

The Western Australian DNA Bank (WADB)

Enabling Grants Round 3 – Special Facilities

1. Contact details:

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Link to the facility website: www.wadb.org.au

2. Description of the facility/activity:

Despite having the best linked population-based health data in the world (the WA Data Linkage System [WADLS]) and world-class informatics resources (WAGER and the Data Linkage Unit in the WA Department of Health), there are currently no core facilities for large-scale biospecimen banking in WA. Core biospecimen banking facilities for human medical research biospecimens in WA have not been funded as part of any previous funding initiative. By building upon extensive population resources, high-capacity technological platforms, and existing bioinformatics resources and expertise, the Western Australian DNA Bank (WADB) will greatly enhance the capacity of WA research groups to undertake genetic and genomics research, and will also enhance the accessibility and value of the WA medical research resources for genetics and genomics research. The establishment of the WADB is a key resource for current and future large cohort studies in WA, such as the Busselton Health Study and the Joondalup Family Health Study.

The WADB was initiated in 2005 and funded by the Commonwealth from January 2006. This project, the recent recipient of a National Health and Medical Research Council of Australia (NHMRC) Enabling Grant, aims to create the WADB in order to enable large scale and cost-effective banking of DNA in Perth. The WADB is therefore a capacity-building project that will build upon the previous work undertaken in Perth by extant DNA banks at the Royal Perth Hospital and Sir Charles Gairdner Hospital. The Western Australian Genetic Epidemiology Resource (WAGER) project will provide the high-end informatics (a laboratory information system [LIMS]) to support this facility. This enabling facility will underpin extant and new data collection activities aimed at understanding the genetic epidemiology of numerous important and common diseases.

The WADB facility will provide the capacity for individual research groups to efficiently and cost-effectively bank DNA with appropriate consent and Health Research Ethics Committee

(HREC) approval. The facility will build upon pre-existing resources and will utilize economies of scale and core resources to enhance extant and new blood collection for genetic epidemiological studies. The new facility will fund necessary core staff and training to enable international best practice multi-site banking of blood samples in accordance with NHMRC guidelines. The establishment of the WADB will greatly enhance existing projects such as WAGER and many disease-specific DNA collections such as those for breast cancer, colorectal cancer, and heart disease.

DNA will be securely stored in ultra-cold freezers using barcodes and state of the art sample-tracking systems at two sites in Perth - at the QEII Medical Centre Site and at Royal Perth Hospital. The biospecimens will be coded and the data kept separately from any clinical data. This project complies with all relevant State and Commonwealth guidelines and has oversight from the University of Western Australia HREC.

- Available data: Final Human Research Ethics Approval for the WADB was obtained on 9 May 2006. We have since instigated the signing of a Memorandum of Understanding between the WADB and researchers from Western Australia who have indicated their desire to curate their DNA with the WADB. DNA will be curated in secure dual site freezer facilities as each Custodian signs the MOU and provides the WADB with evidence of HREC approval for their study.
- Dates from which data will be accessible: DNA is expected to be available in the WADB by the end September 2006, this collection is expected to expand substantially over time.
- Preferred means of access: An Access Policy was approved by the WADB Management Committee on 2 August 2006 (see Appendix A). Applications for Access to DNA samples are preferred via an Access Application Form (see Appendix B).

ACCESS POLICY

The WADB was established in 2006 to provide the infrastructure, consumables and personnel for up-to-date biospecimen processing and dual-site curation of human DNA samples in Western Australia for medical research purposes. A key aim of the WADB is to facilitate access to human DNA collections by the broader Western Australian and Australian research communities. The WADB will establish a common storage and management system for biospecimens in WA as a pre-requisite for making them more widely available as a national resource.

Access to any of the DNA samples and contributing datasets cannot be guaranteed by the WADB as this requires the approval of each of the DNA/data Custodians involved in the request. External users will be required to enter into negotiations with individual Custodians within the WADB for access that will necessarily involve defining authorship and cost recovery. However it is reasonable to anticipate that the infrastructure established under the WADB will greatly increase the opportunities for Australian researchers to access both large population-based genetic epidemiology resources and smaller research datasets held by individual research groups in Western Australia.

Scope

The scope of this Policy covers all requests for access to samples in the WADB collection, 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 data Custodians.

**THIS POLICY IS EFFECTIVE FROM 2 AUGUST 2006
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 WADB website. It is the responsibility of researchers and analysts to be aware of and adhere to any changes.

ACCESS TO WADB COLLECTIONS

- The information obtained from the WADB is not to be used directly for clinical decisions or treatment of individual patients, nor to identify individual service providers.
- Applications to access these collections must abide by the processes and principles outlined in this Policy. With this access comes responsibilities which must be taken seriously. Permission for access may be withdrawn by the WADB, in consultation with the Custodian, if information was provided to the WADB that a researcher has breached any of the processes and principles outlined in this Policy.
- Access by Commercial entities or international researchers is at the discretion of the Custodian.

- It is mandatory that investigators acknowledge the WADB facility in any published work that results from accessing the DNA samples.

WADB Management Committee

The WADB Management Committee is responsible for administering this Access Policy.

All applications are considered by the WADB Management Committee and, in general, access will be granted if:

1. evidence is provided that the appropriate Institutional HREC approval has been granted, and the responsible investigators have undertaken in writing to abide by their stated conditions.
2. evidence is provided that the Custodian of the DNA sample(s) has given approval for access.

Types of Access

Where agreed by the Custodians, and with approval from a Human Research Ethics Committee (HREC), de-identified DNA samples may be provided to the applicant as a stand-alone resource. The amount of DNA supplied to the applicant will be dependent on the quantity available in storage. The Custodians of the DNA, often a clinical group, retain the right to determine how much DNA (“the quantity”) is provided to individual applicants.

The WADB will provide the estimated concentration and purity of each DNA sample but takes no responsibility for the samples after transportation. Where DNA is in limited supply or unavailable the WADB will inform the applicant.

Associated Phenotypic Data

Phenotypic or clinical data is not curated by the WADB and therefore cannot be accessed via the WADB. Approval for access to the associated data must be sought from the Custodian of the DNA samples. If the Custodian consents, data can be obtained directly from the Custodian or from the Western Australian Genetic Epidemiology Resource (WAGER) (if curated by WAGER).

Access Fees

There are two potential fees. The first may be paid to WADB based on full cost recovery for the provision of the DNA samples associated with the costs of consumables, transportation and personnel time. The second may be paid to the WADB based on partial cost recovery for the provision of the DNA samples as outlined above.

Audit

It should be noted that HREC representatives may conduct random audits to ensure all these conditions are met.

Appeals Process

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 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 the independent WADB Advisory Committee.

PROCEDURE FOR THE APPLICATION FOR USE OF WESTERN AUSTRALIAN DNA BANK (WADB) SAMPLES

1. Researchers requesting access to WADB collections must complete a WADB Access Application Form in accordance with the guidelines below.

This will be a short form that will include:

- a. title of study
- b. principal investigator's name and institution, and co-investigators
- c. executive summary of the study (brief)
- d. proposed laboratory protocols (including an estimate of the quantity of DNA required)
- e. anticipated numbers of samples required
- f. any proposed timelines
- g. the name and contact details of the Custodian of the DNA samples

DNA samples will not be provided for approved projects until evidence is provided that the appropriate Institutional HREC approval has been granted. A copy of the HREC approval letters must be attached to the application for access to the WADB samples.

DNA samples will not be provided for approved projects until evidence is provided that the consent of the Custodian has been obtained. A copy of the Custodian's approval letter must be attached to the application for access to the WADB samples.

2. The WADB Manager will inform the Management Committee of the application who will liaise directly with the Custodian to facilitate the progression of the application.
3. The WADB Management Committee will review the application including determination of any fees.
4. The WADB Management Committee will inform the Principal Investigator (PI) of any applicable fees and these must be agreed to in writing by the PI before the application can be finalised.
5. If all of the above conditions are completed satisfactorily, final approval for the application for access to DNA samples will be given by the WADB in writing. In accordance with the WADB material transfer agreement (MTA) the agreed number of DNA samples will then be transported to the address supplied by the PI at a date mutually agreed by the WADB and the PI involved.

DNA Access Application Form

Please submit completed application forms to the Manager WADB

By Email: macnish@waimr.uwa.edu.au

By Post: WAIMR, MBDP 519, B Block, Hospital Ave, Nedlands WA 6009

Before completing this form you are advised to refer to the WADB Access Policy available at <http://wadb.org.au>

Please note: Proof of approval from the following must accompany your completed access form:

- (1) The Custodian of DNA samples curated by the WADB*
- (2) The institutional Human Research Ethics Committee (HREC) that approved your study (high quality scanned copies of documentation will be accepted)*

Date of Application to WADB	<i>dd/mm/yyyy</i>
Title Of Study	
Principal and Co-investigators	<i>Name: Institution: Phone: Email: Co-investigators:</i>
Executive summary of study	<i>1-2 paragraphs only</i>
Proposed laboratory protocols	<i>List names of protocols only (eg PCR, Microarrays, Luminex etc) Please also provide an estimate of the quantity of DNA required (ng/μg)</i>
Anticipated number of DNA samples required	
Proposed timeline of study	<i>Proposed start date: Expected finish date:</i>
Name and contact details of the Custodian of the curated DNA	<i>Name: Institute: Address: Phone: Email:</i>