Western Australian Melanoma Health Study

Data Access Policy

The Western Australian Melanoma Health Study
The Western Australian Melanoma Health Study (WAMHS) is a population-based database and linked bio-specimen resource, established in 2006 to enable investigation into the clinical and genetic epidemiology of melanoma. The study aims to recruit all adult (males and females aged 18 years and over) incident cases of cutaneous primary malignant melanoma, diagnosed since January 2006 in Western Australia. Consenting participants are asked to complete a questionnaire, provide a blood sample, have a scar examination and allow access to their health records.

The WAMHS is a core resource seed funded by the Scott Kirkbride Melanoma Research Centre (SKMRC) and is based within the Centre for Genetic Epidemiology and Biostatistics at The University of Western Australia. Collaborating partners include the Western Australian Melanoma Advisory Service and the McComb Foundation.

Definitions
For the purposes of this Policy:

1. “Committee” refers to the WAMHS Management Committee. The Committee is responsible for administering this Data Access Policy.
2. “Resource” refers to the facility involved in the collection of information from participants in the WAMHS, infrastructure required and the information collected.
3. “Data” includes 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. “Investigator(s)” 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 WAMHS, regardless of who makes the request.

THIS POLICY IS EFFECTIVE FROM 15TH JUNE 2012
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 WAMHS website. It is the responsibility of researchers and analysts to be aware of and adhere to any changes.
ACCESS TO WAMHS COLLECTIONS

Requirements

- The information obtained from the WAMHS is not to be used directly for clinical decisions or treatment of individual patients, nor to identify individual service providers.

- Applications to access the WAMHS 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 WAMHS, if information was provided to the WAMHS that an Investigator has breached any of the processes and principles outlined in this Policy.

- Access by commercial entities or international Investigators is at the discretion of the WAMHS Management Committee.

- It is mandatory that Investigators acknowledge the WAMHS in any published work that results from accessing the WAMHS.

- The required access fees must be paid before samples or data will be released.

- Evidence of ethical approval for the project must be provided before samples or data will be released.

- Any derived data (including biochemical and genetic data) from analyses of WAMHS data must be added to the WAMHS resource.

- A progress report must be submitted annually.

Further detail regarding some of these requirements can be found in the ‘Additional Details’ section of this policy.

How to Apply

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

The Committee will encourage and provide access to the WAMHS Resource and the results that flow from it as widely and openly as possible in order to maximise its use and value for research.

As the steward of the WAMHS Resource, the Committee will act as custodians of all data collected from WAMHS, and will hold all identifying participant information. Identifying participant information will not be available to Investigators. The Committee will use such identifying information only to keep in contact with participants, enable follow up and manage and audit the Resource.

All applications are processed by the WAMHS Scientific Director and reported to the WAMHS Management Committee at completion. In general, access will be granted if:

1. Valid 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 Health Research Ethics Committee (HREC) approval has been given for the proposed research;
4. Resources are available to pay the WAMHS Management Committee and associated service providers for the data and materials, for the work to be done in making the data and biological materials available, and also for any further work proposed by the Investigator; and
5. The responsible Investigators have undertaken in writing to abide by their stated conditions, as per the Undertakings by Responsible Investigators form.

**Types of Data Available to Investigators**

a) Phenotypic or clinical data on participants  
   Data may be made available in the form of a de-identified unit-record data file.

b) Biological samples (blood sera, DNA and RNA) on participants  
   Biological materials may be made available in the form of sera, DNA or RNA specimens, or new analyses on stored specimens may be arranged in collaboration with WAMHS-affiliated personnel. The amount of biological material supplied to the Investigator will be dependent on the quantity available in storage. The Committee retains the right to determine how much biological material (“the quantity”) is provided to Investigators.

c) Data derived from biological sample analyses  
   Data may be made available in the form of a de-identified unit-record data file.

d) Collecting additional information from participants  
   Arrangements can be made for WAMHS-affiliated personnel to collect the additional data on behalf of the Investigators. No name-identified data will be provided to Investigators.

Applications must be in writing and in accordance with the guidelines below. Data and biological materials will not be provided for approved projects until evidence is provided that the appropriate HREC approval has been granted, and the responsible Investigators have undertaken in writing to abide by stated conditions (see ‘Undertakings by Responsible Investigators’ form).

Prior to submission of the formal application, Investigators are encouraged to submit a brief expression of interest and request preliminary investigation of the suitability of the available Data for their research aims.

**Additional Details**

**Access Fees**

There are two fees, both paid to the Committee.

The first is based on full-cost recovery for the programming and other costs associated with the planning, extraction and provision of the Data.

The second is a contribution to the on-going storage, maintenance and other infrastructure costs of the WAMHS. The latter fee depends upon the type and amount of Data required, the intended use of the Data, and whether the principal Investigator is a postgraduate research student, a grant funded researcher or a commercial entity.

**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 a mediator, as per the WAMHS Dispute Resolution Policy.

**Data derived from WAMHS biospecimens**
It is a requirement of access to WAMHS data that any genetic or biochemical data derived from analyses of WAMHS data be included in the WAMHS resource. Once any such derived data are produced (e.g. genotyping is completed) and these data have been analysed as detailed in the application for data access, these data should be provided to the WAMHS Management Committee for inclusion in the WAMHS resource. The period of exclusive publication rights for these data will be considered by the Management Committee on a case-by-case basis but will normally be for a period of one year from completion of analyses. After this specified period, other applicants are able to publish results from analysis of the derived data.

**Additional data collection: Documentation required**
When data are 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.

The Committee also requires details of how subjects were selected from the main WAMHS cohort for the particular study. If WAMHS staff did the original subject selection, the information will be on our records. However, in cases when the entire sample as selected by the WAMHS 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).

All additional data collected and associated documentation should be forwarded to the Scientific Director (details below in section 2 of application procedure).

**Progress Reports**
A progress report must be submitted to the Management Committee annually, to enable the project’s progress to be reviewed. This report can be a copy of an annual progress report submitted to the relevant ethics committee or funding body, detailing the progress made to date.
PROCEDURE FOR THE APPLICATION FOR USE OF WAMHS DATA

1. Guidelines for the preparation of applications
   Investigators requesting access to WAMHS collections must submit an application using the headings detailed below. Sufficient detail should be included to allow an informed and critical review of the proposal.
   
a) Responsible Investigators
   Name, degrees and professional qualifications, title of appointment held, department and institution of each responsible Investigator.
   
b) Proposed Research
   i. Title of project.
   ii. Background and rationale
   iii. Specific aims
   iv. Research plan, including a timeline
   
c) Data and biological materials
   i. Supply full details of data variables and biological materials required
   ii. Specify the form in which the data and biological materials are required
   
d) Resources
   i. What services are requested by the WAMHS Management Committee in provision or analysis of data and biological materials and what funds are available to pay for these services.
   ii. What funds or other resources are available to the Investigator to undertake the proposed work.
   
e) Ethical Considerations
   i. If subjects are to be approached in any way (by WAMHS personnel, on behalf of Investigators), give full details of proposed contact and data collection.
   ii. Provide evidence (at the time of submission or once approval is received) that the proposed research project has been approved by an institutional ethics committee and include a copy of the approved ethics application
   
f) Undertakings and signatures
   Complete and sign an ‘Undertakings by Responsible Investigators’ form.

2. Application submission:
   Applications should be submitted to:
   
   Mail: Professor Eric Moses
   Scientific Director, Western Australian Melanoma Health Study
   Centre for Genetic Epidemiology and Biostatistics
   M409, 35 Stirling Highway
   Crawley WA 6009
   
   Email: eric.moses@uwa.edu.au
   Phone: +61 8 6488 6729
   Fax: +61 8 6488 6750

3. Review of application
   A review of the application to access WAMHS Data will be undertaken by the Committee.

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.