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Information and guidance for primary care sites on informed consent

The purpose of this document is to explain what informed consent is in clinical research, how it is received and documented and how it is different from consent in everyday health care.

1.What is informed consent in research?

According to Good Clinical Practice informed consent is -

A process by which an individual voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the individual's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf (accessed 06/03/2023)

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.

Guidance on good clinical practice can be found here - https://www.ich.org/ (accessed 06/03/2023)

2. How do we inform potential participants about research?

Each study will have a Participant Information Sheet (PIS) that has been reviewed by an NHS Research Ethics Committee (REC).

The participant information will detail no less than: the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks

involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give a reason for withdrawal.

A template Participant Information Sheet can be found here - https://www.hra-decisiontools.org.uk/consent/docs/PIS-Template_version2.pdf (accessed 06/03/2023)

3. How much time are participants allowed to consider a study?

Participants are usually allowed as much time as they need to consider the information in the PIS and make a decision about choosing whether or not to take part. However, in some cases a timeframe may be specified in the protocol.

4. What if participants are undecided?

At the time of providing the PIS it is good practice to arrange a further contact with the participant to discuss the study further. At this point any questions or concerns can be answered and further detail regarding study participation can be explained. During the discussion there must be no undue influence on participants to consent to take part if they remain undecided.

5. Who carries out consent?

The protocol will specify who needs to take consent from the participant. For Clinical trials of Investigational Medicinal Products (CTIMPs) it usually needs to be a qualified physician. However, in some instances the Principal Investigator (PI) can delegate the informed consent process to appropriately trained staff. If this is going to happen it needs to be in line with the protocol requirements and recorded on the study delegation log which is signed by the PI.

6. How should informed consent be documented?

The Informed Consent Form (ICF) provided for use in the study will also have been reviewed by an NHS REC. There will be instructions on how to complete it. The participant should initial the boxes at the side of each statement then sign and date the ICF in the presence of the staff member that is receiving consent from them. The staff member will then sign and date the ICF. This process will be different for postal and verbal consent but it will be described in the protocol.

An Informed Consent Form template can be found here -

https://www.hra-decisiontools.org.uk/consent/examples.html (accessed 06/03/2023)

All aspects of the informed consent process should be documented in the Electronic Patient Record (EPR). As a minimum the following should be documented - Date and time of consent discussion and agreement to participate, study discussed in detail with the participant and their family (if applicable), all queries and concerns answered to their satisfaction, name of staff member receiving consent.

7. What about verbal consent?

In some studies participants do not need to be seen face to face for the informed consent process to be valid; it can be carried out via telephone, video or by completion of an online consent form on a website. The process will be specified in the protocol and there will be an NHS REC approved ICF.

8. What happens to the signed ICF?

The original signed ICF should be filed in the Investigator Site File (ISF), a copy is provided to the participant and a copy should be attached or scanned into their EPR alongside a copy of the corresponding PIS.

9. What happens next?

Once the ICF has been signed the participant can be entered into the study. No study related procedure should take place prior to informed consent. Informed consent is an ongoing process and should be reconfirmed and recorded at each study visit. If there are amendments to the study during their participation, each participant should be informed and reconsented using the updated versions of the PIS and ICF. Again, this should all be recorded in their EPR, including uploading the updated PIS and ICF.

10. What if a participant wishes to withdraw consent?

Participation in research is voluntary and a participant can stop or withdraw their consent at any time. If possible, try to establish why the participant wishes to withdraw from the study as the issue/concern may be able to be resolved. A study protocol may have 'tiered' withdrawal where participants do not have active follow-up, but data may still be collected. Confirmation needs to be obtained from the participant regarding the level of withdrawal and this should be documented in their EPR.

Further information about the informed consent process can be found here -

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/ (accessed 06/03/2023)

Informed Consent training is available via NIHR Learn –

https://learn.nihr.ac.uk/enrol/index.php?id=241 (accessed 06/03/2023)

11. What about consent for adults that lack capacity?

Patients that are classed as lacking capacity can take part in research and further information can be found here –

https://www.hra-decisiontools.org.uk/consent/principles-ALC.html (accessed 06/03/2023)

There is also training on NIHR Learn that can be accessed here -

https://learn.nihr.ac.uk/mod/scorm/view.php?id=7772 (accessed 06/03/2023)

12. What about consent for children?

The Medicines for Human Use (Clinical Trials) regulations prohibit children under 16 from giving consent for drug studies. However, there is no such law for non-drug studies, instead the principle of 'Gillick competence' can be applied. Information regarding consenting children and young adults can be found here -

https://www.hra-decisiontools.org.uk/consent/principles-children.html (accessed 06/03/2023)

The NIHR also provide training for paediatric consent that can be accessed via NIHR Learn –

https://learn.nihr.ac.uk/enrol/index.php?id=265 (accessed 06/03/2023)

13. **Who do I contact if I have further questions?**

For any questions, please email: rdu@shsc.nhs.uk