



the **Australian Society** for **Medical
Research**

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March 18th, 2002

The Executive Director
Australian Law Reform Commission
GPO Box 3708 Sydney 1044

Dear Sir,

Re: Protection of Human Genetic Information Issues Paper

The Australian Society for Medical Research (ASMR) is the peak body representing health and medical researchers. In addition to direct membership, ASMR represents the sector through 42 affiliated professional societies and Medical Colleges, representing some 15,000 people actively involved in health and medical research in Australia. In addition, corporate and disease related foundation memberships bring a further 85,000 Australians with an interest in health and medical research into association with ASMR. ASMR's mission is "to foster excellence in Australian health and medical research, and to promote community understanding and support for health and medical research in Australia". ASMR achieves these goals through public, political and scientific advocacy.

The ALRC/AHEC have compiled an extensive and thorough issues paper and the ASMR commends the production of such an open document. However, it is not necessarily obvious what recommendations will appear in the forthcoming Discussion Paper. Thus, the Issues Paper has raised concerns amongst a significant number of medical researchers, that some of the options canvassed would severely constrain the progress of medical research.

Health and medical research (H&MR) aims to improve the condition and relieve the burden of disease from individuals, families, communities and whole societies. In addition to this longstanding set of goals, current (bipartisan) government policy is to translate the investment in H&MR into health, social and economic outcomes (eg Health and Medical Research Strategic Review – the Wills Review).

As outlined in the submission by the Australian Academy of Science, which ASMR endorses, there is not a fundamental contradiction between the interests of the wider Australian community and the interests of health and medical researchers. While the current state of development of human genetics is providing a number of examples of rapid progress, we must ensure that this progress is harnessed to better the health, social and economic well being of all Australians, not blocked. This said, the ASMR recognises that there are legitimate concerns that should be addressed so that the rights of individuals, families and the community are protected.

While a major treatise could be written on each of the questions asked, this submission will limit itself to specific brief comments on the questions of specific relevance and interest to the H&MR sector.

Q2-1 The ASMR does not believe that genetic information should be treated as being so unique or more powerful than other forms of health information. In part the view that genetic information is more powerful than other forms of health information has arisen from media simplification and public misconceptions based on all too frequent reports of the “identification of the gene for this or that disease”. The Issues Paper rightly addresses the fact that a very small number of dominant or recessive disorders are now categorically identifiable, but remain untreatable (eg Huntington’s Disease). However, for many disorders where research progress in genetics is being made, there is a perception that clear answers are known. For the majority of human disease, specifically the complex disorders, this will always remain untrue. Even after many of the genetic determinants are identified, there may still be poor ability to predict disease outcomes due to the interplay of environmental factors – many of which are still not defined.

Genetic information is part of health information and indeed forms part of normal clinical and other practice. Thus, a “family history” is a normal, necessary and accepted component of clinical diagnosis or insurance underwriting. Moreover, because now, or in the future, it is likely that advances which may impact past clinical interactions, will be made, the ASMR considers it critical that clinical pathology, epidemiological and research samples are not restricted in the ability to contribute to improvements in health and well being.

ASMR accepts that at times genetic information could lead to discrimination. We agree with the AAS that “over the top” rules will not lead to the betterment of Australians, rather specific protection against specific discrimination would provide the best means to ensure that individual and family issues are protected. Thus, we argue strongly that specific, all encompassing genetic legislation would provide considerable burden and limited benefits, whereas amendments to anti-discrimination, insurance and other legislation could provide the necessary safeguards that the public desires.

Q2-2 Both the public and the scientific research community have a strong preference for clarity. Thus, any changes that may be suggested should be adopted under a uniform national approach. This ensures that practices in one state are consistent with practices in another state.

Q2-3 A consistent source of national advice, based on both scientific and public input, would be valuable in ensuring that a rational approach to these complex areas is followed. The lead of the UK and its HGC has created a model for developments in these areas. Such a standing advisory body could well be constituted as part of the NHMRC.

Q3-1 If the suggestions of the ASMR for chapter 2 are adopted, there would be a standing advisory body, which would lead discussion on future ethical requirements.

Attempting to legislate ethics is doomed to failure as the current field is rapidly moving. For example, the current debate on embryonic stem cell cloning would not have been envisioned five years ago. Specific issues that need to be addressed should be through amendment to existing legislation, not through a genetics act.

Q4-1, 2 & 3 The newly adopted Privacy Act, including the protection of 'sensitive information' would appear to provide more than sufficient protection for human genetic information, although in its current form, may need consideration of the essential familial nature of genetic information, both in clinical practice and in research.

Regulating genetic information at a level that is greater than our already compulsory notification schemes eg cancer registries etc. It would be to the detriment of the health of Australians if only genetic information were excluded from the development of new treatments, etc. The suggestion of an opt-out system, although presenting some difficulties, could however, be a way of balancing the likely views of the majority with the strongly held views of the minority.

Q4-4 The Ethics and Familial Cancer Report (4.88) is far more realistic about the essential familial nature of genetic information as has been used for many decades in clinical practice, research, insurance underwriting, etc. It should form the overriding basis of considerations about privacy of genetic information as there are aspects where despite an individuals wishes, the familial nature of the disorder has (potentially life threatening) implications for others.

Q4-6 As stated above, uniform national approaches are to be encouraged. Many families, who will be impacted by the existing legal framework will cross state jurisdictions, highlighting the differential treatment of individuals based on their place of residence.

Q4-7 As stated above, ASMR would support any necessary legislative remedies being through amendment of existing privacy (or other) laws rather than through an entirely new yet overlapping legal bureaucracy.

Q5-1 See Q4-6. ASMR supports the views of the AAS on this point.

Q5-2 See Q4-7. ASMR supports the views of the AAS on this point.

Q6-1 Current government and bipartisan policy is to encourage medical research for the improvements to the health, social and economic benefit of the country. Commercial pressures are not external only, individual researchers are now being asked how to discover, protect and develop new ideas. However, whether externally or internally supported, such research should be conducted appropriately and consistently with the existing statements, guidelines and laws (see Q6-2).

It is critical to note in genetic studies that the information of value is not derived from a single individual, but by the accumulation of data from many individuals and many families. No one individuals data is paramount to the outcome.

Q6-2 In view of the comments made in Q2-1, it would be inconsistent to argue for more specific ethical rules or enforcement of human genetic research relative to other areas of research.

However, since the front line of ethical protection is through Human Research Ethics Committees there should be a consistent national approach and all research involving humans (public or private) should require HREC review and approval.

Q6-4 HREC waiver of consent should be maintained. We note the ALRC found no examples of problems in this area to include in this detailed Issues paper.

Q7-1 & 2 ASMR endorses the views of AAMRI outlined in this chapter.

There would not appear to be any significant examples illustrated to indicate why current regulations, etc relating to genetic databases need to be changed to provide additional privacy protection.

Q7-3 ASMR members are strongly concerned that ethical usage of samples in pathology labs or human tissue banks occurs. However, within this framework, the membership has strong views, similar to those stated by AAMRI (7.27 & 7.28), that blanket restriction on usage of such samples would be to the detriment of medical research in general and to the health and well being of Australians. There should be no higher level sanction applied to genetic data (which would additionally be protected by the Privacy Act) than other items of sensitive personal medical data.

Q7-4 We refer in general to the AAS and AAMRI submissions which highlight the interplay of pathological diagnosis with ongoing research into the causes of disease and the fact that future tests may be applied to historical samples. This forms the core of good clinical practice.

There should be no higher level regulatory burden for genetic versus other studies that use human tissue.

Consent should be the route of choice, but should re-consent be required on tumour samples that are now able to undergo a new form of pathological diagnosis? ASMR suggests that broadening the definition of pathological diagnosis may be a better option to treating such approaches to further regulation. Likewise, we suggest that samples from patients now deceased should not be discarded, as their study may lead to medical and treatment advances that may be important to their family members own well being.

Q7-5 It is critical to note in genetic studies that the information of value is not derived from a single individual, but by the accumulation of data from many individuals and many families. No one individual's data are paramount to the outcome. As such, an individual will have exceedingly small claim to any form of property right. Moreover, how do individuals with no genetic changes, but who are also important in genetic research have their possible property rights considered. It would however be appropriate, when gaining consent, to indicate that overall the research endeavour may lead to discoveries which could be the subject of commercialization arrangements.

Q8-1 Better education in the area of genetics would be invaluable, especially for counseling patients. As indicated by the examples of erroneous interpretation of genetic information (10.62) training regarding the issues of genetic testing would likely increase the value of genetics in clinical medicine, if only because of good patient education.

Q8-2 Genetic testing, as with any medical testing procedure should occur via NATA accredited laboratories.

Q9-1 & 2 Population screening and genetic registers have been important components of the effective delivery of health care in this country. ASMR would be concerned if new actions were taken that would make this genetic information regulated in a differential way to other sensitive medical information.

Q10-1 As stated in Q2-1 above, ASMR would like to see that genetic anti-discrimination provisions are effective and achieved through existing legislation.

Q11-6 As stated in Q2-1 above, ASMR would like to see that genetic anti-discrimination provisions are effective and achieved through existing legislation. In addition, we note that there are a number of mechanisms canvassed which address issues of genetics and insurance. Of note is the recent recommendation of the Investment and Financial Services Association which has already addressed several issues of concern in this field.

In summary, the inclusive approach of the Issues Paper will provide broad input for the development of the Discussion Paper. The ASMR looks forward to its release and the ability to make further specific comment and suggestions on the proposals of the ALRC/AHEC.

Yours sincerely,

Professor Peter R Schofield
President