Clinical practice guidelines for keratinocyte cancer: Administrative Report

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1. Introduction

Keratinocyte cancer (KC), formerly known as non-melanoma skin cancer,¹ comprises basal cell carcinoma (BCC) and cutaneous squamous cell carcinoma (cSCC).

Keratinocyte cancers cause approximately 560 deaths each year in Australia and are the reason for an estimated 939,000 treatments, based on 2015 data.² Keratinocyte cancers accounted for 8% of all health spending on cancer (excluding cancer screening) in Australia in 2008–2009, and Medical Benefits Schedule reimbursements for KC diagnosis, treatment and pathology cost an estimated $703 million in 2015. Thus, these mostly non-fatal cancers represent a large public health problem with disproportionately high costs.

a. Purpose and scope

The aim of these guidelines is to provide clear guidance on the diagnosis and management of KCs in the Australian population, based on current scientific evidence, in order to reduce morbidity (and, potentially, mortality) from these cancers.

These guidelines update the 2008 edition by reviewing literature published in the interim and incorporating new data. They provide up-to-date evidence-based recommendations, relevant to Australians and the Australian health care system, on skin cancer prevention and early detection, including the prevention and treatment of KCs in people at increased risk of the disease. The 2019 edition includes new information on advances in therapy, especially in the Metastatic disease and systemic therapies section. Sections on Organ transplantation and conditions associated with immunosuppression, Radiotherapy and Surgical treatment have been significantly revised. Guidance on managing KCs in patients who have undergone organ transplantation has been added throughout the guidelines, to aid clinicians who are increasingly involved in the care of these patients. A new section on Early detection has also been added.

b. Intended users

These guidelines are intended for use by health professionals, including those advising the general population about risk and prevention of KCs, those advising patients who are at increased risk of KCs (e.g. due to immunosuppression or a previous history of KC) about the need for and timing of future skin checks and follow-up, and all those involved in making the diagnosis or treating patients with KC.

They may also be of interest to policy makers and to educators providing training in medicine or other health sciences.

These guidelines are not intended as health information for the general public.

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¹ The term ‘non-melanoma skin cancer’ (NMSC) still appears in national data sets and reports.
c. Target populations

These guidelines cover the complete range of Australian adult populations and are an appropriate reference for health professionals treating adults of any age group.

It includes guidance on the asymptomatic general public, people at increased risk of KC, patients with KCs and related tumours of any stage, and patients who have received treatment for KC.

In implementing the recommendations, clinicians should consider the specific needs of patients with KC from culturally diverse groups, including younger people, Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities.

For each systematic review, the search strategies specifically included terms designed to identify data relevant to Aboriginal and Torres Strait Islander peoples. However, the literature searches did not identify any studies specifically relevant to Aboriginal and Torres Strait Islander populations that met the inclusion criteria.

Aboriginal and Torres Strait Islander peoples and people with darker skin are also at risk of developing KCs (albeit to a much lesser extent than those with lighter skin types), and it is important to deliver optimal care for all patients. The Optimal care pathway for Aboriginal and Torres Strait Islander people with cancer is a useful reference resource for clinicians.

d. Healthcare settings in which the guideline will be applied

These guidelines apply to the range of public and private healthcare settings in which services are provided for the target populations. These include:

- general practice
- skin cancer clinics
- hospitals
- specialist clinics
- imaging services
- pathology services
- allied healthcare services.

e. Funding

The Australian Government Department of Health commissioned and funded Cancer Council Australia to undertake the current revision and update of these guidelines.

f. NHMRC approved recommendation types and definitions

These guidelines include evidence-based recommendations, consensus-based recommendations and practice points as defined by National Health and Medical Research Council (NHMRC) level and grades for recommendations for guidelines developers (see NHMRC approved recommendation types and definitions in the Summary of recommendations section).

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g. Methodology

The methodology adopted for this guideline revision is described in the Guideline development process and the Technical Report, which lists the clinical questions and includes detailed technical documentation.

It should be noted that throughout this guideline, unless otherwise stated, tumour stage is according to the American Joint Committee on Cancer (AJCC) cancer staging manual 8th edition\(^4\) and Union for International Cancer Control (UICC) TNM classification of malignant tumours 8th edition.\(^5\)

See: Appendix A TNM Staging.

h. Scheduled review of these guidelines

It is inevitable that parts of this guideline will become out of date as further literature is published. Newly published evidence relevant to each systematic review question will be monitored. If strong evidence supporting a change in the guideline is published, the working party will consider if an update is required for a specific section. We recommend that the guideline should be reviewed and updated every 5 years.

i. Acknowledgement

The update of the guidelines was overseen by a multidisciplinary working party with input by subcommittees. We thank the members of the working party, subcommittees, systematic reviewers and all others who contributed to the development of these guidelines.

Medical writing and editing services were provided by Jenni Harman, Meducation Australia.

2. Contributors

a. Management Committee

This Management Committee consists of senior medical experts from relevant disciplines involved in the keratinocyte cancer pathway. Some members were involved in the previous guideline (2008 Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia =). This group brought the required expertise and leadership to effectively oversee this proposed guideline revision project.

A/Prof Stephen Shumack is the Chair of the Management Committee and Revision Working Party, he was nominated by several members of the previous guideline revision Working Party and clinical experts in the field.

The Management Committee acted as a steering committee to establish the scope of the guideline revision and ensure that deliverables relevant to their contribution in the project plan were delivered to acceptable standards in accordance with NHMRC requirements and within the agreed timeframe.


Membership of this Management Committee is as follows:

<table>
<thead>
<tr>
<th>Member name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor Stephen Shumack (Chair)</td>
<td>Dermatologist/Investigator, St George Dermatology &amp; Skin Cancer Centre</td>
</tr>
<tr>
<td>Professor Sanchia Aranda</td>
<td>CEO, Cancer Council Australia</td>
</tr>
<tr>
<td>Dr Peter Callan</td>
<td>Specialist Plastic surgeon, Geelong, Victoria</td>
</tr>
<tr>
<td>Dr Alvin Chong</td>
<td>Adjunct Associate Professor, (Level D), Department of Medicine (Dermatology), St Vincent’s Hospital Melbourne</td>
</tr>
<tr>
<td>Dr Gerald Fogarty</td>
<td>Director of Radiation Oncology, Mater Hospital</td>
</tr>
<tr>
<td>Dr Peter Foley</td>
<td>Head of Dermatology, Department of Dermatology, St Vincent’s Hospital, Fitzroy, Victoria</td>
</tr>
<tr>
<td>Professor Adele Green</td>
<td>Head, Cancer and Population Studies Group, QIMR Berghofer Medical Research Institute</td>
</tr>
<tr>
<td>Associate Professor Alexander Guminski</td>
<td>Associate Professor Medicine, The University of Sydney</td>
</tr>
<tr>
<td>Dr Vicki Howard</td>
<td>Pathologist, Douglass Hanly Moir Pathology</td>
</tr>
<tr>
<td>Dr Morton Rawlin</td>
<td>General practitioner; Medical Director, Royal Flying Doctor Service (VIC)</td>
</tr>
<tr>
<td>Dr David Speakman</td>
<td>Chief Medical Officer, Peter MacCallum Cancer Centre</td>
</tr>
<tr>
<td>Professor David Whiteman</td>
<td>Deputy Director of QIMR Berghofer; NHMRC Senior Principal Research Fellow; Head, Cancer Control Group</td>
</tr>
<tr>
<td>Tamsin Curtis</td>
<td>Project Manager, Clinical Guidelines Network</td>
</tr>
</tbody>
</table>

b. Working Party

The Keratinocyte Cancer Guidelines Revision Working Party comprised relevant Management Committee members, sections lead authors, two pathology and two GP representatives, two consumer representatives and epidemiological experts (see table below).

The Working Party members review the draft guidelines content developed by the section leads and their respective Subcommittee s and attend the face-to-face Working Party meetings pre- and post-public consultation to approve the guidelines content, specifically all recommendations and practice points.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role/s</th>
<th>Speciality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor Stephen Shumack (Chair)</td>
<td>Chair of Working Party / section lead</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Professor Sanchia Aranda</td>
<td>Management Committee member</td>
<td>CEO, Cancer Council Australia</td>
</tr>
</tbody>
</table>
### c. Subcommittees

Subcommittees for guideline sections comprised of experts involved in the field were convened when required to develop evidence-based guideline content based on individual systematic reviews as well as to contribute to those sections to be updated by a general review of the literature. Lead authors engaged additional experts for this purpose, as well as inviting members of the Working Party as appropriate.

Subcommittees were convened as required to develop the response to individual questions. The lead author for the clinical questions co-opted additional experts for this purpose using members of the Working Party and external experts as appropriate, subject to Management Committee approval.

The following tables detail the guideline sections, section lead author(s) and subcommittee members.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Section Lead</th>
<th>Subcommittee Members</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EPIDEMIOLOGY (GENERAL TOPIC)</strong></td>
<td>Professor David Whiteman &amp; Professor Adele Green</td>
<td>Dr Catherine Olsen: Senior Research Officer Division of Population and Clinical Sciences, Queensland Institute of Medical Research</td>
</tr>
<tr>
<td><strong>PREVENTION (GENERAL TOPIC)</strong></td>
<td>Adjunct Associate Professor Craig Sinclair</td>
<td>Professor Gary Halliday: Professor of Dermatology, University of Sydney; Professor Robyn Lucas: Professor and Head, National Centre for Epidemiology and Population Health, at Australian National University</td>
</tr>
<tr>
<td><strong>EARLY DETECTION AND SCREENING (GENERAL TOPIC)</strong></td>
<td>Professor David Whiteman</td>
<td>Professor John Kelly: Dermatologist, Victorian Melanoma Service, Alfred Health, Melbourne; Professor Peter Soyer: Director, School of Medicine, University of Queensland; Director, Dermatology Department, Princess Alexandra Hospital</td>
</tr>
<tr>
<td><strong>CLINICAL FEATURES (GENERAL TOPIC)</strong></td>
<td>Dr Morton Rawlin</td>
<td>Dr Cathy Reid: Dermatologist, St. Peters Dermatology and Skin Cancer Clinic</td>
</tr>
<tr>
<td><strong>PATHOLOGY (GENERAL TOPIC)</strong></td>
<td>Dr Vicki Howard</td>
<td>Dr Cathy Reid: Dermatologist, St. Peters Dermatology and Skin Cancer Clinic</td>
</tr>
</tbody>
</table>
### PROGNOSIS (GENERAL TOPIC)

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

**Section lead:** Professor David Speakman

**Subcommittee members**

- Dr Helena Rosengren  General practitioner

### SURGICAL TREATMENT (SR TOPIC)

**CLINICAL QUESTION SX1:** What factors need to be considered when determining if surgical treatment modalities are optimal over non-surgical modalities for the management and/or treatment of basal cell carcinoma or cutaneous squamous cell carcinoma?

**CLINICAL QUESTION SX2:** What factors need to be considered when determining the optimal surgical technique for those with basal cell carcinoma?

**CLINICAL QUESTION SX3:** In patients undergoing surgical treatment for cutaneous squamous cell carcinoma, which surgery-related factors (margin width, depth of excision) or tumour-related factors (size, histological features, anatomical site) influence clinical outcomes (cure rate, local recurrence, regional lymph node involvement, metastasis)?

**CLINICAL QUESTION SX4:** What should be the protocol to manage incompletely resected basal cell carcinoma?

**CLINICAL QUESTION SX5:** What should be the protocol to manage rapidly growing tumours?

**Section lead:** Dr Peter Callan

**Subcommittee members**

- Dr James Emmett  Plastic surgeon
- Dr Brian De’Ambrosis  Dermatologist

### RADIOTHERAPY (SR TOPIC)

**CLINICAL QUESTION RT1:** When should radiotherapy be used alone, or in combination with surgical excision to treat those with keratinocyte cancers?

**CLINICAL QUESTION RT2:** In which patients with basal cell carcinoma does a radiotherapy modality achieve equal or better outcomes than conventional surgery?

**CLINICAL QUESTION RT3:** In which patients with cutaneous squamous cell carcinoma does a radiotherapy modality achieve equal or better outcomes than conventional surgery?

**Section lead:** Dr Gerald Fogarty

**Subcommittee members**

- Dr Howard Liu  Dermatologist

### CRYOTHERAPY AND ELECTRODESSICATION AND CURETTAGE (GENERAL TOPIC)

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

**Section lead:** Professor Stephen Shumack (Chair) and Dr Peter Foley

**Subcommittee members**

- Dr Michelle Goh  Consultant dermatologist, Peter MacCallum Cancer Centre, the Alfred Hospital and the Skin and Cancer Foundation
- Dr Gilberto Moreno  Dermatologist
**TOPICAL TREATMENTS AND PHOTODYNAMIC THERAPY (SR TOPIC)**

**CLINICAL QUESTION OT1**: What role does ingenol mebutate gel have in the treatment and management of basal cell carcinoma and/or cutaneous squamous cell carcinoma?

**Section lead**: Professor Stephen Shumack (Chair) and Dr Peter Foley

**Subcommittee members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Institution</th>
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<tbody>
<tr>
<td>Dr Michelle Goh</td>
<td>Consultant dermatologist, Peter MacCallum Cancer Centre, the Alfred Hospital and the Skin and Cancer Foundation</td>
</tr>
<tr>
<td>Dr Gilberto Moreno</td>
<td>Dermatologist</td>
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</table>

**ORGAN TRANSPLANTATION AND CONDITIONS ASSOCIATED WITH IMMUNOSUPPRESSION (GENERAL TOPIC)**

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

**Section lead**: Dr Alvin Chong and Professor Adele Green

**Subcommittee members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Institution</th>
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</thead>
<tbody>
<tr>
<td>Dr Hsien Chan</td>
<td>Dermatologist</td>
</tr>
<tr>
<td>Dr Patricia Lowe</td>
<td>Senior Staff Specialist at Royal Prince and Clinical Senior Lecturer, Central Sydney Medical School, University of Sydney</td>
</tr>
<tr>
<td>Dr Sarah Brennand</td>
<td>Dermatologist</td>
</tr>
<tr>
<td>Dr Michelle Goh</td>
<td>Consultant dermatologist, Peter MacCallum Cancer Centre, the Alfred Hospital and the Skin and Cancer Foundation</td>
</tr>
<tr>
<td>Dr Katherine Allnutt</td>
<td>Dermatologist</td>
</tr>
<tr>
<td>Dr Kiarash Khosrotehrani</td>
<td>Dermatologist</td>
</tr>
</tbody>
</table>

**METASTATIC DISEASE AND SYSTEMIC THERAPIES (SR TOPIC)**

**CLINICAL QUESTION MS1**: What should be the protocol to manage or treat locoregionally advanced cutaneous squamous cell carcinoma?

**Section lead**: Associate Professor Alexander Guminski

**Subcommittee members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Institution</th>
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<tbody>
<tr>
<td>Dr Kerwin Shannon</td>
<td>Head and neck surgeon</td>
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</table>

**FOLLOW-UP AFTER TREATMENT FOR KERATINOYCE CANCER (GENERAL TOPIC)**

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

**Section lead**: Dr Morton Rawlin

**Subcommittee members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Institution</th>
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</thead>
<tbody>
<tr>
<td>Dr Helena Rosengren</td>
<td>General practitioner</td>
</tr>
</tbody>
</table>
WHO TREATS AND PROBLEMS TO REFER (GENERAL TOPIC)

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

Section lead: Dr Paul Fishburn and Dr Morton Rawlin

Subcommittee members

No subcommittee.

ECONOMICS OF KERATINOCYTE CANCER (GENERAL TOPIC)

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

Section lead: Associate Professor Louisa Gordon

Subcommittee members

Dr Sophy Shih  Senior Research Fellow/Health Economist at Deakin University

COMMON CONCERNS RAISED BY PATIENTS (GENERAL TOPIC)

Background chapter based on general literature summary. The 2008 content was reviewed and updated where required. Practice points are included as guidance.

Section lead: Dr Helena Rosengren

Subcommittee members

Dr Vicki Howard  Pathologist, Douglass Hanly Moir Pathology
Dr Morton Rawlin  General practitioner; Medical Director, Royal Flying Doctor Service (VIC)

d. Consumer representation

Two consumer representatives are members of the Working Party. Both consumers were engaged through recommendations from Working Party members.

The consumer representatives are invited to review content and attend meetings of the Working Party and are involved in the development of the guidelines content.

e. Project personnel, systematic review team and editor

Project management and governance were overseen by the Project Manager, Clinical Guidelines Network at Cancer Council Australia. The Senior Systematic Reviewer and Project Officer were the primary points of contact for the purpose of developing responses to the clinical questions and performed systematic reviews.

A medical editor was engaged to review and edit all sections of the guideline.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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</thead>
<tbody>
<tr>
<td>Tamsin Curtis</td>
<td>Project Manager, Clinical Guidelines Network</td>
</tr>
<tr>
<td>Dr Albert Chetcuti</td>
<td>Senior Systematic Reviewer, Clinical Guidelines Network</td>
</tr>
<tr>
<td>Annika Stollery</td>
<td>Project Officer, Systematic Literature Reviews, Keratinocyte Cancer Guidelines (May 2018 – May 2019)</td>
</tr>
<tr>
<td>Annie Bygrave</td>
<td>Systematic Reviewer (May – June 2018)</td>
</tr>
<tr>
<td>Dr Adelaide Morgan</td>
<td>Project Officer, Systematic Literature Reviews (May – June 2018)</td>
</tr>
</tbody>
</table>
3. Organisations formally endorsing the guidelines

The following medical colleges, professional bodies and charitable organisations will be approached to endorse the guidelines when they are finalised:

• Skin Cancer College Australasia (SCCA)
• The Australasian College of Dermatologists (ACOD)
• Australian College of Rural and Remote Medicine (ACRRM)
• Clinical Oncology Society of Australia (COSA)
• Medical Oncology Group of Australia Incorporated (MOGA)
• Royal College of Pathologists of Australia (RCPA)
• Royal Australian and New Zealand College of Radiologists (RANZCR)
• Royal Australian College of Physicians (RACP)
• Royal Australian College of Surgeons (RACS)
• Royal Australian College of General Practitioners (RACGP)
• Australian and New Zealand Society of Palliative Medicine
• Australasian Association of Nuclear Medicine Specialists
• Consumer Health Forum.

4. Declaration and management of competing interests for all people involved in the guideline development process

All Working Party members were asked to declare in writing, any competing interests relevant to the guideline development. The Management Committee was responsible for evaluating all statements of competing interests. The Chair’s evaluation of possible conflicts of interest was guided by A Code of Practice for Declaring and Dealing with Conflicts of Interest, which was developed based on the similar document produced by the National Institute for Health and Clinical Excellence. A Code of Practice for Declaring and Dealing with Conflicts of Interest is enclosed as Appendix 1.

A register of disclosed potential conflicts of interest was developed and is enclosed as Appendix 2. The register was available to the Working Party members during the development of the guideline, allowing members to take any potential conflicts of interest into consideration during discussions, decision making, and formulation of recommendations. Members were asked to update their information throughout the development of the guideline if they became aware of any changes to their interests, including the Chair asking for any new declarations at the beginning of each meeting.

There were no instances during the guideline development process where Disclosure of Interest management strategies were employed for guideline authors and co-authors.

In the endeavour to circumvent any potential conflicts of interest, executive representatives from Cancer Council Australia and the Department of Health were not directly involved in the systematic review process, the development of the guidelines or voting on recommendations. Their role was to provide governance, which included the approval of procedures and recommendations made by the clinicians and Subcommittees arising from the systematic review. No exclusion from voting occurred.

When the guidelines enter the updating phase, guideline Working Party members will be responsible for the updating of their Disclosure of Interests statements if new interests arise.

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members will receive a formal reminder to review their statements and ensure they are up-to-date prior to meetings scheduled to review content updates of a specific guideline.

5. **Method used to arrive at consensus-based recommendations or practice points**

The Subcommittees, in collaboration with the CCA systematic review team (who conduct the systematic reviews and provide the technical reports), assessed the evidence and drafted the evidence-based recommendations. This included grade assignment and/or consensus-based recommendations/practice points. Emails, teleconferences and face-to-face meetings were used to facilitate this process.

The draft guideline content underwent several iterations until agreement between the members of the Chapter Subcommittee was reached. When needed, any difficult points or areas of disagreement were flagged for the Working Party to discuss. The procedures and requirements outlined in *NHMRC additional levels of evidence and grades for recommendations for developers of guidelines and Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines* directed this process.

The first face-to-face meeting with Working Party members was held in November 2018 and the second April 2019 to review and finalise the draft guideline for public consultation. Multiple teleconferences were held late 2017 and early 2018 to develop the clinical questions and determine the scope of the content and revision.

In preparing for the two periods of Working Party review and the Public Consultation period, all available draft guideline content was circulated prior to the meetings and teleconferences. All members were asked to review the content, individual recommendations and practice points in detail, and identify and note any controversies and points to be discussed at the group meeting. During the meetings, recommendations and practice points were tabled and discussed so members had the opportunity to discuss any issues and suggest revisions to recommendations and practice points. Each recommendation and practice point were approved once the eligible members (excluding representatives of the funding bodies and members who cannot vote due to Conflict of Interest) reached consensus.

After the public consultation period, all comments will be compiled and sent to the relevant lead Working Party section authors and their Chapter subcommittee members to review their draft content and assess and consider the received comments. Email and teleconferencing will be used to facilitate this review process. Another face-to-face Working Party meeting will be organised after public consultation for July 2019 to review and consider all public consultation comments and the amended draft guideline content. The same consensus process that was followed during the meeting prior to public consultation will be followed. All changes resulting from the public consultation submission reviews will be documented and made accessible once the guidelines are published.

6. **Public consultation and review period**

   a. **Preparation of guidelines for public consultation**

The draft content of the guidelines was finalised by the Working Party section leads and subcommittees, with support provided by Cancer Council Australia project staff, the finalised content was then prepared for Public Consultation.
The draft content was edited by a professional medical writer experienced in NHMRC guideline development and circulated to members of the Working Party for review. Concerns or issues identified were addressed at the Working Party meeting on 8 April 2019 and further revisions were managed via email communication.

After the April 2019 meeting, further editorial changes to the draft content were prepared by the medical editor and Project Manager to ensure language and wording was consistent and adhered to NHMRC requirements.

b. Public consultation timeframe and process

The draft version of the guideline was released for a 30-day public consultation period from 7 June 2019 to 8 July 2019, as required by the National Health and Medical Research Council Act 1992.

The Director-General, Chief Executive or Secretary of each State, Territory and Commonwealth health department, were notified about the public consultation timeframe and invited to comment on the draft guideline.

Additional key professional organisations and consumer organisations that would be involved in, or affected by, the implementation of the clinical recommendations of the guidelines were notified of the public consultation period and invited to comment on the draft guideline, these include:

- Australasian College of Dermatologists (ACOD)
- Australian Skin and Skin Cancer Research Centre
- Australian Society of Plastic Surgeons
- Melanoma Institute
- Melanoma Patients Australia
- Skin & Cancer Foundation
- Skin Cancer College Australasia (SCCA)
- Sun Smart
- The Melanoma and Skin Cancer Trials group
- The Skin Hospital
- Australasian Association of Nuclear Medicine Specialists
- Australian and New Zealand Society for Geriatric Medicine (ANZGSM)
- Australian and New Zealand Society of Palliative Medicine
- Australian Cancer Research Foundation
- Australian College of Rural and Remote Medicine (ACRRM)
- Australian Commission on Safety and Quality in Healthcare
- Cabrini Institute
- Cancer Australia
- Cancer Council ACT
- Cancer Council NSW
- Cancer Council NT
- Cancer Council Queensland
- Cancer Council SA
- Cancer Council Tasmania
- Cancer Council Victoria
- Cancer Council Western Australia
- Cancer Voices Australia / Australian Cancer Consumer Network (ACCN)
- Centre for Health Policy Australian Indigenous Doctors Association NACCHO
- Clinical Oncology Society of Australia (COSA)
- Consumers Health Forum
- General Surgeons Australia (GSA)
c. Independent review

As required by NHMRC, three independent reviewers were engaged to assess the guidelines using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument. They reviewed the draft guideline during the Public Consultation period.

The purpose of the AGREE II instrument is to provide a framework to 1) assess the quality of guidelines, 2) provide a methodological strategy for the development of guidelines, and 3) inform what information and how information ought to be reported in guidelines.7 This instrument enabled the assessment of the guidelines against internationally accepted appraisal instruments.

The AGREE II reviewers were:

- Lyndal Alchin, Research Officer and Database Manager, Surgical Outcomes Research Centre (SOuRCe), Sydney Local Health District
- Jacqueline Buck, Clinical Research Coordinator, NSW Health
- Victoria Freeman, Systematic Reviewer, Cancer Research Division, Cancer Council NSW

Comments provided by the reviewers were discussed by the Working Party, project management personnel and systematic review team, and the guidelines changed where appropriate.

d. Post public consultation

The Working Party met after the Public Consultation to consider all submissions received during that period, and revise the draft guideline content as required, ensuring alignment with the evidence base. A concise register of responses and actions taken in relation to public consultation submissions

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was documented during this process. The Register of public consultation submissions will be publicly available with the final guideline, with submissions de-identified as necessary.

Notable revisions to the guideline post public consultation included:

- amendments to Practice Points – a significant reduction in the number of Practice Points, amendment of the definition of a ‘Practice Point’, and the development of a new feature called ‘Key Points’
- revision of the systematic review reports and evidence statements for four of the systematically reviewed clinical questions.

These changes are outlined in more detail in the Guideline development process.
A Code of Practice for Declaring and Dealing with Conflicts of Interest

Introduction

Conflict of interest refers to instances where private interest overtakes general interest. In practical terms, it is a situation in which an individual in a position of trust, decision-making or an assessment role has competing personal and/or professional interests, and these interests “could make it difficult for [that] individual to fulfil his or her duties impartially, and potentially could improperly influence the performance of their official duties and responsibilities”. However, it is important to note that “there is nothing inherently unethical about conflicts of interests as long as they are acknowledged and openly declared”.

In ensuring that work is conducted in an ethical, fair and impartial manner, individuals seeking to be appointed onto the Management Committee, working party or subcommittees for the revision of Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia (2008) project (the ‘Project’) are required to acknowledge and declare any possible or probable conflicts of interest. This is required to meet Standard A6 of the NHMRC Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines and a pre-requisite of ensuring public confidence in the integrity of guidelines.

This document is designed to ensure that conflicts of interest are identified and therefore can be appropriately negotiated or addressed between the individual and the Guidelines Developer (Cancer Council Australia). The document is to be read in conjunction with the NHMRC policy on identifying and managing conflicts of interest for guideline development.

Areas in which an individual could have competing interests and where conflicts of interest could occur include:

- professional positions
- membership of committees of other organisations

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8 This document has been created by Cancer Council Australia and based on the National Institute for Health and Clinical Excellence ‘Code of Practice for Declaring and Dealing with Conflicts of Interest’ (2007) and ‘Policy on Conflicts of Interest’ (2014) and National Health and Medical Research Council ‘Guidelines development and conflicts of interests. Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines’ (2012).


13 See 12.
• consultancies
• boards of directors
• advisory groups
• family and personal relationships
• financial interests (e.g. receiving recompense in the form of cash, services or equipment from outside bodies to support professional activities or research grants).

The intent of this document is to have appointees to the Management Committee, working party or subcommittees identify any potential conflicts of interests in order that:

• such interests can be assessed by the Management Committee and the National Health and Medical Research Council (NHMRC)
• management plans are developed to appropriately address the identified conflicts of interests when necessary
• individuals can form their own judgment about their appropriateness in seeking inclusion in the guideline development process
• for inclusion in the conflict of interest register for this Project
• to be in line with the NHMRC principles of guidelines development and conflicts of interests.

The policies and principles outlined in this document aim to assist an individual to identify and transparently declare any conflicts of interest with respect to activities and duties performed as a Management Committee, working party or subcommittee member of the Project.

Some issues that require consideration include, but are not limited to, the following.

1. What interests are involved?

The following is intended as a guide to the types of interest that should be declared. If a person covered by this is uncertain whether an interest should be declared, he or she should seek guidance as follows:

• Management Committee members and employees of Cancer Council Australia: from Cancer Council Australia CEO and Chair of the Management Committee
• Working party and Subcommittee members: Management Committee via the Chair
• Evidence contractors’ employees: from his or her head or department

Although attention is given to members’ or employees’ pecuniary interests, Cancer Council Australia is conscious that risks to an individual’s reputation could also be (or perceived to be) prejudicial to his or her advice. Arrangements covering ‘reputational risk’ are therefore also considered in this document (see below).

A. A personal pecuniary interest involves a current personal payment, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘specific’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘non-specific’. The main examples include the following:

• Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
• Any fee-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind, both those which have been undertaken in the 2 months preceding the meeting at which the declaration is made and which are planned but have not taken place.

• Any shareholdings, or other beneficial interests, in a healthcare industry that are either held by the individual or for which the individual has legal responsibility (e.g. children, or relatives whose full Power of Attorney is held by the individual).

• Expenses and hospitality provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences, both which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.

• Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the fund composition.

• Research grants received from Government and non-Government organisations to investigate topics and issues, which are related to the aims of the Project.

No personal interest exists in the case of:

• Assets over which individuals have no financial control (e.g. wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition.

• Accrued pension rights from earlier employment in the healthcare industry.

B. A non-personal pecuniary interest involves payment or other benefit that benefits a department or organisation for which an individual has managerial responsibility, but which is not received personally. This may either relate to the product or service being evaluated, in which case it is regarded as ‘specific’ or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as ‘non-specific’. The main examples include the following:

• The holding of a fellowship endowed by the healthcare industry.

• Any payment or other support by the health industry or by the Guideline Developer that does not convey any pecuniary or material benefit to an individual personally but that might benefit him or her. Examples include:

  i  a grant from a company for the running of a unit or department for which a member is responsible

  ii a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is responsible

  iii the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible

  iv one or more contracts with, or grants from the Guideline Developer.
An individual covered by this Code is under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within the departments for which they are responsible if they would not normally expect to be informed.

C. **A personal non-pecuniary interest** in a topic under consideration might include, but is not limited to:

- A clear opinion, reached at the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review.

- A public statement in which an individual is covered by this consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence.

- Holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration.

- Other reputational risks in relation to an intervention under review.

D. **A personal family interest** relates to the personal interests of a family member and involves a current payment to the family member of the employee or member. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘specific’, or to the industry or sector from which the product or service comes, in which case it is regarded as ‘non-specific’. The main examples include the following:

- Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

- Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

- Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (e.g. children, or adults whose full Power of Attorney is held by the individual).

- Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference).

- Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No personal family interest exists in the case of:

- Assets over which individuals have no financial control (e.g. wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (e.g. the Universities Superannuation Scheme).
• Accrued pension rights from earlier employment in the healthcare industry.

Additionally, individuals appointed to Management Committee, working party or subcommittee are expected to adhere to the Guideline Developer’s vision, mission and values, and to conduct themselves in accordance with its policies and procedures. It is never acceptable for an appointed individual to make public statements that are in conflict with Guideline Developer’s stated policies and positions.

2. Disclosing conflicts of interest

Individuals are required to provide information in relation to their personal and professional activities and interests, which could be perceived as having an apparent\(^{14}\) or a potential\(^{15}\) impact on their impartiality when contributing as a member of the Project.

In being appointed to the Management Committee, working party or subcommittee, an apparent or potential conflict of interest may arise in the following situations (though this list is not exhaustive), where an individual:\(^{16}\)

• Has a contractual or unpaid/paid employment arrangement with an organisation that is involved in a request, which will be under his/her consideration as a Guideline Developer board, Management Committee, working party or subcommittee member.

• Owns shares in, or controls a company or other organisation involved in any current application that is under his/her consideration, or in which he/she has direct involvement.

• Is involved in any other Guideline Developer board, Management Committee, working party or subcommittee process where he/she may have a direct or indirect involvement in the matters being considered.

At the time of accepting an appointment to participate in the Project, an individual must provide information (as detailed in this document) of the financial and other private/professional interests of themselves and their immediate family/partner, which may represent an apparent or potential conflict of interest.

The obligation to disclose an apparent or potential conflict of interest is ongoing. Accordingly, subsequent to the initial disclosure, individuals are required to provide updates to Cancer Council Australia if there are significant changes to their or their immediate family/partner’s private interests as they become aware of those changes. The private information provided by individuals will be treated by Cancer Council Australia as confidential and in accordance with the Information Privacy Principles set out in the Privacy Act.

If an individual appointed to participate in the Project has, or acquires, an interest, pecuniary or otherwise, that could conflict with the proper performance of his or her appointed functions, he or

\(^{14}\) An **apparent** (or perceived) conflict of interest exists where it appears that individual private interests could improperly influence the performance of their duties and responsibilities whether or not this is, in fact, the case. Individuals must be conscious that perceptions of conflict of interest may be as important as an actual conflict. (ARC, 2009, p.3)

\(^{15}\) A **potential** conflict of interest arises where an individual has a private interest which is such that an actual conflict of interest would arise if the member were to become involved in relevant (that is conflicting) official duties and responsibilities in the future. (ARC, 2009, p.3)

\(^{16}\) A conflict of interest may also exist where the individual’s partner or immediate family member has any of the interests or involvements listed.
she must disclose to Cancer Council Australia, in writing, details of the nature of the interest as soon as possible after the relevant facts come to the individual’s knowledge. In cases where a member declares a conflict of interest in relation to a matter under consideration by Cancer Council Australia, Management Committee, guideline working party or subcommittee, the Management Committee will determine the extent to which that individual may be involved in discussion or decisions concerning that matter.

3. When should interests be declared and what action is required?

Sub Appendix A summarises the actions which should be taken when interests are declared.

A. On appointment

Any uncertainty about potential conflicts of members of advisory bodies on appointment should be resolved at the discretion of the relevant Chair and the Management Committee.

B. At working party meetings

Members and other individuals covered by this Code who are attending to take part in the meeting should declare relevant interests at each working party meeting and at appeal panels and state into which of the following categories they believe the interest falls:

- A person declaring a **personal specific pecuniary or personal family specific interest** shall take no part in the proceedings as they relate to the intervention or matter and will normally leave the meeting until the matter has been concluded. In exceptional circumstances he or she may, at the discretion of the Chair, answer questions from other members but should then leave the meeting until the discussion has been concluded.

- A person declaring a **personal non-specific pecuniary interest** may take part in the proceedings unless, exceptionally, the Management Committee rules otherwise.

- A person declaring a **non-personal specific pecuniary interest or a personal family non-specific interest** may take part in the proceedings unless he or she has personal knowledge of the intervention or matter either through his or her own work or through direct supervision of other people’s work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions.

- A person declaring a **non-personal non-specific pecuniary interest** may take part in the proceedings unless, exceptionally, the Management Committee rules otherwise.

- When someone declares a **personal no-pecuniary interest** the Management Committee shall determine, on a case-by-case basis, whether he or she should take part in the proceedings.

C. In evidence publications

Where an individual covered by this Code is responsible for authoring, in whole or part, a document that is prepared specifically to inform the Guideline Developer’s advisory bodies, they must declare any interests in accordance with this Code.

D. Record of interests and their publication
A record is kept at Cancer Council Australia of:

- Names of individuals who have declared interests on appointment, as the interest first arises or through the annual declaration, and the nature of the interest.
- Names of individuals who have declared interests at meetings giving dates, names of relevant interventions and companies, details of the interest declared and whether the member took part in the proceedings.

4. Summary

When an individual is seeking appointment to the Management Committee, working party or subcommittee, he or she is responsible for reading this document, reviewing his or her current activities for apparent or potential conflicts of interest, and bringing any existing and future possible and probable conflicts of interest to the attention of the Guideline Developer.

Guideline Developer contact at Cancer Council Australia: Tamsin Curtis, Project Manager, Clinical Guidelines Network, Email: guidelines@cancer.org.au

Form for Disclosure of Potential Conflicts of Interest

For individuals seeking to be involved in the guideline development, please read this document and the principles outlined in the NHMRC Guidelines development and conflicts of interest publication. Then complete the Form for Disclosure of Interests by providing the information required.

When the completed form is received, the Management Committee will review the content and determine if information provided constitutes a conflict that might disqualify an appointment. If an appointment is to proceed and there are issues which require attention in consultation with the individuals, the Management Committee will determine how the interests will be managed.

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18 The Management Committee may consider engaging an independent assessor to evaluate all COI submissions.
Revision of *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia (2008)*

**Form for Disclosure of Interests**

**Introduction**

The intent of the disclosure of interests is to have the participants in the clinical practice guidelines development identify any potential conflict(s) in order that:

- Such interests can be assessed and managed appropriately
- Each participant can form their own judgment, while taking the interests of other group members into consideration
- To follow best practice in guideline development.

The questions in this document are designed to enable participants in the working party to disclose any apparent, perceived or potential conflict(s) of interest with respect to their activities in guidelines development.

The questions pertain to:

- Relationships you or, as far as you are aware, any immediate family members (partner and dependent children) may have with pharmaceutical companies or other companies whose products or services are related to the diagnosis and management of basal cell carcinoma, squamous cell carcinoma (and related lesions).
- Financial interests or relationships requiring disclosure including, but not limited to, payments, gifts, gratuities, consultancies, honoraria, employment, or stock ownership related to commercial companies that may have an interest in the content or recommendations of the guidelines
- Affiliations or associations with organisations or activities which indicate undue influence due to a competing interest either for or against the issue for which the guidelines are being developed
- Involvement in the development of related guidelines, standards, educational materials or fact sheets.

Declared interests will be recorded in a register of interests which will then be distributed to all other potential members of the working party. Disclosure information will be made available for public scrutiny and will also be included in the final published clinical practice guidelines.

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19 Cancer Council Australia acknowledges this form has been adapted from the Conflict of Interest document for the Clinical Practice Guidelines for PSA Testing and Early Management of Test Detected Prostate Cancer (2015), which is based on the National Health and Medical Research Council form for Disclosure of Interest (Guidelines Development).

Instructions

This form has four sections as follows:

Section 1 – Identifying information
Section 2 – Relates to receipt of benefits from entities with a direct interest in the guidelines
Section 3 – Information about the experience of potential members
Section 4 – Other relationships or activities not covered in sections 2-3.

For sections 2 to 4, complete each row by checking “No” or providing the requested information. Please describe the nature of the interest and/or relationship and identify the relevant commercial or other entity. Please provide this information or any other relevant comments as an attachment to this form and indicate which attachment applies to your response. You also have the option to provide details of any proposal you may have to manage this interest (e.g. divesting the interest, exclusion from discussions on certain topics).

Section 1: Identifying Information

Given Name(s) ________________________________

Family Name ___________________________________________________________________________
**Section 2: Relevant Financial Activities**

<table>
<thead>
<tr>
<th>Type of interest</th>
<th>No</th>
<th>Yes: Personal benefits (received or expected)</th>
<th>Yes: Benefits to immediate family (received or expected)</th>
<th>Please add any further detail, including comments and/or relevant attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In relation to 1: Over the past three years, have you been employed by an entity having a commercial or other interest in the subject of the guidelines or guideline recommendations to be developed?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Employment</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td><strong>In relation to 2: Applies to an entity which has a commercial interest in the subject of the guidelines under consideration (including where stock in the entity is not publicly traded). This includes stock options but excludes indirect investments through mutual funds and the like.</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Ownership interests</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td><strong>In relation to 3-9: Disclosure is required in relation to disbursements over the three years preceding, and any anticipated disbursements in the 12 months following, appointment to the committee or working group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Board membership</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>4. Grants</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>5. Consultancy fees/honorarium</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>6. Support for travel or accommodation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>7. Meals and beverages</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>8. Entertainment, gifts or gratuities</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>9. Other (e.g. registration fees for conferences, institutional interests, etc – see policy)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

**Section 3: Relevant Professional and Organisational Experience**

The following question is designed to provide prompts to assist with completion of the table below:
- Have you published or spoken on or advocated or publicly debated the topic of the basal cell carcinoma, squamous cell carcinoma, or related lesions (including the provision of expert testimony)?

*If you have published extensively and they are listed on your CV, you may provide your CV as a relevant attachment. If the same position has been expressed in multiple publications, an illustrative sample is sufficient, rather than a complete listing of publications.*

<table>
<thead>
<tr>
<th>Relevant Experience</th>
<th>No</th>
<th>Yes</th>
<th>Relevant attachment number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Publications</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>2. Speeches/lectures</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>3. Expert testimony</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>4. Development of related materials, including guidelines, standards, educational materials or fact sheets</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>5. Other (e.g. unpaid advisory roles)</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>
Section 4: Other Relationships or Activities

The following questions are designed to provide prompts to assist with completion of the table below:

- Are you affiliated or associated with any organisations whose interests are either aligned with or opposed to the subject matter of the proposed guidelines?
- Are there any other relationships or activities that could be perceived potentially to influence your contribution?

<table>
<thead>
<tr>
<th>Other relationships or Activities</th>
<th>No</th>
<th>Yes</th>
<th>Relevant attachment number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Relationships</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>2. Activities</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

Declaration

- I declare that the information provided was correct on the date entered below.
- I declare that I have read the document ‘A Code of Practice for Declaring and Dealing with Conflicts of Interest’ and the NHMRC policy Guideline Development and Conflicts of Interest: Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines agree to comply with the policy.
- I agree to this information being provided to other members for their consideration.

In signing this form, I hereby agree to:

- Update this information throughout my involvement with the development of the guidelines if my circumstances change, or otherwise in response to requests to update this information (i.e. at least annually)
- Comply with any interest management plan
- Allow the publication of these disclosed interests and any management plan including in the final clinical practice guidelines.

Signature ______________________________________

Date ________________________________________

Acknowledgement of source material: This form has been adapted from the National Health and Medical Research Council Form for Disclosure of Potential Conflicts of Interest. See: https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/coi_interactive_120924.pdf
# A Code of Practice for Declaring and Dealing with Conflicts of Interest

## Sub Appendix A: Declaring interests at meetings

<table>
<thead>
<tr>
<th>Type of interest</th>
<th>See section</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal specific pecuniary</td>
<td></td>
<td>Declare and withdraw</td>
</tr>
<tr>
<td>Personal non-specific pecuniary</td>
<td></td>
<td>Declare and participate (unless, exceptionally, the Management Committee rules otherwise)</td>
</tr>
<tr>
<td>Personal family specific interest</td>
<td></td>
<td>Declare and withdraw</td>
</tr>
<tr>
<td>Personal family non-specific</td>
<td></td>
<td>Declare and participate (unless, exceptionally, the Management Committee rules otherwise)</td>
</tr>
<tr>
<td>Non-personal specific pecuniary interest</td>
<td>Declare and participate, unless the individual has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people’s work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions</td>
<td></td>
</tr>
<tr>
<td>Non-personal non-specific pecuniary</td>
<td>Declare and participate (unless, exceptionally, the Management Committee rules otherwise)</td>
<td></td>
</tr>
<tr>
<td>Personal specific non-pecuniary</td>
<td>Declare – action is at discretion of the Management Committee</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2 Disclosure of interest register: Clinical practice guidelines for keratinocyte cancer

Disclosures of interest (DOI) were assessed and managed according to Cancer Council Australia’s A Code of Practice for Declaring and Dealing with Conflicts of Interest.20

All Working Party members, including consumer and GP representatives and Cancer Council project staff, were asked to declare in writing any interests relevant to the guideline development. The Chair was responsible for evaluating all statements. The evaluation of possible DOI was guided by A Code of Practice for Declaring and Dealing with Conflicts of Interest. All declarations and the evaluation outcome were added to the register of interests for the guidelines. As per NHMRC recommendation21 the DOI for independent reviewers has not been published, the reviewers submitted DOI forms that were assessed.

Members had the option to submit a curriculum vitae (CV) to summarise their experience, skills and publications. However, it was not compulsory to submit a CV. The Chair could request to view a CV if necessary. The information in the CVs provided is intended to complement or provide additional detail about the individual. If a CV was submitted it is noted as ‘Attachment X’, the CV attachment sections starts on page 13.

This register was available to the Working Party members throughout the development of the guidelines, allowing members to take any potential DOI into consideration during discussions, decision making and formulation of recommendations. Members were asked to update their information throughout the guidelines development process if they became aware of any changes to their interests.

When the guidelines enter the updating phase, Working Party members will be responsible for notifying CCA of any updates to their entry if a new interest arises. Members will receive a formal reminder to review their statements and ensure it is up to date.

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Consumer representatives .................................................................................................. 35
Subcommittee members ..................................................................................................... 36
Cancer Council Australia staff members ........................................................................... 41

## Management Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Relevant financial activities</th>
<th>Relevant professional and organisational experience</th>
<th>Other relationships or activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof Stephen Shumack</td>
<td>• Dermatologist/Investigator, St George</td>
<td>None.</td>
<td>Publications</td>
<td>Member Skin Advisory Group, Genesis Care 2017 – present</td>
</tr>
<tr>
<td></td>
<td>Dermatology &amp; Skin Cancer Centre - Kogarah, 1991 – Present</td>
<td></td>
<td>Speeches/lectures</td>
<td>Shareholder, Genesis Care, 2018 - present</td>
</tr>
<tr>
<td></td>
<td>• Chairman, Skin and Cancer Foundation Australia -</td>
<td></td>
<td>Attachment 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Darlington, New South Wales, 2017 – Present</td>
<td></td>
<td>Speeches/lectures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Associate Investigator, Proby Medical Research, Dermatology</td>
<td></td>
<td>Development of related materials,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Waterloo, Ontario, Canada 2010 – present</td>
<td></td>
<td>including guidelines, standards,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medical Director, The Skin Hospital - Darlington,</td>
<td></td>
<td>educational materials of fact sheets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New South Wales 2016 - Present</td>
<td></td>
<td>Attachment 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Chair - Dermatology, Allergy, and Immunology Clinical</td>
<td></td>
<td>Development of related materials,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Committee, Medicare Benefits Schedule Task Force -Australian</td>
<td></td>
<td>including guidelines, standards,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Government Department of Health</td>
<td></td>
<td>educational materials of fact sheets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Senior Staff Specialist, Royal North Shore Hospital of</td>
<td></td>
<td>Publications</td>
<td></td>
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<tr>
<td></td>
<td>Sydney - St Leonards, New South Wales</td>
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<tr>
<td></td>
<td>• Clinical Associate Dermatology, Northern Clinical School,</td>
<td></td>
<td>Speeches/lectures</td>
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<tr>
<td></td>
<td>The University of Sydney</td>
<td></td>
<td>Attachment 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dermatologist/Sub-Investigator, Central Sydney Dermatology</td>
<td></td>
<td>Development of related materials,</td>
<td></td>
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<tr>
<td></td>
<td>- Ground floor, 225 Macquarie Street, Sydney, New South Wales</td>
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<td>including guidelines, standards,</td>
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<td></td>
<td>educational materials of fact sheets</td>
<td></td>
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<tr>
<td></td>
<td>• Medical Student and Registrars Teacher, The University of</td>
<td></td>
<td>Publications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sydney - St Leonards, New South Wales</td>
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<td>Attachment 2</td>
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<td>Development of related materials,</td>
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<td>including guidelines, standards,</td>
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<td>educational materials of fact sheets</td>
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<td></td>
<td>Guidelines for flap use, largely adopted by MBS</td>
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<td>Other (e.g. unpaid advisory roles)</td>
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<td></td>
<td></td>
<td></td>
<td>AMA Fees Committee 2004 - 2009</td>
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<tr>
<td>Dr Peter Callan</td>
<td>Specialist Plastic surgeon</td>
<td>None.</td>
<td></td>
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<tr>
<td>Dr Alvin Chong</td>
<td>Adjunct Associate Professor, (Level D), Department of Medicine</td>
<td>None.</td>
<td>Publications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Dermatology), St Vincent’s Hospital</td>
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**None.**

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**None.**
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<th>Relevant professional and organisational experience</th>
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</thead>
</table>
| Dr Gerald Fogarty         | Director of Radiation Oncology, Mater Hospital; Clinical Associate Professor of Medicine, The University of Sydney | None.                                                                                                                                 | Speeches/lectures  
Attachment 2  
Development of related materials, including guidelines, standards, educational materials of fact sheets  
Attachment 2  
Other (e.g. unpaid advisory roles)  
Clinical advisor for Cancer Council Victoria                                                                                     | Board Member Melanoma and Skin Cancer Trials Group Ltd; Advisory board 2017 - present Merck Serono Australia Pty Ltd; Grant recipient 2018 Merck Serono Australia Pty Ltd; Share holder Genesis Care 2008 - current                                                                                                                                       |
| Dr Peter Foley            | Head of Dermatology, Department of Dermatology, St Vincent’s Hospital, Fitzroy, Victoria | Consultancy fees/honorarium  
Attachment 4                                                                 | Publications  
Attachment 3  
Speeches/lectures  
Attachment 3  
Development of related materials, including guidelines, standards, educational materials of fact sheets  
Attachment 3  
Other (e.g. unpaid advisory roles)  
Mentor, see Attachment 3                                                                                                                   | Activities  
Advisory board for Sun Pharma – sonidegib Investigator – Roche - vismodegib                                                                                                                                                                                                                                                                                                                                 |
| Prof Adele Green          | Head, Cancer and Population Studies Group, QIMR Berghofer Medical Research Institute (formerly Queensland Institute of Medical Research (QIMRI)) | Grants  
NHMRC program grant to study, among other things, BCC and SCC epidemiology                                                                 | Publications  
Attachment 5  
Speeches/lectures  
Attachment 5  
Development of related materials, including guidelines, standards, educational materials of fact sheets°  
Attachment 4                                                                                                                                  | Relationships  
Member of ICNIRP and ARPANSA Scientific Advisory Council                                                                                                                                                                                                                                                                                                                                                                 |
| A/Prof Alexander Guminski | Associate Professor Medicine, The University of Sydney; Medical Oncologist, Melanoma Institute | Consultancy  
Sun pharma, Roche-advisory board                                                                                                      | Publications  
Attachment 6                                                                                                                       | Regeneron and Sanofi Advisory Board; Regeneron Trial                                                                                                                                                                                                                                                                                                                                                     |
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<th>Relevant professional and organisational experience</th>
<th>Other relationships or activities</th>
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</thead>
<tbody>
<tr>
<td>Dr Vicki Howard</td>
<td>Pathologist, Douglass Hanly Moir Pathology</td>
<td>Support for travel or accommodation&lt;br&gt;Sun Pharma – conference Travel and accommodation Sun Pharma</td>
<td>Speeches/lectures&lt;br&gt;Australian dermatology conference 2018 Expert testimony&lt;br&gt;PBAC Sonidegib listing hearing</td>
<td>Management Committee (Cemiplimab for SCC)</td>
</tr>
<tr>
<td>Dr Morton Rawlin</td>
<td>General practitioner, Medical Director at Royal Flying Doctor Service (Vic)</td>
<td>None.</td>
<td>Speeches/lectures&lt;br&gt;Lectures at the University of Notre Dame&lt;br&gt;Development of related materials, including guidelines, standards, educational materials of fact sheets&lt;br&gt;Authored a skin booklet for publication for GP's and dermatologists</td>
<td>None.</td>
</tr>
<tr>
<td>Dr David Speakman</td>
<td>Chief Medical Officer, Peter MacCallum Cancer Centre</td>
<td>None.</td>
<td>Speeches/lectures&lt;br&gt;Speak to GP registrars twice a year on dermatology and sometimes skin cancer treatment.</td>
<td>None.</td>
</tr>
<tr>
<td>Prof David Whiteman</td>
<td>Deputy Director, Queensland Institute of Medical Research (QIMR) Berghofer Medical Research Institute&lt;br&gt; NHMRC Senior Principal Research Fellow Head, Cancer Control Group</td>
<td>NHMRC Research Fellowship [APP1155413]&lt;br&gt;NHMRC Program Grant [APP1073898]&lt;br&gt;NHMRC Project Grant [APP1063061]</td>
<td>Publications&lt;br&gt;Attachment 7 Speeches/lectures&lt;br&gt;Attachment 7</td>
<td>Skin cancer college of Australia&lt;br&gt;Cancer Council Australia&lt;br&gt;Health Services Advisory Committee&lt;br&gt;Melanoma and Skin Cancer Trials Limited</td>
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## Section leaders

<table>
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<tr>
<th>Name</th>
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</table>
| **Adjunct A/Prof Craig Sinclair** | Head, Prevention Division at the Cancer Council Victoria | None.                        | **Publications**<sup>°</sup>  
**Speeches/lectures**<sup>°</sup>  
**Expert testimony**<sup>°</sup>  
**Development of related materials, including guidelines, standards, educational materials of fact sheets**<sup>°</sup>  
<sup>°</sup>All related to roles as expert advisor to Cancer Council Australia, role as head of prevention at the Cancer Council Victoria, of which a primary duty has been as a media spokesperson | Relationships  
Staff member at Cancer Council Victoria  
Activities  
Staff member at Cancer Council Victoria |
| **A/Prof Louisa Gordon**    | Senior Research Fellow/Lab Head, QIMR Berghofer Medical Research Institute, Brisbane | **Other (e.g. registration fees for conferences, institutional interests etc – see policy)**  
2017 World Congress in Melanoma registration paid | **Publications**  
Attachment 8  
**Speeches/lectures**  
Attachment 8  
**Development of related materials, including guidelines, standards, educational materials of fact sheets**  
Previous guidelines for KC’s in 2008, chapter 15 | None. |
| **Prof Diona Damian**      | Professor of Dermatology, The University of Sydney | None.                        | **Publications**  
Attachment 9  
**Speeches/lectures**  
Attachment 9  
**Development of related materials, including guidelines, standards, educational materials of fact sheets**<sup>°</sup>  
Attachment 9  
**Other (e.g. unpaid advisory roles)**  
Attachment 9 | None. |
## GP representatives

<table>
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<tr>
<th>Name</th>
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<th>Relevant professional and organisational experience</th>
<th>Other relationships or activities</th>
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</table>
| Dr Helena Rosengren | General practitioner      | None                         | **Publications**  
Attachment 10  
**Speeches/lectures**  
Attachment 10                                           | Chair, Research Committee, Skin Cancer College of Australasia  
Senior Lecturer James Cook University                        |
| Dr Paul Fishburn  | General practitioner      | None.                        | **Speeches/lectures**  
Talks to GPs on KCs  
**Development of related materials, including guidelines, standards, educational materials of fact sheets**  
Participates in Melanoma guidelines                          | None.                             |

## Consumer representatives

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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Mr Danny Brennan</td>
<td>Consumer</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td>Ms Ann Strokon</td>
<td>Consumer</td>
<td>None supplied</td>
<td>None supplied</td>
<td>None supplied</td>
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<tr>
<td>Dr Catherine Olsen</td>
<td>Senior Research Officer, Division of Population and Clinical Sciences, Queensland Institute of Medical Research</td>
<td>None.</td>
<td><strong>Publications</strong>&lt;br&gt;Attachment 11&lt;br&gt;<strong>Speeches/lectures</strong>&lt;br&gt;Attachment 11</td>
<td>None.</td>
</tr>
<tr>
<td>Professor Gary Halliday</td>
<td>Professor of Dermatology, University of Sydney</td>
<td>None.</td>
<td><strong>Publications</strong>&lt;br&gt;Attachment 12&lt;br&gt;<strong>Speeches/lectures</strong>&lt;br&gt;Attachment 12</td>
<td>None.</td>
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<tr>
<td>Professor Robyn Lucas</td>
<td>Professor and Head, National Centre for Epidemiology and Population Health, at Australian National University</td>
<td><strong>Support for travel and accommodation</strong>&lt;br&gt;Funded by Consortium of MS Centers to attend 2018 conference</td>
<td><strong>Publications</strong>&lt;br&gt;Review papers on trends in SCC and BCC&lt;br&gt;<strong>Development of related materials, including guidelines, standards, educational materials of fact sheets</strong>&lt;br&gt;Some work on sun exposure guidelines</td>
<td>None.</td>
</tr>
<tr>
<td>Professor John Kelly</td>
<td>Dermatologist, Victorian Melanoma Service, Alfred Health, Melbourne</td>
<td><strong>Ownership interests Superannuation fund owns shares in MoleMap Australia PL. Personal shares in MoleMap Australia since 2005.</strong></td>
<td><strong>Publications</strong>&lt;br&gt;See attachment 13&lt;br&gt;<strong>Speeches/lectures</strong>&lt;br&gt;See attachment 13&lt;br&gt;<strong>Expert Testimony</strong>&lt;br&gt;Medicolegal opinions provided. Development of related materials, including guidelines, standards, educational materials or fact sheets Melanoma Clinical Pathway. Pathology Reporting Expert Group. Cancer Council Melanoma Booklet. None. Last updated: June 2018. Page 2 Other&lt;br&gt;See attachment 13</td>
<td>None.</td>
</tr>
<tr>
<td>Professor Peter Soyer</td>
<td>Director, School of Medicine, University of Queensland; Director,</td>
<td><strong>Board membership</strong>&lt;br&gt;See attachment 14</td>
<td><strong>Publications</strong>&lt;br&gt;See attachment 14</td>
<td>None.</td>
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<tr>
<td>Dr James Emmett</td>
<td>Plastic surgeon</td>
<td>None.</td>
<td>Speeches/lectures</td>
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<td>Not specified.</td>
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<td></td>
<td>Meals and beverages</td>
<td>Development of related materials, including guidelines, standards, educational materials or fact sheets</td>
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<tr>
<td></td>
<td></td>
<td>Entertainment, gifts or gratuities Not specified. Other (e.g. registration fees for conferences, institutional interests, etc – see policy) Not specified.</td>
<td>See attachment 14</td>
<td></td>
</tr>
<tr>
<td>Dr Brian De’Ambrosis</td>
<td>Mohs surgery</td>
<td>Meals and beverages</td>
<td>Speeches/lectures</td>
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<td></td>
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<td>Sun Pharma (Sonidegib); Genesis (VMAT)</td>
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<td>Speeches/lectures Lectures for the Australian Skin Cancer Academy – Mohs Keratinocyte Cancer and Perineural invasion</td>
<td></td>
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<tr>
<td>Dr Howard Liu</td>
<td>Dermatologist</td>
<td>None.</td>
<td>Publications</td>
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Other relationships or activities

- Dermatology Department, Princess Alexandra Hospital
- Grants See attachment 14
- Consultancy fees/honorarium Greenslopes Private Hospital (Qld, AUS); Canfield Scientific (SA); Molemap Australia
- Support for travel or accommodation Not specified.
- Meals and beverages Not specified.
- Entertainment, gifts or gratuities Not specified. Other (e.g. registration fees for conferences, institutional interests, etc – see policy) Not specified.
- Speeches/lectures Not specified.
- Development of related materials, including guidelines, standards, educational materials or fact sheets See attachment 14
- Other (e.g. unpaid advisory roles) See attachment 14
- None.
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<tbody>
<tr>
<td>Dr Michelle Goh</td>
<td>Consultant dermatologist at the Peter MacCallum Cancer Centre, the Alfred Hospital and the Skin and Cancer Foundation</td>
<td>None.</td>
<td>High-Risk Cutaneous Squamous Cell Carcinoma of the Head and Neck: The Randomized Phase III TROG 05.01 Trial. Journal of Clinical Oncology. 2018 Mar; 14. doi: 10.1200/JCO.2017.77.0941</td>
<td>Relationships Activities: Staff member-Department of Surgical Oncology (Dermatology Department) at Peter MacCallum Cancer Centre, Victorian Comprehensive Cancer Centre; Dept of Dermatology St Vincent’s Hospital</td>
</tr>
<tr>
<td>Dr Gilberto Moreno</td>
<td>Dermatologist</td>
<td>None.</td>
<td>Publications</td>
<td>Speeches/lectures: Victorian Comprehensive Cancer Centre (VCCC) Workshop: State of the Art in Complex Cutaneous SCC 15 March 2018</td>
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<tr>
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<td>Development of related materials, including guidelines, standards, educational materials of fact sheets</td>
<td>Other (e.g. unpaid advisory roles): Not specified.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Working Group for Optimal care pathway for people with basal cell carcinoma or squamous cell carcinoma sponsored by Cancer Council &amp; Australian Government Cancer Australia</td>
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</table>

*Relevant professional and organisational experience*:

*Other relationships or activities*:
- Staff member-Department of Surgical Oncology (Dermatology Department) at Peter MacCallum Cancer Centre, Victorian Comprehensive Cancer Centre; Dept of Dermatology St Vincent’s Hospital

*Relationships Activities*:
- Staff member-Department of Surgical Oncology (Dermatology Department) at Peter MacCallum Cancer Centre, Victorian Comprehensive Cancer Centre; Dept of Dermatology St Vincent’s Hospital

*Other (e.g. unpaid advisory roles)*:
- Not specified.
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<tr>
<td>Dr Hsien Chan</td>
<td>Dermatologist</td>
<td>None.</td>
<td>Speeches/lectures Attachment 15</td>
<td>None.</td>
</tr>
<tr>
<td>Dr Patricia Lowe</td>
<td>Senior Staff Specialist at Royal Prince and Clinical Senior Lecturer at the Central Sydney Medical School, University of Sydney</td>
<td>None.</td>
<td>Publications Attachment 16 Speeches/lectures Attachment 16</td>
<td>None.</td>
</tr>
<tr>
<td>Dr Sarah Brennand</td>
<td>Dermatologist</td>
<td>None.</td>
<td>Speeches/lectures Non-Pecuniary: no payment was received for the preparation or delivery of these lectures, and no influence from employers/Australasian College of Dermatologists or ATCA affected the delivery of this material 1. MD2 lecture – skin cancer – Austin Clinical School, The University of Melbourne This is a lecture performed 1 – 4 times a year by myself, and my colleagues in the Dermatology Department of Austin Health for medical students and covers basal cell carcinoma, squamous cell carcinoma and melanoma. This lecture is pre-prepared and set by Associate Professor Alvin Chong and Dr Cater Scarff from the University of Melbourne 2. Skin problems ion organ transplant recipients This is a lecture given for the National Skin School Webinar for the Australasian College of Dermatologists, and for dermatology registrars attending the Skin and Cancer Foundation. It covers basal cell carcinomas, squamous cell carcinoma and melanoma in organ transplant recipients. The lecture</td>
<td>None.</td>
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### Clinical practice guidelines for keratinocyte cancer – Administration report

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<td></td>
<td></td>
<td></td>
<td>has been prepared by Associate Professor Alvin Chong and modified and updated over time by Dr Brennand.</td>
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</table>
|                       |                                               |                               | **3. Skin checks for potential organ donors**  
This is a lecture Dr Brennand was asked to give for the 2018 ATCA Conference (Australasian Therapeutic Communities Association), held at Alfred Hospital. It covers screening patients after brain death for melanoma, but briefly touched on features of basal cell carcinoma and squamous cell carcinoma. This lecture was prepared by Dr Brennand, with the aid of resources and discussion with Associate Professor Alvin Chong and Dr Cate Scarff from the University of Melbourne. |                                  |
| Dr Katherine Allnutt  | Education and Research Fellow, Skin and Cancer Foundation | None.                        | None.                                                                                                             | Education and Research Fellow, Skin and Cancer Foundation (since 1 Feb 2018)  
This organisation’s interests are aligned with the subject matter of the proposed guidelines. |                                  |
| Dr Kiarash Khosrotehrani | Dermatologist                              | Employment:  
Work as a dermatologist. Receive Medicare benefit for the care of BCC/SCC patients | Publications:  
Attachment 17  
Speeches/lectures:  
Attachment 17 | None.                                                                                           |
| Dr Sophy Shih         | Senior Research Fellow / Health Economist at Deakin University | None.                        | Publications:  
Attachment 18  
Speeches/lectures:  
Not specified.                                                                                           | None.                                                                                   |
| Dr Sydney Ch’ng       | Associate Professor of Surgery (Plastic Surgery, | None.                        | Publications:  
Attachment 19                                                                                       | None.                                                                               |
### Relevant financial activities

**Consultancy fees/honorarium**
Member of advisory board for: Menarini (topical treatment for actinic keratosis), Mayne Pharma (topical products for acne) and Sunpharma (biologic drug for treatment of psoriasis).

**Activities**
On the Advisory board for Menarini, not contributing to new guidelines on actinic keratosis.

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### Cancer Council Australia staff members

<table>
<thead>
<tr>
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<th>Position</th>
<th>Relevant financial activities</th>
<th>Relevant professional and organisational experience</th>
<th>Other relationships or activities</th>
</tr>
</thead>
</table>
| Dr Albert Chetcuti          | Senior Systematic Reviewer, Clinical Guidelines Network, Cancer Council Australia | **Employment**
Senior Systematic Reviewer, Clinical Guidelines Network, Cancer Council Australia | None. | None. |
| Tamsin Curtis               | Project Manager, Clinical Guidelines Network | **Employment**
Project Manager, Clinical Guidelines Network, Cancer Council Australia | None. | None. |
| Annika Stollery             | Project Officer, Clinical Guidelines Network | **Employment**
Project Officer, Clinical Guidelines Network, Cancer Council Australia | None. | None. |
| Annie Bygrave               | Systematic Reviewer, Cancer Council Australia (May – June 2018) | **Employment**
Project Officer, Evidence Review, Cancer Council Australia | None. | None. |
| Dr Adelaide Morgan          | Project Officer, Cancer Council Australia (May – June 2018) | **Employment**
Project Co-Ordinator, Cancer Council Australia | None. | None. |