Royal Academy of Engineering

Human Participants in Research, Development and Innovation Policy

Royal Academy of Engineering

Version Control						
Policy No	**Version**	**Date**	**Description of Change**	**Review Cycle**	**Next Review Date**	**Department**
	1.0	25/04/2024	Creation	1year	25/04/2025	Research, Grants and Awards
	1.1	15/07/2025	Document owner and approver, and next review date and request for information addition	2 years	15/07/2027	Research, Grants and Awards

Document Control					
Version	Document Owner	Lead Directorate	Approver	Signature	Date
1.0	Christina Guindy	Research, Grants and Awards	Andrew Clark	Andrew Clark	25/04/2024
1.1	Sarah Dodd	Research, Grants and Awards	Christina Guindy	Christina Guindy	15/07/2025

Royal Academy of Engineering

Table of Content

1.0 Introduction/Purpose

Research, development and innovation involving human participants, human material or personal data can contribute to a better understanding of human health and disease as well as the technological efficacy of new and evolving innovations. The Academy will fund research, development and innovation involving the use of human participants, human material or personal data where it:

- could have a global public benefit,
- aims to generate new knowledge.

The Academy aligns with the World Health Organization's definition of research involving human participants as;

"Any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings:

(1) are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment;

or

(2) become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records."

2.0 Scope

This policy sets out the Academy's expectations for research involving human participants, human material or personal data and applies to all grant applicants, Academy grant holders, recipient organisations, and all involved in reviewing research proposals on behalf of the Academy.

3.0 Policy Statement

Research involving human participants is governed by principles outlined in the Declaration of Helsinki, the Nuremberg Code, and the Council for International Organizations of Medical Sciences (CIOMS) guidelines, all of which set out requirements with regard to the rights and safety of research participants and standards for research design and conduct.

In alignment with these principles, the Academy **requires** grantees to;

- protect the dignity, rights, safety and wellbeing of all participants, particularly when involving vulnerable groups.
- comply with all relevant legislation, including UK General Data Protection Regulations (UK GDPR), and the duty of confidentiality and informed consent.
- have all relevant regulatory and ethical approvals in place.

In addition, the Academy **recommends** grantees;

- consider equity, diversity and inclusion in designing all aspects of their research projects, including dataset selection and participant recruitment,
- consider community consultation (including patient and public involvement) in their research, including co-creating research questions and programme design.
- follow best practice guidance on research involving human participants, including but not limited to UKRIO Code of Practice for Research Chapter 3.6,

For research involving human tissue, the collection, storage and access of human tissue or data must be suitably safeguarded and comply with appropriate legislation, including:

- In England, Wales and Northern Ireland, researchers using human biological samples must comply with the Human Tissue Act 2004.
- In Scotland, researchers must comply with the Human Tissue (Scotland) Act 2006.
- Details of UK legislation that researchers must comply with are on the MRC human tissue legislation summaries website. This includes help to identify:
    - if consent is required for the research
    - if a licence is required to store samples
    - legislation and ethical standards for transport, import and export.

Academy funded research involving international partners, or work undertaken outside the UK, must comply with all applicable legal and regulatory requirements and must tell us in their grant application what law and guidance applies in their area/jurisdiction and how they will comply with these.

If the research is being conducted in a country with no research ethics committee researchers must gain ethical approval from an alternative source, for example an inter-governmental organisation like the Science and Ethical Review Group at the WHO.

Researchers must also avoid exploitation and undue inducement, especially when carrying out research in low- and middle-income countries. Participant expenses may be considered within grant applications but participant payments, in any form, should not be used to induce people to take part.

It is the administering organisation's responsibility to make sure that sufficient insurance or indemnity cover is in place to cover any research participants and/or their dependants against injuries or damage caused by taking part in research. The Academy will not fund the costs of insurance and indemnity cover or be liable for any compensation.

4.0 Procedures

Ethical approval is not required when the grant application is submitted, but researchers must have all approvals in place before the first participant is recruited or the research begins and a clear plan to achieve this.

Pre-application:
Guidance documents for Research, Development and Innovation schemes should link through to this policy.

At application:
For Research, Development and Innovation grants, applicants will be asked to confirm whether their proposed research involves the use of human participants or human material or personal data.

If the response is no, the applicant will skip to the next section, if yes, they will need to provide details on the following:

- The location of the research and the legislative requirements if outside of the UK
- The plan and timing of acquiring all relevant ethical approval and licenses.

- If the research includes the collection and storage of human tissue or data, how it will be safeguarded.

At review:

Reviewers will consider the research proposal and ethical implications and the Academy reserves the right to require additional information or send it to additional independent experts for review.

At contracting:

The Academy's standard terms and conditions require all Awardees to ensure that grant activities are carried out in accordance with all relevant legislation, regulatory and ethical requirements and codes of practice, including but not limited to health and safety, data protection, bribery, and national security.

Awardees are also required to inform the Academy of changes to project activities including changes to the use of human patients or tissues in research.

During the length of the award:

Researchers must ensure that ethical oversight is maintained for the duration of the award and any changes to the research plans involving human participants and human tissues are reported to the Academy.

The Academy reserves the right to see approval documents or ask for further information at any point during the grant and after it has ended.

Requests for information:

Any and all queries with respect to research involving human participants or tissue supported by the Academy should be directed to the Grant Operations team via grantops@raeng.org.uk

5.0 Related policies and relevant references

- UK policy framework for health and social care research
- UKRIO Code of Practice for Research
- Researcher Checklist of Ethics Applications for Research with Human Beings
- Health Research Authority guidance on post-research care
- Patient Involvement Toolkit for Researchers