Dear kConFab families

I would like to introduce myself to you as I became the chair of the kConFab executive committee in December 2021. I am a medical oncologist and group leader at the Peter MacCallum Cancer Centre, Melbourne. My research involves investigating the immunology and genomics of breast cancer growth and resistance. Some of this work has been facilitated over the past 10 years via two kConFab projects that utilise the fresh normal breast tissue collected from BRCA1 and BRCA2 mutation carriers who have undergone a risk-reducing mastectomy to reduce their cancer risk and also tissue collected from participants with advanced cancer who are consented to our CASCADE, rapid autopsy program. As a clinician, I lead many clinical trials of therapy for women with advanced (Her-2 positive and triple negative) breast cancer. I also have a strong interest in identification of biomarkers that will help us detect breast cancer early and treat it in improved ways.

I would like to thank Professor Stephen Fox, the past kConFab chairperson, who guided kConFab over the last 11 years and opened the doors to many new research projects that have led to advances in basic science and clinical translation. Stephen remains an important kConFab member and our main “go-to” for all pathology related work.

Whilst COVID remains a disruptive force in our community, we are pleased to report that there has been much progress, so we would like to update you about new work since our last newsletter.

To make your contact with us easier, we have updated the kConFab home page over the past few months (www.kconfab.org). New features on the home page include a summary of recent kConFab research publications that you may find to be of interest. Under the section “For the Families”, we have added a general summary about our work, explaining why and how our research work is advancing our understanding of familial cancer, leading to improved cancer prevention and treatment.

We have added a dedicated section where you can update your address changes or changes to your cancer treatment.

We have important updates in this edition that cover some of our new research findings, clinical trials and the use of genetic testing to guide treatment options.

These include:

- An exciting area of our work is the translation of our kConFab research findings into clinical practice. One of these studies is being run by a clinical researcher, Professor Kelly-Anne Phillips, who is hoping to recruit women who carry a BRCA1 or BRCA2 gene fault (mutation), and are planning to have risk-reducing removal of fallopian tubes (with and without ovaries) within the next 6 to 24 months. These women can be enrolled into the STICs and STONES clinical trial. It is hoped that this trial will show that aspirin can help prevent fallopian tube/ovarian cancer in women at high risk of developing this disease. (page 3)

- Professor Geoff Lindeman has started recruiting to the BRCA-P clinical trial. This aims to test the effectiveness of a drug called Denosumab to decrease the risk or prevent breast cancer in women who carry a BRCA1 gene mutation. It is important to highlight that this trial has come about due to the collaboration Geoff and his laboratory team have had with kConFab spanning 20 years using normal breast tissue collected from kConFab women having surgery. (page 4)

- Over the past 18 months kConFab has supplied participant donated cancer tissue to many of national clinical laboratories in Australia, enabling laboratories to gain testing accreditation that may guide new treatment options for breast/ovarian/prostate cancer patients who carry an inherited gene fault (mutation) (page 2).

- Professor Shahneen Sandhu recently had an important international publication indicating that kConFab BRCA1 or BRCA2 participants with prostate cancer may be candidates for a new immunotherapy. This is exciting work that potentially opens the door to better treatment (page 7).

- The kConFab laboratory has recently published new work showing that gene mutations (faults) in the ATM and CHEK2 genes can be involved in prostate cancer development. (page 7)

It is important to acknowledge that the National Breast Cancer Foundation (NBCF) have provided financial support to kConFab ever since we began our research work in 1997. We are very appreciative of their support and the close day-to-day relationship with the NBCF team, as they continue to facilitate breast cancer research that will improve
Testing of the cancer tissue is known as “somatic gene testing”, as opposed to “germline genetic testing” (using a blood sample). The cancer tissue test can determine if you have a gene mutation (fault) in the cancer tissue that might assist treatment. Some of those with a fault in the cancer may also be found to have an inherited gene fault in a germline test and this will be important for the family. The retrieval of your donated cancer tissue by kConFab, has enabled the evidence needed so patients can access “somatic gene testing” and potentially new therapy options. This work can also support a more precise diagnosis of tumour characteristics and predict how the tumour might progress or respond in the future. Testing cancer tissue can be beneficial to families who have a family history of cancer but may also guide treatment decisions in women and men without a family history of cancer. Just as importantly, this work has led to the testing of the genes responsible for hereditary breast or ovarian cancer and metastatic prostate cancer now having a rebate by Medicare (MBS). In addition the Pharmaceutical Benefits Schedule (PBS) now has a rebate for the new gene targeted therapies known as PARP-inhibitors, if the genetic test detects somatic and/or germline BRCA1 or BRCA2 gene variants.

**The list of genes we test is expanding.**

In the 2020 newsletter, we reported that from November 2017 there has been a Medicare rebate for genetic testing, now extended (within eligibility criteria), for panel genetic testing for some patients with breast/ovarian cancer, and recently prostate cancer, if these patients have at least a 10% chance of carrying a gene fault in a gene associated with these cancers, e.g. **BRCA1, BRCA2, and some additional genes.** The referring doctor will decide which genes should be tested, depending on the cancers that have been diagnosed in the family.

Often further, extended panel testing is re-done in the clinic as new research information becomes available about genes involved in cancer predisposition, e.g. over the past 12 months rare mutations (faults) in genes known as **BRIP1** and **RAD51C/D** are often tested for in the clinic. For our kConFab families, we can confirm that blood from at least one member of your family (with breast, ovarian or prostate cancer) will have been tested for mutations using a multi-gene panel. If you have consented to receive results, you will have been informed by kConFab if any relevant genetic test results have been found for your family. If you have seen a genetic counsellor in the past, you can also contact the genetics clinic if you wish to know more about testing in your family.

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**An update from Pink Hope**

We have been working on new and innovative ways to offer education and support to our community.

This year our popular Information and Support Days are being offered as a Q&A panel style event where participants are much more involved. Information and Support events are being held in Sydney, Brisbane and Adelaide in 2022. We have launched Instagram Live sessions where we bring in experts to discuss topics relevant to our high-risk cancer community. These discussions are recorded and available after the event. We continue to run our SheShares in person support group events and we grow our resource library with blogs, personal stories, videos and interviews. We are even heading to Canberra where we are holding an Expert Panel events focused on tumour testing for ovarian cancer patients and living well with metastatic cancer. All of our events can be found here. We are fortunate to have support from our industry partners and a high calibre of experts who contribute to all of our events.
If you are a woman with a BRCA1 or BRCA2 mutation who is planning to have risk-reducing surgery to remove your fallopian tubes +/- ovaries within the next 6 to 24 months, you may be suitable for enrolment into the STICs and STONEs clinical trial. The trial is looking at whether a common, safe anti-inflammatory tablet might be useful in preventing ovarian cancer.

Inflammation during ovulation is thought to contribute to the development of ovarian cancer, and therefore the anti-inflammatory medication may help to prevent it. Participants in the STICs and STONEs trial will receive either the anti-inflammatory tablet or a placebo (inactive “sugar tablet”), and will be asked to take 1 pill a day for 6 months to a maximum of 2 years, prior to their planned surgery.

STICs and STONEs is led in Australia by the Australia New Zealand Gynaecological Oncology Group (ANZGOG) and the NHMRC Clinical Trials Centre (University of Sydney), is the Australian trial coordinating centre, in collaboration with the Canadian Cancer Trials Group (CCTG). It is hoped that this trial will show that the anti-inflammatory medication can help prevent fallopian tube and ovarian cancer in women at high risk of developing this disease.

STICs and STONEs will enrol 414 patients in hospitals across Australia and Canada, and the ANZGOG Study Chair of this trial is Professor Kelly-Anne Phillips. There are already 34 Australia women enrolled on this trial and over 100 internationally. For more information about STICs and STONEs call 1800 111 581 or email stics.study@sydney.edu.au, visit the trial website at https://ctc.usyd.edu.au/our-work/research-divisions/cancer/cancer-divisions/gynaecological-cancers/open-trials/stics-and-stones/ or speak to your treating clinician about whether you are eligible to participate. The study is available at the following locations in Australia:

**NSW**
- Prince of Wales Hospital and the Royal Hospital for Women, Sydney
- Westmead Hospital, Sydney
- Royal Prince Alfred Hospital, Sydney

**VIC**
- Peter MacCallum Cancer Centre and the Royal Women’s Hospital, Melbourne

**WA**
- St John of God Subiaco, Perth
- King Edward Memorial Hospital, Perth
The BRCA-P Trial – the first international breast cancer prevention study for BRCA1 mutation carriers.

By Professor Geoffrey Lindeman
Joint Head, Stem Cells and Cancer Division at the Walter and Eliza Hall Institute and Medical Oncologist, The Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne.

The international BRCA-P clinical trial opened its doors to women in Australia in 2020 and continues to recruit new participants across the country. The aim of the study is to understand if a drug called denosumab can decrease or prevent the risk of developing breast cancer in women with a BRCA1 gene mutation.

Approximately one in 400 women in Australia have a mutation in the BRCA1 gene, which is associated with an approximate 70% risk of developing breast cancer and 40% risk of developing ovarian cancer, over the course of their lifetime.

There are limited options to reduce the risk of breast cancer for women with a BRCA1 mutation, and currently some women opt for surgical removal of their breasts. Most women, however, don’t opt for immediate mastectomy and rather undergo regular screening. The BRCA-P trial is exploring a non-surgical prevention option for women who do not wish to undergo mastectomy (or who are deferring this decision). The hope is that denosumab will reduce the need for mastectomy in the long-term.

Denosumab is already used in the clinic to reduce the risk of bone fracture in patients who have thin bones (osteoporosis) and to keep bones strong for patients who have cancer that has spread to bone. Its safety profile is therefore well understood.

Denosumab works by switching off a molecule in cells called RANK ligand. Previous work in the laboratory showed that using denosumab to switch off RANK ligand could also target the culprit cell that gives rise to breast cancer in women with a BRCA1 mutation.

These laboratory findings led to the design of the global BRCA-P clinical trial, which is being undertaken in 7 countries and includes 15 sites across Australia. The study aims to recruit about 2,900 patients (300 from Australia).

Women who participate in the BRCA-P trial will continue to receive close monitoring and scans through their own specialist(s) and will receive additional follow-up in partnership with the BRCA-P study team.

Participants will be randomly assigned to receive denosumab (50%) or placebo (50%) for up to 5 years. Participants will be followed up every 12 months for a further five years. The study is ‘double blinded’. This means that participants (and the team) will not know whether they are being treated with denosumab or placebo. Using a placebo in half the participants is very important, as it is the only way to properly determine whether denosumab has breast cancer prevention properties and to identify if there are any unwanted side effects or other benefits (such as strengthened bones).

The study is being led in Australia by Breast Cancer Trials – Australia’s largest clinical trials research group, which has been conducting clinical trials research for more than 40 years.

To be eligible for the BRCA-P prevention trial, participants must:

• Be women who carry a BRCA1 gene mutation
• Be aged 25 - 55 years
• Never have had breast or ovarian cancer
• Not be pregnant or not trying to get pregnant right now. Eligibility can be discussed with the BRCA-P team if a future pregnancy is planned.
• Not have had a mastectomy to prevent breast cancer
• Not be taking any breast cancer prevention drug such as Tamoxifen

More information about the BRCA-P trial can be found online at the Breast Cancer Trials Breastolution website. If you are interested in discussing the study with a BRCA-P team member, you can register interest through the Breastolution website or call the BRCA-P Hotline on 1800 777 253.

The National Breast Cancer Foundation (NBCF) has awarded 20 game-changing research projects worth nearly $12.4 million to support its vision of Zero Deaths from breast cancer.

The 20 research projects span the breast cancer research continuum from prevention and risk, detection, new and improved treatments, and better quality of life. This funding will support 50 full-time researchers to conduct breast cancer-focused research across NSW, Victoria, Queensland, South Australia and Western Australia over the next four years. Among the latest NBCF-funded projects, are those led by researchers who participate in the kConFab working committee, including Prof Georgia Chenevix-Trench at the QIMR Berghofer Medical Research Institute, Queensland. Prof Chenevix-Trench’s project aims to examine whether Senicapoc, a drug originally developed for the treatment of sickle cell anemia, could be an effective anti-cancer agent in preclinical models of hard-to-treat breast cancers, eliminating the need for time-consuming and costly work involved in new drug discovery. Prof Chenevix-Trench’s team will also investigate whether this drug can be used as a safer risk reduction medication in patients with BRCA1 and BRCA2 mutations. Another project, led by A/Prof Liz Caldon at the Garvan Institute of Medical Research NSW, will focus on investigating whether drugs that can target and neutralise a survival mechanism in cancer cells can be used in combination with anti-oestrogens and targeted treatments to overcome therapeutic resistance in metastatic oestrogen receptor positive breast cancer.

NBCF will continue to support research into understanding the genetics of familial breast cancer risk with a project led by Prof Ian Campbell at the Peter MacCallum Cancer Centre, Victoria. The focus of this project is to search for unknown variants in non-coding regions of well-established breast cancer genes, example, BRCA1/2, PALB2, using 12,000 genetic samples from the BEACCON study (6,000 women with familial breast cancer and 6,000 cancer-free women) in an attempt to explain some of the unknown factors influencing breast cancer risk. These three projects together with 17 others this year will take us closer to reaching our vision of zero deaths from breast cancer.

NBCF is also proud to announce that it has once again offered the NBCF Joseph Sambrook prize for the best student or post-doctoral researcher presentation at the 2022 Familial Aspects of Cancer Research and Practice meeting in Kingscliff, NSW. This prize is aimed at advancing the career of an early – mid career researcher who gives the most outstanding breast cancer presentation at this meeting and would support the awardee to attend and present their findings at an international conference of their choice and visit local laboratories.

NBCF is funded entirely by the generosity of the Australian public, receiving no government support to fund the very best breast cancer research via our rigorous peer review scheme. You can help support NBCF by taking part in our fundraising campaigns such as the Pink Ribbon Breakfast Campaign this October. Please visit www.pinkribbonbreakfast.org.au for further information.
kConFab survey results.

As many of you are aware, kConFab began enrolling families with a family history of breast and/or ovarian cancer in 1997 and has since involved more than 2,095 families and 20,000 family members.

Some of these individuals have therefore been contributing to, and receiving information from, kConFab for 25 years. Given kConFab’s important role in identifying clinically significant genetic information for families and returning this information, as well as contributing biospecimens from our families to research efforts, we wanted to determine how kConFab was tracking against participant expectations. Further, it was important to determine whether the kConFab communication to participants was adequate and to invite suggestions for improvement.

A survey was developed in collaboration with our community representatives, our funding agency, a genetic counsellor from each Australian State and Territory, and the psychosocial cancer genomics research team in the Parkville Familial Cancer Centre.

The questionnaire was hosted online using REDCap at the Peter MacCallum Cancer Centre and participants were invited to complete the survey in September 2021. A total of 7,359 invitations, 1,703 via text message and 5,656 via emails, were sent with the online survey link to all kConFab participants with an email or mobile telephone number registered in our database.

The questionnaire was completed by 863 individuals (12%).

The majority of participants were aware consenting to kConFab involved: using samples for genetic research to identify pathogenic variants associated with cancer (88%); using samples multiple times for different research studies (84%); and accessing participant medical records (79%). Most participants agreed with statements that participation benefited themselves and family (97%), they knew how to contact kConFab (75%), and they were aware they could withdraw consent (82%).

Participants reported that feedback could be improved in some areas, including: updates on the utility of an individual’s polygenic risk score; findings from our research; new genes found to be associated with breast, ovarian and prostate cancer and new treatment types relevant to kConFab participants. These are all points that we will work towards improving in our communication with you in the future.

Approximately half indicated they would be interested in exploring an introduction to others around the world with the same gene variant, through a potential collaboration between kConFab and the ‘connectmyvariant’ program based at the University, USA. Therefore, if you have attended a genetics clinic and are known to carry a gene fault (mutation) associated with cancer risk e.g. a BRCA1, BRCA2, ATM, CHEK2, PALB2 variant we would like to hear from you if you are potentially interested in being involved in the project. We would also like to hear from those participants that aren’t interested in being involved so we don’t annoy you with an approach that is not wanted.

To register your intent you can email Heather at: heather.thorne@petermac.org or log into the kConFab home page at www.kconfab.org and click thru on the “Contact Us” section.

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### If kConFab found personal clinically significant genetic information, how would you like to be notified?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>A letter with information and instructions</td>
<td>46%</td>
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<tr>
<td>A letter + a follow-up call from a genetic counsellor</td>
<td>49%</td>
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<tr>
<td>Via an online portal</td>
<td>12%</td>
</tr>
<tr>
<td>A health service for communicating research results</td>
<td>6%</td>
</tr>
<tr>
<td>I prefer not to be notified of any (more) clinically significant genetic information</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
</tbody>
</table>

### What updates would you like kConFab to provide?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Updates on kConFab’s progress</td>
<td>40%</td>
</tr>
<tr>
<td>Updates about what my sample contributed to</td>
<td>65%</td>
</tr>
<tr>
<td>Updates about current research made possible by kConFab participants as a group</td>
<td>78%</td>
</tr>
<tr>
<td>I dont want any updates from kConFab</td>
<td>8%</td>
</tr>
<tr>
<td>Other updates</td>
<td>4%</td>
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</tbody>
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RESEARCH UPDATES

The immune environment of prostate cancer in men with and without an inherited gene fault (mutation).

By Professor Shahneen Sandhu
Consultant medical oncologist and researcher &
Dr Anna Trigos,
Postdoctoral Researcher in computational biology, bioinformatics and prostate cancer, Peter MacCallum Cancer Centre, Melbourne.

Compared to cancers such as melanoma and lung cancer, most prostate cancers don’t trigger a strong immune response and therefore immunotherapy has not been considered an effective treatment for most men with advanced prostate cancer.

However, our recent data suggests that immunotherapy may be more effective in the subset of prostate cancer patients with an underlying DNA repair defect such as BRCA1 and BRCA2 gene faults (mutations).

We have just published our findings where we profiled the make-up and distribution of immune cells in prostate cancer tissue donated by kConFab participants with an inherited BRCA1 or BRCA2 gene mutation. We compared this to prostate cancer tissue from participants without an inherited BRCA1 or BRCA2 gene mutation. We showed that the BRCA1 or BRCA2 gene mutated cancers (tumours) had more immune cells closer to the tumour and a more immune activated gene signature, suggestive of a more activated immune response. Further, we showed that having an immune activated gene signature was associated with a longer time to biochemical recurrence (the cancer has returned) and metastasis (the cancer spread).

If validated in subsequent studies, these data will help us to identify patients with advanced prostate cancer most likely to benefit from new immunotherapy treatment.

Novel inherited mutations in a kConFab Men with Prostate Cancer.

By Romy Mondschein,
kConFab, Peter McCallum Cancer Centre, and Austin Health, Urology Melbourne and
Heather Thorne,
kConFab, Peter McCallum Cancer Centre.

In a recently published study we identified new gene mutations (faults) that contribute to prostate cancer development in men who have multiple relatives with prostate.

We have previously demonstrated an association with BRCA2 gene mutations (faults) and prostate cancer development. In this new study we detected novel gene mutations (faults) in the ATM and CHEK2 genes. It is important to note that the new ATM and CHEK2 mutations are rarer and not detected with the same frequency as a BRCA2 mutation but testing other family members with prostate cancer demonstrated that the gene mutation was associated with prostate cancer in all carrier families.

This study contributes to the correlation of rare genetic variants with clinically significant prostate cancer. Incorporation of gene panel testing into clinical practice will allow clinicians to identify patients with a family history of prostate cancer who are at risk of this cancer. Confirmation of mutation status can facilitate intensive treatment rather than active surveillance for carriers. Other benefits include early disease detection and access to novel gene targeted and immunotherapy.

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Collaborating Family Cancer Centres

**Melbourne**

The Parkville Familial Cancer Centre  
Peter MacCallum Cancer Centre &  
The Royal Melbourne Hospital  
Peter MacCallum Cancer Centre  
Level 1B 305 Grattan Street,  
Melbourne, 3000  
Contact: Ms Alexandra Lewis  
Tel: 03 8559 5322

The Royal Melbourne Hospital  
Level 2 Centre, Infill Building, Grattan  
Street, Parkville, 3050  
Contact: Mr Michael Bogwitz  
Tel: 03 9342 7151

Peter MacCallum Cancer Centre  
Level 1B 305 Grattan Street,  
Melbourne, 3000  
Contact: Ms Alexandra Lewis  
Tel: 03 8559 5322

Contact: Mr Michael Bogwitz  
Tel: 03 9342 7151

**Monash Medical Centre**  
Clayton, 3168  
Contact: Dr Marion Harris  
Phone: 03 9594 2009

**Austin Health Clinical Genetics Service**  
Level 8, Harold Stokes Building  
Austin Hospital  
HEIDELBERG VIC 3084  
Tel: 9496 3027

**Sydney**

Familial Cancer Service  
Westmead Hospital  
Westmead, 2145  
Contact: A/Prof Judy Kirk  
Phone: 02 8890 6947

Prince of Wales Hospital  
Hereditary Cancer Clinic  
High Street, Randwick, 2031  
Contact: A/Prof Kathy Tucker  
Phone: 02 93825107

St George Community Hospital  
Hereditary Cancer Clinic  
Kogarah, 2217  
Contact: A/Prof Kathy Tucker  
Phone: 02 93825107

St Vincent’s Cancer Genetics Clinic  
Darlinghurst, 2010  
Contact Professor Allan Spigelman  
Phone: 02 9355 5647

The Hunter Family Cancer Service  
Cnr Turton & Tinonee Roads  
(PO Box 84) Watarath NSW 2298  
Phone: 4983132  Fax: 4983133  
Email: HNELHDFamilyCancerService @health.nsw.gov.au

**Brisbane**

Genetic Health Queensland  
Royal Women’s and  
Children’s Hospital  
Bramston Terrace, Herston, 4029  
Contact: Dr Hilda High  
Phone 02 3646 1686

Nicholson St Specialist Centre  
Suite 107, Level 7  
83 Nicholson Street  
Greenslopes, QLD 4120  
T: 07 3217 8244  F: 07 3217 8255  
E: michael.gattas@brisbanegeenetics.com.au  
W: brisbanegeenetics.com.au

**Canberra**

ACT Genetics Service  
Level 5, Building 1  
The Canberra Hospital  
Yambla Drive, Garran 2605  
Contact: Dr Linda Warwick  
Phone: 02 6244 2133

**Adelaide**

Adult Genetics Unit  
Royal Adelaide Hospital  
Level 8 (8F/01.52; MDP 63)  
Port Road ADELAIDE SA 5000  
Contact: Dr Nicola Poplawski  
P (+61) (0)8 7074 2697  
F (+61) (0)8 7044 2133

**Perth**

Genetic Services of Western Australia  
King Edward Memorial Hospital  
374 Bagot Road, Subiaco, 6008  
Contact: Dr Nicholas Pachter  
Phone: 08 6458 1524

**Tasmania**

Tasmanian Clinical Genetics Service  
Royal Hobart Hospital  
P.O. Box 1061  
Hobart, Tasmania 7001  
Phone: 03 6266 8296  
tcgs@ths.tas.gov.au

**Wellington – New Zealand**

Genetic Health Service NZ –  
Central Hub  
Wellington Hospital  
Private Bag 7902, Wellington 6242  
NZ local call 0508 364 436  
International +64 3 385 5310  
www.genetichealthservice.org.nz

**Christchurch – New Zealand**

Genetic Health Service NZ –  
South Island Hub  
Christchurch Hospital  
Private Bag 4710, Christchurch 8140  
NZ local call 0508 364 436  
International +64 3 378 6195  
www.genetichealthservice.org.nz

For all general kConFab enquires please contact:  
kConFab National Manager  
Heather Thorne  
Cluster 6, 11th Floor Research Department  
The Peter MacCallum Cancer Centre  
Melbourne, 3000  
Phone: 03 8559 6626  
Toll free throughout Australia:  
1800 221 894  
Email: heather.thorne@petermac.org

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Research into FAmilial Breast Cancer  
Kathleen Cuningham Foundation  
CONsortium for research into FAmilial Breast Cancer