Policy and Procedure

Informed Consent

Purpose

The purpose of this policy is to give clear direction to South Western Sydney PHN (SWSPHN) staff, PHN commissioned providers, research participants and iRAD participants when obtaining informed consumer consent by providing relevant information to consumers regarding the purpose, importance, benefits, risks, possible costs of health care and use of personal information arising from service engagement, research engagement and/or software usage.

Policy

SWSPHN is committed to implementing processes to enable partnership with consumers in decisions about their care, including informed consent to treatment.

- As recommended by World Health Organisation (WHO), obtaining genuine informed consent is best viewed as a process of sharing information and addressing questions and concerns, rather than simply obtaining a signature on a prescribed form.
- All consumers have the choice whether or not to engage with care or treatment. Written consent or appropriate verbal consent must be obtained from all competent adults prior to the provision of support and/ or services by SWSPHN program staff.
- Where a consumer is less than 14 years of age, written consent must be obtained from a child's parent/carer or guardian. The consent of either parent is adequate, even in the case of separated parents, except where a court order has been issued stipulating that one parent has responsibility to the exclusion of the other.
- Consent is not required where immediate treatment is necessary to save a person's life.
- Consent is required to allow communication and sharing of patient information between SWSPHN staff, SWSPHN commissioned services and providers, the referring health practitioner and other health providers, for continuity of care and effective care coordination.
- Consent is also required for sharing of patient information between SWSPHN and the Department of Health or parties acting on behalf of the Department of Health and Aged Care (e.g. Primary Mental Health Care Minimum Dataset).
- Consent may also be required for secondary use of patient information for purposes such as conducting research, population health planning and linking datasets.
- All consumers must be provided with sufficient information for there to be a genuine understanding of the proposed support and/or services, material risks, benefits, likely result if services and/support is not undertaken and the time and cost involved. The use of consumer's personal information should also be explained.

- Adequately informing consumers and obtaining their consent in regard to service and/or support is both a specific legal requirement and an accepted part of best practice. Pre-prepared material such as brochures (translated where relevant) may be used in conjunction with discussion between staff and consumers.
- Staff should assist the consumer to understand the material, explaining anything that is unclear. Written material is not to be used as a substitute for ascertaining through discussions whether the consumer understands the nature of the support/services planned and any risks involved.
- At the time of gaining consent for the delivery of health care services, the consumer should also be advised of their rights, as outlined in the Australian Charter of Healthcare Right (2008).
- Consent should be collected, recorded and stored in a suitable way to ensure consent forms or recording of consent is legible and accessible as required, and scanned and saved/recorded in a customer relationship management tool or directly stored into clinical software.
- Consent will remain valid until it is withdrawn by the consumer, or a new referral is received, adjusting the management plan.
- Informed consent is obtained when the consumer has a clear understanding of the purpose, importance, benefits, risks and possible costs of health care. It is therefore necessary to engage the services of a professional interpreter for consumers who are not fluent in English or are deaf. Also refer to Equity of Access and Health Literacy Policy.
- Refer to the Information Management and Privacy and Confidentiality Policies and Procedures.

Applicability

SWSPHN commissioned services and providers, SWSPHN-led research activities, iRAD participants and any other activities legally required to gain informed consent.

Associated documents

Legislation and best practice guidelines:

- Privacy Act 1988
- Health Records and Information Privacy Act 2002 (NSW)

Internal policies and documents:

- Consumer Identification Policy and Procedure
- Consumer Health Record Policy and Procedure
- Equity of Access and Health Literacy Policy and Procedure
- Privacy and Confidentiality Policy and Procedure
- Mental Health Clinical Governance Manual
- Clinical Governance Framework

Roles and responsibilities

Policy owner	Ensure that this policy document is published and implemented, progress is monitored and that it is reviewed according to the document control schedule outlined in the policy.
Program Manager	• Support and oversight of program staff in the implementation and compliance with the policy.

	• Ensuring regular opportunities for upskilling PHN staff to ensure they are aware of policy and procedure updates around informed consent. • Ensuring inclusion of informed consent within program materials e.g. referral forms and contract documents. • Ensuring inclusion of informed consent requirements within contract requirements of commissioned providers, research participants and iRAD participants.
SWSPHN Commissioned Providers	• Providing consumers with adequate information to obtain informed consent; ensuring records of informed consent are kept in consumer health records. • Maintaining clearly outlined informed consent policies and procedures with new service recipients, consistent with contract requirements.
Executive sponsor	Provide advice to the Policy Owner, approve the final document and present it to the Clinical Council or Senior staff meeting for approval.
Board	Oversee implementation of policy in the context of the policy framework.
Executive	Ensure implementation of the policy. Resolve operational barriers to implementation of policy.
Management	Support implementation of the policy. Resolve operational barriers to implementation of policy.
SWSPHN Staff	Ensuring informed consent processes are built into program design.

Procedure

- Informed consent documents are to include:
    - Approved patient identifiers.
    - Agreement that the consumer has read and understood the informed consent form and has been given the opportunity to have any relevant questions answered.
    - Permission to exchange consumer health records with the referring health practitioner and other health professionals as required, to facilitate the continuity of care and effective care coordination.
    - Acknowledgement that information has been provided, outlining the purpose, importance, benefits, risks and possible costs of health care.
    - An outline of how consumer data will be used, for example de- identified data may be used for research purposes.
    - An outline of how data may be used to better inform need for and improvement of commissioned services
- Once consumers have read and understood a written consent form, they should sign and date it and the staff member obtaining consent should also sign and date the form.
- At all times consent should be gained in writing if possible. If a consumer consents verbally but declines to sign the relevant consent form, the consent is still considered valid. In these cases, the staff member obtaining consent must clearly document on the relevant consent form or in their records that consent was provided verbally.
- The signed consent form is to be filed in a secure location together with the consumer health record. If scanned to an electronic record care must be taken that it is done so in its entirety. Once scanned the original can be shredded. Consumer consent is voluntary. If consent is withdrawn at any stage, it should be documented and adequately followed through.

- Where commissioned services and providers are responsible for gaining informed consent, this should be checked at regular contract review meetings with SWSPHN to ensure sufficient process. Additionally, responsibilities for informed consent will be clearly outlined within the service agreements with newly commissioned providers or agreements with other parties such as iRAD participants, as necessary.

Definitions

Word/Term	Definition
Commissioned services	Services provided to a client by a third party on behalf of SWSPHN.
Communication	An exchange of information that occurs between treating clinicians. Communication can be formal (when a message conforms to a predetermined structure for example in a health record or stored electronic data) or informal (when the structure of the message is determined solely by the relevant parties; for example, a face-to face or telephone conversation).
Competent	There is no single legal test or definition of competence. It is generally taken to be a person's ability to comprehend and retain information and consider that information in order to reach a decision.
Consent	Voluntary agreement to some act, practice or purpose. Consent has two elements: knowledge of the matter agreed to, and voluntary agreement.
Consumer (health)	Client/patients and potential patients, carers and organisations representing consumers' interests.
IRAD participant	Operator of a medical practice or is otherwise a healthcare provider who wishes to be a participant in and a user of the iRAD Interoperability System
Material risk	A risk is material if in the circumstances, a reasonable person in the consumer's position, if warned of the risk, would be likely to attach significance to it.
Secondary use	Any application of data beyond the reason for which they were first collected (known as the primary use or purpose). For example, the primary use of data collected to treat a patient in a hospital is to provide the patient with the care they need in that hospital episode; a secondary use could be to aggregate patients' data to compare hospital performance across Australia.

Document control

Policy review every (choose most applicable) ☐ 1 year ☐ 2 years ☑ 3 years

Version	Date Commenced	Policy Owner	Change Description	Review Date	Authorising Executive
V1.0	March 2016	Health Programs Manager	New Policy	March 2019	Director of Planning and Performance
V2.0	December 2017	Commissioning Manager	Policy Review	December 2020	Director of Planning and Performance
V3.0	December 2020	Commissioning Manager	Policy Review	December 2023	Director of Planning and Performance
V4.0	October 2024	Commissioning Manager	Review & Brand Refresh	October 2027	Director of Planning and Performance

This Policy and/ Procedure will remain in effect until replaced.