ACCESS POLICY

Information for applicants for access to GRA services and/or materials

Overview Genetic Repositories Australia (GRA) is a national genetic repository for DNA & cell lines derived from disease-specific & population-based studies. GRA is an NHMRC-funded Enabling Facility established in 2006, to provide medical researchers with a central national facility for the processing, long-term secure storage and distribution of human genetic samples. This includes the production and provision of immortalised lymphoblast cell lines and DNA samples derived from appropriately consented bio-specimens. GRA is based at Neuroscience Research Australia (previously the Prince of Wales Medical Research Institute) in Sydney.

Mission Our goal is to provide appropriately consented bio-specimen resources through an ethically-based system that will both protect the rights & privacy of participants and allow for open access by the research community to expedite research into the causes and treatments of disease.

Scope This policy covers all requests for fair and equitable access for all Australian researchers to GRA services and/or materials that have been appropriately consented and made available for subsequent distribution, regardless of who makes the request. This policy does not cover requests for access to the associated clinical and phenotypic data collections. Such requests must be made directly to the custodian or keeper (Recruiting Scientist).

Governance The GRA *Management Committee* has been established to oversee the day-to-day management of the GRA and comprises the four Chief Investigators (CIs), Professor Peter Schofield, Associate Professor Juleen Cavanaugh, Dr Susan Forrest, Professor John Hopper and the Facility Manager, Mr Steve Turner.

The GRA *Scientific Advisory Committee* (SAC) consists of nine members and is comprised of a majority of external appointments. The SAC also includes the four CIs plus the Facility Manager (Ex Officio) as these are the individuals with the responsibility to deliver the grant outcomes. The SAC membership has been chosen to reflect a skills-based committee, with a mix of expertise to allow the provision of advice in areas that cover the operations of the facility including: commercial experience and biotechnology; ethical and legal matters; expertise in genetics, Cell and DNA Repositories, cohort or epidemiological studies, IT; and a representative of the research user community. The external SAC members include Professor Don Chalmers, Professor Graham Macdonald, Mr Theo Magoulas, Professor Phil Mitchell and Dr Bruce Ross.

An *Independent Appeals Committee* has been established to resolve any dispute concerning access to or operations of the facility and comprises individuals outside both Management and the SAC. The committee comprises a lawyer, a researcher with experience in NHMRC Enabling Grants and a consumer representative.

Access to GRA Services and/or Materials The GRA Management Committee is responsible for administering this Access Policy. Applications for access to GRA Services and/or Materials by researchers are processed by the GRA Facility Manager and reviewed by the GRA Management Committee. In general, access will be granted if evidence is provided that appropriate Institutional Human Research Ethics Committee (HREC) approval has been granted and the responsible investigators/researchers have undertaken in writing to abide by their stated conditions. The GRA Management Committee retains the right to prioritise applications for services and will not necessarily support all funded or fundable projects. This ruling applies irrespective of the type of service or amount of material requested from GRA. Where a member of the GRA Management Committee has a conflict of interest, other qualified persons will assist in making the ruling under these guidelines.

Researchers interested in applying for GRA Services and/or Materials must conform to the following guidelines -

- Access to GRA Services and/or Materials is in accordance with NHMRC Enabling Facility requirements and is provided with the intention of addressing the needs of all Australian researchers to store and access DNA collections as an essential part of genetic and epidemiological studies that aim to deliver new knowledge and improved health care outcomes.
- The samples must be used in the manner described in the application provided to GRA. Applications to access GRA Services and/or Materials must abide by the processes and principles outlined in this Policy. Any proposed modification or extension to the agreed project must be communicated in writing to the GRA Management Committee who reserves the right to withdraw support. GRA Services and/or Materials will be made available to the Recipient Scientist on the terms and conditions as set out in, and only upon completion of a Services and Material Transfer Agreement . Permission for access and/or use of materials may be withdrawn if information is provided to the GRA Management Committee that a researcher has breached any of the processes and principles outlined in this policy.
- Applications for access by researchers to GRA services and/or material must be scientifically sound and demonstrate that the material will be used efficiently. The scientific merit of the project will be reviewed by the GRA Management Committee.
- Material will not be processed or provided by GRA until a full application is submitted and approved by the GRA Management Committee and a Services and Material Transfer Agreement is completed.
- Assessment of the project will be made solely on the information supplied in the application. The application form and Services and Material Transfer Agreement are available electronically at www.neura.edu.au/GRA
    - GRA Facility Access Application Form which includes a Statement of Research Intent
    - Services and Material Transfer Agreement
- This policy will be reviewed by the GRA Scientific Advisory Committee and updated as required. The latest versions of relevant policies, procedures and documentation are available on the GRA website www.neura.edu.au/GRA It is the responsibility of the Chief Investigator and Researcher to be aware of and adhere to any changes.
- Conditions for GRA Sample Storage - The collecting scientist is responsible for ensuring use of correct collection tubes for any and all subsequent biochemical tests to be performed on stored samples as well as viability and reproducibility of these tests particularly the impact of freeze/thaw on reliability of estimates.
- GRA Sample Distribution - It is GRA policy that the distribution/return of DNA and/or cell line "material" occurs once and once only to the original project Principal Investigator irrespective of the number of collaborators and such distribution is covered within our current rates. GRA will only consider requests for distribution of material to other collaborators from the project's Principal Investigator. All costs for these additional services will be borne by the Principal Investigator as full fee-for-service.
- Oragene saliva DNA (bacterial DNA versus human genomic DNA) - DNA extracted from saliva may represent both bacterial and human genomic DNA (*Rylander-Rudqvist et al Cancer Epidemiol Biomarkers Prev 2006;15(9). September 2006*). Because the ratio of human genomic DNA to bacterial DNA is not determined GRA accepts no responsibility for the performance of DNA extracted from saliva on any downstream platform.

Types of Access Where agreed by the GRA Management Committee and with HREC approval, GRA Services and/or non-identifiable material (DNA and/or cell line) may be provided to the applicant. The amount of DNA will be dependent on the quantity available; generally a 20μg aliquot in TE buffer will be supplied. The GRA Management Committee retains the right to determine how much DNA ("the quantity") is provided to individual applicants. GRA will provide the cell line and/or the estimated concentration and purity of each DNA sample but takes no responsibility for samples after transportation. Where access has been denied, researchers can appeal the decision of the GRA Management Committee via the Independent Appeals Committee.

Associated Clinical and Phenotypic Data Non-identifiable samples are accompanied by *minimal* clinical data set (clinical diagnosis, variant / subtype, race, year of birth, age at diagnosis, age at sampling and sex). Additional clinical or phenotypic data is not stored by GRA and therefore cannot be provided. Researchers wanting access to the associated phenotypic datasets will need to enter into negotiations with the original Recruiting Scientist who submitted the sample/cohort to obtain this data, which may be via formal collaborations.

Access Charges GRA offers a tiered costing structure. The costing structure will be subsidised to reward Australian academic researchers if their samples are appropriately consented and made available for de-identified distribution to other suitably qualified and approved research projects. This structure will provide incentives for fostering collaboration and advancing biomedical research in Australia. Fee-for-service work can also be performed for samples not available for distribution with a rate for academic users and a higher rate for non-academic, international or commercial users such as biotechnology and pharmaceutical companies.

Cost recovery for material obtained or services provided by GRA is essential to maintain the operational feasibility and sustainability of the facility. The cost recovery schedule is transparent and accurately reflects research costs associated with sample collection, processing, costs of consumables storage and distribution charges. In all case, fees are charged either on a partial (subsidised academic rate) or full cost recovery (fee-for-service) for the provision of GRA services and/or samples. The investigator will be advised of these charges on a case-by-case basis.

Appeals Process for Dispute Resolution If any dispute or difference arises between parties in respect of any matter referred to in this document, then either party may, by notice in writing, specify the nature of the dispute or difference whose decision will be final.

In the event that an applicant wishes to dispute the decision of the GRA Management Committee, the following mechanism will apply:

- Within 30 days of receiving notice from the GRA Management Committee why access will be denied either totally, or for specified aspects of the project, or where the GRA Management Committee proposes changes to the use of materials which are deemed not acceptable, written objection from the Chief Investigator(s) must be lodged with the GRA Facility Manager.
- The grounds of the objection must be clear and all evidence supporting the appellant's case must be lodged with the GRA Facility Manager.
- The GRA Facility Manager will forward this documentation along with the complete application and all pertaining correspondence to the GRA Management Committee who will endeavour to resolve the matter. The Management Committee may seek the input of the GRA Scientific Advisory Committee to assist in resolving the matter
- In the event a mutually acceptable resolution is not reached within 60 days, either party can request the dispute be referred to the GRA Independent Appeals Committee.
- The Independent Appeals Committee will then review the documentation and within 60 days make a final ruling.
- The GRA Management Committee will accept the decisions of the Independent Appeals Committee.

Issues of Liability/Risk Management Screening of materials processed and/or held by GRA for the presence of such pathogens (HIV, Tuberculosis, Hepatitis, etc) is not routine. Therefore GRA advises investigators to treat all samples as "potentially infectious" and handle all material with the appropriate care to prevent transmission of pathogens. GRA will take no responsibility for injury or illness that may occur to staff handling any material processed or distributed by GRA.

Acknowledgement It is a mandatory requirement that researchers acknowledge the GRA Facility in any published work that results from accessing GRA materials. A hardcopy or electronic copy of any publications is to be forwarded to the GRA Facility Manager. The following wording will be used in the acknowledgement section of all publications.

"*DNA/Cell lines (delete as applicable) were provided by Genetic Repositories Australia, an Enabling Facility supported by NHMRC Grant 401184. Samples were originally collected by [insert name of Recruiting Scientist] of [insert name of Recruiting Scientist's organisation]*".

PROCEDURES FOR USE OF GRA SERVICES AND/OR ACCESS TO MATERIALS

HOW TO APPLY

1 To expedite your application, GRA encourages you to discuss your proposal prior to formal submission. As an NHMRC enabling Facility, GRA is committed to provide fair and equitable access to all Australian researchers**.**

2 Researchers requesting access to GRA Services and/or Materials must complete the *GRA Facility Access Application Form* which includes a *Statement of Research Intent.*

This form is available electronically and can be downloaded at www.neura.edu.au/GRA An electronic copy of the completed *GRA Facility Access Application Form* together with a copy of your *institutional HREC approval* for the intended project may be sent to the GRA Facility Manager, Steve Turner by email to gra@neura.edu.au A hard copy of the original application containing all documents and bearing the investigators' original signatures must also be provided.
Note – Applicants are strongly advised to apply for ethical approval well in advance of making a formal request for access to GRA Services and/or Materials.

3 Researchers must be able to provide evidence that they have funding in place to complete the proposed project. This may include providing details of a peer-reviewed grant or award or in the case of non-grant supported sources, a statement that funding is available for the work to be carried out. Note – In all cases, costs associated with distributing the material will be borne by the applicant/institution requesting the service or material and not by GRA. The GRA Facility Manager will inform the Chief Investigator of any applicable fees and these must be agreed to in writing by the Chief Investigator before the application can be finalised.

4 The GRA Management Committee will review applications. The committee will assess whether the application proposes a scientifically justifiable, feasible and high priority use of the material and resources currently available. The applicant may be asked to respond to the committee's comments in writing.

5 Once the above conditions are completed satisfactorily, the researcher must then complete a Services and Materials Transfer Agreement for receipt of GRA held samples or access to GRA services via sample deposition of fee for service work. GRA will then provide the requested material and/or services to the applicant at a mutually agreed date.

6 Any material provided by GRA must not be given or sold to other investigators, nor used for commercial purposes or used for any other purpose unless prior written approval has been obtained from the GRA Management Committee. The materials must only be used for purposes described in the Services and Material Transfer Agreement.

7 Further Information - Please contact - GRA Facility Manager, Steve Turner, Neuroscience Research Australia, Barker Street Randwick NSW 2031 Australia. Tel: +61 2 9399 1068 Fax: +61 2 9399 1005, Email: gra@neura.edu.au Web: www.neura.edu.au/GRA