Policies, Standards, and Guidelines

Discussion Paper on Consent

Approved by ASUM Council June, 2018

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Discussion Paper on Consent

1. Summary
Consumers of medical ultrasound examination have the right to make an informed choice in providing consent or refusing a procedure. Informed consent should always be obtained for invasive procedures.

Maintenance of accurate records regarding consent including Consent Forms is an essential part of professional ultrasound practice and highly recommended. In doing so, the ultrasound practitioner ensures that the patient understands why and how an examination may be performed and the associated risks, benefits and cost of the examination. A patient retains the respected right to withdraw consent at any time without giving a reason.

The aim of this Discussion Paper is to provide a rationale for all involved in the clinical practice of diagnostic medical ultrasound in obtaining a patient's Informed Consent. A consistent process involving informed consent, outlining the documentation of valid consent and the purpose of maintenance of thorough record-keeping. Sonographers/Sonologists who do not obtain and record the informed consent from their patients may be liable to legal and/or disciplinary action.

Where the document references patient interaction with regards to the consent process, it is implied that in instances where the patient due to their medical or other condition is incapable of meaningful participation in such process, the same framework of principles applies to the surrogate decision-maker, in most instances the Next of Kin or Person Responsible.

2. Background
Fundamental to ultrasound practice as part of patient-centred health care and treatment is an informed decision-making process of the consumer, consisting of effective two-way communication between patient and health professional. A successful relationship between healthcare provider and patient relies on communication and trust. An informed decision-making approach involving the consumer’s right to accept or refuse health care, based on them being given adequate information, is now deemed a valid and essential part of that process. It is based on the fundamental human right and ethical principle that a person has the right to decide what is appropriate for them, taking into account their individual circumstances, beliefs and priorities.

Patient consent involves the granting of agreement or permission by a consumer to an ultrasound procedure. If consent is not established, there may be legal consequences for health professionals. Patient consent must be gained voluntarily, without coercion and with respect for the patient’s autonomy. Under the law of trespass, patients have a right not to be subjected to an invasive procedure without consent or other lawful justification, such as an emergency or other valid necessity. For a patient to exercise this right to decide, they require information that is relevant to them and their own circumstances including knowing and understanding the risks and benefits of the proposed health care and treatment. The health professional is responsible for providing the relevant and material information and obtaining consent before embarking on the health care and treatment.

In Australia, all competent adults can consent to or refuse a test or medical treatment. Under the law of trespass, patients have a right to not be subjected to an invasive procedure without their consent or other lawful justification (for example under Duty of Care, in the case of time-critical procedures undertaken to preserve life, where patient consent is unobtainable and a surrogate decision-maker is
unavailable, consent or other lawful justification. If the patent waives his or her right to be informed, this should be noted in the patient record.

3. Guiding Principles

Informed consent should reflect the following principles:

- **Is given in a voluntary manner** – the decision to either consent or not consent to the proposed procedure must be made by the patient themselves, and has not been unduly influenced by health professionals, friends or family.
- **Informed** - The patient has provided his/her consent based on a full understanding and informed decision based on the provision of relevant and sufficient information supplied by the provider on the nature of the procedure and any inherent risks.
- **The patient has the capacity** to understand the information presented to them, appreciate what is involved regarding any potential consequences, and to make an informed decision. The information is provided in a form that the patient understands. Capacity may be diminished by illness, age, language barrier, medication, drugs and alcohol (amongst other things).
- **The currency** of the consent given has not been diminished through a change in the patient’s circumstances (including treatment options and risks, health state), or has been updated due to an excessive time lapse.
- **The consent given is specific and covers the ultrasound procedure/treatment to be performed** - treatment provided must fall within the scope of consent that has been given by the patient.

Consent is always sought, except in special circumstances such as an emergency. For informed consent to be valid, the person explaining the procedure must be familiar with it, understands the risks involved, alternative treatments or procedures that may be available, any potential complications and answered all questions the patient may have. An interpreter may be required if English is not the person’s first language.

The assessment of patient competence is often complex. It relies on an ability of the patient to comprehend, retain and compare information regarding options to make a decision, and be able to communicate that decision to the healthcare professional. If someone doesn’t have the decision-making capacity for providing informed consent, normally a power of attorney, guardian, prescribed relative or person responsible consents to medical procedures/treatment.

Consent should be given by an adult (or over 16 years, for example, in SA). In all cases, check with local jurisdictions. For example, in SA, the provision of medical procedures/treatment to children under the age of 16 years may be provided with:

- the consent of a parent or guardian, or
- the consent of the child, if a medical practitioner considers the child is capable of understanding about the nature, consequences and risks of the proposed treatment, the treatment is necessary for the child’s health and wellbeing and there is a second medical opinion supporting that treatment.

The type of consent provided will vary based on the procedure being performed, local requirements and governing bodies. The nature and type of information supplied to inform the consumer’s consent will be in accordance with any local legal, professional, ethical, or other relevant standards.

In some cases, verbal consent may be all that is required before proceeding with an ultrasound. Informed consent should always be obtained and documented for invasive procedures. The ultrasound examiner should indicate to the patient those risks which are significant. More information regarding the risk of harm is required for a patient with a serious condition and/or undergoing a more complicated or invasive procedure. Significance involves (i) the likelihood of occurrence and (ii) the
seriousness of the risk. If a severe potential complication of a procedure is detailed, it is recommended that the incidence be conveyed.

Obtaining written consent involves the patient signing a permission form, finalising the consent process and indicating an understanding of information provided about the ultrasound procedure. Sonographers/sonologists should ensure they are aware of local policies and requirements. For Australian practitioners who have to comply with DIAS, please note DIAS Standard 2.2, Consumer Consent and Information Standard.

Certain procedures, for example, genital examinations under anaesthetic, transvaginal ultrasound scans and evaluations for suspected sexual assault should be performed only by those who have satisfactorily completed relevant training. For example, if performing a transvaginal scan, local recommendations/policy on the consent process of the transvaginal scan should be adhered to. For practitioners in WA, the transvaginal scan is an invasive imaging procedure which requires written consent. Local policies requiring the use of a chaperone and patient privacy issues should be adhered to.

Practitioners in New Zealand must adhere to the Code of Rights of Consumers and Duties of Consumers, specifically:

- **Right 6: Right to be Fully Informed**
  1. Provision of a clear explanation of the patient’s condition, options, any side effects, risks.
  2. The right to information helping inform choices and consent.

- **Right 7: Right to Make an Informed Choice and Give Informed Consent**
  1. Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.

Carefully filed and securely stored documentation maintain a confidential record of the informed consent procedure, the conversation that occurred, and that the patient agreed to the proposed treatment.

Informed consent involves a patient’s right to understanding treatment options, what procedures are involved, likely outcomes, benefits, any risks and any potential complications.

It should be noted, that depending on relevant local policies and regulations, consent for a procedure involving medical imaging does not automatically constitute consent for use of the recorded images (even if de-identified) for any other purpose. It is recommended to always obtain and document consent if there is perceived potential for images obtained during a procedure to be later used for educational or scientific purposes.

**Related/Supporting documents**

The following documents are required to give effect to this policy:

1. ASUM Guidelines on the Performance of a Gynaecological Scan.
2. Guidelines for Reprocessing Ultrasound Transducers.

**Supporting information/References**

The following documents provide support and further information regarding the points raised in this Discussion Paper:

1. NZ Health & Disability Commissioner, *Code of Health and Disability Services. Consumers’ Rights* 2018
4. NSW Health, *Your Health Rights and Responsibilities* 2011
5. NSW Health, *Consent to Medical Treatment - Patient Information* 2005
6. SA Health, *Consent to Medical Treatment and Health Care Policy Guideline* 2014
7. NZ Ministry of Health, *Consent in Child and Youth Health: Information for Practitioners* 1998
8. NZMC, *Information, choice of treatment and informed consent* March 2011
9. RANZCOG, *Consent and provision of information to patients in New Zealand regarding proposed treatment* March 2013, reviewed March 2016
15. Faculty of Radiation Oncology RANZCR, *Guidelines for Informed Consent Version 2.0* 2017

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Approval

This Discussion Paper has been approved and issued by the ASUM Council.

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