

# Ethical review of research involving human beings: study design and conduct

Applications for ethical review should provide documentation detailing study design and conduct, participant information and how consent will be obtained. If there are concerns, ethics committees may refer for further assessment by institutions, sponsors or regulatory authorities.

## Study design

The ethical review should cover:

- Clarity of study design
- Methodology to collect and analyze data
- Sample size
- Feasibility in the proposed time frame
- Clinical trial registration
- Data storage and sharing
- The host organization's agreement to the research being undertaken
- Compliance with international, national and institutional guidelines on data protection, lone-worker policy and safeguarding policy

## Dissemination and future plans

The following points need to be considered:

- Participant de-identification and publication
- Participant access to the final study findings and reports
- Duration of storage of data and biological samples
- Future use of data or biological samples in other ethically approved studies.
- Data sharing

## Conduct

The ethical review should cover:

- Recruitment processes
- Potential for coercion
- Use of deception
- Time frame for participants to assess information and provide consent
- Capacity to consent
- Ability to refuse consent without adverse consequences
- Ability and time frame to withdraw and rights to request destruction of already collected data and biological samples
- Risks and management of emergency situations and unexpected findings
- Review of adverse events and annual as well as final study reports

Amendments to a research project after approval need ethical review.

## Further information

Health Research Authority <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>

World Health Organization. Ensuring ethical standards and procedures for research with human beings <https://www.who.int/activities/ensuring-ethical-standards-and-procedures-for-research-with-human-beings>