

Checklist for Written Consent: Unregistered Use of Medicine

Includes off label medicine use* or medicine available via Special Access Scheme (SAS) or Authorised Prescriber Scheme (APS)**

- Consent is a process - not a piece of paper.
- Consent can be withdrawn at any time.
- Do not use abbreviations as these may not be understood.
- For people under 16 years of age or those aged over 16 who do not have capacity to give consent, consent must be obtained from the Parent/Guardian or Person Responsible, respectively. They should provide their signature, printed name, address, phone number, and relationship to patient/ reason for representation. Effort should be made to include the person (patient) in the decision-making and consent processes.
- Use a Health Care Interpreter (not family member) when the person is not fluent in English. Provide details of interpreted language, interpreter name and signature, employee ID/provider number and date and time.

***Off-label use of a medicines** describes the use of a TGA-registered product in ways other than those specified in the Australian TGA product information and may include medicine use for a non-approved indication, at a different dose, via an alternate route or for a patient whose age or gender is outside the registered use. In general, off-label use should only be considered when the TGA-approved use of a registered medicines does not address the clinical needs of a patient.

Because these medicines are being used outside their approved (registered) use, written informed consent with documented reasons for use is required. (The one exception is for *routine* off-label use where the usual process for consent is applicable - see CATAG [Guiding Principles for quality use of off-label medicines](#) for further information.)

****SAS or APS:** In certain circumstances, unregistered medicines may be obtained via the [Special Access Scheme](#) or [Authorised Prescriber Scheme](#). These medicines will not have been evaluated for quality, safety, or efficacy in Australia by the TGA and hence require increased consent requirements. The prescriber accepts responsibility for the use of an "unapproved" therapeutic good and any associated adverse reactions.


The following should be included in the consent process and documentation for unregistered use of a medicine when using a generic consent form:

<input type="checkbox"/> Prescriber details: Name of prescriber who is providing necessary information and obtaining written consent (provide further details if prescriber and consenting clinician different).		
<input type="checkbox"/> Explain: <ul style="list-style-type: none"><input type="checkbox"/> The proposed therapy- its off-label/unregistered status, what is involved/ how it will be used.<input type="checkbox"/> What the proposed therapy will treat.<input type="checkbox"/> The reason why other registered treatment(s) are not suitable.<input type="checkbox"/> The expected benefits and the possible harms of the proposed therapy including the possibility of unknown and/or late side effects.	<input type="checkbox"/> Ask: <ul style="list-style-type: none"><input type="checkbox"/> Is there anything else the patient/ Person Responsible would like to know?<input type="checkbox"/> Is there anything else patient/ Person Responsible does not understand?	<input type="checkbox"/> Provide written information
<input type="checkbox"/> Document the consent process as per local policy including the declaration from the patient or person responsible that they have understood the explanations for use including the nature and risks of off-label/unregistered use, had opportunity to ask questions, are satisfied with the answers and agree to receive the medicine. Include signatures of patient/person responsible, witness (and name), consenting clinician and interpreter, if applicable.		

Further information: [NSW Health Consent to Medical and Healthcare Treatment Manual](#) (Consent Manual)

An example of a Consent Form for Unlicensed Use of Medication is provided below.

Example: Consent Form for Unlicensed Use of Medication (page 1), with acknowledgements to NSLHD

 Health Northern Sydney Local Health District	FAMILY NAME		MRN
	GIVEN NAME		<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
	D.O.B. DD / MM / YYYY	M.O.	
	ADDRESS		
			PH
	M/C	FIN	
	LOCATION / WARD		ADM DD / MM / YYYY

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

Provision of Information to Patient

I _____ (clinician name) have discussed with the patient/authorised representative, the administration of:
 Medication.....
 Route of administration.....
 Commencement dose and frequency.....
 for the medication treatment of.....

I have informed this patient of the matters detailed below including the nature, likely results and material risks of the proposed medication treatment.

Name Signature

Designation Date: / /

Patient/Authorised Representative Consent

..... (clinician name) and I have discussed the present condition and the various ways in which it might be treated, including the above medication treatment.

The clinician has told me that:

- The product is not currently approved (i.e. registered or listed) for the intended use in Australia.
- The possible benefits of the medication to myself/the patient are: (state possible benefits of the medication)

.....

- There are some possible adverse effects or risks in taking the medication which include: (state possible adverse effects or risks)

.....

- There is also the possibility of unknown risks and late side effects.
- The reasons why any alternative medication treatments using approved products are not appropriate for use are: (state reasons)

.....

I understand the nature of the medication treatment and that undergoing the medication treatment carries risks.
 I have had the opportunity to ask questions and I am satisfied with the explanation and the answers to my questions.
 I understand that I may withdraw my consent.


see over

CATALOGUE NUMBER NS1056 APR18/V4

MARGIN - NO WRITING

CONSENT TO UNLICENSED USE OF MEDICATION

Example: Consent Form for Unlicensed Use of Medication (page 2), with acknowledgements to NSLHD

	Health Northern Sydney Local Health District	FAMILY NAME	MRN	
		GIVEN NAME	<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	
Facility: COM HKH MQE MVH RNS RYD		D.O.B. DD / MM / YYYY	M.O.	
<h2 style="margin: 0;">CONSENT TO UNLICENSED USE OF MEDICATION</h2> <p style="margin: 0;">I request and consent to the medication treatment described above for me/the patient.</p> <p style="margin: 0;">If the patient is under 14 years of age or does not have capacity the authorised representative must sign to consent to this medication treatment.</p> <p style="margin: 0;">If the authorised representative has provided consent, please provide their details below:</p> <p style="margin: 0;">Name Date of Birth: ___ / ___ / ___</p> <p style="margin: 0;">Address</p> <p style="margin: 0;">Relationship to Patient Contact Number</p> <p style="margin: 0;">Reason the Authorised Representative has Signed</p> <p style="margin: 0;">.....</p> <p style="margin: 0;">Signed By:</p> <p style="margin: 0;"><input type="checkbox"/> Patient <input type="checkbox"/> Authorised Representative</p> <p style="margin: 0;">Name Signature</p> <p style="margin: 0;">Designation</p> <p style="margin: 0;">Witnessed By:</p> <p style="margin: 0;">Name Signature</p> <p style="margin: 0;">Date: ___ / ___ / ___</p> <p style="margin: 0;">Clinician:</p> <p style="margin: 0;">Name Signature</p> <p style="margin: 0;">Date: ___ / ___ / ___</p> <p style="margin: 0;">If the patient cannot converse adequately in English, please use a Health Care Interpreter for discussion leading to the signing of this form. Do not rely on relatives and other parties for interpreting.</p> <p style="margin: 0;">Interpreted By:</p> <p style="margin: 0;">Name Signature</p> <p style="margin: 0;">Language Group Date: ___ / ___ / ___</p>		ADDRESS		
		M/C		PH
		LOCATION / WARD		ADM DD / MM / YYYY
		COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE		

EXAMPLE

EXAMPLE

Holes punched as per A52828-2012
 BINDING MARGIN - NO WRITING

MARGIN - NO WRITING

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