

Western Australian Genetic Epidemiology Resource (WAGER) Collection External Access Policy

Version 2.0

WHAT IS WAGER?

WAGER provides enabling infrastructure to facilitate the development and integration of existing and future disease-specific clinical, epidemiological and genetic resources available in WA with biospecimen banks and with the core WA Data Linkage System. WAGER also provides analysis capabilities and services to facilitate access to these resources.

Scope

The scope of this Policy covers all requests for access to existing WAGER data collections, regardless of who makes the request. This Policy does not cover requests for access to the biospecimens associated with study data. Such requests must be made directly to the biospecimen Custodians. This Policy also does not cover requests for access to WAGER resources for the purpose of conducting new or ongoing studies.

Access to any of the contributing datasets cannot be guaranteed by WAGER as this requires the approval of each of the data Custodians involved in the request. External users will be required to enter into negotiations with individual Custodians within WAGER for access that will necessarily involve defining authorship and cost recovery. However it is reasonable to anticipate that the infrastructure established under WAGER 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.

**THIS POLICY IS EFFECTIVE FROM 1 JULY 2007
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 WAGER website. It is the responsibility of researchers and analysts to be aware of and adhere to any changes.

WAGER Management Committee

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

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

1. serious scientific research is proposed that is consistent with the overall program of research activities;
2. research proposed does not conflict with work in progress;
3. the interests and personal privacy of individual research subjects are protected and appropriate Institutional Health Research Ethics Committee approval has been given for the proposed research; and
4. resources are available to pay WAGER and associated service providers (e.g., the DLU) for the data and materials and for the work to be done in making the data materials available, and also for any further work proposed by the investigator.

What does WAGER expect of researchers?

WAGER expects researchers to submit a well designed study, preferably after consultation with the WAGER Governance Committee and other relevant scientists regarding methodological and feasibility issues. Researchers must have approval for the study from an appropriate Human Research Ethics Committee (HREC).

Once a study has been approved, WAGER asks the researcher to provide feedback on the study's progress and to forward all relevant information to the WAGER Governance

Committee. Researchers are asked to complete annual reports on their on-going studies associated with WAGER and to notify WAGER of any publications that result from that research. The researcher should supply WAGER with two reprints of all publications that result from the study.

The researcher should ensure that the involvement of WAGER is acknowledged in all publications related to the study.

As WAGER's databases enable the linking of data between studies and with the core WA Data Linkage System, researchers are asked to lodge a copy of any new data produced on WA research subjects as a result of collaborations enabled by WAGER with WAGER once the study is completed and the data has been checked and cleaned. WAGER considers that the data collected by researchers for a particular study belongs to the researchers. It will hold copies of the data in confidence and will not make a study's data available to other researchers unless it has permission from the original researchers concerned. If they so wish, the original researchers may place conditions on access to the data by third parties.

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 WAGER Advisory Committee.

PROCEDURE FOR THE APPLICATION TO ACCESS EXISTING WAGER COLLECTIONS

1. Researcher makes a Data Access Request submission to WAGER. This is a short form that includes:
 - o title of study
 - o principal investigator's name and institution, and co-investigators
 - o executive summary of the study
 - o proposed design and protocols
 - o name of collections for which access is required
2. WAGER will review the Request for Data Access.
3. Researcher makes a formal application to WAGER. Assuming the request meets with the WAGER guidelines, WAGER provides the contact details of the Custodians.
4. When the WAGER Manager obtains written agreement from the Custodian(s) to provide access to the Study data, a Memorandum of Understanding (MOU) will be forwarded to the applicant for signing.
5. WAGER assists in the development of a Material Transfer Agreement (MTA) for the transfer of data between WAGER and the Researcher.
6. When the signed MOU and MTA have been received by the WAGER Manager the data will be provided via the WAGER website. Data will not be provided for approved projects until evidence is provided that the appropriate Institutional HREC approval has been granted, and the responsible investigators have undertaken in writing to abide by stated conditions.

The information obtained from WAGER 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 a responsibility which must be taken seriously. Permission for access may be withdrawn by WAGER, in consultation with the Custodian, if

information was provided to WAGER 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 WAGER facility in any published work that results from accessing the WAGER data.

Types of access

Data may be made available in the form of completed statistical analyses, data summaries such as cross-tabulations, or a de-identified data file.

Access fees

There are two potential fees. The first may be paid to WAGER based on full-cost recovery for the programming and other costs associated with the planning, extraction and provision of the data. The second may be paid to the curators of the original dataset(s) for any costs associated with access to their specific dataset(s). These fees will depend upon the type and amount of data required, the association of the investigators with the WAGER program of activities, the intended use of the data, and whether the principal applicant is a postgraduate research student.