In November 2000 we published Whose hands on your genes?, a consultation paper which raised a wide range of issues related to personal genetic information. Since then we have played a part in the important public debate which our society has been having about the broader implications of advances in human genetics.

The public response to our consultation was extremely encouraging. We have now completed our discussions and it is a very great pleasure to finally publish our report. This summary outlines our main conclusions and recommendations. Some of our recommendations are very specific and are addressed to Ministers, others are intended for people and organisations involved with the use of personal genetic information in all its different settings.

In the subtitle of this report we talk of balancing interests. This is an important aspect of our work. I am very much aware of the fact that people approach this issue of personal genetic information from varying perspectives. We have tried here to take account of a wide spectrum of views and have attempted to reach conclusions which are morally defensible and sensitive to the different interests involved.

Helena Kennedy QC,
Chair, Human Genetics Commission

May 2002
Who and why

1. The Human Genetics Commission is the Government’s independent advisory body on social and ethical issues in human genetics. We have carried out a broad enquiry into the way people’s genetic information is stored and used and how it is protected. We have heard from a wide range of organisations and people about how this happens now and their suggestions for how this could be done in the future. We have discussed this in detail at several of our meetings and have come to a number of conclusions based on what we have heard. These conclusions and our recommendations to Government are set out in full in our report “Inside Information – Balancing interests in the use of personal genetic data”

Why did we review personal genetic information?

2. When we consulted people about our first work plan, personal genetic information emerged as a priority area. We felt that it was important to look at the broad range of issues involved in collecting, storing and using information about people’s genetic characteristics. One of our first pieces of work was a large-scale survey of public attitudes towards personal genetic information. This confirmed that people really are very concerned about how information about their DNA is going to be stored and used. But the survey also showed that the vast majority of people recognise the importance
of medical research in this area. Continued research is vital and this will require the co-operation and trust of large numbers of people. We want to ensure that the exciting prospects for genetic research will not be impeded by public anxiety.

How
3. One thing we quickly decided was that our review had to be broader than previous ones that had considered only the issues surrounding genetic testing. We decided that our review would consider issues like family medical history and information about family relationships – such as that provided by paternity testing. We also considered questions about consent, confidentiality and protection of genetic information in medical practice, and in medical research as well as in other areas such as insurance, employment and police investigations. In November 2000 we launched a discussion document called “Whose hands on your genes?” which sought views on this. We had a very good response to this document, both from organisations and individuals. We also held two large public meetings, at which we had the opportunity to discuss these issues face to face with a wide range of interested people.

4. We met a number of key national and international organisations to discuss relevant areas of concern and drew on the work of the Science and Technology Committees of the House of Commons and the House of Lords. Finally, we sent details of our recommendations to our new Consultative Panel of people affected by a genetic
disorder (106 people with experience of a range of genetic conditions, either themselves or in members of their family) to see what they thought.

What have we concluded?
5. In the main, people see genetic information as special and as a private matter and we agree that there are sometimes good reasons for this. However, not all genetic information has the same level of sensitivity. Some information is especially sensitive, for example a test result that tells whether someone will develop a serious genetic condition in the future. We feel this type of information needs additional protection. In particular, we see a need for specific protection against the wrongful or malicious use of personal genetic information.

6. People need to feel confident that proper safeguards are in place, and maybe more importantly, that they are rigorously monitored. But we must not miss out on the major benefits that medical research using genetic information can bring and we should not hinder research with unworkable restrictions. So society needs to achieve the right balance between an individual’s interest in privacy and the interests of others in benefiting from the use of personal genetic information for medicine or research. People have concerns about the potential misuse of personal genetic information so we need to establish a system that promotes public trust about how it is handled. This trust, of course, must be justified and we believe that a new offence covering cases where, for non-medical purposes, genetic information is wrongfully obtained or disclosed could help achieve this.
7. There was wide support for the idea of genetic non-discrimination and we recommend that the Government look at drawing up separate UK legislation to prevent such discrimination in areas such as employment and insurance.

**What is personal genetic information and is it special?**

8. We need to be clear about what personal genetic information is before we can make recommendations about the ways it which it should be used. We have decided to adopt a broad definition: that personal genetic information is any information about the genetic make-up of an identifiable person, whether it comes from DNA testing or from any other source (including the details of a person’s family history). Within this definition we have identified different types of information based on how observable or private it is, and how sensitive it is. Some personal genetic information is not considered private because people can see it, for example your eye colour. Other information, that is not directly observable, is nonetheless private and a person will want some control over who has access to it. Genetic information of a medical nature (such as disease carrier status, or the results of a DNA test about the type of cancer someone has and how easily it can be treated) is an example of this sort of information.

9. In some situations genetic information, either observable or private, can be especially sensitive to a person or his or her “blood relatives” (for example a test result that reveals someone will
Most predictive genetic tests would fall into this category. The sensitivity of this sort of information also depends on whether or not the person involved can be identified. If the personal identifiers have been removed and the information cannot be linked to the person it came from, then it cannot be used in any way that will affect that person.

10. Some types of personal genetic information are more sensitive than others and we recommend that the level of protection needed will depend on how sensitive the genetic information is. Our findings show that people feel that private and sensitive personal genetic information should be treated confidentially, which in many cases will mean treating genetic information like other medical information and protecting it in the same way. But in some cases this type of information may need additional protection and our report highlights situations when this should happen.

**General principles for the way we treat personal genetic information**

11. We have set out general principles to promote the use of genetic information in a fair and ethical way. Genetic knowledge may bring people into a special relationship with one another. We lead our lives as members of large and small communities and we have certain duties to other members of these communities. Such duties can include not causing harm to others and doing things to help them. Sharing our genetic information can give rise
to opportunities to help other people and for other people to help us and we have a common interest in the benefits that medically-based genetic research may bring. We have, therefore, set out a concept of **genetic solidarity and altruism**. This supports the idea that, for example, although nobody should feel pushed into taking part in genetic research, when they make this decision people should be aware that by taking part they might help those suffering from disease.

12. We have drawn up some principles based on the overarching idea of the respect for persons, which means that everyone should have their rights and dignity respected in the same way regardless of their genetic characteristics. We need to be sensitive to the special role that genetic identity has come to play in people’s lives. From the broad principle of respect for persons we have concluded:

- that everyone is entitled to privacy and should not have to disclose information about personal genetic characteristics;
- that private genetic information should not be obtained or held without a person’s consent;
- that private personal genetic information should be treated as confidential and not communicated to others without a person’s consent; and
- that no one should be unfairly discriminated against on the basis of his or her genetic characteristics.

(There will of course be certain exceptions, for example where public safety issues are involved.)
Protecting personal genetic information

13. Our findings and discussions have led us to the conclusion that there must be systems in place that promote public trust about the ways that clinicians, researchers and ultimately the State handle genetic information. People need to feel confident that their information is safe from being used in the wrong way. We examined existing protections and have made recommendations for their monitoring and possible improvement.

14. We also looked at possible ways in which genetic information might be wrongfully used and considered whether these are covered by existing laws. In particular we identified some possible malicious or deceitful ways in which personal genetic information might be obtained or used, for example:

- if an unscrupulous journalist secretly takes an everyday object used by a public figure, for example a coffee mug, and having analysed the DNA sample obtained from it, publishes their genetic information;
- if someone finds out the names of people who have given samples for a research study by breaking the code protecting their identity and then passes these details on to an insurance company or a research organisation;
- if a suspicious family member secretly tests a child to see if the child is really related to another family member or not.

15. This sort of activity would often be a gross intrusion into another’s privacy and we do not think
there is sufficient legal protection to prevent this at the moment. We therefore recommend that the Government consider whether there should be a criminal offence of deceitfully obtaining and analysing another person’s genetic information for non-medical purposes.

**Personal genetic information in clinical practice**

16. We support a right to genetic privacy which entitles people to have control over their genetic information and requires that they give consent before genetic tests are carried out. The requirement of consent is made clear in all major professional codes. People need information before they can give a valid consent, and we feel that the amount of information needed depends on whether the test is likely to reveal sensitive genetic information or not.

17. Not surprisingly, people want the details of their genetic information to be treated confidentially. Health professionals are used to dealing with confidential medical information, and there are already general protections in place. Breaching a patient’s confidence is usually treated as a matter of serious professional misconduct. We agree with this approach. However people must have confidence in the way wider medical information is stored. We do not think it would be sensible or possible to make separate arrangements to store genetic information within the health service. At the same time, we stress the sensitive nature of genetic information and the need to keep it confidential and to encourage the relevant professions and employers to make sure that all staff are fully aware of the need to respect confidentiality.
18. Having stressed the importance of consent and confidentiality, we have identified some cases when special rules apply. For example, care needs to be taken when children are to be tested for genetic disorders that only cause symptoms in later life; in general such tests should wait until a child can make up his or her own mind about the test. In some cases adults may not have the capacity to give consent to genetic testing and so the decision may need to be made on their behalf. We make some detailed comments about how best to approach the issue of consent in such cases. Sometimes it may be necessary to test a person after death to help a living relative and we recommend in general that doctors should presume that the dead person would have wanted to help the relative and therefore would have given their consent to post mortem testing.

19. Disclosure of sensitive personal genetic information without consent may be justified in rare cases where a patient refuses to consent to such disclosure but the benefit to other family members or the wider public substantially outweighs the need to respect confidentiality. We would expect this to remain an exceptional situation.

Medical research and personal genetic information

20. Much research will be needed before scientific advances like the sequencing of the human genome can be translated into practical medical benefits. In our discussions we have recognised the scientific importance of genetic research and the need to
make sure people feel able to participate in it. Codes and guidelines already exist to regulate biomedical research and our findings do not suggest that there needs to be a separate regime for research involving human genetic material. However, we recommend that an independent ethics committee should approve all research projects using human genetic information or material that can be linked to an identifiable person.

21. In obtaining consent from research participants we feel that researchers should use clear terms so that people understand how and to what extent their information will be protected. They may also need to know whether and how samples and information will be anonymised (so that research materials cannot be linked to a particular person). People should understand the general nature of the research, and should be asked to give their consent again if research of a fundamentally different nature is then proposed. We have suggested how samples and genetic information that has been made permanently anonymous can be treated differently.

Insurance and employment

22. Our ability to carry out predictive genetic testing has increased with the growth of genetic knowledge. It is therefore increasingly important to ensure people are not treated unfairly because of their genetic characteristics. We found there was a great deal of opposition to “genetic discrimination” and we have identified a good case for new legislation to stop this. People have already raised concerns about unfair discrimination in employment and insurance, but any
legislation will need to be wide enough to cover future areas of concern such as education and healthcare.

23. We recommended last year that there should be a moratorium on the use of adverse genetic test results in setting insurance premiums. We are aware that people feel strongly about this. We welcome the agreement by the insurance industry and Government to a five-year moratorium covering the vast majority of insurance policies. The moratorium gives time for more public discussion of the issues and we suggest some areas for further discussion and research during the moratorium. We have already said that we wish to look at the use of family history information, but we do not believe that it should be covered by the moratorium at this stage.

24. There is no evidence that employers in the UK are systematically using genetic test results to recruit people or using such tests as part of workplace health programmes. We feel that at present there are better methods of detecting a person’s risk of future ill health. We support previous recommendations that employers must not demand that employees take genetic tests as a condition of employment. There might be some cases where an employer will want to offer genetic testing to an employee, and we recommend that employers, unions and other interested groups bring these cases to our attention so that we can consider the implications.

Forensic uses of personal genetic information

25. Our findings show that there is much support for the use of the National DNA Database to help the police to investigate crime. Some people and
organisations have expressed concerns about certain aspects of the present arrangements and we feel that these could affect public confidence in the database. For example, people are concerned about samples being taken for relatively trivial offences and about how long samples are kept. We draw an important distinction between the DNA fingerprint – a numerical barcode on a computer – and the original sample that is kept in storage. Because the samples contain the full genetic information of the individual, we believe that the future use of such samples should be subject to controls. We recommend that in order to increase and maintain public confidence there should be an independent body, which would include lay members, to oversee the way the National DNA Database works.

26. Forensic DNA-related research is also being carried out. For example, there is research into ways of building up a “genetic photo-fit” of the appearance of the person on the basis of genetic information found in a sample from a crime scene. More controversially, this might be extended to behavioural traits and even medical information. We are aware of possible public concerns over using genetic information to predict the characteristics of a person, which is significantly different from using it for comparison and identification purposes.

27. We also recommend that the police and other official bodies should not have access at all to genetic research databases and that this should be clarified in law. Otherwise, we are concerned that people will not want to be part of important new research projects like BioBank UK.
Parentage testing and family relationships

28. We have also considered the use of DNA testing techniques to establish family relationships. These tests – often called paternity tests – are used widely to check child support or immigration claims, in civil court cases for divorce and child custody or inheritance. The techniques used are similar to police DNA fingerprinting. We are broadly happy with the regulation of UK paternity testing companies which abide by a Government code of practice. But more and more people are making use of companies overseas which advertise on the Internet. We recognise the difficulty of regulating this and we shall be considering the matter more fully as part of our review of the provision of genetic testing services offered directly to the public that the Government has asked us to complete by the end of 2002.

Find out more
29. Full copies of our report “Inside Information – Balancing interests in the use of personal genetic data” can be obtained from:

    PO Box 777
    London
    SE1 6XH

    fax: 01623 724524
    e-mail: doh@prolog.uk.com

Or visit our website
www.hgc.gov.uk/insideinformation/.
Our conclusions and recommendations in full

The following is taken from our full report and gives more details about the issues that we have considered and the conclusions that we have reached. Our formal recommendations to Ministers – about policy or areas that we wish to consider further – are indicated in **bold type**. In other cases, we make recommendations, often about what we deem to be best practice, that others may wish to consider. The numbers in brackets refer to the relevant paragraphs of the full report.

**Scope and general principles**

We consider personal genetic information to be information about the genetic make-up of an identifiable person, whether derived directly from DNA (or other biochemical) testing methods or indirectly from any other source. Within that definition we have identified several sub-categories, based on criteria of observability, privacy, and sensitivity (1.11).

While we may not share all of the concerns that have been voiced, our enquiry confirms the view that people do feel that personal genetic information is a private matter and we believe that there are good reasons for this (1.26).

We therefore do not feel that all personal genetic information be treated in the same way in every set of circumstances. Requirements of consent and confidentiality, for example, may be expected to differ according to the specific circumstances (1.26).

Our aim in this report is to suggest how interests in genetic privacy and confidentiality can be protected in a way that does not harm comparably important interests of others. We have set out a number of principles to achieve this, many of which are laid down in international declarations and conventions which seek to establish a common ethical framework. **One such instrument which we believe to be particularly important is the Council of Europe’s Convention on Human Rights and Biomedicine, and we**
recommend that the Government take steps towards signing and ratifying this Convention (2.7).

Genetic knowledge may bring people into a special moral relationship with one another. We have therefore proposed the following concept of genetic solidarity and altruism, which promotes the common good (2.11):

We all share the same basic human genome, although there are individual variations which distinguish us from other people. Most of our genetic characteristics will be present in others. This sharing of our genetic constitution not only gives rise to opportunities to help others but it also highlights our common interest in the fruits of medically-based genetic research.

We share the assumption of our society that individual persons have the highest moral importance or value. This requires us to be sensitive to the special role that genetic identity has come to play in people’s lives. We therefore express the following key principle of respect for persons (2.20):

Respect for persons affirms the equal value, dignity and moral rights of each individual. Each individual is entitled to lead a life in which genetic characteristics will not be the basis of unjust discrimination or unfair or inhuman treatment.

We believe that a number of secondary principles may be derived from this overarching principle, taking account of the possible claims of genetic solidarity and altruism (2.22):

The principle of privacy

Every person is entitled to privacy. In the absence of justification based on overwhelming moral considerations, a person should generally not be obliged to disclose information about his or her genetic characteristics.
The principle of consent
Private genetic information about a person should generally not be obtained, held or communicated without that person’s free and informed consent.

The principle of confidentiality
Private personal genetic information should generally be treated as being of a confidential nature and should not be communicated to others without consent except for the weightiest of reasons.

The principle of non-discrimination
No person shall be unfairly discriminated against on the basis of his or her genetic characteristics.

Clinical practice
Genetic information about an individual should be under that person’s control. The consent of the individual is therefore required before this information can be obtained. This also protects him or her from being given information that he or she may not wish to know. We therefore recognise that people have an “entitlement not to know” genetic information about themselves (3.6).

We conclude that the nature and extent of information that is required in seeking consent for a genetic test depend on whether the test in question is likely to reveal sensitive genetic information - information which has special significance for the patient or for the patient’s relatives. We offer some points to consider in seeking consent for different sorts of genetic test (3.18).

Genetic testing may reveal unexpected information, for example about parentage. We recommend that best practice for clinicians is that, however remote, the wider implications of testing should be discussed before consenting to a genetic test (3.24).
We also wish to give further consideration to pharmacogenetic testing, especially to the wider social and ethical implications of its increased use in the regulation and prescribing of medicines (3.30).

We do not believe that it is feasible for separate arrangements to be made for the storage of genetic information within the health service, but nonetheless we point out that the potentially sensitive nature of this information underlines the importance of protecting the confidentiality of patient medical information in general (3.36).

We intend to monitor any future schemes for the ready storage and accessing of genetic information for prescribing purposes (3.37).

We believe that the requirements of medical confidentiality need to be clearly understood, at all levels and across the entire medical and biomedical research field. Adherence to confidentiality should become an essential part of employment contracts and of membership of relevant professional bodies. This should be backed by sanctions. We comment on the possible need for a broader offence against breach of medical confidence, which is beyond the scope of this report (3.39; 3.48).

However, it appears to us that the law may not sufficiently protect against the unauthorised obtaining of genetic tests or the unauthorised disclosure of genetic information in a non-medical setting.

We recommend that consideration be given to the creation of a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes (3.60).

We believe that it would be sensible to conduct our review of direct access to genetic tests in the light of our recommendation relating to a new criminal offence (3.61).
The general duty to maintain the confidential nature of personal genetic information is not an absolute one. We note circumstances where it may not be appropriate, such as where consent is given or where it is in the interest of the patient, of relatives, or of the wider public (3.62).

Bearing in mind the principle of genetic solidarity and altruism, we take the view that the disclosure of sensitive personal genetic information for the benefit of family members in certain circumstances may occasionally be justified. This would arise where a patient refuses to consent to such disclosure and the benefit of disclosure substantially outweighs the patient’s claim to confidentiality (3.68).

In some cases a person may wish to disclose confidential information if he or she feels that is necessary for reasons of public safety. We believe that in exceptional cases it should be permissible to reveal personal genetic information in order to avert substantial harm to others (3.72).

Although we understand the concerns of relatives over the revealing of family medical history, we believe that it is proper for questions in this area to be asked by clinicians and genetic counsellors, and we believe that the patient has a right to disclose it (4.1).

**We believe that there may be a need for secondary legislation to ensure that the holders of information about genetic relatives in a clinical context are specifically exempted from their normal obligations of notification and provision of information to such relatives under the Data Protection Act (4.7).**

Carrier testing is used to determine whether a person carries the gene for a recessive genetic condition. Consent to this form of testing requires information about the implications of carrier status, both in terms of the psychological and social impact on the affected person and in terms of the implications it may have for reproductive decisions (4.15).
We intend to consider the matter of prenatal genetic testing in more detail in our work on genetic testing and reproductive choice (4.21).

At present, we recommend that where multiple genetic tests are carried out, it should be explained to the patient what the principal purpose of testing is, and that it will reveal additional information. We recommend that before new multiple genetic tests are introduced, the implications for adequately informed consent are considered carefully (4.26).

The placing of a large amount of genetic information about a person on a single electronic record could also pose a challenge to privacy. We conclude that there are no persuasive reasons to resist the introduction of new information storage technologies even if these do present some challenges to confidentiality. At the same time, we stress the importance of incorporating the traditional principle of medical confidentiality into the regulation of such technologies (4.32).

Genetic screening programmes are important in preventing ill health, but they raise certain ethical issues which we discuss in this report.

We shall be monitoring developments in national screening programmes and will be considering screening issues as part of our planned work on genetics and reproductive choice (4.35).

There are particular legal and ethical issues involved in those cases where consent cannot be obtained from the person being tested. We endorse the recommendation of the Advisory Committee on Genetic Testing that great caution should be observed in the testing of children for late-onset disorders (4.38).

We conclude that benefit to a relative, and hence indirect benefit to the interests of the tested person, should be factors to be taken into account in deciding whether genetic testing should be carried out on a person who is unable to consent to it (4.57).
There may be some clinical situations where genetic information about the dead is needed in order to assess a risk to a living relative. This information may be obtained by testing samples removed from an individual during life. The approach we favour is that a presumption should be made that the dead person would have consented in his or her lifetime to such testing and that this justifies post-mortem testing (4.67).

In other cases, if testing of samples from the dead is not justified by weighty reasons such as the significant interests of other family members or of the wider public, then such testing should be regarded as unethical (4.73).

Research and genetic databases
Our understanding of genes and of how they work in the human body is the result of prolonged and extensive research efforts. If this understanding is to be translated into therapeutic benefit, such research must be given every encouragement. Genetics is a vital part of this and we therefore all have an interest in successful genetics-based medical or health-related research (5.1).

The ethical implications of dealing with genetic material and information differ according to whether or not the material or information is anonymised – i.e. separated from information that can link it to an individual. It is important that satisfactory techniques of encryption be used where the anonymisation is to be reversible. **We recommend that the Government gives a firm commitment to funding research and development initiatives on this important aspect of data security (5.13).**

The very nature of DNA limits the process of complete anonymisation, because it may be possible to link a sample by use of “DNA fingerprinting”. We nonetheless feel that for practical purposes the concept of anonymisation is valid (5.14).
The need to obtain the consent of the participant at the outset is a fundamental principle of ethical research. We devote considerable attention to issues that must be addressed in consent procedures for different types of research (5.15).

We acknowledge the importance of initial consent, but consider that repeated processes of re-consent for subsequent use are impractical and, moreover, may be unnecessarily intrusive. We therefore consider that it is acceptable to seek general consent where there is to be anonymisation of data and samples. We consider that specific consent may be required where data or samples are not anonymised (5.19).

The Health and Social Care Act 2001 entitles the Secretary of State to authorise the use of patient information in research without seeking patient consent to this use. We note the objection that this constitutes a significant exception to the normal rule of confidentiality and to the principle that research on patient information should proceed only with the consent of the patient in question. At the same time, we appreciate the importance of such research in areas such as cancer registries. We intend therefore to monitor the use of these powers and seek to work with the Patient Information Advisory Group on this issue (5.21).

In all cases, we consider that best practice requires that the consent should clearly specify the arrangements for withdrawal from the study and the subsequent fate of samples and data (5.22).

Access to samples and personal genetic information may need to be made available to commercial organisations engaged in health-related research of public benefit. We note some public disquiet, but the development of medicines and treatments is largely a commercial undertaking and would be severely limited if commercial access were denied. We conclude that best practice requires that the question of commercial involvement in research or access to genetic databases should be fully explained at the time of obtaining participants’
consent. This should include a brief explanation of any intellectual property issues. In order to allay concern about wider uses it might be necessary to give commercial access only to companies engaged in health-related research (5.25).

There are important collections of samples which were obtained in the past and which may not be covered by any donor consent to research use. It is our view that it would be undesirable to prohibit the use of such material in cases where it is not possible to trace the donors and obtain their consent. We therefore endorse the advice given by the Medical Research Council that samples from historical collections may be used subject to certain conditions (5.27).

Tissue left over from surgical operations provides a rich potential source of research material. We believe that best practice requires that tissue left over from surgical procedures should only be used for research if the patient has consented. But we believe that it is acceptable to use older collections already obtained and where consent was not sought. Such samples, however, must be anonymised (5.28).

We note the different ways in which ethical oversight and approval of research is provided. We do not recommend the separate regulation of genetics research, but we are aware of criticisms of the current system of ethics committee regulation, which need to be addressed. We conclude that best practice requires that all genetic research on human non-anonymised tissue samples or bodily materials should be subject to review by an independent research ethics committee and should be monitored for compliance through clearly specified arrangements (5.33).

We do not at this stage believe that it is necessary for the Government to introduce new legislation to ensure ethical oversight of all genetic research. It may be sufficient for the Government and other bodies to make a clear public statement on this matter. We recommend that the Government should encourage relevant research institutions, professional bodies and funding organisations to establish clear
policies aimed at ensuring compliance with emerging best practice in ethical research. We also recommend that compliance with best practice and the application to research in genetics of the new standards for the governance of research ethics committees is formally reviewed in three to five years' time (5.37).

We comment on aspects of the research use of current and planned large genetic databases. The question of who benefits from the setting up of these databases is a complex one. In return for altruistic public involvement in such research, there should be some benefit for the participants, or, in the widest sense, the community from which they are drawn. All we would affirm at this stage is that large-scale population genetic databases, established with and supported by public funding, constitute a national asset. This means that national benefit and interest should be taken into account in determining the terms upon which access is to be granted to such databases. We think that a morally sensitive regime can and should be worked out for the use of large-scale genetic databases and we propose to continue our discussions on this, and other issues, with those responsible for BioBank UK (5.44).

We consider what mechanisms should be in place to weigh conflicting claims and priorities in deciding on access to research genetic databases or collections. We therefore recommend that the governance of genetic research databases and DNA collections should allow for oversight by an independent body - whether it is an ethics committee or another body - which is separate from the owners and users of the database (5.45).

The confidentiality of the information stored in the database is a major concern for participants. We recommend that the operators of all genetic research databases should be required to take rigorous steps to ensure that unauthorised access or disclosures are prevented (5.49).
We recommend that genetic research databases established for health research should not be used for any purpose other than such research and that this be put beyond any doubt, by legislation if necessary (5.50). We touch on this in later sections relating to forensic uses of personal genetic information.

Insurance and employment

We consider how personal genetic information obtained in a clinical or research setting is used in other areas. We have primarily looked at the use of personal genetic information in life and health insurance and in employment. Indeed, we detect close links between the two (6.1).

We welcome the clear statement that genetic test results obtained from research will not be used by insurance companies. We would welcome assurance from the main employer groups, trades unions and professional bodies connected with occupational health and recruitment that individual genetic research results will not be considered in making employment decisions about that person (6.19).

We consider the concept of “genetic discrimination” in some depth. The Government asked HGC and the Disability Rights Commission to consider the need to amend the Disability Discrimination Act 1995. We have concluded that there are legal and pragmatic reasons why this would not adequately address concerns. In the light of our recommendation on separate legislation to address genetic discrimination, we recommend that no further consideration be given to amending the Disability Discrimination Act to include protection for those who have a pre-symptomatic genetic condition (6.31).

There is an opportunity to consider “genetic non-discrimination” legislation as part of the review of genetic information in employment (due in 2005) and during the moratorium on the use of genetic information in insurance (to 2006).
We recommend that the Government consider in detail the possible need for separate UK legislation to prevent genetic discrimination and that this evaluation form part of a long-term policy review on the use of personal genetic information in insurance and employment (6.41).

In May 2001 we published interim recommendations calling for a moratorium on the use of genetic information in insurance. In October 2001, the Government and the Association of British Insurers (ABI) responded to the House of Commons Science and Technology report on genetics and insurance. We welcome the Government response and action taken by the Association of British Insurers and the opportunity that this offers during the five year moratorium for a fuller discussion of the use of genetic information in insurance underwriting (7.7).

Our interim recommendations noted that the use of family history information by insurers presents particular difficulties. We have considered the arguments on both sides and noted the work of the insurance industry and of others.

We do not at present recommend that the insurance moratorium should be extended to the use of family history information (7.16).

We further recommend that in reviewing its criteria for judging applications the Genetics and Insurance Committee (GAIC) consider the evidence which the insurance industry uses to justify its use of family history evidence to set insurance premiums (7.17).

We recommend that the Government and insurance industry should continue to fund independent research on genetics and family history. We also believe that the ABI should encourage their member companies to consider publishing the results of their own research and analysis in peer-reviewed journals (7.18).
We note a possible consumer perspective that people with no adverse family history should be able to make use of their genetic information to obtain lower premiums. This ‘preferred-life’ underwriting is superficially attractive but we recommend that it should not be introduced into the UK insurance market and note that the ABI have recommended against this in their Code of Practice (7.27).

The expanded GAIC is well placed to both receive and investigate reports that some people are advised to have a genetic test in order to obtain cheaper insurance. However, we also recommend that research be commissioned to establish the extent to which patients raise insurance considerations during consultations that precede genetic tests (7.28).

In our view, the effect of [data protection] provisions is to emphasise the importance of ensuring that insurance companies request only the minimum amount of specific information about the applicant’s family history that is needed to make an insurance underwriting decision (7.36).

Because many genetic conditions are rare and complex, people often have better knowledge of their own condition than a prospective insurer. Arranging affordable insurance may require considerable effort on the part of that person. **We recommend that the Government promote the mechanisms set out in the 1999 White Paper “Modern markets – confident consumers” to help establish consumer information partnerships which could provide access to affordable insurance for those with a genetic condition (7.50).**

We welcome the Government’s commitment that GAIC will review the criteria for judging applications to use genetic test information in insurance. We offer some comments based on responses to our consultation. We look forward to a closer working relationship with the reformed GAIC and would welcome both formal and informal opportunities for collaboration (7.56; 7.59).
We highlight some of the risk pooling models that have been proposed by insurance industry experts.

We recommend that during the period of the moratorium risk pooling and other models should be explored further by independent experts from the actuarial profession, the insurance industry and the genetics community (7.64).

We intend to continue to play a role in the debate and review of genetics and insurance and we shall recommend to Government a programme which will encompass this (7.65).

Personal genetic information may be used by an employer to make decisions about people’s susceptibility to hazards in the workplace. It may also be use to determine whether employees may pose a safety risk to others or whether they may have long periods of illness or inability to work on medical grounds. Increasingly genetic information may also be used in decisions about access to employee benefits such as occupational pensions, private health insurance and other forms of insurance. Although we recognise these possibilities, we conclude at present there is no evidence in this country of any systematic use of predictive personal genetic information in employment (8.9).

We generally believe that – in accordance with the principle of respect for persons – employers must not demand that an individual take a genetic test as a condition of employment (8.15).

At present, we conclude that given the current uncertainties about interpreting genetic information, at present it may be more appropriate to monitor the health of a person by other, more direct, means (8.18).

We do not consider that a body like GAIC should be established at this stage to decide whether particular genetic tests are relevant for employment purposes. However, we wish to give more thought to the broader ethical and social
implications of this issue, with a view to advising Government in the future.

**We would therefore encourage a voluntary undertaking by employers or other groups to inform HGC of any proposals to use genetic testing for health and safety or recruitment purposes (8.19).**

The proposed review of the use of personal genetic information in employment by 2005 is timely, but these issues should be addressed before then.

**We recommend that a joint Committee be formed to monitor developments in genetic testing and employment and that this committee should include representatives from HGC, the Health and Safety Commission, the Disability Rights Commission and other interested parties (8.23).**

The Information Commissioner has consulted on a draft Code of Practice on the use of personal data within employer/employee relationships. We would suggest that the Commissioner clarify that the relevant parts of this code cover both the results of previous genetic tests and other personal genetic information (such as a family history of a genetic condition) (8.26).

**We believe that any future discussions on the use of genetic information in private insurance should also consider the wider implications for employment-benefit schemes that are based wholly or partly on financial products that are based on the recognised principles of private insurance underwriting (8.27).**

**Forensic uses of genetic information**

The ability to generate DNA fingerprints and the resultant development of national forensic DNA databases is a powerful tool for crime detection. We comment on the implications of forensic DNA use and on the views put to us
during our consultations. We note the significant changes introduced by the Criminal Justice and Police Act 2001 relating to the retention of DNA profiles and samples.

Given that the Scottish legal position differs from that which applies in England and Wales, we recommend that consideration should be given to the adequacy of arrangements to ensure that Scottish DNA profiles and samples on the UK National DNA Database are handled in accordance with the provisions of the relevant Scottish legislation (9.15).

We note public concern about extending DNA profiling to relatively trivial offences.

**We would urge the Government to promote a greater degree of public dialogue about the justification for the apparent increase in the range of offences for which samples may be taken (9.20).**

Such dialogue may also serve to maintain, and possibly improve, public confidence in the National DNA database.

The recent legislation affects the arrangements for samples given voluntarily to eliminate a person from a crime inquiry. It includes separate consent procedures for participation in the elimination screen and to have the profile retained on the National DNA database. This latter consent cannot be revoked.

**We recommend that the Home Office guidance and police consent forms clearly set out the important differences between the two consents that are being obtained. Where possible the obtaining of consent to provide the initial elimination sample should be separated physically and/or temporally from consent to retain the sample and profile (9.26).**

We took note of concerns about the oversight arrangements for the National DNA database. The Government has indicated that it will consider the idea of an independent body to oversee the samples and that it will also conduct a
review aimed at improving the security and efficiency of the National DNA Database.

We recommend that, at the very least, the Home Office and Association of Chief Police Officers establish an independent body, which would include lay membership, to oversee the work of the National DNA Database custodian and the profile suppliers (9.32).

We also draw a clear distinction between the retention of the DNA profile (the “DNA fingerprint”) on a computer and the original sample (the “CJ sample”) in a freezer. The latter may potentially be retested and used in ways not considered when it was originally taken. We welcome the Government’s willingness to consider an independent oversight body for CJ samples.

We recommend that any review leading to the establishment of such a body should have a sufficiently broad remit to consider first whether or not CJ samples should be retained (9.39).

We note the important research into the use of DNA techniques in crime detection. This includes ways of identifying commonplace characteristics so that in the future a “genetic photo-fit” could be built up from a sample left at the scene of a crime.

We recommend that in the short-term the Home Office and Forensic Science Service establish an independent research ethics committee to approve such research (9.45).

It appears to us that there is a clear distinction between using DNA for comparison or identification purposes (which the public broadly accepts) and using it to predict the characteristics of a person. We take the view that the public might have concerns about such uses.

We therefore recommend to the Government that any proposal to use sensitive personal genetic information for forensic purposes should be subject to a full public
debate in order to examine the ethical, consent and confidentiality issues (9.48).

We share general concerns about police access to research genetic databases, both from an ethical and a scientific point of view (as this may affect the range of volunteers who are prepared to participate in such research).

We therefore recommend that consideration be given to legal means of preventing access to biomedical genetic databases by police and other law enforcement agencies (9.55).

DNA parentage testing

We review the increasingly widespread use of DNA relationship testing – commonly called paternity testing.

A large amount of paternity testing is done for Government purposes, by bodies such as the Child Support Agency or the Home Office. We recommend that there be clear official guidelines for the use of DNA testing for child support and immigration control purposes, and that these should reflect the concerns about the intrusiveness and potential consequences for family members of DNA parentage testing. In our view, such guidelines should state that DNA testing should only be used in situations where no other evidence is available (10.20).

Private paternity testing, such as that commissioned for civil court cases, may fall under a voluntary UK Code of Practice on Genetic Paternity Testing Services. However, the Code of Practice is not legally enforceable and does not apply to paternity testing services offered by overseas providers. We recommend that the effectiveness and relevance of the Code of Practice on DNA Paternity Testing should be considered as part of our review of direct offering to the public of genetic testing services (10.27).
You can get copies of the full report and the summary by writing to:

PO Box 777
London
SE1 6XH

Or by faxing: 01623 724524

Or by emailing: doh@prolog.uk.com

We drew on a wide range of evidence during our review of personal genetic information. This evidence and the full and summary report are available on our website www.hgc.gov.uk/insideinformation/.

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