

**The Skin Cancer College of Australia and New Zealand (SCCANZ) Surgical
Audit Research Project
Consent Information Sheet**

This information sheet has been prepared for medical practitioners who are considering participation in the SCCANZ Surgical Audit – Research Project.

This is a research project owned by the Skin Cancer College of Australia and New Zealand (SCCANZ). The principle investigator is Dr Ben Cook. The other investigators are Dr Cliff Rosendahl, Dr Peter Bourne, Dr Jeff Keir, Dr Martin Baker, Dr Mike Reid and Dr Tony Dicker .

Contact details for these investigators are via email at audit@skincancersociety.com

There are three versions of this project.

The first version, referred to as the “Pathology Company Version” involves participants recording surgical log data on the reverse side of the pathology request form when submitting skin specimens for histological evaluation. This data is used as the basis of the “SCCANZ Surgical Audit – Self Audit Tool. The pathology company transfers the data onto a database on its computer system and subsequently adds information about the histological diagnosis and adequacy of surgical margins. As part of its clinical reporting process the pathology company issues a report to the participant at intervals with those participants’ analysed data compared to pooled data.

The second version, referred to as the “Personal Computer Version” involves participants recording surgical log data on a database program provided to them by the SCCANZ, on their own computer. This data is used as the basis of the “SCCANZ Surgical Audit – Self Audit Tool.

The third version, referred to as the “On-line” version, works exactly the same as the “Personal Computer Version” with the exception that there is no software necessary on the participating doctor’s computer and all of the patient data and program software is located on a remote server. The participating doctor accesses his or her program via the internet. It is securely password protected and patient identity is encrypted, that encryption only being able to be unlocked by the participating doctor

The associated “SCCANZ Surgical Audit – Research Project” involves the passing of de-identified patient data from the pathology company (in the “Pathology Company Version”) or from the participant (in the “Personal Computer version” or the “On-line” version) to the SCCANZ. That data is then pooled on a database and analysed for two purposes. Firstly for participants using the “Personal Computer Version”, or the “On-line” version, they can at any time access a “local report” with respect to their data and they can access a “pooled report” of the collective data. Secondly it is intended that the pooled data be analysed for the purpose of a research project with intended publication of results.

Involvement in this project is voluntary. Prospective participants may decline to participate or they may withdraw from the project at any time and they may withdraw any unprocessed data previously supplied.

If you decide to take part, you are still free to withdraw at any time, without giving a reason.

If you are required to participate in this audit project as part of a tertiary education curriculum requirement, and even if you have as a result agreed to provide your report data to that tertiary institution, you can not be compelled to participate in the research project and so you do not have to sign the consent form to participate.

To withdraw, contact Dr Cliff Rosendahl on phone (07) 3245 3011 or via email audit@skincancersociety.com or Ms Samantha Chakraborty, RACGP National Research and Evaluation Ethics Committee, contactable by phone (03) 8699 0481 or via email ethics@racgp.org.au

Participants may choose to participate in the “Self-Audit Tool” but decline to participate in the “Research Project”. Such participants would submit their data, receive a report comparing their personal data to pooled data but their de-identified data would not be included in the pooled data used for the research project..

With respect to the “Pathology Company Version” the data forwarded to the SCCANZ will be de-identified both with respect to the patients and the doctor. The pathology company will hold and secure the key matching the code to both the doctor and patient. Doctors will be identified by category only.

With respect to the “Personal Computer Version” and the “on-line version” the data forwarded to the SCCANZ will be de-identified with respect to the patient and the participating doctor will hold and secure the key identifying the patient on his or her computer. The doctor however ***will be identified*** to the investigators named above (so that the data of doctors who choose not to participate in the research project can be excluded and also for purposes of administering the data and ensuring its integrity. This can at times be necessary- for example if a doctor inadvertently re-exports data to the pool which is already in the pool- this duplicate data needs to be identified and removed. The investigators undertake to use their knowledge of doctor identity only for administration purposes and not to reveal it to any other person. Prior to pooling of the data for research purposes the doctor identity will be removed and the SCCANZ investigators named above will hold and secure that key.

Participating doctors should be aware that if a sample size is small (for example if only one dermatologist participates) then anonymity may not be guaranteed as that doctor may be identified by category.

Participating doctors should also be aware that confidentiality can only be protected within the limitations of the law- for example it is possible for data to be subject to subpoena.

SPECIFIC DETAILS OF HYPOTHESES TO BE TESTED

“We postulate that with respect to primary care skin cancer management in Australia, the use of dermoscopy improves diagnostic accuracy and increases the proportion of lesions operated on which are malignant.”

We will aim to demonstrate that training and experience in skin cancer medicine, most often gained outside the Australian university and hospital environments, and specifically involving dermoscopy instruction, significantly translates into a higher standard of clinical practice with respect to accuracy of diagnosis and surgical management technique. Our feeling is that many special interest primary care skin cancer doctors currently practice at a level at least equal to that of their specialist colleagues. We also feel that the training required to attain this level is available to all family GPs in Australia.

As a secondary objective, the data will be analysed in order to gain an overview of primary care skin cancer practice in Australia. The collective data will afford us the opportunity to examine trends in skin cancer management in a variety of settings.

Surgical options employed by different categories of practitioner will be analysed along with adequacy of surgical margins achieved. Surgical complication rates with respect to different categories of practitioner will also be assessed.

As well, such issues as the prevalence of various skin cancers encountered and the interdependence of this incidence data will be examined e.g. the ratios of new basal cell carcinomas encountered to new melanomas.

CUSTODY OF DE-IDENTIFIED DATA

The SCCANZ intends to hold de-identified data in electronic form indefinitely for the purpose of ongoing research.

ETHICS COMMITTEE DETAILS

The name and contact details of the executive officer of the RACGP ethics committee that has granted approval for this project is Ms Samantha Chakraborty, RACGP National Research and Evaluation Ethics Committee, contactable by phone (03) 8699 0481 or via email ethics@racgp.org.au