The Biobanking Stakeholders Network Pre-operative Consent Project 2013-14

Developing a model for patient consent to biobanking and health data linkage in NSW

Written by Ms Nicki Meagher

**PROJECT TEAM**

<table>
<thead>
<tr>
<th>NAME</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof Nicholas Hawkins</td>
<td>Translational Cancer Research Centre</td>
</tr>
<tr>
<td>Prof Philip Crowe</td>
<td>Translational Cancer Research Network (TCRN)</td>
</tr>
<tr>
<td>Ms Nicki Meagher</td>
<td>Translational Cancer Research Network (TCRN)</td>
</tr>
<tr>
<td>Ms Lena Caruso</td>
<td>Translational Cancer Research Network (TCRN)</td>
</tr>
<tr>
<td>A/Prof Deborah Marsh</td>
<td>Sydney Vital</td>
</tr>
<tr>
<td>Ms Ussha Pillai</td>
<td>Sydney Vital</td>
</tr>
<tr>
<td>Prof Rodney Scott</td>
<td>Hunter Cancer Research Alliance (HCRA)</td>
</tr>
<tr>
<td>Ms Amanda Koegelenberg</td>
<td>Hunter Cancer Research Alliance (HCRA)</td>
</tr>
<tr>
<td>Ms Sally Dean</td>
<td>Hunter Cancer Research Alliance (HCRA)</td>
</tr>
<tr>
<td>Ms Sarah Nielsen</td>
<td>Hunter Cancer Research Alliance (HCRA)</td>
</tr>
<tr>
<td>Ms Susan Goode</td>
<td>Hunter Cancer Research Alliance (HCRA)</td>
</tr>
<tr>
<td>A/Prof Lisa Horvath</td>
<td>Sydney Catalyst</td>
</tr>
<tr>
<td>Prof James Kench</td>
<td>Sydney Catalyst</td>
</tr>
<tr>
<td>Dr Sonia Yip</td>
<td>Sydney Catalyst</td>
</tr>
<tr>
<td>Mr Adam Walczak</td>
<td>Sydney Catalyst</td>
</tr>
</tbody>
</table>

**ACKNOWLEDGEMENTS**

We would like to thank Ms Claire Thompson for her editorial contribution to this report. We would also like to thank the staff at the participating hospitals, in particular the surgical teams and supporting hospital and pathology staff, for their involvement.
# Table of contents

Executive Summary ...........................................................................................................3
Background .........................................................................................................................4
  CINSW BSN Consent Projects .........................................................................................4
Project aims .......................................................................................................................4
Methods .............................................................................................................................5
  Project materials .............................................................................................................5
Applications and approvals ..............................................................................................7
Stakeholder engagement and education ...........................................................................7
  Endorsement ..................................................................................................................7
  Project champions .........................................................................................................7
  Educational initiatives ..................................................................................................7
Pilot studies .......................................................................................................................8
  Data collection ..............................................................................................................9
Results .............................................................................................................................9
  Approvals .....................................................................................................................9
  Pilot studies .................................................................................................................10
  Surgical team feedback ...............................................................................................11
Findings and Discussion ..................................................................................................11
Conclusion .......................................................................................................................13
Key recommendations ......................................................................................................14
References .......................................................................................................................14
Appendices .....................................................................................................................14
EXECUTIVE SUMMARY

This report reviews the development and implementation of the Cancer Institute NSW (CINSW) Biobanking Stakeholders Network (BSN) Consent Project across eight NSW hospitals. The primary aim of this project was to embed biobanking consent into routine peri-operative workflows, enabling better engagement of hospital staff and increased tissue and data collection from eligible patients. This report seeks to showcase the steps that led to this goal being successfully achieved.

A series of consent pilot projects were facilitated by four translational cancer research centres (TCRCs) and rolled out across eight hospital sites. Staff across the four TCRCs worked collaboratively to develop a suite of project materials, including patient consent forms and promotional and educational materials, that were shared in various formats across the participating hospitals. Each TCRC was required to obtain relevant ethical and regulatory approvals prior to commencing the project. In some cases, the approval of hospital forms committees was also required. All TCRCs developed and rolled out an extensive series of stakeholder engagement initiatives to build awareness among hospital staff.

The project team sought to measure two key outcomes relating to patient consent to biobanking and health data linkage: rate of request for consent (the number of patients who were asked to consent to participate as a proportion of the total number of operations for a malignancy) and the participation rate (the proportion of those patients asked to participate in the biobank who actually agreed).

The rollout of the consent projects was completed at five of the eight hospital sites, with projects at the remaining sites still in progress at the time of writing. Participation rates were very high: 99% of patients across all sites who were asked to participate agreed to have their specimens banked and their health data collected. The rate of request for consent was satisfactory; however, the project team identified significant opportunities for improvement of these rates by making consenting materials more accessible to hospital staff.

The following aspects had a significant impact on both the participation and request for consent rates for this project:

- The integration of biobanking consent processes into routine hospital workflows
- The inclusion of biobanking consent forms in existing hospital documentation
- The mapping of patient pathways in participating hospital departments to inform when and where consent should be offered
- The identification of project champions to promote staff engagement
- The development of ongoing educational activities to keep biobanking initiatives visible to clinical staff.
BACKGROUND

Obtaining patient consent is an essential component of the biobanking process; however, consenting is typically labour intensive\(^1\), requiring dedicated staff who are usually funded by specific research grants. In the cancer setting, patient populations display strong willingness to take part in biobanking initiatives, with reported participation rates as high as 86-99%\(^1,3\). One of the key challenges is creating a sustainable model for biobanking that supports scientific advancement without creating financial or administrative inefficiencies. One way to approach this is to embed the process of consent to participate in biobanking and health data collection within routine clinical practice.

CINSW BSN Consent Projects

The Cancer Institute NSW (CINSW) Biobanking Stakeholders Network (BSN) funded a project to develop processes for the gaining of consent to participate in biobanking within hospitals in NSW. In order to meet the project objectives, the consent process was designed to be integrated into day-to-day hospital workflows. This approach was developed with a view to achieving high rates of engagement by clinical staff and high numbers of consented patients, resulting in significant quantities of tumour samples being collected for storage in institutional biobanks. The consent process needed to be efficient, acceptable to both patients and staff and scalable across multiple hospital sites. The model sought to establish capture of patient consent contemporaneously with consent for a surgical procedure.

The project was a collaboration across four Translational Cancer Research Centres (TCRCs), representing eight hospitals.

<table>
<thead>
<tr>
<th>TCRCs</th>
<th>Participating hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunter Cancer Research Alliance (HCRA)</td>
<td>John Hunter Hospital, Newcastle</td>
</tr>
<tr>
<td></td>
<td>Calvary Mater Hospital, Newcastle</td>
</tr>
<tr>
<td>Translational Cancer Research Network (TCRN)</td>
<td>Prince of Wales Hospital, Sydney</td>
</tr>
<tr>
<td></td>
<td>Royal Hospital for Women, Sydney</td>
</tr>
<tr>
<td></td>
<td>St George Hospital, Sydney</td>
</tr>
<tr>
<td>Sydney Vital</td>
<td>Royal North Shore Hospital, Sydney</td>
</tr>
<tr>
<td>Sydney Catalyst</td>
<td>Royal Prince Alfred Hospital, Sydney</td>
</tr>
<tr>
<td></td>
<td>Chris O’Brien Lifehouse, Sydney</td>
</tr>
</tbody>
</table>

*Table 1: Participating Translational Cancer Research Centres and hospitals*

PROJECT AIMS

1. **Knowledge and resource sharing**

   Develop and deliver processes that support the widespread dissemination of standardised ethics applications for biobanking across BSN sites in a way that both facilitates ethics approvals at local sites, and ensures internal consistency of ethics approvals across those sites.
2. Mechanisms for improved consent processes
Develop a process by which staff can reasonably obtain consent for biobanking as part of standard pre-operative surgical admission procedures.

3. Support consent processes through relationship building and communication
Identify individuals and roles within routine care teams that are able to consent for biobanking, and develop and provide education/training for those individuals.

4. Performance monitoring
Develop processes for monitoring of performance of consenting, and use data so obtained to identify and manage patient, staff or systems factors that prevent or limit consenting of cancer patients in NSW public hospitals.

5. Embedding consent into the healthcare system
Implement the preferred consenting process, as well as standardised processes for monitoring, evaluating and reporting performance, across multiple sites and tumour streams in NSW.

METHODS
The project team sought to measure two key outcomes: rate of request for consent (the number of patients who were asked to consent to participate in the consent pilot project as a proportion of the total number of eligible operations for a malignancy) and participation rates (the proportion of patients who agreed to participate when asked).

PROJECT MATERIALS
Each TCRC involved in the consent pilot project was tasked with developing a suite of project materials to aid the patient consenting process. These included patient consent documents and promotional and educational materials for hospital staff. TCRC staff within the four participating organisations shared their content with one another to fast track the rollout of the project across the hospital sites. See appendices for samples of materials.

<table>
<thead>
<tr>
<th>Materials</th>
<th>HCRA</th>
<th>TCRN</th>
<th>Sydney Vital</th>
<th>Sydney Catalyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Health District approved patient consent form</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient consent sticker (for inclusion in Recommendation for Admission (RFA) booklet)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient information brochure</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Promotional biobanking poster</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Blood collection request form</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Education presentations for hospital staff</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Hospital staff FAQs</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Project materials developed by each site
Across the four participating TCRCs, two different consent formats were developed and piloted: a stand-alone consent form and a consent sticker.

**Stand-alone consent form (TCRN, Sydney Vital, Sydney Catalyst)**

The stand-alone consent form was developed as a tool to obtain biobanking consent in key areas where clinical staff interacted with patients. These key areas included:

- consultants’ rooms
- pre-admission clinics
- outpatient clinics
- peri-operative units
- in-patient wards.

Some surgical registrars from participating teams were also given consent materials to carry with them or to store in their lockers near the operating theatres.

Once a patient had given consent for tissue and health data collection to occur, the completed consent form was kept in his/her medical record, at which point it became part of formal hospital documentation. It was then either separated, and the original duplicate copy retrieved from the Medical Records department by the biobank team (1 site, form SES020.063), or scanned into the electronic medical record (1 site, form NS11029/V2) after patient discharge.

**Consent sticker within Recommendation for Admission (RFA) booklet (HCRA, see appendix iii, page 15)**

HCRA used both an electronic (appendix iii, page 16) and paper-based method for obtaining preoperative consent. In the paper-based method, a condensed version of the existing consent form was re-purposed as a consent sticker. This sticker was applied to the back of the ‘Request/Consent for Medical Procedure/Treatment’ (SMR020.001) form, in a blank section under the standard ‘Use of Removed Tissue’ consent wording. The form, including consent sticker, was located in the hospital pre-surgical Request for Admissions (RFA) booklet. Hospital admissions staff applied the sticker to RFA booklets, which were then supplied to participating surgical teams.

Staff in the Medical Records department scanned all completed biobank consent forms for inclusion in each patient’s electronic medical record within 48 hours of the patient undergoing his/her scheduled surgical procedure. The consent form was then checked electronically by the biobank technician upon receipt of a tissue/tumour sample.

HCRA’s statistics also included patient consent as indicated by a signature on the existing ‘Use of Removed Tissue’ section when the specific biobank consent sticker was not present. Consent provided by these cases is limited to tissue without access to linked data; however, this has formed part of the biobanking practice at the John Hunter Hospital.

The electronic method of consent capture was established so that when a staff member entered a patient’s procedure consent information into an electronic health record, the system provided an automated prompt asking whether it was cancer-related and then printed out the HCRA biobank consent wording (as per consent sticker) alongside the medical procedure consent form in all eligible cases. The patient then signed the consent form as per paper-based process.
APPLICATIONS AND APPROVALS

Prior to commencing the pilot project, all of the participating TCRCs were required to obtain approvals from an accredited Human Research Ethics Committee and Local Health District research governance office.

Materials for each of the applications were shared between participating TCRCs in an effort to streamline and fast track application processes. The TCRN, Sydney Vital and Sydney Catalyst also sought approval from their Local Health District Forms Committee for the use of the official hospital-endorsed consent form. In addition, the TCRN acquired approval from the Department of Human Services to link patients’ de-identified Medicare and Pharmaceutical Benefits Scheme records to the biobank data. Similar applications made by Sydney Vital and Sydney Catalyst were subsequently refused; this issue remains unresolved at the time of writing of this report.

STAKEHOLDER ENGAGEMENT AND EDUCATION

Endorsement

Effective stakeholder engagement was key to the success of the biobank consent project. Each of the participating TCRCs sought varying degrees of endorsement from local health district executives, clinical directors and clinical and quality councils. For example, the TCRN developed a formal letter of agreement and a Memorandum of Understanding that was signed by the local health district and UNSW Australia, while other sites simply consulted heads of department to garner support for the project. This approach was intended to help formalise the project concept with participating stakeholders, establish a governance framework for the biobank as a whole and to build the project’s credibility and potential for longevity among target audiences.

Project champions

Project champions were identified to advocate for biobanking within the participating hospitals. The role of the champions was to motivate their colleagues, workshop processes to create efficiencies within units participating in the consent project, and generally endorse biobanking within the internal hospital environment. Most champions were selected on the basis of influence and inherent belief and interest in the objectives of the project.

Educational initiatives

Keeping stakeholders aware of and focused on the project required a variety of promotional and educational activities. Representatives from each of the participating TCRCs were responsible for educating hospital staff about the consent process. Education (see appendix iii) was provided in the form of:

- presentations at multi-disciplinary team meetings, cancer grand rounds and other forums
- one-on-one meetings with key hospital staff
- hospital in-services
- reminder emails about consent, including pilot study results.
The TCRN has made the biobank a standing item on the surgical registrar orientation program, which runs every six months. All sites worked with participating hospital staff to keep them engaged with the project by providing regular reminders about project progress. This included reminder visits to MDTs and outpatient clinics, regular emails providing updates on the numbers of patients who had been consented, and the publication of regular news articles about the project in electronic newsletters distributed across TCRC and hospital networks.

<table>
<thead>
<tr>
<th>Departments</th>
<th>HCRA</th>
<th>TCRN</th>
<th>Sydney Vital</th>
<th>Sydney Catalyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Anatomical Pathology</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cancer Services</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pre-admissions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Admissions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Peri-operative/short-stay unit</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Theatres</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Medical Records</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Inpatient wards</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

*Table 3: Hospital departments engaged by TCRCs to participate in the biobank consent project*

**PILOT STUDIES**

Pilot consent projects were delivered across the following hospital sites:

- Prince of Wales Hospital, Sydney (POWH)
- Royal Hospital for Women, Sydney (RHW)
- St George Hospital, Sydney (SGH)
- John Hunter Hospital, Newcastle
- Royal North Shore Hospital, Sydney

Pilot studies at Royal Price Alfred Hospital and the Chris O’Brien Lifehouse in Sydney were in progress at the time of writing of this report.

In consultation with project champions and clinical staff, up to two tumour streams at each hospital were selected to pilot the consent project. Patient pathways were mapped for each stream. The mapping process sought to understand patient flow through various hospital departments and to identify potential points along the patient journey that were suitable for requesting consent.
**Data collection**

The pilot project teams sought to collate data on two key outcomes:

- **Rate of request for consent**, or the number of patients offered consent by surgical staff (based on receipt of a signed consent form/sticker). This information showed how many patients were asked to consent as a percentage of all possible cases.

- **Consent participation rate**, or the total number of patient who gave consent as a proportion of those who were asked.

The following data were also collected to provide a broader picture of the pilot process:

- The number of surgical resections in participating tumour streams (based on theatre lists) This data provided information on the total number of possible consents with a given tumour stream.

- The number of signed consents on the Use of Removed tissue form in the RFA (HCRA only).

- Timing of consent (pre or post-surgery), with pre-operative consent serving as the best indicator for whether the process was being integrated within routine care pathways.

- Final diagnosis of possible and actual consents (based on anatomical pathology reports), which allowed non-malignant cases to be identified and removed from the analysis.

The TCRN systematically collected feedback regarding the consent process from surgical registrars during an evaluation workshop and one-on-one meetings at the end of the data collection period at Prince of Wales Hospital. All staff were asked the same set of questions in an attempt to identify barriers to offering consent and to elicit suggestions for improvement. Feedback was collated and used to refine project processes going forward.

**RESULTS**

**APPROVALS**

Approval times for ethics and governance were relatively short (see table 4). The exception was Sydney Catalyst, which has unresolved governance issues due to a public-private partnership of a newly established cancer care centre. The TCRN, the first site to apply to the Commonwealth Department of Human Services obtained approval; however, the applications from Sydney Catalyst and Sydney Vital that followed resulted in a request to obtain an additional approval from the Department of Health Human Research Ethics Committee. This Committee was not prepared to provide approval to access MBS and PBS data for future unspecified research. This issue remains unresolved at the time of writing of this report.
PILOT STUDIES

Consent pilot results varied by tumour stream (tables 5-7):

- The TCRN (Table 5) saw the highest rates of consent being offered in the peritonectomy group (69%) with an overall combined rate of request for consent for all tumour streams of 54% of malignant cases.
- The HCRA (Table 6) saw the highest rates in the gynaecological tumour group (78%), with an overall pilot rate of request for consent of 63% of malignancies. In addition to the signing of the consent sticker, the signing of the ‘Use of Removed Tissue’ section in the RFA was assessed in this calculation. All consents (100%) were offered pre-operatively.
- Sydney Vital (Table 7) engaged one tumour group who requested consent from 31% of patients. The second tumour group approached to participate were not prepared to be involved without funding or support for other staff to approach patients.
- Sydney Catalyst were still establishing their pilot programs at the time of writing. No results were therefore available.

Only one patient refusal was reported out of the 194 malignant cases seen during the 5 pilot studies, resulting in an overall participation rate of 99%.

<table>
<thead>
<tr>
<th>Tumour stream</th>
<th>Period</th>
<th>Eligible operations (malignancies only), n</th>
<th>Consent requested, n (%)</th>
<th>Agreed, n (%)</th>
<th>%consents pre-operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>POW/RHW Breast</td>
<td>06/05/13 – 21/06/13</td>
<td>13</td>
<td>6 (46%)</td>
<td>6 (100%)</td>
<td>100%</td>
</tr>
<tr>
<td>POWH Colorectal</td>
<td>06/05/13 – 21/06/13</td>
<td>10</td>
<td>3 (30%)</td>
<td>3 (100%)</td>
<td>100%</td>
</tr>
<tr>
<td>POWH Upper Gastrointestinal</td>
<td>16/09/13 – 06/12/13</td>
<td>5</td>
<td>3 (60%)</td>
<td>3 (100%)</td>
<td>67%</td>
</tr>
<tr>
<td>POWH Urology</td>
<td>16/09/13 – 06/12/13</td>
<td>26</td>
<td>12 (46%)</td>
<td>12 (100%)</td>
<td>42%</td>
</tr>
<tr>
<td>SGH Peritonection</td>
<td>12/12/13 – 20/06/14</td>
<td>45</td>
<td>31 (69%)</td>
<td>31 (100%)</td>
<td>100%</td>
</tr>
<tr>
<td>SGH Gynaecological Oncology</td>
<td>11/03/13 – 20/06/14</td>
<td>11</td>
<td>4 (36%)</td>
<td>4 (100%)</td>
<td>75%</td>
</tr>
</tbody>
</table>

Table 5: TCRN consent pilot results (stand-alone consent form)
The consent sticker alone (22 cases) resulted in a rate of request for consent of 100%; that is, in all cases where the consent sticker was present, consent was sought by a hospital staff member from the patient.

Table 7: Sydney Vital consent pilot results (stand-alone consent form)

<table>
<thead>
<tr>
<th>Tumour stream</th>
<th>Period</th>
<th>Eligible operations (malignancies only), n</th>
<th>Consent requested, n (%)</th>
<th>Agreed, n (%)</th>
<th>% consents pre-operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>15/06/14 – 14/09/14</td>
<td>16</td>
<td>5 (31%)</td>
<td>4 (80%)</td>
<td>0%</td>
</tr>
</tbody>
</table>

**SURGICAL TEAM FEEDBACK**

The TCRN requested feedback from participating surgical teams to develop a better understanding of barriers to requesting consent from their patients. Consultant surgeons cited being time poor and having difficulty remembering to seek consent from patients as the main barriers. While all consultants approached by the biobank teams to participate in the consent process were supportive of the initiative, the majority believed that registrars were responsible for the task. This is made difficult by the fact that the registrars rotate every six months, meaning regular education is required to ensure continuity with staff change over. Registrars cited limited time in the pre-operative period and difficulties remembering to request consent from patients, particularly if the consent form was not at hand, as the main reasons for not obtaining consent where it could otherwise have been requested. All surgical staff unreservedly supported the inclusion of the consent form as a page within the Recommendation for Admission booklet to streamline and facilitate the process.

**FINDINGS AND DISCUSSION**

Across the participating hospital sites, a number of factors impacted the outcome of the pilot programs, resulting in significant variation in numbers of patients being asked to give consent. The development of an official Local Health District-approved consent form was one of the project’s most significant achievements. The form showcased the biobanks as valid and valuable hospital-based research initiatives, and allowed the consenting process to be easily integrated into standard hospital procedures.
The use of the HCRA consent sticker within the Recommendation for Admission (RFA) booklet resulted in the highest levels of consent sought in the gynaecological oncology group (78%), demonstrating its efficacy as a tool when embedded within the surgical procedure consent process. The comparatively lower rates of consent being requested in the HCRA gastrointestinal group (55%) was largely a reflection of consent materials being less available in private clinics, and the lag-time between the start of the pilot and full accessibility of consent materials. This issue was identified and addressed during the pilot phase, with higher rates of request for consent seen in the second half of the pilot project.

The HCRA materials of a sticker and electronic capture of consent resulted in 100% occurring pre-operatively, reflecting the greatest success in embedding the process within the standard of care. Post-operative consent on the ward during patient recovery or at a subsequent outpatient visit represents a different pathway whereby staff are required to retrieve forms from different locations and find a suitable opportunity to discuss biobanking with the patient.

The success of using the consent stickers indicates that when the consent materials are embedded within the RFA, many of the barriers to consent being offered are overcome. Despite this, the sustainability of manually adding a sticker to each booklet is an important consideration, and formal approval from hospital/health district forms committees to add biobanking consent to the booklet is the most likely way to ensure ongoing implementation of such a process.

The St George Hospital peritonectomy group added the consent process to the Ambulatory Care Unit patient checklist (appendix ii). As such, requesting consent became part of a standard half-day pre-operative consultation that patients undergo at the hospital and could help to explain the relatively higher rate seen in this group (69%, see Table 5) compared to other TCRN sites.

Environments such as Sydney Vital, where requesting patient consent for biobanking is routinely performed by dedicated tumour bank staff, had relatively low compliance when consent was embedded in the hospital workflow. This may reflect a lower personal investment by clinic staff in supporting research activities.

Visibility and availability of consent forms was a key factor impacting the rate of request for consent across all sites. Two sites routinely scanned the biobank form into patients’ electronic medical record, which made consent more visible for biobank project staff, clinicians and anatomical pathology staff.

In terms of patient participation, only one patient refusal was reported during the pilots. While it is possible that some of the missed requests for consent represented a verbal refusal, as the reason for the missed request for consent was not recorded, feedback from participating surgeons indicates that it is more likely that consent was not sought at all, rather than being declined. This suggests that the main barrier to seeking consent is not to do with patient preference about biobanking and health data collection, but rather challenges in making the process of requesting consent part of routine hospital practice.
CONCLUSION

The project was successful in establishing a novel process for requesting patient consent for tissue and data collection that was integrated into routine hospital workflows. This approach, the delivery method of the pilot programs and the data gathered from the TCRCs and participating hospital sites has much to offer other organisations seeking to develop and implement a hospital-based biobanking project. Specifically, understanding and mitigating the barriers that prevent hospital staff from requesting consent from patients is key to maintaining strong numbers of patient samples and data available for research.

Sharing information assisted the four participating TCRCs to increase the speed with which consent pilots were launched at new hospital sites and improved the efficacy of a range of processes that impacted the projects’ success. For example, lessons learnt in the first pilot conducted by the TCRN demonstrated that educating hospital staff about the project needed to start well before the beginning of the official consent phase. Other TCRCs were able to apply this information to their own processes, resulting in better education outcomes (such as staff engagement) in subsequent pilot projects.

The mixed success of the site approvals processes across the participating hospitals reflects, amongst other things, differences between the public and private sector in establishing governance arrangements for hospital biobanking. Involving private practice in hospital-based research presents an additional challenge for research staff, regardless of whether the involvement is around overall governance or public patients seen in private rooms. Figures relating to requests for consent for private patients who underwent surgery in the private system were not included in this pilot due to the difficulty of tracking them. This was largely the result of private hospitals’ separate medical records departments and the fact that their theatre lists are not visible from NSW Health systems.

In addition, unresolved issues with the Commonwealth for access to data to establish a databank for future projects suggests that further work in the area of health data linkage for biobanks needs to be done to overcome access barriers. The 2014-15 funded CINSW BSN Project ‘Essential clinical annotation for NSW Biobanks through data integration using State and Commonwealth datasets’ aims to demonstrate the utility of linked administrative health data in enhancing the translational potential of biobanks.

Overall, the project demonstrated the viability of hospital-based biobanking projects if suitable groundwork is done to integrate the projects into basic hospital workflows. Hospital staff across a wide range of departments are generally supportive of the concept of biobanking and recognise its value in both a research and clinical context. The development of suitable and ongoing educational activities are important for reminding hospital staff of their role in in biobank consent projects, and the identification and appointment of project champions who have significant influence in the clinical sphere is a crucial component of keeping staff engaged.
KEY RECOMMENDATIONS

1. The biobank consent form should be formally incorporated as a page within the Recommendation for Admission booklet. This approach ensures compliance with the biobank process and ease of use for surgical staff who are involved in requesting consent from suitable patients. A state-wide process should be adopted in response to this finding.

2. Champions for biobanking within each key hospital area and surgical group are highly valuable in motivating teams. Champions should be identified and engaged before starting a hospital-based biobanking project is commenced.

3. It is important to map out the patient pathway for each tumour stream separately to understand where and when consent should be sought. Managing consent of public patients in private rooms should be considered.

4. Targeted education of hospital staff is necessary to inform groups about the purpose and value of biobanking. This approach also ensures that staff are regularly reminded about the importance of the project and their role within it.

5. The consent process is a fluid concept that requires continual fine-tuning to meet the changing need of hospital workflows and processes. Continued investment is therefore integral to the development of effective and sustainable systems.

6. Perceived ethical and custodial issues around release of linked administrative health data for unspecified research need to be addressed, potentially at a policy level.

REFERENCES


APPENDICES

i. HSA Biobank consent materials (TCRN)

ii. St George Hospital pre-admission checklist (TCRN)

iii. HCRA Consent and patient and staff educational materials

iv. Sydney Vital patient biobanking information poster
Consent for HSA BIOBANK

- I ______________________________ agree to participate as a subject in the HSA Biobank described in the patient information brochure provided.

Or (if applicable)

- I ______________________________ as guardian/power of attorney for ______________________________ agree for their participation in the HSA Biobank described in the patient information brochure provided.

- I have read the patient information brochure or have had it read to me in my first language, and I understand it.

- I have been given the opportunity to ask any questions and I have received satisfactory answers.

- I understand that I can withdraw consent at any time without affecting any medical treatment or care now or in the future.

- I agree that research data gathered from the results of the Biobank may be published, provided that I cannot be identified.

- I understand that if I have any questions relating to my participation I can contact the HSA Biobank directly using the contact details provided in the patient information brochure.

- I acknowledge receipt of a copy of the patient information brochure for my own records.

Please read carefully and tick either YES or NO.

1. I give my permission for the collection of tissue/fluid and blood/saliva samples and their use in future research.  Yes ☐ No ☐

2. I give my permission for the collection of clinical hospital data, the linkage of data from other sources and its use in future research. Yes ☐ No ☐

3. I give permission to the Department of Human Services to provide my/the participant’s Medicare and/or Pharmaceutical Benefits Scheme periods (PBS) claims history for the period 1/1/2009 to 31/12/2033 for the HSA Biobank study. Yes ☐ No ☐

Medicare Card Number ___________________________ / __________
- A copy of this consent form will be sent to Department of Human Services
- Additional information about Medicare/PBS claims history will be provided to you, or can be found on the HSA Biobank website.

PARTICIPANT PRINT NAME ___________________________ SIGNATURE ___________________________ Date

GUARDIAN/POWER OF ATTORNEY NAME (if applicable) ___________________________ SIGNATURE ___________________________ Date

Original - HSA Biobank  Copy - Medical Record

No Writing
The HSA Biobank

Banking today for better health outcomes

For how long will my samples be stored?
Your samples will be stored until they are used in research. Non-identifiable images and clinical information may be made available indefinitely for research and education purposes.

Will I know when my samples are being used in the future?
You will not be contacted when your samples are used, however you can obtain information on research conducted on samples stored in the HSA Biobank at this website: www.tcrn.unsw.edu.au/hsa

Research findings will be published in medical and scientific journals and presented at conferences. Findings will always be provided in such a way that you cannot be identified.

Similarly, research is conducted in such a way that individual results generally cannot be returned to participants.

Will drug or biotechnology companies be able to use my samples for profit?
Research involving your blood or tissue samples may result in a product or treatment that is profitable for a company. You will not receive any financial benefit from discoveries arising from the use of your samples or data.

What happens if I suffer injury or complications as a result of the HSA Biobank?
There is no physical risk in collecting tissue for the HSA Biobank beyond that of your hospital procedure. The collection of a blood sample will occasionally cause bruising. Any injuries or complications suffered as a result of the negligence of any parties involved in the HSA Biobank may entitle you to compensation; the cost of your treatment would be paid out of such compensation.

How can I get further information?
If you have any questions about the HSA Biobank, please contact us through the Lowy Biorepository at:

E: biorepository@unsw.edu.au
T: +61 2 9385 1493

Additional information can be found at www.tcrn.unsw.edu.au/hsa

At your request we will print this information for you.

Thank you for taking the time to consider participating in the HSA Biobank.
If you wish to take part, please sign the associated consent form.

This information brochure is for you to keep.

The HSA Biobank has been approved by the South Eastern Sydney Local Health District - Northern Sector Human Research Ethics Committee. Any person with concerns or complaints about the conduct of the HSA Biobank should contact the Research Support Office on: 02 9382 3587, or email: ethicsnhn@sesiahs.health.nsw.gov.au and quote reference number 11/160.

Version 3.3, April 2014
What is the HSA Biobank?
The Health Science Alliance (HSA) Biobank is an initiative of the Translational Cancer Research Network, developed through a partnership between UNSW Australia and NSW Health.

A biobank is a collection of human samples such as tissue and blood, linked to patient information, which is stored and made available to researchers, now and into the future.

The HSA Biobank will provide a valuable resource to researchers and teachers, so that they can increase our knowledge and understanding of disease. The HSA Biobank will enable high quality medical research, leading to better health outcomes for all.

What are we requesting from you?
We are asking you to give consent for the collection of a sample of your tissue, blood or fluid and associated clinical data for storage in the HSA Biobank. Your consent to the HSA Biobank would mean that your specimens and health data are stored for use in future research and education.

Please read this Patient Information Brochure carefully. Feel free to ask questions and to discuss the HSA Biobank with a relative, friend or your local health care worker.

Once you understand what the Biobank is about and you agree to take part, you will be asked to sign a consent form.

Do I have to consent?
Participation is voluntary. You can withdraw at any time by contacting the HSA Biobank. If you decide to withdraw, your samples and collected health information will be destroyed.

Your decision to say no or withdraw consent will not affect your medical treatment or your dealings with Medicare Australia.

What does consent involve?
If you give your consent, the following will be collected:
- A small piece of tissue and/or fluid from the sample removed during your procedure.
- A blood sample (approx. 10mL or two teaspoons); or a mouth swab/saliva sample.

If you have had a prior operation that relates to this procedure, we may also access this tissue. If you have another operation in the future within this Local Health District, signing the HSA Biobank consent form will also allow collection of tissue from that procedure.

The HSA Biobank will also request access to relevant health information about you from the following possible sources
- Hospital, pathology, emergency department records.
- State and national databases such as: Admitted Patients Data Collection; Registry of Births, Death and Marriages; and the NSW Cancer Registries.
- Medicare Benefits Scheme records (your visits to health professionals) and the Pharmaceutical Benefits Scheme (your use of prescription medicines).

What will happen to my samples and data?
Your samples and health data will be stored in the Lowy Biorepository at the University of New South Wales until they are requested for research or education. Future research will examine causes of disease, prevention, diagnosis, treatment and genetics. Future education will involve teaching medical, science and nursing students.

All future projects must be approved by a Human Research Ethics Committee before access to your samples or data can be granted.

Will users know my name and identifying details?
No. Your samples and other information will be given a unique identification code used by researchers, teachers and students. Your name and identifying details will be in a separate file that is not available to others. This maintains your confidentiality. All information is stored securely.
HEALTH SCIENCE ALLIANCE BIOBANK

Prince of Wales Hospital, Prince of Wales Private Hospital, the Royal Hospital for Women and St. George Hospital

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the HSA Biobank described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Prince of Wales Hospital, Prince of Wales Private Hospital, the Royal Hospital for Women, St George Hospital or my medical attendants.

Signature of participant  Please PRINT name  Date

________________________________  ______________________  _____________

The section for Revocation of Consent should be forwarded to:

Lowy Biorepository Manager
Lower Ground Floor
Lowy Research Centre
University of NSW
Kensington NSW 2052

OR contact directly to withdraw consent:
biorepository@unsw.edu.au
02 9385 1493
Facility:

PERITONECTOMY PRE-ADMISSION CHECKLIST FOR AMBULATORY CARE – SGH

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Patient to be commended on clear fluids from lunchtime Monday</td>
<td>☐ Pre Admission assessment undertaken</td>
<td>☐ Document chemotherapy script for: Hyperthermic Intraperitoneal Chemotherapy - HIPEC</td>
<td>☐ Surgical Team has reviewed patient</td>
<td>☐ Re-assess patient and determine site for stoma</td>
<td>☐ Patient is reviewed, procedure clarified and re-educate patient/family</td>
</tr>
<tr>
<td>☐ Perform and document patient height and weight</td>
<td>Contact: Anaesthetic-page 999</td>
<td>Contact: Medical Oncology Registar (Dr Liauw’s Registar pg 917) via switchboard</td>
<td>☐ Written Consent obtained</td>
<td>Contact: Clinical Nurse Consultant - page 224</td>
<td>Contact: Clinical Nurse Consultant: page 279</td>
</tr>
<tr>
<td>☐ Document baseline observations</td>
<td></td>
<td></td>
<td>☐ Full Medical Admission completed including:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Pathology as an outpatient</td>
<td></td>
<td>☐ Document chemotherapy script for: Hyperthermic Intraperitoneal Chemotherapy - HIPEC</td>
<td>• Chart bowel prep</td>
<td>☐ Re-assess patient and determine site for stoma</td>
<td>☐ Patient is reviewed, procedure clarified and re-educate patient/family</td>
</tr>
<tr>
<td>☐ ECG</td>
<td></td>
<td>Contact: Medical Oncology Registar (Dr Liauw’s Registar pg 917) via switchboard</td>
<td>• Chart vitamin K, 10mgs</td>
<td>Contact: Clinical Nurse Consultant - page 224</td>
<td>Contact: Clinical Nurse Consultant: page 279</td>
</tr>
<tr>
<td>☐ Inform patient of bed Management contact details for them to call between 1700-1800</td>
<td>To identify what ward and time they need to present to the day of surgery on ext 32928</td>
<td></td>
<td>• Clear fluid until midnight, then NBM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ ECG</td>
<td></td>
<td></td>
<td>• DVT prophylaxis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Ted stockings</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Ideally patients should receive vaccines at least 2 weeks before elective splenectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Pathology Forms completed (NB If a public holiday is on Monday blds to be collected as an outpt on Sat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>FBC, UEC’s, Coags, Cross match, tumour markers, MRSA nasal swab, VRE and MRAB rectal swab</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ HSA Biobank consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Contact: Registar - page 939 or Intern - page 353</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At the discretion of the nursing staff in the Ambulatory Care Unit, patients are able to leave the Ambulatory Care Unit once all of the above has been attended and an inpatient ward bed has been identified.
BSN Consent Project (2013 – 2014)

HCRA / HCB Attachments

Attachment 1: HCB Patient Information Pamphlet
Attachment 2: HCB Frequently Asked Questions
Attachment 3: HCB Information Poster
Attachment 4: HCB Consent Education
Attachment 5: HCB Consent Pilot: weekly email
For FUTURE RESEARCH

What are my options?

The decision to donate is entirely up to you.

If you decide to donate and later change your mind, just contact your doctor or the Hunter Cancer Biobank. At any time your information and tissue can be removed from the Hunter Cancer Biobank if you wish, or if you prefer, tissue already collected can be retained in a completely non identifiable form.

Your treatment will not be affected in any way whether or not you decide to donate.

Confidentiality

To protect your privacy, only authorised Hunter Cancer Biobank personnel have access to personal information.

When materials and information are released to researchers they are made anonymous (de-identified) and labelled with a unique number. This means that individuals contributing to the Hunter Cancer Biobank cannot be identified by the researchers.

Where can I get further information?

For further information speak to your doctor, or contact the Hunter Cancer Biobank:

Hunter Area Pathology Service
(a division of Pathology North)
Tel: (02) 4921 2808
Email: HNELHD-cancerbiobank@nsw.gov.au

The Hunter Cancer Biobank (HCB) has been approved by the Hunter New England Human Research Ethics Committee.

Any person with concerns or complaints about the conduct of the Hunter Cancer Biobank should contact the Human Research Ethics Committee Officer:

Dr Nicole Gerrand on (02) 4921 4950, or email: nicole.gerrand@hnehealth.nsw.gov.au (quote reference no. 12/06/20/5.03).

‘Delivering improved patient care & clinical outcomes’
**What is the Hunter Cancer Biobank?**

The **aim of the Hunter Cancer Biobank** is to build up a large collection of cancer tissue samples and information about people with cancer that can be used for future research.

Biobanking is the storage of biological specimens such as blood, genetic material and tissue. The samples stored in a biobank may also be linked anonymously to information about the health and treatment of the tissue donors.

**The Biobanking Process**

After a person has cancer surgery, the removed tissue is examined by a pathologist who prepares a report that is used to plan future treatment. Only a portion of the tissue removed is required for this process. The remainder of tissue is either stored in wax blocks in the pathology department or discarded.

**Can I donate?**

Anyone meeting **all** of the following criteria is invited to participate in the Hunter Cancer Biobank:

- over 18 years of age
- provisional or confirmed diagnosis with any form of cancer
- having a procedure to remove solid tissue
- admitted to a participating hospital in the Hunter New England region

**For Future Research**

**What happens if I agree?**

If you agree to take part, the Hunter Cancer Biobank will:

- ask for permission to store excess tissue to be used for future research
- ask for permission to link health and medical information in a way that would not identify you
- obtain informed consent for your participation in the biobank

**What will my samples be used for?**

If you agree to be a donor, a small sample of the cancer tissue and some normal surrounding tissue that is removed in your operation (and is not required for diagnosis) will be stored in the Hunter Cancer Biobank.

The stored tissue samples are to be linked to clinical information (pathology reports, medical records or NSW cancer registry) in a way that **will not identify you.** The linked information includes your treatment and progress over time.

Biobank tissue samples and linked information are available to scientific and clinical researchers looking into the causes, development, diagnosis and treatment of cancer. **Only cancer researchers** can apply to use the stored tissue and accompanying information.

**Who will have access to my tissue?**

Any cancer researcher can apply to the Hunter Cancer Biobank requesting the use of materials and information for a research project. However, **prior to receiving any samples** the researcher must first **obtain approval from both:**

1. A panel of scientists and doctors
   **AND**
2. Human Research Ethics Committee

The results of research performed on the tissue are intended to improve our understanding of cancer and to provide general benefits to cancer patients.

As tissue and information is collected for future research, it is not possible to know exactly which projects your tissue may be used for.

**Are there any risks?**

As tissue has already been collected as part of your surgery, there will be no physical risks if you agree for your excess tissue to be stored in the Hunter Cancer Biobank.

As research can often take many years, information from research conducted on your tissue is unlikely to have specific relevance to you or your family’s health, but may assist others in the future.
Frequently Asked Questions

My Tissue

If I decide to donate, will extra tissue be removed during surgery?
No extra tissue is removed. Only left-over tissue not required for pathology is stored.

How long will the tissue be stored for?
Your tissue will be stored for as long as the tissue is still useful for research.

Where and how is the tissue and linked clinical information stored?
Once the consent form has been received authorized biobank personnel will gather and store the tissue and required clinical information under a unique number in a secure database.

My Clinical Information

What does de-identified mean?
De-identified means that the information stored and provided to researchers has no identifiable information i.e. no name, date of birth, address, phone number.

If I say ‘yes’ to the biobank linking my health information, who has access to my medical records?
Only authorized biobank personnel will access your personal information.

What of my personal information is provided to researchers?
Only clinical information is provided to researchers.

Frequently Asked Questions

If I don’t consent, will it affect my treatment/diagnosis?
Whether or not you decide to donate, your treatment/diagnosis will not be affected in any way.

My Role in the Biobank

Do I have control over what research my tissue is used for? Who makes the decision?
As the tissue and information collected is for future research, it is not possible for you to know exactly which projects your tissue may be used for. However, before your tissue is provided to a research project, scientific and ethical committees must review and approve the research to have clinical significance.

Are there any additional requirements? i.e. tests, questionnaires, additional tissue removed?
There are no additional requirements upon signing consent.

Will there be any additional costs involved i.e. time or financial?
There are no additional costs outside of your routine standard of care.

When do I need to make my decision by?
While consent prior to surgery is recommended, it is important that you have time to fully consider all information in order to make an informed decision.
Cancer researchers look into the causes of cancer, trying to find new methods for detection, diagnosis, and treatment.

To assist cancer researchers, cancer tissue samples linked to health and medical information is needed.

**Ever thought about donating your tissue to research?**

**Hunter Cancer BIOBANK**

Storing *excess cancer tissue*, removed during *routine* surgical treatment, *linked* to medical information.

- Are you over the age 18 years?
- Are you soon to have a procedure to remove cancer at a hospital in the Hunter New England region?
- Are you willing to donate excess tissue taken during surgery to research?

You may be able to donate to the Hunter Cancer Biobank. All that is needed is your written consent.

For more information:

**Speak**— to your doctor or surgical team

**Read**— the ‘*Information About Donating Tissue*’ pamphlet

The decision to donate is up to you!
The Hunter Cancer Biobank

Maximising value through informed consent

ACTIVE AND TAKING TISSUE DONATIONS NOW!

May 2014
What is biobanking?

• storage of biological specimens
• linked to health information/outcomes
• used for cancer research into;
  – Identification of risk
  – Early detection
  – Sub-classification (prognostic/predictive biomarkers)
  – Identification of new drug targets & treatments
Why help Hunter Cancer Biobank (HCB)?

• Assist with the development of leading cancer research
• Facilitate specimen collection for local clinical and laboratory cancer researchers
• Help make the Hunter New England region a global leader in cancer research
• Ultimately, help improve patient outcomes
Essential Requirement for PP2A Inhibition by the Oncogenic Receptor c-KIT Suggests PP2A Reactivation as a Strategy to Treat c-KIT+ Cancers

Kathryn G. Roberts1,2, Amanda M. Smith1,2, Fiona McDougall1,2, Helen Carpenter1,2, Martin Horan1,2, Paolo Neviani3, Jason A. Powell4, Daniel Thomas4, Mark A. Guthridge4, Danilo Perrotti3, Alistair T.R. Sim1,2, Leonie K. Ashman1,2, and Nicole M. Verrills1,2

Abstract

Oncogenic mutations of the receptor tyrosine kinase c-KIT play an important role in the pathogenesis of gastrointestinal stromal tumors, systemic mastocytosis, and some acute myeloid leukemias (AML). Although juxtamembrane mutations commonly detected in gastrointestinal stromal tumor are sensitive to tyrosine kinase inhibitors, the kinase domain mutations frequently encountered in systemic mastocytosis and AML confer resistance and are largely unresponsive to targeted inhibition by the existing agent imatinib. In this study, we show that myeloid cells expressing activated c-KIT mutants that are imatinib sensitive (V560G) or imatinib resistant (D816V) can inhibit the tumor suppressor activity of protein phosphatase 2A (PP2A). This effect was associated with the reduced expression of PP2A structural (A) and regulatory subunits (B55α, B56α, B56γ, and B56δ). Overexpression of PP2A-Aα in D816V c-KIT cells induced apoptosis and inhibited proliferation. In addition, pharmacologic activation of PP2A by FTY720 reduced proliferation, inhibited clonogenic potential, and induced apoptosis of mutant c-KIT+ cells, while having no effect on wild-type c-KIT cells or empty vector controls. FTY720 treatment caused the dephosphorylation of the D816V c-KIT receptor and its downstream signaling targets pAkt, pSTAT5, and pERK1/2. Additionally, in vivo administration of FTY720 delayed the growth of V560G and D816V c-KIT tumors, inhibited splenic and bone marrow infiltration, and prolonged survival. Our findings show that PP2A inhibition is essential for c-KIT-mediated tumorigenesis, and that reactivating PP2A may offer an attractive strategy to treat drug-resistant c-KIT+ cancers. Cancer Res; 70(13): 5438–47. ©2010 AACR.
Partners Working Together

The Hunter Cancer Biobank (HCB)

• Formally established in 2012
• Located at Pathology North (HAPS) - John Hunter Hospital
• Embedded into routine practice
• FFPE tumour & paired normal tissue taken from all solid cancers.
• Comprehensive collection of tissue with annotation and validation.

State-of-the-art resource for local, national & international cancer research community.
Current HCB Specimens
(as of 31 Dec 2013)

9800 FFPE specimens
(from >2900 patients)
Users of HCB Tissue

• Royal College of Pathologists Australasia
  – Quality Assurance & Continuing Education Programs.

• Dr Judith Weidenhofer (University of Newcastle)
  – Regulation of CD151, CD82 and CD9 in breast cancer.

• Dr Pradeep Tanwar (University of Newcastle)
  – Role of Wnt-PI3K-mTOR signalling in testicular cancer.
HCB Eligibility Criteria

• Anyone meeting all of the following criteria is invited to participate in the HCB:
  – Over 18 years of age
  – Provisional or confirmed diagnosis of any form of cancer
  – Having a surgical procedure to remove solid tissue
  – Admitted to a participating hospital in the Hunter New England region (HREC # 12/06/20/5.03)
How can you help?

Support the HCB

- Identify eligible patients
- Provide information to patients
- Gain informed consent via RFA / eRFA

RFA paper form
Ensure your RFA consent form has additional data-linkage sticker and signed in 2x places.

Electronic RFA
Ensure you select ‘cancer related procedure’ on any eRFA so the HCB consent prompt appears.
HCB Tissue Banking Consent
Paper based form

I understand that the above procedure may involve the removal of some bodily tissue which may be required for the diagnosis or management of my condition.

I consent/do not consent* to such tissue being used for any medical, therapeutic or scientific purpose, in addition to purposes related to the diagnosis or management of my condition.

My consent is conditional on the following terms:

This consent extends only to tissue, which is removed for the purposes of the above procedure.

SIGNATURE OF PATIENT

To be completed by the patient:
I consent for my tissue to be stored in the Hunter Cancer Biobank for future research.

I also consent for my health and medical information to be linked to the stored tissue. I understand that only de-identified information together with my tissue sample will be given to the researchers.

I have had time to consider consenting to the Hunter Cancer Biobank and have been able to ask questions, and my questions have been answered to my satisfaction.

Patient signature: ________________________________

Administrative use: To be completed by a staff member if patient doesn’t consent to tissue banking

☐ The patient has declined tissue banking
☐ The patient has not been asked to consent to tissue banking
USE OF REMOVED TISSUE (See Section 33 of Circular)

To be completed by the patient:

I understand that the above procedure may involve the removal of some bodily tissue which may be required for the diagnosis or management of my condition.

I consent to such tissue being used for other medical, therapeutic or scientific purposes in addition to purposes related to the diagnosis or management of my condition.

Is this a cancer related procedure? [ ]

I consent for my tissue to be stored in the Hunter Cancer Biobank for future research.

I also consent for my health and medical information to be linked to the stored tissue. I understand that only de-identified information together with my tissue sample will be given to the researchers.

I have had time to consider consenting to the Hunter Cancer Biobank and have been able to ask questions, and my questions have been answered to my satisfaction.

My consent is conditional on the following terms:

Insert terms, if any:

This consent extends only to tissue, which is removed for the above procedure.

Administrative Use Only: To be completed by a staff member if a patient doesn’t consent to tissue banking:

- [ ] The patient has declined tissue banking
- [ ] The patient has not been asked to consent to tissue banking

Signature of Patient / Parent / Guardian

Submit Signed Document

Date of Signature (If Signing Printed Copy)

SIGN HERE

SIGN HERE
Remember:

Be sure to add your new registrars to the eRFA list, so that they can use the eRFA system to consent patients to the HCB!
Informing your patients

1. Introduce biobanking
   - what is biobanking, what happens to the tissue, who has access to info.

2. Show consent form & provide HCB brochure
   - Explain data-linking

3. Explain pertinent information
   - Risks, freedom of choice, confidentiality

4. Go through the patient information brochure
Cancer researchers look into the causes of cancer, trying to find new methods for detection, diagnosis, and treatment.

To assist cancer researchers, cancer tissue samples linked to health and medical information is needed.

**Ever thought about donating your tissue to research?**

**Hunter Cancer BIOBANK**

Storing excess cancer tissue removed during routine surgical treatment, linked to medical information.

- Are you over the age 18 years?
- Are you soon to have a procedure to remove cancer at a hospital in the Hunter New England region?
- Are you willing to donate excess tissue taken during surgery to research?

You may be able to donate to the Hunter Cancer Biobank. All that is needed is your written consent.

For more information:
- Speak to your doctor or surgical team
- Read the ‘Information About Donating Tissue’ pamphlet

The decision to donate is up to you!
Some FAQ’s

1. Do I have to make my decision today? No
2. Can I remove my tissue from the registry after I have consented? Yes
3. Will you take extra tissue? No
4. How long is the tissue stored for? Until no longer usable
5. What happens if I die? Tissue remains in the bank
6. What happens if I say ‘no’, will it effect my treatment? No
7. Will there be any additional requirements? No
Thank you for your time & support

Any further questions contact:

Sarah Nielsen
HCB, Anatomical Pathology, Pathology North
P: 02 4921 2808
M: 0421 528 908
E: sarah.nielsen@hnehealth.nsw.gov.au
HNELHD-CancerBioBank@hnehealth.nsw.gov.au
Dear Gynae Oncology Team,

Thank you for your ongoing support of the Hunter Cancer Biobank (HCB) and your assistance in gaining pre-operative consent to store tissue samples in the HCB.

**eRFA: Biobank consent is live**- You can use the electronic RFA forms to consent to the Hunter Cancer Biobank. Simply select *yes* to the prompt question: *Is this a cancer related procedure* and the HCB consent wording will appear. If you are noticing any issues with this process, please let us know.

Please remember, if using the paper based consent, to optimise the value of patient samples collected by the HCB, we require the patient to sign the RFA in 2 places; *(1) the RFA tissue consent and (2) HCB specific consent sticker.*

Please find below an overview of the consent rates obtained during the third week /surgical period following implementation of our pre-operative consent process.

Table 1: HCB Consent rates: week 3 surgical period (17 March – 21 March 2014)

<table>
<thead>
<tr>
<th>MRN</th>
<th>Tumour stream</th>
<th>Procedure</th>
<th>Surgery Date</th>
<th>Consultant</th>
<th>RFA Tissue Consent</th>
<th>HCB Consent Sticker</th>
<th>Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>0732842</td>
<td>Gynaec Oncology</td>
<td>Hysterectomy</td>
<td>18/03/2014</td>
<td>Jaaback</td>
<td>No</td>
<td>eRFA</td>
<td></td>
</tr>
<tr>
<td>0292647</td>
<td>Gynaec Oncology</td>
<td>Salpingo-oophorectomy</td>
<td>18/03/2014</td>
<td>Jaaback</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2822194</td>
<td>Gynaec Oncology</td>
<td>Hysterectomy</td>
<td>20/03/2014</td>
<td>Jaaback</td>
<td>Yes</td>
<td>eRFA</td>
<td></td>
</tr>
<tr>
<td>0877031</td>
<td>Gynaec Oncology</td>
<td>Laparotomy</td>
<td>22/03/2014</td>
<td>O'Sullivan</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

NB: As the HCB specific consent stickers were only placed on the RFA forms in late Feb 2014, we are expecting to see more HCB completed consents over the coming weeks / surgical periods.

Thank you for your efforts and please let us know if there is anything we can do to assist you with the consenting process.
Kind Regards

Sarah and the HCB Team.
Have You Been Asked About Tumour Banking?

The Kolling Institute Tumour Bank collects tissue and blood samples from patients having tumours or cancers surgically removed.

Samples are stored for use in future ethically approved research looking at ways to develop new methods to diagnose and treat cancer.

You may be eligible to donate:
- Are you 18 years and over?
- Are you having an operation to remove a tumour or cancer at Royal North Shore Hospital?

For more Information:
SPEAK to your doctor or surgical team

OR

READ the Tumour Banking for the Future Participant Information Brochure

THE DECISION WHETHER TO DONATE OR NOT IS ENTIRELY UP TO YOU

www.kolling.usyd.edu.au/research/tumour-bank