For the public, for the profession, for optimal health care

Standard Guidelines for Informed Consent

1. Introduction

Informed consent is a key ethical and legal requirement in medical practice. Consent must be obtained before any examination, investigation, treatment, or procedure, except in emergencies where consent cannot be secured, and immediate intervention is crucial to save lives or prevent significant harm. Informed consent should not be reduced to the patient's signature. It is a dynamic process centred on clear communication. It ensures that patients' rights are respected and protects practitioners from legal liability in cases of adverse outcomes.

2. Ethical and Legal Foundations

The concept of informed consent is based on core ethical principles:

- **Respect for Autonomy:**
  All competent individuals have the right to make voluntary and informed decisions regarding their bodies and medical care.

  Adults over 18 years of age are presumed competent to make decisions about their own health.

- **Beneficence and Non-maleficence:** The healthcare provider must act in the patient's best interest at all times, while avoiding inflicting harm.
- **Justice:** The process of obtaining consent must be fair and non-discriminatory.

3. Principles of Informed Consent

- **Competence –** The patient must have the capacity to understand and make informed decisions.
- **Disclosure –** The clinician must provide adequate, relevant, and comprehensible information in a language the patient understands and minimise the use of medical jargon.
- **Understanding –** The patient must understand the information shared.

- **Voluntariness –** The decision must be made freely, without coercion or undue influence.
- **Consent –** The patient's agreement (verbal or written) to proceed.

4. Essential Elements to be Disclosed

The clinician should ensure that the patient receives and understands information relating to:

- The nature and purpose of the proposed treatment or procedure.
- The expected benefits and likelihood of success.
- The common, serious, and significant risks or complications.
- Reasonable alternative treatment options and their risks and benefits, including the option of declining treatment altogether.
- Who will perform the procedure (and under whose supervision).
- Post-procedure expectations and recovery process.
- Any applicable costs.

5. Documentation of the Consent Process

5.1. General Requirements

- All consent discussions must be recorded in the patient's medical records. Documentation should include:
- Date, time, and location of the discussion.
- Name and professional designation of the person obtaining consent.
- A summary of information provided (including nature, purpose, risks, and alternatives).
- The patient's questions and the responses given.
- Confirmation that the patient understood and agreed to proceed.
- Signature of the patient (or guardian), practitioner, and a witness (if required).

5.2. Format

- Verbal consent: appropriate for low-risk or routine procedures (e.g. physical examination, blood draw) but should still be recorded in the notes.
- Written consent: required for higher-risk procedures (refer to section 7).

Best practice for documentation includes using a standardised consent form supplemented by narrative entries in the patient's record summarising the discussion. A signed consent form alone does not necessarily equate to informed consent.

Consent forms for surgical procedures should specify the procedure name, the type of anaesthesia, and any foreseeable risks or complications. Any changes or additions after signing must be clearly dated, initialled, and explained.

Documentation Example (Medical Record Entry):

Discussed with the patient the indication for laparoscopic cholecystectomy, benefits, potential risks including bile duct injury, bleeding, infection, and anaesthesia risks. Alternatives (medical management, open surgery) were explained. Patient verbalised understanding and agreed to proceed. Written consent obtained. — Dr. A. B, 07/10/2025."

6. Consent for Anaesthesia

6.1. Pre-anaesthetic Consent

The anaesthetist must obtain separate consent for anaesthesia, explaining:

- Type of anaesthesia (general, regional, local, sedation).
- Common and significant risks (e.g., nausea, sore throat, allergic reactions, rare but serious complications).
- Available alternatives (if any).

The patient must be given the opportunity to ask questions.

6.2. Documentation

- Document the discussion in the anaesthesia record.
- Obtain written consent for general, regional, or spinal anaesthesia.
- Verbal consent may suffice for local anaesthesia during minor procedures, provided it is recorded in notes.

7. Consent for Surgical Procedures

Written informed consent is mandatory for:

- All invasive or surgical procedures, including biopsies.
- Any procedure under general, spinal, or regional anaesthesia.
- Blood transfusion and use of human tissues or implants.
- Participation in research, clinical trials, or teaching demonstrations.
- Procedures with significant risk of complications or permanent outcomes (e.g. male and female sterilisation, amputations, cosmetic surgery).

The surgical consent form should include:

1. Patient identifiers and procedure details.
2. Explanation of risks, benefits, and alternatives.
3. Confirmation of discussion about anaesthesia and blood transfusion.
4. Signatures of patient, practitioner, witness, and date/time.

8. Consent in Special Situations

Situation	Guidelines
Minors (<18 years)	Consent must be obtained from parent/guardian. The minor should be involved in the discussion to the extent of their maturity ("assent").

Emergency care	If the patient cannot provide consent and delay would threaten life or cause serious harm, treatment may proceed under implied consent. The justification and circumstances must be documented.
Patients lacking capacity	Decisions should be made by a legally authorised representative or next of kin in the patient's best interest.
Language barriers	Use a trained interpreter, document name and role of interpreter.
Refusal of treatment	If the patient is competent, their decision to refuse treatment must be respected. The discussion and the patient's understanding of the consequences should be documented, and written refusal obtained where possible.

9. Review and Storage

- Consent forms become part of the patient's permanent medical record.
- Copies should be made available to the patient on request.
- Consent should be reconfirmed if there is a significant delay between obtaining consent and the procedure, or if new information becomes available.

10. References

Contents and principles included in these guidelines are derived from the following documents:

1. World Medical Association (2015). Declaration of Lisbon on the Rights of the Patient. (https://www.wma.net/policies-post/wma-declaration-of-lisbon-on-the-rights-of-the-patient/)
2. World Medical Association (2013). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. (https://www.wma.net/policies-post/wma-declaration-of-helsinki/)
3. CIOMS (2016). International Ethical Guidelines for Health-related Research Involving Humans. (https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf)
4. General Medical Council (UK). Guidance: Decision-making and consent (2020) (https://www.gmc-uk.org/cdn/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf)
5. Medical Practitioners and Dentists (Disciplinary Inquiries) (Amendment) Regulations 2017 (S.I. 11 of 2017) (https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://seylii.org/akn/sc/act/1994/15/eng%402012-06-30/source&ved=2ahUKEwja5Ji5o_uRAxUjBfsDHdxDEV0QFnoECBwQAQ&usg=AOvVaw3qYL8fKMpXhqRBKU9oDaus)
6. American Society of Anesthesiologists. Statement on Documentation of Anaesthesia Care (2023). (https://www.asahq.org/standards-and-practice-parameters/statement-on-documentation-of-anesthesia-care)

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