

## **DEFINING HUMAN RESEARCH PARTICIPANTS, PERSONAL DATA AND HUMAN TISSUE**

In order for the University Research Ethics Policy to work effectively, some basic definitions are necessary with respect to the scope of its application. The Research Ethics Policy applies to research involving human participants, personal data, or human tissue.

### **1 HUMAN PARTICIPANTS**

In the first instance, research involving human participants can be broadly defined as research that:

- *directly involves people in research activities through their actual participation as research subjects: 'actual participation' may involve invasive research processes (e.g. surgery) and/or non-invasive research processes (e.g. interviews, questionnaires, surveys or observational research carried out face-to-face, or via telephone, email or the internet), and may mean 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 (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, sectioned psychiatric patients, 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 must be reviewed via one of the routes outlined in the Research Ethics Approval Procedure section of this Policy.

These three categories of participation do not, however, exhaust the possibilities for human participation in research. Other people - such as academics, research workers, students, technicians, administrators, secretarial staff and maintenance staff - participate in research, inasmuch as they take part in, and contribute to, whatever processes are necessary to produce and collect data. Thus even natural science laboratory research, for example, necessarily involves human participation.

There may also be indirect participation by people other than research subjects *per se*. Any research may take place in proximity to passers by and bystanders, if not attracting an actual audience; this is particularly true for field research, which takes place outside laboratories, classrooms or other environments dedicated to research. These people are indirect participants in that they are, potentially at least, open to effects, whether

positive or negative, deriving from the research in progress in their vicinity. Their safety and well-being should always be considered.

Indirect participation is particularly an issue in auto-ethnographic research, in which the researcher uses her/his own life experience as a primary source of data. However, no life is lived in a social vacuum and information about other people can never be excluded from auto-ethnography. These other people are, therefore, indirect participants, which raises questions about their anonymity and opportunity to exercise informed consent. For further discussion of auto-ethnography, see Research Ethics Policy Note no. 2, on 'Consent', and the relevant Specialist Research Ethics Guidance Paper.

The safety and well-being of human research participants in the very broad senses outlined in the two paragraphs immediately above should be taken into account when planning research. These aspects of research do not, however, require formal ethics review within the University's procedures. They are, however, like all formally University-sponsored activities, subject to health and safety at work legislation and similar regulations, and governed by a duty of care and other common law considerations.

## **2 PERSONAL DATA**

The University's Research Ethics Policy uses the Data Protection Act's (1998) definition of personal data:

'Data which relates to a living individual who can be identified from those data, or from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.'

'Sensitive' personal data consists of information about:

- the racial or ethnic origin of the data subject;
- his or her political opinions;
- his or her religious beliefs or other beliefs of a similar nature;
- whether he or she is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992);
- his or her physical or mental health or condition;
- his or her sexual life;
- the commission or alleged commission by him or her of any offence, or
- any proceedings for any offence committed or alleged to have been committed by him or her, the disposal of such proceedings, or the sentence of any court in such proceedings. (Source: Part I, Preliminary to the Data Protection Act 1998)

In addition to the requirements of the Data Protection Act, researchers should, as an aspect of the routine ongoing negotiation of consent, recognise and attend to the sensitivity of data that relate to any personal matter that research participants may find painful or embarrassing or particularly wish not to be attributable to them in reports or publications.

### **3 HUMAN TISSUE**

The United Kingdom 2004 Human Tissue Act (HTA) defines human tissue as:

‘Relevant material that has come from a human body and consists of, or includes, human cells’.

The ‘relevant’ materials covered by the HTA 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 (although primary cell cultures are). Storage of cell lines for research does not require a licence nor does research using cell lines require ethical review. The storage and use of human reproductive cells is regulated separately by the Human Fertilization and Embryology Act (2008). The HTA does not cover hair and nails; however, the Act makes it a criminal offence to hold human tissue, including hair, nail, and gametes (i.e. cells connected with sexual reproduction), with the intention of its DNA being analysed for research, without the consent of the donor or close relatives of a deceased donor.

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’.