University of Central Lancashire

UCLan Ethics Pack

For Research Degree Students

V1 (2015)

UCLan Ethics Pack for Research Degree Students

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

Document A – e-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 Committee Application Form
Use this form if you are seeking 'Ethical Approval'[1]

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 roffice@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

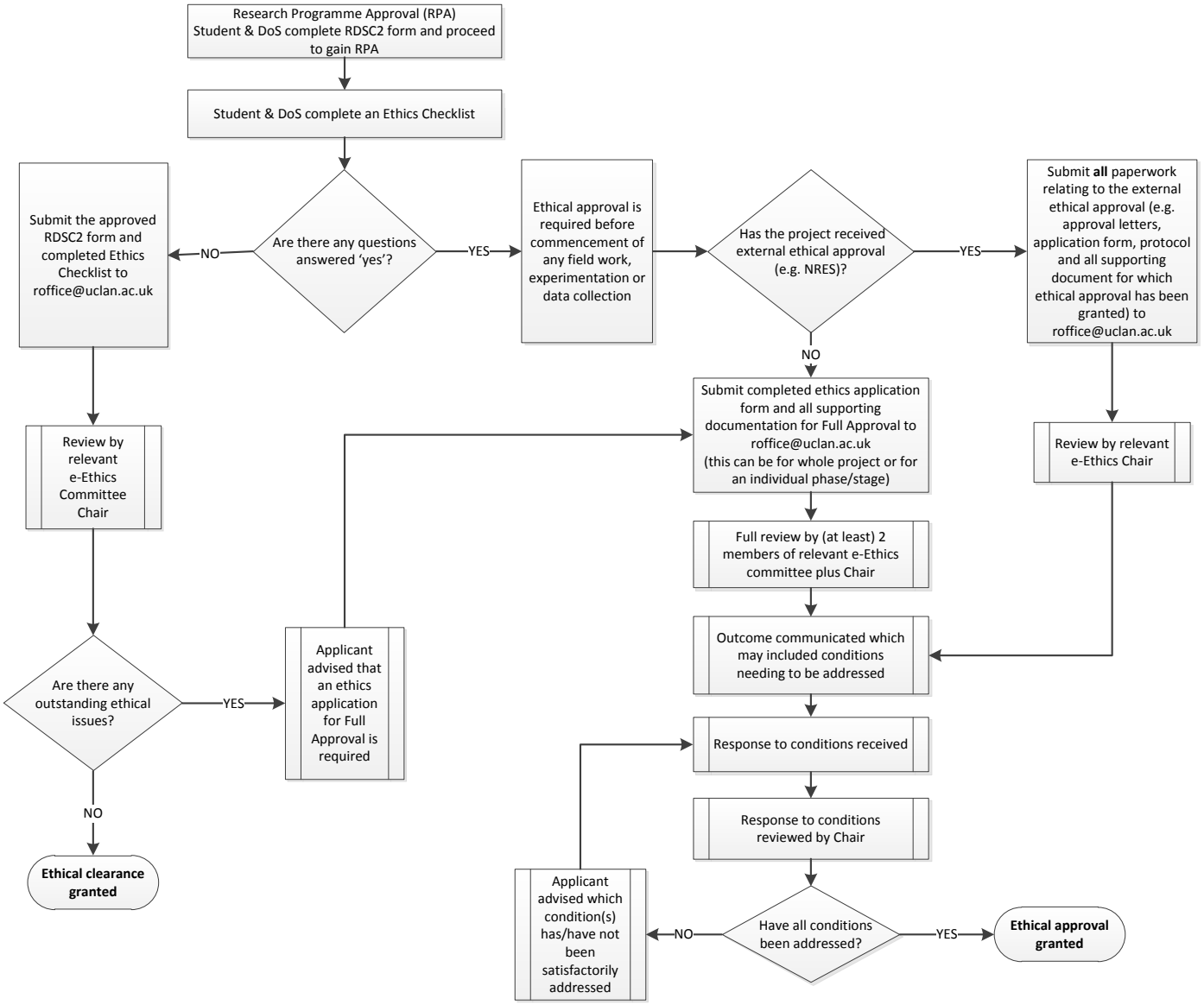
University of Central Lancashire

e-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 committee.

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, all questions are answered '**Yes**' then refer to **Full Approval** notes below.

If, on completion of the Ethics Checklist, all questions 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 roffice@uclan.ac.uk (please prefix the subject line of the email with the appropriate ethics committee acronym).

The Chair of the ethics committee will review the documentation and provide confirmation that the student's research programme approval proposal has received ethical clearance[2] 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 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.

Full Approval

Where the need for Full Approval has been identified, either on completion of ethics checklist or notification from UCLan ethics committee 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.

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 roffice@uclan.ac.uk. A review by (at least) two members of the ethics committee will then take place providing feedback on the application. It will then be passed to the Committee Chair. The Chair, after reviewing the paperwork and the reviewers' feedback/comments, will then provide a decision on the application.

External approval (e.g. NRES – IRAS)

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 roffice@uclan.ac.uk to be reviewed by the Chair of the relevant ethics committee as opposed to completing UCLan ethics application form. E.g. if the project has been approved through the IRAS process (NHS National Research Ethics Service – NRES - application system), then the paperwork to be submitted is the completed IRAS 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.

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

Outcome / Decision

The ethics committees can make five kinds of decisions on an application:-

1. Outline approval or approval in principle (may include exemption from full review)
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 from

https://www.uclan.ac.uk/students/research/research_governance.php

Contacts

BAHSS (Business, Arts, Humanities and Social Science)
PSYSOC (Psychology and Social Work)
STEMH (Science, Technology, Engineering, Medicine and Health)

Administrators: Stuart Holmes - 4031 & Alison Naylor - 2728
Email ROffice@uclan.ac.uk

DOCUMENT B

University of Central Lancashire

UNIVERSITY OF CENTRAL LANCASHIRE

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 committee it should be referred to. 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 relevant ethics committee.

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 committee.

- ***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 committee 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/e-Ethics_guidance_notes_re_Research_Degree_Student_V3_amendmentApr13.docx

Further details on the e-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	Original research		Research degree		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: names and positions [e.g. student]											

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 committee 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 roffice@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 e-Ethics Committee. Submission can be just the external organisation ethics application paperwork (e.g. Brain Tissue North West) – email details to roffice@uclan.ac.uk to check.*	

Continued/…

	For all other activities involving human participants, their data or materials*, *complete and submit UCLan Ethics Committee Application Form to relevant e-Ethics Committee – 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 arising of physical, social, emotional or psychological harm, distress or discomfort to the researchers or participants; 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, or genetically modified micro-organism?**	**Yes/No**
	If so, process via UCLan Biological Safety Committee before submitting to the relevant e-Ethics Committee	
C)	**Does the activity involve scientific procedures being applied to a vertebrate animal (other than humans) or cephalopods?**	**Yes/No**
	If so, please email roffice@uclan.ac.uk requesting application form and submission deadlines for AP Committee	
D)	**Does the activity involve collection of rare plants or endangered species?**	**Yes/No**
	If so, complete and submit UCLan Ethics Committee Application Form to relevant e-Ethics Committee – BAHSS; PSYSOC or STEMH.	
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 roffice@uclan.ac.uk*	
F)	**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 roffice@uclan.ac.uk*	

UCLan Ethics Committees

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

- Art, Design and Fashion
- Film, Media and Performance
- Humanities and the Social Sciences
- Journalism, Language and Communication (inc iSLanDs)
- Business
- Management
- 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 Committee for Psychology and Social Work (PSYSOC) has responsibility for the following Schools:

- Psychology
- Social Work, Care and Community

The Ethics Committee 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 Research Development and Support Team (roffice@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

If your project has been approved through the IRAS process (NHS Research Ethics Committee - NREC-application system), please submit **all** your IRAS paperwork (NREC approval letters, IRAS application form, protocol and all supporting document for which ethical approval has been granted - i.e. information sheet, consent form, etc) to ROffice@uclan.ac.uk to be reviewed by the Chair of the relevant ethics committee as opposed to completing the ethics application form.

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/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 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
Ethics Committee 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 Committees (BAHSS; PSYSOC & STEMH). Where this document refers to 'Ethics Committee' this denotes BAHSS; PSYSOC & STEMH (see Appendix 1 for list of Schools associated with each ethics committee). These Ethics Committees deal with all staff and postgraduate research student project. Taught (undergraduate and MSc dissertation projects) will normally be dealt with via School process / committee.

If you are unsure whether your activity requires ethical approval please complete an UCLan Ethics Checklist. If the proposed activity involves animals, you should not use this form. Please contact the Research Development and Support Team within Research & Innovation Office – roffice@uclan.ac.uk – for further details.

Please read the Guidance Notes before completing the form. Please provide all information requested and justify where appropriate. Use as much space as you need – the sections expand as you type. Click on box or circle to select relevant option (e.g. type or Yes/No) and click on 'grey oblong shape' to start typing for the free text entry questions. Each question on this form has instructions on how to answer that particular question. In addition links to relevant documents (e.g. templates, examples, etc.) and further guidelines are available in the Guidance Notes which can also be access from the question by clicking on appropriate question number. 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.

Your application needs to be filled in electronically and emailed to roffice@uclan.ac.uk. Please insert in the subject line of your email the acronym of the committee that needs to deal with your application. Committee acronyms are BAHSS, PSYSOC or STEMH – see Appendix 1, at the back of this form, for list of Schools associated with each ethics committee.

PLEASE NOTE – 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.

If this application relates to an activity which has previously been approved by one of the UCLan Ethics Committees, please supply the corresponding reference number(s) from your decision letter(s).

Section 1
DETAILS OF PROJECT

All applicants must complete Section 1

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 Researchers / Student:**		
Name	School	Email
	Choose an item.	
	Choose an item.	
	Choose an item.	

1.4 Project Title:

Please provide your project title. If your project title has both a short and long title, please enter your short title here.

1.5 Anticipated Start Date:

Click here to enter a date.

1.6 Anticipated 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 lay'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 investigation. 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 activity been assessed**? (select all that apply)

☐Independent external review

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

☐Research Programme Approval gained on Click here to enter a date. ***(Please that RPA is a prerequisite for Research Degree Student 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 for your data for the next 5 years** – as per UCLan requirements

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

☐Peer reviewed journal

☐Internal report

☐Conference presentation

☐Other publication

☐Written feedback to research participants

☐Presentationto 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 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)?
☐Yes ☐No
If Yes, please provided details of the external organisation / ethics committee and attached letter of approval NB – external ethical approval **must** be obtained before submitting to UCLan ethics.
1.14 **The nature of this project is most appropriately described as research involving:-** (more than one may apply)
☐Behavioural observation ☐Self-report questionnaire(s) ☐Interview(s) ☐Qualitative methodologies (e.g. focus groups) ☐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 ☐Archaeological excavation/fieldwork ☐Re-analysis of archaeological finds/ancient artefacts ☐Human remains analysis ☐Other (please specify in the box below)
If 'Other' please provide details

Please read all the following questions carefully and if you respond 'Yes' then you should provide all relevant details and documentation (including risk assessments), and justify where appropriate.

Section 2
HUMAN PARTICIPANTS, DATA OR MATERIAL

2.1 **Are you using human participants (including use of their data), tissues or remains**?
(please select the appropriate box)
☐Participants [proceed to next question 2.2] ☐Data [proceed to question 2.20] ☐Tissues /Fluids / DNA Samples [proceed to question 2.21] ☐Remains [proceed to question 2.24] ☐No [proceed to Section 3]
2.2 **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 ☐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, medical students ☐Other vulnerable groups (please list in box below)
If 'Other' please provide details
2.2a **Justify their inclusion**
*Ethical approval covers **all participants** but particular attention must be given to vulnerable participants. Therefore you need to fully justify their inclusion and give details of extra steps taken to assure their protection. Where the 'Other vulnerable groups' box has been selected, please also describe/list.*

2.2b **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.
☐Yes ☐No
If Yes, please advise status of DBS clearance (e.g. gained; in process; etc)
2.3 **Please indicate exactly how participants in the study will be (i) identified, (ii) approached and (iii) recruited**?
N.B if a recruitment advertisement is to be used, please attach *State how you will identify, approach and recruit participants including how you will ensure no coercion will be used in your recruitment.*
2.4 W**ill consent be sought from the participants and how will this be obtained**?
N.B. if a written consent form is being used, please attach *Please specify what information you will provide in order that consent be informed, and whether consent will be given verbally or in writing. If consent is not to be obtained, please explain why not.*
2.5 **What information will be provided at recruitment and briefing to ensure that consent is informed**?
N.B. if an information sheet is being used, please attach *Give details of any particular steps to provide information and justify where an information sheet is **not** being used.*
2.6 **How long will the participants have to decide whether to take part in the research**?
Indicate whether this is days or weeks and if less than 24 hours please justify.
2.7 **What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs**?
Gives details of what arrangements have been made (e.g. translation, use of interpreters, etc).
2.8 **Payment or incentives: Do you propose to pay or reward participants**?
☐Yes ☐No
If Yes, please provided details
2.9 **Does the activity involve conducting a survey, interviews, questionnaire, observational study, experiment, focus group or other research protocol**?
☐Yes ☐No
If Yes, please provide details and attach copy of what you will be using

Give details of the specific procedures/activities being used and indicate where documentation (i.e. questionnaire or agendas) will be developed as part of the project. Also include what is the experience of those administering the procedures

2.10 **Will deception of the participant be necessary during the activity**?

☐Yes ☐No

If Yes, please provide justification

Gives details of the exceptional nature of this project that necessitates the need for deception and explain why the deception is absolutely necessary.

2.11 **Does the activity (e.g. Art) aim to shock or offend**?

☐Yes ☐No

If yes, please explain

Give details, justify and what measures are in place to mitigate.

2.12 **Does your activity 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 the participant's participation is purely voluntary and not influenced by the relationship in any way.

2.13 **Does the procedure involve <u>any</u> possible distress, discomfort or harm (or offense) to participants or researchers** (including physical, social, emotional, psychological)?

☐Yes ☐No

If Yes, please explain

Describe the potential for distress, discomfort, harm or offense for research participants as a result of their participation in your study 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 participants.

2.14 **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.

2.15 **What mechanism is there for participants to withdraw from the investigation and how is this communicated to the participants**?
*Describe exactly how, and when, participants may withdraw if they change their minds about taking part including how participants **know** they have the right to withdraw.*
2.16 **What is the potential for benefit**?
Briefly describe the main benefits and contribution of the study. Include any immediate benefits to participants as well as the overall contribution to knowledge or practice (e.g. educational purposes only).
2.17 **What arrangements are in place to ensure participants receive any information that becomes available during the course of the activity that may be relevant to their continued participation**?
Describe how participants will be made aware of relevant information that was not available when they started.
2.18 **Debriefing, Support and/or Feedback to participants**
Describe any debriefing, support or feedback that participants will received following the study and when.
2.19 **Adverse / Unexpected Outcomes**
Please describe what measures you have in place in the event of any unexpected outcomes or adverse effects to participants arising from their involvement in the project
2.20 **Will the activity involve access to confidential information about people without their permission**?
☐Yes ☐No
If yes, please explain and justify *State what information will be sought, from which organisations and the requirement for this information.*
2.21 **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 2.22 If yes, please detail and answer questions 2.21a & 2.21b *Clearly state the source of the material (a tissue bank governed by its own HTA licence such as Brain Tumour North West, or purchased from overseas, etc.)*
2.21a **Will the human tissue be stored at UCLan?**
☐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.

2.21b **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

2.22 **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. de-identified samples or data (i.e. a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)?	☐	☐
c. participants having the consented option of being identified in any publication arising from the research?	☐	☐
d. 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** proceed to question below*
*If **no to all**, please skip to question 2.24*

2.23 **Which of the following methods of assuring confidentiality of data will be implemented**? (Please select all relevant options)

N.B. Please attach completed DP Checklist (click here to see further data protection advice)

☐data and codes and all identifying infomration to be kept in separate locked filling cabinets

☐access to computer files to be available by password only

☐other (please specify in the box below)

If other, please describe method.

2.24 **Does the activity 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.

Section 3
BIOLOGICAL ORGANISMS/ENVIRONMENT

3.1 **Does the activity involve micro-organisms, genetic modification or collection of rare plants**?
☐Yes ☐No
If yes please provide further details below State the type and source of the samples to be used in the project and include compliance with relevant legislation. *If no please proceed to section 4*

Section 4
HAZARDOUS SUBSTANCES

4.1 **Does the activity involve any hazardous substances**?
☐Yes ☐No
If yes please continue *If no please proceed to section 5*
4.2 **Does the activity involve igniting, exploding, heating or freezing substances**?
☐Yes ☐No
4.3 **Does the activity involve substances injurious to human or animal health or to the environment**?
☐Yes ☐No
4.4 **Are you using hazardous chemicals**?
☐Yes ☐No
*If **Yes to any** please attach all relevant COSHH (single substance OR multi/complex substance) and/or risk assessment forms* N.B. Please address issues of quantity involved, disposal and potential interactions as well as a thorough evaluation of minimisation of risk

Section 5
OTHER HAZARDS

5.1 **Does the activity relate to military equipment, weapons or the defence industry**?
☐Yes ☐No
If yes please provide details and attach relevant permissions and risk assessments. Describe the hazard, clearly explaining the risks associated and specify how you will minimise these *If no please continue to next question*
5.2 **Does the activity relate to the excavation of modern battlefields, military installations etc**?
☐Yes ☐No
If yes please provide details and attach relevant permissions and risk assessments. Discuss the provisions for examination and the management of any community/public concerns, legal requirement, associated risks, etc. *If no please continue to next Section*

Section 6
FIELDWORK/TRAVEL

6.1 **Does the activity involve field work, lone working or travel to unfamiliar places**?
☐Yes ☐No
If yes, answer the following questions *If no, go to Section 7*
6.2 **Where will the activity be undertaken**?
N.B. If your work involves field work or travel to unfamiliar places (e.g. outside the UK) please attach a risk assessment specific to that place *Give location(s) details (e.g. UCLan campus only)*
6.3 **Does the activity involve lone working**?
☐Yes ☐No
If yes please provide further details below and attach a completed risk assessment form *Describe the lone working element, clearly explaining the risks associated and specify how you will minimise these*
6.4 **Does the activity involve children visiting from schools**?
☐Yes ☐No
If yes please provide further details below and attach a completed risk assessment form *Describe the nature of the visit, clearly explaining the risks associated and specify how you will minimise these*

Section 7
ETHICAL AND POLITICAL CONCERNS

7.1 **Are you aware of any potential ethical and/or Political concerns that may arise from either the conduct or dissemination of this activity** (e.g. results of research being used for political gain by others; potential for liability to the University from your research)?
☐Yes ☐No
If yes please provide details below *If no please continue to next question*
7.2 **Are you aware of any 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 yes please provide details below *If no please continue to next question*
7.3 **Are there any other ethical issues which may arise with the proposed study and what steps will be taken to address these**?
☐Yes ☐No
If yes please provide details below *If no please continue to next Section*

Section 8
DECLARATION

This section needs to be signed by the Principal Investigator (PI), and the student where the study 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 roffice@uclan.ac.uk. Where available insert electronic signature, if not a signed version of the submitted application form should be retained by the Principal Investigator.

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 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 Committee* has given a favourable opinion and any conditions of the Ethics Committee in giving its favourable opinion.
• I undertake to seek an ethical opinion from the Ethics Committee before implementing substantial amendments to the study plan or to the terms of the full application of which the Ethics Committee 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 Committee within 24 hours of the occurrence, via roffice@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 will be held by the University and that this will be managed according to the principles established in the Data Protection Act.
• I understand that the information contained in this application, any supporting documentation and all correspondence with the Research Ethics Committee 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.

* Ethics Committee refers to either BAHSS, PSYSOC or STEMH

• 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.	
• **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 safety, 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.

Section 9
ACCOMPANYING DOCUMENTATION

Please indicate here what documentation you have included with your application:
☐Proposal / protocol ☐RDSC2 form – Application to Register for a Research Degree / Application for Research Programme Approval ☐External ethics approval letter ☐Letter of permission ☐Participant consent form(s) ☐Participant information sheet(s) ☐Interview or observation schedule ☐Questionnaire(s) ☐Advert(s) ☐Debrief Sheet(s) ☐Data Protection Checklist ☐Risk Assessment Form(s) ☐COSHH Form(s) ☐Other
If 'Other' please list/describe

Appendix 1
BREAKDOWN OF SCHOOLS TO ETHICS COMMITTEES

The Ethics Committee for **Business, Arts, Humanities, and Social Science (BAHSS)** has responsibilities for the following Schools:

- Art, Design and Fashion
- Film, Media and Performance
- Humanities and the Social Sciences
- Journalism, Language and Communication (inc iSLanDs)
- Business
- Management
- 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 Committee for **Science, Technology, Engineering, Medicine and Health (STEMH)** has responsibilities 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)

The Ethics Committee for **Psychology & Social Work (PSYSOC)** has responsibilities for the following Schools:

- Psychology
- Social Work, Care and Community

Appendix 2
GUIDANCE NOTES

Forms will only be considered if they are typed in to the ethics application pro-forma.
Do not attach these guidance notes in your submission.
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 nine sections with each section requiring at least an initial question to be answered then depending on the nature of your study; further questions may also need to be completed. This guidance mirrors the application form and is designed to help you to complete the form to a high standard. In order to grant ethical approval, the Ethics Committee needs sufficient detail to be able to judge the ethical issues presented by, and addressed in, the design of the study.
To return to the application form – click on the relevant question number or Section header.

Section 1 – Project Details

All questions in this section must be completed.

Q1.2 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) . Otherwise, all UCLan supervisors should be listed under Q,1.3 'Other Researcher / Student'. We strongly recommend that all supervisors review the documentation prior to submission for ethical approval.

Q1.4 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).

Q1.6 Note that Ethics Committee approval is normally deemed to expire **five years** form the approval date unless otherwise requested.

Q1.7 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.

Q1.8 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 study is following up another, or is perhaps testing a theory presented in another).

Q1.9 Indicate how the research question(s) outlined in the answer to Q1.8 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.

Q1.10 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.

Q1.11 See UCLan Code of Conduct for Research; UCLan Data protection checklist and LIS IT Security Policy.

Q1.13 If your project has been approved by an external ethics committee (e.g. NHS Research Ethics Committee or properly-constituted ethics committee at another UK University or at another organisation) include a copy of the letter of approval. A properly-constituted ethics committee is one in which has terms of reference, membership with appropriate expertise and which includes lay members (i.e. at least one member independent of the organisation). Ethics committees in other Universities or organisations may or may not be properly constituted. It is the applicant's responsibility to check these details. If you are unsure, you are recommended to contact the Research Development & Support Team for advice or simply to respond 'No' here.

If you have been informed that you need not apply to an NHS REC (usually because your research is classed as audit or service evaluation by the NHS), this is not the same as having received their ethical approval, so you should not select the box indicating approval by an NHS Research Ethics Committee. However, you are recommended to include such communication amongst the documentation submitted (and to list this under 'Other'). Please note that this does not mean that your project may not be managed as research by this committee.

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.

Please note that in such cases application to the Ethics Committee should only be submitted once external approval has been obtained.

Section 2 – Human Participants, Data or Material

Q2.1 Select the appropriate box and then proceed to the question as directed.

Q2.2 Tick as many boxes as applicable and then describe 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.

Q2.2b Certain activities and/or potential participant groups (e.g. children or vulnerable adults) may require researcher(s) to gain a DBS (Disclosure and Barring Service) certificate. Full information, including guidance on completing a DBS application form, is available at Disclosure and Barring Service (formerly Criminal Records Bureau – CRB) website. If you need a DBS application form please contact roffice@uclan.ac.uk.

Q2.3 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.

Q2.4 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.

Q2.5 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.

Q2.6 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.

Q2.7 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.

Q2.8 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.

Q2.9 Procedures to be undertaken include all other forms of intervention, so this includes assessment focused questionnaires, and psychological or educational tests. Give details of any invasive procedure and any samples or measurements to be taken. Attach the questionnaire/test, etc. and provide details and supporting evidence of staff experience/expertise administering them.
Questionnaires and/or interview schedules and/or focus group agendas should normally be submitted with the application. If these are to be developed as part of the project, please ensure that this is clearly stated. 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. 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 proposal or in a separate document.

Q2.10 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.

Q2.11 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).

Q2.12 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.

Q2.13 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?).

Q2.14 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 divulged 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.

Q2.15 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.

Q2.16 A lot of projects result in no direct benefit to the participant at the time and it is acceptable to write 'no direct benefit'. 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.

Q2.17 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.

Q2.18 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).

Q2.19 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)?

Q2.20 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.

Q2.21 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. Further Guidance is available from Human Tissues Authority (HTA).

Q2.22 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 the School'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.

Q2.23 See UCLan DP checklist and LIS IT Security Policy.

Q2.24 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.

Section 3 – Biological Organisms / Environment

Q3.1 Health & safety issues are carefully regulated (Containment; Special attention to pregnant women and the immunologically compromised; MOs can be mutated forms, unable to replicate outside the lab). The ethical issue is usually whether or not the risks can be justified by the potential benefits. Environment considerations are minimum disruption to natural environments unless purpose is improvement and respect rights of landowners. Study of rare species must be approved by appropriate bodies (e.g. English Nature). Follow guidelines for archaeology (see Q2.24 guidance).

N.B. If your project requires UCLan Biological Safety Committee (BSC) approval, please use their application form and only once BSC approval has been gained should submission be made to Ethics Committee.

Section 4 – Hazardous Substances

Health & safety issues are carefully regulated – see UCLan guidance notes on hazardous substances and risk assessment. The ethical issue is usually whether or not the risks can be justified by the potential benefits. If the project involves the use of hazardous substances (chemicals, fire, etc.), what detail is needed in the relevant COSHH forms and Risk Assessment forms. What is most important to provide is a list of the potential hazards of the work you propose to do, and not just a list of how you will minimise the risks. For example, you may be working with two chemicals. Neither one on its own is a particular problem, but if the two are accidentally combined – they explode.

Section 5 – Other Hazards

Research related to defence and arms industries may contradict general ethical principles (e.g. avoidance of harm). Approval of such work must involve University Senior Management.

Section 6 – Fieldwork/Travel

Q6.2 The location, or locations, of the investigation should be given. These should be places suitable for the type of investigation to be undertaken and where both participants and investigators are safely able to carry out the work. If this is not apparent then please outline the risks / hazards and specify how you will or intend to minimise these. If your project requires travel away from the university, you will need to submit a Travel Risk Assessment form – UK/Overseas. See UCLan guidance on field work / travel to unfamiliar places.

Q6.3 See UCLan guidance on lone working.

Q6.4 See UCLan guidance on School visits to UCLan.

Section 7 – Ethical and Political Concerns

Please use this section to identify, as far as possible, all potential concerns – ethical / political/ collaborator or any other not raised elsewhere on the form.

Section 8 – Declaration

This section needs to be signed by the Principal Investigator and the student where the study relates to a student project. Electronic submission of the form is required to roffice@uclan.ac.uk. Where available insert electronic signature, if not a signed version of the submitted application form should be retained by the Principal Investigator.

Section 9 – Accompanying Documentation

Use this checklist for enclosure of relevant supporting documentation.