

Policy name: Consent Policy 1.5

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Version Control			
Version	Author	Date	Changes
1	Sandra Haughton	Jul 2015	First draft
2	Sandra Haughton (SH)	Feb 17	Major Changes to document to stay in line with compliance with current law
3	Adam C E Kennaugh	Mar 2020	Review
4	Karen Clandon (KC)	Mar-23	Minor changes
5	Eileen Jones (EJ)	Feb 2024	No minor changes
6.	Karen Clandon (KC)	March 2025	No Major changes
7	Daryll Nesmejanow	Jan 2026	Slight changes to reflect current practice/ personnel
8	Adam C E Kennaugh	August 2026	Amendments

1.5.1 Policy Statement

iSIGHT is committed to ensuring that valid consent is obtained before any examination, investigation, treatment or surgical procedure is undertaken.

Consent is a fundamental legal and ethical principle that protects the rights, dignity and autonomy of patients. All patients have the right to make informed decisions about their healthcare, including the right to refuse treatment.

iSIGHT will ensure that consent processes comply with:

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Montgomery v Lanarkshire Health Board [2015]
- General Medical Council (GMC) Decision Making and Consent Guidance
- Equality Act 2010
- UK General Data Protection Regulation (UK GDPR)
- Data Protection Act 2018

All consent must be:

- Voluntary
- Informed
- Given by a person with capacity to make the decision
- Recorded appropriately

Consent may be verbal, written or implied depending on the nature and complexity of the treatment. Written consent is required for all surgical procedures and invasive treatments undertaken by the clinic.

1.5.2 Purpose of Consent

The purpose of obtaining consent is to ensure that patients:

- Understand the proposed treatment or procedure.
- Understand the expected benefits.
- Understand any material risks and potential complications.
- Are informed of reasonable alternative treatment options.
- Understand the option of declining treatment.
- Have sufficient opportunity to ask questions.
- Make a voluntary decision free from coercion or undue influence.

A signed consent form provides evidence of the consent discussion but is not, by itself, proof that valid consent has been obtained.

Patients may withdraw consent at any stage before or during treatment provided they have capacity to make that decision.

1.5.3 Principles of Consent

Valid consent requires that the patient:

Has Capacity

The patient must have the mental capacity to make the specific decision at the time it is required.

Is Adequately Informed

Patients must receive information about:

- The proposed treatment or procedure.
- Expected benefits.
- Material risks.
- Potential complications and side effects.
- Reasonable alternatives.
- Consequences of declining treatment.

Gives Consent Voluntarily

Consent must not be obtained through pressure, coercion or undue influence.

1.5.4 Material Risks and Patient Information

In accordance with *Montgomery v Lanarkshire Health Board* [2015], clinicians must ensure that patients are informed of:

- Any material risks associated with a proposed treatment.
- Reasonable alternative treatment options.
- The option of no treatment.

A risk is considered material if:

- A reasonable person in the patient's position would likely consider it significant; or
- The clinician knows, or should reasonably know, that the particular patient would consider it significant.

Information must be tailored to the patient's individual circumstances, concerns and preferences.

All questions must be answered honestly and accurately.

The consent discussion must be documented within the patient's clinical record.

1.5.5 Scope

This policy applies to:

- Medical Director
- Consultants and Surgeons
- Optometrists
- Nurses
- Clinical Services Manager
- Theatre Manager
- Healthcare Assistants
- All registered healthcare professionals involved in patient care

Only appropriately trained and competent individuals may obtain consent.

1.5.6 Responsibilities

The Medical Director has overall responsibility for ensuring compliance with this policy.

All healthcare professionals involved in obtaining consent are responsible for:

- Following this policy.
- Maintaining competence in consent procedures.
- Ensuring patients receive appropriate information.
- Assessing capacity where required.
- Recording consent appropriately.
- Escalating concerns regarding capacity or safeguarding.

1.5.7 Mental Capacity Act 2005

iSIGHT recognises and adheres to the five statutory principles of the Mental Capacity Act 2005:

Principle 1

A person must be assumed to have capacity unless it is established otherwise.

Principle 2

A person must not be treated as unable to make a decision until all practicable steps have been taken to help them do so.

Principle 3

A person must not be treated as lacking capacity merely because they make an unwise decision.

Principle 4

Any act or decision made on behalf of a person lacking capacity must be in their best interests.

Principle 5

Any decision made on behalf of a person lacking capacity must be the least restrictive option available.

1.5.8 Assessing Capacity

Capacity is:

- Decision-specific.
- Time-specific.

A patient lacks capacity if they are unable to:

- Understand relevant information.
- Retain information long enough to make a decision.
- Use or weigh information as part of the decision-making process.
- Communicate their decision by any means.

Capacity assessments must be documented in the patient record.

1.5.9 Adults Who Lack Capacity

Where an adult lacks capacity to make a healthcare decision, treatment may only proceed where:

- It is in the person's best interests; and
- Any legal decision-makers have been consulted as required.

Clinicians must consider:

- The patient's previous wishes, feelings, beliefs and values.
- Views of family members and carers where appropriate.
- Any valid Advance Decision to Refuse Treatment.
- Any Health and Welfare Lasting Power of Attorney.
- Any Court-Appointed Deputy with relevant authority.

Best interest decisions must be clearly documented.

Relatives cannot automatically provide consent on behalf of an adult who lacks capacity unless they hold legal authority to do so.

1.5.10 Patients Unable to Sign

Where a patient has capacity but is physically unable to sign:

- Verbal or non-verbal consent may be accepted.
- The consent process must be documented.
- An independent witness should confirm the patient's consent.

The witness should sign and date the consent documentation.

1.5.11 Children and Young People

Young People Aged 16 and 17

Young people aged 16 and 17 are presumed to have capacity to consent to medical treatment unless there is evidence to the contrary.

Children Under 16

Children under 16 may provide valid consent if they are assessed as having sufficient understanding and intelligence to understand the proposed treatment (Gillick Competence).

Where appropriate:

- Parents or those with parental responsibility should be involved in discussions.
- The child's views and confidentiality rights must be respected.
- The involvement of parents should reflect the child's best interests and legal rights.

Assessments of Gillick Competence must be documented in the patient record.

1.5.12 Obtaining Consent

Before obtaining consent, the healthcare professional must:

- Explain the procedure in clear language.
- Discuss benefits and risks.
- Explain alternative treatments.
- Explain likely outcomes without treatment.
- Answer questions fully.
- Confirm understanding.

Patients should be given adequate time to consider their decision wherever possible.

Patients may choose to have a relative, friend or advocate present during discussions.

1.5.13 Accessibility and Communication Needs

iSIGHT is committed to ensuring information is accessible to all patients.

Where required, the clinic will provide:

- Professional interpreters.
- Accessible written information.
- Large print documentation.
- Alternative communication formats.
- Appropriate support for patients with disabilities or sensory impairment.

Family members should not normally be used as interpreters except in exceptional circumstances or emergencies.

Reasonable adjustments will be made in accordance with the Equality Act 2010.

1.5.14 Cataract Surgery

Written consent must be obtained prior to cataract surgery.

The consent process must be undertaken by a healthcare professional who:

- Has sufficient knowledge of the procedure.
- Has been trained in the consent process.
- Is able to discuss risks, benefits and alternatives.

The consent discussion must be recorded within the patient's clinical record.

1.5.15 Refractive Procedures

Written consent must be obtained prior to treatment.

Patients must receive information regarding:

- Expected outcomes.
- Alternatives.
- Risks and complications.
- Post-operative requirements.

Consent must be completed before administration of any sedation or anxiolytic medication.

1.5.16 Minor Surgery, Laser Procedures and Intravitreal Injections

Written consent shall be obtained for all invasive procedures.

The healthcare professional obtaining consent must possess appropriate knowledge and competence relating to the procedure.

1.5.17 Anaesthesia

Patients must receive information regarding:

- Type of anaesthesia.
- Benefits.
- Risks.
- Alternatives where appropriate.

Responsibility for ensuring valid consent for anaesthesia rests with the appropriately qualified healthcare professional involved in the patient's care.

1.5.18 Photography, Video and Audio Recording

Separate consent must be obtained before any patient photography, video recording or audio recording is undertaken for:

- Clinical purposes.
- Training.
- Education.
- Research.
- Marketing or promotional activities.

Patients must be informed:

- Why recordings are being made.
- How recordings will be used.
- How recordings will be stored.
- Their right to refuse.

Refusal to consent will not affect the patient's care or treatment.

1.5.19 Medical Records and Confidentiality

Patient information will be processed in accordance with:

- UK GDPR
- Data Protection Act 2018
- Common Law Duty of Confidentiality

Consent will normally be obtained before confidential information is shared with third parties unless disclosure is permitted or required by law.

Information may be disclosed without consent where:

- Required by law.
- Ordered by a court.
- Necessary for safeguarding purposes.
- Necessary to prevent serious harm.
- Required for public health obligations.

All disclosures must be appropriately documented.

1.5.20 Monitoring and Compliance

Compliance with this policy will be monitored through:

- Clinical audits.
- Consent form reviews.
- Incident reporting.
- Complaints analysis.
- Patient feedback.
- Staff training records.

Findings will be reviewed by the Executive Team and action plans implemented where necessary.

References

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Montgomery v Lanarkshire Health Board [2015] UKSC 11
- General Medical Council: Decision Making and Consent
- Good Medical Practice
- UK General Data Protection Regulation (UK GDPR)
- Data Protection Act 2018
- Equality Act 2010
- NHS Accessible Information Standard
- Children Act 1989
- Children Act 2004