



Guidance for researchers requesting access to data from the PACE trial

This document provides guidance for researchers, employed by research institutions, who request to use data from the PACE trial dataset for secondary analyses.

We support the use of PACE trial data for additional, ethically approved research, with justified scientific objectives, and a pre-specified analysis plan. We prefer to collaborate directly with other researchers. On occasion, we may provide data without direct collaboration, if mutually agreed.

There are a number of steps to be undertaken before data sharing in accordance with best practice in transparency, patient confidentiality, data security, and good statistical practice.

- Applicants should apply to one of the [co-principal investigators](#).
- Applicants should state the purpose of their request, their objectives; qualifications and suitability to do the study, data required, precise analytic plans, and plans for outputs. See [published protocol](#) for details of data collected.
- A formal agreement should be drawn up between Institutions i.e. the owner of the data and the Institutions employing those requesting data. Agreement is needed regarding safe data transfer, secure storage, and legitimate use of the data.
- Data will be provided with personal identifiers removed. Applicants must agree not to use the data to identify individual patients, unless this is a pre-specified purpose for record linkage.
- Individual researchers who will see the data must sign an agreement to protect the confidentiality of the data and keep it secure.
- In the event that the request is declined, reasons will be communicated to the requestor.
- An [independent appeal process](#) is available.

After data release:

- Recipients must acknowledge receipt of data and to check it swiftly for problems.
- Whilst final decision to publish using the data remains with the researchers who have used the data, it is requested that a draft report or paper including the results and interpretation be shared with PACE co-principal investigators for feedback.

This guidance is consistent with data sharing guidance policies of [Queen Mary University of London](#) and the [Medical Research Council](#), which funded the PACE trial.

