

Research Guidance Note 3

Informed consent

Gaining informed consent

When research involves human participants it is necessary for the researcher to obtain consent from those individuals. Consent must be given freely and voluntarily and under no circumstances should coercion or indirect pressure be used to obtain a person's consent to participate in research.

Wherever possible, and bearing in mind the nature of the research activity, an individual's consent should be obtained in writing. This is the 'gold standard' of informed consent. Where this is not possible, oral consent is an acceptable alternative. Ideally, oral consent should be tape-recorded or obtained in the presence of at least one witness.

Informed consent is not just simply asking if an individual wishes to be involved. They need to know what it is they are being involved in, and what will happen to the data collected. It therefore consists of two components (information and consent) which are of equal importance.

Information is key to 'informed' consent

Prior to participating, an individual should be fully informed about all aspects of the research project that might influence their decision to participate. This might include some or all of the following:

- The title of the study
- Purpose of the study
- A description of the procedures, purpose, length of time required and how participants will be involved
- Full explanation of any technical terms used
- Who is undertaking and sponsoring the project
- Any discomforts or inconveniences expected
- Any potential risks
- Any potential benefits that may result
- How confidentiality, anonymity and privacy will be maintained
- What will happen to the data, who will have access to it and how it will be stored

- Sources for information and assurances that researcher will provide further and ongoing information (for example the name and contact phone number of the researcher)
- how to raise concerns or to complain about the research, and to whom
- the consequences of non-participation (such as alternative treatments in the case of medical research, or alternative school activities in the case of some educational research).

This information should be written in simple language that is easily comprehensible by any potential research participants. Participants should be given sufficient time to study any information and to ask questions from relevant parties as needed. A copy of the information should be provided for the participant to retain.

Gaining consent is a process

Potential participants should be able, freely and voluntarily, to consent or refuse to participate in research.

Giving and obtaining consent is a process, not a one-off event that happens at the beginning of a person's involvement in research. During their active involvement, participants have the right to change their minds and withdraw consent. 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.

The researcher should be mindful that the individual also needs to be able to provide an informed response. An individual cannot give informed consent if:

- the intended research and their part in it is not clearly explained
- they are children or young people under the age of 18 years (for more details see [Research Guidance Note 5](#)).
- They do not have the capacity to make a judgement due to, for example, a disability or medical condition of some kind (for example, Alzheimer's disease, learning disabilities).

Advocates or the representatives may be able to give consent for vulnerable participants; guidance should be sought from the School 'gatekeeper' in this type of situation.

An example of a consent form can be found at the end of this research note. An example is also given for a consent form that could

be used with children or young people. Further details on working with vulnerable groups and gaining consent can be found [in Research Guidance Note 5](#).

Research in public contexts

In certain types of research, obtaining consent from every individual present is neither practical nor feasible (for example, observing behaviour in public places, attending large meetings or observing discussions on the internet). When explicit consent cannot be obtained, implicit consent should not be assumed. For example, when observing a group of people in a public place implicit consent cannot be assumed. Instead consideration of the risks and benefits must be conducted before proceeding.

In research of this kind the researcher should ensure that:

- The research is conducted in public contexts (for example, in areas that do not require negotiation or agreement in order to gain access to them)
- If relevant, approval is sought from relevant authorities
- If relevant, appropriate stakeholders are informed that the research is taking place
- specific individuals are not identified, explicitly or by implication, other than public figures acting in their public capacity (for example, reporting a speech by a public figure)
- attention is paid to local cultural values and to the possibility of being perceived as invading the privacy of people who, despite being in an open public space may feel they are unobserved.

Example of a consent form¹⁵**[TITLE OF STUDY]**

Edinburgh Napier University requires that all persons who participate in research studies give their written consent to do so. Please read the following and sign it if you agree with what it says.

1. I freely and voluntarily consent to be a participant in the research project on the topic of [some words of explanation] to be conducted by [your name], who is an undergraduate/postgraduate student/staff member at Edinburgh Napier University.
2. The broad goal of this research study is to explore [broad description of study only — to avoid premature shaping of participant’s responses]. Specifically, I have been asked to [brief overview of procedure], which should take no longer than [estimated length of study] to complete.
3. I have been told that my responses will be anonymised. My name will not be linked with the research materials, and I will not be identified or identifiable in any report subsequently produced by the researcher.
4. I understand that any of my personal data collected will be handled under the principles of Data Protection Legislation. This means by law that the researcher must process, use and destroy any of my personal data appropriately according to the legislation.
5. I also understand that if at any time during the [survey/interview/session/other] I feel unable or unwilling to continue, I am free to leave. That is, my participation in this study is completely voluntary, and I may withdraw from it without negative consequences. However, after data has been anonymised or after publication of results it will not be possible for my data to be removed as it would be untraceable at this point.
6. In addition, should I not wish to answer any particular question or questions, I am free to decline.
7. I have been given the opportunity to ask questions regarding the [interview/survey/ procedure] and my questions have been answered to my satisfaction.
8. I have read and understand the above and consent to participate in this study. My signature is not a waiver of any legal rights. Furthermore, I understand that I will be able to keep a copy of the informed consent form for my records.

 Participant’s Signature

 Date

I have explained and defined in detail the research procedure in which the respondent has consented to participate. Furthermore, I will retain one copy of the informed consent form for my records.

¹⁵ An editable form in Word format is available to download at <https://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx>

 Researcher's Signature

 Date

Example of a consent form for use with children and young people^{16,17}
CONSENT FORM*

To be completed by the participant

	✓	✗
I have been given enough information about this project		
It has been explained to me how the information I give will be used		
I agree to take part in the research on [insert brief details]		
I understand that I can leave at any time and do not have to answer all of the questions if I don't want to		
I am happy for you to record what I say		
I give permission for my words to be used in a report but I understand that my name will not be mentioned		

 Participant's Signature

 Date

I have explained and defined in detail the research procedure in which the respondent has consented to participate. Furthermore, I will retain one copy of the informed consent form for my records.

 Researcher's Signature

 Date

¹⁶ An editable form in Word format is available to download at <https://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx>

¹⁷ Adapted from 'Practical Guidance on Consulting, Conducting Research and Working in Participant Ways with Children and Young People Experiencing Domestic Abuse' (September 2009). Available at <http://www.scotland.gov.uk/Resource/Doc/284756/0086482.pdf> [last accessed December 2015]

