

Useful websites

National Electronic Library for Health

www.library.nhs.uk/trials

The National Research Register

www.nrr.nhs.uk

INVOLVE

www.invo.org.uk

MRC Clinical Trials Unit

www.ctu.mrc.ac.uk/TakePart.asp

Current Controlled Trials

www.controlled-trials.com

National Institutes of Health

www.clinicaltrials.gov/ct/gui/c/w1bscreen/PrintURL?file=resources.html&JServSessionIdcscurrent=e7rhe2u5q5

Cancer BACKUP

www.cancerbackup.org.uk/Home

The National Cancer Research Network

www.cancertrials.org.uk

National Cancer

www.cancer.gov/clinicaltrials/findtrials

National Research Ethics Service

National Patient Safety Agency

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www.nres.npsa.nhs.uk

Explaining
research

The public supports medical research and wishes it to continue, but this is not an unquestioning acceptance.

Researchers need to demonstrate that their work is conducted to high ethical standards and is explained clearly.

The stipulation that researchers seek consent after providing appropriate information is a central theme in modern research ethics.

We have produced this guidance* after consulting researchers, reviewers and patients, to guide all those involved in research, whilst recognising that there may be times when variation will be necessary.

The National Research Ethics Service (NRES) would be pleased to receive comments and reference to other published work on these areas for inclusion in the main guidance, which is available at:

www.nres.npsa.nhs.uk/rec-community/guidance

If you wish to do so, please email infosheets@nres.npsa.nhs.uk

*Key points are taken from NRES's Information sheets and consent forms. Guidance for researchers and reviewers.

Explaining research: giving people information

This leaflet highlights some of the key points outlined in the Information sheets and consent forms.

Guidance for researchers and reviewers.
www.nres.npsa.nhs.uk/rec-community/guidance

The guidance is divided into three sections:

Section one provides general comments on information sheets.

Section two gives guidance for the design of information sheets for adults.

Section three offers guidance on the design of information sheets for children/young people.

Annexes provide supplementary information and references to an 'evidence base for research ethics'.

Key design points for information sheets

- Information sheets are only one part of the process of seeking informed consent.
- One size will not fit all: length should be dictated by the complexity and risk of the research.
- Where appropriate, the information sheet could be divided into two parts. Part one should allow the participant to decide whether the study is of interest to them; part two should explain it further.

Part one should provide brief, clear information on the essential elements of the study: the condition or treatment under study; the voluntary nature of involvement; what will happen during and after the trial, what treatment may be withheld; the participant's responsibilities; the potential risks, inconvenience or restrictions, benefits, and the alternative(s).

Part two should contain additional information on factors such as confidentiality and data protection, communication with the GP, indemnity and compensation, and publication. This should be read and understood before the participant decides whether they want to participate.

Additional guidance

- Write in an open, invitational style.
- Use non-technical terms.
- Use appropriate font size for easy reading.
- Address whether diagrams or pictures may be more appropriate.
- Ask for comments from those who may be recruited as lay people.
- Test your consent process.
- Involve patients and ask for feedback from potential participants.
- Search for, and use, other material that might help potential participants.

Information sheets for children

- These should be designed for the appropriate age range and reflect comprehension and development.
- It is important to indicate how the study will affect the child at home, school and his/her social activities.
- Show your information sheets to some children of similar age before submitting to the Research Ethics Committee (REC).
- Provide an additional information sheet for parents or guardians.
- Recognise that arrangements for consent will vary according to the type of study proposed, ethical considerations and applicable law.