

# University of Central Lancashire

## University Ethics Committee

### Concerns Procedure

The operational contact point for a project, including that for reporting adverse events, is the project's principal investigator or suitably delegated individual. Participants should use this point of contact to confirm or clarify any information about the project, and to report any outcomes. This should be made clear in the information sheet, or equivalent. If a participant wishes to raise a concern about the study, and in particular about the conduct of the study or the individuals involved, that would be inappropriate to raise with the principal investigator, they should use the concerns procedure. This should also be made clear in the information sheet, or equivalent.

Concerns should be addressed to the University Officer for Ethics at [OfficerForEthics@uclan.ac.uk](mailto:OfficerForEthics@uclan.ac.uk). Information provided should include the study name or description (so that it can be identified), the principal investigator or student investigator or researcher, and the substance of the complaint.

The University Officer for Ethics will document the concern, and refer it to the Chair of the relevant e-Ethics sub-committee within two working days.

The Chair will be responsible for investigating the concern, and for responding to the applicant.

Dependent on the nature of the concern and the outcome of the investigation, the Chair may withdraw ethical approval from the project, require changes to the study design, require changes to the implementation of the study design, or refer the matter to the Research Integrity Sub Committee (RISC) for further consideration under the Code of Practice for Allegations of Research Malpractice. The Chair should endeavour to complete this investigation within two weeks of receiving the concern, informing the applicant and the PI (if appropriate) of the outcome. The Chair should report the outcome of any concerns to their sub-committee, and subsequently to the University Ethics Committee.