Adult and Health Services and



Children and Young People's Services

Step 4 - Guidelines for informed consent and information sheets

Introduction

Potential participants must be given sufficient information to allow them to decide whether or not they want to take part in a research study.

Where research involves face to face interviews, focus groups, direct observation or similar methods of data collection, participants should be given an information sheet, covering letter or leaflet and asked to sign a consent form.

Information sheets, leaflets and covering letters

An information sheet, covering letter or leaflet should be printed with full contact details and be written in simple, non-technical terms and be easily understood by a lay person

While it is always important to ensure that adequate information is given, the way in which the information is presented will need to be adapted to the individual circumstances of the study, for example a younger age group.

An example of an information sheet and what is should contain is provided below at appendix 1.

Consent form

Where participants are asked to complete and return a questionnaire, the questionnaire should be accompanied by a participant information sheet but no consent form is needed: **consent is implied by returning the questionnaire**.

For other research, clear evidence must be obtained that the participant has given informed consent to take part in the study. This will usually be in the form of a signed consent form).

An example of a consent form is provided below at appendix 2.

Appendix 1 PARTICPANT INFORMATION SHEET

Study title

The title should be simple and self-explanatory to anyone.

Invitation paragraph

This should explain that the individual is being asked to take part in a research study. The following is an example of how this may be phrased:

'You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully'.

What is the purpose of the study?

The background and the aim of the study should be given here. You should say how long the study will run and outline the overall design of the study.

Why have I been invited to participate?

You should explain how the individual was chosen to take part in the study and how many other people will be asked to participate.

Do I have to take part?

You should explain that taking part in the research is entirely voluntary. For example, you could say:

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason'.

If your study involves the recruitment of students or pupils you must explain that by choosing to either take part or not take part in the study will have no impact on their marks, assessments or future studies.

What will happen to me if I take part?

You should explain your methods of data collection, including what the individual will be asked to do and how much time will be involved.

What are the possible disadvantages and risks of taking part? (where appropriate) You should describe any disadvantages or 'costs' involved in taking part in the study, including the time involved.

What are the possible benefits of taking part?

You should outline any direct benefits for the individual and any other beneficial outcomes of the study, including furthering our understanding of the topic.

Will what I say in this study be kept confidential?

You should explain that all information collected about the individual will be kept strictly confidential (subject to legal limitations) and describe how confidentiality, privacy and anonymity will be ensured in the collection, storage and publication of research material.

Research data must be kept securely at all times, especially when collected in the field and when being transported. Laptops and other devices should be encrypted; password protection alone is not adequate.

Data generated by the study must be securely retained in accordance with the Data Protection Act 2018 principles. You should include a statement that the data generated in the course of the research must be kept securely in paper or electronic form and destroyed securely after the completion of a research project.

What should I do if I want to take part?

Explain exactly how the participant should 'opt in' for the study. You also need to explain that the participant can opt out at any time and provide details of who they should contact to opt out.

What will happen to the results of the research study?

You should tell the individual what will happen to the results of the research Will they be used in your dissertation or thesis? Will they be published? Need to make it clear that any published data or data used in the thesis will be anonymised. How can they obtain a copy of the published research?

Who is organising and funding the research?

You should explain that you are conducting the research as a student or researcher of "organisation" and where appropriate give your department name as well as the school name.

You should also state the organisation that is funding the research (e.g. Economic and Social Research Council, Nuffield Foundation, Tesco, etc.) if appropriate.

Contact for Further Information

You should give the individual a contact point for further information. This can be your name or that of your supervisor. You should add details of the person they should contact if they have any concerns about the way in which the study has been conducted.

Date and Thank you

Remember to date the sheet and thank the individual for taking time to read the information sheet.

Appendix 2 CONSENT FORM

Full title of Project:

Name, position and contact address of Researcher:

- 1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason. (see details below for information about how to withdraw)
- 3. I agree to take part in the above study.

The following statements should be included if appropriate. If not, please *delete* from the consent form:

4. 5. 6.	I agree to the interview / focus grou being audio recorded I agree to the interview / focus grou being video recorded I agree to the use of anonymised o	up / consultation	Yes	No
7.	stored (after it has been anonymise	y data gathered in this study may be has been anonymised) in a specialist nd may be used for future research.		
ļ	Name of Participant	Date		Signature
I	Name of Researcher	Date		Signature

Please initial box





Please initial box

Data Protection Act 2018

Durham County Council complies with all relevant statutory obligations. Personal information processed by the Council will be handled in accordance with the Council's privacy statement, which can be accessed at http://www.durham.gov.uk/media/13508/Corporate-privacy-statement/pdf/DCCCorporatePrivacyStatement.pdf?m=636669124973630000

If you change your mind you can withdraw your consent from participation in the research at any time. To do so please contact: (researcher name and contact details)

If you have any concerns about how your data is handled, please contact either the Data Protection Officer at <u>DPO@durham.gov.uk</u> or the Information Commissioner's Office <u>casework@ico.org.uk</u>.

Please ask us if you would like this document summarised in another language or format.				
العربية (Arabic) (中文 (繁體字)) (Chinese) العربية (Urdu)				
polski (Polish) ਪੰਜਾਬੀ (Punjabi) Español (Spanish)				
বাংলা (Bengali) हिन्दी (Hindi) Deutsch (German)				
Français (French) Türkçe (Turkish) Melayu (Malay)				
ResearchApprovalGroup@durham.gov.uk				
03000 267 362 (Children) / 03000 268 421 (Adults)				
Braille (Addie AAA Large Print				