

Procedure Protocol

Who	All Southern Health Clinicians
Expected Outcomes	All clinicians will be aware of the process for introducing a technology/clinical practice at Southern Health
Precautions	<p>Approval must be obtained from the Technology/Clinical Practice Committee (TCPC) before commencing use of any new technologies or clinical practices on any Southern Health patient, private or public. It is imperative that approval by the TCPC be obtained before the new technology/clinical practice is carried out at Southern Health. There may be adverse legal implications for both the clinician and Southern Health if approval from the TCPC has not been obtained.</p> <p>Any new interventions undergoing development and/or trial are to be considered as experimentation or research and must, in addition, be reviewed by the Southern Health Human Research Ethics Committee.</p>
Why	<p>Encourage Southern Health clinicians to engage with new technology/clinical practice which have the potential to improve the provision of healthcare, within a framework which protects the interests of patients, clinicians and the organisation.</p> <p>To ensure that:</p> <ul style="list-style-type: none"> ▪ the ramifications of each new technology/clinical practice are considered at all levels and in all departments ▪ appropriate training is provided to all staff so that each new practice is performed (and new equipment is handled) safely ▪ every patient is cared for safely and appropriately throughout an episode of care.
Definition	<p>A new “Technology/Clinical Practice” is a therapeutic intervention (including prostheses; implantable devices; high cost pharmaceuticals; medical, surgical or other clinical procedures) or diagnostic procedure that is considered by a reasonable body of clinical opinion to be significantly different from existing clinical practice.</p> <p>It includes a procedure that has not been performed at Southern Health, as well as any variation to an existing procedure or treatment where a new device or item of equipment is introduced, including situations where new devices are provided by manufacturers without charge.</p> <p>A new “Technology/Clinical Practice” does not include the situation where a clinician proposes to use a technology/clinical practice that is already being undertaken within Southern Health but which has not been previously used by that clinician.</p> <p style="text-align: right;">(DHS, 2006)</p>
Role of TCPC	<p>The primary role of the TCPC is to oversee and support Southern Health in the safe and appropriate introduction of a technology/clinical practice that has not previously been undertaken.</p> <p>Aim</p> <p>To establish a process that will facilitate quality and safety and protect patients, clinicians, managers and the organisation in ensuring that:</p> <ul style="list-style-type: none"> ▪ the clinical and financial effects of each TCP are considered at all levels and in all departments ▪ appropriate training is provided to all staff so that each TCP is performed and equipment is handled safely ▪ every patient is offered the opportunity to give valid consent to new procedures and is cared for safely and appropriately throughout an episode of care.

	<p>The TCPC reviews written submissions from clinicians within Southern Health who wish to introduce a new technology/clinical practice. Each review will consider the following criteria:</p> <ol style="list-style-type: none"> 1. Safety – What are the main adverse events? Safety in relation to current practice? 2. Effectiveness – Volume of evidence, consistency, clinical impact, generalisability and applicability 3. Cost – How affordable is the new technology/clinical practice? Does the cost represent value for money? 4. Clinical Feasibility – Resource implications and credentialing and competency assurance undertaken 5. Access and Equity 6. Legal and Ethical Implications <p>Once a new technology/clinical practice is approved, the secondary role of the TCPC is to monitor the performance of that procedure for 2 years or such other period as the TCPC may consider appropriate.</p> <p>The Centre for Clinical Effectiveness (CCE) is the Secretariat for the Southern Health TCPC</p>
Who may apply to the TCPC?	<p>Applicants may be:</p> <ul style="list-style-type: none"> ▪ Individual clinicians seeking to introduce a new technology/clinical practice. ▪ Heads of Departments/Units may refer a matter for the attention of the TCPC where a new technology/clinical practice is sought to be introduced by a staff member
Written Submissions	<p>Any clinician who wishes to introduce a new technology/clinical practice is required to provide a written submission to the TCPC, which includes the following:</p> <ul style="list-style-type: none"> ▪ Summary of information ▪ Conflict of interest statement ▪ Overview of technology/clinical practice ▪ Clinical need ▪ Evidence of safety, efficacy and clinical effectiveness ▪ Evidence of cost effectiveness ▪ Clinical feasibility ▪ Governance ▪ Estimated financial impact ▪ Implementation ▪ Patient Information
Equipment	<p>Application forms and related resources and templates are available online http://www.southernhealth.org.au/page/Health_Professionals/TCPC/ or from the Secretariat of the TCPC, as detailed below.</p>
Step 1	<p>Advice regarding appropriateness of the submission or assistance with completion of the application form can be sought from the Secretariat of the TCPC.</p> <p>Dr Anjali Dhulia Executive Officer TCPC Phone: 9594 2180 Email: anjali.dhulia@southernhealth.org.au</p> <p>Note: All applications are to be completed and returned electronically to the Secretary of the TCPC.</p>
Step 2	<p>The applicant consults with and obtains approval from their unit head before lodging the electronic submission.</p>
Step 3	<p>TCP applications must be submitted before the due date for the next scheduled meeting of the TCPC to enable them to be circulated with the agenda.</p> <p>Where there is a genuine urgency attached to a request for approval, a short explanation should be attached to the electronic submission and brought to the attention of the Secretary.</p>
Step 4	<p>Applications will be registered and confirmation of receipt provided to applicants.</p>
Step 5	<p>Unless otherwise notified the applicant will be required to attend a brief meeting with the TCPC to respond to any matters raised by its members so that a fair and informed assessment of the application is made.</p>
Step 6	<p>The TCPC consults with the relevant Head(s) of Departments/Units and Program Director(s).</p>

Step 7	The TCPC, as part of its review process, determines whether each person proposing to introduce the TCP is both competent and credentialed, and whether there is any conflict of interest.
Step 8	After consideration of all of the material presented, the TCPC makes a decision in respect to the application.
Step 9	Communication with applicants concerning changes in their application recommended by the committee will take place through the Secretary.
Step 10	The Chair of the Committee will advise the Southern Health Executive of applications and outcomes of the Committee's decision.
Step 11	Applicants will be informed of the outcome of the application. Successful applicants will be informed of reporting requirements and the dates for reporting.
Step 12	Unsuccessful applicants may appeal to the Southern Health Chief Executive.
Step 13	The relevant Head of Department/Unit will provide a Progress Report to the Committee at six monthly intervals (January – June and July – December) for all patients referred and treated. http://www.southernhealth.org.au/page/Health_Professionals/TCPC/
Step 14	The applicant must notify the Secretariat in writing of any minor changes made, in light of actual experience, to the technology/clinical practice as approved by the TCPC. The Secretariat will advise applicants if a 'change of use' application form is required to be submitted.
Step 15	If an adverse event occurs with an approved TCP, the applicant or relevant Head of Department/Unit must immediately notify the TCPC and the Therapeutic Goods Administration. The applicant must also complete a Southern Health incident report form. Please see Southern Health protocol CP-QR01 'Incident reporting'.
Step 16	If, in case of a genuine emergency, approval is required for immediate use of a new clinical practice, including a new or new use of a device, one use only approval may be given by either the Chair of the TCPC or the Chief Medical Officer.
Step 17	Unless otherwise determined, proceedings of the Committee shall remain confidential.

References

- NSW Health 2003. *Model Policy for the Safe introduction of New Interventional Procedures into Clinical Practice*. Circular No.2003/84
- NACS/ASERNIP-S. *General Guidelines for Assessing Approving and Introducing New Procedures into a Hospital or Health Service*. Royal Australasian College of Surgeons, Melbourne.
- NHS. *National Institute for Clinical Excellence, Interventional Procedures at* <http://www.nice.org.au>
- DHS. 2006. *Guideline for Health services to establish Technology/Clinical Practice Committees*. Department of Human Services, Victoria.

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	March 2009
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	March 2011

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