



## Briefing Document:

### Privacy and Confidentiality Protections for Participants in the Joondalup Family Health Study

The team at the Joondalup Family Health Study (JFHS) realizes that the most important part of this Study will be forging a strong partnership with the whole community. We have, and will continue to spend, considerable time talking with City of Joondalup residents to ensure they fully understand and are in agreement with all aspects of the Study. As a critical part of building this partnership, we take our commitment to protecting the rights and privacy of future participants in our Study very seriously.

The JFHS aims to set the world-wide standard in terms of the ethical and legal safeguards to protect those who take part in such a Study. This document will briefly detail these measures.

#### Current Commonwealth Legal Protections

The Joondalup Family Health Study will implement a number of measures to give participants the strongest possible protections available under Australian law.

#### **Privacy Act 1988 (Cth)**

A key part of this plan is to voluntarily bring the JFHS under the coverage of the Commonwealth [Privacy Act](#) 1988 (Cth) (the Act). To do this, the Joondalup Family Health Study Foundation – the charitable trust with overall responsibility for the Study – will “opt in” under Part II of the Act.

This means that the JFHS has the *legal obligation* to protect the privacy of the Study participants’ personal information.

The JFHS will be subject to ten [National Privacy Principles](#) (NPP) that set out how the Study should collect, use, keep secure and disclose Study participants’ personal information. For example, the NPPs prevent the Study from releasing medical research data to third parties, such as employers, insurers or the police, except in very limited circumstances. These include when the Study participant has given his/her consent, when it is required or authorised by law (by court order, for example), or when it is necessary to prevent or lessen a serious or imminent threat to someone’s life, health or safety.

The NPPs will also govern the *kinds* of information the JFHS can collect and the standards the JFHS needs to meet in order to keep it secure. Further, when the JFHS collects information from participants it must provide detailed information about who will be collecting the information and why it is being collected.

The NPPs will also give participants the right to access and correct information the JFHS may hold about them, as well provide legal remedies if they believe their personal information has been mishandled.

### **Recent Commonwealth Law Reform on Genetic Privacy Issues**

Participant safeguards will be further strengthened by new reforms recently adopted by the Federal Government to address genetic privacy concerns.

These reforms were part of a [major review](#) on genetic information privacy by the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC).

Margaret Otlowski, Professor of Law at the University of Tasmania and Deputy Director of the Centre for Law and Genetics was one of the consultants to this report, titled [Essentially Yours](#). She was also one of the expert panelists at the Joondalup Family Health Study [Community Forum](#) held late last year. According to Professor Otlowski, a high level of protection for medical research data already exists under current legal and ethical regulations.

For example, the existing Commonwealth [Privacy Act](#) (which the JFHS will be subject to) already prohibits the unauthorized release of information – including genetic information – to any third parties such as insurers, employers or police. Further, under national health legislation, genetic data is already excluded from consideration for health insurance. (Health insurance refers to the types of coverage provided by groups such as Medicare, HBF and Medibank Private).

With these new measures however, Australia will become a world leader in the legal protections for genetic privacy.

For example, the Government has agreed to tighten and clarify the coverage of the Commonwealth [Privacy Act](#) in relation to genetic information. That is, though it was always considered as such, genetic information will now be *expressly* included as a category of information which attracts a higher level of protection. Furthermore, under the Commonwealth [Disability Discrimination Act 1992 \(Cth\)](#) it was already effectively illegal for employers to unlawfully discriminate against people on the basis of their genetic makeup. Under [reform changes](#), the government will amend the Disability Discrimination Act to strengthen and clarify these protections. It will become illegal for employers to even ask for genetic information from employees or job applicants for improper discriminatory purposes.

Other recommendations adopted will make non-consensual genetic testing a criminal offence – not only for the person who conducted the test, but also the person who submitted that sample for testing.

The Government has also supported recommendations for increasing the regulation of the use of genetic test information for life insurance. The Government has established a new Human Genetics Advisory Committee to oversee the life insurance industry, to assess and make recommendations on what genetic tests are, or are not, scientifically and actuarially justified for use by life insurers.

## **State Privacy Legislation in WA**

The JFHS fully supports the initiative to create a Western Australian Privacy Act, and State legislators plan to introduce such privacy legislation some time this year (2006). This will provide an extra layer of legal protection for participants. It is expected that the provisions of the State Privacy Act will more or less reflect the provisions in the Commonwealth [Privacy Act](#), and the JFHS will be bound to meet the standards required by both.

## **Oversight and Governance**

To express our commitment to setting the new best-practice standard for protecting participants' information, the JFHS has established an internal and external governance framework to work alongside the legal protections in place for participants.

*Bona fide* medical researchers wanting to use JFHS data will need clearance from at least three committees.

### **Scientific Oversight**

Researchers will firstly need scientific approval from the Scientific Advisory Committee. This Committee will consist of eminent researchers and health professionals. Its role will be to evaluate the scientific merit and health objectives of the proposed research.

### **Ethical Oversight**

Researchers will also require ethical approval from at least two ethics committees. These ethics committees are constituted and operate under the NHMRC's [National Statement on Ethical Conduct in Research Involving Humans](#) (1999). Their job is to prescribe the ethical standard of conduct that researchers must meet before they receive clearance to use Study data. They are also responsible for monitoring the conduct of researchers once clearance has been granted. If, at any time, researchers do not meet these standards, these committees have the power to terminate the project, move to have the researcher's funding severed and ban access to the data.

The JFHS will establish an Ethics Oversight Committee. The Committee has, as its core mission, to protect the interests of participants and to ensure that the data is being used according to the participants' consent. This will be a multidisciplinary group, made up of not just doctors or medical researchers, but also lawyers, social workers and community representatives. Every researcher wishing to use JFHS data will need clearance from this Committee, which also monitors the day-to-day operations of the JFHS. These researchers will also need to show ethical clearance and monitoring by their own home institution(s).

In addition, the Human Research Ethics Committees of The University of Western Australia and Edith Cowan University will provide external oversight over the collection and handling of data by the JFHS itself. Both universities have had, and continue to have, leading roles in medical research in WA. Both have a history of "best practice" in relation to ethical research, including proper protection for data.

## **Conclusion**

The Joondalup Family Health Study team is always mindful of how indebted we are to the Joondalup community – and we recognize that at its core, this Study belongs to the community. As such, we owe it to participants not only to protect them legally, but to ensure that we go above and beyond our legal obligations, to honour their rights to dignity, choice and respect.



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