

## **PRINCIPLES OF TRANSPARENCY AND CONSENT**

### **1 TRANSPARENCY**

Individuals have a right to be fully informed about all the aspects of a research project in which they are considering participating that might reasonably be expected to influence their willingness to participate. The researcher should explain any other aspects of the research about which prospective participants may enquire. Taken together, these aspects of research should normally include:

- the nature and purpose of the project;
- the legal basis for the collection and use of the participants' data (as set out in the University's Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>);
- the research methods to be employed by the project;
- full explanation of any technical terms used;
- the conditions under which the project will be conducted;
- who is undertaking and who is sponsoring the project (i.e. the details of the 'Data Controller', the research team, the funder and/or the research governance sponsor if applicable);
- the potential risks and inconveniences that may arise;
- the potential benefits that may result;
- what participation in the research will require in practice and what data will be collected;
- information about the right to withdraw from the research, and how to go about this;
- what will happen to the data and who will have access to it (including any further use of the data beyond the immediate research project, and any intention to transfer data outside of the EU, and the appropriate safeguards that will be adopted);
- how participant confidentiality will be safeguarded;
- how the data will be stored, and when it will be destroyed (or the criteria that will be used to determine when it will be destroyed);
- how to raise concerns, or to complain, about the research, and to whom (see note below); and
- the consequences of non-participation (such as alternative treatments in the case of some medical research, or alternative educational activities in the case of some educational research).

In connection with the above, it should be noted that the appropriate channels for the registration of complaints within the University, should a participant be unhappy with their treatment and unable to resolve them directly with the researcher and/or research team, is the Head of the relevant department. Participants should also be informed of their right to contact the Data Protection Officer for the Data Controller organisation, or the Information Commissioner's Office, if they have a complaint about the use of their personal information within the research.

In many contexts, taking into account the language and literacy of potential participants, a fact-sheet summarising the above is a useful and documented means of providing this information. Further discussion of anonymity, confidentiality and data protection can be found in Research Ethics Policy Note no. 4.

## **2 OBTAINING INFORMED CONSENT**

Prior to a person being able to participate in research activities as a 'research subject/human participant in research', the lead researcher, or her/his delegate, is responsible for obtaining that person's informed consent to participate wherever it is appropriate to do so, and for documenting this consent. This is an important principle of research ethics.

Consent must be given freely and voluntarily and under no circumstances must direct coercion or indirect pressure be used to obtain a person's consent to participate in research (see section 3 of this Policy Note, dealing with 'Coercion'). Wherever possible, and bearing in mind the nature of the research activity concerned and the research methods to be adopted, an individual's consent should be obtained in writing. This is the 'gold standard' of informed consent.

Where this is not possible, documented oral consent is an acceptable alternative. Ideally oral consent should either be tape-recorded or obtained in the presence of at least one witness. Witnessed consent is required for particularly vulnerable participants who have intellectual or cultural difficulties of speech or understanding, but who are deemed capable of giving consent. Witnessed consent should be specified during the ethics approval process and involve an approved form for witness and researcher to sign.

Giving and obtaining consent is a process, not a one-off event that happens at the beginning of a person's involvement in research, and during their active involvement participants have the right to change their minds and withdraw consent. If a researcher doubts whether a person participating in research still consents to participating s/he should clarify this with the person in question. However, the right to withdraw cannot, practically, extend to the withdrawal of already published findings or be invoked in such a way as to compromise aggregate, anonymised data sets. This should be made clear to participants as part of the process of informed consent.

One issue that has created problems with respect to consent concerns people who may be named, or otherwise referred to, in publications arising from the research. In such circumstances, unless it is a matter of a public person acting in her/his public capacity, the researcher(s) must either (1) anonymise the person, so that they cannot be identified, or (2) ensure that they have obtained the informed consent of the individual concerned.

There are, however, circumstances in which consent may not be possible or necessary, or in which the scope for consent may be constrained by the specific demands or nature of the research. For further details, see the relevant sections contained in this Policy Note, particularly 'Consent in research involving adults who lack mental capacity', 'Consent in research involving children', 'Research involving principled deception', and 'Research in public contexts and with groups'.

When consent is necessary - which is the case in most research with human participants - researchers should make it clear to potential participants, prior to their participation:

- that they have the right to refuse to participate in the research in question;
- that, at any time during their active participation, they have the right to withdraw from the research, without having to give a reason, regardless of whether payment or other inducements have been offered, and with the assurance that any service or help they are receiving in relation to the research will not be affected in any way; and
- that these rights cannot, however, extend to the withdrawal of already published findings or be invoked in such a way as to compromise anonymised data sets that are being used as specified in the original consent agreement.

In some cases, a prospective participant may, for a range of reasons, be unable to understand the implications of participation. In the case of a pre-competent child, the researcher is responsible for obtaining the informed consent of the parent(s) or legal guardian(s). With respect to adults who cannot understand the implications of participation, however, no-one can in law consent on their behalf, other than in certain clinical situations. Extreme caution should therefore be exercised: when in doubt it is generally better to err on the side of such caution and not proceed. For further discussion, see sections 4 and 5 of this Policy Note.

Where a Research Ethics Committee has specifically instructed a researcher to obtain the informed consent of participants, or where a research funder specifies that informed consent must be obtained from participants as a condition of its award, then fully informed consent must be obtained.

See also the discussion in Research Ethics Policy Note No. 6, 'Research involving vulnerable people'.

### **3 COERCION**

The quality of the consent of participants requires careful consideration, particularly but not exclusively with respect to those who are potentially or actually dependent on the researcher, the research sponsor, or a research gatekeeper (e.g. as employees, patients, students, and so on). In such cases, willingness to volunteer may be influenced by the expectation of benefits or rewards, or the fear of penalties.

If research is being conducted with detained persons (e.g. prisoners, 'sectioned' psychiatric patients, asylum seekers, elderly people in a residential care home) particular care should be taken over informed consent. Particular attention should be paid in these circumstances to the factors that may affect the person's ability to give informed consent freely and voluntarily.

People volunteering to participate in research may be paid for their inconvenience and time. Financial payments might, for example, cover reimbursement for travel expenses and/or time. However, payments made to individuals to *enable* them to participate in research activities must not be so large as to *induce* them to take risks beyond those that would

usually be part of their established life-style. Any risks resulting from participation should be acceptable to participants even in the absence of payment.

Agreements about compensation for damage, injury or loss of income to participants as a result of participating in research activities should be carefully framed, to avoid any possible interpretation as coercion by inducement. If there is any doubt about this, professional legal advice should be sought.

#### **4 CONSENT IN RESEARCH INVOLVING ADULTS WHO LACK MENTAL CAPACITY**

Research with adults who are considered to lack mental capacity is very complex, legally and ethically. The relevant legal framework can be found in (a) the Mental Capacity Act (2005) and (b) Directive 2001/20/EC of the European Parliament and of the Council (*Good clinical practice in the conduct of clinical trials on medicinal products for human use*), implemented in England in the *Medicines for Human Use (Clinical Trials) Regulations 2004/1 03*.

Legally, consent to research can be given on behalf of non-competent adults, but only with respect to clinical research that is specifically concerned with their medical condition, and only under tight regulation.

This does not mean that non-clinical research with adults with learning disabilities or mental health problems, for example, is impossible. It does mean that gaining consent in such cases will be complex and require imaginative and inclusive approaches to the provision and explanation of information about research participation. An inability to obtain defensible informed consent should, therefore, not simply be assumed; the need for effort and innovation, based on inclusion and respect, in providing information on which to base consent, should. There are no easy or formulaic approaches to the negotiation of informed consent with adults who are deemed to lack mental capacity.

Some of these complex and sensitive issues are discussed in further detail in the Specialist Research Ethics Guidance Papers entitled 'Research involving adult participants who lack the capacity to consent' and 'Doing research with people with learning disabilities'.

#### **5 CONSENT IN RESEARCH INVOLVING CHILDREN**

If infants, children and/or young people under the age of eighteen are involved in a research project, where appropriate and feasible the informed consent of one of their parents or their legal guardian should be obtained. However, in some circumstances obtaining the informed consent of a parent may be inappropriate (e.g. research with children who have been abused by a parent) or infeasible (e.g. research involving homeless children).

When possible, a researcher undertaking research with children and/or young people under the age of eighteen should *also* obtain the child's or young person's free and voluntary consent to participate. However, the ability of a child to give free and voluntary consent depends on that child's competence, which varies with age, experience and confidence. The type of research that s/he is being invited to participate in, and the skill with which the researcher talks with that child and help her/him to make free and voluntary informed decisions, are also significant factors. Even if a child is deemed insufficiently competent to give fully informed consent, their assent (e.g. willingness or agreement) to participate should still be sought.

So, as a general principle, where a child or young person under the age of eighteen participates in research, researchers should, *when this is possible*, obtain the informed consent of both a parent or legal guardian *and* the consent or assent of the child (regardless of whether or not the research is invasive or involves sensitive topics). This principle may be set aside where consent is not being used as the legal basis for the use of the child's personal data, where a parent or legal guardian is not available *and* it can be demonstrated that the research is not against the best interests of the child or young person concerned. Children aged 16 and older are assumed to be capable of giving consent for their participation in clinical trials of Investigational Medicinal Products, without the need for parental consent.

Within the NHS, the Confidentiality Advisory Group (CAG)) has the authority to override the need for consent where it is infeasible, under Section 251 of the NHS Act 2006 (e.g. CAG has ruled that it is not necessary to have patient consent to use their data in a cancer registry; similar assurances have been made for epidemiological research concerned with CJD).

In the case of research in educational settings, any special school policies or procedures should be followed. Ideally, explicit, opt-in informed consent processes should be used, unless there is an alternative legal basis for the processing of personal data (for example, where processing is necessary 'for the performance of a task carried out in the public interest').

For further discussion, see the Specialist Research Ethics Guidance Papers entitled 'Principles of anonymity, confidentiality and data protection' and 'Ethical considerations in research with children and young people'.

## **6 RESEARCH INVOLVING PRINCIPLED DECEPTION**

In certain research disciplines (such as psychology and anthropology) it may sometimes be necessary to withhold information about the true objectives of the research from the people participating in it in order to ensure the viability and validity of the research. In research of this kind it is inappropriate to obtain informed consent from the participants. Wherever possible such research should be avoided and ethics reviewers should pay particular attention to this issue. However, when such research is judged to be necessary, researchers should exercise particular caution. In these circumstances the lead researcher has three, equally important, special responsibilities under this Policy:

- to ensure that there is an appropriate alternative legal basis for the processing of the participants' personal data (since this cannot be achieved via consent) – see section 2 of this Policy Note for more details);
- to demonstrate unequivocally in the research ethics application that alternative procedures to avoid withholding information or deliberate deception are not available, or, if available, are not feasible for the particular research in question; and
- to explain in detail why withholding information, or an element of concealment or deception, is necessary for the viability and validity of the research.

Another type of research that falls under the heading of 'principled deception' is covert research, in which the very fact that research of any kind is being undertaken is deliberately concealed. Examples in the past have included research into criminal activity, ultra right-wing political organisations, and secretive religions: these are all settings in which informed access is (a) unlikely and (b) likely to alter the behaviour of those present. This is research that has much in common with investigative journalism, and it can be very controversial, not least when

the 'participants' discover that they have been researched. Typically, it is justified by a 'public interest' defence. Research of this kind should only be considered in the most unusual circumstances. In such circumstances the lead researcher has five, equally weighty, special responsibilities under this Policy:

- to ensure that there is an appropriate alternative legal basis for the processing of the participants' personal data (since this cannot be achieved via consent) – see section 2 of this Policy Note for more details);
- to provide a convincing case for researching the topic or organisation in question;
- to demonstrate unequivocally that the research in question cannot be done using any other, more transparent 'above board', approaches;
- to explain in detail what steps will be taken to protect, and to monitor the safety and well-being of, the researcher(s); and
- to explain in detail what steps will be taken to protect, and to monitor the welfare, dignity and rights of, the participant(s).

In some cases of research involving principled deception, retrospective consent may help to ensure that the research is, and is seen to be, properly ethically managed. In these cases, participants may be informed of the nature of the deception involved via a de-brief at an appropriate point, and their consent to publication or other dissemination can then be sought. In such cases, researchers should be prepared for refusals and should notify funders, where relevant, of this possibility.

## **7 CONSENT IN PARTICIPANT AND NON-PARTICIPANT OBSERVATION**

There is a 'grey area' with respect to consent in ethnographic research, particularly participant observation in which the researcher sets out to become a part of the social setting that is the context or focus of the research. This is an established research approach, but it entails risks of misunderstanding that underline the need to regard consent as an ongoing process of negotiation and discussion.

In particular, among others, the following scenarios are possible:

- local participants may over time 'forget' that the researcher is actually only in the setting in question as a researcher, to collect data;
- the researcher and participants may forge personal relationships of friendship in which the norms of confidence and openness will differ from those that apply in a research relationship; and
- there may be situations in which the researcher her/himself is unsure of her/his role, particularly with respect to when s/he is 'off duty' as a researcher.

The boundaries between the personal and the professional may become blurred. In some sense, situations such as these are a mark of successful participant observation, but they may result in inappropriate or risky personal disclosures. In such cases the researcher has an imperative duty of care to participants: to exercise confidentiality, as much vigilance as possible, judgment, and restraint in the use of data. When in doubt, it may be best to destroy any field notes about which there is a question, or at least not use the material. It may be even better to exercise caution with respect to what is recorded in the first place.

See also the discussion in Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in participatory research / participatory action research'.

## 9 RESEARCH IN PUBLIC CONTEXTS AND GROUPS

In certain types of research obtaining consent from every individual present is neither practical nor feasible (e.g. observing behaviour in public places, attending large meetings, attending a music concert or play). Research of this kind stretches the definition of what it actually means to be a human participant in research. In research of this kind researchers should ensure the following:

- that such research is only carried out in public contexts, defined as settings which are open to public access;
- that, if relevant, approval is sought from the relevant authorities;
- that, if relevant, appropriate stakeholders are informed that the research is taking place;
- that specific individuals should not be identified, explicitly or by implication, in any reporting of the research, other than public figures acting in their public capacity (as in reporting a speech by a named individual, for example); and
- that attention is paid to local cultural values and to the possibility of being perceived as intruding upon, or invading the privacy of, people who, despite being in an open public space, may feel they are unobserved.

If individuals may be photographed or filmed as part of a research project, then the potential for people to be identifiable in the resulting materials should be considered carefully. Data protection legislation must be complied with in any case where identifiable material will be obtained. For further guidance (e.g. concerning how to provide appropriate information to people who may be filmed in a public space) is provided in the 'surveillance' guidance developed by the Information Commissioner's Office: <https://ico.org.uk/for-organisations/education/>.

The privacy and psychological well-being of people participating in observational research or in research activities in which the researcher may actually be acting as a fellow participant, for example as part of a wider group, must be respected. In such group-based, participatory research activities every effort should be made to ensure that the group leader(s), or others in positions of responsibility, as well as other individuals of a group, understand they are being observed for research purposes. In such activities researchers should at least obtain the consent of the group leader(s) or the consent of others in positions of responsibility to undertake the research.

It is recognised that in certain types of observational research or organisational settings it may be more difficult to explain to people participating their right to withdraw. However, in such types of research, researchers are expected to consider whether it is practicable, and to take this approach wherever possible.

For further discussion, see Research Ethics Policy Note no. 14 'Research Involving Social Media Data' and the Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in participatory research / participatory action research'.

## **10 AUTO-ETHNOGRAPHIC RESEARCH**

In auto-ethnography, the researcher uses her/his own life experience as a primary source of data. Since no life is lived in isolation, information about other people can never be completely excluded from auto-ethnography. These other people are, therefore, indirect participants, raising questions about their opportunity to exercise informed consent with respect to the nature of their representation in auto-ethnographic material. In principle, informed consent should always be sought from anyone who may be recognisable in an auto-ethnographic account. For further discussion of auto-ethnography, see the Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in autoethnographic research'.