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Guide to Consent for Medical Ultrasound Examinations

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I Introduction

Purpose of the guide

This document has been developed to provide general guidance to sonographers on the principles and requirements ofobtaining consent for medical ultrasound examinations. The goal is to reduce potential harm, improve patient satisfaction, and manage medico-legal risk.[1]

Scope and applicability

Consent is a process by which a patient voluntarily confirms their willingness to undergo a particular examination, after having been informed of all aspects of the examination that are relevant to their decision.[2]

Consent should be obtained before commencing any ultrasound examination and sonographers must respect the autonomy and the right of the patient to determine what happens to their own body,[2-4] and to refuse the examination.[5]

This guide covers the process that sonographers should use to obtain consent, including what the patient needs toknow, and how consent should be recorded. It includes the process of consent for sonographers, including special circumstances that may arise. This guide does not cover consent for intimate examinations.

This guide is provided to inform members of the Australasian Sonographers Association (ASA) on general consent procedures. It should be read with other guidelines, the ASA Sonographer Code of Conduct, additional documents related to ASA membership, workplace protocols and other relevant regulation (see Appendix 1: Resources for Sonographers). Consent should be appropriate to the examination being undertaken and comply with laws of the relevant jurisdiction(s). More broadly, non-ASA members, other healthcare professionals, patients and other stakeholders may find this document provides useful information. This document provides information and guidance only. It does not provide legal advice. Members should seek independent legal advice as required.

Disclaimer

Date, Review date

This guide was produced in May 2024 by the ASA's Research and Standards team after consultation with ASA's Sonographer Policy and Advisory Committee and members. Feedback was obtained from key stakeholders. ASA Board approval September 2024. This guide will be reviewed September 2027.

II General principles

Role of Sonographer in consent process

Patients have a legal and ethical right to be given the opportunity to accept or decline any ultrasound examination. This is based on the fundamental human right and ethical principle that a person has the right to decide what is appropriate for them,[5] considering their individual circumstances, beliefs, and priorities.[1]

The sonographer's role in the consent process, is part of a continuum involving a wider health team involved in patient care.[3] In medical imaging (i.e., ultrasound), it is the responsibility of the person conducting the examination to obtain consent and they must do so before touching or examining a patient.[6] The sonographer should never make assumptions:

- that the patient has already provided consent for the examination to another health professional or support staff,
- about the information the patient wants or needs,
- about the things that are important to the patient,
- and/or about the level of knowledge or understanding about the examination that the patient has.[6] The sonographer must be sure the patient is genuinely consenting to the examination being undertaken.[4]

What is consent?

Consent must be voluntary and specific to an examination, the patient must be provided with accurate and sufficient information to enable them to make an informed decision.[7] The patient must fully understand what has been explained to them and they must be given the opportunity to ask questions and discuss any concerns they may have.[2,7,8]

Suitable consent for ultrasound examinations [6,7]

Verbal consent: is provided by the person when they say they agree to undergo the ultrasound examination. Verbal consent involves a full and open discussion, followed by clear verbal agreement from the patient. It is suitable for low-risk routine examinations.

Written consent: Written consent is provided by the patient when they provide written evidence of their agreement to the examination, for example, by signing a consent form. This should be held within the person's record. Written consent is onlywritten evidence, it does not replace the process to obtaining consent, i.e. providing the patient with relevant information about the examination.

Written consent by a person must be obtained when required by law or by the policies of the state, territory or healthcare organisation from the person undergoing the examination.[2] Written consent is appropriate when the examination is complex or has significant risk and/or side effects. Examples are examinations involving contrast administration or interventional procedures. Written consent should also be considered when clinical care is not the primary purpose of the examination (for example clinical trials, research studies), or if there are significant consequences for the person's personal/work life. In almost all cases, written consent is not required for non-interventional ultrasound examinations. When performing interventional or intimate ultrasound examinations, sonographers should be guided by local protocols or relevant legislation. More information can be found in ASA's Consent and Chaperones for Intimate Medical Ultrasound Examinations guide.

III Process of obtaining consent

What information should be provided?

The type and amount of information provided will depend on the reason for the examination, the complexity of the examination and associated risks, the person's temperament, health, wishes, the surrounding circumstances, any local legal, professional, ethical, or other relevant standards,[5] and any questions the patient ask.[7] If sonographers are asked questions that are outside of their knowledge or scope of practice, then they should defer the question(s) to either the treating/referring/ health professional or the medical specialist responsible for the examination. Such questions may include those about the patient's clinical management, or the consequences of not proceeding with the proposed ultrasound examination or a proposed alternative.

At minimum, the patient should understand: [3,4,7]

- That having the ultrasound examination is voluntary, they have a right to refuse without consequence, and consent may be withdrawn at any time without consequence.
- Who is undertaking the examination. Patients can expect that their examination will be performed by a qualified and competent sonographer working within their scope of practice[1], or by a student who is supervised by a qualified and competent sonographer. If a student is undertaking the examination, the patient should be aware of this.
- The nature of the examination (i.e. what to expect, its invasiveness, any pain, discomfort, or other sensations they may feel, and how long it will take).

How should information be provided?

Consent relies on sonographers effectively communicating with their patients (or with their decision makers/support persons). The discussion regarding consent should be a two-way and ongoing conversation.[5,6]

Verbal information should be provided in plain language. Always check that the person understands the information provided. If a patient has difficulty in demonstrating an understanding of the information provided, then the reasons for this need to be assessed. Reasons may include lack of capacity, health literacy, cultural differences, education level, or physical issues (such as hearing or speech impairment). Information must be presented in ways that overcome these difficulties. A patient should be given the opportunity to choose a support person, or carer, to be part of discussions.

The following are suggestions a sonographer might consider when communicating in verbal or written formats, to ensure the patient understands the purpose and scope of an examination for the purposes of securing consent.[1]

- **Children as Patients**: Treat each child as an individual. Use age-appropriate vocabulary and incorporate illustrations to aid understanding.
- **Patients with Learning Disabilities**: Simplify the explanations and consider incorporating symbols and images into visual material. Consider using supportive materials like videos or books. Seek guidance from caregivers, support groups, and professionals.
- **Patients with Hearing Impairments**: Offer written information or use Australian Sign Language (Auslan) or New Zealand Sign Language (NZSL) interpreters. Transcription smartphone/tablet apps such as "Live Transcribe" may be useful. Consult with caregivers if appropriate to ensure comprehension.
- **Patients with Visual Impairments**: When presenting written material, use large, clear print (at least

14-point font). Consider using audiotapes, electronic text, or Braille, depending on the patient's needs. Avoid using reversed-out text and ensure there is a strong contrast between text and background for readability.

- **Non-English-Speaking Patients**: Provide translated text using a reliable translator. Remember that some languages are spoken but not written, so check this beforehand. Consider using other resources like audiotapes,videos, and professional interpreters where appropriate. Translation apps may be useful but should only be used in circumstances when professional interpreters are not available.
- **Patients with Reading Disabilities**: Think about using audiotapes and videos as alternatives to written information sources.
- **Expert Patients**: These are patients with long-term medical conditions who often have a deep understanding of their condition, related vocabulary, research, and information. They may require specially researched information by experts or assistance in finding the most reliable and current information.

Sufficient time must be given to the patient, their decision maker, or their support person(s) to consider the information and provide them with an opportunity to ask questions or raise concerns. Except in emergencies (see Emergencies in Section IV), this may require discussions over an extended time interval, or delaying/rescheduling the appointment especially for complex examinations, or when patients need longer time to assimilate the given information and make decisions.[2]

The sonographer must ensure that their patient does not feel pressured or obligated to proceed with the proposed examination,or that the patient does not feel pressured to proceed by another person. The patient should not feel as though they have no choice but to proceed.[8] It can be useful to provide the patient with relevant written or oral information prior to the appointment, such as at the time of booking, or to have written material or displays available in waiting rooms.

Sonographers can be satisfied that a patient has understood the information provided by[6]:

- Asking the patient or decision maker to summarise what they have understood in their own words.
- Providing the opportunity for questions and tailoring responses to the patient's (or patient's decision maker's) level of comprehension.

Consent; an ongoing process

A tick box approach to information-giving and consent is not appropriate in a professional context nor is it helpful for the individual. Consent is a flexible process, and sonographers should be aware that a patient can withdraw consent at anytime,[9] even after signing a form or after an examination has commenced. If consent is withdrawn the sonographer should not proceed with the examination. Sonographers should also be aware, throughout the examination, of any cues provided by the patient of discomfort or reluctance to proceed. If this occurs, then consent to proceed needs to be re-established before continuing with the examination.

Documentation

Consent may be verbal or in writing.[6] In the case of written or verbal consent having been obtained, confidential records must be kept,[6] such as on a referral letter, sonographer worksheet, medical report or within an electronic record.The method of recording consent at the time of the examination, will vary depending on the degree of significance of the examination to that person, the potential risks and benefits of the examination,[9] the characteristics of the examination, and whether the imaging is time-critical (e.g. in emergency situations). It is more important to have the consent process and its outcomes formally documented when the examination is

complex, invasive and carries high risks. The method of reporting is discretionary depending on departmental protocols, and legislative requirements.

Documentation not only serves as a record of the consent process but also demonstrates adherence to professional standards and legal requirements. At minimum, regardless of if written consent was obtained or not, we recommend that the sonographer records:

1) whether consent was verbal or written,

2) if consent was not given or withdrawn and the reasons why (if this information has been volunteered by the patient).

It is also prudent to record any relevant details of the consent process, such as discussions about any implications of not consenting, and any perceived difficulties in obtaining consent.[6] Documentation of the conversation may assist in the event of a complaint or legal proceedings.

IV Special considerations

Sonographers will encounter patients who are vulnerable or who are not capable of, or do not legally have capacity to provide consent. A person is deemed to have legal capacity to make a decision about having the examination if they:

- comprehend the information provided to them,
- can retain the information and recall the details,
- can weigh up the risks and benefits of consenting or not consenting,
- can communicate their decision and the implications of the decision.[2]

The sonographer must be confident that the person i.e. the patient or a substitute decision maker, consenting to the examination understands the information and their ramifications in the consent discussion. If there is any question as to whether the patient or decision maker may not appreciate the nature and consequences of the consent discussion due to a language barrier, the healthcare practitioner requesting the intervention must ensure that someone is present that can provide translation.[9] If there is any doubt of the patient'scapacity to provide informed consent, you should not proceed. Instead, consult with the medical practitioner responsiblefor the examination (i.e., radiologist) and/or refer the patient back to the referring physician/authorised health professional for acapacity assessment and/or consent discussion. You should also document your discussions and actions in the appropriate patient record.[6,8]

Vulnerable people

In some scenarios, patients lack the ability or desire to be assertive at a time when they are potentially vulnerable. In these situations, they may need an advocate, or person to 'speak on their behalf.[4] Special consideration needs to be given to establishing capacity and obtaining consent from patients who are; injured, in pain or in shock, drug or alcoholaffected, sleep deprived.[1]

Intellectually disabled people or persons with reduced mental competency

These people cover a spectrum of disability. If the sonographer is concerned that the patient is not capable of giving consent, the legal guardian (i.e., parent or other legally appointed decision maker)should be approached to provide consent. If further difficulties arise in obtaining consent an approach should be made to the appropriate guardianship tribunal or authority in different jurisdictions (see Table 1 in Appendix 1: Resources for

Sonographers).

Pregnancy

Although ultrasound is the preferred method of assessing fetal health, it is important to address any fetal safety questions and/or concerns that pregnant patients may raise to ensure consent is obtained.

Children or young people

A combination of common law principles and statutes guide the consent process for medical procedures on minors, and these will vary by jurisdiction. It is important to balance parental (or guardian) authority with a child's evolving maturity and capacity to make informed decisions about their healthcare.[10]

Persons over the age of sixteen are able to provide or refuse consent to most ultrasound examinations, if they are able to understand the nature, purpose, and consequences of having, or not having, the examination.

Persons under the age of sixteen may be able to consent to an ultrasound examination, provided they are able to understand the nature, purpose and consequences of having, or not having, the examination.

Persons over or under the age of sixteen who do not have this level of competency may not be capable of giving consent. Different jurisdictions have specific provisions/legislation for dealing with the ability of minors to provide consent.

It is advised that whenever possible, even if a minor has the capacity to make decisions about their healthcare, the consent of a parent or guardian should be sought. This may not be possible if a minor with decision making capacity specifically requests that the parent or guardian should not be involved in the decision-making.

Emergencies

In an emergency when consent cannot be obtained the ultrasound examination should be performed for anyone who needs it, provided the examination is limited to what is immediately necessary to save life and avoid significant deterioration in the person's health. The best interests of the person are paramount in these situations.

In less time-critical emergencies consent should be obtained and decisions should be made with the consent of the next of kin or legal guardian wherever possible.[7]

Student/trainee

Before a student/trainee can conduct an examination, it is important to ensure that[1]:

- Trainee/students are introduced to the patient to ensure it is clear they are students.
- Patients are aware they have a right to decline consent to the student observing/providing care.
- Students are appropriately supervised and operate within the limits of their professional competence.

Aboriginal and Torres Strait Islanders

Patients identifying as Aboriginal and/or Torres Strait Islanders, whilst having capacity to make decisions, may choose to involve a substitute decision maker for cultural reasons.[11] This should be discussed with the patient prior to the examination. The services of an Aboriginal or First Nations Liaison Person or health worker may be offered to the patient where available.[12]

When obtaining consent, communication should be respectful of culture and respect Aboriginal and Torres Strait Islander knowledge. Sonographers should be aware of potential past and existing trauma experienced by Aboriginal patients and consider the health literacy of Aboriginal patients.

Māori people

Requesting consent to touch or examine a Māori person is crucial before scanning. Be clear in explaining what parts of the body will be touched, and why they will be touched. Avoid touching the patient's head casually. Any whānau member(s) who is present may not wish to remain during the examination; check with the patient and the whānau as to what the preferences are.[13] Whānau refers to family or extended family.

V Training and Education

Sonographer training should include knowledge and skills development in the consent process. It is the responsibility for sonographers to stay updated with the latest legal requirements, relevant to their jurisdictions and best practices.

VI References

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VII Appendices

Appendix 1: Resources for Sonographers

Table 1: Contact and websites for information relating to different guardianship and/or medical treatment legislation across different jurisdictions.[2]

State/territory	Contact
ACT	Public Trustee and Guardian 02 6207 9800 www.ptg.act.gov.au
NSW	NSW Civil & Administrative Tribunal Guardianship Division 1300 006 228 and press 2 13 14 50 (interpreter service) Email: gd@ncat.nsw.gov.au www.ncat.nsw.gov.au
NT	Office of the Public Guardian 1800 810 979 Email: public.guardian@nt.gov.au http://publicguardian.nt.gov.au
QLD	Office of the Public Guardian 1300 653 187 Email: publicguardian@publicguardian.qld.gov.au www.publicguardian.qld.gov.au
SA	South Australian Civil and Administrative Tribunal 1800 723 767 Email: sacat@sacat.sa.gov.au www.sacat.sa.gov.au
TAS	Guardianship and Administrative Board Tasmania 1300 799 625 Email: guardianship.board@justice.tas.gov.auwww.guardianship.tas.gov.au
VIC	Office of the Public Advocate 1300 309 337 mail: opa_advice@justice.vic.gov.au www.publicadvocate.vic.gov.au
WA	Office of the Public Advocate 1300 858 455 or 08 9278 7300 Email: opa@justice.wa.gov.au www.publicadvocate.wa.gov.au
NZ	Ministry of Justice, New Zealand 0800268787 https://www.justice.govt.nz/ Care of Children Act 2004, Parliamentary Counsel Office, New Zealand https://www.legislation.govt.nz/act/public/2004/0090/latest/DLM317462.html