The Informed Consent form is signed by participants to confirm that they have had sufficient information to enable them to make an informed decision. Its format and details are likely to vary from project to project, depending on the subject matter, but the following guidance should always be adhered to.

It should have a brief introduction, stating:

* Project Details – Title, name of researcher
* Statement of confirmation
* Name of participant, signature and date

Clear instructions should be given to the respondent. ‘Tick boxes’ are usually easy to understand. Your statements should be written in the first person, for example:

|  |  |
| --- | --- |
| I have read and understand the purpose of the study  | 🞐 |
| I have been given the chance to ask questions about the study and these have been answered to my satisfaction  | 🞐 |
| I am willing to be interviewed  | 🞐 |
| I am willing for my comments to be tape-recorded | 🞐 |
| I understand that I can withdraw at any time if I change my mind and this will not affect my treatment/education/care | 🞐 |
| I am aware that my name and details will be kept confidential and will not appear in any printed documents.  | 🞐 |

*NB: This is* ***not*** *a complete list of statements, or necessarily pertinent to all studies – it is for guidance only.*

A statement should be included that advises participants they should contact the relevant ADRI (giving contact details), should they wish to make a complaint about the conduct of the research.

You should provide a space on the form for the participant’s signature alongside your own and make sure the form has a version number and is dated. If your study involves participants with different levels of understanding, for example NHS staff and patients with learning difficulties, or teachers, pupils and parents, you must include separate consent sheets for each sample group.

Where participants are unable to give consent, for example young children or people with severe communication or learning difficulties, you must look at the process of assent and have an appropriate form for the person who is going to assent to that person’s participation. You will also need to be aware of the Mental Capacity Act (see Chapter 4) which addresses issues in relation to consent. If you are applying for NHS approval, there is a specific section of the NRES form that has to be completed in relation to capacity to consent.

There are two forms of consent: direct consent from individuals who are able to give informed consent and assent or proxy consent for those individuals who are unable to give informed consent.

If the procedure changes, all participants must be informed in writing and new consent forms must be signed. All data collected must be rendered anonymous, unless the participants have waived anonymity. Where the research involves a level of risk to participants beyond that encountered in everyday life, an independent witness should also be present to sign the consent form.

N.B. If submitting an example to an external ethics committee please make sure your form is in line with their requirements.

A typical statement of confirmation will look like this:

This information will be held and processed for the following purpose(s):

 (Project title)

I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act 1998.

Name

Signature Date

Or, where parental consent is required, the same statement can be applied with the following addition:

Child’s Name Child’s Signature

Parent’s/Guardian’s Signature Date

The signed consent form should be stored securely by the researcher along with other project documentation.