Clinical Oncological Society of Australia

Tissue Banking for Cancer Clinical Trial

Workshop Report

October 2008

NOVARTIS ONCOLOGY

Roche

Tissue Banking for Cancer Clinical Trials

Clinical Oncological Society of Australia (COSA)

Stamford Hotel, Sydney Airport 24 October 2008

Summary report

Workshop report prepared by Alison Evans Consulting on behalf of COSA

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BACKGROUND

Cancer clinical trials are research studies that test whether new or modified approaches to the prevention, diagnosis or treatment of cancer are safe and effective. Some trials may also explore aspects of supportive care such as quality of life.

Biological studies involve correlation of clinical outcomes with markers that predict response to treatment or that have prognostic value through analysis of tissue or blood samples. In addition, such studies can provide information about markers of underlying disease, such as serum markers used to detect occult malignancy in apparently disease-free patients. Such studies require the appropriate collection and storage of fixed or frozen tissue and blood samples as well as mechanisms to facilitate timely access to these biospecimens for analysis.

There is considerable interest in linking biological studies with cancer clinical trials and it is increasingly common for trial protocols to include a biological sub-study. In many cases a biological question is already included as part of the trial, particularly in studies exploring combination use of 'biological' agents and conventional chemotherapy or radiation. Such trials have the potential to make a significant contribution to cancer care, providing the capacity for a targeted approach to treatment that is individualised to a patient's needs.

Examples of biological studies with therapeutic relevance for cancer include:

- the development of therapies targeting HER2-positive breast cancer
- recent data about the influence of *K-ras* mutation status on response to cetuximab in advanced colorectal cancer.[1]

COOPERATIVE CLINICAL TRIALS GROUPS

There are currently 13 Cooperative Cancer Clinical Trials Groups (CCTGs) in Australia (see Appendix I). These trials groups receive funding from a variety of sources including:

- National Health and Medical Research Council (NHMRC) Enabling Grants awarded through the Clinical Oncological Society of Australia (COSA)
- Cancer Australia's Priority-driven Collaborative Cancer Research Scheme
- funding obtained through trial activity itself (mixture of philanthropic donations, competitive grants and industry support).

Trials overseen by these groups vary in size and complexity but are typically multicentre studies recruiting patients in several states and territories and in some cases New Zealand and other countries. Some studies are multinational, and these may be managed centrally by an overseas collaborating group or by the Australian CCTG.

CURRENT STATUS OF BIOBANKING IN AUSTRALIA

Biobanking of specimens from patients enrolled in cancer clinical trials in Australia is currently undertaken predominantly by the pharmaceutical industry. Most of this activity

involves collection of blood samples for pharmacogenomic[1] or pharmacogenetic research[2] conducted exclusively by/for the sponsor company, with specimens and data often sent overseas for analysis. While some CCTGs have been actively involved in biobanking, each group typically collects specimens only for a particular trial and there is currently no standardised or systematic approach to biobanking for multisite clinical trials.

Tumour biobanks have been established at many sites in Australia (see Appendix II). A number of these have started to work cooperatively – most notably the seven biobanks involved with the Australasian Biospecimen Network – Oncology (ABN), the National Leukaemia and Lymphoma Tissue Bank (NLLTB), the Breast Cancer Biospecimen Resource, the Australian Prostate Cancer Collaboration (APCC) BioResource, the Victorian Cancer Biobank (VCB), kConFab and the Australian Ovarian Cancer Study (AOCS).

These cooperatives are funded from a variety of sources, including competitive grants, State government and philanthropic donations. Funds are used not only for costs associated with specimen collection and storage, such as salaries and consumables, but also for the development of standard operating procedures to ensure consistency and quality assurance, and, in some cases, for database design, web-based cataloguing of specimens and education.

Tissue banks linked to cancer clinical trials clearly have a vital and growing role in improving patient outcomes, maintaining Australia's international standing in medical research and enabling Australia to remain a country of choice for clinical trial conduct in an increasingly competitive international market.

COSA is ideally placed to facilitate a collaborative and coordinated approach to biobanking of specimens collected as part of cancer clinical trials conducted by CCTGs in Australia. A 1-day workshop of key stakeholders held in October 2008 represented an important first step in standardising and rationalising approaches and identifying future needs.

[1]The study of the human genome to identify genes involved in the mechanism of action or metabolism of drugs

[2]The study of a limited number of genes involved in the mechanism of action or metabolism of drugs

WORKSHOP OVERVIEW

COSA convened a 1-day workshop in October 2008 with the aim of exploring a coordinated approach to the collection, storage and efficient utilisation of clinical trial specimens as well as appropriate mechanisms for funding tissue banking and access within the CCTGs in Australia. The workshop program is provided as Appendix III.

The workshop was attended by 50 participants from biobanks, CCTGs and cancer registries as well as consumers and representatives from relevant cancer organisations such as Cancer Australia (see Appendix IV).

WORKSHOP INTRODUCTION

Professor David Goldstein, President of COSA, welcomed participants and highlighted the need for practical and collective strategies to enhance the relationship between cancer clinical trials and the collection, storage and distribution of tissue in Australia.

The workshop facilitator, Professor Ian Olver, CEO of the Cancer Council Australia, asked participants to focus particularly on the role that COSA could take in facilitating tissue banking for trials conducted by the CCTGs. He emphasised the importance of achievable outcomes that build on existing initiatives and avoid duplication of effort.

SUMMARY OF PRESENTATIONS

The workshop opened with a series of presentations providing context for the later group discussions. A brief outline of the key points covered in each presentation is provided below.

The statistical considerations

Professor John Simes *(Director, NHMRC Clinical Trials Centre, University of Sydney) and* ***Dr Chee Lee*** *(Researcher, NHMRC Clinical Trials Centre, University of Sydney)*

Professor Simes and Dr Lee described the importance of both prognostic and predictive biomarkers in defining therapeutic choices in order to ensure individualised treatment and avoid under or over treatment.

- A **prognostic marker** is a single trait or signature of traits that separates different populations with respect to the risk of an outcome of interest in absence of treatment or despite non targeted ‘standard’ treatment (identifies who needs treatment).
- A **predictive marker**: a single trait or signature of traits that separates different populations with respect to the outcome of interest in response to a particular (targeted) treatment (identifies which treatment is best).

The presenters highlighted key statistical considerations to be factored into the design of trials examining biomarkers, including:

- the potential impact of cancer heterogeneity on clinical trial outcomes if not accounted for in the trial design
- the importance of selecting the appropriate trial design based on the clinical question(s)
- the risks associated with discovery-based research and the potential for generating results by chance when using multivariate models.

The strengths and limitations of a number of different trial designs were described.

- **Enrichment design**: used when there is strong biological evidence that treatment efficacy is limited to biomarker-positive populations. This design has the benefit of

requiring only a small number of randomised patients because those who are unlikely to benefit from treatment are excluded from the trial. However, this design only establishes treatment effectiveness in a specific subgroup of patients and requires an adequate definition of 'positive' and 'negative' and a validated method of biomarker testing.

- **Unselected design**: used when the biological basis for selecting biomarker-positive patients is less than compelling. In such studies, both biomarker-positive and negative patients are included in the trial, with stratification used to test hypotheses in biomarker-positive and negative populations. This design permits testing of the utility of treatment and the biomarker test but requires a large sample size and adequate power calculations from the outset.
- **Retrospective design**: uses pre-existing randomised controlled trial data and archived tissue specimens to compare treatments for which a biomarker is proposed to be predictive. This design has the benefit of being time and cost effective but requires the availability of adequate and representative archived specimens and the development of a prospective analysis plan prior to performing assays to avoid spurious outcomes.

Given the benefits of both prospective and retrospective studies, the presenters recommended that tissue and blood collection is included as part of every trial protocol and that patient consent includes the potential to use stored samples to test hypotheses that can be validated in future trials.

The importance of tissue banking in clinical trials

Professor Paul Waring *(Professor of Pathology and Laboratory Medicine, University of Western Australia)*

Professor Waring presented data from major US pharmaceutical companies illustrating the escalating costs of drug development and the associated decline in new drug approvals over the past 25 years. Noting the need for increased efficiency in the drug development process, Professor Waring identified the following strategic imperatives for cancer clinical research in relation to tissue banking:

- identify those indications in which the tumour is truly dependent upon the targeted pathway (**indication selection**)
- determine in phase I and II studies whether there is drug-induced modulation of the target pathway in the tumour (pharmacodynamic markers)
- choose the right patients for phase III trials using biomarkers that predict therapeutic benefit (**prospective patient selection**)
- ensure that each study is designed and powered to identify a responder subset in the event the trial fails in 'all comers' (**retrospective subset analysis**)
- understand the mechanism of primary and secondary resistance to help guide the development of second-generation drugs (**drug-resistance mechanism**).

Professor Waring added to the previous presentation, describing the logistical and regulatory implications of different trial designs, including:

- **prospective tumour biomarker validation** – may represent an accelerated path to regulatory approval but disincentives include enrolment delays, uncertainty about the biomarker's predictive value and requirement for a validated assay to be available prior to commencement of the study

- **retrospective studies** – overcome enrolment delays but represent an uncertain route to regulatory approval, are dependent on prior approval for use of specimens for unspecified exploratory research and may be limited by the number and quality of available samples.

He described the following barriers to the conduct of biomarker studies:

- **lack of incentives** for pathology laboratories to provide archived samples from clinical trial participants
- **sub-optimal processing** of diagnostic samples for biomarker studies, precluding their use for pharmacodynamic biomarker studies and limiting predictive biomarker development
- **use of inappropriate samples** for validation and testing of biomarkers – for example use of diagnostic samples from primary tumours rather than the metastatic tumour being treated.

In closing, Professor Waring used an example from the US to illustrate the benefits of collaboration between diagnostic companies and cooperative tissue banks, with the generation of a validated and commercially available prognostic test for breast cancer.

Overview of ALLG clinical trial collection

Dr Paula Marlton *(Head of Leukaemia and Lymphoma Services, Princess Alexandra Hospital, QLD)*

Dr Marlton presented an overview of the development of the National Leukaemia and Lymphoma Tissue Bank, which was launched in 2002 following 3 years of planning. Dr Marlton indicated that philanthropic, funding together with a NHMRC Enabling Grant, has facilitated an increase in staffing and a steady increase in tissue sample activity. In 2007–2008, the Tissue Bank provided samples for 13 research studies in Australia and overseas, with an additional study currently under consideration.

Tissue requests, and strategic and policy decisions are made by a Tissue Bank Management Committee comprising investigators from the NHMRC Enabling Grant, representatives from each state, and a consumer representative. Key staffing roles include a Tissue Bank Manager, Tissue Bank Research Scientist, Tissue Bank Scientist, Sample Co-ordinator and Administrative support. An automated robot has recently been purchased to assist with extraction processes.

Dr Marlton described a number of new and proposed strategic initiatives for the Tissue Bank, including:

- a plan to include routine tissue banking as part of all ALLG trials (opt-out process)
- targeting of regional centres to encourage and support the conduct of research and participation in tissue banking
- approaches to collaboration and linkage, including other trial centres, paediatric trial groups and the Australian Biospecimen Network
- logistical initiatives, including development of a web-interfaced database to facilitate national access to information about specimen availability, improved integration with clinical trial data and development of minimum data sets for non-trial samples
- pro-active marketing of the availability of samples and tendering of priority-driven projects
- new approaches to sample collection, including collection of matched normal tissue, familial cancer samples and transplant donor recipient collections.

While providing an excellent example of what can be achieved through a strategic approach to planning and development, Dr Marlton's presentation also highlighted the importance of long-term funding to ensure sustainability, particularly given the minimal income generated through cost-recovery from Tissue Bank activities.

An update on current tissue banking in Australia

Ms Heather Thorne *(kConFab Manager, Peter MacCallum Cancer Centre)*

Ms Thorne summarised the current status of tissue banking in Australia, describing the large number of oncology tissue banks across the country and the high degree of cooperation and collaboration that exists between them (see Appendix II). She summarised current guidelines and legislation that guides the collection and distribution of tissue samples as outlined below.

- **NHMRC National Statement on Ethical Conduct in Research Involving Humans** (developed in 1999 and updated in 2007):[2] provides guidelines for researchers, Human Research Ethics Committees and Institutions for the ethical conduct of human research. There are specific sections on Tissue banks (Section 3.4) as well as genetic research (3.5) and Clinical Trials (3.3). In addition Sections 2.2 and 2.3 deal with general principles of consent.
- **Privacy Act (Commonwealth (1988) and Private (2001), which include Health Privacy Principles**: provide standards for the collection, handling and disposal of health information in Commonwealth and private domains at national level. Some States have enacted their own Privacy Acts, which operate alongside the federal legislation and fill the gap left by the Commonwealth and private acts not addressing state and territory public institutions.

Ms Thorne stated that there is currently no unified process for obtaining patient consent or ethics approval for multisite studies run in different states and territories involving the collection of biological specimens.

Other issues highlighted included the need for:

- improvements in database design and data linkage
- increased involvement of biobanks in clinical trials to facilitate translational oncology research
- greater unification to maximise use of funds and avoid duplication of effort
- consideration of commercial aspects and appropriate approaches for liaison with industry
- strategies to limit the bureaucratic load on the system that can delay the conduct of trials.

Review of NSW tissue banks

Dr Parisa Glass *(Research & Information Advisor, Cancer Institute NSW)*

Dr Glass described outcomes from a review of tissue banks in NSW undertaken by the Cancer Institute NSW with a view to consolidating effort, increasing access and improving the quality and consistency of specimens. Through a survey of 150 contacts across NSW, 17 formalised biobanks have been identified to date covering a range of tumour types. The majority of the biobanks identified combine multiple collection sites with single storage facilities. Common issues identified through the review included the inadequacy of funding to support tissue banks, and the lack of consistency in reporting and measures of success.

Barriers to specimen access identified by Dr Glass included:

- the dispersed nature of biobanks and specimen locations
- lack of a central register that would allow researchers to locate specimens or a single scientific advisory committee for submission of applications to access samples from multiple sites
- requirement by HREC for details of ethics approvals of biobanks to which the researcher is applying
- inadequacy of research funding to cover costs associated with biospecimen access other than freight costs.

Enablers to specimen access identified by Dr Glass included:

- a central register of specimen locations, ideally grouped by cancer type
- streamlined approval process for ethics at researcher institution and for scientific advisory committee approval and access to specimens at housing institutions
- minimising the costs associated with biospecimen access, unless covered by the grant.

Dr Glass summarised a range of issues to be considered as part of strategies to improve coordination and consistency of tissue banking, including governance issues, development of standard operating procedures, consent and ethics issues, approaches to funding and cost recovery and marketing strategies.

Potential models for clinical trials collections

Dr Nik Zeps *(Research Manager, St John of God Pathology and Radiation Oncology, Sir Charles Gairdner Hospital; incoming Chair of the COSA Research Group)*

Dr Zeps presented a range of questions and issues for consideration by workshop participants in relation to the role COSA could play in facilitating a more streamlined, uniform and cost-effective approach to tissue banking for oncology clinical trials conducted by the CCTGs in Australia.

Questions identified included:

- who should coordinate and run tissue banks (CCTGs/subcontractors)?
- what questions should be considered by the Trial Management Committee in relation to a biological study:
    - which samples and how should they be processed (issues for tissue/blood/DNA)?
    - who should collect samples (centralised or distributed)?
    - who should store/manage samples (how can access be improved)?
- what roles could COSA play in facilitating new approaches:
    - clearinghouse/information role (register of tissue banks/register of specimens/links to relevant protocols)?
    - tendering role?
    - facilitating partnerships/collaborations/linkages (RCPA/tissue banks/clinicians/researchers)?

    - quality assurance role?
- what are the potential barriers?
- what are the likely costs and how can funds be sought?
- what are the measures of success?

These questions provided a foundation for subsequent small group discussion in the remainder of the workshop.

WORKSHOP OUTCOMES

Participants were asked to consider four issues in relation to tissue banking for CCTGs in Australia:

1. minimum data elements
2. standardised consent/ethics
3. collection and storage of samples
4. distribution of samples and sustainability.

Issues and recommendations were identified through discussion by four self-appointed multidisciplinary groups. Time limitations precluded a full consensus approach and the outcomes reported below summarise key outcomes reported back to the plenary group.

All groups recognised the importance of avoiding duplication and building on existing national and international initiatives.

Minimum data elements for a tissue bank linked to cancer clinical trials

The minimum data elements identified for a tissue bank linked to cancer clinical trials related to demographic identification of the trial and specimen, with specific data elements identified for the trial and the specimen itself.

Minimum data elements for the *trial**	**Minimum data elements for the *specimen***
Primary questions for the tissue sub-study	Trial name/identifier
Contact details of the trial group/principal investigator	Patient identifier
Type of specimen collected (as defined by the trial protocol)	Tumour type
Type of consent (generic or specific to the trial)	Type of tissue (tumour, blood, plasma, serum, DNA etc)
Potential availability for collaborative research (Y/N/qualified)	Collection method (fresh, frozen, paraffin-embedded etc)
	Date of collection
	Storage location
	Type of consent

*To be based on the World Health Organisation minimum data set for clinical trials[3]

Standardised consent/ethics

Current issues identified in relation to consent and ethics approval for the collection and storage of tissue samples as part of cancer clinical trials included the need for:

- increased awareness and application of national guidelines for consent and ethics such as those developed by the Australian Health Ethics Committee (AHEC)[2] and issued by the NHMRC as well as the Harmonisation of Multi-centre Ethical Review (HoMER) project[4]
- public engagement about the benefits of tissue collection and the importance of information collected from specimens held in biobanks.

It was suggested that the ultimate goal in Australia should be to obtain consent for the collection and storage of tissue samples for the purposes of research from all patients at the point of diagnosis. One possibility would be an opt-out rather than an opt-in policy and would ideally include storage of samples for germ line sampling and assessment of somatic mutations. However, there are major health consumer concerns with such an approach and much would need to be done to gain wide acceptability. The need for a streamlined, efficient process that could be applied beyond cancer was identified.

Questions to be considered in developing a standardised approach to consent included:

- timing of obtaining consent (at diagnosis vs on entry to the clinical trial)
- who should obtain consent
- process for informing the patient or family members about the implications of the information obtained from sample analysis
- implications of use of tissue after death
- sampling considerations (for example, collection of normal tissue, blood samples and relapse tissue).

Possible roles for COSA in facilitating a standardised approach to consent and ethics included:

- lobbying for legislation around the process of consent for tissue banking (while raised as an option there was some debate about whether such an approach is appropriate)
- liaison with the Royal College of Pathologists of Australasia (RCPA)
- undertaking a review of international and national consent procedures
- development of common guidelines, templates and procedures
- public engagement about the altruistic benefits of tissue collection and storage.

Collection and storage of samples

The following obstacles to the collection and storage of tissue samples by CCTGs were identified:

- lack of pathology contact before trial initiation
- lack of standardisation in approaches to sampling and storage
- lack of financial incentives for pathologists to be involved in the collection, storage and release to third parties of tissue for research purposes
- quality issues associated with different sampling approaches – eg difficulties associated with obtaining frozen samples and limitations of paraffin-embedded samples
- lack of awareness by funders and policy makers of the complexities of tissue collection and storage.

Possible solutions to encourage a consistent approach to storage of tissue samples included:

- greater involvement of pathology from the trial outset, including inclusion of a pathologist on Trial Management Committees and, where possible at each participating site, and subsequent scientific acknowledgement of pathology input

- consideration of reimbursement options for pathologists involved in tissue sampling, including the option of a Medicare item number for collection and preparation of tissue by pathologists for the purposes of research
- pre-definition of a biological or translational research question with a clinical trial that has a clear clinical objective to promote clinician engagement and encourage the collection of a sufficient quantity of tissue of appropriate quality for testing
- creation of a virtual network to allow samples to be collected and stored locally but accessed nationally
- standard collection of a second block of tissue to be stored locally for future studies (aspirational goal).

Possible roles identified for COSA included:

- collaboration with the RCPA to centralise coordination of pathology input
- collaboration with appropriate partners to lobby government for a Medicare number to reimburse pathologists for collection of tissue for research purposes
- tendering for activities to support localised collection and storage of tissue samples.

Distribution of samples

The heterogeneity of existing tissue banks was identified as a key issue in limiting the distribution of tissue samples for the purposes of clinical research. It was suggested that additional tissue samples collected in relation to a specific clinical trial should be quarantined from translational research samples. Such clinical trial samples should remain under the governance of the Trial Management Committee. In contrast, access to 'open collection' samples for biomarker discovery, pre-clinical studies and translational research should be managed by the respective tissue bank.

The sustainability of tissue banks was considered to be dependent on:

- international best practice[5] and standard operating procedures
- database management and clinical linkages
- long-term funding through a range of avenues, including federal and state government, grants and philanthropic groups
- amalgamation of consortiums to maximise efforts.

The potential role of COSA in advocating for funding was discussed.

OPPORTUNITIES FOR FUNDING

A range of potential sources of funding were identified to support the collection, storage and distribution of tissue for oncology clinical trials and translational research in Australia.

Category	Examples
Government/government bodies	• Enabling grants/infrastructure grants (eg NHMRC, Cancer Australia) • Tax revenue • Medicare items for sample collection
Trial sponsors/commercial entities	• Pharmaceutical companies • Health instrument/consumable suppliers

Category	Examples
Philanthropic donations	• Banks • Health insurance companies • Disease-specific charitable foundations (eg Leukaemia Foundation)
Non-government organisations	• Cancer Councils • Australian Cancer Research Foundation
Overseas funding sources	• National Institutes of Health (USA) • National Cancer Institute (USA) • Department of Defence (USA)
Other potential sources	• Private hospital associations

Questions to be considered in relation to funding of tissue banks included:

- who should receive funding – clinical investigators/tissue bank groups/research scientists/health departments/hospitals?
- who 'owns' the tissue/specimen?
- what is the long-term cost-effectiveness of targeted approaches to cancer treatment developed through analysis of biomarkers?

Options to be considered in ensuring long-term sustainability included:

- embedding value-added research in clinical trials and making clinical questions more cost-effective
- exploring the potential for commercial opportunities/partnerships (eg providing new pathology services to measure known biomarkers)
- prioritisation of translational research involving tissue banks, with priority given to collections from randomised controlled trials with linked high-quality clinical data that allow analysis of prognostic and predictive markers
- centralisation, standardisation and linking of approaches and knowledge to improve efficiency and maximise use of available funds
- conduct of a national audit of existing biobanks and processes to build and learn from existing initiatives
- consideration of cost-efficiencies in shared approaches to infrastructure
- engagement of consumer advocacy groups such as Cancer Voices Australia to assist in lobbying for change.

Specific actions to be considered by COSA in moving forward included:

- joint submission with the RCPA to government in relation to the creation of a Medicare item number for preparation of specimens for the purposes of research
- coordination of a committee to seek a 5-year funding grant from the Australian Cancer Research Foundation to support a tissue bank coordinating centre
- exploration of options for 7-year renewable funding for cancer clinical trial tissue banking
- building on the existing NHMRC enabling grant to facilitate new initiatives

- commissioning of an analysis of the cost-effectiveness of tissue banking activities, in partnership with the pharmaceutical industry and/or Pharmaceutical Benefits Advisory Committee
- appointment of a project officer to assist in building a business case and identifying and engaging relevant stakeholders
- consideration of approaches to capture and promote the international value of the Australian situation to international bodies such as the Wellcome Foundation.

WHERE TO FROM HERE?

Professor David Goldstein *(President, COSA)*

In closing, Professor Goldstein thanked the sponsors, speakers, participants, facilitator and Working Group members for their interest and participation. He outlined the following priorities for action:

- development of a health economic model to support the need for tissue banking
- scoping activities to identify options for tissue banking linked to cancer clinical trials and map existing initiatives
- identification and pursuit of potential funding sources.

Professor Goldstein indicated COSA's commitment to building a business case for tissue banking linked to cancer clinical trials in Australia. COSA will employ a project officer to oversee commissioned projects and ensure that identified goals are achieved. He emphasised the importance of the meeting in setting a solid foundation and direction for future activities to guide a consolidated approach to tissue banking in Australia and encouraged ongoing dialogue and collaboration to facilitate progress in this important area.

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- Professor David Goldstein (Chair)
- Professor Stephen Ackland
- Dr Anna deFazio
- Dr Anne Thompson
- Ms Heather Thorne
- Dr Nik Zeps
- Dr David Roder
- Margaret McJannett
- Kathy Ansell.

COSA would also like to thank the workshop presenters Professor John Simes, Dr Chee Lee, Dr Paul Waring, Dr Paula Marlton, Dr Heather Thorne, Dr Parisa Glass and Dr Nik Zeps.

The workshop report was developed by Dr Alison Evans from Alison Evans Consulting.

REFERENCES AND FURTHER READING

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2. National Health and Medical Research Council and Australian Research Council Australian Vice Chancellor's Committee. National Statement on Ethical Conduct in Human Research. Canberra: Australian Government, 2nd ed, 2007.

3. World Health Organization. Technical Consultation on Clinical Trials Registration Standards. 2005. http://www.who.int/ictrp/news/ictrp_meeting_april2005_conclusions.pdf (accessed October 2008).

4. National Health and Medical Research Council. Harmonisation of Multi-Centre Ethical Review (HoMER) project. http://www.nhmrc.gov.au/health_ethics/homer/index.htm (accessed December 2008)

5. International Society for Biological and Environmental Repositories. 2008 Best Practices for Repositories. Collection, Storage, Retrieval and Distribution of Biological Materials for Research. Cell Preservation Technology 2008;6(1).

USEFUL WEBSITES

Australian Health Ethics Committee

http://www.nhmrc.gov.au/about/committees/ahec/index.htm

Australian Government Health Privacy Principles

http://www.privacy.gov.au/health/index.html

State and Territory Privacy Laws

http://www.privacy.gov.au/privacy_rights/laws/

International Society for Biological and Environmental Repositories

http://www.isber.org/

NHMRC Enabling Grants

http://www.nhmrc.gov.au/grants/types/granttype/enable.htm

APPENDIX I: COOPERATIVE CLINICAL TRIALS GROUPS IN AUSTRALIA

- Australia and New Zealand Melanoma Trials Group (ANZMTG) http://www.anzmtg.org/
- Australian New Zealand Breast Cancer Trials Group (ANZBCTG) http://www.anzbctg.org/
- Australia New Zealand Germ Cell Trials Group (ANZGCTG) http://www.ctc.usyd.edu.au/trials/cancer/germ_cell.htm
- Australia New Zealand Children's Haematology and Oncology Group (ANZCHOG) http://www.cancercouncil.com.au/editorial.asp?pageid=508
- Trans-Tasman Radiation Oncology Group (TROG) http://www.trog.com.au/
- Australasian Lung cancer Trials Group (ALTG) http://www.altg.com.au/pages/home.php
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) http://www.anzgog.org.au/
- Australasian Leukaemia & Lymphoma Group (ALLG) http://www.petermac.org/allg/
- Australasian Gastrointestinal Trials Group (AGITG) http://www.gicancertrials.org.au/
- Australian Prostate and Urogenital Cancer Group (APUG)
- Co-operative Trial Group for Neuro-Oncology (COGNO)
- Psycho-Oncology Cooperative Research Group (PoCoG) http://www.pocog.org.au/
- Australia Sarcoma Study Group (ASSG).

APPENDIX II: ONCOLOGY BIOBANKS

Biobanks supported by NHMRC Enabling Grants

Title of project and granting agencies	Institute and participating sites
National Leukaemia and Lymphoma Tissue Bank (NLLTB) Funding: NHMRC, Pricewaterhouse Cooper Foundation and the Leukaemia Foundation	Princess Alexandra Hospital with member sites: • Royal Melbourne Hospital • Mater Newcastle • Concord Hospital • Geelong Hospital • St Vincent's Sydney • Nepean Hospital • Box Hill Hospital • Westmead Hospital • Mater Brisbane • Adelaide Hospital • Gosford Hospital • Canberra Hospital • Adelaide Hospital
Australian Ovarian Cancer Study: A multidisciplinary ovarian cancer resource for the genomic era Funding: US Department of Defence, NHMRC and state Cancer Councils.	• Peter MacCallum Cancer Centre • QIMR Royal Brisbane Hospital • Westmead Hospital • University of Melbourne • 21 Australian public and private hospital collection sites
kConFab - Kathleen Cuningham Foundation Consortium for Research into Familial Breast Cancer Funding: NHMRC and NBCF	• Peter MacCallum Cancer Centre • QIMR Royal Brisbane Hospital • 32 Australian/NZ public hospitals and research institutions.
The Western Australian DNA Bank ***Not exclusively an oncology bank*** Funding: NHMRC	• University of Western Australia
Australasian Biospecimen Network – Oncology (ABN) Funding: NHMRC, state Cancer Councils/Institutes/Department of Health Services & philanthropic organisations, National Breast Cancer Foundation and local infrastructure funds	Member banks: • Peter MacCallum Cancer Centre Tissue Bank • Gynaecological Oncology Tissue Bank, Westmead Hospital • kConFab, Peter MacCallum Cancer Centre • Australian Mesothelioma Tissue Bank, Perth • Western Australian Research Tissue Network, Perth • The Children's Hospital at Westmead Tumour Bank • QIMR Royal Brisbane Hospital Cell Line Bank

Title of project and granting agencies	Institute and participating sites
Breast Cancer Biospecimen Resource Funding: NHMRC, National Breast Cancer Foundation and Cancer Institute NSW	The University of Sydney/Westmead Hospital with members sites: • Westmead Millennium Institute • Garvan Institute • Kolling Institute • Hunter Medical Research Institute • NSW Breast Cancer Institute • Newcastle Mater Hospital • Prince of Wales Hospital • Royal Prince Alfred • St Vincent's Hospital • Australia New Zealand Breast Cancer Trials Group
Australian Prostate Cancer Collaboration (APCC) BioResource Funding: NHMRC, Commonwealth Bank, Andrology Australia and the Prostate Cancer Foundation of Australia	Queensland Institute of Technology and member sites: • Hanson Institute of Medical Research • Queensland University of Technology • Monash Medical Centre Melbourne • St Vincent's Hospital • Garvan Institute • Prince of Wales Hospital • Royal Prince Alfred Hospital Sydney

Biobanks supported by non-NHMRC Enabling Grants

Title of project and granting agencies	Institute and participating sites
The Australian Melanoma family and population consortia's Funding: NHMRC, Cancer Councils in NSW, Qld and Vic, National Institutes of Health (USA)	• Queensland Institute for Medical Research and Westmead Hospital
The Australian Breast Cancer Family Study (ABCFS) Funding: NHMRC, VicHealth, Cancer Council NSW and the National Institutes of Health (USA)	• The University of Melbourne
Victorian Cancer Biobank (VCB) Funding: Cancer Council Victoria and the Victorian Government	• The Cancer Council of Victoria (lead agency) • The Austin Hospital • The Peter MacCallum Tissue Bank • Melbourne Health Tissue Bank • Southern Health Tissue Bank • Plus 14 hospitals

Title of project and granting agencies	Institute and participating sites
The Wesley Tissue Bank, Brisbane Funding: Queensland Government	• Wesley Hospital, Brisbane
The Royal Prince Alfred Hospital Prince Sydney Funding: In house	• Sydney Breast Cancer Institute • Royal Prince Alfred Hospital, Sydney
The Royal Children's Hospital Paediatric Tumour Bank Brisbane Funding: In house and philanthropic	• The Royal Children's Hospital
Kolling Institute Sydney Tumour Bank Funding: NHMRC, Cure Cancer Australia, Ramaciotti Foundation, Northern Sydney Health, Sydney University	• Kolling Institute Sydney
Prince of Wales Hospital (formerly St Vincent's Hospital Sydney)	• St Vincent's Hospital Sydney

APPENDIX III: WORKSHOP AGENDA

COSA Tissue Banking Forum
Meeting the needs for clinical trials research
Friday 24 October 2008
Stamford Hotel, Sydney airport
Facilitator: Professor Ian Olver, CEO, Cancer Council Australia

Time	Session title	Speaker
08:50	Welcome & Introduction	Professor David Goldstein
09:00	Forum Objectives	Professor Ian Olver
09:10	The statistical considerations	Professor John Simes Dr Chee Lee
09:30	The importance of tissue banking in clinical trials	Professor Paul Waring
09:45	Overview of ALLG clinical trial collection	Dr Paula Marlton
10:00	An update on current tissue banking in Australia.	Ms Heather Thorne
10:15	Review of NSW Tissue Banks.	Dr Parisa Glass
10:20	MORNING TEA	
10:35	Potential models for clinical trials collections	Dr Nik Zeps
10:50	Round table discussions on models for clinical trials collection • minimum data elements • standardised consent/ethics • storage of samples (i.e. where) • distribution of samples (who decides- i.e. governance) sustainability	
12:15	LUNCH	
13:00	Presentation of round table outcome	
13:30	Opportunities for funding and how to go forward	
14:30	BREAK	
14:45	Presentations from round table discussions	
15:30	Review of outcomes and recommendations	Professor Ian Olver
15:45	Where to from here?	Professor David Goldstein
16:00	MEETING CLOSE	

APPENDIX IV: LIST OF ATTENDEES

Name	Discipline
Professor Steve Ackland	Hunter New England Health Area Director of Clinical Cancer Research, NSW
Ms Kathy Ansell	Project Officer, COSA
Clinical Associate Professor Michael Bilous	Institute of Clinical Pathology & Medical Research, University of Sydney, NSW
Associate Professor Fran Boyle	Director, Patricia Ritchie Centre, Mater Hospital, and Associate Professor of Medical Oncology, University of Sydney, NSW; representing ANZBCTG.
Ms Candace Carter	Melanoma Tumour Bank, Sydney University
Dr Daniel Catchpole	Head, Tumour Bank, Oncology Research Unit The Children's Hospital, Westmead Hospital, NSW
Professor Christine Clarke	Department of Medicine, University of Sydney and NHMRC
Professor Judith Clements	Head of Hormone Dependent Cancer Program, Queensland University of Technology
Dr Michelle Cummins	Trial Coordinator, NHMRC Clinical Trials Centre
Professor David Currow	CEO Cancer Australia
Dr Anna deFazio	Senior Clinical Lecturer, Department of Obstetrics and Gynaecology, University of Sydney, and Director, Gynaecological Oncology Research Group, Westmead Institute for Cancer Research, NSW
Ms Lisa Devereux	Research Manager, Research Division Peter MacCallum Cancer Centre, Vic
Professor Peter Downie	Royal Childrens Hospital, Melbourne, Vic; representing ANZCHOG
Dr Alison Evans	Alison Evans Consulting (report writer)
Professor Stephen Fox	Director Anatomical Pathology, Peter MacCallum Cancer Centre, Vic
Dr Parisa Glass	Research & Information Advisor, Cancer Institute NSW
Professor David Goldstein	President COSA; Medical Oncologist, Prince of Wales Hospital, NSW
Professor Nick Hawkins	Pathologist, School of Medical Sciences, University of New South Wales, NSW
Associate Professor Joy Ho	Institute of Haematology, Royal Prince Alfred Hospital, Sydney, NSW; Chair of Laboratory Sciences Committee of ALLG
Associate Professor David Horsfall	National Project Manager, Australian Prostate Cancer BioResource and South Australia Oncology Tissue Bank, SA

Name	Discipline
Ms Amber Johns	Clinical Research Coordinator, Pancreatic Cancer, Garvan Institute, NSW
Dr Chee Lee	Medical Oncologist and Researcher, NHMRC Clinical Trials Centre, NSW
Dr Geoff Lindeman	Molecular Genetics of Cancer Division, Walter & Eliza Hall Institute of Medical Research, Vic
Dr Marian Macnish	Manager, Western Australia DNA Bank, (WAIMR), WA
Dr Paula Marlton	Head of Leukaemia and Lymphoma Services at the Princess Alexandra Hospital, QLD; representing ALLG
Ms Kerrie McDonald	Cerebral Tumour Research Group, Kolling Institute, NSW
Ms Margaret McJannett	Executive Officer, COSA
Ms Wendy-Jane Murray	Tissue Bank Manager, Wesley Research Institute, QLD
Dr Paul Jelfs	Assistant Statistician, Social Analysis and Reporting Branch, Australian Bureau of Statistics, ACT
Associate Professor James Kench	Department of Anatomical Pathology, Royal Prince Alfred Hospital, Sydney, NSW
Professor Soon Lee	Chair of Pathology, University of Western Sydney and Royal Prince Alfred Hospital, NSW
Dr Huw Lewellyn	ACT Pathology; representative of National Cancer Data Strategies, ACT
Professor Ian Olver	CEO, Cancer Council Australia (meeting facilitator)
Professor Lyle Palmer	Director, Centre for Genetic Epidemiology and Biostatistics, University of Western Australia, WA
Dr Nick Pavlakis	Medical Oncologist, Royal North Shore Hospital, NSW; representing ALTG
Ms Rosemary Radovan	Account Manager, NSW Roche, Ventana
Associate Professor Danny Rischin	Medical Oncologist, Peter MacCallum Cancer Centre; representing ANZGOG
Ms Rachel Rowntree	Novartis
Professor Pamela Russell	Director, Oncology Research Centre, Prince of Wales Hospital, NSW
Professor John Simes	Director, NHMRC Clinical Trials Centre, NSW
Professor Bernard Stewart	Department Head, Cancer Control Program, South East Sydney Area Health Service Public Health Unit; outgoing Chair, COSA Research Professionals Group
Mr John Stubbs	Executive Officer, Cancer Voices Australia
Dr Ann Thompson	Executive Officer, Victorian Cancer BioBank, Vic
Ms Heather Thorne	kConFab Manager, Peter MacCallum Cancer Centre, Vic
Mr Dan Thurley	Associate Medical Director, Roche Products Pty Ltd

Name	Discipline
	(Australia)
Ms Nadia Traficante	Project Manager, Australian Ovarian Cancer Study, Peter MacCallum Cancer Centre, Vic
Dr Katrina Vanin	Medical Scientific Liaison-Oncology, Novartis
Ms Alex Walther	Research Support Office , Prince of Wales Hospital, NSW
Professor Paul Waring	Dean, Pathology and Laboratory Medicine, University of Western Australia, WA
Dr Scott Williams	Researcher; representing APUG
Professor John Zalcberg	Director, Division of Haematology and Medical Oncology, Peter MacCallum Cancer Centre, Vic; representing AGITG
Dr Nik Zeps	Research Manager, St John of God Pathology and Radiation Oncology, Sir Charles Gairdner Hospital, WA; incoming Chair, COSA Research Professionals Group