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ACKNOWLEDGEMENTS

"I do solemnly and sincerely declare and promise that I will observe and be obedient to the Statutes, Bye-Laws and Ordinances of the Royal College of Surgeons in Ireland, and that I will to the utmost of my power, endeavour to promote the reputation, honour and dignity of the said College.

I promise to place the welfare of my patients above all else.

I promise to be respectful of my fellow healthcare professionals and will readily offer them my assistance and support. I further promise to continue to learn and teach and maintain my competence, for the benefit of my patients, trainees and the society in which I serve."

RCSI Fellows Pledge 2025

Foreword

The ethical and professional obligations of all doctors are set out in the Guide to Professional Conduct and Ethics for Registered Medical Practitioners (9th Edition), 2024 (The Medical Council's Ethical Guide) published by the Irish Medical Council and available on their website.

This edition of the code of practice has been updated specifically to reflect changes in the provision of healthcare in Ireland following the commencement of certain legislation including the Assisted Decision-Making (Capacity) Act 2015 (2022) and the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, as well as updated Medical Council guidance and other regulatory and legislative changes since 2018. We have drawn from the publications of other Colleges, the literature and international guidelines on ethical best practice and we have consulted with the surgical community.

You should read this guide in conjunction with the <u>Medical</u> <u>Council's Ethical Guide</u>, the <u>HSE National Policy and</u> <u>Procedure for Safe Surgery (2022)</u>, the <u>HSE National Consent Policy (2022)</u>, and the <u>National Policy on Open Disclosure (2019)</u>.

Specific training has been developed by the HSE to support the rollout of the new legislative requirements of the Assisted Decision-Making (Capacity) Act 2015. Should any guidance in this document differ from the guidance set out in the Medical Council's Ethical Guide, the guidance in the Medical Council's Ethical Guide shall prevail.

Surgical care is now being delivered in a very complex and rapidly changing environment. Rather than a rulebook, we have set out to articulate a straightforward set of principles that each and every surgeon can use to inform their own practice. Inevitably, circumstances will change and, while we intend this guide to evolve over time, individual surgeons must also exercise their own informed professional judgement on how best to meet new challenges that frequently arise in clinical practice.

We intend that this guide should be useful to all fellows of RCSI (regardless of their country of practice) but it is specifically focussed on surgeons in practice in Ireland. We recognise that there are differing regulatory requirements between the Republic of Ireland and Northern Ireland and have tried to accommodate this issue where possible.



Professor Deborah MacNamara FRCSI

President RCSI, Dublin 2025



1. Good clinical care

1.1 PROVIDING A GOOD STANDARD OF SURGICAL CARE





HSE National Policy and Procedure for Safe Surgery



HSE National Consent Policy



HSE Policy on Open Disclosure



In order for a surgeon to provide good clinical care you:

- must ensure that patients are treated according to the priority of their clinical need
- 2. must communicate compassionately, clearly and effectively with patients and / or persons with decisionmaking authority in relation to the patient and (with the patient's consent) with family members, other supporters and, in the case of children, with their parent(s) or legal guardians
- should carry out surgical procedures in a timely, safe and competent manner
- 4. should provide elective care for patients with non-urgent conditions and carrying out procedures on them that lie within the range of your competence
- should ensure patients are cared for in an appropriate and safe environment that provides for any special needs they may have
- 6. sshould ensure that adequate resources are available for safe patient care and mitigating risk where resources are inadequate by consideration of postponing planned procedures where appropriate
- should ensure that you are aware when timely access to outpatient or inpatient care is compromised by lack of resources
- 8. should escalate your concerns appropriately, through local channels initially, where you feel the safety of patients may be compromised by a lack of resources
- must ensure patients receive satisfactory postoperative care and that relevant information is promptly recorded and shared with the caring team, the patient and their supporter(s)

- 10. must ensure that, on the discharge of a patient from hospital care, appropriate information is shared with the patient and/or persons with decision-making authority in relation to the patient (s) and (with the patient's consent) that a record is also sent to the patient's General Practitioner, and other doctors or healthcare professionals involved in their care
- must ensure that any instruction to withhold or withdraw treatment (for example, resuscitation, ventilation or dialysis) is;
 - a. taken in consultation with the patient (and/or persons with decision-making authority in relation to the patient) and, where appropriate, is aligned with the patient's will and preference as expressed in a valid legally binding advance healthcare directive
 - b. authorised by the appropriate senior clinician
 - c. appropriately recorded in the patient's clinical record as set out in the HSE National Consent policy
 - d. reviewed from time to time or when clinical circumstances change
- 12. should accept patients on referral from General
 Practitioners, consultant colleagues or as an emergency
 through the Emergency Department. If you agree to see
 a patient directly without referral, the patient should be
 informed that, a report will be sent to their General
 Practitioner
- 13. should consult appropriately with other clinicians and transferring the care of the patient, when appropriate, to another colleague or unit where the required resources and skills are available

- 14. must ensure that your care decisions are appropriately informed following discussion within a multidisciplinary team meeting where this is appropriate
- 15. should ensure that you are aware of current clinical guidelines in your field of practice. You should explain to patients the reasons for not following such guidance if an alternative course of clinical management is followed
- 16. must discuss with patients (and/or persons with decision making authority in relation to the patient) alternative forms of treatment, including non-operative care, and recording the reasons for your decisions
- 17. must provide treatment only if you have appropriat training and experience and are competent to do so
- 18. should delegate treatment only to others who are competent and who possess sufficient skills to deliver safe and appropriate care. You should ensure that those who deliver care on your behalf are sufficiently competent to obtain appropriate consent in advance of treatment and have enough knowledge to discuss all relevant treatment options, complications and outcomes.
- 19. should ensure parents or legal guardians and the child (to the level of their understanding) are fully informed while protecting the child's privacy.
- 20. should escalate your concerns where you believe that the safety of patients may be compromised by a lack of resources (delaying access to care or compromising the quality of care), to the appropriate clinical director, the hospital Director of Safety and Risk and/or the Chief Executive of the hospital (or other appropriate office holders) and you should keep a record of these communications

- 21. should raise your concerns outside the local governance structures including with the relevant regulatory authority or through the applicable notification or disclosure pathways if having appropriately and responsibly escalated your specific concerns within the local governance structures, you believe that the deficiencies have not been addressed.
- 22. should do so responsibly and ensure at all times that the privacy of individual patients is protected when raising your concerns outside the clinical governance structure of the hospital, such as in the national (or social) media.
- 23. should ensure that when using telemedicine, it is delivered at the same standard as in person care
- 24. should acknowledge that you have a duty of care to follow patients and provide care or arrange follow-up if you have a conscientious objection to a lawful procedure that they have undergone by another practitioner.

1.2 THE TREATMENT OF EMERGENCIES

Emergency care is a major component of surgical practice. When on-call, you should:

- accept responsibility for the assessment and continuing care of every emergency patient admitted under your care unless, or until, they are formally transferred to the care of another doctor
- 2. be available to give advice throughout the duty period
- 3. ensure you can respond promptly to a call to attend an emergency patient

- 4. ensure arrangements are made for the safe transfer to another unit of emergency patients when the complexity of the patient's condition is beyond your experience or the resources available for their proper care. This must be accompanied by a comprehensive timely report containing all pertinent patient information.
- delegate assessment or emergency surgical operations only when you are confident of the competence of those trainees and non-consultant hospital doctors to whom the patient's operative care will be delegated
- 6. ensure the formal handover of patient care to an appropriate colleague following periods on duty.

In an emergency, unfamiliar operative procedures should be performed only if there is no clinical alternative, if there is no more experienced colleague available or if transfer to a specialist unit is considered a greater risk.

1.3 ORGAN AND TISSUE TRANSPLANTATION

Surgeons undertaking organ or tissue transplantation:

- must comply with current laws and ethical rules relating to the use of human tissue. The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Act 2024 will, for the first time, provide a national legislative framework for operating organ donation and transplant services in Ireland. This will be introduced on a phased basis.
- 2. should ensure recipients are chosen solely based on medical suitability

- 3. should fully inform recipients of hazards and likely outcome when seeking informed consent
- 4. should fully inform living donors of risks and outcome to themselves and of the benefits and risks for the recipient. Living organ donation must never be acquired by coercion or for profit
- 5. must obtain consent from the patient or a validly appointed decision maker or healthcare representative
- 6. when using cadaver donors or other tissue, must conform to current regulations regarding, for example, certification of brain death.

1.4 RECORD KEEPING

As a surgeon, you:

- must ensure all medical records created by you are legible, complete, accurate, up-to-date and contemporaneous and have the patient's identification details on them
- should ensure that when members of the surgical team make case-note entries they are dated and legibly signed (and timed where the clinical condition is changing rapidly)
- should ensure that the record includes the name of the most senior surgeon seeing the patient at each visit
- 4. should ensure that a record is made by a member of the surgical team of important events and communications with the patient or supporter, with appropriate consent (for example, prognosis or potential complication). Any change in the treatment plan should be recorded

National Policy and Procedure for Safe Surgery



World Health Organisation (WHO) Surgical Safety Checklist



HSE Patient
Safety Strategy



- 5. must ensure that that you adopt and implement the National Policy and Procedure for Safe Surgery. This endorses the principles of the World Health Organisation (WHO) Surgical Safety Checklist and the HSE Patient Safety Strategy to ensure that all patients undergoing surgical procedures do so safely, by providing guidance for safe practice throughout the surgical patient pathway, and introducing key safety steps that can be incorporated into the operating theatre. Patient safety can be maximised and incidents minimised.
- 6. should ensure that there are legible operative notes (or electronic records) for every operative procedure. The notes should accompany the patient into recovery and to the ward (or be available in electronic format to those providing postoperative care) and should contain sufficient detail to enable continuity of care by another doctor.

The notes should include:

- ~ date and time
- ~ identity of the patient
- ~ elective/emergency procedure
- ~ the names of the operating surgeon(s) and assistant(s)
- ~ the operative procedure carried out
- ~ preoperative antimicrobial prophylaxis
- type of skin preparation used to facilitate an aseptic technique
- ~ the side of the body where appropriate
- ~ the incision
- ~ the operative diagnosis
- ~ the operative findings
- ~ any problems/complications

- any extra procedure performed and the reason why it was performed
- ~ details of tissue removed, added or altered
- identification of any prosthesis used, including the serial numbers of prostheses and other implanted materials
- details of any retained packs, wicks or drains including instructions for their removal
- ~ details of closure technique
- ~ postoperative care instructions
- ~ a signature
- should ensure that follow-up notes are sufficiently detailed to allow another doctor to assess the care of the patient at any time
- 8. must ensure that the records you keep meet the requirements of the General Data Protection Regulations, and that such records are securely stored in compliance with the provisions of the Act. Please consult the "General Data Protection Regulations (GDPR):
 A Guide for surgeons". RCSI 2018
- should ensure that notes are not amended and if it is necessary to write a retrospective note this should be dated at the time of entry while also specifying the date, time and event it relates to
- 10. should maintain patient confidentiality at all times. Patient records, including photography, can only be provided to third parties, who are not involved in the patient's clinical care, with the patient's explicit consent. You should be vigilant in preventing inadvertent disclosure of confidential data during conversation in public places including ward rounds, hospital corridors, canteen and coffee shops etc.

RCSI General Data Protection Regulations (GDPR): A Guide for surgeons



- 11. should adhere to Medical Council guidelines and GDPR regulations when using personal mobile devices to share confidential patient data, including photographs and other images, between members of surgical teams. The devices used for communication and the data exchanged should be encrypted. If recording patients via video or photography adopt caution regarding storage of these records. These should be retained in the patients' medical records. Where you determine that recording is necessary, either for patient care or for education and training purposes, you must explain this to the patient and obtain their informed consent to both the making and sharing of their recording.
- 12. should consider facilitating their request if a patient wishes to record all or part of an outpatient consultation. If you consider that recording of this consultation and facilitating their request could have a negative impact on your consultation, you should explain this to your patient and, if possible, come to agreement.
- 13. should ensure that confidential patient medical records are retained for as long as required by law or for as long as they remain clinically relevant. Patients have the right to get copies of their medical records. Where the contents of this record may pose a risk of serious harm, access can be restricted

2. Maintaining competence

2.1 PROFESSIONAL COMPETENCE





As a surgeon, you must ensure that you maintain your competence in all areas of practice.

This can be demonstrated by:

- enrolling in a Professional Competence Scheme. You can access the RCSI guidance on Maintaining Professional Competence on www.rcsi.com/portal/surgery. If you are working in another jurisdiction, you must enrol in a mandatory scheme to ensure you maintain your professional competence and/or participate in a revalidation process
- assessing your own professional development needs, identifying activities to address any deficits and ensure that you maintain your knowledge and skills
- participating in relevant courses, conferences and other professional activities relevant to your scope of practice and the professional development needs you have determined
- 4. participating in the development of, quality improvement activities in your practice including multidisciplinary team meetings
- participating in any national audit of clinical practice relevant to your scope of practice, examining your own outcomes and the outcomes of your unit compared to other similar surgeons and best practice elsewhere
- identifying quality improvement opportunities and advocating responsibly for the implementation of these improvements
- 7. identifying other areas of your clinical activity that should be audited and advocating for the resources to establish reliable audit on a permanent basis

- 8. establishing and maintaining an up-to-date and valid professional portfolio as provided within your professional competence scheme or elsewhere
- 9. producing evidence that you are maintaining your competence when required to do so
- 10. seeking guidance from the Professional Competence Office in RCSI if you have difficulty understanding what you should do to maintain your own professional competence
- discussing the issue with your clinical director or, if you are an NCHD, with your consultant supervisor if you have difficulty meeting your professional competence obligations.
- 12. ensuring that you are sufficiently proficient in the use of the English language (both written and verbal) to enable you to communicate with patients and colleagues
- 13. having the applicable professional indemnity cover for all healthcare services you provide

2.2 OPEN DISCLOSURE





Surgeons must be open, honest, compassionate, consistent and timely in communicating with patients, and, where appropriate, their family, carers and/ or supporters, following patient safety incidents. The event should be reported to the appropriate office in the Hospital and, if appropriate, ensure that the incident is adequately investigated. The National Policy on Open Disclosure (2019) provides clear guidance in these circumstances and has been endorsed by RCSI.

The Patient Safety Act (2023) sets out an open disclosure procedure that doctors (and other healthcare practitioners) are obliged to follow in certain defined clinical circumstances such as wrong patient surgery, wrong site surgery, wrong operation performed or inadvertent retained foreign bodies etc leading to death. The list (which may be amended by ministerial order) and the procedure are set in the Act and local processes should be put in place by each healthcare provider to ensure and demonstrate compliance.

2.3 NEW SURGICAL TECHNIQUES

Robotic Surgery Governance in Ireland - A guide



New techniques include:

- a new operation you have developed yourself or in consultation with others
- 2. any major modifications to an established procedure
- 3. the introduction of a procedure not previously performed by you or in the Hospital
- 4. the use of a new medical device.

Doctors commencing robotic approaches to surgical care should read <u>Robotic Surgery Governance in Ireland: A guide to good practice</u>

When a new technique is to be used, the patient's best interests, rights and safety must be considered paramount. Therefore, you:

- must ensure that you have completed the training necessary (including certification where available) to undertake the procedure safely and that all necessary clinical facilities are available
- must avail of mentoring where required for your first time to perform new operative procedures/technology until you are signed off as competent to complet independently. The number needed may vary widely across procedures and technologies.
- should be open and transparent with patients informing them of the new procedure, your lack of experience in doing this and the lack of long-term follow-up in your hands
- should discuss the technique with colleagues who have relevant specialist experience and/or the relevant specialist association

- should discuss the technique with the Clinical Director and develop and or follow local protocols regarding ethics committee approval or other clinical governance procedures
- 6. must ensure that patients, their approved alternate decision-makers and their supporters know that a technique is new when obtaining their consent and that all the established risks, alternatives and benefits are fully explained prior to obtaining their full informed consent to proceed
- 7. must be open and transparent with the patient regarding the sources of funding for the development of any new technique especially where you have any financial interest in a technique or device
- 8. if you are involved in any way in promoting or endorsing specific healthcare products or services, you must declare any financial or commercial interest you have in the organisation or company providing the products or services.
- 9. Should establish a process to audit outcomes and review this audit with a peer group
- 10. should ensure that any new device complies with European standards and is certified by the competent body (for example, the Health Products Regulatory Authority in Ireland www.hpra.ie

In the setting of emergency surgery, one should exercise judgement in the setting of new surgical approaches which may require the adoption of novel or atypical steps to complete the procedure.





3. Teaching, training and supervising

3.1 MEDICAL STUDENTS

If they have a formal role in training, Consultant surgeons should supervise trainees and make sure they act within the limits of their competence.

You should:

- explain to patients that they have the right to refuse to participate in student teaching and reassure patients that such a refusal will not prejudice their treatment in any way
- 2. ensure that students are introduced to patients
- ensure that privacy and confidentiality are maintained and that students understand and respect this requirement
- 4. ensure that when a student is involved in specific examinations or procedures on patients under general anaesthesia, consent has been obtained giving the full extent of the student's involvement
- communicate respectfully with students and refrain from dismissive or intimidating behaviour and inappropriate, offensive or pejorative language
- 6. not discriminate against, bully, or sexually harass a student under your supervision.

3.2 SURGICAL TRAINEES



If they have a formal role in training, Consultant surgeons should supervise trainees and make sure they act within the limits of their competence. The onus is on individual doctors to ensure they are registered appropriately with the Medical Council of Ireland and do not practise if not registered.

A surgeon should:

- 1. participate in the education of students, trainees and other healthcare professionals
- delegate duties and responsibilities only to those other doctors whom you know to be competent in the relevant area of practice (including obtaining informed consent from patients before surgery or other procedures)
- 3. provide guidance to trainees when more senior advice and assistance should be sought
- 4. ensure the trainee is suitably supervised throughout the procedure
- when on duty, be available to advise/assist the trainee at all times unless specific arrangements have been made for someone else to deputise
- 6. ensure that the trainee maintains an up-to-date portfolio that complies with the GDPR regulations and is accurate, legible and frequently updated
- ensure that you are competent to train, assess and mentor trainees by attending appropriate training courses provided by RCSI or another appropriate agency
- demonstrate that you are a competent trainer by keeping appropriate records of your training activities in your Professional Competence Portfolio

- take reasonable steps to ensure that the trainee is fit to undertake their responsibilities particularly with reference to fatigue, ill health or the influence of alcohol or drugs
- 10. ensure that assessment of trainees is carried out regularly, thoroughly, honestly, openly and with courtesy. A satisfactory assessment should only be provided when it is justified and you should record deficiencies or areas of practice that require improvement when required to do so. You should complete all required assessments in the trainee's portfolio in a timely and complete fashion.
- 11. communicate respectfully with trainees and refrain from dismissive or intimidating behaviour and inappropriate, offensive or pejorative language
- 12. must behave respectfully towards all colleagues, including students. You must not engage in any form of bullying, harassment, abuse, discrimination, undermining of colleagues, or condone such behaviour by others.

3.3 LOCUM/ TEMPORARY SURGEONS

Surgeons should not act as or be appointed as a locum/temporary Consultant Surgeon unless they are competent to do so and ideally are on the Specialist Division of the Medical Council Register. Local hospital arrangements may facilitate locum appointments from the General Division of the Medical register. Locum/temporary surgeons must perform to the standards detailed in this document.

Consultant surgeons involved in the selection of locum or temporary consultant surgeons should endeavour to ensure that the appointee:

- 1. is fully conversant with the routines and practices of the surgical team
- 2. is familiar with, and takes part in, the audit processes of the unit
- 3. does not become isolated and knows from whom to seek advice on clinical or managerial matters
- 4. is not required or expected to work outside their field of expertise.

3.4 RESPONSIBILITIES OF SURGICAL TRAINEES OR OTHER DOCTORS INVOLVED IN SURGICAL CARE

In addition to the requirements of all surgeons set out in this document, trainees should

- act, at all times, within the limits of your competence and, when presented with situations outside your competence, make your trainers or clinical supervisors aware of the situation
- ensure continuity of care for patients for whom you are responsible by formally handing over the patient's care to a responsible colleague at the end of their period of duty
- 3. be aware of the circumstances in which you are expected to seek advice and assistance from a more senior member of the team, understand the importance of seeking advice from someone with more experience, and know which consultant is on-call and seek advice or assistance when appropriate
- be available according to a rota published in advance, provide reasonable notice of planned absences (leave, training courses, examinations) and ensure rosters are appropriately amended in advance

- maintain all records relating to your training including an accurate contemporaneous logbook of all the procedures you undertake
- maintain legible and up-to-date clinical records (including operation notes as described earlier in this document)
- 7. support and assist your colleagues, especially more junior trainees
- 8. be prepared to share concerns about possible shortcomings in professional performance that you perceive in those with whom you work, whether senior or junior to you
- 9. inform the responsible consultant before a patient is taken to the operating theatre for a surgical procedure
- 10. recognise when you are unfit to work through fatigue, illness or the influence of alcohol or drugs and excuse yourself from duty in those circumstances and seek appropriate professional help.

4. Relationships with patients

4.1 CONSENT

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication in which the patient (or alternate decision maker) has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention. This process involves a supportive dialogue between the surgeon and the patient (and/or their approved alternate decision maker) and their supporters.

It is a legal and ethical requirement which must respect the patients' autonomy. It must be given freely. Patients must understand that they have the right to give, decline and withdraw consent at any time.

4.2 ASSISTED DECISION-MAKING ACT

The law relating to consent is currently evolving in Ireland and clinicians need to be aware of these changes. The Assisted Decision-Making (Capacity) Act 2015 provides for 3 tiers of decision-making support arrangements for people who lack capacity.

A patient may appoint a **decision-making assistant**, a **co-decision maker**, or a **decision-making representative** may be appointed by the Court. These roles are regulated by the Decision Support Service (DSS) which also maintains a register of co-decision-making agreements and decision-making representation orders.

The Assisted Decision-Making (Capacity) Act 2015 also allows for advance healthcare planning. A patient can now make an Advance Healthcare Directive, which is a legally binding document which enables patients to:

- Make an advance expression of their will and preferences concerning treatment decisions that may arise if they subsequently lack capacity and/or
- Appoint a designated healthcare representative who will have authority to make those decisions for them should they be unable to do so themselves.

If a patient is assessed as lacking decision-making capacity, you should take all reasonable steps to find out if the patient has an Advance Healthcare Directive. A person may lack capacity to make a decision if they are unable to understand, retain, use or weigh up the information needed to make the decision, or if they are unable to communicate their decision, even if helped.

Where a patient is not competent to participate in the consent process, their written will and preferences as set out in a valid Advance Healthcare Directive (Assisted Decision-Making Act 2022) must be respected. A request for specific treatment in an Advance Healthcare Directive is not legally binding but must be considered.

A refusal of treatment set out in an Advance Healthcare Directive shall be complied with if

- 1. at the time in question, the directive-maker lacks capacity to give consent to the treatment
- 2. the treatment to be refused is clearly identified in the directive
- 3. the circumstances in which the refusal of treatment is intended to apply are clearly identified in the directive' (e.g., might result in my death).



Basic care may not be refused. In the Act, basic care is defined as warmth, shelter, food and liquids provided orally and hygiene measures.

"A request for a specific treatment" is not legally binding but shall be taken into consideration during any decision-making process. A decision-making representative or designated healthcare representative for a relevant person may not refuse consent to the carrying out or continuation of life-sustaining treatment or consent to the withdrawal of life-sustaining treatment for the relevant person.

Where a patient does not have decision-making capacity, the doctor treating the patient must consider the views of any

person named by the patient as a person to be consulted, and any decision-making supporter or person with legal authority to act on behalf of the patient, and may also consider the views of a carer or any person with a bona fide interest in the welfare of the patient.

Only a registered decision- making representative or a designated healthcare representative may consent to treatment on behalf of a patient.

A legally designated Enduring Power of Attorney (EPA) has powers to make non-medical decisions only and is explicitly not permitted to make healthcare decisions.

The procedures set out in the Assisted Decision-Making (Capacity) Act 2015 to appoint decision-making representatives replaces the ward of court process. All current Wards of Court are currently undergoing review. As part of this transition process, the Court must decide whether a current Ward of Court needs a decision supporter. During the transition process, if surgery is indicated for a patient who remains Ward of Court, an application should be made to the President of the High Court to obtain consent for the procedure.

4.3 GOOD PRACTICE IN RELATION TO CONSENT

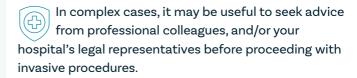
In addition to meeting the legal requirement above, a surgeon should:

- establish whether a patient has a close supporter whom the patient would like to be involved in the consent process as early as possible in the relationship and record this clearly on their notes
- 2. presume that every adult has capacity to consent
- 3. ensure that the registered doctor obtaining consent should have sufficient knowledge of the procedure, consequences, complications and alternatives to adequately inform the patient in advance. Doctors who do not feel they have sufficient knowledge to obtain consent should defer to senior colleagues
- 4. ensure that patients, including children, are given information about the treatment proposed, any alternatives and the risks, side effects and complications prior to a final decision to operate. You should also explain the nature of and expected outcome from non-operative alternative treatments
- 5. provide time for patients, their supporter(s) and representatives to discuss the proposed procedure and provide an opportunity for the patient to make a fully informed and unhurried decision to agree to the treatment proposed and to indicate, where possible, by signing a consent form that they are willing to proceed. It may be helpful to provide written or online material to help patients and their supporters understand the condition and the proposed treatment, and you should record that this was provided
- 6. give the patient the opportunity to indicate any procedure they do not wish to be carried out and ensure that those wishes are respected

- 7. make sure that the patient understands, and agrees to, the participation of students and other professionals in their operation and ensure their wishes are complied with as far as practicable
- ensure that the patient specifically consents (in writing)
 to the creation of video, photographic, audio or other
 records made for purposes other than the patient's
 records (for example, teaching, research or public
 transmission)
- 9. follow appropriate guidance for the retention of tissue
- 10. ensure the operative site is clearly marked with the patient's involvement while they are awake and prior to pre-medication
- 11. verify the operation to be undertaken by checking the consent form and, where possible, confirming this with the patient rather than relying solely on the printed operating list for the procedure being performed
- 12. ensure that written consent and the notes include, when appropriate, the side to be operated on using the words 'left' or 'right' in full
- 13. ensure that digits on the hand or foot are named and/o numbered and similarly marked with the patient' involvement while they are awake and prior to premedication
- record all discussions about consent in the patient's records
- 15. in an emergency, you should follow the known will and preference of the patients, provide appropriate urgent treatment and explain the proposed treatment to them and seek their assent. In seeking to establish the patient's will and preference, you should consult with the patient's

family where appropriate. A second opinion may be useful where there is a difference of opinion between you and the family. Where it is not possible to obtain a patient's consent, you should provide such treatments as are immediately necessary to save the patient's life or prevent serious harm to their health, unless you are aware of a valid and applicable advance refusal of such treatment.

- 16. ensure that patients with specific physical, cognitive, neurodiverse, cultural and language needs have access to the supports they require to engage in the consent process.
- 17. ensure that where consent is being sought for treatment in the setting of a language barrier that may have a significant impact on the patient's health and wellbeing, an interpreter proficient in the patient's language is available to facilitate informed consent. A professional interpreter should be used where practicable. The use of family (in particular of children and young people) and friends should be avoided if at all possible.
- 18. obtain patient consent prior to recording their surgical procedures. These may be edited and subsequently used for educations purposes, with the patient's consent.



4.4 CONSENT FOR TRANSFUSION

Surgeons should establish the views of their patients regarding their position in relation to transfusion as certain forms of transfusion may be unacceptable to the patient. You should respect those views and help patients avoid treatment which is inconsistent with their beliefs even when you believe that a successful clinical outcome is more likely with transfusion.

You should seek advice from colleagues and consider referring patients where special arrangements (autotransfusion, use of stored blood or cell saver equipment) is available. In the case of children, you should seek legal advice, as the courts may authorise transfusion in children when required despite parents' objections.

4.5 MAINTAINING TRUST

A surgeon should:

- ensure your working arrangements allow adequate time to listen and properly communicate with patients and their supporter(s).
- fully inform patients and their supporters of the plans and procedures for their treatment, the risks and anticipated outcomes and any untoward developments as they occur, or as soon as possible afterwards
- support any request for a second opinion and give assistance in making the appropriate arrangements including the timely supply of written or electronic records
- 4. obtain the patient's verbal consent before carrying out any clinical examination
- obtain consent to perform an intimate clinical examination (including breast, genitalia and rectum) and document this in the medical notes
- offer a chaperone when required to perform an intimate clinical examination and document this in the medical notes
- explain the purpose and nature of any intimate examination and observe local policies and guidelines relating to the conduct of such intimate examinations
- support a request by a patient for a third person to be present while they are undergoing any clinical examination
- 9. be aware of cultural differences and sensitivities and respect them
- 10. contribute to patient surveys and respond to their findings.

4.6 COMMUNICATION

All surgeons should:

- listen to and respect the views of patients, their will and preference as expressed by a valid decision supporter and the patient's supporters
- 2. listen to and respect the views of other members of th team involved in the patient's care
- 3. recognise and respect the varying needs of patients (or their alternate decision makers) for information and explanation and maximise the patient's ability to make his or her own decisions by providing information in a manner that is accessible to the patient and supporting all practicable measures to facilitate the patient's understanding of the information and communication of his/her decision
- 4. ensure that time be made available for a detailed explanation of the clinical problem and the treatment options
- encourage patients to discuss the proposed treatment with their supporter(s)
- 6. fully inform the patient and his/her supporter of progress during treatment
- 7. explain any complications of treatment as they occur and explain the possible solutions
- 8. act immediately when patients have suffered harm, openly disclose what has happened and apologise when appropriate. The HSE National Policy on Open Disclosure sets out your professional obligations in relation to open disclosure. You must comply with the requirement for mandatory open disclosure in certain circumstances set out above and, in detail, in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.





Apart from exceptional circumstances, surgeons should make formal arrangements for cover where they will be absent from practice. However, in exceptional circumstances, surgeons should take responsibility for patients under the care of an absent colleague even if formal arrangements have not been put in place.

4.7 WORKING WITH COLLEAGUES

A surgeon should:

- work effectively and amicably with colleagues in multidisciplinary teams, participate in multi-disciplinary team meetings, share decision making, develop common management protocols, where possible, and discuss patients' problems with colleagues. When sharing information about a patient with other healthcare professionals, you should ensure that there is a justifiable basis for doing so and only share such information as is necessary.
- 2. continue to participate in the care of and decisions concerning your patients when they are in the intensive care unit or the high dependency unit
- 3. respond to calls for help from trainees and others in the operating theatre and elsewhere as a matter of priority
- 4. ensure there is a formal handover of continuing care of patients to another colleague at the commencement of leave
- ensure that, when acting as manager or director, your practice is subject to the same scrutiny as the practice of others
- 6. ensure they do not denigrate another medical colleague or healthcare professional to the patient but raise concerns about the performance of healthcare colleagues in an appropriate way.



Ineffective team working must not be allowed to compromise patient care.

5. Probity in professional practice

Guide to
Professional
Conduct and Ethics
for Registered Medical
Practitioner



Surgeons should adhere to all the principles set out in the Guide to Professional Conduct and Ethics for Registered Medical Practitioner (9th edition 2024) and any updates or revisions.

In particular, when providing information to patients, a surgeon should:

- avoid any material that is designed to promote your own expertise, either in general or in relation to a specific treatment or procedure
- declare any commercial involvement that might cause a conflict of interest
- not seek to enhance their own practice by actively denigrating or inhibiting the practice of another surgeon
- 4. not criticise a colleague in an untruthful, misleading or deceptive manner
- 5. ensure that the literature and any promotional material provided by the institution where you work does not make unreasonable claims
- 6. exercise judgement in any interview in the media or on social media to avoid promoting your expertise or the performance of your institution
- 7. demonstrate honesty and objectivity when providing references for colleagues and team members
- 8. if providing medico-legal reports as an Irish Medical Council-registered practitioner, you should remember your duty is to the Court and be honest and objective in all your spoken and written statements.
- consider your primary duty when acting as an expert witness is to assist the relevant court or tribunal in providing an independent expert opinion

- 10. make clear the limits of your knowledge and competence when acting as an expert witness
- 11. not act as an expert witness in areas outside your scope of practice, experience and expertise
- 12. be aware that these obligations override any instructions from the person paying you a professional fee for your expert opinion.
- 13. note that you are legally responsible for anything you publish in work-based social media accounts.
- 14. consider how they might be viewed by patients or the public if comments or images made in your private social media account were to become more widely available

5.1 PRIVATE PRACTICE

A surgeon working in private practice:

- should take reasonable steps to ensure that the colleague or service to whom you delegate has the knowledge and skills to provide that care. Delegation involves requesting another health care professional or team to provide care on your behalf.
- should check that they understand and accept responsibility for the patient's care when you handover care of a patient to another healthcare professional, team and/or institution
- should maintain the expected standard of record keeping (Section 1.5) and audit your surgical activity and outcomes
- 4. should be honest in financial and commercial matters relating to work
 - a. ensure that patients are made aware of the fees for their services and cost of any treatment by quoting, where possible, your professional fees in advance
 - b. inform patients if any part of the fee goes to any other doctor
 - c. you must not allow commercial incentives to influence or appear to influence treatment given to a patient
- should make clear to patients the limits of care available in the hospital where they will be treated (for example, the level of critical care provision provided and the level of resident medical cover)
- should not commit to your private practice in a way that prevents you from meeting your public ethical and contractual obligations

- should not use public staff or resources to aid your private practice unless specific arrangements have been agreed with Hospital management in advance
- 8. should ensure that claims made to insurers, the SE and other providers are legal, honest and appropriate to the service provided.

5.2 RESEARCH

HSE National Framework for the Governance, Management and Support of Health Research











The HSE National Framework for the Governance,
Management and Support of Health Research (RGMS
Framework) articulates the requirements for appropriate
governance and management of research in health services.
All research should be conducted according to the RGMS
Framework principals.

If you act as an investigator in a clinical trial or any form of medical research, you must submit and receive approval from the relevant research ethics committee before the research begins. You must make sure that the trial conforms to the <u>Declaration of Helsinki</u> and any relevant national policies and legislation.

Surgeons who undertake research should:

- engage with local, regional or academic research office and follow requirements for conducting research studies
- identify the category of their research study; research, clinical audit, registry, service evaluation to identify processes required for conducting their study by referring to <u>hseresearch.ie</u>
- consult with a statistician to ensure study design is appropriate for the research objectives
- 4. consider Equality Diversity and Inclusion within study design to ensure broad clinical relevance and adoption

- engage with patients/ persons with lived experience when designing study protocols and patient-facing documents such as the Patient Information leaflet (PIL), consent form, questionnaires and any advertising material
- 6. ensure the PIL details the aim of the study, what is expected for participation, the risks and benefits to participating, alternative treatment options, details on confidentiality and how their personal data will be used, advising that participation is not mandatory, information on their right to withdraw participation at any time, an that it will not have an impact on their clinical care. Contact details of the study team should be included
- 7. ensure that a signed consent form is in place prior to including a patient in a study
- 8. not offer incentives to patients, either financial or other, in such a way that they may influence a patient's decision to participate in the research
- 9. endeavour to consider the assisted decision-making capacity act when including participants in their study.
- 10. identify the relevant ethics committee to apply to; local hospital ethics committee, academic research & ethics committee, National Research Ethics committee, European Medicine Agency and comply with their requirements <u>hseresearch.ie/research-ethics</u>
- fulfil the strict regulations of the appropriate legislation when obtaining permission to carryout research on animals - <u>RCSI research-ethics</u>
- 12. identify a trial sponsor if the study is interventional. Any study that randomises patients is considered interventional. Sponsorship is provided by an













Health Research
Consent Declaration
Committee



ICH E6 Good clinical practice - Scientific guideline



HSE Data Protection and research



- academic or industry partner. Hospitals or Investigators cannot be sponsors of interventional trials. Non interventional studies do not require a sponsor.
- 13. contact the <u>HPRA</u> if their study involves the use of a medical device, irrespective of its CE mark status or use as standard practice, to check if it is considered a regulated Clinical Investigation. <u>Devices@HPRA.ie</u>
- 14. contact the HPRA if the study involves a medicine, irrespective of whether its use as per standard care and being used within its authorised licence, to check if it is considered a regulated Clinical Trial clinicaltrials@hpra.ie
- 15. check the requirements for a consent declaration with the <u>Health Research Consent Declaration Committee</u> (HRCDC) if research involves patients who do not have the capacity to consent, such as those with cognitiv impairment <u>hrcdc.ie</u>
- 16. ensure all appropriate contracts and insurance is in place where relevant.
- 17. conduct research that adheres to <u>ICH-GCP</u> which is a set of internationally recognised ethical and scientific quality guidelines that must be followed when designing, conducting, recording and reporting research.
 <u>ICH E6 Good clinical practice Scientific guideline</u>
- 18. conduct research according to the General Data protection Legislation (GDPR) and the Health Research Regulations (HRR) and identify local data protection requirements by engagement with the Data Protection Officer and conducting a Data Protection Impac Assessment (DPIA) where appropriate HSE Data Protection and research

- 19. report any data breaches as per the local hospital policy
- 20. report any fraud that is detected or suspected to the relevant research ethics committee.
- 21. not publish research findings in non-scientific media before reporting them in reputable scientific journals or at meetings
- 22. disclose all financial interest in, for example, pharmaceutical companies or medical device manufacturers in study documentation and publications. This is a mandatory obligation
- 23. ensure that anything regarding the project that may be published online or elsewhere follows ethical principles and does not contain any patient identifiable information

5.3 ADVERTISING

Informing the public about medical procedures is important. There is a difference between information and advertising.

Surgeons should

- ensure that all advertising of their services complies with Advertising Standards Authority of Ireland and Medical Council Guidelines. Information must be evidence based, factually accurate, ethical, truthful and not misleading
- ensure that unrealistic claims about surgical outcomes are avoided and information provided must be true and verifiable, does not make false claims and does not have the potential to raise unrealistic expectations
- 3. not make false claims regarding their qualifications, experience and membership of professional bodies
- 4. include reference to your having a specialty if the specialty is one recognised by the <u>Medical Council</u> and you are entered for that specialty in the Specialist Division of the Register
- be personally responsible for the nature and content of all advertising relating to your services, including any advertising undertaken by a 3rd party using their name

The above includes all verbal and written statements on websites, electronic and other media.





6. Health

As a surgeon, you must not compromise the safety of patients or other healthcare professionals because of your ill health, fatigue or the effects of drugs or alcohol on your performance.

Surgical procedures place surgeons at particular risk of acquiring and transmitting blood-borne viruses which can cause serious communicable diseases such as hepatitis and HIV. You must take appropriate precautions and follow established guidelines when operating on high-risk patients.

All surgeons have a duty of care to their patients and you must seek appropriate professional help if you believe your performance may be impaired due to illness (including drug or alcohol dependency) and that you may place your patients at risk or otherwise fail to meet your professional responsibilities as outlined in this document.

If you have concerns about your health, you should consider seeking guidance and support from colleagues and /or family and friends, or support services provided by a professional body or organisation. If you have a condition which could be a risk to patients or which could seriously impair your judgement, you must consult an appropriately qualified professional and follow their advice. This professional will have a dual role: to help and advise you, and to make sure you do not pose a risk to yourself, patients and others. If such a risk exists, you must inform the Medical Council as soon as you become aware of it.

Surgeons also have a duty of care to inform the appropriate authority if you know of a colleague who may have a serious illness which is liable to put patients at risk.





7. Surgical care in special settings

7.1 ARMED CONFLICT

- Ideally, only operate at the request of the patient. If the
 patient is incapable of giving consent, then you should
 provide such treatments as are immediately necessary to
 save the patient's life or prevent serious harm, unless you
 are aware of a valid and applicable advance refusal of
 such treatment.
- 2. You must not discriminate between the protagonists and should treat on the basis of clinical need alone
- 3. Within the limitations of the circumstances, you should maintain the highest professional standards
- 4. Take personal precautions consistent with providing the highest level of care.



You should not put yourself or others at risk of harm when assessing or treating a patient.

7.2 LOW RESOURCE ENVIRONMENTS

Surgeons seeking to participate in healthcare provision in low-income countries through the provision of surgical services should do so responsibly. You should do so with the intention of providing high quality care to individual patients within the resource limits in that territory.

In undertaking work of this nature, a surgeon should:

- identify appropriate placements that match your skill set using existing programmes or agencies with experience in this area.
- ensure that the service you can provide is responsive to local needs and that you do not undermine existing local surgical services. Ideally, establishing long term collaborative interactions will best ensure sustainability and the provision of long-lasting support for the local healthcare providers.
- 3. avoid using complex technology in rural settings to ensure sustainability, but promote local innovation and participate in creating frugal solutions.
- 4. ensure that time is set aside to train these local healthcare providers making sure that such training is not an additional burden on other time commitments and usual workloads. You should consider including other healthcare professionals in your group to facilitate this process. Team training initiatives and multi disciplinary educational activities are encouraged.
- ensure that surgical trainees accompanying you on such trips are adequately supervised. These trainees should be able to teach and train and the training of local health providers should take priority.
- ensure that the outcomes following surgery are monitored and establish follow up protocols for specific/ prevalent cases

- consider the financial impact on the host institution and ensure the reduction of this burden, in order to maintain sustainability
- 8. ensure that surgical initiatives work in conjunction with, and in support of, local and regional training programmes
- 9. ensure that you comply with all local legal requirements including those relating to registration and indemnity
- 10. never participate in mutilating operations
- 11. ensure any related research is undertaken to a high ethical standard, with the full awareness and agreement of the local and national communities and health agencies, and with local faculty involvement. IRB submissions and consent forms should be prepared far in advance and reviewed by local stakeholders according to their laws and institutional regulations. Approval of such documents must happen at both institutions (foreign and local).

Further guidance is available in <u>Guidelines for Surgeons on Establishing Projects in Low-Income Countries</u> (Grimes et al) which is endorsed by RCSI.

Guidelines for Surgeons on Establishing Projects in Low-Income Countries



7.3 PRISONS

All of the provisions of this document apply when treating prisoners.

You must not condone or contribute to inflicting physical or mental suffering whether deliberately, systematically or wantonly. You should report evidence of abuse and deliberate injuries to the appropriate authority. You should respect the patient's right to privacy.

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HSE Research and Development hseresearch.ie

Acknowledgements

RCSI would like to recognise the contribution of our fellows and members who provided comprehensive feedback on this document during a consultation process.

In addition, we would like to recognise the particular contribution of the following:

Mr Dara Kavanagh FRCS, Head of Surgical Policy and Practice Development, RCSI

Mr Kieran Ryan, Managing Director, Surgical Affairs

Ms Marie O Boyle and Ms Miriam Kennedy, PCS Team RCSI

Dr Anne Marie Byrne, Operations Director / National Surgical Research Support Centre (NSRSC)

Medisec Ireland for their valuable insights

The late **Professor Arthur Tanner** FRCSI who authored the first version (2004) and the late **Professor Sean Tierney** FRCSI who authored the second version (2016)

In addition, we would like to recognise the particular contribution of the members of the **Professional**Development and Practice Committee and Committee for Surgical Affairs (2025)

Mr Paddy Kenny FRCS, RCSI Council member and Chair of the Professional Development and Practice Committee (2024-2026)

Professor Laura Viani (President RCSI, 2022-2024)

Professor Deborah MacNamara (President RCSI, 2024-2026)

Professor John Quinlan FRCS, RCSI Council member and Chair of Committee for Surgical Affairs (2024-2026)

RCSI Council (2024-2026)

