Addendum A

Research Ethics review and approval process information

A1 Research ethics review and approval process

- A.1.1 The process of obtaining ethical review for and approval may require consideration of ethical implications by academic supervisors, PhD Coordinators, University or College Research Ethics Committee, or a appropriate external ethical review body.
- A.1.2 A completed Research Ethics Application which has been subject to peer review and academic methodology consideration should be provided to an ethical approval body.
- A.1.3 Staff, doctoral researchers and postgraduate taught students and undergraduate Psychology students, should complete applications for ethical review using the using the University's online research ethics system. All other undergraduate students requiring ethical review (Class 2 or above only) would require their Supervisor to complete the Research Ethics Application in collaboration with them, via the University's online research ethics system.
- A.1.4 Where a Research Ethics Application for ethical review must be provided to an external ethical review body, and the University does not have the remit to provide its own review and approval, a researcher may not proceed until external approval or favourable opinion has been gained and this approval or favourable opinion has been gained and this approval or favourable opinion has been confirmed by the University.
- A.1.5 When providing evidence of external ethical approval or favourable opinion to the University, copies of the completed and final external research ethics application form and any supporting documentation and conditions and/or approval/favourable opinion letters received by the researcher, must be provided to the relevant University or College Research Ethics Committee.
- A.1.6 Where the external organisation is outside the UK and ethical approval or conditions have already been received, the original documentation should be submitted to the University Research Ethics Committee for consideration. The University may consider the ethical review is sufficient depending on the standards followed by the external organisation, or may choose to conduct its own review and/or set additional research ethics related conditions. The University retains its right to request any additional compliance or governance conditions.
- A.1.7 Additional external permissions may be required for compliance purposes such as organisational permission to conduct research on external premises, use participants or data belonging to an external organisation.

A2. Procedure

A.2.1. The University aims to promote good academic practice in research by asking individual researchers to complete and retain a research ethics self-assessment form to demonstrate that research ethics implications have been considered – this

will be the Part A Research Ethics Application Form. Where there are potential research ethics implications, an application for ethical review must be completed and submitted to an appropriate Research Ethics Committee or research ethics review body.

Supervisors for taught students are responsible that the Research Ethics Application meets required standards in terms of research design , methodology and the identification of ethical issues.

- A.2.2. All doctoral researchers must complete the Annual Progress Review 1 (APR 1) which is scrutinised and signed off by the Director of Studies, an assessor independent of the supervisory team, the School Doctoral Coordinator and the Graduate School Board. Completion of this process provides evidence that research design and a provisional assessment of ethical implications have been considered. The process includes research ethics consideration as good academic practice.
- A.2.3. Research ethics implications should be considered at the design phase of all taught UG and PG student research project preparations when proposals are initially scrutinised by a supervisor.
- A.2.4 Applicants and Supervisors are encouraged to consult the Research Integrity Office (UKRIO) researcher check-list available at <u>https://ukrio.org/publications/checklist-for-</u> researchers/
- A.2.5. Applications for research ethics review are dealt with at respectively College or University level (University or College Research Ethics Committee).
- A.2.6. All proposals for conducting research field work (off-site research) in the UK or overseas requires consideration and completion of a risk assessment in line with University Safety, Health and Wellbeing requirements.
- A.2.7. All staff and students submitting proposals for conducting research fieldwork in the UK or overseas will be required to follow the protocol as approved by the relevant Research Ethics Committee, in line with this Code of Practice, in order to avoid invalidating insurance cover. Any proposed changes to protocol would require re-consideration by the appropriate ethics review body and a new insurance cover note where needed, prior to commencement. Urgent Safety Measures are detailed earlier in this Code.
- A.2.8. All proposals for conducting research fieldwork and/or for travel for purposes of University research, require travel insurance cover in line with the University Procurement policy requirements.
- A.2.7 Ethical approval shall be obtained before the commencement of any research which has the potential for ethical implications. A Research Ethics Committee may allow part of the research to commence, prior to full approval being granted, for those aspects of the research which do not relate to the ethical implications but which are intended to contribute to the final piece of research.
- A.2.8 A College Research Director, Supervisor or other designated named person e.g. Research Ethics Committee Chair or Secretary will be available to give advice concerning the ethical implications of an application, if required.

- A.2.9 A Research Ethics Committee reserves the right to request modifications or clarifications of any applications and proposals received for review.
- A.2.10 A Research Ethics Committee should review proposals in terms of ethical issues they raise, not the scholarly or scientific merits of the research. The scholarly or scientific standards of the proposal should be considered prior to its submission to an ethics review body. By signing the application, the applicant confirms this has been carried out within the norms of regular professional practice. Such practice may include supervisory discussion or peer review, as appropriate to the application.
- A.2.11 Exceptionally, where a Research Ethics Committee has concerns that the methodology described in an application may unnecessarily increase the likelihood of risk of harm, then it may return the application for further clarification proportionate to the risks involved. Where a Research Ethics Committee needs to appraise the value of a project in order to make a judgment about research ethics issues arising from potentially methodologically unsound research, the advice of an experienced researcher independent to the project and the Research Ethics Committee, who has experience in the proposal's methodology and paradigm, should be sought.
- A.2.12 A Principal Investigator or researcher cannot attend any discussion at a College or University Research Ethics Committee involving their own research proposal even if they are members of the relevant committee, unless invited. Members must also declare any special interest including personal, School, College or financial.. If the Committee Chair is involved in any such conflict of interest(s) then the vice-Chair or nominee will take over until the discussion is concluded. A conflict of interest must be recorded in the Minutes by the Committee Secretary.
- A.2.13 Dates of University Research Ethics Committee meetings will normally be published in the University Calendar. Applications for University Research Ethics Committee review, should reach the Secretary no later than ten working days before the meeting at which they are to be reviewed.

A.3 Life Cycle of Research and Research Ethics Approval limitations

- A.3.1 A research ethics proposal should clearly state the proposed date when the research will start and end, and any ethics approval would be related to this specific time frame only.
- A.3.2 This Code contains further details regarding ongoing ethics consideration of a research study by the Principal Investigator, including the need to re-visit consent and participant information where new data or new participants or donors may be used for which previous research ethics approval was not gained.
- A.3.3 Secondary uses of research data which did not receive ethics approval previously must be submitted to an ethics review body, where potential ethical implications exist and where the data is not currently in the public domain. Similarly other changes in the protocol which are significant and/or raise potential ethical implications, which did not exist or were not known previously when review or consideration was given by an ethics approval body or in a research ethics self-assessment respectively, should be submitted for review as a 'significant amendment to protocol' in the University's research ethics online system .

A4. Pre and post award research good practice and research ethics

- A.4.1 Applicants to external funding bodies or organisations should consider the external organisations Codes for research good practice and research ethics and take these into account, along with the University Research Codes and Policies prior to applying for funding.
- A.4.2 Researchers proposing to undertake contract research or consultancy should consult and consider the good practice and ethics guidance within the contract or Company Corporate Social Responsibility Statements (or similar professional good practice guidance).
- A.4.3 Some external funding bodies will require full ethical consideration or expedited ethical consideration by the University to be carried out prior to the award of the grant, and in some cases they require this to be carried out when making the grant application itself. Please check the guidance of the funding body.
 - A.4.3. As well as evidence of ethics review and consideration the funding body may require the University to confirm the research good practice and training requirements as a condition of the grant, this may involve training to carry out the research ethically, as well as insurance and other liabilities.

A5. Decisions

- A.5.1 Following consideration and review of each Research Ethics Application, a Research Ethics Committee decision shall be either:
- to approve the application;
- to approve the application subject to conditions or modifications;
- not to approve the application.
- A.5.2 On occasion a Research Ethics Committee may not be able to reach any of the decisions outlined above, without a request for further information from the Principal Investigator or to invite the Principal Investigator to a meeting of the Committee to discuss the proposal further.
- A.5.3 In any case, the Principal Investigator shall be notified of the Committee's decision or request for further information, within ten working days of the meeting at which the application was considered.
- A.5.4 Any application which has been approved subject to conditions and/or clarifications should be submitted with revisions or response to clarifications as required, to the Committee Secretary within 10 working days of the response from the Committee having been provided to the Principal Investigator. The research should not begin until a response to conditions has been provided and approved by the Committee, or by Chair's action.
- A.5.5 If a proposal has been rejected (not approved) and new information becomes available, a revised application may be submitted by the Principal Investigator.
- A.5.6 A Research Ethics Committee may require that changes are made to a research protocol for health, safety and wellbeing reasons. Please see Section 12 of the Code.

- A.5.7 Research ethics approval, in exceptional circumstances may be granted, with the Committee's approval, outside the Committee meetings (e-meeting or in person). Advice should be sought from the Committee Secretary regarding this.
- A.5.8 Approval shall normally be for the duration of the research project, which should be stated in the Research Ethics Application form.

A.6. Appeals

- A.6.1 An appeal against a decision by a College Research Ethics Committee may be made to the University Research Ethics Committee only on the grounds that there has been demonstrable material irregularity in the conduct of the Committee's procedures. The decision of the University Research Ethics Committee will be final.
- A.6.2 The appellant shall submit his or her appeal in writing to the University Research Ethics Committee no later than 10 working days after the receipt of the relevant Committee's decision.
- A.6.3 An appeal against a decision with reference to an application considered by the University Research Ethics Committee may be made to the Research Committee only on the grounds that there has been demonstrable material irregularity in the conduct of the University Research Ethics Committee procedure.
- A.6.4 The appellant shall submit in writing his or her appeal to the Research Committee no later than 10 working days after the receipt of the University Research Ethics Committee's decision.
- A.6.5 The conclusion of an appeal may determine:
- That the appeal is upheld and referred back to the University Research Ethics Committee for review; or
- That the original decision of the University Research Ethics Committee is upheld and that no further action be taken.

A.6.6 The result of an appeal will be notified in writing to the appellant within 10 working days of the decision being reached.