

## Guidance Document

### University Ethics Exemption for Data only overseas studies

The University guidance states that projects that take place overseas can go forward with approval from an overseas ethics committee without University ethical approval provided a Cambridge ethics committee confirms that the approval is of sufficient rigour. Projects that take place overseas and partly in the UK require UK ethical approval for the research that takes place in the UK.

The Council of the School of Clinical Medicine has approved an exemption from ethical review for certain types of overseas studies subjected to a governance check by the Clinical School governance team.

This exemption from University ethical approval applies only to researchers in the School of Clinical Medicine where all of the following points apply to the project concerned:

- a) The project is health-related and the University of Cambridge contribution is limited to data analysis.
- b) The project is not led by University of Cambridge and the data is collected abroad by individuals who are not University of Cambridge employees (i.e. University of Cambridge researchers are undertaking data analysis as part of a wider project led by another party).
- c) The data received by University of Cambridge researchers is not identifiable to them on receipt.
- d) Ethical approval has been granted by an overseas ethics committee of comparable rigour to that of a UK ethics committee.
- e) The data received by University of Cambridge researchers is provided under a Data Transfer Agreement or Collaboration Agreement that warrants the data has appropriate consent or, for anonymised data for which consent was not required for collection, that the provider is entitled to provide the data, for use as described in the relevant agreement.

Any researchers in the School of Clinical Medicine wishing to rely on this exemption in place of University of Cambridge ethics approval must first consult with the Clinical School Research Governance Team who will confirm whether the points above apply to the project concerned.

Such an exemption does not apply where:

- a) funders require ethics approval both overseas and locally,
- b) the University of Cambridge is named as the project lead on an overseas project or the research project does not fulfil the five criteria set out above,
- c) the research project includes materials transferred from overseas.

The normal ethical review process is required where the University of Cambridge is named as the project lead on an overseas project or the research project does not fulfil the five criteria set out above.