



## Genetic Support Council of WA Inc

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# Biobanking in WA – GSCWA Position Statement

### Background

In December 2006 the Genetic Support Council WA was invited by the Office of Population Health Genomics to participate in the WA Stakeholder Advisory Group which had been established to review issues relating to biobanks and associated databases in Western Australia.

The consultations provided an opportunity for a range of stakeholders representing professional, clinical, research and consumer interest groups to comment on issues including:

- I. maintaining and improving existing biobank infrastructure and competence
- II. developing, promoting and upholding best practice in ethical review and governance
- III. growing community understanding and support for biobanks.

In August 2008 members of the Genetic Support Council WA participated in a deliberative consumer engagement forum to help inform the Council's development of policy relating to biobanks in Western Australia.

The consumer engagement forum "Biobanking in WA" was held over four days and encouraged participants to deliberate on what values and interests ought to be considered in the establishment, regulation and use of biobanks for health research. Through the process participants:

- Learned about biobanks and a range of perspectives on biobanks
- Shared views with each other, explained and give reasons to each other
- Worked towards consensus, identified areas of persistent disagreement; and
- Made recommendations to inform policy development

This forum developed a set of recommendations as a basis to inform the development of this positions statement.

### Consultation Process

The consumer engagement forum participants were drawn from across GSCWA's membership, including those living with a genetic condition, family members and/or carers of these individuals. The member patient/consumer groups of GSCWA support people with rare conditions, common conditions, early onset conditions and late onset conditions.

The participants represented themselves, not their groups or organisations. An earlier draft of this statement was the subject of broad consultations with members throughout 2008/09. This statement incorporates the comments and feedback received.

We would like to acknowledge the Office of Population Health Genomics (OPHG) for their support and commitment to community and consumer engagement. This partnership with OPHG enabled our members to gain an understanding of Biobanking issues and the opportunity to engage in informed debate to develop a wide ranging stakeholder report outlining recommendations for the development and governance of Biobanks in WA.

## **POSITION STATEMENT ON BIOBANKING IN WA**

For the purposes of this position statement, biobanks are defined as collections of samples of human bodily substances (e.g. cells, tissue, blood, or DNA as the physical medium of genetic information) that are, or can be, associated with personal data and information on their donors. Biobanks have a twofold character, as collections of both samples and data.

These recommendations relate exclusively to human biobanks and genetic research databases used for medical research. These include biobanks containing samples and data originally collected or recorded for medical purposes – e.g. diagnosis – but subsequently to be employed for medical research.

### **RECOMENDATIONS:**

#### **Establishment of Biobanks in WA**

1. Public trust and support are essential to the successful operation of biobanks. Consultation with community members and other stakeholders must be undertaken prior to the establishment of a biobank to ensure that community members have a clear understanding of the purpose of the biobank and can assess any perceived risks or benefits in context.
2. Biobanks should define the scope and purpose of their database in a way that can be clearly understood. All potential research studies that may use data from this database cannot be anticipated or explained in detail at the time the database is being created, however, efforts should be made to describe the types of studies that could be undertaken.
3. Biobanks should describe what their database will not be used for. This is an opportunity to be open and transparent about the proposed research. This may reassure potential research participants and the community that although future research purposes are not specified in detail, all research will occur within National Health Medical Research Council (NHMRC) guidelines, Information Privacy Principles' etc.
4. Whether private or public in ownership all biobanks must have operational and technical infrastructure that ensures complete privacy protection for donors.
5. Where human biobanks and genetic research databases are established and supported with public funding there should be some benefit to the research participants or the community. The public benefit and interests should be taken into account in determining research priorities.
6. Only research that is ethically approved by Human Research Ethics Committees should be undertaken following the NHMRC guidelines for the ethical conduct of research in humans.

#### **Consultation**

7. The community is largely unaware of the fundamentals of biobanking, and its benefits. Ongoing information that focuses on fostering dialogue and reporting information back to stakeholders and the wider community should be provided to assist in maintaining public trust and community support for biobanks. The inclusion of community representatives on review panels and ethics committees will support openness and transparency.
8. As a general principal researchers should communicate their findings to research participants. Many research studies are reported in peer reviews or abstracts which may be difficult for members of the public to access or understand. Efforts should be made to develop lay summaries of research studies which could be made available by internet, newsletter, or regular mail.

## Consent

9. Participation in biobanks should be voluntary.
10. Recruitment of participants should be undertaken in a way that respects cultural and religious differences.
11. Potential research participants should be provided with clear and concise information about the nature of the research and the risks and benefits of participation. The likely benefit may be to the participants, to the wider community, or to both.
12. Consent to participate in research must be informed i.e. the donor has the capacity to give consent, the consent is given voluntarily and the donor has been appropriately informed of the purposes, nature, significance and implications of the collection and use. Consent must always be subject to appropriate information relevant to the donor's decision being available.

These as a rule should include:

- the voluntary nature of participation
- the purposes, nature, extent and duration of the proposed use
- the extent of, and conditions for, the possible transfer of samples and data
- the possibility or otherwise of communication of research results to the donor
- information on the possible consequences of the communication of results of genetic analyses for the donor and his relatives, including possible obligations to divulge to third parties (e.g. to police, courts, insurance institutions)
- the form of data storage and combination
- anonymisation of samples and data
- other ancillary donor protection measures
- any provision for third party access to samples and data
- the right to withdraw consent
- the fate of samples and data if consent is withdrawn or if the biobank closes down
- any commercial prospects of the proposed research (including the possibility of filing patent applications on the results)
- issues of payment of expenses, remuneration or benefit sharing

It should not under any circumstances be possible to dispense with the provision of this information to participants.

13. Levels of Consent should be offered to participants which reflect options to participate at varying levels including:
  - One time consent where participants allow their samples to be used for research, on the understanding that an ethics committee will decide the studies for which samples are used
  - A re-consent process for each intended use
  - Consent to a single, specific research study
14. Donors must have the right to withdraw their consent to the use of their samples and data at any time. It should not be possible to waive this right. However, there should be provision for donors to consent to samples and data to continue to be used, in the case of withdrawal, if they are anonymised.

## **Governance**

15. Any governance should be developed in consultation with community and stakeholders. Community members must be included on governance bodies.
16. Confidentiality and security of the information is a major concern for community groups. The potential for misuse of data should be addressed by ensuring rigorous policies and procedures around data management, storage and use are in place and the protection of participants must be guaranteed.
17. Best Practices Principles must continue to evolve to incorporate improved practices and innovative solutions which will develop over time. To facilitate this process policies and standards for human biobanks and genetic research databases should be formally reviewed every three years. These reviews should also be used to influence required legislative/policy changes.
18. Governance of human biobanks and genetic research databases should require oversight by an independent advisory panel which is separate from the owners or users of the database to be established. This panel should have oversight of all Biobanking activities in WA and have appropriate powers to address inappropriate activity.
19. The independent advisory panel should review compliance with legal and regulatory requirements, monitor complaints or assess breaches of protocol. Reports from such reviews should be made available to the public. This would include:
  - Access accountability including who has been provided access, for what purpose and what type of access was allowed.
  - Disclosure to third parties and who these would be.
20. Participants should be advised if their information will be linked with other biobanks or data collections.
21. Audit systems must keep a record of access and use of biobank samples and data. All access to samples and data must be in accordance with participants consent and ensure the protection of their privacy and confidentiality.
22. Participants should be satisfied that there are appropriate mechanisms in place to ensure security of the information when it is stored, sent or received, including electronically.
23. Appropriately qualified person(s) should be appointed to act as the guardian of the human biobanks and associated databases, and have responsibility for monitoring and ensuring compliance with the principles of confidentiality and security. The participants should be notified of the name and contact details of the guardian and be advised of any changes in guardianship.
24. Safeguards must be in place to ensure that there is no inappropriate or unauthorised use of or access to information in databases, and to ensure the authenticity of the data. When data is transmitted, there must be arrangements in place to ensure that the transmission is secure.

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