Australian
Prostate Cancer
BioResource

The Australia Prostate Cancer BioResource is an initiative of the Australian Prostate Cancer Collaboration and is supported from 2010-2014 by an Enabling Grant from the NHMRC and an infrastructure grant from the PCFA.

BioResource Tissue Access Policy

Tissue Availability and Tissue Access Policy Statements

Tissue Availability

The aim of the Australian Prostate Cancer BioResource (APCB) is to provide access to quality tissue samples for prostate cancer researchers. Tissue collection for the ABCB began late 2005 at the hospitals affiliated with the 4 collection sites (nodes): Hanson Institute of Medical Research (Adelaide), Queensland University of Technology (Brisbane), Monash Institute of Medical Research (Melbourne), Garvan Institute of Medical Research (Sydney).

Tissue/clinical data collection

Samples of fresh frozen prostate cancer and normal prostate tissue, archival formalin-fixed paraffin-embedded prostate cancer, and blood products are banked at each node. Clinical and pathological data at patient diagnosis, immediately post surgery, and sequential follow up data over a number of years is also collected at each node.

Timing for release of tissues

Fresh Frozen Prostate: Because of the importance to research of clinically annotated tissue samples, a limit was placed on the quantity of fresh frozen prostate to be released to researchers between 2006-2010. A maximum of 50% of any single patient's tissue samples was released prior to 2010. To compensate for this the APCB (via the Project Manager) facilitated collaboration between researchers who needed access to fresh frozen prostate and research institutions which have tissue collections that predated the BioResource. The tissues supplied by both avenues were clinically annotated to the extent that follows up data permits.

Tissue Micro-Arrays: A number of TMA sets are being constructed from paraffin-blocked tissues held in pathology archives. TMAs from these retrospective collections will be progressively released from mid 2006. Currently available are:

- a Gleason array (n= ~150 patients with annotation at clinical diagnosis only),
- human pilot array, for preliminary testing and optimisation of probes, containing cores of non-malignant and malignant tissue from 10 men only with prostate cancer (without clinical annotation)
- transgenic mouse (TRAMP) prostate pilot tissue array, for similar usage to above
- TRAMP prostate tissue array (in progress) from mice bearing either hormone sensitive or resistant tumours.

For further information, or if you have a specific requirement please contact the Project Manager.

Blood Products: Guthrie blots, frozen serum, plasma, and buffy coat cells are available under the same 50% release restrictions to conserve the resource during the clinical follow up period for each patient. Clinical annotation will be provided with supplied materials to the extent that follow up data permits. DNA will be produced from buffy coat cells by the BioResource for distribution to researchers.

Tissue Access Policy

The APCB welcomes requests for prostate cancer tissues from all researchers. Tissues will only be released to researchers who provide ethics approval from the Clinical Investigation /Human Research Ethics Committee of their host institution. This applies to researchers who request even a single sample for testing, in order to safeguard patient rights.

All projects will undergo a peer review for the APCB *Tissue Access Committee* (TAC) in order to determine, the likelihood of successful outcomes and the quantity and types of tissue(s) requested. The TAC will accept copies of the NHMRC and State body reviews. The committee retains the right to prioritise and will not necessarily support all funded or fundable projects to protect the longevity of this limited resource. This ruling applies irrespective of the types or numbers of specimens sought from the BioResource.

Where access has been denied or insufficient tissue numbers provided, researchers can appeal the decision of the TAC via the independent *Tissue Access Appeals Ombudsman*.

Guidelines for Applications for Tissue and Data Access

A *Letter of Intent* (LOI) may be submitted to the project manager trina.yeadon@qut.edu.au and a preliminary review will be performed upon receipt. If the project manager determines that the APCB can fulfil your request, then you will be asked to submit a Full Application. This application must be made within one year of submitting the LOI otherwise a new LOI must be submitted prior to the full application.

Procedure:

1. A *Letter of Intent* (LOI) must first be provided to the Project Manager, containing:

- Your name , Institution, mailing and email addresses, and telephone / fax numbers
- The types of cases required and approximate numbers for each type
- Statistical justification for the number and types of cases required
- A statement of the aims / hypotheses of the proposed research
- A brief description of the technical approach
- Evidence that the proposed measurement technique(s) can be used on the specimens requested, for example does the proposed antibody work for immunohistochemistry in paraffin-embedded specimens
- Clinical and outcome data required
- Funding available to project
- Copy of ethics approval to conduct proposed research

A LOI can be downloaded from the website www.apccbioresource.org.au which can be submitted to trina.yeadon@qut.edu.au or by mail to:

Dr Trina Yeadon
National Project Manager
Australian Prostate Cancer Bio-Resource
C/- Australian Prostate Cancer Research Centre-Queensland
Level 1, Building 1, Princess Alexandra Hospital
199 Ipswich Rd, Woolloongabba, Brisbane, QLD, 4102

Full Applications - Procedure:

I. Before making an application, researchers may wish to confer with the Project Manager to discuss the appropriateness of BioResource specimens for the proposed study.

II. Guidelines and Application Forms can be obtained from the Project Manager via the website. At least 2 weeks before the application is submitted, applicants must send an LOI to the Project Manager. This LOI will be provided to the TAC for comment and in the case that DNA or RNA is to be produced from the requested materials the LOI may be circulated to BioResource members to identify other researchers who would like to use/share the same material, either independently of, or in collaboration with, the applicants. This provision is made to increase the longevity of the resource. For example, where RNA/DNA is extracted from frozen prostate or buffy coat cells by researchers, the amount produced is likely to far exceed the immediate requirements of the project for which tissues were provided. Excess materials must be returned to the APCB by arrangement, on production. When resources permit, the APCB will undertake production of DNA/RNA for release to researchers.

III. Applications must be made on and according to the Application Form, attaching relevant documents. Completed applications may be sent by email, but a **hard copy** containing all documents and bearing the investigators' signatures **must be provided** to the Project Manager according to the above timing schedule.

IV. Full applications that have not had prior peer review will be sent out by the TAC to appropriate referees. If a proposal is currently under peer review by a granting agency, the Project Manager can provide a letter stating that the samples requested are available, subject to approval by the TAC once funding is obtained. The TAC would appreciate receiving any available peer reviews for the project.

V. Applications and referees' reports will be reviewed by the TAC, which will assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the biological material currently available. The applicant may be asked to respond to the reviewers' comments in writing. The TAC may suggest some changes to the proposed application and will try to facilitate communication and collaboration between groups working on similar topics. Any member of the TAC with a conflict of interest will be excluded from this review. Reasons will be given for refusal of all or part of the proposed use of material, and this may occur even if the overall grant proposal has approved funding. Conditions on, or restrictions of, use may be made. In the event of an unpopular decision, the researcher can approach the Appeals Ombudsman for an independent review of the assessment and decision.

VI. Simultaneously, the application will be reviewed by the Project Manager so that a mechanism and timescale for the delivery of the requested specimens and data can be determined.

VII. An acceptance letter will be provided to approved applicants, outlining the conditions on tissue provision as per this policy document. On receipt of a *Material Transfer Agreement* signed by the applicant(s), and evidence of ethical approval, the project can proceed according to the agreed protocol.

VIII. Any significant deviations from the agreed protocol must be sent by the applicant(s) in writing for approval before proceeding.

IX. Data and biological material will be supplied as soon as possible after a request is approved. The onus is on the investigator to re-submit the application at a later date as the BioResource collection grows, if additional material is required for the same project.

X. The APCB will levy a fee to the applicants for the preparation and shipping of biological materials.

XI. The APCB reserves the right to withhold the supply of further material if the rate of progress is unacceptable.

XII. Annual progress reports must be sent to the Project Manager for presentation at the TAC meeting that occurs in July each year. The Project Manager will notify all investigators in May that progress reports are due by June 30th.

XIII. At the conclusion of the project, residual materials must be returned or destroyed by agreement of the BioResource, all requested research data will be transferred to the BioResource database, and a final report prepared by the applicants.

Responsibilities of Investigators who use BioResource material

The Chief Investigator(s) of the project must agree:

- *To sign the APCB Material Transfer Agreement* and not to distribute the material or data to investigators or institutions who are not named in the approved application.
- *To list The Australian Prostate Cancer BioResource as an author* on any resulting publications, in addition to any APCB members who fulfill authorship criteria for the study as it progresses. This is required as an outcome measure of APCB productivity.
- *To lodge copies of relevant manuscripts* utilising the prostate cancer collection with the Project Manager of the APCB, for examination, prior to journal review.
- *To acknowledge the agencies that support the core activity of the BioResource* in any resulting publications.
- *To submit an annual report* on the project by June 30th for presentation to the TAC meeting that occurs in July each year.
- *To propose a timeline* for monitoring the project.
- *To meet the costs involved* in preparing and shipping biological specimens and in extracting data from the central database.
- *To notify the APCB of study completion.* All studies will be deemed complete after three years unless re-application is lodged.
- *To submit all requested research data* back to the Project Manager for inclusion in the APCB database, within 12 months following completion of the project. The research data requested will be decided between the TAC and the researcher. This will facilitate powerful collaborative meta-analyses by the APCB. It will benefit the researcher providing the data, the APCB, and Australian prostate cancer research.
- *To return unused materials* to maintain the longevity of the resource, *or destroy the material* by agreement of the APCB.
- *To obtain a signed MTA from any collaborator to whom they wish to pass on material for use in the approved project.* This should be forwarded to the Project Manager with a request that the TAC consider the addition of the collaborator to the project.

Appeals Mechanism

In the event that an applicant(s) wishes to dispute the decision of the TAC, the following mechanism will apply:

- Within 30 days of receiving notice from the TAC why access will be denied either totally, or for certain aspects of the project, or where the TAC proposes changes to the use of the materials which are deemed not acceptable, written objection from the Investigator(s) must be lodged with the Project Manager
- The grounds of the objection must be quite clear, and all evidence supporting the appellant's case must be made available to the Project Manager
- The Project Manager will forward this documentation along with the complete application for tissue access, including peer reviews, the applicant's track record, the transcript of the TAC deliberations, the reasons for denial of access, and all pertaining correspondence, to the Ombudsman
- The Ombudsman will then review the documentation and within 60 days make a ruling in favour of one party or the other
- The Ombudsman is permitted to refer to other qualified persons to assist in the making of a ruling, provided no conflict of interest is involved
- Where the Ombudsman has a conflict of interest, a Reserve Ombudsman will review the documentation and make a ruling under the above guidelines
- The Ombudsman's decision will be final.

Contact Information and Officers of the BioResource

First Point of Contact for the Australian Prostate Cancer BioResource:

Dr Trina Yeadon
National Project Manager
Australian Prostate Cancer Bio-Resource
C/- Australian Prostate Cancer Research Centre-Queensland
Level 1, Building 1, Princess Alexandra Hospital
199 Ipswich Rd, Woolloongabba, Brisbane, QLD, 4102
Phone: 0427-579-824, Fax 07-3176-7440, email: trina.yeadon@qut.edu.au

Executive Chairman, BioResource Management Committee:

Professor Judith Clements, NHMRC Principal Research Fellow, Program Leader QUT Cancer Research Program and Scientific Director, Australian Prostate Cancer Research Centre-Queensland, Executive Chairman of the APCB

Executive Members, BioResource Management Committee:

Professor Gail Risbridger, Centre for Urological Research, Monash Institute of Medical Research, Monash Medical Centre, Clayton, Victoria

Professor Robert Sutherland, Cancer Research Program, Garvan Institute of Medical Research, Darlinghurst, Sydney, New South Wales

Professor Wayne Tilley, Dame Roma Mitchell Cancer Research Laboratories, Hanson Institute, University of Adelaide, Adelaide, South Australia

Members of the BioResource Management Committee:

A/Prof Lisa Butler, Adelaide
Dr Kris Rasiah, Sydney
Mr John Stead, Brisbane
A/Prof Frank Gardiner, Brisbane
Dr Renea Taylor, Melbourne
Dr Jyotsna Batra, Brisbane

Members of Australian Prostate Cancer BioResource Tissue Access Committee:

Dr Trina Yeadon, Project Manager and Chair
Dr James Kench, pathology representative
Dr Grant Buchanan, molecular biology representative
Dr Gianluca Severi, biostatistics representative
Dr Elizabeth Williams, scientist representative
Dr Kate Mahon, medical Oncology Representative
Dr Niall Corcoran, Urology Representative

Australian Prostate Cancer BioResource Appeals Ombudsman:

Professor Jock Findlay, Prince Henry's Institute of Medical Research, Melbourne
Reserve Ombudsman (for conflict of interest situations), vacant

Principal Investigators of the NHMRC Enabling Grant Underpinning the BioResource Prospective Tissue Procurement Program

Professor Judith Clements, NHMRC Principal Research Fellow, Program Leader QUT Cancer Research Program and Scientific Director, Australian Prostate Cancer Research Centre-Queensland, Executive Chairman of the APCB

Professor Wayne Tilley, Dame Roma Mitchell Cancer Research Laboratories, Hanson Institute, University of Adelaide, Adelaide, South Australia

Professor Gail Risbridger, Centre for Urological Research, Monash Institute of Medical Research, Monash Medical Centre, Clayton, Victoria

A/Prof Lisa Horvath, Garvan Institute of Medical Research, Sydney, New South Wales

Professor Villis Marshall, University of Adelaide and Royal Adelaide Hospital, Surgical Specialties Services, Adelaide, South Australia

Professor David Roder, Adelaide University, Royal Adelaide Hospital, Adelaide, South Australia

A/ Prof Frank Gardiner, University of Queensland, Dept of Surgery Royal Brisbane Hospital and Queensland Institute for Medical Research, Brisbane, Queensland

A/ Prof David Nicol, Royal Marsden Hospital, London, England

Associate Prof Mark Frydenberg, Monash Medical Centre and Cabrini Hospital, Malvern Victoria

Dr John Pedersen, Anatomical Pathology, Alfred Hospital, Melbourne, Victoria

Dr Phillip Stricker, Dept of Urology, St Vincent's Hospital, Sydney, New South Wales