

Guidance Document

University Ethics Exemption for Tissue only overseas studies

The University guidance states that projects that take place *entirely* 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.

Overseas health research exemption from University ethics review for researchers in the School of Clinical Medicine

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 tissue analysis and the researcher is based in the School of Clinical Medicine
- b) The tissue will be stored in a facility covered by a Human Tissue Authority licence and the department designated person has given written permission to store the tissue under the licence. **If the tissue is “relevant material” and is NOT going to be stored in a Human Tissue Authority licenced facility the researcher will legally be required to get ethics approval from the Human Research Authority (HRA)**
- c) The project is not led by the University of Cambridge and the tissue is collected abroad by individuals who are not University of Cambridge employees (ie University of Cambridge researchers are undertaking tissue analysis as part of a wider project led by another party).
- d) The tissue received by University of Cambridge researchers is not identifiable to them on receipt.
- e) Ethical approval has been granted by an overseas ethics committee of comparable rigour to that of a UK ethics committee.
- f) The tissue received by University of Cambridge researchers is provided under a Material Transfer Agreement or Collaboration Agreement that warrants the tissue has appropriate consent or, for anonymised tissue for which consent was not required for collection, and that the provider is entitled to provide the material, for use as described in the relevant agreement.
- g) The Clinical School governance team has undertaken the necessary governance checks to confirm that the points above apply to the project concerned and to confirm to the relevant contract manager and tissue manager that all the above conditions have been met.

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 required ethics approval both overseas and locally.
- b) the University of Cambridge is named as the project lead on an overseas project or
- c) the research project does not fulfil the six criteria set out above.

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 criteria set out above

Researchers should note the above guidance does not override any legal or regulatory requirement for a research project to have UK ethical approval. All researchers must ensure that the Designated Individual for the relevant dept has permitted the transfer of material