ anonymity and how the data will be used, as well as details of right to withdraw, all in a jargon free accessible manner. In cases where distress is possible, it may also contain advice about possible sources of help and support. Where an information sheet is required in another language, it is the applicant's responsibility to ensure that a faithful translation of the copy being used with participants is provided as part of the submission.

Please note the requirement to provide copies of all relevant documents with your ethics submission – advertisement (e.g. Internal UCLan notification, flyer or poster) and/or information sheet. Please ensure that such advertisements are in line with UCLan's Regulations governing Posters, Notices, Temporary Signs and Distribution of Literature.

Question 1.18 Consent: Confirm how consent is to be obtained, and whether there are any special problems in obtaining informed consent. Indicate whether consent is provided verbally or in written form. If written consent of the participants is not being sought, the investigator must provide justification as to why such consent is unnecessary, impractical or inappropriate or why a non-written method of consent is being used. When postal questionnaires are used to collect the research data, it is usually deemed unnecessary to require formal consent for questionnaires containing no personal, sensitive or identifiable data as the return of the questionnaire will usually suffice to provide implicit consent.

Whichever form of consent you use, you should keep appropriate records of the consent (e.g. written witnessed consent, taped verbal consent) for audit purposes.

Where it is expected that participants will not be able to provide informed consent, indicate who will give consent on their behalf. In research with infants and children under the age of 18, informed consent should normally be obtained from a parent or someone with legal

responsibility for the child. In addition, children who are deemed competent to make their own decisions about participating in the project should also give their agreement (assent). Exceptionally, and only with clear justification as to why research would be unethical (or perhaps impossible to carry out) if consent from parents or those with legal responsibility for the child were required, the research may proceed using consent/assent only from a competent child. Consent involving adults unable to consent for themselves should follow the guidance of the Mental Capacity Act using the consultee approach.
Obtaining consent for observational research is particularly problematic: 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, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.
Where a written consent form is being used - the Consent Form should, ideally, include a list of statements to indicate to what the participants have consented with each item being initialled by the participant before giving witnessed written consent to the whole form. If a written consent form needs to be in another language, it is the applicant's responsibility to ensure that a faithful translation of the copy being used with participants is provided as part of the submission.

Question 1.19 Timeframe for decision to participate: The proposed participants must be given time to think through the implications of volunteering/participating. They should be able to ask questions and reflect. Participants should not be rushed into decisions. There are no fixed guidelines and each project should be considered on its own merits, the more burdensome studies will require a longer time for deliberation. However it is good practice for it to be a minimum of 24 hours after receiving full details of the project exceptions being time critical medical trials etc. There will be cases, such as responding to questionnaire or a website link, where the length of time is determined by the potential recruit.

Question 1.20 Communication / Translation: If applicable, include here a description of how you will make information accessible to small children/adults with disabilities. Describe use of translation services where applicable.

Question 1.21 Payment or Incentives: If people taking part in your project are to be offered any payment or incentive to do so over and above appropriate expenses, you must explain. Any form of payment or incentive to take part will need to be clearly justified. It is permissible to pay out of pocket expenses or recompense time and effort, but not any proposal that amounts to an inducement to take a risk which is against the interests of the participants (i.e. it is inappropriate to offer participants excessive payments which might induce them to participant in a project against their better judgement). If names need to be taken to acknowledge payment, please consider whether this compromises anonymity.

Question 1.22 Deception: Deception is allowable in exceptional circumstances where it is not only essential to achieve the research results required (i.e. alternative methodologies are not available) and the research objective has strong scientific merit but an appropriate

risk management and harm alleviation strategy is in place. Participants must also be made aware of the deception at the earlier feasible opportunity and be given an opportunity to remove their data from the study after being informed of any deception. Further guidance is available in The British Psychological Society's Code of Ethics and Conduct and Code of Human Research Ethics.

Question 1.23 Potential imbalance of power/authority/status: Research involving persons in dependent or unequal relationships (for instance, teacher/student) may compromise a participant's ability to give consent which is free from any form of pressure (real or implied) arising from this unequal power relationship. Therefore it is recommended that, where possible, investigators choose participant cohorts where no dependent relationship exists. If, after due consideration, the investigator believes that research involving people in dependent relationships is purposeful and defensible, then please provide additional information setting out the case and detailing how risks inherent in the dependent relationship will be managed. You will also need to provide reassurance that refusal to participate will not result in any discrimination or penalty.

Question 1.24 Distress, discomfort or harm (or offense): Identify, as far as possible, all potential risks to participants (e.g. physical, psychology, social, legal or economic) associated with the proposed activity/research. Please consider all possible causes of distress carefully, including likely reactions to the subject matter, debriefing, deception or burdens imposed and any preparatory requirements (e.g. special diet, exercise). If there is **any** possibility of distress, please give details and say what steps are to be taken to protect the participants.
Details should also be given of any potential risks to investigators (e.g. are there any specific risks to investigators that are greater than those encountered in normal day to day life?).
Art can sometimes deliberately shock and offend. This is legitimate but consideration must be given to likely effects and possible safeguards (e.g. warnings, age restrictions).
Describe the measures in place in the event of any unexpected outcomes or adverse effects to participants arising from their involvement in the project. An adverse event may be defined as one which is 'related' (i.e. it can be attributed to the research procedure) and 'unexpected' (i.e. not listed in the protocol as an expected occurrence, or its manifestation was more severe than expected). For example, how will any problems identified by the investigator during the study be referred onwards or dealt with (e.g. helpline numbers given, counsellor available)?

Question 1.25 Illegal activities or materials: Before starting a project that will involve research with persons engaged in potentially illegal activities you need to consider under what circumstances you might be legally required to divulge information about your research participants. You need specifically to consider when you anonymise your research data. You also need to consider under what circumstances you might become implicated in the illegal activities and how you will ensure that this does not happen.

Question 1.26 Withdrawal: How exactly do participants withdraw if they change their minds about taking part? Make sure in your instructions that participants **know** they have

the right to withdraw. Please also specify exactly **when** participants may withdraw: for example, can they contact you later to have their data withdrawn, or is withdrawal only possible until the end of the research session (e.g. until they hand in the questionnaire, or finish the experiment)? Consider whether withdrawing from the data collection session poses any risks to the participants health or well-being – for example, will it mean that they miss the debrief or don't have sufficient time to recover from a physiological effect brought on within the research session – and put safeguards in place if necessary.

Question 1.27 Potential benefit: A lot of projects result in no direct benefit to the participant at the time and it is acceptable to write 'no direct benefit' or 'educational purposes only'. However, any project that involves an intervention may result in an immediate direct benefit and this should be stated e.g. gains in reading skills from a literacy intervention for poor readers.

Question 1.28 Debriefing, Support and/or Feedback: Although this may be an unusual occurrence in a non-medical situation, it is an ethical principle that participants should be made aware of relevant information that was not available when they started. You need to state that if any information, pertinent to the study, becomes available as the study progresses then participants will be informed immediately and that participants will be reminded that their participation is voluntary and they are free to withdraw at any time.
A debriefing of participants may be appropriate in some investigations, for example to enable participants to express how they felt during an investigation, to offer counselling, or to communicate views on the whole process that they were not able to do previously, possibly to explain a study which involved deception. For any project where participants are entitled to full debriefing, this means explaining any deception and why it was necessary, making sure that any negative feelings aroused by participation are nullified, and giving participants enough information to complete their understanding of the nature of the project.
Other feedback, includes how will the results of the project be made available to the participants? It is only courteous, wherever practicable, that participants should have access to any report. It is appropriate for research participants to be able to receive feedback on project they have been involved in, in an appropriate format, where this is possible. You should consider the issue of informing the participants of the results of the project or where they may be able to get access to information (although participants may not be able to be given their individual results).

Question 1.29 Access to confidential information: If the project involves access to personal and/or confidential data (including student, patient or client data) without the participant's specific consent provide details of the information being sought, from which organisation (include any relevant), any legal requirements/conditions of access and justification for use of this information.

Questions 1.30 Confidentiality/Anonymity: Generally, it will be necessary to say more than 'all your data will be confidential' and we would advise against these kinds of statements in

participant information sheets. One of the reasons for this is that, in everyday understandings of the word 'confidential' it could be taken to mean that none of the information that participants give will be passed on to any other person. Clearly, in a research context, this is not the case. We would also advise that researchers think very carefully before promising participants that only certain, named, individuals will see their information. The first difficulty with this is that it may actually not be legally or practically possible to follow through with this promise. What if you want to reanalyse the data later with a different colleague and they need to see it in order to work with you? You could kick yourself for promising participants that "nobody but myself and my supervisor" will see the information you provide. Also, you might consider that providing information (even in statistical form) to the media or in papers, publications or presentations does actually constitute somebody seeing 'their information' – especially in interview or observational studies.

Sometimes, it might be in the best interests of the research and the participants if you say something more general that you know you will actually be able to stick to and that really does give genuine information about how the information will be used and stored. So, you might say something like "only people with a legitimate professional need will see your actual completed questionnaire" and then go on to explain in what form(s) you will use and pass on the information they give. For example, you might say that "the information you provide will be used to write reports and may be seen publicly" whilst reassuring them that "at no point will you be identified in these reports because the information we give will be numerical and will be information about the group of participants to which you belong, rather than about you personally". You could then even add that "the information you provide will be anonymous; that is, your name will not be recorded anywhere and we will not reveal any personal information about you individually from which you could be identified". Obviously, what you actually say will depend upon who your potential participants are and on what your research procedures will be. It often helps to use examples, if you are concerned that participants will not understand your descriptions of how the data will be stored and used. However, this is the kind of thing that we will expect to see – rather than the relatively uninformative "all data is confidential".

If you are using a participant pool (e.g. School of Psychology's participant pool) in your project that is otherwise intended to be anonymous, you will need to ensure that you have a system that keeps their names (which you may need to give them participant points later) separate from their anonymous research data. People often use tear-off slips for this that can then be placed in separate sealed envelopes.

You also need to think about the role of identifying information when you give participants information about confidentiality and anonymity. This issue most often applies to things like interview data – where, for example, it would be normal to use excerpts from interviews in publications. You may not even know yourself how likely it is that a person might be identified from what you repeat. If the information is highly sensitive or personal and the population is one that is small and very easy to identify (e.g., Vice Chancellors of UK Universities, Heads of Primary Schools in isolated parts of the Scottish Islands) you may even need to consider letting participants see the transcripts and look themselves for identifying information. However, it is important to remember that survey information and

questionnaire data can lead to these kinds of problems with identifying information and so you need to think about these possibilities at the design stages of your project and within your ethics submission. That is, don't fall into the trap of glibly saying 'all data is confidential and anonymous' without thinking through all the ramifications of this and how you will ensure that it can be ensured.

Question 1.31 (including sub-questions 1.31a-c) Human Tissue: Please provide details on how the medical research will be undertaken, including confirmation that all human tissue samples and/or body fluids used will be obtained lawfully and with appropriate consent, and be handled and used sensitively and responsibly by investigators. Please justify the use of human tissue in this project (e.g. in order to answer the research aims as identified in Question 1.9).
The Human Tissue Act 2004 (hereafter, "the Act") is the legislative framework in England, Wales and Northern Ireland which governs the removal, storage, use and disposal of 'relevant human material' from the living and the deceased for 'scheduled purposes'. The Act focuses on both consent and licensing, making consent the fundamental principle underpinning the lawful removal, storage and use of human body parts, organs and tissue. The Human Tissue Authority (HTA) is the competent authority for implementing the Act and licenses establishments to store and use relevant material. Certain types of material/samples as well as where they are being sourced from and for what purpose they are being used may be stored without the need for a licence. Consent for human tissue (including DNA samples) is required regardless of the need for HTA Research Licence.
Further Guidance is available from Human Tissues Authority (HTA).
Until such time as the University gains its own HTA Research Licence, human tissue that is for a 'scheduled purpose' and not sourced from a BioBank or part of an NREC approved project can only be stored for a maximum of 5 days.

Question 1.32 Excavation / Study of human remains: Before carrying out any work on the objects, people or other remains of the past, all investigators must consider the ethical implications of their work. There are particular issues surrounding the study of human remains or access to archaeological sites, landscape and artefacts within different countries. All of the major archaeological associations have published codes of conduct and many professional bodies have guidance on how to handle human remains or artefacts.
Study of human remains
For handling human remains please see the BABAO code of conduct, and the Institute for Archaeologists guidance documents. If your project involves the destructive sampling of human remains or objects please outline how the research objectives outweigh the negative implications of intrusive sampling and how damage is to be limited or mitigated against. Do you have permission to conduct intrusive sampling and how will this be documented?

If applicable please outline where your research collection is housed, i.e. in a museum, at UCLan, or as yet to be excavated. Is it subject to any legal conditions? If part of an on-going excavation within the UK does that project have an active Ministry of Justice Licence and what are the conditions of that licence (only applies to sites excavated after 2008). If they are within an existing museum collection please refer to the museums own published codes of conduct and rules where applicable.

Access to Archaeological Materials and Landscapes

All studies must be conducted within the boundaries of the Law, in the UK these laws focus on scheduled monument consent, and the excavation of human remains (other laws may also be implicated for example the Treasures Act, and the Museums Act). Please outline which of these apply, if any, and how the project will meet the criteria of those laws. In other countries archaeological excavation may require a licence, or be affected by local laws and procedures which should be described and addressed. Archaeological field work or museums work will require permission from collection managers or land owners, it may not always be possible to document this (Museums are often too understaffed to provide formal documentation and others will be reluctant to issue written, and so legal documents, should they wish to withdraw permission at any point).

However, you should state how permissions will be sought and outline how you will keep track of any emails, phone calls or physical evidence in a project archive.