



FAQ Number 2: Ethical, Legal and Social Issues

Addressing the ethical, legal and social context of medical research studies is a key focus of the Joondalup Family Health Study (JFHS) team and our collaborators.

The collection of human DNA for genetic research into the causes of common diseases is often used as an example of a potential unique ethical issue related to large, population-based study such as the JFHS. However, the Joondalup Family Health Study faces the same ethical, legal and social issues that arise in most modern research studies. For example, Western Australia (WA) has a proud history of population-based research; projects such as the Busselton Health Study, the Health-In-Men Study, and the Raine Cohort Study are world-class medical research resources, and recognized internationally as such. All of these studies, in common with most human medical research studies conducted over the last decade in Australia, have collected blood (and DNA) with informed consent from adults and children. Blood samples are considered an important element of modern medical research because of the increasingly useful information that can be gained from biochemical measures and biomarkers (e.g. serum lipid levels), and also because of the potential to undertake genetic research using DNA.

The Study team takes the ethical, legal and social issues surrounding our research very seriously. This FAQ discusses some of the ethical, legal and social issues related to the Joondalup Family Health Study, and what is being done to address them.

1. What legislative safeguards are there to prevent the Study data being misused by third parties, such as insurers and employers?

The JFHS will have some of the strongest possible protections available under Australian law to keep study data away from these groups. The Joondalup Family Health Study (JFHS) will voluntarily be bound by the Federal *Privacy Act 1988* (Cth) (“the Act”) and its ten National Privacy Principles (“NPP”). The NPPs govern how the JFHS must use, keep secure and disclose Study participants’ personal information. The JFHS will also be regulated by an independent JFHS Ethics Oversight Committee and by Human Research Ethics Committees from WA universities and hospitals. Further, DNA and health data will be encoded when stored and analysed, and stored separately from any identifying information.

Under the Act it is illegal to release any medical research information to third parties, such as police, employers, lawyers or insurers except in very limited circumstances. More specifically, the participant would have to consent to have their information released, the release would have to be required or authorized by law (eg by a court order), or release would have to be necessary to prevent or lessen a serious or imminent threat to someone’s life, health or safety. It is important to remember that court orders are not unique to research studies and are used beyond the research study context – it would be illegal for anyone to stop police or other parties accessing anything if a court order is issued.

A further layer of legal protection for participants is expected when WA legislators introduce a state-based *Privacy Act* later in 2006. The JFHS team strongly supports the initiative to create WA’s own privacy legislation. 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 by both laws.

Safeguards will be further strengthened by recommendations newly-adopted by the Federal Government to address genetic privacy concerns. Already, the JFHS will be prohibited under the *Privacy Act* from making unauthorized releases of information. With these reforms however, Australia is set to become the world leader in the legal protections for genetic privacy. Recommendations adopted include making it expressly illegal for employers to unlawfully discriminate against people on the basis of their genetic makeup, and making non-consensual genetic testing a criminal offence. The Federal Government has already established a National Human Genetics Advisory Committee as part of this reform, which will monitor and regulate the use of genetic tests in the life insurance industry. The recommendations were part of a review into genetic privacy issues carried out by the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) regarding genetic privacy issues contained in their major (1,200 page) report, *Essentially Yours*.

For more information, please refer to our briefing document “Privacy and Confidentiality Protections for Participants in the Joondalup Family Health Study” available at www.jfhs.org.au/downloads/jfhsprotections.pdf

In addition to this, the JFHS team plans to exceed the level of data protection set by the current Australian regulations. We are committed to establishing the international best-practice standard in terms of the legal and ethical safeguards in place to protect our future Study participants. The JFHS team has looked closely at other countries that have attempted similar projects, to see where those researchers have been successful and where they could have improved their procedures. We have also been guided by international guidelines and standards from bodies such as the World Medical Association and the United Nations Educational, Scientific and Cultural Organisation (UNESCO).

2. How are longitudinal studies possible on de-identified data?

When we receive any research information from a participant, personal identifiers such as names and addresses are removed and replaced by a study code. Individual research information is entered into a computer data file using that code and becomes what is known as “coded information”.

Researchers using JFHS data will only ever work with this coded information. That is, as they follow the health of participants over many years, they will not know their identities, only their code numbers.

From time to time there may be a genuine need to be able to reconnect a study code number to a name. For example, when participants return for a follow-up health update, their information will need to be correctly placed with any previously collected information. Similarly, if a participant chooses to withdraw from the Study, the JFHS will need to know their study code number in order to find and remove their information from the system if necessary. It may also be necessary if researchers, during their course of their work, find something significant about a participant’s health, the participant can be contacted.

For these reasons, the JFHS will retain an electronic decryption key which will be kept under the highest security conditions. The electronic key will be stored on a network-isolated, encrypted and password-protected computer housed in the secure server room located within the Western Australian Institute for Medical Research. Only authorised personnel can access this electronic key, and this access will require special clearance from the JFHS Ethics Oversight Committee and the signing of an enforceable confidentiality agreement. A similar protocol has served the Busselton Health Study well over the past four decades. The server room is protected by access-card security, has its own uninterruptible power supply (UPS), with closed circuit television cameras (CCTV) both inside and outside the room.

3. What happens if a possible illness is detected?

One of the primary aims of this Study is to provide participants with the opportunity to receive a detailed and informative current “whole health” picture. Consistent with this philosophy, participants who give informed consent will also be informed if researchers identify a current or potential illness during the course of their research. Where appropriate, up-to-date support information can be provided through the JFHS to participants and/or their GPs about management of specific conditions identified as a result of being in the Study.

However, it is the policy of the JFHS that feedback will not normally be given to participants regarding personal genetic research information. This is because the Study will not be testing for specific single-gene (“monogenic”) diseases such as cystic fibrosis or Huntington’s disease. Instead, researchers will be investigating the genes underlying complex diseases such as asthma, cancer, and heart disease. These genes will be of modest effect for each individual, and will generally act in concert with other factors, such as the presence of other genes, the environment, or unhealthy lifestyles, to increase disease risk. The disease risk attributable to each factor will be small, and we do not yet know exactly how these elements all interact, so releasing genetic information would not be clinically meaningful, or useful to the individual.

4. What are the disclosure requirements for participants in relation to health insurance, life insurance or if an illness or predisposition to illness is identified?

Health insurance is different to life insurance. Health insurance covers the costs related to using hospital and ancillary medical and health services. Products from groups such as Medicare, Medibank Private or HBF are some examples of health insurance. Life insurance covers different matters, such as policies that provide payment upon death, continuous disability or trauma.

Participants are not obliged to disclose any feedback they may receive from the Study to their health insurer. Under national health legislation, health insurers must charge the same premium and provide coverage regardless of one’s health. Therefore taking part in the Study will not impact on health insurance.

On the other hand, people applying for life insurance policies have a special obligation to inform their insurer about all information that is known, or which reasonably ought to be known, to be relevant to the insurer. The insurance application form may have questions about illness or predisposition to illness which they would be required to answer truthfully. The form

may also request recent medical test results, which participants may already have from taking part in the Study.

It is important to remember that feedback regarding a participant's genetic research information will not normally be provided to participants, therefore issues relating to genetic disclosure on a life insurance application will not be affected by participation in the JFHS. Furthermore, under the Commonwealth *Privacy Act* (which the JFHS will be bound by) insurers could not approach the Study directly to access any information about a participant's life insurance application.

The Government has also recently supported recommendations to increase the regulation of the use of genetic test information for life insurance. The Government has established a 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. Please refer to our briefing document on JFHS privacy and confidentiality protections for more information (www.jfhs.org.au/downloads/jfhsprotections.pdf)

5. Who will really benefit from this Study?

The Busselton Health Study is a similar study and a model for the JFHS. It is a useful example to highlight the benefits that the JFHS is likely to generate. Without large-scale population based health studies such as the JFHS and the Busselton Health Study, researchers face significant obstacles to generating research breakthroughs leading to new treatments and tests. For example, the Busselton Health Study played a vital role in the clarification of the test for the blood disorder hemochromatosis, which causes iron overload.¹ Thanks to this research, diagnosing hemochromatosis is easier, more affordable and therefore more widely available to the public of WA.

JFHS participants, and/or their GPs, will be able to receive detailed and informative information regarding their current health for a very large number of parameters – including cardiovascular, respiratory, ophthalmic, aural, endocrinological, neurological, rheumatological and lifestyle risks. We also expect that, as in the Busselton Health Study, previously undiagnosed findings will be detected and participants (and/or their GPs), with informed consent can be told about this with a recommendation to see their GP for treatment options. In fact, several studies have shown that the regular surveys in Busselton resulted in improved health outcomes and lower death rates in that community.² However, it will be carefully explained to participants that the Study is a research and not a health-care initiative. Taking part in the Study therefore must not, in any way, take the place of their regular GP care.

Other indirect health outcome benefits have been harder to predict. A notable example comes from one of the 2005 Nobel Prize winners from WA. University of WA researcher Professor Barry Marshall officially launched the Community Engagement Program for the JFHS on

¹ Olynyk JK, Cullen DJ, Aquilia S, Rossi E, Summerville L, Powell LW. A population-based study of the clinical expression of the haemochromatosis gene. *New England Journal of Medicine*. 341(10):718-24, 1999 Sep 2

² Knuiman MW, Clarkson JP, Bulsara M, Bartholomew HC, 'Evaluating the impact of repeated community-wide health surveys on cardiovascular morbidity and mortality in the Busselton population' *Australian and New Zealand Journal of Public Health* 28(3):267-72 2004 Jun.

Knuiman MW, Cullen KJ, Bulsara MK, Welborn TA, Hobbs MS, 'Mortality trends, 1965 to 1989, in Busselton, the sit of repeated health surveys and interventions' *Australian Journal of Public Health* 18(2):129-35 1994 Jun.

November 16, 2005. At the event, he recounted how seeing the success of the Busselton Health Study many years ago gave him the inspiration to conduct an initial community-based study in order to expand his research into the causes of stomach ulcers. His research ultimately led to a Nobel Prize, changed the standard treatment prescribed for these ulcers, and has prevented over 100 million cases of the condition world-wide.

The most important health benefits of this Study may only be realized many years from now, and may largely help future generations. The Study is designed to provide a resource to understand the factors that contribute to complex diseases, such as asthma, cancer, heart disease and diabetes. Through this, there is the potential to develop public health interventions and new medicines as well as improve health-service delivery in the Joondalup community.

Furthermore, the Study is also designed to focus on improving science and health education in schools and the wider community, and to deliver a new model for effective community engagement and health consumer participation in research. These elements are critical to Joondalup residents being able to gain maximum benefit from the JFHS, and to make informed choices regarding this long-term, population-based health study. Our ongoing program of community engagement is designed to result in the Joondalup community being better informed decision makers and health consumers.

6. What governance structures are in place to protect confidentiality?

To express our commitment to setting the international best-practice standard for protecting participants' information, the JFHS has established an internal and external governance framework. This will work in combination with the legal protections in place for participants. For more information, please refer to our briefing document on the privacy and confidentiality protections in place for JFHS participants, available at www.jfhs.org.au/downloads/jfhsprotections.pdf

The governance structure is designed to ensure a high degree of control and transparency. The Study will operate under a charitable trust – the Joondalup Family Health Study Foundation, and very “practice aspect” of the Study (data collection, encoding, custody, research etc) will fall under the jurisdiction of at least one of the following key governing bodies:

1. JFHS Scientific Advisory Committee
2. Ethics Oversight Committee/Human Research Ethics Committee
3. JFHS Board

Scientific Oversight

Bona fide medical researchers wanting to use JFHS data will need clearance from at least three committees, one of which is the JFHS Scientific Advisory Committee. This Committee will consist of eminent senior researchers and health professionals. Its role will be to evaluate whether the proposed project looks at a legitimate scientific question and has a health objective acceptable to the greater community.

Ethical Oversight

In addition to scientific approval, researchers will need ethical clearance from at least two ethics committees. Ethics committees are constituted and operate under the NHMRC's [*National Statement on Ethical Conduct in Research Involving Humans*](#) (1999). Their role is to

prescribe the ethical standard of conduct that researchers must meet before they can conduct any research or access any Study data. For example, the ethics committees will ensure that any research proposing to use JFHS data will not impose an unfair burden on certain groups of participants. They are also responsible for ensuring that researchers have sufficient measures in place to protect participant privacy. (These ethical standards are always at least as, if not more, strict than any applicable legal standards).

The ethics committees are also responsible for monitoring the conduct of researchers once clearance has been granted. If, at any time, researchers do not meet these ethical 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. This 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 of not just doctors or medical researchers, but also lawyers, social workers and, importantly, Joondalup community representatives. Every researcher wishing to use JFHS data will need clearance from the Ethics Oversight Committee, which also monitors the JFHS' day-to-day operations. These researchers will also need to show ethical clearance and monitoring by the ethics committee of their own home institution(s).

In addition, the Human Research Ethics Committees of WA universities and hospitals will provide external oversight over the collection and handling of data by the JFHS itself. Our universities and hospitals have had, and continue to have, leading roles in medical research in WA. They have a history of "best practice" in relation to ethical research in WA, including proper protection for data. The JFHS will continue to have access to their assistance in relation to data protection, legislative changes and standards in medical research.

The JFHS will also be incorporating other measures to protect participants. For example, to ensure that participants' privacy is protected at every stage, the individuals who collect the data will not be the same individuals who encode the data. Further, as a baseline, all personnel involved with the JFHS must sign an enforceable confidentiality agreement. This binds them to respect the confidentiality of the information they will work with and to abide by a stringent Code of Practice.

JFHS Board

The JFHS Board of Trustees will have the overall decision-making authority over access to and use of the JFHS resource. Its aim is to ensure an overall commitment to the spirit of the Study, that is, the advancement of medical research and knowledge. This independent board will draw from the expertise of prominent leaders within the Western Australian academic, health, medical research and general business community.

7. How long does the study period extend and for what period is consent given?

We want to be able to revisit the Joondalup community for regular health updates for as long as we possibly can. Untangling how genes, environment and lifestyle interact to cause disease – and developing medicines and public health interventions using this information - will be a long-term process. It can take many years, so we would like participants to be part of the Study

for as long as possible and to agree to being regularly re-assessed. As such, consent for research will extend for the duration of the Study.

The JFHS will be asking for the participants' informed consent when they first join the Study, and again every time we revisit participants for a new health survey. However, if participants wish, they may change their consent preferences or withdraw from the Study at any time.

8. Will participants be able to give informed consent, and withdraw it later?

Yes. People who volunteer to be part of the JFHS may withdraw at any time and can choose to have their information removed from the Study if they wish. Of course, if the information was part of a research study that has already been published, it cannot be taken out of the analysis for that publication. In any case, identifiable names would not have been used.

9. How can participants make sure that their information is no longer being used if they withdraw from the Study?

Commonwealth privacy legislation (which the JFHS will be bound by) and the stringent JFHS governance framework will ensure that researchers will not use research data from participants who inform the Study team that they no longer want their information used.

Firstly, under the Commonwealth *Privacy Act*, the JFHS would be prohibited from continuing to use a participant's research information while knowing that they no longer want their information used. The Act also provides legal remedies to a participant if they believe their personal information has been mishandled.

In addition, as mentioned above, at least two ethics committees will closely monitor researcher conduct. Researchers risk having their funding cut off, their research project terminated, being reported to their home institution and their access to the JFHS data permanently barred by the ethics committees if they are found to be using data improperly.

Finally, the Commonwealth Government has approved recommendations to make non-consensual genetic testing of samples a *criminal* offence – not only for the person conducting the test, but also the third party who submits a sample for testing without consent from the person from whom the sample was taken.

10. What about commercial use of data or use by third parties?

Ultimately the results of JFHS research will assist drug companies and other industry groups to develop new therapies and improve existing therapies. Drug companies rely heavily on research breakthroughs from major studies such as the JFHS, as a launching point to develop new medicines. As the group who actually produces medicines, drug companies play an important role in “bringing science to the bedside”. That is, translating research breakthroughs into tangible improvements in people's health outcomes.

However, the JFHS resource at its core belongs to the Joondalup community. As such, raw research data or samples will not leave WA and will not be sold to any third parties.

Rather, the JFHS may collaborate with industry groups within strict guidelines and only with approval from the JFHS Ethics Oversight and Scientific Advisory Committees. To control the way the research data is used, individual data as well as raw data will not be made available to industry groups. JFHS researchers will analyse the data 'in-house', and industry groups will be provided only with the summarized results of this analysis. That is, the results given to industry will be at the population level, not at the individual level.

Industry collaborators will be obliged to pay a fee and to share any intellectual property generated with the JFHS. Any funds generated through industry collaboration will be used to support medical research, educational programs, and community programs in the City of Joondalup, and to cover the costs of maintaining the JFHS resources.

11. If the information will be available to third parties what contractual arrangements, including penalties, will be in place to ensure the information is used in accordance with the participant's consent?

Bona fide medical researchers wishing to use JFHS data must sign a legal agreement which sets out what they can and cannot do with the data, according to the participant's consent. If they do not comply with the agreement, the JFHS reserves the right to impose heavy penalties on the researcher, permanently bar them from any access to the database, have their ethics approval withdrawn (and their project then terminated), and/or report their conduct to their home institution or employer. These penalties will be in addition to the legal remedies under the Commonwealth *Privacy Act* mentioned above.

12. Will JFHS participants have a say in what research gets priority?

It is the intent of the JFHS team to ensure that the Joondalup Community have the maximum possible say in what research gets priority.

The JFHS team has spent the past five months investigating what people living in the City of Joondalup think about taking part in a proposed Family Health Study in the area, with a view to ensuring their needs, wants and concerns are addressed. To our knowledge, this is the most comprehensive public consultation process ever undertaken anywhere in the world for a study of this nature. Furthermore, members of the Joondalup community will sit on two of the Study's core governing bodies to ensure that the Study remains accountable to the community and the wishes of the community are reflected in the Study management.