Consent to Examination or Treatment Policy

Summary	This policy sets out Capmed Diagnostics' approach to obtaining, documenting and reviewing consent for non-invasive medical procedures, specifically Capsule Endoscopy (small bowel and colon capsule). It aligns with UK law and national guidance (see Legal and Regulatory Framework).
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Target Audience	All clinical and administrative staff involved in scheduling, consenting, delivering and reporting Capsule Endoscopy
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Contents

Introduction

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent is therefore an essential component of healthcare when touching a patient and is a matter of common courtesy

Capmed Diagnostics, herein referred to as the company, is committed to person-centred, lawful and ethical consent for all care and treatment. Consent is a continuing, shared decision-making process, not a single signature. This policy operationalises that approach for non-invasive procedures delivered by the company, with specific application to Capsule Endoscopy (CE).

Scope

Applies to all Company activities related to: pre-assessment, information provision, scheduling, remote and face-to-face consultations, administration of patency capsule, ingestion of video capsule (patency, small bowel, colon and Crohns capsule), data acquisition, retrieval and reporting, and post-procedure follow-up. Applicable to adults (over 18 years of age).

Excludes invasive endoscopy performed by third parties, including, but not limited to, endoscopy procedures performed as a result of findings reported within the Capsule Endoscopy tests delivered by the company.

Definitions

Term	Definition
Consent	A voluntary, informed decision by a person with capacity, given without coercion, covering the proposed intervention and reasonable alternatives.
Material Risk	A risk to which a reasonable person in the patient's position would likely attach significance, or that the clinician should reasonably know this particular patient would regard as significant.
Capacity	Under MCA 2005, ability to understand, retain, use/weigh relevant information, and communicate a decision for the specific matter at the time.
Gillick competence	A decision-specific assessment of whether a child under 16 has sufficient understanding and intelligence to consent to treatment.
Best Interests	Decision framework under MCA 2005 when a person lacks capacity, considering wishes, feelings, beliefs and values, consulting those close, and choosing the least restrictive option.

Roles and Responsibilities

Company Directors

- Approves policy;
- ensures resources and governance.

Clinical Leads

- Implements clinical aspects
- assures information quality
- oversees consent practice and audit.

Clinicians

- Conduct shared decision-making;
- assess capacity;
- obtain and document consent;
- escalate complex cases.
- Provide information;
- check understanding;
- document ongoing consent;
- raise concerns.

Administrators

- Issue patient information in accessible formats;
- schedule cooling-off periods;
- manage records.

Data Protection Lead

- Ensures privacy notices, lawful bases, and security for special category data.

Procedures and Processes

The GMC (09 November 2020, page 4) describes consent as “a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between a doctor and patient is essential in good decision making. Serious harm can result if patients are not listened to or if they are not given the information they need – and time and support to understand it – so they can make informed decisions about their care.” ‘Seeking consent’ in the context of this policy may be described as ‘joint decision-making': the patient and health professional agreement on choice of treatment based on the patient's values and preferences and the health professional's clinical knowledge.

The company will endeavor to provide pre-procedure information as early as possible in multiple formats (written, verbal, digital), tailored to individual needs, including benefits, material risks, uncertainties, and reasonable alternatives (e.g., cross-sectional imaging, device-assisted enteroscopy as appropriate).

Throughout their pathway, the company encourages questions from patients and/or their relatives and carers. Company representatives will endeavor to explore what matters to the person (values, circumstances, concerns) and provide honest, factual and timely answers to any questions raised. Any patient-specific material risks will be documented as part of clinical noting.

All patients will be offered a period of cooling-off time offered except where the procedure is deemed to be clinically urgent.

Consent will be captured electronically prior to or as part of a pre-assessment appointment. Should the electronic system be unavailable, consent will be documented on the appropriate physical form and will be scanned and stored in the clinical record (express written consent). Consent will be reconfirmed on the day of the procedure (ongoing consent). **The clinician providing the treatment or investigation is responsible for confirming that the person has given valid consent before treatment begins.**

Any person seeking consent must:

- Have clear knowledge of the procedure, alternatives (including no treatment) and the potential risks and complications of all options.
- Be satisfied that a patient has the mental capacity to make a decision about their care and treatment; or otherwise ensure that appropriate legal representatives are involved / best interest decisions are applied.

If a patient requires patency capsule testing prior to a Capsule Endoscopy test, then separate consent should be obtained for the patency capsule, covering its purpose, process, and distinct risks, including making the patient aware that further imaging may be required to verify that the patency capsule has left the patient's body.

Consent is a continuing process during preparation, capsule ingestion, and data retrieval; the company respects the patient’s right to withdraw consent at any point throughout the pathway and this will be documented in the patient's clinical notes..

Capacity, Children and Young People

A person has capacity to make their own decisions if they are able to understand, retain, use and weigh the relevant information, and communicate their decision.

Where capacity exists the following are applicable when giving or withholding consent:

- **A person aged 16 or over** can consent / refuse consent for themselves.
- **An adult aged 18 or over** can consent / refuse consent for a child or young person (aged under 18) for whom they have parental responsibility.

- **A child under the age of 16** – The company does not currently offer procedures to anybody under the age of 16.

If capacity is in doubt, this should be documented within the patient's record of care. A person may not have mental capacity because of a problem with the way their brain functions, for example:

- a serious brain injury
- an illness, such as dementia
- severe learning disabilities

Mental capacity can come and go (for example, with dementia and some mental illnesses). A person can also recover mental capacity (for example, following a severe stroke).

Before any further treatment can be carried out, the company requires the clinician performing the treatment or investigation to check that the patient has mental capacity to make a decision at the time it needs to be made.

A patient will lack capacity to make a decision if, after all appropriate help and support have been given to them, they cannot fulfil one or more of the following:

- Understand the information they need - for example, what the consequences will be if the procedure or investigation is not carried out.
- Remember the information for long enough to make the decision.
- Weigh up the options and make a choice.
- Communicate their decision in any way - for example, by blinking or squeezing a hand

If any of the above conditions cannot be met, then in the context of this policy the patient will be deemed to 'lack capacity' to make an informed decision about treatment with the company and no further treatment should take place unless the exception below iapplicable.

Where a patient does not have capacity to give or withhold consent:

- A best interest decision may be given by someone authorised under a Lasting Power of Attorney (LPA) for Health and Welfare or someone who has the authority to make treatment decisions as a court appointed deputy.

In both the above cases, the company may require appropriate documentation and reserve the right to take time to consider and/or seek independent advice before agreeing to carry out any procedure or investigation. This may mean that pre-agreed dates of appointment may need to be altered until the company is assured that the appropriate individual can consent on the patient's behalf.

No patient can be deemed to lack mental capacity because the clinician, relative, carer thinks they have made a bad or strange decision with regard to treatment (list not exhaustive).

Accessibility, Equality and Data Protection

The company will endeavor to provide information in line with the Accessible Information Standard (formats, language, communication needs) and commits to making reasonable adjustments under the Equality Act 2010 for all patients.

All company privacy notices must explain purposes, lawful bases or contract, retention, sharing and rights. The company respects and applies the common law duty of confidentiality with respect to all patient data and respects a patients right in respect of national data opt-out where applicable.

The company commits to secure handling of recordings and reports created as part of any pathway related to procedure or investigation offered by the company.

Record-Keeping, Audit and Governance

The company requires those seeking consent to record consent discussions, questions, specific material risks, alternatives discussed, and patient preferences electronically or otherwise should the electronic system be unavailable.

Consent should be obtained electronically in the first instance but should electronic consent not be possible then signed consent forms will be scanned and stored electronically in the patient record.

The company commits to annual review of a sample of CE cases for consent completeness and quality. This will be discussed as part of the regular business cycle and the company commits to act on findings to ensure that this policy and a patient's rights within the context of this policy are respected at all times.

Training and Competency

All staff who obtain consent must complete induction and annual refreshers on consent law, MCA, CQC expectations, and CE-specific risks. Any new starters with the company that will deliver procedures or seek consent prior to procedure delivery will be supervised until deemed competent.

Compliance and Enforcement

The company respects the patient’s right to consent, and any non-compliance may trigger retraining, supervision, or disciplinary action.

Serious breaches are reportable under clinical governance and, where applicable, to the CQC and ICO.

Related Policies

- Safeguarding Adults and Children Policies
- Raising Concerns/Complaints Policy
- Privacy Notice and Data Protection Policy

Legal and Regulatory Framework

Common law of consent as clarified by Montgomery v Lanarkshire Health Board [2015] UKSC 11 (material risks and reasonable alternatives).

• General Medical Council (GMC) Decision making and consent (2020).

• Care Quality Commission (CQC) Regulation 11: Need for consent; and related expectations for provider registration and inspection.

• Mental Capacity Act 2005 (MCA) and Code of Practice: five statutory principles; capacity assessment; best interests; least restrictive option.

• Family Law Reform Act 1969 s.8 (consent by 16–17-year-olds); Gillick competence for under-16s.

• Children Act 1989 and safeguarding duties.

• UK GDPR and Data Protection Act 2018; Common Law Duty of Confidentiality; NHS national data opt-out.

• Equality Act 2010 and the Accessible Information Standard.