Consent for participation in research

Assurance that consent for participation in a research project has been obtained in accordance with local legislation is an absolute requirement for publication. Written consent with copies retained by the researcher or organization and the participant is the traditional method, but others can be used.

Key clauses for consent forms

- The participant has read and understood the participant information sheet or other mode of informing and has been able to ask questions about the research and have them satisfactorily answered
- Participation is voluntary with no negative consequences for refusal
- Participants can withdraw from the research and up to what time point without justification to the research team, and what will happen to the data/samples collected up to that point
- Consent has been obtained for storage and destruction of data/tissue samples/recordings. The duration of storage and by whom should be specified
- Where relevant, consent has been obtained for data sharing
- Prospective consent has been obtained for all anticipated further studies, i.e. consent for future use of data or samples in other ethically approved studies
- National and international data protection legislation will be respected
- Anonymity will be maintained should quotations and images be published, except where participants have consented or requested otherwise
- Consent should be obtained for audit/examination by institutions, regulatory authorities or sponsors of the research
- 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

Some countries have frameworks to allow inclusion in clinical trials without consent for emergency situations (e.g. randomized trials of interventions for the management of cardiac arrest).

Recording of consent and storage of records

Records of participant consent need to be auditable, culturally sensitive and stored in accordance with local legislation. The records can take different forms:

- Written (which may be scanned)
- Verbal (witnessed)
- Audio recordings
- Electronic

Consent may be obtained from participants or their legal representative. The latter may provide consent if patients lack mental capacity, are under the legal age to provide consent, or are deceased. The legal age for providing consent varies between countries.

Further information

Open University. Informed consent https://research.open.ac.uk/environment/ethics/human/consent

UK Research and Innovation https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/research/clinical-research-governance/clinical-trials-regulations