Preparing a consent form

A consent form should normally be used to record the consent process and a participant's agreement to take part in your study.

The consent form should be produced on headed paper or equivalent if recording consent electronically.

Ensure that the study title is clearly displayed. You may also wish to include a study identification number.

You may wish to include spaces for site or centre ID and/or participant ID.

If you are producing a number of consent forms for your study (e.g. for different types of participant, or to be used in different UK location), ensure that each consent form is clearly identified.

When producing your consent form you should consider what is appropriate for your type of study and the participants who will be involved.

For many studies the following paragraphs will be sufficient to accurately record agreement to take part. You may not need to include all; think about what you are asking potential participants to give their consent to (remember one size doesn't fit all - only include what is appropriate for your research):

- I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
- (If appropriate) I agree to my General Practitioner being informed of my participation in the study.
- I agree to take part in the above study.

You should provide a box after each item on your form for potential participants to initial, tick or provide the answers 'yes' or 'no', to indicate their specific agreement with each statement.

If you are producing consent forms to be used by legal representatives, ensure that the language used addresses them appropriately. Make it clear you are asking them for consent on behalf of, or advice with respect to a child / young person or adult lacking capacity.

Itemising specific elements

For some studies you may choose to provide an itemised or tiered consent form covering specific issues, especially where additional elements are optional for the participant. This is not obligatory but may include:

- Additional invasive tests or samples required for study purposes only;

- Consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs. If these can be done in an anonymised way, then specific consent is not needed;
- Transfer of data/samples to countries outside of the European Economic Area (EEA) with less data protection. This will be subject to the University obtaining assurance from the third party to whom data/samples are transferred about data security. It may be that data/samples can be transferred in an anonymised (or at least pseudonymised way;
- Agreement to receive individual feedback from testing.

Only offer potential participants options if you are confident that you can deliver all combinations of accepted or rejected options.

Signatories, witnesses and legal representatives

The signatories on the consent form should be those who are involved in the consent process, e.g. the participant, the researcher or the participant's legal representative / consultee. Variation from obtaining written informed consent may, in exceptional circumstances, be acceptable. Justification for the variance must be provided.

Consent forms for a participant's legal representative should address them directly and should be written appropriately. The consent form must be clear that they are being asked for consent on behalf of the research participant.

An independent witness is not routinely required except in cases where potential participants are not able to read or write, or who are visually impaired etc.

Recording consent electronically

Informed consent must be recorded in writing, however electronic methods for documenting consent can be considered to be in writing. You will still need to provide a copy of the signed consent form to the participant and so you should consider whether this will be a physical or electronic copy.

As part of recording consent electronically you are likely to need to use electronic signatures. Electronic signatures can take a variety of forms and are classified in different ways. You should check what type of electronic signature is acceptable for your research.

When recruiting adults lacking capacity in England or Wales, to a research study that is not defined as a Clinical Trial of an Investigational Medicinal Product (CTIMP), you will be asking a consultee to advise on whether to include the adult in your study or not. The advice they provide should be recorded on a Consultee Declaration Form.

You must ensure that all consent forms carry appropriate version control (date, version number and IRAS ID). This will help you manage consent documentation throughout the life of your study, and will be referenced by others who review and/or approve specific study-related paperwork (e.g. Research Ethics Committees, NHS R&D Offices etc).

Readability Scores

This example shows how Flesch Reading Ease score or Fog score can be calculated. This helps improve readability of your Participant Information Sheet and Consent form.

Count the words and sentences.
Divide the number of words by the number of sentences.
Count the long words (more than two syllables).
Divide the long words by total words, and multiply by 100.
Add the two scores together and multiply by 0.4 to give the fog index.

To place Fog Scores in context, here are some examples:

A newspaper advertisement 4.
A popular novel 8.
A report on information technology 20.

Accessibility guidance is available from the Royal National Institute for the Blind (The Royal National Institute for the Blind: Advice for professionals). The Plain English Campaign offer guidance or assessment (www.plainenglish.co.uk). You can use the readability statistics function available in Microsoft Word to calculate a readability score.
Other free readability calculators can be found at (www.readabilityformulas.com).