

Western Australian Genetic Epidemiology Resource (WAGER) Study Support Services 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 utilise WAGER study support services for the purposes of conducting a study, regardless of who makes the request. This Policy does not cover requests for access to existing WAGER data collections or to the biospecimens associated with existing study data. Refer to the WAGER Collection Access Policy for the processes associated with accessing existing data collections. Biospecimen requests must be made directly to the biospecimen Custodians.

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) and submit drafts of all documents, including approach letters and questionnaires, to be used in the study.

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.

PROCEDURES FOR THE APPLICATION TO USE WAGER STUDY SUPPORT SERVICES

1. Researcher makes an Expression of Interest application to WAGER. This is a short form that includes:
 - a) title of study
 - b) principal investigator's name and institution, and co-investigators
 - c) executive summary of the study
 - d) proposed design and protocols
 - e) eligibility criteria
 - f) anticipated numbers required
 - g) any proposed funding strategy
 - h) any proposed timelines
2. WAGER will inform the Governance Committee of the intended/existing study, and may assign an Executive member or other person to act as a liaison person for the study. Their job will be to help facilitate design, applications for funding, application to WAGER, and conduct of the study. This will be particularly important for new researchers.
3. Researcher(s) make(s) a formal application to WAGER, which will include any grant proposal. The grant proposal should include only procedures and timelines agreed by WAGER. The costing of any activities to be carried out by the WAGER should also be agreed and included in the grant application. The grant proposal should include a letter from WAGER, or a statement, indicating that WAGER gives its approval in principle to the grant application and the planned procedures and timelines specified therein. WAGER should be involved in response to reviews provided as part of the funding process.
4. WAGER 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.
5. For new studies ethics application to an appropriate institutional Human Research Ethics Committee will be made in collaboration with WAGER, including agreed protocols, approach letters, plain language statements, etc. This may also involve

approval from The University of Western Australia Human Research Ethics Committee.

6. If all of the above are completed satisfactorily, a Memorandum of Understanding (MOU) will be forwarded to the applicant for signing.
7. When the signed MOU has been received by the WAGER Manager the WAGER study support services will be configured to support the study

Applications to utilise the WAGER study support services 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.

Types of study support

Existing study support services include:

- LIMS provisioning and support
- Study data management

Support fees

There are two potential fees that may be paid to WAGER. The first is based on full-cost recovery for the programming and other costs associated with the planning, development, delivery and support of application functionality. The second is for the storage and management of study data. These fees will depend upon the type and amount of application support, volume of data storage required, the association of the investigators with the WAGER program of activities, the intended use of the compiled data, and whether the principal applicant is a postgraduate research student.