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Submission to the

Australian Law Reform Commission

regarding their discussion paper on the

Protection And Use Of Human Genetic Information.

By

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And

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For and on behalf of the

Androgen Insensitivity Syndrome (AIS) Support Group Australia.

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ABOUT THE AIS SUPPORT GROUP AUSTRALIA (AISSGA) AND THIS SUBMISSION.

The Androgen Insensitivity Support Group Australia (AISSGA) is a long-established, self-funded peer support group run by volunteers for those with intersex conditions, their parents, families and partners. Intersex conditions may be broadly described as conditions that result in the birth of a child with a condition able to be medically identified at birth that results in anatomical or biological sex differentiation that varies from that most commonly found in male and female births. These variations specifically relate to reproductive organs and/or sex chromosomes and do not include those born completely male or female physically but with the 'brain sex' of the opposite gender. Thus, care should be taken not to confuse intersex conditions with transsexualism, particularly as some transsexual people make erroneous claims in this area. Intersex was previously known as hermaphroditism and is as common as 1 in 1000 births.

The role of the AISSGA is to provide direct support and information, contact with others, contact with the medical profession and advocacy services. Our membership includes medical practitioners considered by the AISSGA to provide best practice treatment of members, particularly those that challenge older inappropriate practices by advocating full disclosure to patients about their condition and challenging early surgical based intervention. Our membership also includes genetic counsellors and geneticists. We have strong links with the Genetic Support Network of Victoria, the Royal Children's Hospitals in Melbourne and Brisbane, the Mater Children's Hospital in Brisbane and the various other paediatric hospitals around Australia.

The AISSGA has a direct interest in the outcome of discussion, formulation and any guidelines regarding the use, or ultimate statute protection of, genetic information. Those with intersex conditions have the same ultimate desire as most others in the general population, that of being able to live without fear of discrimination or identification on the basis of their medical condition.

This submission has been prepared to outline the points of view of members of the AISSGA about various issues raised by the ALRC inquiry into safeguarding the use of human genetic information. On the whole, the committee of the AISSGA supports the proposals put forward in the discussion paper and are pleased to submit any comments or exceptions in this submission as detailed below.

We would like to thank the Federal Government and the ALRC for conducting such an inclusive, detailed and thorough community consultation on this very important and difficult issue.

ABOUT THE AUTHORS.

Andie Hider is the current second term Secretary and Medical Liaison Officer of the AISSGA. She has formerly held positions as the State Representative of the AISSGA for a number of States. Andie represents the AISSGA on medical projects and is the principal AISSGA point of contact for the medical profession. Andie is a tertiary qualified mechanical engineer with a defence science related research background and she also has completed postgraduate subjects in science and law. She is also a harassment contact officer for her employer.

Tony Briffa is the current third term President of the AISSGA. He has previously held other positions on the support group's committee, including that of Secretary. Tony represents those with intersex conditions on Government and other advisory committees and was instrumental in various legislative changes in Australia including anti-discrimination legislation providing protection for those with intersex conditions. Tony has wide experience as an advocate for those with intersex conditions, being quoted in many magazine and newspaper articles about the subject and appearing on television and radio. Tony is also a community representative on the Western Health Ethics Committee and Treasurer of the Genetic Support Network of Victoria. Tony is a tertiary qualified engineer with considerable experience in the aviation industry and with a broad technical background. He is also a foster parent

STANDING ADVISORY BODY ON HUMAN GENETICS

The proposal that a Human Genetics Commission of Australia (HGCA) be established to oversee genetics related ethical and legal issues and provide advice to Government and other bodies is supported by the AISSGA, as long as includes wide legal, medical and consumer based membership to ensure all issues are considered in the widest possible light.

The Centre for Law and Genetics has suggested that responsibility for considering legal and ethical issues arising from the use of genetic information might lie with them or a similar group via the mechanism of a watching brief. Committee members of the AISSGA recently attended a symposium organised by the Centre for Law and Genetics, Breaking the Code, at which it became very apparent that the views of community and genetic support and information groups, such as the AISSGA, would virtually be ignored by such an approach. Whilst the concept of the symposium was excellent, not a single representative from any one of the vast number of genetic support and information groups were asked to speak and none of the papers presented considered the needs of consumer groups from an experiential point of view.

Abstract legal and ethical discussions are a necessary and important part of consideration of the wider issues involved in the use of Human Genetic Information. In the view of the AISSGA, however, these discussions should always be balanced against the experiences of those for whom issues such as genetics based discrimination are already a reality.

We can also see the benefits of establishing separate Technical and Ethical/Social committees within any Human Genetics Commission, however, it should not be the case that they operate entirely independently of each other.

Ensuring that meetings of both the Technical and Ethical/Social committees are open to the public, will ensure not only transparency of the proceedings but the potential for experts that may not form part of a committee to have a say about issues being discussed. Making known in advance subjects and issues for discussion at the Commission, would ensure widest possible consultation amongst genetics support and information groups and medical/scientific experts alike.

Quality assurance reviews of HREC decisions as a standing agenda item of the Human Genetics Commission, might also be a way of reinforcing the appropriateness of such decisions in the view of wider genetics support and information and medical/scientific groups.

HGCA, AHEC, peak medical associations and bodies and genetics information groups should be responsible for developing standards for all genetic tests, including those used for insurance, employment/OH&S, population screening, familial testing, parentage testing, immigration, aboriginality, law enforcement and civil proceedings. HGCA and AHEC should responsible for regulating and the use of established test standards and tests not conducted in compliance with the standards should be unlawful.

REGULATING ACCESS TO GENETIC TESTING

Overall public confidence in the use of human genetic information will depend to a large degree upon the generally perceived accuracy of the technology associated with it. Given the wide spread interest in human genetic information and the uses of that information, media organizations have traditionally seized upon any instances where the use of this emerging technology has been controversial.

External accreditation of testing authorities, ensures a degree of transparency and independent review that not only goes some way to enforcing an industry standard but also being *seen* to conform to a national standard in the eyes of the public generally. The view of the AISSGA is that all laboratories conducting genetic testing should be NATA accredited.

It is very unlikely given the exponential increase in the desire to access this technology, that all laboratories offering access to genetic testing will seek regulated external accreditation with NATA. Making legally inadmissible any genetic test carried out by a non-accredited testing authority would achieve the two-fold aims of ensuring accuracy of genetic tests put before tribunals of fact and a high degree of compliance with regulated external accreditation, if only because of the commercial ramifications of not doing so.

There is an argument that to insist on NATA accreditation by all testing authorities would mean increased costs for customers thus limiting access to the technology. This cost must be weighed against the overall damage to the technology if customer and wider public confidence in the use of human genetic information is affected.

The AISSGA also believes, as outlined in our previous submission to this inquiry, that the use of human tissue samples for any form of genetic testing without express consent, is not ethically defendable given current ethical and social standards. For this reason we believe that the consent of the person from whom a sample is taken should be given by the person from whom it came, or from both parents of a child where testing is to be carried out using a sample from a child. We believe this should also be the case where genetic testing for parentage is conducted.

It is probably impractical to completely regulate Home DNA tests given the proliferation of organisations offering such tests over the internet. A standard of practice developed by an HGCA, including making such tests inadmissible in tribunals of fact, would go a long way to maintaining the integrity of human genetic testing as a science.

There would be many difficulties associated with prosecuting an offence for the submission of genetic material without consent, however, there is no doubt the existence of such an offence would act well as a general deterrence.

INFORMATION AND HEALTH PRIVACY LAW

Codification of law has occurred in Australia in many areas of civil and criminal law. Not only does codification simplify application of the law but prevents "legislative shopping" between States. Respective State human tissue Acts generally reflect a codified approach to legislation, but truly harmonised legislation in respect to the use of human genetic information is still some time away. Having Commonwealth and State genetic privacy legislation that mirrors respective approaches to the issue of privacy of human genetic information, is the best way of ensuring there is no ambiguity when considering the complex issued involved.

Amending the Privacy Act 1988 (Cth) to expressly define and regulate human genetic information is an excellent first step to providing a consistent approach to genetic privacy issues. At the very least, such amendments will provide a fallback position to regulate the use of human genetic information where State legislation fails to do so. In considering the technical detail of legislative amendments, the Privacy and Information Protection Act 1998 (NSW) might be considered as a starting point from which to draft appropriate legislation, but the view of the AISSGA is that any legislative reform should be uniquely and specifically drafted with the privacy of human genetic information in mind. The President of the AISSGA has recently been involved in obtaining assurances from the QLD Attorney General because of a similar well intentioned but misguided attempt to enact legislative reform using NSW legislation as a template. Whilst the spirit of the QLD legislation involved was to improve human rights for minority groups, inappropriate consultation resulted in the potential for erosion of human rights for people born with intersex conditions.

Paramount for any piece of legislation that might involve investigation of breaches of privacy relating to human genetic information, is ensuring that handling of complaints, investigations and any subsequent prosecutions are conducted in such a way that further breaches of privacy do not occur. To this end it may be appropriate to have such complaints investigated under specific HGCA guidelines by appropriately trained investigators and then heard by a tribunal having specific expertise in this area of the law, once again operating to strictly established procedures.

It is currently the case that Australia does not allow extradition in cases where legislation is not reciprocal, for instance political offences, or where the death penalty is applied to an offence. If we are going to allow export of human tissue samples, the same reciprocity of law should apply especially since a general principle of informed consent for the use of such samples should apply. The alternative is to require express informed consent of the person providing a sample that allows export to a country that does not have the same regulatory framework as Australia.

Except on very rare occasions, genetic information is always going to be about the health of a person regardless of the reason it is obtained. Amending the Privacy Act so that the definition of 'health information' includes genetic information 'whether or not the information is collected in relation to the health of, or the provision of a health to, an individual' is something the committee and members of the AISSGA would fully support.

Recent amendments to privacy legislation to additionally regulate private sector organisations, have added vitally needed accountability for information they have about individuals. Groups like the AISSGA have operated subject to our own very strict internal privacy guidelines irrespective of external regulation; however, it has not been our experience that other groups or indeed other professionals operate in such a manner. Increasingly, small businesses are offering testing for genetic information or are keeping human genetic information. Amendments to the Privacy Act that include small business operators should be seen as a vital part of reducing the temptation to use information in an unethical manner and to maintain public confidence in privacy legislation and regulation.

ANTI-DISCRIMINATION LAW

Established procedures currently exist for dealing with various forms of discrimination attributes prescribed in State, Territory and Federal legislation. Enacting legislation that mirrors existing legislation to deal only with genetic information would be cumbersome at the very least. Adding specific attributes for human genetic information and medical record to all Australian anti-discrimination legislation would provide a more workable solution that attempts to prevent discrimination on these grounds.

It is important to consider language when discussing legal issues, both because of the sensitivities involved and because it affords easier identification of legal protection for those persons unaccustomed to using the law. Amending Disability Act titles to include the attribute 'genetic' would allow both an easier understanding of the purpose of such acts and recognise that **those who possess such variations consider not all genetic variations disabilities.**

As a general comment, including discrimination on the basis of association with a person with an impairment or disability is a worthwhile and probably overdue addition to anti-discrimination legislation. This is particularly important in the case of those caring for a person with a disability or medical condition.

ENFORCING COMPLIANCE WITH THE NATIONAL STATEMENT

Consideration of ethical standards, without a statement of generally accepted ethical principles, becomes mired in subjective comparisons of personal moral standards against any given set of circumstances. The National Health and Medical Research Council Act 1992, attempts to provide a national set of standards for human research in Australia. The NHMRC National Statement on Ethical Conduct in Research Involving Humans acts as a practical guide against which intended research should be measured by HREC. In the ten years since the NHMRC Act became law, advances in genetic science have been manifold and could not have been foreseen by those drafting the legislation. Compliance with the NHMRC Statement for anyone conducting genetic research should be the minimum required standard.

Members of the AISSGA believe that in the current ethical and social environment informed consent for research should apply to any human tissue sample used for research and that the NHMRC National Statement should be amended to reflect this. The AISSGA believes it unacceptable that samples provided for other purposes are being used for research without express consent.

Central to any discussion about human genetic research is the definition of such research. The AISSGA submits the following as our view of the definition of human genetic research.

Human genetic research is any research, whether or not such research uses human or other tissue, the outcome of which either by design or consequence:

- *Identifies genetic information that applies or is likely to apply to the entire human genetic profile, and/or;*
- *Identifies genetic information that applies or is likely to apply to a single person or group of persons, and/or;*
- *May be used for identification, testing, modification or confirmation of existing human genetic information or genetic expression.*

Where any research body fails to comply with national standards regulating genetic research they are damaging not only their own reputation and that of the scientific community in general, but eroding public confidence in a system designed to represent the public interest when such decisions are made. Failure to comply with the national standard should result in any organisation that conducts genetic research being prohibited from conducting any further research.

HUMAN GENETIC RESEARCH AND CONSENT

As a general rule the AISSGA submits that HREC should never provide a waiver of consent under the NHMRC National Statement. We recognise, however, that such a prohibition would present considerable difficulties in some circumstances. Given the point of view of our members, we do not consider it inappropriate that HREC provide written advice to AHEC and the proposed HGCA within 28 days of making a decision to grant approval to conduct research with a waiver of consent.

Reports to AHEC and the HGCA should include information provided by the research applicant to the HREC that addresses all relevant criteria for seeking access without consent. Any circumstance where HREC have approved research without express consent and where approval was granted without addressing specific criterion should be the subject of a variation report detailing the reasons why such approval was granted outside the guidelines.

The view of the majority of AISSGA members is that human genetic information should be granted specific legal protection. Generally speaking, however, the National Statement and Privacy Act guidelines provide adequate protection when considering the use of the human genetic information for research. As a general rule though, we do not believe consideration of the financial burden for failure to grant permission for research a valid measure of the importance of granting approval.

As stated in our initial submission all human tissue samples obtained where there is any possibility they may later be used for research unspecified at the time of collection, should require consent for that unspecified use if even in general terms. It is certainly not defensible in our opinion to obtain human tissue samples for reasons other than research and then use these samples for research without consent for research later being obtained in some form.

ENCOURAGING BEST PRACTICE IN HUMAN GENETIC RESEARCH

AHEC and the proposed HGCA should, as a priority, establish model research protocols for human genetic research. HREC provide a good measure of ethical consideration to proposed research, but they are far from the social conscience they need to be, considering the wide social application of emerging genetics issues. Having AHEC and the proposed HGCA develop a 'standardised' consent form as part of the overall research model would provide important safeguards at the initial stage of all research. Given that the nature of initial consent to use human tissue for research is likely to generate the greatest number of complaints, standardising the requirements for initial written informed consent is a crucial first step to safeguarding public confidence in the HREC system.

STRENGTHENING REVIEW BY HRECS

HREC are a crucial part of the ethical checks and balances applied to applications for research. Their role and composition, however, have remained largely unchanged since their widespread introduction despite considerable advances in the areas of scientific research they consider.

As mentioned earlier in this submission, we believe that all instances of approved research where consent is not specifically obtained, should be reported to AHEC and to the proposed HGCA. Likewise, we believe that any instance where commercial interests are involved in research using human tissue this should be reported in the same manner.

HREC should be empowered and resourced to provide on-going monitoring of research projects using human genetic information. Aside from the need to actively monitor the research in light of contemporary ethical issues, there is another emerging commercial trend that is causing considerable concern to many researchers and genetics groups. Some private companies have begun to actively seek

out genetic research conducted by public institutions that may have a commercial application. Once the research is at a stage where it is becoming clear a commercial application is viable, companies provide "grants" to complete the research providing the research outcomes then become the intellectual property of the company providing the financial support. In this way, much research conducted by public institutions becomes commercially owned intellectual property late in the life of the research project and no longer available publicly in the way it would otherwise have been. The practice of providing financial support for research in this way has been described by some researchers as "genetic piracy".

HREC should have the power in such circumstances to stop research at the point this is going to occur and refer the matter to both AHEC and the proposed HGCA for consideration. As a minimum, companies that engage in this type of behaviour should then have to refund all research costs to date to the public institution involved and be licensed to use the intellectual property rather than owning it. It is vital for such a system to work for HREC to have an ongoing monitoring and regulatory function.

HUMAN GENETIC DATABASES FOR RESEARCH

Public knowledge about and interest in scientific and medical research is increasing by the day. Inevitably, negative publicity surrounding research generates more public interest than does publicity about ethically sound research. There has been much negative publicity about human tissue collections built up around what the AISSGA referred to in our previous submission as "Grey Samples". A national standard that regulated collection of human tissue samples and the subsequent use of genetic databases would go a long way to maintaining the generally high public and professional opinion of human genetic research.

Amending the NHMRC national statement to provide ethical standards for the operation of human genetic research databases would provide a valuable ethical base-line against which the operation of human research genetic databases could be measured. Already used by HREC in such a way, the national statement would then encompass all steps of the research process.

All genetic research databases should be licensed, including those used for law enforcement purposes. There should also be a general legislative prohibition on the use of human genetic information for research or law enforcement purposes that has not originated from a licensed source.

Any collection of human genetic information that is not used solely for direct and immediate feedback to patients in a clinical environment, should be considered a genetic research database, including databases used for quality assurance purposes or law enforcement. Institutions should provide regular reports to AHEC and the proposed HGCA about use of information from human genetic research databases and auditing of use should be a subject of any licensing arrangement.

Information in human genetic databases obtained for research purposes or as part of population screening should be prohibited from use by law enforcement agencies except in the case of disaster victim identification (DVI).

HUMAN TISSUE COLLECTIONS

Every paediatric and children's hospital in Australia, currently keeps information on Guthrie cards and have done so for many years. There are millions of such cards Australia wide and the amount of information potentially available on them is substantial. Information contained on Guthrie cards has in all cases been obtained without the consent of the person to whom it directly relates.

We believe that information on Guthrie cards should not be available for law enforcement purposes except for DVI. There is no way of arguing from any reasonable point of view that such information has been obtained with anything like the consent usually required before any information can be used for law enforcement purposes other than if a person is deceased. Even in cases where Guthrie card information is used for law enforcement purposes, any familial or genetic information that relates to the deceased should be destroyed once the DVI has been confirmed beyond any reasonable doubt.

We support the proposal that the Australian Health Ministers Advisory Council (AHMAC) in collaboration with key medical professional bodies legislate to regulate the use of human tissue samples, regardless of the use of those samples.

OWNERSHIP OF HUMAN GENETIC SAMPLES

The argument over ownership of human tissue samples is complicated and there are many different ideas about ownership of human tissue put forward. The AISSGA believes that limited individual rights to ownership of human tissue samples by the person from whom the sample is taken should be the case. Such rights should not extend to individual sale of personal tissue (except in limited cases as described in State and Territory Human Tissue Acts) and should allow retention of preserved tissue samples by hospitals where such samples are not used for medical or scientific research. The only exception to such a rule would be if the individual has given fully informed consent for the sample to be used for research.

HEALTH PROFESSIONALS AND FAMILY GENETIC INFORMATION

Genetic conditions evoke a range of emotions from those who have a genetic condition, are related to someone that has one of the conditions, or live or care for someone that has a genetic condition. Most people have also at some time in their lives imagined what it must be like to live with a genetic condition, including many in the medical profession. In many cases though, the perceptions of those who do not

have a genetic condition vary greatly from those who live with the condition itself. In some cases, health departments list as serious conditions that have little or no bearing on the quality of life of those with the condition simply because it is easily tested for and identified. Clearly the definition of a serious medical condition varies according to the point of view from which it is considered. Amending NPP so disclosure of a genetic condition can take place where failure to disclose would place health or life of a genetic relative at serious risk is an admirable idea in theory, in practice though such a condition would be very difficult to clearly define.

As an example, it could be argued that a person (either male or female) born with an intersex condition such as Androgen Insensitivity Syndrome (AIS), therefore with an XY chromosome pattern, infertile and with a reduced (if not absent) response to androgens, has a serious medical condition that would place health or life of a genetic relative at serious risk. It is sometimes the case that the emotional strain of coping with information about AIS is considerable, both for parents and for the person with the condition. The risk to the actual physical health of the parents or the person with AIS, however, is virtually non-existent and appropriate counselling and information virtually eliminates any psychological effect of the condition. Many people with AIS do not want their condition disclosed to other family members. This is further complicated because approximately one third of all cases of AIS result from a spontaneous mutation and has no impact on other family members.

To propose disclosure in such circumstances, a list of genetic conditions considered to be such that they "would place health or life of a genetic relative at serious risk" would have to be established. Establishing such a list could be done only after very careful consultation with medical professionals that specialise in those genetic conditions, people that live with the conditions and the parents of children with genetic conditions that have received appropriate medical support. Even were this list established, the severity of many genetic conditions varies from family to family and from person to person so consistent application of this test to determine if disclosure is appropriate would be difficult.

Ideally, Commonwealth Privacy legislation should regulate disclosure of medical information to family members. If such a solution is unworkable, then there should be a ban on disclosure until such time as State and Territory Governments develop mirror legislation in concert with bodies such as the NHMRC an the proposed HGCA.

We agree with the proposal that the NHMRC should develop guidelines for medical practitioners that address disclosure of and access by family members to genetic information. We would also suggest that the HGCA be involved in drafting any guidelines to be used in this way.

GENETIC REGISTERS AND FAMILY GENETIC INFORMATION

Genetic registers and family genetic information have the potential to provide valuable assistance understanding the familial incidence of genetic conditions. Pedigree established via this same

information also greatly assists genetic counsellors provision of accurate information about the nature and likelihood of the physical manifestation of a genetic condition in genetic relatives. Conversely, the information is also intensely private in nature, can be very damaging if not used appropriately in explanations of genetic conditions and has the potential to seriously impact upon the privacy of family members who do not wish information about themselves given to other family members.

The AISSGA believes that genetic registers and family genetic information should be exempt from privacy principles only where they relate to medical conditions that pose a serious risk to the health or life of genetic relative as described in the proceeding section or only where specific permission has been given for the information to be obtained or disclosed. As with the proceeding section we believe that any exemptions under privacy legislation to disclose or obtain information, including from other medical professionals, should be specific to a list of appropriate conditions and regulated by legislation.

GENETIC COUNSELLING AND MEDICAL EDUCATION

Committee members of the AISSGA have attended various meetings with State and Federal Government representatives where the issue of Genetic Counselling has been discussed. Given the widespread acceptance of genetic medicine into medical practice, very few would argue against the need for more genetic counsellors or for appropriate standards for genetic counselling as a profession.

We fully support any proposal that will increase access to genetic counselling, particularly a proposal that includes standardisation and registration of Genetic Counselling professionals. There exist currently within Australia, recognised Genetic Counsellors that have undergone extensive graduate and post-graduate training. The Royal Children's Hospital Melbourne has a well-established training program for Genetic Counsellors that is well regarded amongst the medical community.

We support the proposal that the HGCA work with established and recognised Genetic Counsellors, Clinical Genetics Services, appropriate training establishments and genetics information groups to develop guidelines for provision of Genetic Counselling and appropriate standards for Genetic Counsellors. In many cases, genetics information groups such as the AISSGA will have lists of Genetic Counsellors able to provide advice to the HGCA about various issues.

We also support proposals that would introduce and enhance clinical genetics, genetic counselling and genetic ethics training to medical practitioners at graduate and post graduate levels. Medical practitioners should have at least a base level genetics qualification before they are able to provide genetic testing on behalf of and subsequent results to their patients.

GENETIC DISCRIMINATION IN INSURANCE

Of the all contexts in which the potential for genetic discrimination is most often discussed, insurance and employment are the most frequently mentioned. Not only are insurance and employment practical aspects of every day life in Australia, there have emerged strong social conscience arguments about those who for various reasons do not have insurance or are not employed. Although most of the insurance arguments have been generated because of Federal Government moves to "encourage" all people over the age of 30 to take our private health insurance policies, it is likely that other types of insurance will become topics of discussion if the current trend to reduce social services continues.

Irresponsible use of genetic information by insurers has the potential to be very damaging to both ethical and financial social structure. Experience of members of genetics information groups like the AISSGA is that insurers often have little or no idea of the actual risks involved with insuring someone with a genetic condition. It is clear that some sort of external standards need to be developed, adopted and regulated. To this end the AISSGA fully supports HGCA monitoring of insurance use of genetic information.

Of the proposed models we have heard suggested, the two-tier system as adopted in the United Kingdom seems to us the fairest system. Aside from providing safeguards for insurers and those seeking insurance, it will also minimise the need to undertake genetic tests and to consider a number of other genetic disclosure issues such as disclosure of genetic tests on children and the results of taking part in research. We believe that adults should not have to disclose information obtained as a result of genetic tests that they did not consent to as children. There are also circumstances where a person might wish to take part in genetic research, but is reluctant to take part in the research or take advantage of any benefits of that research because of the implications of having to disclose outcomes they learn as a result. A two-tiered system provides a safeguard for parents who wish to consent to genetic testing for their children, for that child as an adult and also for those people who wish to take part in genetic research as only those people seeking unusually high insurance cover would have to disclose the results of genetic tests.

No predictive genetic tests should be used by anybody if they are not carried out in accordance with established test procedures by NATA accredited laboratories. Many organizations require that their employees undergo workplace drug testing, this is done by accredited laboratories using well-established procedures and completely independently. Insurers who underwrite mutually agreed insurance policies on the basis of clients who are willing to undergo genetic testing should have to abide by a similar process, ideally processes established by the HGCA.

We do not believe that it is acceptable to use the medical history of any person not a party to an insurance policy. Family medical or genetic information should not be used to underwrite insurance policies as it provides medical information about other family members not a party to the policy.

If insurers are allowed access to genetic information then they should have to fully explain in writing reasons for not providing insurance on the basis of that genetic information. Any such explanation should include the statistical basis for arriving at a decision and all information relating to that risk

assessment should be available upon request of the applicant. Reviews of unfavourable decisions where requested by an applicant should be conducted by an independent body of appropriately qualified members, not insurers. Findings should provide binding precedents that prevent that or other insurers from assessing subsequent applicants based on the same erroneous information.

Many problems encountered with insurers by members of genetic support and information groups such as the AISSGA, are because of a complete lack of understanding of the actual risks associated with having a genetic condition. Many insurers, upon hearing the name of a genetic condition they have no information about, simply refuse to provide a policy rather than researching the condition named in the application. Insurers should have to provide training for staff and assessors regarding the use of genetic information for any purpose.

The AISSGA cannot stress enough the problems associated with groups, including insurance companies, assuming all genetic conditions are 'defects' and physically and/or mentally disabling. Conditions such as AIS do not result in disabled or otherwise 'defective' people.

INSURANCE AND GENETIC PRIVACY

Genetic information is very sensitive by nature of not only that which can be substantiated but that which is implied. Consent allowing others access to personal genetic information should not be considered lightly and only when fully informed.

Consent forms provided by insurers should provide accurate, concise and up to date information so that consent to access genetic information is fully informed. If necessary, insurance consent forms should contain advice suggesting an appropriate medical practitioner explain the contents if there are any doubts about the document.

The practice of blanket or bundled consents should not be applied to genetic information. It should be clear where a person consents to their genetic information being used for any purpose, the purposes for which the information can be used and any other person to whom the information can be disclosed. A person who gives consent for access to their genetic information should also have the option of specifying the purpose or purposes for which the consent is given, not the all or nothing approach offered by blanket consents. They should also be told that they could withdraw their consent at a later date.

GENETIC DISCRIMINATION IN EMPLOYMENT

There are many circumstances where genetic information could be relevant to employment, especially now that employers are seeking to use genetic information to meet duty of care obligations to employees and the public. The AISSGA believes, however, that employers should never have direct access to

genetic information about their employees. We believe that detailed job descriptions should be provided that include health risks associated with the position and a certificate of fitness should be provided by an appropriate medical specialist after genetic tests have been carried out if appropriate. In addition to using this approach to determine medical fitness for a position, we consider that this approach should be extended to OH&S screening in the workplace. Our reasons for this approach were detailed in our first submission to the ALRC and AHEC inquiry.

INHERENT REQUIREMENTS OF THE JOB AND RELATED ISSUES

It is precisely because of the apparently predictive nature of genetic information that we need to exercise the utmost care when considering using genetic information for employment purposes. As with other attributes in equal opportunity legislation, only current ability to perform inherent requirements of the job should be considered but the temptation is to use genetic information to predict future ability (or inability) to undertake particular occupations. Amending the DDA, Equal Opportunity and Workplace Relations legislation to clarify the meaning of the term 'inherent requirements' to limit application to current ability would remove any temptation to misuse or misinterpret the legislation.

Provision of clearly defined job descriptions by employers is an integral part of any approach that relies on assessment of the competency of an applicant or incumbent for a particular role. We support the proposal that peak employer associations should encourage members to produce clearly defined job descriptions for all positions in the workplace, but believe this information should be provided to a medical practitioner to determine if an applicant or incumbent is medically suitable for a position as described previously.

EMPLOYMENT AND GENETIC PRIVACY

The AISSGA believes that employee records should not contain genetic information under any circumstances. As per our earlier comments, we believe that employees should only provide a certificate of fitness for a particular role. There should be no reason to have any medical information on medical files other than medical certificates for absences from the workplace or certificates of fitness to undertake a particular role. Adopting such an approach would eliminate the need to amend privacy legislation in relation to medical or genetic information in employment records as there would be no need to keep such information on file.

HARMONISATION OF FORENSIC PROCEDURES LEGISLATION

For a country with a relatively small population, Australia is legally characterised by legislative inconsistencies. Like all legislation in Australia, Forensic procedures legislation should be consistent across all States and Territories. Sharing of information should only take place after consistent

legislation is enacted in all jurisdictions and sharing arrangements should be clearly defined in legislation. Legislation should also prevent use of genetic database information obtained from someone other than as a suspect being used to compare with suspect DNA.

CRIMINAL INVESTIGATIONS

As detailed in our first submission to the ALRC/AHEC inquiry, the AISSGA believes that consent provisions should be removed from forensic procedures legislation due to the complex nature of genetic information and arguments that truly informed consent would be impossible to obtain. Exceptions in relation to volunteers should be exercised only with a full description of the forensic procedure to be undertaken and the ultimate disposition of any samples taken.

There are many forensic procedures that have a legislated requirement to destroy forensic material once it is no longer required. Destruction in such circumstances is physical destruction and procedures are in place to ensure that all samples are physically destroyed. It has been suggested that the complete physical destruction of DNA samples would be virtually impossible, however, there are many practicalities that cause problems for the destruction of other forensic material but all reasonable effort must still be made to destroy those samples.

CRIMINAL AND CIVIL PROCEEDINGS

The AISSGA fully supports all proposals in relation to Criminal and Civil proceedings especially those that are intended to provide education to members of the judiciary and legal professions in relation to genetics issues. The AISSGA maintains that the only way to prevent the proliferation of mis-information about genetics issues is to ensure widest possible education about genetics.