Participant information in healthcare research

Consent for participation in research differs from that provided for therapeutic interventions. Thus, participants must be provided with appropriate information with which they can decide to take part in a research project or not. Research may involve more than one group of participants.

Documents and other items to be provided

The documentation needs to include:

- Information for all participant groups
- Information in all modalities: written, audio-visual and so on
- Recruitment materials: emails, advertisements, social media posts

Information should be provided for the legal representatives of those who lack the capacity to consent for themselves.

Information should be provided in a style and at a level that is appropriate for the individuals.

Key points to include in participant information

- Participation is voluntary
- Lack of participation will not affect healthcare
- An explanation of the study and its rationale
- Why participants are being approached
- What participation involves
- Benefits and risks of participation
- Ability and time frame to withdraw and rights to request destruction of already collected data or biological samples
- What will happen when the study finishes: healthcare, publication, final report and where to access these and the findings
- Reimbursement of reasonable expenses for participants and, if appropriate, accompanying persons
- Duration of storage of data or biological samples
- Future use of data or biological samples in other ethically approved studies
- Data sharing
- Confidentiality
- Reference to national and international data protection legislation
- Information on who is funding the study
- Whom to approach for further information or to discuss concerns
- Specification that the research has been approved by a research ethics committee or institutional review board (IRB), giving the name of the committee, reference and date
- Researcher contact details

Further information

Health Research Authority. Informing participants and seeking consent https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/

World Health Organization. Templates for informed consent forms https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms