AUSTRALIAN GENOMICS AND CLINICAL OUTCOMES OF GLIOMA

DATA ACCESS POLICY

Version 1.2

(25/06/2010)

What is Australian Genomics and Clinical Outcomes of Glioma?

Australian Genomics and Clinical Outcomes of Glioma (AGOG) is a national population-based database and linked biospecimen research resource with specific focus on clinical care patterns, functional genomics and the genetic epidemiology of glioma.

The AGOG resource was established in 2008 to provide the infrastructure, consumables and personnel assistance for up to date clinical and epidemiological data collection, biospecimen processing and curation of human glioma samples in Australia.

AGOG aims to recruit all adult (males and females aged 18 years and over) incident cases of glioma in Australia.

What does AGOG do?

Consenting participants are asked to complete a questionnaire, provide a blood sample, provide a tumour tissue sample where appropriate, and allow access to their medical records. A key aim of the AGOG resource is to develop and optimise Data collection and facilitate Data sharing across involved sites. Involved sites are defined by those sites that have site specific approval from their respective human research ethics committees. The AGOG resource will establish a common storage and management system for data as a pre-requisite for making them more widely available as a collaborative national resource.

How is AGOG funded?

Funded by a Strategic Research Partnership Grant from the Cancer Council NSW, AGOG is based within the University of Western Australia. Collaborating partners include the Cancer Council NSW; the Centre for Genetic Epidemiology and Biostatistics at the University of Western Australia; the Kolling Institute of Medical Research at the University of Sydney; the Centre for Minimally Invasive Surgery; the Lowy Cancer Research Centre at the University of New South Wales and involved sites across Australia. The study is supported by the Western Australian DNA Bank; the Western Australian Genetic Epidemiology Resource; the Australasian Brain Tumour Bank; and the Cure For Life Foundation Neuro-oncology Laboratory.

Definitions

For the purposes of this Policy:

1. "*Committee"* refers to the AGOG Executive Management Committee, comprising appointed Chair; Chief Investigators of the Cancer Council NSW STREP Grant SRP-08; The Cancer Council NSW CEO (or representative); and the consumer representative.
2. "*Resource"* refers to the facility involved in the collection of information from participants in AGOG, infrastructure required and the information collected.
3. "*Data"* refers to all information (in anonymised form) available for access by approved Investigators, relating to individual participants' health, lifestyle and environment, biological samples and data derived from sample analysis.
4. "*Investigators"* refers to the user, or group of users, of the Data requested.
5. "*Policy"* refers to this Data Access Policy.

Scope of this Policy

The scope of this Policy covers all requests for access to Data in the AGOG Resource, regardless of who makes the request.

THIS POLICY IS EFFECTIVE FROM 25TH JUNE 2010 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 the AGOG website (www.agog.org.au). It is the responsibility of researchers and analysts to be aware of and adhere to any changes.

TABLE OF CONTENTS

1. Principles of Access

1.1 General

The AGOG Executive Management Committee is responsible for administering this Access Policy. The Committee will encourage and provide access to the AGOG Resource and the results that flow from it as widely and openly as possible in order to optimise its use and value for research, and for public benefit. All Data obtained from AGOG is not to be used directly for clinical decisions or treatment of individual patients, nor to identify individual service providers. Access by commercial entities or international researchers is at the discretion of the AGOG Committee.

Patients and their family members may request their specific genetic results, and these will only be provided with the appropriate interpretation and guidance.

All applications are processed by the Chair of the AGOG Executive Management Committee and reported to the AGOG Executive Management Committee at completion. In general, access will be granted if:

1. serious scientific research is proposed that is consistent with the overall program of research activities;
2. the research proposed does not conflict with work in progress;
3. the interests and personal privacy of survey subjects are protected and appropriate Institutional Human Research Ethics Committee (HREC) approval has been given for the proposed research;
4. resources are available to pay the AGOG Executive Management Committee and associated service providers for the data and materials and for the work to be done in making the data and biological materials available, and also for the further work proposed by the Investigator;
5. the responsible Investigators have undertaken in writing to abide by their stated conditions, as per the Undertakings by Responsible Investigators form; and
6. the investigators can demonstrate that they have the facilities, personnel and experience to complete the research within the agreed timeframe in the research proposal.

Collaborative applications are strongly encouraged and will be favoured by the AGOG Executive Management Committee.

Applications to access these collections must abide by the processes and principles outlined in this Policy. With this access come responsibilities which must be taken seriously. Permission for access may be withdrawn if information was provided to the Committee that a researcher has breached any of the processes and principles outlined in this Policy.

Under the *Federal Privacy Act 1988* (Cth), it is illegal for the Committee or Board to release any medical research information to third parties such as police, employers, lawyers or insurers except in very limited circumstances. More specifically, the participant must consent to have their information released, the release would have to be required or authorised by law (e.g. by a court order), or release would have to be necessary to prevent or lessen a serious or imminent threat to someone's life, health or safety. The Committee is likely to take necessary action to resist access for police or forensic use, in order to defend participants' trust and public confidence in AGOG. This may include representation in all court applications for such access.

1.2 Approvals

Researchers are required to obtain additional approval from:

- An appropriate Human Research Ethics Committee (HREC)

The Chief Investigator nominated in the Access Application will ensure that all committees (HREC and AGOG Committee) are notified of any change in the personnel, protocol or physical location of the research extract or any derivatives. Written approval from the relevant committee(s) is required before any of these changes are acted upon.

The Chief Investigator must also ensure that all research and IT staff with access to the Data are made aware of their responsibilities and have signed the WAGER Covenant of Confidentiality, and immediately notify the Committee of any change in the list of researchers working with the Data.

2. Access to Data and Participants

Data available to Investigators includes:

1. Questionnaire data or clinical data on participants.
2. Biological samples (blood sera; blood plasma; blood DNA; blood RNA; frozen tumour; DNA extracted from tumour and RNA extracted from tumour) of participants.
3. Serial imaging from the AGOG Imaging sub study.
4. Data derived from biological sample analyses.

Access to protected material will only be permitted by application. The process for application to use the Data for research will be fair, standardised and transparent. Access to Data will only be permitted for research use that is consistent with the Principles of the AGOG, has been ethically and scientifically approved by appropriate bodies and the consent of participants. Applications that meet these criteria will be encouraged.

Where the scope of proposals is beyond the expertise available in the Committee, the relevant expertise will be co-opted to the Committee.

The Committee will not offer access to Data or any particular part of it to any single user or group of users on an exclusive basis, though access to finite Data will be regulated as necessary.

De-identification of Data

As the steward of the AGOG Resource, the Committee will act as custodians of all Data collected from AGOG, and will hold all participant identifying information. This will not be available to Investigators unless additional consent is specifically obtained to do so. The Committee will use such identifying information only to keep in contact with participants, enable follow up and manage and audit the Resource. All information identifying participants will be removed before Data are released to Researchers. Privacy protection methods will be applied to Data before release and additional safeguards will be in place (e.g. signing of deeds of confidentiality) to further reduce the risk of identification of participants from released datasets.

2.1 Prioritisation of access

Prioritisation of requests for access to samples or to approach participants to seek their consent to participate in further research will be determined according to criteria for prioritisation to be set by the Committee.

2.2 Access to samples for analysis

When an application is approved, the Committee, or more likely, a laboratory contracted by it, will undertake the analysis.

The results of the analysis will be released to the user concerned on the terms of the Access Agreement. The Committee will permit the researcher who requested the analysis up to **one year** of exclusive use from the date of release of the Data set or the relevant part of it, though shorter periods may be applied if six months is deemed unnecessary. Longer periods may be permitted on request, but such requests must be made at the point of application so that they can be considered appropriately.

The Committee will retain copies of the results of sample analyses for general use after the exclusivity period ends.

2.3 Physical release of samples

The Committee will only physically release samples to researchers where a case can be made to significantly justify such a request. Where the analysis involves a test that is proprietary to the user concerned, arrangements will be put in place to maintain confidentiality or otherwise protect the IP involved. A Sample Analysis Fee will be payable, as described Section 3.2.

If samples are approved for release to a Researcher for analysis, a Materials Transfer Agreement will govern the release. This will require that the samples are used for the agreed purposes only in accordance with the consent of participants. In addition, it will require that analyses are completed and the results returned to the Committee within specified time limits. It will include standard limitations of liability to the Researcher, and also an undertaking not to attempt to identify participants and a requirement to return surplus material within the time limit specified, or otherwise appropriately destroyed.

2.4 Access to participants

Where participants need to be re-contacted, the Committee will make all initial contact. This may be for reasons including to collect new information or samples, to seek additional consent to proposed new uses that do not fall within the existing consent or to ask participants whether they would be willing for Researchers to contact them to discuss possible involvement in other studies.

The Committee may charge Researchers an Administration Fee for seeking additional consent from participants. The Committee's decision on whether re-contact is appropriate in a given case may involve approval from relevant ethics committees. The level of contact with participants will be monitored to ensure that patients are not overburdened.

The Committee also requires details of how subjects were selected from the main AGOG cohort for the particular study. If AGOG staff did the original subject selection, the information will be on our records. However, in cases where the entire sample as selected by the AGOG staff could not be used, there should be an indication of how the cases that were used were chosen (e.g. all those with sufficient serum remaining; all those aged 40+ when blood was collected).

3. Terms of Access

3.1 Access Agreement

Every Researcher accessing Data will be required to enter into an Access Agreement. This will specify the Researcher and the specific purpose for which use of the Data are to be used. It will include standard terms as to the ownership, exploitation and dissemination of results, including return of Data to AGOG.

This Agreement will specify the fee payable for access to Data and include requirements that the Researcher conforms with the consent of participants and this Policy. It will also prevent the Researcher using any future patents based on the Data to restrict research use of such material by AGOG or its users.

The Access Agreement will also specify that the project must be completed within an agreed time frame. An application must be made to the Chair of the Committee with at least 30 days notice for any extension to the timeframe.

The Researcher must agree not to attempt to make an unauthorised merger with any other data set, including Data files provided for separately approved projects. The Researcher must also agree not to use the Data files for any purpose other than to achieve the research objectives specified in the approved project.

3.2 Fees

An access fee, payable to the Committee, is based on partial-cost recovery for the programming and other costs associated with the planning, extraction and provision of the Data. The Committee will determine the standard fee structure, which will be set at a level that will not discourage use. This fee may be negotiated, depending upon the type and amount of Data required, the association of the Investigators with the AGOG program of activities, the intended use of the Data, and whether the principal Investigator is a postgraduate research student.

There may be three forms of fees:

1. **Data access fee** – for access to Data
2. **Administration/Service fee** – for any services provided by AGOG Committee, such as data preparation
3. **Sample Analysis fee** – for analyses of samples.

The fee structure is yet to be determined by the Committee, and will be appended to this Policy when developed.

Neurosurgeons who bank their patients' tumour tissue with AGOG will <u>not</u> be charged to access those samples.

3.3 Security Measures

Researchers who are granted access to Data must ensure the following security measures are met:

- The media (e.g. USB, CD or DVD) containing the Data extracts must be kept in a locked filing cabinet located in a secure approved workspace.
- Any confidential electronic health data must be encrypted and kept separately from any service or clinical data
- Decrypted copies of Data extracts must be kept in password protected files, on secure servers located within a physically secure approved workspace.

- Decrypted copies of Data extracts must not be taken from or accessed from outside the approved workspace.
- Decrypted copies of Data extracts should never be attached to, or included in, an email.
- All Data must be stored under secure conditions such that none other than researchers identified in the Access Application can gain access to the data.
- While in transit, all Data extracts must be encrypted
- At the completion of a project, all Data must be returned to the Committee or destroyed.

3.4 Reach through Royalties

The Committee may claim a share of any royalties generated from the results of research conducted using the Data (reach through royalties).

Where there are collaborations between the Committee and Researchers, or where the Committee provides additional input over and above the standard collection or curation of Data, it may negotiate arrangements to recognise this. Such arrangements will take into account the contributions of the parties involved (e.g. input of intellectual or financial nature).

Any royalty income will be used by AGOG to further its purpose for public benefit subject to the reach through royalties requirements of the Cancer Council NSW.

4. Dissemination of Research Results

4.1 Details of current research

The Committee may publish the title, summary and a scientific abstract of each research project for which access to the Data has been granted. This may be done shortly after such access is granted, prior to the identification and/or publication of any results. Modifications may be permitted to scientific abstracts prior to publication to preserve future patent rights, or to protect commercially sensitive information.

Researchers will forward any copies of annual progress reports of research prepared for institutional ethics/research committees to the Committee.

4.2 General dissemination of results

Researchers will disseminate results of their research as widely and openly as possible. They will be encouraged to discuss their research with other research groups and the public. Researchers will undertake to notify the Committee when publishing their results.

It is mandatory that investigators acknowledge the Resource in any published work that results from accessing the AGOG Data, in addition to listing the AGOG Network as an author on any resulting publications.

4.3 Return of results to AGOG

Researchers will be required to provide the Committee with a copy of all results of their research based on the Data – including negative findings and supporting data, for incorporation into the Resource.

Details of specific techniques used must be outlined for any Researchers who have been granted access to samples. This is to allow the comprehension of research results by other Researchers.

Researchers will also be required to copy the Data, including biospecimens or data derived from biospecimens (including genetic data), and associated documentation to the Committee on terms that permit them to be used for research by users of the AGOG Resource without charge (other than those fees defined in section 3.2).

When data is given to the Committee to be added to the database it should be accompanied by sufficient documentation to enable other researchers to interpret it. The minimum documentation required is:

- a definition of what each measurement is *(e.g. serum creatinine, serum total cholesterol)*,
- coding used, if applicable *(e.g. 11=normal, 12=heterozygous, 22=homozygous, blank=not measured)*,
- units used if applicable *(e.g. mmol/l)*,
- date of measurement (minimum of month and year is required if full date is not available),
- contact details of a person who can answer queries about the data.

For laboratory measurements, information about the assay method used would be considered very useful.

Researchers will be required to send Data to the Resource within six months of deriving results suitable for publication or patenting. A delay in the release of results may be permitted, upon formal application to the Committee.

Researchers must make available all resulting manuscripts or reports based on the analysis of any Data to the Committee and allow for the opportunity to comment within 30 working days.

They must also inform the Committee of ALL presentations, publications and reports of results of analysis. Researchers must supply the Committee with two reprints of all publications that result from the study.

5. Breaches of Conditions

Researchers must immediately notify the Committee of any breach of the above conditions, whether it was intentional or unintentional, and regardless of who committed the breach.

It should be noted that the AGOG Committee or HREC representatives may conduct random audits to ensure all the conditions of this policy are met.

5.1 Sanctions for Breaches of Conditions

Consideration will be given for each actual or possible breach of conditions according to the facts of the case. The action(s) taken in response may include any, or any combination, of the following:

1. No action (e.g. because the conclusion is that no breach took place).
2. A request for rectification of the circumstances causing the breach.
3. Counselling in the form of a warning.
4. A sanction, which may include:
    - revision of the project approval so as to require stricter conditions;
    - cancellation of the project approval (with the requirement that all data files are returned or destroyed immediately);
    - barring the Researcher(s) responsible for the breach from future access to linked data for a period of time or indefinitely;
    - reporting the Researcher(s) responsible for the breach to their institutional ethics committee(s) and/or employer(s) with a complaint of misconduct;
    - reporting the Researcher(s) responsible for the breach to the funding agency that has supported the approved project with a complaint of misconduct;
    - where applicable, reporting the Researcher(s) responsible for the breach to the appropriate statutory registration board (such as a medical, dental, nurses or psychologists board) with a complaint of misconduct; or
    - the instigation of civil legal proceedings such as a claim for damages due to breach of contract or criminal investigation in the case of a serious breach of Commonwealth or State law.

Failure to notify any known breach of conditions is generally regarded as serious misconduct.

6. Appeals Process

If any dispute or difference arises between parties in respect of any matter referred to in this policy, then either party may by notice in writing to the other, specify the nature of the dispute or difference. In the event a mutually acceptable resolution is not reached, either party can call for its submission to a mediator, as per the AGOG Dispute Resolution Policy.

7. Application Process

7.1 Expression of Interest

Before applying for funding, the researcher(s) must complete and submit an Expression of Interest application to the Committee. This process will allow the Committee to assess possible study designs, available cohorts and existing data.
This will be a short form that will include:

1. title of the study
2. chief investigator's name and institution, and details of co-investigators
3. aim of the study
4. proposed design and protocols
5. type of AGOG data being requested
6. proposed funding strategy
7. proposed timelines

AGOG Liaison

The Committee will assign a member of the AGOG Executive Management Committee or other person to act as a liaison person for the proposed study. The liaison person will work with the Researcher and can give an indication of the study's feasibility and suitability of involving the AGOG Resource. They will also provide details regarding sample availability, assistance in drafting approach documentation, discussion regarding possible limitations and advice regarding methodology.

"In Principle" Approval

The Committee will provide "In Principle" approval for project deemed feasible and consistent with AGOG Principles. This approval can be used to tick relevant boxes on grant applications.

The Committee reserves the right to request an external review of any project wishing to access the Resource.

7.2 Formal Application

Following receiving "In Principle" approval, Researchers requesting access to Data must complete an Access Application Form. The Access Application Form will require the following details:

1. title of study
2. chief investigator's name and institution, and co-investigators
3. aim of the study
4. proposed design and protocols
5. type of AGOG data being requested
6. proposed funding strategy
7. proposed timelines
8. copies of all contact letters, information sheets, consent forms, phone call follow-up scripts, questionnaires and any other material relevant to the study.

Grant Proposals

Any grant proposals are to be included with this application. The grant proposal should include only procedures and timelines agreed to by Committee. The costing of any activities to be carried out by the Committee should also be agreed and included in the grant application. The grant proposal should include a letter from the Committee, or a statement, indicating that the Committee gives its "In Principle" approval to the grant application and the planned procedures and timelines specified therein. The Committee should be involved in response to reviews provided as part of the funding process.

Linkage with other datasets
Proposals to request information from other datasets (e.g. the DLU or government registries) should also be included in this application. The application will include agreed protocols, approach letters, consent forms, information sheets, questionnaires, plain language statements, etc. as required by the external dataset.

Human Research Ethics Application
An ethics application to an appropriate institutional Human Research Ethics Committee will be made in collaboration with the Committee, including agreed protocols, approach letters, plain language statements, etc.

Storage and Access
The application must include a description of the secure location(s) where the Data extract(s) will be stored and processed.

WAGER Covenant of Confidentiality
All research and IT staff who will have access to the Data must be named in the Access Application Form. All research and IT staff with access to any linked or confidential information must sign a WAGER Covenant of Confidentiality to respect the confidentiality of the information being received. Copies of this Deed must be attached to the Access Application Form.

7.3 Review of Application

The Committee may seek one or more independent reviews to assess the scientific validity and appropriateness of the study. This is most relevant to studies that are not funded following scientific review through a grant application, or are not submitted for scientific review.

7.4 Final Approval

If all of the above conditions are completed satisfactorily, final approval for the conduct of the study will be given by Committee in writing.

7.5 Access Agreement

The Researcher will sign an Access Agreement to ensure all conditions for access are agreed upon and understood, and the research project may proceed.

8. Principles of AGOG

The Australian Genomics and Clinical Outcomes of Glioma Executive Management Committee will be responsible for upholding the following Principles of AGOG.

Responsibility
The protection of interests of all stakeholders involved in AGOG – including participants, researchers and affiliated institutions – will be of highest priority for AGOG.
All steps will be made to honour commitments made to participants and act within the scope of their consents.
The promotion of the common good will is the driving force behind AGOG.

Mutual Respect
AGOG will be developed on collaboration, mutual respect and trust between participants, researchers and their associated institutions.

Accountability
All processes and procedures will be developed on the basis of consensus. All information collected from participants will be protected to the highest standards of privacy and propriety – while at the same time enabling the promotion of data-sharing and openness for the benefit for all.

Promotion of Best Practice
Through local, national and international collaboration, AGOG will strive to promote best practice in health research, community engagement and bioethics. AGOG will also ensure compliance with all relevant legal and regulatory requirements.