10. Consent for specific treatment/procedures

10.1. Blood transfusions

The administration of a blood transfusion or the administration of blood products requires written consent. Blood products include red cells, white cells, platelets, albumin products, fresh frozen plasma, Anti-D Immunoglobulin, coagulation factors, autologous transfusions and any biologically-derived products such as thrombin products.

Consent for a blood transfusion or the administration of blood products must be obtained by the Admitting Medical Officer or a Health Practitioner to whom the task is properly delegated. In most cases, it should be obtained by a Medical Practitioner.

These requirements may not be practical in small rural hospitals where there are no resident medical staff to provide the information to the patient and obtain a completed consent form. There are also circumstances where it is appropriate for Nurses or Midwives to administer standardised therapeutic interventions (for example routine administration of Anti-D). Health Services may develop local policies to address these situations. In developing such policies, Health Services should have regard to the following:

- The decision to recommend a blood transfusion or administer blood products to a patient must be made on a case-by-case basis. To ensure that the clinical need for such treatment is established, appropriate arrangements should be put in place so that such decisions are made by a Health Practitioner who is fully informed of the clinical circumstances of the patient.
- Health Services should provide, where necessary, additional training to appropriately skilled Nurses or Midwives so that they can provide clinically relevant and accurate information. The need for additional training as circumstances change should be considered.
- Consideration should be given to developing patient information sheets in English and other languages to assist with the consent process. These should be reviewed on a regular basis.

The provision of information to patients and the obtaining of a valid consent for blood transfusions should, whenever practicable, be documented using a consent form, except in emergency situations where the patient is unable to give a valid consent.

A refusal of blood products should be documented in the patient's Health Records and on the consent form. Where a patient will accept some but refuses other blood products (for example a person of Jehovah's Witness faith), blood products that are accepted or refused must be carefully documented using the relevant form (SMR020.010 Refusal of Blood and/or Blood Products)..

10.2. Information and Consent requirements for pregnancy and birth related tests, procedures and interventions

Early discussions with respect to the range of pregnancy and birth related tests, procedures and interventions ensure women have adequate information and time to consider their options, express preferences, make choices and where necessary give valid consent. During the antenatal period, the Health Practitioner should provide prepared information to support these discussions (for example, the NSW Health *Having a Baby* book) and the woman's preference should be recorded in her Health Record (noting that preferences may change over time).

The principles informing these discussions should focus on shared decision making, informed consent and respecting the choices of the woman. The relative merits, material risks, implications for mother and baby, the timing of these interventions and any potential alternatives to the interventions should be discussed and documented in the Health Record.

10.2.1.Antenatal testing and screening

Written consent is not required for routine antenatal testing and screening (including ultrasound scans, blood tests and CTGs) and choices about models of care. Verbal consent (or informed refusal) should be recorded in the Health Record.

10.2.2. Planned pregnancy, labour and birth related procedures and interventions

If consent to a particular pregnancy or birth related procedure is given in the antenatal period or where the consent is obtained in the obstetrician's private rooms, this consent should be confirmed on the day of the procedure and the woman given an additional opportunity to ask questions about the procedure/intervention. This confirmed consent must be documented in the Health Record.

Written consent is required for all planned pregnancy, labour and birth related procedures and interventions (as opposed to unplanned or emergency – see below) using the *Consent to Medical Treatment/Procedure (Adult with Capacity)* Form.

This may include procedures including but not limited to elective caesarean section, vaginal birth after caesarean, induction of labour, planned vaginal twin birth, planned vaginal breech birth or external cephalic version (ECV) and termination of pregnancy.

Written consent is not required for a spontaneous vaginal birth.

10.2.3. Unplanned labour and birth-related procedures and interventions

For unplanned labour and birth-related procedures and interventions, where practicable in the circumstances and where time allows, the woman's written consent should be recorded using the *Consent to Medical Treatment/ Procedure (Adult with Capacity)* Form. Examples include insertion of an epidural block or an instrumental birth. If a procedure or intervention is required in an emergency to save a life, written consent is not required, however, the woman's oral or implied consent should be recorded in the Health Record.

Written consent is not required for perineal repair under local anaesthetic performed in a birth unit.

10.2.4. Refusal of recommended treatment in a maternity setting

This Consent Manual refers to choosing to decline treatments as refusal of treatment, as this is how these cases are described in a legal context.

There may be circumstances where a woman refuses care and/or advice which would amount to a departure from the Health Service or NSW Health policy or guidelines, for example, declining screening tests, continuous fetal heart rate monitoring, caesarean section or induction of labour. There are various reasons why a woman may refuse recommended medical treatment including social, religious or personal views and, in some cases, a fear of medical treatment.

The law is that unless the woman lacks capacity, the woman's right to refuse medical treatment prevails over preservation of a potential life. Where time allows, advice may be obtained from the Ministry of Health, Legal Branch if there is a dispute or concern about the woman's capacity. Although it may not always be possible, the early identification of women who wish to decline specific interventions will assist with early multi-disciplinary collaboration and planning.

Refusal of treatment may result in a conflict between the woman's wishes and the recommendations of the treating Health Practitioner. Such refusal of treatment may, in some circumstances, be considered to pose a serious risk to the welfare of the fetus or the woman. In these circumstances the Health Practitioner should clearly advise the woman of the risks of refusing the treatment and, where possible, obtain written acknowledgement of the provision of information by the Health Practitioner of the risks and the refusal of the recommended treatment. The *Procedure/Treatment Refusal Acknowledgement (Patient with Capacity)* form can be used for this purpose.

There may be circumstances where the refusal of treatment in this context provides grounds to suspect that the baby may be at risk of significant harm after birth. In these cases, a prenatal report may be made to the Child Protection Helpline or assistance sought from the NSW Health Child Wellbeing Unit.

10.2.5. Refusal of recommended treatment in a maternity setting – Local Level Policy

Health Services must implement a local level policy to support women and staff when a woman is declining recommended medical treatment.

The local level policy must:

- emphasise a collaborative approach to maternity care. Allow the woman an opportunity for informed refusal whereby she is provided with information regarding the benefits of treatment from her Health Practitioner so that she can make a decision that reflects self-determination, autonomy and control.
- clearly state the current law in NSW. A competent adult is free to choose whether they will consent to medical care. A court is unlikely to qualify a pregnant woman's right to refuse treatment even if her decision might pose a serious threat to her welfare or to that of the fetus, unless the capacity of the mother is in question.
- require a capacity assessment. Where a woman is refusing recommended medical treatment and the refusal of treatment could lead to serious risks to her welfare or the fetus, the Health Practitioner must consider whether there is any reason to consider that a woman's capacity may be reduced to the point that she is unable to understand the nature and consequences of the decision she is making. If there is a question regarding the woman's capacity, a capacity assessment should be conducted. Where time allows, advice should be obtained from the Ministry of Health, Legal Branch.
- emphasise open and continuing communication with the woman. It is important that good communication with the woman is maintained by providing unbiased and accurate information regarding the options available and the consequences of each. Utilise techniques to build agreement on the recommended treatment which may include:
  - time and repeated discussion
  - second medical opinion
  - involvement of a neutral third party
  - transfer to the care of another Health Practitioner.

Acknowledgement and understanding of cultural sensitivities may assist Health Practitioners to reach agreement with the woman regarding recommended medical treatment and, where time allows, the involvement of specialist cultural advisors within NSW Health may be beneficial for example, the Aboriginal liaison team.

- require meticulous record keeping regarding the discussions that have taken place with the woman and Health Practitioners is essential. If the woman maintains her refusal of the recommended treatment, and, subject to the Health Practitioner having made reasonable efforts to reach agreement with the woman by way of a full and frank discussion, the Health Practitioner should complete a *Refusal of Treatment* form. The Health Practitioner must be sure to record the discussions that have taken place with the woman including the proposed treatment, its nature, material risks and the possible consequences of refusing the treatment. Once completed, the woman should be requested to sign the form and the form filed in the woman's Health Record. If the woman chooses not to sign the form, this should be noted on the form and the completed form should be signed by the Health Practitioner and filed in the woman's Health Record.
- include mechanisms for support and debrief of staff involved. In situations where a woman's refusal of recommended medical treatment results in injury or death to a woman or the fetus, all staff involved should be provided with appropriate support and an opportunity to debrief following the incident.

Further guidance

- NSW Health Policy Directive *Maternity – National Midwifery Guidelines for Consultation and Referrals* (PD2020_008)
- NSW Health Policy Directive *Framework for Termination of Pregnancy in NSW* (PD2021_018)

10.3. Anaesthetics

Patients must be informed about the material risks associated with anaesthesia for their planned procedure. This information may be provided by the Admitting Medical Officer, or in some cases (such as for regional anaesthesia) a Nurse Practitioner. However, if the Admitting Medical Officer considers the anaesthesia to involve particularly high risks or there are other circumstances in a particular case that warrant a separate consultation, the Admitting Medical Officer should arrange a separate consultation with the anaesthetist.

Where there is a separate consultation with the anaesthetist, the patient should be asked to sign a separate consent form in relation to the anaesthetic.

If alternative types of anaesthetic, for example, regional or general are commonly used for the procedure, these must be discussed together with their advantages and disadvantages and these discussions should be documented.

10.4. Organ and tissue donation

Consent requirements for organ and tissue donation are addressed in the *Human Tissue Act* and the *Human Tissue Regulation*. Specific consent forms are provided under that Act.

Further guidance

- NSW Health Policy Directive Organ and Tissue Donation, Use and Retention (PD2024_022)

10.5. Consent to use tissue removed from a living patient during treatment

Consent requirements for the use of any tissue removed during medical, surgical or dental treatment for any medical, therapeutic or scientific purposes, other than the on-going treatment of the patient are addressed in the *Human Tissue Act* and the *Human Tissue Regulation*.

Further guidance

- NSW Health Policy Directive *Organ and Tissue Donation, Use and Retention* (PD2024_022)

10.6. Research (including clinical trials)

Research conducted on humans at Health Services requires the approval of a registered Human Research and Ethics Committee (HREC) following the principles set out in the *National Statement on Ethical Conduct in Human Research* (National Statement).

The HREC's role is to review and approve specific consent protocols for all operations, procedures and treatments that are part of clinical trials or studies. As a general rule, the same legal principles apply when seeking a patient's consent for clinical trials or research as for medical treatment or procedures. Researchers should ensure they follow any specific consent requirements, including the provision of patient information sheets, which have been approved by the reviewing HREC in accordance with the National Statement. Generally, written consent will be required where research involves any type of operations, procedures or treatments but may not be necessary in every situation, for example, research involving surveys may not always require written consent but can be implied through the completion of the survey.

Further guidance

- NSW Health Guidelines *Human Research Ethics Committees – Standardised Patient Information Sheets (PIS)* (GL2007_016)
- NSW Health Guidelines *Use of Human Tissue for Research* (GL2023_008)
- National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research 2018*
- Therapeutic Goods Administration *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6 (R2)*
- NSW Health Policy Directive *Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations* (PD2010_055).

10.6.1. Consent for children participating in research or clinical trials

Whilst an HREC may occasionally allow for patients between the ages of 16 and 18 to provide consent to their own participation in a clinical trial or medical research, it is generally recommended that a parent/guardian consent to participation in clinical trials or research for children up to the age of 18.

Chapter 4.2 of the National Statement provides guidelines with regard to the values, principles and themes to be applied when obtaining consent in regard to research involving children. In addition to obtaining substitute consent of the parents or guardians, researchers should consider, where appropriate to the child's maturity, obtaining the assent or agreement of the child to participate in the clinical trial or research. Obtaining the assent of a child is in accordance with accepted ethical standards in research in Australia. Ultimately, the HREC should make the determination as to whether assent should be obtained from a child participant, taking into account the provisions of the National Statement and the specifics of the relevant study. However, this is recommended only when the child is considered to have sufficient maturity to be able to understand the clinical trial or research process and is able to express a view on whether they would like to be a participant.

Both the consent and assent processes require that children understand the research process and are informed about their involvement. Information should be provided to children in a way that they understand, and they should be provided with the opportunity to seek further information and receive satisfactory answers. Where a child's participation in a research project is on-going, researchers should obtain consent from the patient in their own capacity once they obtain the age of 18 years.

Further guidance

- National Health and Medical Research Council National Statement on Ethical Conduct in Human Research 2023 – updated 2023

10.6.2. Consent for persons 16 years or above without capacity participating in research or clinical trials

Special arrangements apply where a person is 16 years of age or above and is unable to consent to participate in clinical trials and research. Under part 5 of the *Guardianship Act 1987*, clinical trials which seek to involve persons 16 years of age or older without capacity must be approved by the Guardianship Division of NCAT. The purpose of the provisions is to ensure that people who lack the capacity to consent are not deprived of medical treatment that is only available through a clinical trial and to ensure that they are only provided with treatment that promotes their health and wellbeing.

Further guidance

- Section 7 – Patients (16 years or over) who do not have capacity to consent
- NSW Civil and Administrative Tribunal, Guardianship Division Clinical Trials
- NSW Health Guidelines *Use of Human Tissue for Research* (GL2023_008)

10.7. Procedures that may impact on people other than the patient

Some procedures, such as genetic testing, may have implications for persons other than the patient undergoing the test or procedure.

In these situations, it is advisable to discuss the possible test results with the patient and ascertain whether the patient intends to inform identifiable, potentially affected third parties of the results. It may be possible to obtain the patient's written consent to disclose results to an identifiable third party at this early stage.

Since 2014, the *Health Records and Information Privacy Act 2002* has included provisions and processes for the disclosure of genetic information to genetic relatives without patient consent in limited circumstances. Genetic relative means a person who is related to an individual by blood, for example, a sibling, parent or descendant of the individual.

Under the amended Health Privacy Principles 10 and 11, genetic information can be used and disclosed where:

- the disclosure is to a genetic relative of the individual to whom the genetic information relates
- it is reasonably believed to be necessary to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of that genetic relative
- the disclosure is made in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph.

The NSW Privacy Commissioner has issued guidelines *Use and disclosure of genetic information to a patient's genetic relatives.* The guidelines recommend that Medical Practitioners take all reasonable steps to obtain consent from the patient and to consult with other experienced Health Practitioners. If a disclosure occurs, only information that is necessary to communicate the risk of harm should be disclosed and, where possible, the patient should be notified.

Further guidance

- NSW Information and Privacy Commission *NSW Genetic Health Guidelines: Use and disclosure of genetic information to a patient's genetic relatives: Guidelines for organisations in NSW*
- NSW Health *Privacy Manual for Health Information*, section 11.2.3.4, Genetic Information

10.8. Medical and Forensic examinations

A medical and forensic examination is an examination which includes injury documentation and the collection of forensic samples which can be used as evidence in a police investigation and any subsequent prosecution. A medical and forensic examination occurs in the context of an integrated psychosocial, medical and forensic response to a victim of criminal violence, abuse or neglect. A medical and forensic examination may be conducted by a registered Medical Practitioner or, in relation to the sexual assault of people 14 years and over, a specially trained Sexual Assault Nurse Examiner (SANE).

The principal focus of a medical and forensic examination is the care and treatment of the patient and the secondary focus is the collection of evidence to be used for an investigation or criminal prosecution.

Medical and forensic examinations require careful adherence to consent procedures. Written consent must be obtained before a medical and forensic examination is provided. Further detail on the consent requirements are set out in the documents below.

The patient will be asked to consent to the examination, and separately consent to release information obtained in the examination to the NSW Police Force. A patient may consent at a later time to the release of information to the NSW Police Force.

Further guidance:

- NSW Health Policy Directive *Responding to Sexual Assault (adult and child) Policy and Procedures* (PD2020_006) section 15 Medical and Forensic Assessment and Management
- NSW Health Policy Directive *Photo and Video Imaging in Cases of Suspected Child Sexual Abuse, Physical Abuse and Neglect* (PD2015_047)
- NSW Health Policy Directive *Child Wellbeing and Child Protection Policies and Procedures for NSW Health* (PD2013_007)
- NSW Health Guideline *Suspected Child Abuse and Neglect (SCAN) Medical Protocol* (GL2014_012)
- Department of Communities and Justice *Preventing and responding to abuse of older people (Elder Abuse) NSW Interagency Policy*
- NSW Civil and Administrative Tribunal out of hours Guardianship Applications 1300 006 228.

10.9. Restrictive practices

In general, a competent adult patient has the right to consent to, or refuse, any treatment, including seclusion or restraint. As a result, where possible, seclusion and restraint should only be used with the informed consent of the person.

Differing requirements apply for some types of situations and patients, as set out below.

10.9.1.Restraint in emergency situations

In an emergency, where restraint or seclusion is necessary to address an immediate threat to the life, health or safety of the patient or others, consent is not required.

10.9.2. Mental Health patients

No consent is needed to provide treatment to involuntary patients. An authorised medical officer of a mental health facility may give, or authorise the giving of any treatment the officer thinks fit to an involuntary patient.

The *Mental Health Act* also permits an authorised medical officer to take any action that the officer thinks fit to protect a patient or person detained in a mental health facility, or any other person in a mental health facility, from serious physical harm

10.9.3. Minors

Minors assessed as having sufficient understanding and intelligence to understand fully what is proposed, may give their own consent to the treatment or intervention. Where a Minor does not have capacity to provide consent, the consent of their parent or guardian should be obtained.

10.9.4 Patients 16 and over who do not have capacity to consent

Where a patient aged 16 and over lacks capacity, and it is not an emergency, the law requires health practitioners to obtain consent from the patient's Person Responsible (which can include their guardian).

A Person Responsible can consent to medical and dental treatment. Therefore, a Person Responsible can consent to an intervention required to treat a medical condition.

If the purpose of the intervention is not to treat a medical condition (for example, the purpose is to address a behavioral issue), the Person Responsible may not be able to provide consent, and consent from a guardian with a restrictive practices function may be required.

Further guidance

- NCAT Fact Sheet *Restrictive Practices and Guardianship*