# The Australian Pancreatic Cancer Genome Initiative (APGI)

## BioSpecimen & Data Access Policy

Version 5.0

**Scope:**

This policy covers all requests for access to BioSpecimens and clinical data managed by the APGI, regardless of who makes the requests.

**THIS POLICY IS EFFECTIVE FROM 02 SEPTEMBER 2011 AND WILL BE APPLIED TO ALL CURRENT AND FUTURE APPLICATIONS.**

*This policy will be updated as required and the latest versions of relevant documents will be available on www.pancreaticcancer.net.au. It is the responsibility of researchers to be aware of and adhere to any changes.*

## 1. Overview

The Australian Pancreatic Cancer Genome Initiative (APGI) was established in 2009 and funded by The Cancer Council NSW and the National Health and Medical Research Council (NHMRC). It brings together experts in pancreatic cancer from research and clinical specialties across Australia. The APGI aims to comprehensively analyse the genomes, epigenomes and transcriptomes of 500 pancreatic tumours to identify novel genes in the development of pancreatic cancer, as part of the International Cancer Genome Consortium (ICGC, www.icgc.org). This information will be related to clinico-pathologic features with a view to characterising potential therapeutic targets. The APGI commits to improving the management of pancreatic cancer patients by facilitating communication between clinicians, researchers, patients and their families. A key APGI priority is to continue to build capacity in translational research by acquiring biological material and clinico-pathological data for all types of pancreatic disease, which will provide an unparalleled base for ongoing studies.

As of 2010 the APGI incorporates the NSW Pancreatic Cancer Network (2006-2010). This was a STREP funded initiative to form a network of specialists in NSW, to build capacity in translational pancreatic cancer research by the formation of large cohorts of well-annotated archival material representing the spectrum of pancreatic cancer. This was a landmark study and underpinned Australia's successful bid for the ICGC. Given the cessation of the funding period and overlap of activities, the continued management of the tissue resource and remaining operational duties were brought under the management of the APGI. This ensures the fundamental work of the NSWPCN can continue to be recognised and built upon as part of the APGI.

As of 2016, the APGI BioResource continues to be managed and refined with the support of a three-year Avner Pancreatic Cancer Foundation Accelerator Grant. This funding ensures that the accrued biospecimens and clinico-pathological data retain their value and remain available for high quality pancreatic cancer research projects around the globe.

This policy also incorporates the Australian Familial Pancreatic Cancer Cohort (AFPaCC, 2011-2014, (http://www.pancreaticcancer.net.au/research-familial/), The IMPaCT Clinical Trial (2013-2015, http://www.pancreaticcancer.net.au/research-impact-trial/) and all other studies conducted under the auspices of APGI that collect and manage BioSpecimens.

This policy provides governance oversight for all studies conducted under the APGI.

## 2. Governance Structure

The Principal investigator of the APGI is Anthony Gill, who in consultation with the leadership team, is responsible for overall strategy, direction and output for the APGI. Their primary roles is to direct and develop APGI research and strategy, and are responsible for reporting back to the primary funding bodies regarding progress.

Given the expansive and global nature of the APGI, a Leadership Team has been appointed

to direct and develop. The Leadership and Executive Team also assists in development and management of overall strategy, but is primarily responsible for operation of the APGI and the approval of access to material and data held by the APGI.

All requests to access Biospecimens and Data are reviewed and approved by the APGI Leadership Team.

## 3. Accessing the APGI BioSpecimen and Data Resource

### i. Who Can Apply, and What is Available to apply for?

- Researchers world-wide, with appropriate research questions and resources can apply for access to APGI BioSpecimens and data. The APGI is committed to respecting the privacy and intentions of research participants with regard to how data pertaining to their individual information is used, therefore access is intended only for scientific investigators pursuing research questions that are consistent with the informed consent agreements provided by research participants. Furthermore, investigators provided access will be expected to utilise appropriate data security measures.

- The consent of APGI participants is strictly limited to cancer research, and we are unable to support projects outside this area in our current capacity.

- Access to archival material, TMAs, clinical data sets, cell lines (generated from patient derived xenografts) and blood products are currently open to all researchers in line with the above. Please refer to our BioSpecimen Availability Summary for more information

- As of September 2015, The APGI has a cost recovery schedule implemented. The details are provided on our website: APGI BioResource Cost Recovery. All applicants should be familiar with the schedule and consult APGI staff prior to application if any issues are envisaged.

- Please note that the APGI uploads genomic (somatic) data (including gene expression, methylation and copy number) regularly to the ICGC Data Portal. This data is publicly available via the above link. Probe level gene expression data, raw genotype calls, genome sequence files and germline data are Controlled Access Data sets and approval must be granted by the ICGC Data Access Compliance Office. Please note the ICGC has its own application and approval process independent of the APGI. The ICGC also has a Publication Policy, which applicants must be aware of and adhere to upon application.

- If involvement of the APGI is required of that beyond basic access to samples or data (such as pathology review, data analysis etc), authorship must be discussed as part of the application with the individuals most involved.

- We strive to provide quick turn around times for applications- and applicants will be notified if delays are expected. Providing all paperwork is in order, generally most applications are approved within 2 weeks.

- Applications requesting patient-derived cell lines (PDCL's), with no accompanying clinical or genomic data, may have the review and approval process expedited. Full review of the APGI application may not be necessary, and a standard MTA will be initiated and managed by the Cancer Therapeutics group within the APGI.

- Applications for material that have been peer reviewed by major scientific bodies (NHMRC, NIH, CINSW etc) will be subject to nominal review in a scientific aspect.

- First priority will be given to peer reviewed, funded, research projects. Second priority will be given to developmental projects and new researchers developing projects in academic centres.

- Industry are welcome and encouraged to apply for access to material and data. Please consult the APGI Cost Recovery Guidelines for specific information.

## ii. Pilot Studies

- Definition of a pilot study is limited to proof of principle experiments requiring small numbers of specimens which may lead to a subsequent larger scale project.

- Projects meeting these criteria are able to apply for limited material as follows:
    - Tissue sections: 1-6 cases, 1-4 sections per case
    - TMA sections: 1-6 sections from an already constructed test array or training set cohorts. The ICGC Cohort is NOT available to be accessed for pilot studies.
    - Blood or DNA/ samples: 1-6 cases
    - Bulk fresh tissue is not normally made available to pilot projects.

## iii. How to Apply

The APGI serves to provide timely, equitable, and appropriate access to BioSpecimens and data without undue administrative burden. In return for this service applicants must demonstrate scientific merit, proven experience with the proposed method, Human Research Ethics clearance and when appropriate institutional research qualifications. General information about accessing our resource can be found at: APGI BioResource Sample Access.

1. As mentioned above, there are limitations on the uses of some of the APGI materials. By way of example:
    a. Some materials were not collected for broad research use, or have restrictions arising from the ethical conditions under which they were approved for collection.
    b. Samples collected and managed as part of core ICGC studies (i.e Tissue Microarrays, DNA analytes etc), must be applied for by a principal or primary

investigator (PI), not a student or research assistant. By way of definition the PI serves as the authorised individual from the institution and has responsibility for the project and for fulfilling all obligations entered into through the MTA. These conditions are in place to secure the durability of the resource, due to its importance, value and scarcity.

c. In addition to the above, samples collected under ICGC auspices are not available for purely discovery, initiation or hypothesis generating studies. They are only to be used under strict criteria, at the Leadership Team's discretion; as validation material, or when verified or published data exists.

Considering this, you are strongly recommended to contact the APGI Project Manager on research@pancreaticcancer.net.au to discuss your application and it's BioSpecimen and/or data requirements from the outset.

2. Obtain relevant HREC approval at your local institution or hospital site, or waiver of approval (if appropriate). Please note that the ***Ethics section of the APGI BioResource Request Form cannot be left blank***. If the section is not completed applications will not be considered.
    a. Studies involving no more than low risk (as defined by the National Statement on Ethical Conduct in Human Research 2007, Section 2.1) or where research is thought to be exempt from ethical review, processes can be enacted as per the National Statement section 5.1.18-5.1.23 as an alternative to HREC review, in consultation with all required parties. HREC's can issue a waiver of approval for such research, which meets appropriate conditions. This will depend on the stipulations of your institution or local HREC, and the APGI can provide advice on this process and offer a letter of support accompany your application. Please email us at if you require assistance with this or any supporting documentation.
    b. The APGI has ethical approval to collect, curate and utilise biospecimens for its internal defined studies, we do not have ethical approval to cover additional hypothesis or studies that other investigators wish to pursue using APGI resources. Given this, each ***investigator and application MUST seek their own ethical approval*** where indicated for the conduction of individual projects and provide evidence of this as supporting documentation.

3. Complete the APGI BioResource Request Form. Please note this is the only application source that is accepted.

4. Read the Guidelines surrounding the APGI Cost Recovery Schedule on our website. A quote will be prepared and sent to investigators detailing the costs associated with the application.

5. It is the responsibility of the applicant to organise and fund the cost of transporting BioSpecimens and data transfer (where necessary).

6. All personnel who will be accessing, utilising or are involved in any data analysis (either directly or not) need to be identified on the application form.

7. All forms are submitted electronically. Appropriate supporting documentation must also be attached i.e. Human Research Ethics Committee (HREC) Approval letter for your proposed research.

8. The APGI Project Manager will review applications initially for availability of samples and feasibility of study. Studies will be reviewed on a first come, first served basis. Additional information may be required from the applicant. Requests for PDCL's without clinical data may be approved at this stage.

9. The APGI Leadership Team will review the application from here. The team will assess whether the application proposes a scientifically justifiable, feasible and high priority use of the material and or data currently available. The applicant may be asked to respond to the committee's comments in writing.

10. If there are issues raised or concerns unable to be resolved within the Leadership Team, or the project is requesting on-going access to samples or high quantities of sample, the application may be referred to The APGI Clinical & Scientific Support Team for further review. Applicants will be notified of this.

11. A common problem may be requests for large amounts of material or for material that is in very limited supply. The APGI will have to balance such requests against competing demands and availability of samples.

12. On approval of the study, a material transfer agreement (MTA) will be raised where applicable from the Garvan Institute and sent to the applicant for signing prior to material being sent. This is raised electronically through Garvan's MTA Management system and outlines further conditions on use of material, independent of APGI requirements. An MTA is always required for external collaborators.

13. A Purchase Order will be requested from the investigators institution and is required prior to final approval of projects and any distribution of material or data.

14. An invoice will then be raised and sent to the applicant or delegate containing the PO number for payment within 30 days.

## 4. Conditions of Use for BioSpecimen and Data Resources

1. The applicant/investigator agrees that the material provided will be used only for the purposes specified in the application.

2. Investigators and researchers will be expected to utilise appropriate data security measures. Standard data security measures are outlined in the APGI Application for Access to Clinical Data and BioResource Request Form. The APGI reserves the right to request the investigators institutions data security policies at any time for review of adherence.

3. The recipient agrees that it shall not sell any portion of the tissues or products. The recipient also agrees that they shall not transfer tissue (or any portion thereof) supplied by the APGI to third parties.

4. The APGI biological materials and data are provided in a coded manner, i.e. without revealing the donors name or date of birth. This code will be re-identifiable ONLY by select APGI staff directly involved in data management. No attempts are to be made by the project investigators to identify the donors. If additional information is required it is to be requested through the APGI project manager.

5. All care is taken to select tumour tissue, however the APGI will not accept responsibility for the inadvertent provision of incorrect tissue. The APGI collects and manages its material to the highest international quality standards, and conducts reviews on tissue samples at regular intervals.

6. All projects must be undertaken under the guidelines of the National Statement on Ethical Conduct in Human Research, if conducted in Australia.

7. Although the APGI avoids collecting BioSpecimens from patients with highly infectious agents, all BioSpecimens should be handled as if potentially infectious. The APGI takes no responsibility for injury or illness that may occur to staff handling the BioSpecimens.

8. Amendments to existing projects are welcomed, provided they are within reasonable context of an existing approved project. Examples of common amendments include requesting additional BioSpecimens for larger powered studies, or additional cohorts for further validation. Additional hypothesis or major deviations from the approved application will require a new application. To seek an amendment, a letter should be written from the original applicant (or PI- whoever is nominated on the original application), outlining the goals of the amended project and where the work will be carried out. Additional investigators details must also be listed. If the amendment requires new BioSpecimens or data, details must be outlined in this letter as to the type, numbers, justification etc. This letter must be signed and authorised by the PI (who is the authorised individual from the institution).

9. Approved users agree to a synopsis of the study (not including any analyses) being placed on the APGI website for the public to view.

10. We request that the APGI be acknowledged in publications arising from the use of BioSpecimens and/or data. This acknowledgment must appear in the Methods or Acknowledgements section as a minimum. Recommended wording is as follows: *‘ Biospecimens and/or clinical data were provided by the Australian Pancreatic Cancer Genome Initiative (APGI, www.pancreaticcancer.net.au’) which is supported by an Avner Pancreatic Cancer Foundation Grant, www.avnersfoundation.org.au.*

## 5. Data Sharing Guidelines and Statement

As part of our commitment to improving outcomes for patients with Pancreatic Cancer we are committed to making data available to the entire research community in a rapid and responsible way. We are dedicated to maximizing the potential of research through effective and responsible data sharing, and it is the policy of the APGI that members are encouraged to work towards ensuring that data sets can be shared to greatest extent possible while recognizing differing legal and ethical requirements. As a global network the APGI will have access to new technologies and expert communities to assist its work, as well as through which it can disseminate its gained knowledge. As research groups and program types will span different jurisdictions with differing regulatory and institutional requirements, there will be limitations in how and with whom some data can be shared. We follow the belief that members should be encouraged to share as widely as is possible and will work with groups to maximize data sharing to greatest extent possible within accepted legal and ethical boundaries.