

**The University of Sheffield
Research Ethics Policy Note no. 1**

DEFINING HUMAN RESEARCH PARTICIPANTS, PERSONAL DATA AND HUMAN TISSUE

The Research Ethics Policy applies to research involving human participants, personal data, or human tissue.

1 HUMAN PARTICIPANTS

Research involving human participants can be broadly defined as research that:

- *directly involves people in research activities through their actual participation as research subjects* during which research data will be collected from them: 'actual participation' may involve invasive research processes (e.g. surgery, administration of medications) and/or non-invasive research processes (e.g. interviews, questionnaires, surveys carried out face-to-face, or via telephone, email or the internet, or observational research), and may refer to the active or passive involvement of a person;
- indirectly involves people in research activities as research subjects, through their provision of, or access to their, personal data and/or tissue; or
- involves people in research activities while they are acting on behalf of others who are research subjects, during which research data will be collected from them (e.g. as parents or legal guardians of children or mentally incapacitated people, or as supervisors of people in controlled environments, such as prisoners, pupils, asylum seekers, psychiatric patients whether sectioned or not, etc.).

The nature of participation in research and the degree of commitment and intensity of effort that may be requested from participants, subject to their consent, will vary from one research project to another. Regardless of such variations, however, all research that involves human participation in any of three senses outlined above, whatever the status/position/role of the individual(s) concerned, must be reviewed via one of the routes outlined in the Research Ethics Approval Procedure section of this Policy.

A table has been developed using examples to provide further guidance regarding what constitutes human participation in a research project, and therefore whether ethics approval is required. The table can be found at the end of this document.

It should be noted that all research projects will involve or affect people in ways that do not constitute participation in line with the definition above, but which nonetheless require consideration as part of the design and implementation of the project. This may include members of the public who may be in the vicinity as a project takes place, or University colleagues involved in the processes that take place at various stages of a project. The University's Good Research & Innovation Practices policy sets out in more detail a researcher's obligations in relation to these issues.

2 PERSONAL DATA

The University's Research Ethics Policy uses the General Data Protection Regulation (GDPR) definition of personal data:

“personal data’ means any information relating to an identified or identifiable natural (living) person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person’

Once an individual’s personal data has been robustly anonymised, such that the individual is no longer identifiable, then the data is no longer classed as personal data. However, researchers should consider carefully any situation in which the individual may potentially be re-identified by means that are ‘reasonably likely’ to be used (e.g. taking into consideration the cost and amount of time required for re-identification and the technology available).

According to data protection legislation, for research undertaken by staff or students of the University of Sheffield, the Data Controller (the individual or organisation which determines the purposes and means of processing personal data) will usually be the University (i.e. not a particular individual or research team). Collaboration with other institutions may result in joint Data Controllers. In practice, in the case of discrete research projects, it is highly unlikely that members of the research team will come into contact with data from other parts of the University that may result in the re-identification of participants whose data has been anonymised. However, researchers should think carefully about this possibility when seeking to anonymise their data; strictly speaking, if there is any possibility that anonymised data could be traced back to the individual that provided it via any other data held by, or likely to come into the possession of, the Data Controller, then the data has in fact only been ‘pseudonymised’. This means that it would in fact still be classed as personal data. Two examples of situations in which this problem is more likely to arise include:

- administrative research, in which research staff may have access to central University records that may link data to the participants that provided it;
- types of research which there are particular identifiers that are widely used outside the research team (e.g. health research involving NHS numbers).

Some personal data also falls under a ‘special category of personal data’ in the data protection legislation This includes information about:

- racial or ethnic origin;
- political opinions;
- religious or philosophical beliefs;
- trade union membership;
- data concerning health;
- data concerning a person’s sex life or sexual orientation;
- processing of genetic data or biometric data for the purpose of uniquely identifying a natural person;
- criminal records or allegations

Data that falls into any of the above categories are subject to additional requirements under the GDPR; processing of such data is allowed only in a number of specific circumstances, which are discussed further in the Specialist Research Ethics Guidance Paper, ‘Principles of Anonymity, Confidentiality and Data Protection’.

Aside from these regulatory requirements, from an ethical point of view, researchers should consider whether their research involves the collection of other types of information which may be considered sensitive. For example, collecting data about drinking habits may not be seen as sensitive for many people in many situations, but this may be different if collecting data about drinking habits among people who have problems with alcoholism. Further information about topics of research that may be considered sensitive is given in Research Ethics Policy Note no. 6 'Research involving vulnerable people'.

3 HUMAN TISSUE

Human tissue is defined by the *Human Tissue Act 2004* (HTA Act) as *relevant material* (the HTA website: www.hta.gov.uk). The relevant materials covered by the HTA Act include materials that have come from a human body, whether living or dead, including body parts, organs and human cells. Cell lines are not relevant material under the Act (although primary cell cultures are). Cell lines which are intended for human application (i.e. for clinical uses or treatment) are considered relevant material under the European Union Tissue and Cells Directive (Directive 2004/23/EC). Storage of cell lines for research-only purposes does not require a licence; storage of cell lines for potential human application does. The HTA Act does not cover hair and nails from a living person. However, the HTA Act makes it a criminal offence to hold relevant material – including hair, nail, and gametes (i.e. cells connected with sexual reproduction) – for the purpose of DNA analysis, without the informed consent of the person from whom the relevant material came (or of those close to them if they are deceased).

For further discussion of the legal and other issues attendant upon research involving human tissue, see Research Ethics Policy Note no. 11, 'Research Involving Human Tissue', and Specialist Research Ethics Guidance Paper, 'Human tissue research'.

Guidance relating to Research Ethics Policy Note no.1 - Examples of human participation in a research project

The following tables aim to provide further guidance with respect to what constitutes human participation in a research project, and therefore whether ethics approval is required or not. The tables do not seek to cover every possible type of human participation, but to give examples which help to clarify when ethics approval is required. It should be noted that there may be 'grey areas' for which it is still not clear whether ethics approval is needed; these will need to be considered by the UREC on a case by case basis as and when they arise. If you would like the UREC to consider a case, or have an example which could be added to the table below, please contact Lindsay Unwin, Secretary to the UREC (l.v.unwin@sheffield.ac.uk, ext. 21443)

Examples of when ethics approval IS required:

In general terms, ethics approval is required where the project will involve interaction with people* in order to **collect individuals' opinions and/or personal information as research data, in a systematic way for analysis and/or reporting as research, or as part of a student research assignment.** Research data can be defined as 'the evidence used to inform or support research conclusions'

* 'people' could refer to members of the public, community groups, stakeholders, clients, experts, academics who are not part of the research team itself, professionals, key informants, consultants.

Examples	Why is ethics approval required?
A research project involving asking research questions at an academic conference workshop and collecting responses from the attendees to analyse and publish findings.	Although the attendees will be mainly academics, and may be considered 'experts' on the topic, they still constitute human participants in research as their opinions are being systematically collected for analysis and publication as part of a research project, and hence ethics approval is required.
Holding focus groups and interviews with employees of an organisation to research the training and development opportunities available to them, and publish generalisable findings.	Recruiting people from an organisation to obtain their opinions as part of a research project, where opinions will be analysed and research findings will be shared outside the organisation itself, constitutes human participation in research, and hence ethics approval is required.
Systematically collecting or eliciting the opinion of academics from <i>outside</i> the research team on the appropriate parameters for a statistical model, where	Obtaining the opinion of members of the research team/collaborators on the project - where these individuals will be named as authors/acknowledged on any publications – would NOT require ethics approval; however, obtaining the opinion of others from outside the research team, for the purposes of analysing their

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<p>the responses will be analysed quantitatively as research data.</p>	<p>opinions as research data, would constitute human participation in research and hence ethics approval is required.</p>
<p>A co-production research project in which the members of a community group will work with the academic researchers to collect and analyse research data from the wider community, including providing their own opinions as research data.</p>	<p>Co-production methodologies may involve external partners in a wide range of ways, including contributing to both the design and the conduct of a project, providing their own opinions, contributing to the analysis of data, and/or seeking the opinions of other community members e.g. via interviews. In projects where research data will be collected from the external partners themselves, to inform or support the research conclusions, then ethical approval is required. It should be noted that a phased approach to ethical approval may be appropriate due to the continually evolving nature of this type of research. It should also be noted that even aspects of the project that do not require specific ethics approval may generate complex ethical issues that require careful consideration.</p>
<p>A student teaching assignment in which measurements of brain activity will be taken from students during a taught session, and the data will be stored and then analysed by the students in a workshop a week later.</p>	<p>Although there is no intention for the findings to be published formally as research in this case, the Ethics Policy does specifically cover work of educational value designed to improve understanding of the research process, and as the data will need to be stored for analysis at a later date, there are ethical implications in terms of data protection which need to be considered as part of an ethics application. Hence ethical approval is required.</p>

Examples of when ethics approval is NOT required:

In general terms, ethics approval is NOT required where a project will involve interaction with people* **in order for them to contribute only to an activity which does not constitute research (e.g. where they are only contributing to the design of a research project itself, or the design of a specific product, or a news report) with no intention to disseminate the data/findings as academic research.** It should be noted that even where ethics approval is not required, people should be treated in an ethical way (including obtaining informed consent where appropriate), and personal data must be obtained and handled in compliance with the Data Protection Act (or, from 25 May 2018, the General Data Protection Regulation).

Guidance relating to Research Ethics Policy Note no.1 - Examples of human participation in a research project

Examples	Why is ethics approval NOT required?
<p>A staff consultation project to develop a new car part for an external partner organisation, in which discussions are held with the staff of the organisation and an industrial steering group to agree the design parameters, and to discuss progress throughout the project. Outcomes of the discussions are used only by the project team and partner organisation to contribute to the design of the product.</p>	<p>Providing opinions are being obtained from relevant stakeholders solely for the purposes of contributing to the design of a product, and will not be analysed and published as research, or as part of a student's research assignment, this does not constitute human participation in research and therefore no ethics approval is required.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>
<p>A student design project to develop an improved building design, drawing on discussions with building owner and users. Outcomes of the discussions are only used by the student design team (including any supervisors/assessors/examiners for assessment purposes only), and the building owner, to contribute to the design plan.</p>	<p>Providing opinions are being obtained from relevant stakeholders solely for the purposes of contributing to the design of a product, and will not be analysed and published in order to inform or support research conclusions, this does not constitute human participation in research and no ethics approval is required.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>
<p>Focus groups with patients to discuss and advise researchers on how a study should go about recruiting participants from a particular patient group [this may be referred to as Public or Patient Involvement (PPI)].</p>	<p>Providing opinions are being obtained from members of the public or patients solely for the purposes of contributing to the effective <i>design</i> of a research project, and will not be analysed and published as research data in order to inform or support the research conclusions, this does not constitute human participation in research and no ethics approval is required.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>
<p>Seeking the opinion of a clinical consultant on best clinical practice in order to inform the interpretation of research data.</p>	<p>Providing opinions are only being obtained from key individuals with relevant experience or expertise, for the purposes of obtaining their views on the research data itself, and/or advising on the implications of the findings, then ethics approval is not required. In this case, the opinions are not being analysed and reported as research data, but are being used to inform the next phase of the research itself,</p>

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	<p>and any individuals consulted in this capacity should be referenced within any publications.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>
<p>Interviewing members of the public for purposes of reporting on a piece of breaking news, as part of a student's vocational training as a journalist</p>	<p>Obtaining people's opinions as a news-gathering exercise, for reporting solely as news, does not constitute academic research and hence does not require ethics approval.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>
<p>Contacting an official or representative of an organisation or government body, in order to request information (e.g. statistics) or obtain documents which will inform the research. This process may include clarifying details relating to the information or documents received.</p>	<p>Contacting people in order to seek information or materials which are of research interest does not constitute participation in a research project, and hence does not require ethics approval, providing those people are not being asked to provide personal data or opinions which will be used for analysis as research data.</p> <p>NB. If these criteria are NOT met, ethics approval will be required.</p>