

Procedure for Human Interventional Studies / Clinical Trials

If your research meets the definition of a 'human interventional study' or 'clinical trial' (see https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/decision_tree/index) and it is sponsored by the University, then it will be subject to a quality assurance process before you can begin to collect data. This is to ensure that the University are adhering to their responsibility as a sponsor by making sure that such research is managed robustly and to identify and disseminate good practice across the University.

The University's definition of a human-interventional study is: *'Research studies designed to answer specific questions about intervention(s) in human participants, whose purpose is to investigate the effectiveness of the intervention(s) and to assess clinical or physiological outcomes.'*

If you are unsure as to whether your project is a human interventional study / clinical trial, then you should contact Lindsay Unwin or Anita Kenny in Research & Innovation Services (l.v.unwin@sheffield.ac.uk or a.j.kenny@sheffield.ac.uk), or Dr Thomas Webb, as Chair of the Department of Psychology Research Ethics Committee (t.webb@sheffield.ac.uk).

If your research meets the definition of a human interventional study / clinical trial then you must indicate this on your application and submit a 'Risk Assessment Checklist' (available here <https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rgp>) alongside your application. The ethics committee will then calculate a 'risk score' from your answers, and inform you which of three categories your project has been assigned to (low, medium, or high risk).

For low risk studies (which it is anticipated that most projects will be) you will be asked to sign and return a self-certification statement. If everything is satisfactory, then an authorisation letter will then be issued giving approval to start. For studies deemed to be of medium or high risk, additional monitoring procedures will be required, as described here <https://www.sheffield.ac.uk/rs/ethicsandintegrity/clinicaltrials/levels>