PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

A REPORT BY
THE BIOETHICS ADVISORY COMMITTEE

SINGAPORE

May 2007

FOREWORD

Singapore has made much progress in developing talent and infrastructure in biomedical sciences over the past five years. As the biomedical sciences initiative enters the next phase, new initiatives have been planned for strengthening capabilities in clinical and translational research. Such research critically depends on the use of personal information. If continuing success is to be maintained, public confidence in physicians and biomedical researchers is essential. Thus, a comprehensive statutory framework is necessary for the protection and use of personal information in research. This report considers the ethical principles for data protection and makes recommendations for the establishment of such a framework.

Much research into existing regulatory standards, policies and practice guidelines of international and national ethics and professional bodies was carried out in producing the recommendations in this report. The recommendations were finalised after careful consideration of the views and comments from international and local experts as well as those from healthcare, research and governmental institutions, and professional and religious organisations. The BAC is much indebted to the various parties and individuals for their contribution.

It is hoped that these recommendations, which balance the need to ensure privacy and confidentiality and the need to facilitate research with legitimate public interest, will help to align Singapore with international best practices.

I would like to thank my fellow committee members and members of the Human Genetics Subcommittee, which was chaired by Associate Professor Terry Kaan, for their commitment and dedication to the project. They have endeavored to ensure that the recommendations are a considered, balanced and fair response to difficult and sensitive issues pertaining to the use of personal information in biomedical research.

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The Bioethics Advisory Committee (BAC) was established by the Singapore Cabinet in December 2000 to examine the ethical, legal and social issues arising from research in the biomedical sciences and to develop and recommend policies on these issues. It aims to protect the rights and welfare of individuals, while allowing the biomedical sciences to develop and realise their full potential for the benefit of mankind.

The BAC reports to the Steering Committee on Life Sciences (formerly the Life Sciences Ministerial Committee).

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   Department of Community, Occupational and Family Medicine, Yong Loo Lin School of Medicine, National University of Singapore

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PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

EXECUTIVE SUMMARY

Introduction

1. Biomedical research is critical to advances in medical science and technology and leads to improvement in the health of the public. This Report discusses the need to use personal information in biomedical research and makes recommendations aimed at establishing principles for data protection and confidentiality consistent with legitimate research needs.

2. We identify five issues for discussion:

   (a) What is personal information?

   (b) Do we require a legal framework for the protection of privacy and confidentiality?

   (c) Issues of privacy and confidentiality;

   (d) Issues of informed consent; and

   (e) Issues of access by third parties such as employers or insurance companies.

Personal Information

3. This Report considers personal information to be any information about an individual. For example, a blood sample may yield information about a person's blood group and this information is personal information. Personal information may be categorised into identified personal information and de-identified personal information. In the latter, the identifying particulars are separated from the rest of the information. The separation can be reversible or irreversible.

4. Only if proper steps are taken to protect the identity of research participants may their personal information be used for research purposes without breach of privacy. For this reason, de-identified personal information is used where possible in research. There are various ways in which a greater or lesser degree of security can be obtained using de-identification procedures. In general, the more sensitive the information, the more care is needed to ensure that the identities of the individuals concerned are protected and their personal information kept secure.

5. Sometimes the personal information needed for research is information provided to a physician for the diagnosis or treatment of a patient. Such medical information is kept in medical records. Sometimes the information needed is obtained from volunteers who are not patients. Sometimes the information is genetic information, which may or may not be medical information.

The Legal Protection of Personal Information

6. The Report considers whether or not some legal framework is needed, and concludes that it is. A legal framework that protects privacy while allowing the legitimate use and exchange of information may be valuable in its own right, and may be essential if researchers in Singapore are to collaborate with researchers in other jurisdictions.

7. Singapore's existing laws provide for data protection and confidentiality in specific circumstances, such as between banks and their customers, and between solicitors and clients, but there is no comprehensive statutory framework for the protection of personal information. A legal regime for personal information protection could provide a general framework for public engagement and for policy development.

8. A data protection law could also assist the development of realistic expectations on the part of researchers and prospective research participants regarding the use of personal information in biomedical research. In addition, the management of de-identified information, the right of access to research data by participants, and the use of information for epidemiological and public health research, are all matters where particular provisions may be helpful.

Privacy and Confidentiality

9. Personal information should be stored and managed in ways that provide proper security and confidentiality. While a researcher collecting data from consenting individuals will know their identities, such information should be stored and managed as de-identified information as far and as early as possible.

10. Researchers are expected not only to take proper security safeguards with data, but to refrain from attempting to identify an individual from de-identified information. Moreover, research data should not be made available to insurance companies or employers, because it is not obtained for health or employment purposes and can be misleading if used outside the research context.

11. Irreversibly de-identifying personal information will severely limit the research value of the information and disable certain types of research, such as those that require further information from records over a period of time. Nevertheless, certain types of personal information may be especially sensitive such that irreversible de-identification is the only means by which the privacy interests of the individuals concerned may be sufficiently protected. Irreversibly de-identified information, however, should not be subject to privacy and confidentiality requirements, provided that proper measures are taken to ensure that the de-identification is really irreversible.

12. When personal information is to be reversibly de-identified, the extent and thoroughness of de-identification should be balanced against the harm that might follow in the event that an individual is identified. It is the responsibility of the research ethics committee or Institutional Review Board (IRB) to consider the extent and means of de-identification proposed.

13. The level of confidentiality safeguards, whether in the extent of de-identification or secure safekeeping of data, should be commensurate with the potential risk of harm to research participants. Generally, the confidentiality obligation of research institutions involved in large-scale research initiatives will be greater than that of research performed by a single researcher.

Informed Consent

14. Voluntary informed consent and confidentiality safeguards are the fundamental means to privacy protection. Generally, the use of personal information in biomedical research requires the consent of the individual concerned and the approval of an IRB.

15. Specific consent is consent for a specific research project or for a specific purpose. General consent is consent that does not limit the use of the information or tissue contributed for a specific project or purpose. When general consent for future research is given, it relieves the researcher of the need to re-contact the individual concerned for a fresh consent.

Consent and Proportionality

16. The process of obtaining consent should be such as to ensure appropriate understanding of what is being consented to. Details of information to be

provided should be in proportion to the sensitivity of the research and risk of harm to the research participants. Consent should be explicit, in writing and include detailed information where the risk of harm is appreciable. Where the risk is low, less information may suffice for the individual to feel able to give consent.

17. We are of the view that specific consent is required for sensitive research or when the research involves identified personal information or tissue samples. General consent should be a sufficient requirement for subsequent unspecified research, subject to de-identification of the information or tissue used as well as IRB review.

Consent and Reciprocity

18. There are many important research uses of medical information that do not contribute directly to the healthcare of individuals, but are beneficial to society. Such research can be granted ethical endorsement under the principle of reciprocity, which encompasses the idea that accepting benefit from past medical research, inherent in the utilisation of medical services, carries some expectation of a willingness to participate in research for the common good.

19. While informed consent should generally be obtained for the research use of medical information, including information derived from tissue samples, the procurement of consent may not be possible or practicable in every situation. Where the research poses minimal risk to individual privacy and confidentiality of information but promotes public good, the consent requirement may be waived, although appropriate privacy and confidentiality safeguards must be ensured. The types of research that typically qualify for such special treatment are epidemiological research and public health research.

20. Information held in disease registries and other national registries is essential to disease prevention, public health planning and policy-making, as well as research aimed at improving public health. We consider it to be ethically proper for medical information to be disclosed by physicians to national disease registries without patients' consent, provided that adequate privacy and other ethical safeguards are in place, and patients are appropriately informed.

21. Medical records may be stored as paper or electronic records, but in either case the ethical principles of consent and confidentiality would apply. Much valuable medical knowledge has resulted from the study of patients' medical records and there is every reason to encourage this established practice, provided patient privacy and the confidentiality of the medical information are safeguarded. We therefore recommend that IRBs be legally empowered to waive the patient consent requirement in situations where the research involves only the use of medical records, with no patient contact. For such research, IRBs should be satisfied that:

(a) the research is justified and poses minimal risk of harm to the patients concerned;

(b) the research would not be possible without the use of medical records;

(c) there are appropriate safeguards to protect patients' privacy and the confidentiality of their information;

(d) obtaining consent is not practicable; and

(e) the researchers are professionally and legally bound through appropriate contractual terms and undertakings to maintain patient privacy and the confidentiality of medical information.

22. Healthcare institutions should develop procedures to inform patients that their medical records may sometimes be used for research and explain the reasons for such research. They should also assure patients that all research will require the approval of an IRB, that there are safeguards to protect their privacy and the confidentiality of their medical information, and they should answer any questions patients may have.

23. Table 1 and Chart 1 on pages 42 and 43 summarise the consent requirements for the use of personal information and tissue in research.

Additional Considerations about Consent

24. Two additional considerations about consent are included in the Report - vulnerability and withdrawal of consent.

25. Vulnerability may be thought to exist if one's ability to give voluntary consent is compromised or if one would be at heightened risk of adverse consequences from the research. Three common categories of vulnerable person are:

(a) children and adolescents;

(b) the mentally impaired; and

(c) persons in dependent relationships.

26. When vulnerable persons are involved in research, they are entitled, as a general rule, to the same considerations of privacy and confidentiality protection as any other research participants, and this principle needs to be kept in mind in the conduct of the research.

27. Participants should be able to withdraw consent to participate in research at any point, and be made aware of the procedure for withdrawal and its implications

when consent is sought. Researchers should assure potential participants that no reason need to be given for withdrawing consent and that such decisions will not compromise the quality of any care or entitlements that might be given to them or their families, where applicable.

Access to Medical Information by Employers and Insurers

28. The Report also discusses third party access to medical information. Medical information should not be disclosed to third parties without the individual's consent, although there are circumstances when an employer or an insurance company may reasonably expect disclosure of medical conditions, with consent.

29. The main ethical difficulties arise when predictive information is involved, e.g. genetic information. Predictive health testing often entails a high level of uncertainty and even for monogenic (single gene) disorders there will often be rather limited predictability of severity and time of onset of the diseases. The key issue is the concealment of immediately relevant information. In the case of employment, the use of valid genetic or other health testing by employers is appropriate to address imminent health and safety concerns, or where the detected or predicted condition is incompatible with the requirements of the job.

30. In the case of insurance, we recognise the potential adverse selection problem that may arise if relevant information is withheld, and that risk evaluation for the purposes of determining insurance coverage inherently involves discriminating between applicants. However, we empathise with the public's concern over possible unreasonable discrimination in the availability of insurance coverage. Nor do we wish to see individuals deterred from obtaining needed information about their medical conditions for fear that they might then be obliged to disclose it.

31. In our view, much of the difficulty arises from uncertainty as to the actuarial value of genetic information, and our preferred solution is a moratorium, as in the UK, whereby predictive genetic test results will not be used by insurers, although certain exceptions apply.

LIST OF RECOMMENDATIONS

The Legal Protection of Personal Information

Recommendation 1: We recommend that the relevant authorities consider establishing a comprehensive statutory framework relating to the use and protection of personal information in biomedical research.

Privacy and Confidentiality

Recommendation 2: Personal information used for research should be de-identified as far and as early as possible and should be stored or transferred as de-identified information.

Recommendation 3: Researchers should take adequate measures to prevent inadvertent identification of individuals. Should an individual be identified inadvertently from de-identified information, the confidentiality and privacy rights of this individual are not abrogated by such identification, and steps should be taken to reinstate and secure them.

Recommendation 4: Irreversibly de-identified personal information need not be subject to privacy and confidentiality requirements.

Recommendation 5: Privacy and confidentiality safeguards should be commensurate with the potential risk of harm from disclosure, and should be proportional to the sensitivity of the information and the kind of research being carried out. When reversibly de-identified information is used for research, IRBs should consider the adequacy of the extent and means of the de-identification in proportion to the risk.

Consent and Proportionality

Recommendation 6: Specific consent should be obtained for sensitive research or when the research involves identified personal information or tissue samples. General consent should be a sufficient requirement for subsequent unspecified research involving the use of de-identified information or de-identified surplus or stored tissues. The information to be provided to the individual when taking consent should depend on and be proportional to the sensitivity of the research and the risk of harm.

Consent and Reciprocity

Recommendation 7: We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to national disease registries by physicians; and establish mechanisms enabling national registries and healthcare institutions to facilitate the use of personal information held or controlled by them for biomedical research that can significantly advance the public good, while safeguarding privacy.

Recommendation 8: We recommend that IRBs be legally empowered to waive the patient consent requirement for research involving only the use of medical records, while ensuring patient privacy and confidentiality of medical information.

Vulnerable Persons

Recommendation 9: We recommend that IRBs, when reviewing research proposals, ensure that any concerns in regard to vulnerable persons are appropriately addressed.

Withdrawal of Consent

Recommendation 10: Research participants should be allowed to withdraw their consent to participate in the research at any time without explanation and without prejudice, and should be informed of the procedure for withdrawal and its implications when consent is sought.

Access to Predictive Genetic Information by Employers and Insurers

Recommendation 11: We recommend that the government consider implementing a moratorium on the use of predictive genetic information for insurance purposes, consider the long-term implications of the accessibility of predictive genetic test results by employers and the insurance industry, and monitor developments in this area.

PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

I. Introduction

1.1 Modern scientific medicine, in its entirety, is a research-based enterprise, and biomedical research has been critical to advances in medical science and public health. Research has improved understanding of the effects of medication, of how environmental and lifestyle factors relate to diseases (such as smoking and cancer, heart and lung diseases) and longevity, and of the effectiveness of preventive and therapeutic practices. Sound research promotes public good and the facilitation of biomedical research is a public interest. Such research critically depends on the use of personal information.[1]

1.2 Personal information may be medical information, genetic information, demographic information, or other information of a private nature. The people from whom it is obtained include patients and volunteers who have agreed to participate in research (i.e. research participants); they may be alive, or deceased. The information may be derived from tissue samples, medical records, researchers' data files, or institutional databases; and these institutions may be of a public or private character. In all cases, the privacy of the persons concerned needs to be protected, since the information is personal and may be sensitive. Consequently, there are rules and conventions regarding the confidentiality and use of research data in general, and medical records in particular.

1.3 Despite these rules and conventions, people may nevertheless be concerned that information about them may be used against their interests, or in ways that they did not approve. These concerns are fed by awareness of the extent to which information can be captured, stored and used by electronic means, and are especially apt in the case of research. Such concerns are not unique to Singapore. They drive privacy and data protection issues in many parts of the world.

1.4 The modern view is that there should be regulation of who may access personal information, and what it can be used for. In the case of research, many scientifically advanced countries have established ethical and legal frameworks to maintain public confidence in and support for the research enterprise.[2] In addition, efforts directed at engaging the public in consultation and education

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1 The term 'personal information' is explained in paragraph 2.1 of this Report.

2 Office for Human Research Protections, US, *International Compilation of Human Subject Research Protections, 2007 Edition*, 2006.

have significantly increased in Australia, Japan, North America and Western Europe.

1.5 This Report considers the need for similar provisions in Singapore, where despite a commitment to developing biomedical research capabilities, the ethical and legal standards for the use of personal information for biomedical research are not always clear. It attempts to strike a balance between ensuring privacy concerns through appropriate safeguards on the one hand and facilitating research of legitimate public interest on the other. We identify five important issues that serve to structure the Report as a whole:

(a) What is personal information?

(b) Do we require a legal framework for the protection of privacy and confidentiality?

(c) Issues of privacy and confidentiality;

(d) Issues of informed consent; and

(e) Issues of access by third parties such as employers or insurance companies.

1.6 In preparing this Report, we have been mindful of the need to distinguish between ethical issues, and the limitations of the current legal or regulatory frameworks arising from recent advances in biomedical science. We have therefore not only made recommendations on ethical issues, but have at several points proposed clarifying the legal framework governing research.

1.7 Many of the ethical issues reviewed in this Report will have relevance to the work of research ethics committees, or Institutional Review Boards (IRBs). It is important that IRBs, whose primary function is to safeguard research participants, feel able to make the best decision, having regard to the needs of the researchers and the value of the research. They must feel able to do this without pressure to adopt the safest and most conservative decision just to avoid legal repercussions, either for themselves or the institutions that appoint them.

1.8 The aim of this Report is to outline applicable ethical principles and best practices in the use of personal information for biomedical research, many of which have already been implemented by IRBs in Singapore. The establishment of a culture in which biomedical research flourishes entails that researchers are clear as to acceptable ethical, legal and social boundaries, as well as the mechanism by which their proposals are reviewed. This explication will also help to assure the public that the procedures which researchers observe are mandatory and enforceable.

1.9 In addition to the consent and privacy concerns discussed in this Report, we note that as a general ethical requirement, research must be conducted in ways that ensure the welfare and safety of individuals. In a multi-cultural and multi-religious society, researchers and healthcare professionals should also be sensitive to the religious and cultural perspectives and traditions of individuals.

1.10 This Report was finalised after careful consideration of the feedback and suggestions received following the issue of a Consultation Paper entitled *The Use of Personal Information in Biomedical Research*, prepared by the Human Genetics Subcommittee of the Bioethics Advisory Committee (BAC). The Consultation Paper, which is reproduced at Annex B, was publicly released on 14 June 2006. Seventy healthcare, research and governmental institutions, and professional and religious organisations were invited to provide comments. A list of these organisations is provided in Annex C. Twenty-five written responses to the Consultation Paper were received and are set out in Annex D. In addition, the BAC held dialogue sessions with members of IRBs and researchers, to better understand their concerns relating to the Consultation Paper. An online discussion forum was set up for public comments on the Consultation Paper, and a public forum was conducted on 15 July 2006. The recommendations also take into account advice, comments and suggestions from local experts and the members of the BAC's International Panel of Experts. Four position papers from local experts are reproduced at Annex A.

II. Personal Information

2.1 Personal information is any information about an individual. It is a very broad term that includes personal particulars, details of medical conditions and healthcare management, physical or psychological measures, dietary requirements and religious or other beliefs. Personal particulars comprise information that identifies a specific individual, such as name, address, date of birth, image (eg. picture, photograph, video), voice recording, National Registration Identification Card (NRIC) number or other means of identification. Personal information may be obtained through written or electronic records, opinions, survey questionnaires, images, interviews, recordings and biochemical or other tests, or from analysis of human tissue.[3]

2.2 In this Report, we consider the use of personal information for the purposes of biomedical research. We are not concerned with the collection, management and use of medical information solely for clinical purposes, since these are already subject to clear ethical and legal requirements.

2.3 When personal information is used in research, it is necessary to ensure the confidentiality of the information and secure the privacy of the person concerned throughout the research process and in any publication resulting from it. Both these aims are usually achieved by de-identification of the information. De-identification refers to the separation of the identifying particulars from the rest of the information. We distinguish identified personal information from de-identified personal information, as follows:

(a) *Identified* personal information: Information where identifying particulars are included, so that the identity of the individual is known, for example, in a medical record;

(b) *De-identified* personal information:

(i) Reversibly de-identified personal information, in which personal identity information has been separated from the information, and a code or system of codes or encryption substituted, so that the identity of the person becomes unknown but could be restored using the codes or reversing the encryption; and

[3] Human tissue is defined as "all kinds of human biological materials derived from living or cadaveric donors, including solid body tissues, organs, foetuses, blood and other body fluids and their derivatives, cord blood, embryos, gametes (sperm and eggs) or any part or derivative thereof." BAC, *Human Tissue Research*, 2002, paragraph 2.1.

(ii) Irreversibly de-identified personal information, which is information that has been permanently stripped of identifying details and cannot be used to identify an individual.[4]

2.4 The extent to which personal information should be de-identified will depend on the sensitivity of the information, which in turn reflects the harm that might arise in the event of disclosure. This will be considered in Part IV, together with the ethical implications and treatment of each of these categories of personal information.

2.5 The most restrictive treatment of personal information should be reserved for the most sensitive information. Some information may not be especially sensitive (like height and weight), but very often, it may be sensitive and should be regarded as private. However, such information should only be considered private if alone or in combination with other information it *identifies* the individual. For example there are unusual situations where an extremely rare condition in a small community might identify an individual even when the individual is not named. In most cases, sensitive personal information relates to living individuals. However, personal information of deceased persons can also be sensitive.

2.6 Medical information is a particular kind of identified personal information. It refers to all information about a patient provided to a physician[5] or derived for the purpose of diagnosis or treatment, and includes the results of medical investigations or tests ordered by the physician. Information so collected is typically recorded, managed and used as medical records, which are governed by ethical and legal requirements, notably those set out by the Singapore Medical Council.[6]

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4 Internationally there is no agreed terminology for the categories of personal information, so explicit definition is important. For discussions of the terminological confusion in this area and the need for harmonisation, see: BS Elger and AL Caplan, "Consent and Anonymization in Research involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework," *European Molecular Biology Organization Reports* 7 (2006): 661-666; and BM Knoppers and M Saginur, "The Babel of Genetic Data Terminology," *Nature Biotechnology* 23 (2005): 925-927.

5 A physician is a person qualified to practice medicine under the Medical Registration Act (Cap. 174), Singapore.

6 Paragraph 4.1.2 of the *Ethical Code and Ethical Guidelines* of the Singapore Medical Council states the general content of clinically relevant information that should be documented as medical records: "All clinical details, investigation results, discussion of treatment options, informed consents and treatment by drugs or procedures should be documented." The same paragraph stipulates that medical records be kept in a manner that is clear, accurate and legible, made during consultation or shortly thereafter, and of "sufficient detail so that any other doctor reading them would be able to take over the management of a case." In addition, paragraph 4.2.3.1 states that a physician is to "respect the principle of medical confidentiality and not disclose without a patient's consent, information obtained in confidence or in the course of attending to the patient."

2.7 Certain personal information, such as genetic information, blood group, or current medication, may or may not be considered medical information, since this depends on whether or not it was provided to a physician for the purpose of treatment or diagnosis. Genetic information broadly refers to any information about the genetic makeup of an individual. It can be derived from genetic testing or from any other source, including a family history of a genetic condition.[7] The term 'personal information' in this Report includes all personal genetic information used in biomedical research.[8] In our Genetic Testing and Genetic Research report, we focussed on issues relating to the derivation of genetic information, and provided recommendations for the ethical derivation, management and use of genetic information. In many respects, considerations in this Report follow from points made in that report.

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7 BAC, *Genetic Testing and Genetic Research*, 2005, paragraph 3.1.

8 The term 'biomedical research' refers to Human Biomedical Research, which includes Direct Human Biomedical Research and Indirect Human Biomedical Research as defined in paragraph 3.7 of the IRB report of the BAC (*Research Involving Human Subjects: Guidelines for IRBs*, 2004). It does not include research in the social sciences or humanities. Direct Human Biomedical Research is "any kind of human biomedical research that involves any direct interference or interaction with the physical body of a human subject, and that involves a concomitant risk of physical injury or harm, however remote or minor" (paragraph 3.7(a) of the IRB Report). Indirect Human Biomedical Research is "any research (not qualifying as Direct Human Biomedical Research) involving human subjects, human tissue, or medical, personal or genetic information relating to both identifiable and anonymous individuals, undertaken with a view to generating data about medical, genetic or biological processes, diseases or conditions in human subjects, or of human physiology or about the safety, efficacy, effect or function of any device, drug, diagnostic, surgical or therapeutic procedure (whether invasive, observational or otherwise) in human subjects whether as one of the objectives or the sole objective, of the research study, trial or activity, and which research, study, trial or activity has the potential to affect the safety, health, welfare, dignity or privacy of the human subjects involved in the study, or of the donors of human tissue or information used in research, or of the family members of any of the human subjects or donors thereof, or to which such medical, personal or genetic information relates" (paragraph 3.7(b) of the IRB Report).

III. The Legal Protection of Personal Information

3.1 The trend in many countries is towards the establishment of a uniform legal framework for the protection of personal information. Much impetus to such a trend arises from unprecedented advances in information technology, allowing the enhanced accessibility and manipulation of electronically stored information. This creates new research opportunities, but poses new risks to the violation of privacy and confidentiality.[9] Scientifically advanced countries have considered it necessary to establish legal regimes for data protection in order to facilitate the exchange of personal information. Their experiences have been instructive and their most relevant provisions for the use of personal information in biomedical research are as follows:

(a) Research use of personal information is regulated within a comprehensive but general personal information protection regime that applies a minimum privacy standard across various ways of using information, including for biomedical research. Personal information that ceases to be identifiable or is unlikely to cause harm to anyone is generally exempted from the requirements of the regime. Such exempted information is typically irreversibly de-identified personal information or aggregate information that cannot identify any particular individual. The extent to which personal information protection regimes should apply to reversibly de-identified information, however, has been a contentious issue. We address this in Part IV of this Report;

(b) Personal information protection regimes generally allow individuals the right of access to their identified personal information held in a databank or registry, to ensure correctness of the information. However, access is not feasible in the case of biomedical research databases held in de-identified form since the researcher is unable to identify an individual;

(c) Data protection provisions usually limit information collection, storage and use to specific purposes, but such provisions may not be applicable in research, since it is not possible to foresee all the research uses of the information. Similarly, while the destruction of information after a suitable period is usually mandated under data protection laws, research data should normally be preserved in case fresh information or theories require further analyses;

[9] By 'privacy' we mean the quality of being secluded from the presence or view of others, thus, the keeping of one's personal information away from others. By 'confidentiality' we mean the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not without permission be divulged to others in ways inconsistent with the understanding of the original disclosure. In other words, one has some right to privacy, and one has the right to expect that proper safeguards will operate to ensure that private information is treated as confidential by those to whom it is divulged.

(d) Personal information protection regimes generally specify requirements for the transfer of personal information across national boundaries. One such requirement is for an independent body, for example an IRB, to consider if the mode of information transmission ensures effective data protection; and

(e) Many personal information protection regimes explicitly recognise the public interest as including certain kinds of research. Special mechanisms have been established to make available personal information for epidemiological research and public health research. We consider this in greater detail in Part V below.

3.2 The general support of our consultation parties and members of the public for the establishment of a personal information protection regime confirms our view that the majority of respondents expect the Government to ensure that their privacy interests are safeguarded, and that physicians and researchers alike will act responsibly and sensitively in managing their personal information. The establishment of a personal information protection regime carries a two-fold benefit. First, it provides a framework for public engagement and for policy development. We note that policy-makers in Australia, Japan, North America and Western Europe rely heavily on various forms of public consultation for formulating appropriate levels of data protection. Given the nature of the subject matter, this process of public engagement is an ongoing one. Second, it promotes the development of realistic expectations on the part of both researchers and prospective research participants regarding the use of personal information in biomedical research. Even though internationally recognised standards and best practices are available, every jurisdiction that has established a personal information protection regime has had to decide for itself the fundamental concerns it has in relation to personal privacy and the kinds of public interest that can override these concerns. A clear and realistic appreciation of privacy concerns is the foundation of public confidence.

3.3 With the globalisation of research, we anticipate that the collaborative exchange of de-identified personal information will become increasingly necessary. If this occurs, countries with data protection regimes will expect equivalent protection in countries with which such information is exchanged. We are therefore of the view that this is an appropriate time for the relevant authorities in Singapore to consider establishing a comprehensive statutory framework relating to the use and protection of personal information in biomedical research. This framework should include consideration of issues relating to the transfer of personal information to a third party and should provide judicial remedies and sanctions for any breach. We note that in many jurisdictions a public authority or government agency is established to administer data protection regimes.[10]

[10] For instance, privacy commissioners are responsible for ensuring compliance with privacy requirements in Australia and in Canada. In the US, the Office of Civil Rights of the

3.4 While we support the establishment of a personal information protection regime in Singapore, both regulators and the public should understand that the objective of the regime is to facilitate (rather than limit) the appropriate use of personal information, through the provision of proper safeguards. Regulators, IRBs and custodians of information should guard against a disproportionate emphasis on restrictive requirements under the regime, notably the requirement of specific informed consent for the use of personal information, which is a general requirement in such regimes. This occurred in Germany, Canada, the US and the UK,[11] and it severely limited important public health research, necessitating subsequent remedial regulatory action.

3.5 The reputation of Singapore as a centre for responsible biomedical research requires the development of a robust but sensible legal framework for personal information protection, taking into account practical concerns of researchers, and internationally recognised standards and best practices, including data protection mechanisms designed to enable research while maintaining privacy. We note that many of such standards and best practices have already been implemented by IRBs in Singapore.

3.6 Personal information is widely used in biomedical research. As with other leading jurisdictions, we consider the ethical principles of informed consent and confidentiality to be the key principles in such use, because it is these principles that protect the privacy of the individual. Wherever possible, individuals should know how personal information which they have provided in the course of medical care or for research may be used, how their privacy will be protected, and should be given the opportunity to withhold consent if they so wish.

Recommendation 1: We recommend that the relevant authorities consider establishing a comprehensive statutory framework relating to the use and protection of personal information in biomedical research.

Department of Health and Human Services serves to safeguard the privacy of individually identifiable health information.

[11] J Illman, "Cancer Registries: Should Informed Consent be Required?" *Journal of the National Cancer Institute* 94 (2002): 1269-1270; and JR Ingelfinger and JM Drazen, "Registry Research and Medical Privacy," *New England Journal of Medicine* 350 (2004): 1542-1543.

IV. Privacy and Confidentiality

4.1 Personal information that is used in biomedical research is often held in databases, particularly in the form of electronic databases. Most researchers will have a database, in the sense of having a system to store and access the data collected in the research, including any personal information. When a database is large, accessed by many researchers, contains particularly sensitive information, or is to be linked with other databases, ethical considerations of data protection become more pressing.

4.2 It is not our intention to specify particular means by which such databases may be established or managed. Indeed, we recognise the importance of diversity in research databases, and such diversity necessitates different approaches to their creation and operation. However, we suggest that IRBs note and approve data management arrangements, taking into account these guidelines as applicable:

(a) A procedure should be available for research participants to obtain information, make inquiries and withdraw their consent to participate in the research;

(b) Safeguards should be in place to ensure that there is no inappropriate or unauthorised access to information in the database, and to ensure the authenticity of the information;

(c) Depending on the sensitivity of the information or research concerned, a record may need to be kept of who has accessed information in the database and when;

(d) There should be proper limits established to any family contact, and the role of the research participant's attending physician, if any, should also be clearly established, if relevant;

(e) Procedures should be stated for re-contacting research participants or others such as relatives;

(f) Procedures should be stated for obtaining consent related to incompetent research participants;

(g) Research participants should understand, when consenting to participate, the extent and nature of any feedback that they might expect to get on the results of the research as it progresses, and that they can refuse such feedback; and

(h) In the case of deceased persons whose information or tissues may be in a database or tissue bank, access for research should be a matter for the

custodian of the information or tissues, having regard to any explicit objection by the deceased.

4.3 Insurance companies and employers should not have access to personal information in a research database. Research data is not obtained with the aim of providing research participants with specific information about their health status. As such it is of little value to insurance companies and employers, and may be misleading when used outside the research context. In addition, other sensitive information may be derived from research data, such as information about paternity or about the presence of heritable conditions. Researchers have an obligation to protect the privacy of research participants and other third parties such as the close genetic relatives of the participants, and to ensure the confidentiality of all information derived from the research. Issues concerning access to medical information by insurers and employers are further discussed in Part VI.

4.4 When it is necessary for identified personal information to be disclosed due to compulsion by law or other public interest requirements, the research participant should be informed promptly so that he or she may have the opportunity to challenge such compulsion.

4.5 It is the responsibility of researchers to prevent breaches of privacy in respect of personal information in their control or possession. A researcher will normally have access to personal information when it is collected from individuals who have agreed to participate in the research. Even though it is ethically proper for the researcher to hold personal information for purposes covered by the consent, the information should be de-identified as far and as early as possible in the process of information management. In particular, the storage and transfer of personal information should be effected as de-identified information whenever possible. Typically, reversible de-identification should adequately protect the privacy interests of research participants, although the decision to de-identify personal information on a reversible or irreversible basis would greatly depend on balancing the privacy interests of research participants with research requirements.

4.6 Researchers should ensure that personal information is protected by security safeguards appropriate to the sensitivity of the information and the risk of harm, actual or perceived. These safeguards should protect against loss or theft, as well as unauthorised access, disclosure, copying, use and modification. The degree and extent of safeguards should generally be proportionate to the sensitivity of the information held and the potential consequences that may arise from any inadvertent disclosure. Security safeguards should be comprehensive in proportion to the scale of the research when sensitive personal information is involved.

Recommendation 2: Personal information used for research should be de-identified as far and as early as possible and should be stored or transferred as de-identified information.

4.7 Legal scholars and ethicists have indicated that there may be circumstances where de-identification may fail to safeguard the privacy interest of research participants. For instance, de-identification may not sufficiently protect the privacy interest of those affected by diseases that are typically found only in identifiable groups of people, such as Tay-Sachs disease in Ashkenazim populations or sickle cell anaemia in people of African descent. The effectiveness of de-identification may also be limited in small and close knit populations, if extensive information is collected.

4.8 All researchers should respect the privacy of individuals concerned. They should not attempt to identify an individual from de-identified information without proper justification supported by an IRB, as it is a serious breach of ethics to do so. Researchers should also take adequate measures to prevent inadvertent identification of individuals.

4.9 A researcher accessing a de-identified database has no direct contact with and is unaware of the identity of the individuals contributing to the database. In the event that the researcher becomes aware of the identities of these individuals, whether through having access to a code or through other means, the researcher is obliged to treat the information as confidential.

Recommendation 3: Researchers should take adequate measures to prevent inadvertent identification of individuals. Should an individual be identified inadvertently from de-identified information, the confidentiality and privacy rights of this individual are not abrogated by such identification, and steps should be taken to reinstate and secure them.

4.10 Biomedical research that uses personal information (other than information that is irreversibly de-identified), or information that is not already in the public domain, must be approved by an IRB. If a personal information protection regime is established in Singapore (as *per* Recommendation 1), this requirement should be included. However, we have highlighted in our earlier discussion the fact that irreversibly de-identifying personal information would severely limit the research value of the information and further disable certain types of research, such as those that require further information from records over a period of time. Nevertheless, certain types of personal information may be especially sensitive such that irreversible de-identification is the only means by which the privacy interests of the individuals concerned may be protected.

4.11 There appears to be a consensus that irreversibly de-identified information should not fall within the purview of personal information protection regimes in

countries that have such a regime.[12] We agree with this position. Because such information effectively becomes data that is no longer traceable to a particular individual, breach of confidentiality and privacy is no longer possible. Such information may be treated in the same manner as information in the public domain. We recognise that the autonomy of individuals might arguably extend to determining the use of their irreversibly de-identified information, but we are of the view that the principle of reciprocity, which we discuss in Part V, Section B, should apply once de-identification is assured.

Recommendation 4: Irreversibly de-identified personal information need not be subject to privacy and confidentiality requirements.

4.12 For reversibly de-identified information, it is less clear how far such information should still be regarded as within the purview of personal information protection regimes. Leading scientific jurisdictions are still working towards a resolution. One of the key ethical issues is the extent of de-identification that is required before research information is considered to fall outside privacy and confidentiality requirements.

4.13 For some biomedical research, follow-up information concerning the same individual is needed. Hence, reversibly de-identified information is required. Such information should not attract the same legal and ethical obligations that attach to identified information. The extent of de-identification needed is a matter of proportion. The effectiveness of de-identification should be balanced against the level of sensitivity of the information and the harm that might follow in the event that an individual is identified. Since research involving reversibly de-identified information must be subject to IRB approval, it is the responsibility of the IRB to consider the extent and effectiveness of de-identification proposed.

4.14 When identified information is procured, it is the responsibility of researchers to ensure its confidentiality. We have discussed various confidentiality considerations above. These considerations include the storage and transmission of personal information as reversibly de-identified information whenever possible. Accordingly, even if a researcher has obtained the informed consent from a research participant to hold personal information about him or her, it would be prudent for the researcher to store the information in such a manner that the complete personal profile of the research participant is not readily accessible. For instance, the researcher may want to maintain a system of de-identification, through systems of coding or encryption of personal information;

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12 See definitions of 'personal data' in section 1 of the Data Protection Act (1998), UK; and 'human subject' in paragraph 46.102 of the Office for Human Research Protections, *Federal Policy for the Protection of Human Subjects: 45 CFR Part 46*, US 2005. See also: Privacy Advisory Committee, Canada, *CIHR Best Practices for Protecting Privacy in Health Research*, 2005, p 78; and National Health and Medical Research Council, Australia, *National Statement on Ethical Conduct in Research Involving Humans*, 1999, p 13.

through separate storage of coded or encrypted personal and identifying information; or by having the link between the codes or encryptions held by an independent third party. When an independent or trusted third party system[13] is properly operated, it is possible to link various items of personal data from different databases for research purposes, without revealing the identities of the individuals concerned.

4.15 We emphasise that the level of confidentiality safeguards, whether in the extent of de-identification or otherwise, should be commensurate with the potential risk to research participants. Generally, the confidentiality obligation of research institutions involved in large-scale research initiatives will be greater than that of research performed by a single researcher. In addition, researchers must comply with all regulatory requirements governing the confidentiality of information received from any custodian of personal information.

Recommendation 5: Privacy and confidentiality safeguards should be commensurate with the potential risk of harm from disclosure, and should be proportional to the sensitivity of the information and the kind of research being carried out. When reversibly de-identified information is used for research, IRBs should consider the adequacy of the extent and means of the de-identification in proportion to the risk.

[13] For a discussion on the trusted third party system and an illustration, please refer to the position paper in Annex A of this Report, on "Ensuring Data Privacy in Biomedical Research Involving Record Linkages" by Prof Chia Kee Seng.

V. Informed Consent

5.1 Generally, the use of personal information in biomedical research requires the voluntary and informed consent of the individual concerned and the approval of an IRB. In many situations, a researcher will only require access to reversibly de-identified personal information. In these cases, specific consent need not be obtained if the individuals have earlier provided a general consent for their personal information to be used for research, and the research has been approved by an IRB.

5.2 Specific consent is consent for a specific research project or for a specific purpose. General consent is consent that does not limit the use of the information or tissue contributed for a specific project or purpose. General consent is thus usually taken for future research, when no specific project has been planned. When a general consent is to be taken, patients or research participants must be given sufficient explanation to make an informed decision and be assured that all future research has to be approved by an IRB, with safeguards to protect their privacy and the confidentiality of their personal information.

5.3 Medical confidentiality requires that a patient's consent be obtained before his or her medical information may be used in research. Such consent requires that appropriate meaningful information should be provided to the individual. This obligation arises from the requirement that an individual's involvement in research must be voluntary. Even if the information is de-identified, the individual concerned must at some point have consented to the use of his or her information in research unless such research falls within the limited exceptions discussed below.

5.4 The need for informed consent and to safeguard privacy and confidentiality are two separate and necessary requirements for the use of personal information in research. The fact that consent has been obtained does not mean that privacy and the confidentiality obligations are abrogated. Similarly, even if privacy and the confidentiality of personal information are assured, informed consent must still be obtained in order for it to be used in research. This acknowledges the principle of autonomy by which individuals are held to have the right to determine how their information is used.

5.5 While the general ethical requirement is that informed consent must be obtained for the use of personal information in biomedical research, there are arguably certain exceptions. The provision of medical information by physicians to national disease registries is one such case that we discuss in Section B below. In addition, the experience of scientifically advanced countries suggests the need of a mechanism whereby the consent requirement may be dispensed with in exceptional situations involving research that poses minimal risk to the

individuals concerned and advances public benefit. Such research usually relates to public health, and certain bodies or authorities (such as an IRB or a government agency) are empowered by legislation to determine if research access should be permitted. In Section B, we propose that a similar mechanism be established in Singapore. But first, we consider the manner in which consent requirements should take into account the principle of proportionality.

Section A: Consent and Proportionality

5.6 It is of the nature of informed consent that one must consent with understanding. It should be self-evident that the language, occasion and manner of explanation, the level of detail offered, and the process by which the consent is taken, should all be aimed at helping the potential research participant understand what consent is being asked for. Provision of a large quantity of difficult information is not, in itself, a guarantee of understanding, which may require less information and more explanation.

5.7 Informed consent is generally required for obtaining personal information or tissue samples for research. When personal information or tissue is to be stored and used for future research, additional consent should be obtained, whether the research participant is a patient or not. This additional consent may be a general consent, in that no specific type of research need be identified at the time of consent-taking.

5.8 When a research participant is also a patient, his or her consent for research use of personal information or tissue samples, including surplus tissue left over following medical diagnosis or treatment, should be separate from the consent needed for any treatment. If information or tissue obtained in the course of medical treatment is to be stored and used for future research, consent should also be sought. This additional consent for future research use may be a general consent. It can be taken prior to treatment, or subsequent to it, depending on circumstances and it has to be taken in a timely and sensitive manner.[14]

5.9 In instances where patients may be potential research participants, we reiterate that particular caution is necessary when the attending physician is also the researcher, lest patients feel under an obligation to their physicians. IRBs should be sensitive to this possibility, and where the risk of pressure on a prospective research participant is seen as significant, IRBs may require an independent competent third party to take consent.

[14] Paragraph 8.3 of the *Human Tissue Research* report (2002) of the BAC states: "It is beyond our remit to suggest how valid requirements of consent be formally met. We cannot prescribe the particulars of how consent should be formally obtained, and we take the view that it is the responsibility of institutions to work out their own consent procedures and consent forms with their legal advisors, and to train their staff accordingly." This remains the view of the BAC.

5.10 At the time when a general consent is taken, researchers should provide the assurance that all subsequent research use of information or tissue would require the approval of an IRB, that such materials would not be used in ways likely to identify the research participant individually, that the research participant has the right to withdraw his or her consent at any time without giving any reasons and that if he or she is a patient, refusal to consent will not affect the quality of the medical care to which he or she is entitled. In addition, any expectation of commercial use of the information or tissue should be indicated. The extent of information to be provided will depend on the degree of actual or perceived risk.

5.11 Researchers and IRBs should be mindful of possible public sensitivity towards certain types of research. General consent is inappropriate for research involving the use of identified personal information or for sensitive research. If it is likely that personal information or tissue contributed by research participants may be used in any type of sensitive research, specific consent must be obtained. The UK Nuffield Council on Bioethics has considered certain types of genetic research that may be of public concern, such as those relating to personality, behavioural characteristics, sexual orientation or intelligence.[15] Where it appears to an IRB that an issue of public sensitivity may arise, the IRB may require specific consent to be obtained for the use of personal information or tissue, unless it cannot be used to identify participants, for example, through irreversible de-identification.

5.12 We stress, however, that biomedical research using personal information benefits the public through advances in medical science. It often requires the use of de-identified information, which carries little risk of harm. It would not be prudent to constrain such research by always insisting on the stringent standards needed to manage exceptionally sensitive information.

5.13 Accordingly, the process of obtaining consent should be detailed in proportion to the sensitivity of the research and the actual or perceived risk of harm to the individual concerned. Consent should be explicit and in writing[16] where the risk of harm to the individual is appreciable, for example, if tissue is sought for research via a surgical procedure, as in oocyte donation by healthy donors. In such cases the information provided should be correspondingly detailed. Where the risk is low or non-existent, less information may suffice for the individual to feel able to give consent.

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15 Nuffield Council on Bioethics, UK, *Genetics and Human Behaviour: The Ethical Context*, 2002.

16 Consent is legally valid whether it is in writing or not. However, putting consent in writing makes for easier resolution in the event of any dispute over whether consent was taken or what was consented to. It is generally desirable in research, where the researcher is the party requesting information or tissue samples. In the case of consent for clinical procedures, existing conventions for taking consent will apply.

5.14 Personal information or tissue that is provided for research by way of a general consent may be used in subsequent research without further consent. This relieves the researcher of the need to re-contact the individual concerned for specific consent. So long as the individual was fully informed and agreed to the future research application of his or her personal information or tissue, we are of the view that consent has been obtained, although other ethical obligations (such as to undergo IRB review and to keep the information secure and confidential) will continue to apply. If the individual is also a patient, the consent-taking process must allow the patient to decline without prejudice to his or her treatment.

5.15 In summary, we are of the view that specific consent is required for sensitive research or when the research involves identified personal information or tissue samples. General consent should be a sufficient requirement for subsequent unspecified research, subject to de-identification of the information and tissue as well as IRB review. Re-consent for future research is then not necessary.

Recommendation 6: Specific consent should be obtained for sensitive research or when the research involves identified personal information or tissue samples. General consent should be a sufficient requirement for subsequent unspecified research involving the use of de-identified information or de-identified surplus or stored tissues. The information to be provided to the individual when taking consent should depend on and be proportional to the sensitivity of the research and the risk of harm.

Section B: Consent and Reciprocity

5.16 Essentially, the consent requirement ensures that an individual's decision to participate in research by providing personal information (whether subsequently de-identified or not) is a free choice. However, the value of free choice does not supersede all other values in our society. Similarly, freedom from intrusion into one's private life is not an absolute value. There are circumstances where other legitimate public interests take priority.

5.17 In our Human Stem Cell[17] and Genetic Testing and Genetic Research[18] reports, the guiding principles of 'justness' and 'sustainability' highlighted the need to respect the common good of both present and future generations, together with the importance of fair sharing of social costs and benefits. The reciprocity implied in these principles also applies in research; research depends on informed voluntary contributions or participation, and need not benefit the participants, but it benefits others in the future.

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17 BAC, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*, 2002, Chapter 7, paragraph 3.

18 BAC, *Genetic Testing and Genetic Research*, 2005, paragraph 4.38.

5.18 While it is generally accepted that the requirement of informed consent is important, as it acknowledges the principle of autonomy, this principle should not be rigidly applied, but should be considered in relation to the risk of harm to research participants, and the value of the research where important public interest may be served. Procedures for obtaining consent from research participants were considered in a UK report, in this case for the collection and retention of biological samples that could be used for genetic analysis.[19] The report recommended that consent procedures include notice to prospective research participants that:

> "(i) the medical treatment that all receive is based on studies carried out on very many earlier patients and that the request is for them to provide similar help for future generations;
>
> (ii) because medical science is changing very rapidly, some of the valuable uses to which the data could sooner or later be put are not foreseeable".

5.19 These recommendations entail the principle of reciprocity. This is the idea that accepting benefit from past medical research, inherent in the utilisation of medical services, carries some expectation of a willingness to participate in research for the common good or public interest. This is an especially important consideration in societies, including Singapore society, where individuals are seen as incurring obligations to others through their membership of and roles in society. In the wider public interest, therefore, we see the principles of autonomy and reciprocity as complementary.[20]

5.20 In general, under the principle of reciprocity, one might presume that de-identified information should be available for benevolent purposes. In a similar vein, de-identified information extracted from clinical records or from tissue collections should be available, provided the research is IRB-approved. The goal of ethics guidelines is to ensure ethical propriety in the conduct and regulation of biomedical research. Such guidelines are intended to promote a culture of confidence that facilitates rather than hampers responsible research.

5.21 There are many important uses of personal and medical information that do not contribute directly to the healthcare of individuals, but are beneficial to society. These uses include epidemiological research and public health protection requirements, where personal information may be used without the explicit consent of individuals concerned. Such uses are likely to promote public welfare without posing risk of harm to individuals concerned and are gaining ethical endorsement internationally, under the principle of reciprocity.

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[19] House of Lords' Select Committee on Science and Technology, UK, *Fourth Report: Human Genetic Databases: Challenges and Opportunities*, 2001, paragraph 7.65.

[20] See the position paper in Annex A on "The Use of Personal Information in Biomedical Research: Some Philosophical Issues" by Associate Professor Nuyen Anh Tuan and the written submission by Majlis Ugama Islam Singapura in Annex D of this Report.

Disease Registries

5.22 The National Disease Registries Office (NDRO) was established in 2001 as a department under the Health Promotion Board to manage and develop the Singapore Cancer Registry, the Singapore Renal Registry and the Singapore Stroke Registry. Apart from these registries managed by the NDRO, other national disease registries in Singapore include the Singapore Myocardial Infarction Registry, the National Thalassaemia Registry, the Singapore Myopia Registry and the National Birth Defects Registry. These registries collect patient information, analyse the data and report incidence and trends of diseases in Singapore. Their work is critical to sound public health policy formulation and programme planning, as well as for research in general. For example:

(a) A recent study on trends in cancer incidence in Singapore from 1968 to 2002 relied on data derived from the Singapore Cancer Registry and other sources. In the last 35 years several types of cancer have increased, but cancers of the stomach, liver, oesophagus and nasopharynx have declined substantially;[21]

(b) About 10,000 Singaporeans are admitted into hospitals for strokes and transient ischaemic attacks every year, thereby making stroke the fourth leading cause of death;[22]

(c) Research using data drawn from the Singapore Myocardial Infarction Registry from 1988 through 1997 indicated that women who have heart attacks tend to be older than men and are more likely to have prior ischaemic heart disease, atypical symptoms and worse prognosis than men if they are aged 64 years or below;[23] and

(d) In 2000, it was found that 47% of all new cases of end-stage kidney disease in Singapore were due to complications of diabetes, making Singapore the country with the second highest incidence of such cases of kidney failure in the world. This finding is important for devising preventive measures.[24]

5.23 Not surprisingly, all major scientific countries have established disease registries. However, when many of these countries first implemented personal information protection regimes, a disproportionate emphasis was placed on the

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21 Singapore Cancer Registry *Report No. 6: Trends in Cancer Incidence in Singapore 1968–2002*, 2004, p 34.

22 National Neuroscience Institute, *Community-Based, Tri-Racial, Cross-Sectional Study on Prevalence of Stroke among Chinese, Malay and Indian Singaporeans*, www.nni.com.sg/Newsroom/MediaRelease/Stroke+Prevalence.htm (accessed Mar 20, 2007).

23 R Kam, et al, "Gender Differences in Outcome After an Acute Myocardial Infarction in Singapore," *Singapore Medical Journal* 43 (2002): 243.

24 A Vathsala and HK Yap, "Preventive Nephrology: A Time for Action," *Annals of the Academy of Medicine* 34 (2005): 1-2.

need to obtain specific consent from patients before information in their medical records could be disclosed to such registries by physicians. In many of these countries, epidemiological research, as well as public health research, was severely affected as a result.[25] In Part III above, we have noted our concern to prevent a similar occurrence in Singapore.

5.24 Medical information is protected by medical confidentiality and may not ordinarily be disclosed without the consent of the patient concerned. However, it is important to understand that it is inappropriate to apply a strict informed consent requirement for every kind of biomedical research using medical information. The UK Academy of Medical Sciences clearly identified problems that can arise:[26]

(a) It may be impracticable to seek consent for a number of reasons, including temporal or geographical distance, and insupportable time and expense. Researchers have in the past analysed and linked thousands of medical records with data from other sources (including death records). These patients were not contacted for consent to use their information for research, and it would have been impossible to do so since many had died. However, confidentiality safeguards were observed so that the privacy interests of these patients were protected. Such research allowed the identification of risk factors for diseases, enabling preventive measures to be taken;

(b) Strict insistence on informed consent may compromise effective population coverage, which is critical for population studies and disease registries. If many people decline, the data may no longer be representative, especially since the difficulties of obtaining consent are higher for certain segments of populations, such as the legally incompetent, the elderly or the socially disadvantaged. In such circumstances, a requirement for informed consent can lead to a significant bias or diminution in the quality of the data, which may be rendered useless;

(c) Patients may be inconvenienced or distressed at being contacted for the use of their personal information in research. There are also patients who do not wish to be reminded of a disease diagnosis or may be in denial; and

(d) The reliability and generalisability of studies may be reduced, since a strict consent requirement will increase the cost of such studies, thereby

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25 J Illman, "Cancer Registries: Should Informed Consent Be Required?" *Journal of the National Cancer Institute* 94 (2002): 1269-1270; and JR Ingelfinger and JM Drazen, "Registry Research and Medical Privacy," *New England Journal of Medicine* 350 (2004): 1542-1543.

26 The Academy of Medical Science, UK, *Personal Data for Public Good: Using Health Information in Medical Research*, 2006, pp 58-61.

leading to smaller study size and larger random errors. In some cases, consent may introduce unacceptable bias into the research findings and penalise some groups (such as schizophrenic patients).[27]

5.25 As a matter of ethics, the use of medical information to secure or advance public health in a way that does not prejudice the patients concerned is an important practical expression of the principle of reciprocity. Existing patients are receiving the benefits of improved medical care through the use of medical information from past patients for research. There is little ethical justification for them to refuse a similar use of their medical information where their interests are not likely to be compromised. The principle of autonomy should not be applied mechanically, such that epidemiological and public health research directed at advancing the common good of improved medical care for future patients is hampered without good cause. Accordingly, we consider it to be ethically acceptable for medical information to be disclosed by physicians to national disease registries provided that adequate privacy and other ethical safeguards that we have discussed in this Report are in place, and that patients are appropriately informed. The essential principle is that the privacy of the patient should be primarily protected by appropriate privacy safeguards, rather than by the exercise of patient discretion in the use of information for the general good.

5.26 We have considered the experience of scientifically advanced countries that share a common legal heritage with Singapore. It appears that an ethical position on the disclosure of medical information for the purposes of important epidemiological and public health research may not be adequate in the absence of clear common law precedents, and legislative action may be required. Recently, the provision of medical information to a cancer registry for public health purposes became the subject of controversy in the UK.[28] The question was whether the provision of medical information to such a registry and its subsequent use in research required patients' consent, and if it did, at what point and in what form. The main concern was the possibility that individuals might be identified. As a result, the UK Government had to introduce new legislative and regulatory guidelines in 2001 to put transfer of medical information to these registries on a sound legal footing.[29] Safeguards were proposed to ensure the anonymity of those on the registry to the fullest extent possible.[30] These guidelines allow disclosure of medical information to the cancer registry and for the registry to use such information for biomedical research that serves the general good, even without consent.

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27 L Roberts & S Wilson, "Argument for Consent may Invalidate Research and Stigmatise Patients", *British Medical Journal* 322 (2001): 858.

28 House of Lords' Select Committee on Science and Technology, UK, *Fourth Report: Human Genetic Databases: Challenges and Opportunities*, 2001, Chapter 7.

29 Health and Social Care Act (2001), UK, Section 60; and *Statutory Instrument 2002 No. 1438, The Health Service (Control of Patient Information) Regulations*, 2002.

30 For instance, Section 61 of the Health and Social Care Act (2001), UK, requires the Secretary of State to act upon the advice of the independent statutory Patient Information Advisory Group.

5.27 Similar developments have also been observed in the legal and regulatory landscapes of Australia and Canada, and in certain non-common law countries. For instance, the Swedish Personal Data Act (1998) provides that sensitive personal data may be processed for research and statistics purposes, even without the consent of patients, provided that the processing is necessary and that the interest of society is greater than the risk of improper violation of the integrity of the patients concerned. It further provides that research ethics committees or IRBs must approve the processing of personal information. Integral to this arrangement is the requirement that hospitals and custodians of personal information must consider privacy and confidentiality concerns before allowing access to personal information.

5.28 We generally consider these developments to be positive. In the past, it may have been acceptable for public healthcare institutions in Singapore to provide medical information to government entities for epidemiological or public health purposes. However, these healthcare institutions have been privatised in recent years and it has become unclear if government entities are able to require disclosure of medical information without the explicit consent of the patients concerned. In addition, the legality of non-consensual disclosure of sensitive medical information to public health authorities for the protection of public health has long been recognised and provided for under the Infectious Diseases Act (Cap. 137). Under this legislation, a physician, or indeed anyone who has reason to believe or to suspect that an individual is suffering from a specified infectious disease (such as the Severe Acute Respiratory Syndrome, or SARS) or is a carrier of that disease, is required to notify the Director of Medical Services. While infectious diseases continue to be of grave concern to public health authorities, many more Singaporeans are today affected by conditions that are serious but not infectious, such as cancer, heart disease, renal disease and stroke. These conditions are the primary interest of national disease registries, and they are of no less public health significance.

5.29 As such, we recommend that the relevant government authorities consider adopting measures similar to those in the abovementioned countries, in order to enable the disclosure of medical information to national disease registries subject to privacy safeguards. Such disclosure should be made by all physicians, whether practising privately or in public institutions. These measures should include mechanisms to allow the use of registry information in important epidemiological research and public health research, because it is almost always impossible or impractical to obtain consent from all patients and there is little or no risk of harm to those concerned.

Epidemiological Research and Public Health Research

5.30 Apart from medical information in disease registries, personal information held in other national registries, such as the Registry of Births & Deaths, is also an invaluable resource for important biomedical research (typically epidemiological

research). From an ethical perspective, it can be argued that reversibly de-identified information could be released from disease registries and other national registries for such research, provided that adequate de-identification and privacy safeguards are in place. Technical and organisational systems that permit linkage of data exist, such that information needed for research can be made available without prejudicing the privacy of the persons to whom the data relate. A system of this kind provides an ethical method of protecting privacy.

5.31 The informed consent of individuals concerned is generally required before identified information about them may be used. In addition, if it is anticipated that such identified information would be shared with other researchers or used in other research, then the consent obtained should reflect agreement to such extended use. However, this consent requirement need not apply to the use of reversibly de-identified information in epidemiological research and public health research.

5.32 Important public health justification, with minimal risk of harm to individuals, has been considered in some jurisdictions to provide sufficient justification for the research use of personal information without the need to obtain informed consent.[31] The types of research that typically qualify for such special treatment are epidemiological research and public health research. In many of the scientifically advanced countries, legal mechanisms have been implemented to facilitate such use. For instance, in Australia and Sweden, ethics review committees are empowered to make such public interest valuations.[32] Section 60 of the UK Health and Social Care Act 2001 was similarly enacted to mitigate the strict consent requirement.

5.33 In the light of these precedents, we take the view that it is ethically acceptable for researchers conducting IRB-approved epidemiological research and public health research to be allowed access to personal information from disease registries and other national registries, without the usual consent requirement, if the risk is minimal and safeguards are adopted for the protection of patient's privacy. Various mechanisms are available to allow research access to personal information in ways that do not significantly compromise confidentiality and privacy concerns. We consider the availability of such mechanisms to be to the general good. Some of these mechanisms may only be put in place through legislative means and we recommend that the relevant authorities consider establishing them.

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[31] National Health and Medical Research Council, Australia, *National Statement on Ethical Conduct in Research Involving Humans*, 1999, paragraph 14.4; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 2005, article 2.1c; and Office for Human Research Protections, US, *Federal Policy for the Protection of Human Subjects: 45 CFR Part 46*, 2005, §46.116.

[32] Privacy Act (1988), Australia, Section 95; National Health and Medical Research Council, Australia, *Guidelines under Section 95 of the Privacy Act 1988,* 2000, clauses 2.4 and 3.3; and Personal Data Act (1998), Sweden, Section 19.

Recommendation 7: We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to national disease registries by physicians; and establish mechanisms enabling national registries and healthcare institutions to facilitate the use of personal information held or controlled by them for biomedical research that can significantly advance the public good, while safeguarding privacy.

Use of Medical Records in Biomedical Research

5.34 In a healthcare institution, all personnel who handle medical records are under a legal and ethical obligation to observe the confidentiality of the information in the records and to safeguard the privacy interests of patients concerned. We are of the view that a similar obligation should extend to any other person coming into contact with medical records.

5.35 Medical records are likely to be increasingly electronic in nature. The Electronic Medical Record Exchange (EMRX) is an initiative of the Ministry of Health (MOH) to enable hospitals and polyclinics from the two healthcare clusters, Singapore Health Services and National Healthcare Group, to electronically share medical information for better patient care.

5.36 The MOH has identified the benefits of the EMRX to be:

(a) improvement to the quality of care provided;

(b) increase in safety, since patients' drug allergies and current medications will be readily accessible to attending physicians; and

(c) reduction to medical cost, as physicians can now view the results of any recent blood tests, X-rays and investigations online without having the need to repeat such tests.[33]

5.37 Currently, only physicians and healthcare staff involved in the care of a patient may legitimately access that patient's information in the EMRX, and information protection safeguards have been implemented. The MOH does not permit research access to information in the EMRX. However, information in the EMRX may be a potential source of personal information for research. If research access were to be considered, the ethical principles of informed consent and confidentiality would apply. This also applies to institution-based disease databases, created primarily for patient care.

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33 Ministry of Health, Singapore, *Electronic Medical Record Exchange (EMRX) - Sharing of Hospital Inpatient Discharge Summaries across Public Healthcare Clusters*, 2004, www.moh.gov.sg/corp/about/newsroom/pressreleases/details.do?id=18382854 (accessed 20 March, 2007).

5.38 Much valuable medical knowledge has resulted from the study of patients' medical records and there is every reason to encourage this established practice, provided patients' privacy interests are safeguarded. Some of these studies have led to improved patient care, others to a better understanding of the nature of specific diseases and their treatment.

5.39 We therefore recommend that IRBs be legally empowered to waive the patient consent requirement in situations where the research involves only the use of medical records, with no patient contact[34]. For such research, IRBs should be satisfied that:

(a) the research is justified and poses minimal risk of harm to the patients concerned;

(b) the research would not be possible without the use of medical records;

(c) there are appropriate safeguards to protect patients' privacy and the confidentiality of their information;

(d) obtaining consent is not possible or practicable; and

(e) the researchers are professionally and legally bound through appropriate contractual terms and undertakings to maintain patient privacy and the confidentiality of medical information.

5.40 The findings of research based on medical records may subsequently be published. Such publications do not and should not include any identified patient information. Photographic images may sometimes be included to support or illustrate the findings, and these too should not identify the patient concerned unless specific consent has been obtained. We note that anonymity is in any case required by journal editors, who will only publish identified patient information with the patient's explicit consent.

5.41 Healthcare institutions should develop procedures to inform patients that their medical records may sometimes be used for research and explain the reasons for such research. They should also assure patients that all research will require the approval of an IRB, that there are safeguards to protect their privacy and the confidentiality of their medical information, and they should answer any questions patients may have.

Recommendation 8: We recommend that IRBs be legally empowered to waive the patient consent requirement for research involving only the use of medical records, while ensuring patient privacy and confidentiality of medical information.

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[34] In paragraph 3.15 (a) of the report *Research Involving Human Subjects: Guidelines for IRBs* (2004), the BAC suggested that writing up or reporting individual patients' clinical results by their doctors could be exempted from IRB review. This remains the view of the BAC.

5.42 Table 1 and Chart 1 on pages 42 and 43 summarise the consent requirements for the use of personal information and tissue in research.

Section C: Additional Considerations about Consent

Vulnerable Persons

5.43 Vulnerability may be thought to occur if an individual's ability to give informed and voluntary consent is compromised or if he or she would be at heightened risk of adverse consequences from the research. In our Genetic Testing and Genetic Research report[35] we identified three common categories of vulnerable persons, namely:

(a) children and adolescents;

(b) the mentally impaired; and

(c) persons in dependent relationships: such persons include but are not limited to students, junior research assistants, medical or paramedical staff, personnel under military discipline, or prisoners.

5.44 Vulnerable persons raise particular ethical issues in research, especially where consent is concerned. This is because their individual interests must be considered, if necessary by proxy, and their participation sought only when other research participants are unavailable or unsuitable. As a group, however, they may have a particular interest in the benefits of research, and participating in research can sometimes be regarded as also serving their collective interest.

5.45 Where personal information is concerned, it is our view that individuals in these categories are entitled, as a general rule, to the same considerations of privacy and protection as any other research participants.

5.46 In the case of children and adolescents, and still more in the case of infants, much of their personal information is naturally known to parents or guardians. It is the responsibility of researchers to ensure on the one hand that parents or guardians are appropriately informed when consent for their children to participate in research is sought, and on the other that children or adolescents are also informed and their consent sought, in a manner appropriate to their level of understanding. We emphasise that persons responsible for the care of children and adolescents should only act in the best interest of the latter. This 'best interest' principle also applies when such a person is to provide informed consent on behalf of a child or an adolescent for the use of his or her personal information in research. In any case, personal information relating to infants,

[35] BAC, *Genetic Testing and Genetic Research*, 2005, paragraphs 4.8-4.18.

children and adolescents should be accorded the same privacy protection by researchers, as would be granted to information from any consenting adult.

5.47 In the case of mentally impaired persons who are legally incompetent, a similar principle applies. Consent to participate in research may be managed by persons who are authorised by law to make such decisions on their behalf and they are obliged to consider the best interest of such persons in their care. In any event the research participant should be involved as far as possible in the decision process, and enjoy the same privacy safeguards with respect to personal information as any consenting adult of sound mind.

5.48 In the case of dependent persons, it is important to avoid situations where an individual might feel obligated to participate in research. For example, serving National Servicemen may feel obliged to give consent to those with authority over them, and it would be desirable for an IRB to consider if consent-taking should be undertaken by an independent third party rather than through the line of command. Similarly, it might be wise for researchers not to rely on their own staff or students to serve as research participants. Notwithstanding considerations of consent, however, we again stress that personal information from dependent participants should enjoy the same protection as that of any other participant.

5.49 We are therefore of the view that IRBs when reviewing research proposals should take note of cases where research participants might appear to be vulnerable, and satisfy themselves that any concerns over the informed and voluntary nature of the participation are appropriately addressed.

Recommendation 9: We recommend that IRBs, when reviewing research proposals, ensure that any concerns in regard to vulnerable persons are appropriately addressed.

Withdrawal of Consent

5.50 Regardless of how a research participant is involved (whether in the provision of tissue, personal information or other forms of involvement), he or she should be able to withdraw consent to participate at any point. Researchers should assure potential participants that no reason need to be given for withdrawing consent and that such withdrawal will not compromise the quality of any care or entitlements that might be given to them or their families, where applicable.

5.51 Research participants need to be aware that it may or may not be possible to identify and remove their data or tissue samples from a research project, should they withdraw. Participants may, in any case, be willing to allow their information or tissue to be used, after they withdraw, provided they themselves have no further involvement with the research. The essential principle is that the participant needs to be aware, when they consent to participate, of the procedure for withdrawal and its implications.

Recommendation 10: Research participants should be allowed to withdraw their consent to participate in the research at any time without explanation and without prejudice, and should be informed of the procedure for withdrawal and its implications when consent is sought.

VI. Access to Medical Information by Employers and Insurers

6.1 Medical information should not be disclosed to a third party without the individual's consent. However, there are circumstances where a person may be required to make available his or her medical information in order to obtain access to certain economic, political or social goods. The possibility and extent of access to medical information by third parties is very relevant to public confidence in the capability of existing healthcare institutions to safeguard the interests and welfare of individuals. In this Part, we focus on access to medical information for two main non-therapeutic and non-research purposes: obtaining employment and obtaining insurance coverage.

Employers

6.2 An employer is reasonably entitled to ensure that a prospective employee is able to meet the requirements of the job by virtue of good health, either before or during employment. Many employers in Singapore do take into account the health status of job applicants, particularly if they provide employees with some measure of health insurance.

6.3 Employers will often arrange for prospective employees to undergo a medical examination with the understanding that acceptance for employment is subject to satisfactory medical examination. Pre-employment medical examination is considered acceptable so long as the information derived from the examination is relevant to the nature of the job that the prospective employee is expected to undertake. However, the usual ethical obligations attending medical information apply even though such information is not held by an employer for the purposes of healthcare provision or biomedical research. Once an employee leaves the employment, or if an employer declines to employ an applicant, the relevant medical reports should be carefully disposed of by the employer within a reasonable time.

6.4 Employers might also wish to carry out specific medical tests on applicants or employees. For instance, employers might seek to conduct tests to reduce workers' compensation claims, to meet occupational health and safety obligations, or to increase productivity, by screening out employees who are most likely to be absent from work due to illness. In addition, the testing could potentially take the form of predictive genetic testing in an attempt to identify if an individual who is currently asymptomatic has a genetic profile that increases the likelihood that he or she will develop a disorder as a result of the workplace environment.

6.5 The usefulness of predictive health testing of any kind, whether genetic or not, depends heavily on the validity of the tests as predictors, the level of probability associated with any prediction, and the nature of the effects of the disease or

disorder. As gene technology is still very much in its infancy, there is often a high level of uncertainty in the predictive value of genetic information. We are concerned that potential employers may discriminate on this basis. Even for monogenic diseases, it is usually not possible to predict the severity or time of onset of the disease in question and there is the possibility that the disease may not even manifest itself during the working life of the individual.

6.6 An employer may not arbitrarily discriminate against a prospective employee on irrelevant grounds without ethical compromise. This issue can arise if employers discriminate on grounds of age, gender, race or religion, for example. In general we take the view that merit in the form of ability to do the job is the important criterion. In a similar way, discrimination based on the possibility of developing late-onset health problems, or on relatively irrelevant or minor health grounds, would be difficult to defend. However, a measurable and relevant impairment of ability, at the time of application or soon thereafter, incurs a cost on an employer, and may entail a risk to the employee or to the public.

6.7 We are of the view that genetic testing should not be part of pre-employment medical examination. However, we agree that the use of valid genetic or other health testing by employers is appropriate to address imminent health and safety concerns, or where the detected or predicted condition is incompatible with the requirements of the job, especially insofar as these affect third parties.

Insurers

6.8 In order to obtain life and health insurance, a person may be asked to provide detailed information about his or her health, the health of his or her parents and siblings, and certain lifestyle information such as smoking and drinking habits. A person may also be required to undergo a medical examination. The possibility of including predictive genetic test results as part of this information has surfaced as a concern in several jurisdictions.

6.9 There are costs to an insurance company if it is denied relevant health or medical information, genetic or otherwise. These costs are borne by other policy holders. A system of national insurance can absorb this cost in the public interest of avoiding an uninsured population, but private insurers are not under any obligation of this nature.

6.10 Concealing relevant information to which an insurance company is entitled may void a policy. If the insurance company is not entitled to the information but the policy applicant has it, an 'adverse selection'[36] situation is created. On the other hand, it is not in the public interest, that individuals become reluctant to

[36] For a discussion on adverse selection, see paragraphs 2.8–2.10 and 2.15 of the position paper by the Life Insurance Association of Singapore on "Genetics and Life Insurance" in Annex A of this Report.

undergo necessary genetic or other health testing for fear of having to disclose the results. If this were to occur, both the ability of physicians to provide the best healthcare to patients and the potential benefits of biomedical research could be reduced.

6.11 We recognise the potential adverse selection problem that may arise as a result of inequality of information and that risk evaluation for the purposes of determining insurance coverage involves discriminating between applicants. However, we empathise with the public's concern over possible unreasonable discrimination in the availability of insurance coverage. It is reasonable to argue that the onus is on insurance companies to show that requested information can be used in valid ways, since the actual risk may be quite small and difficult to predict. Moreover, no one should be compelled to undergo genetic testing in order to obtain insurance coverage.

6.12 A detailed review was undertaken by the UK House of Commons' Select Committee on Science and Technology in 2001.[37] The Select Committee recommended that the Genetics and Insurance Committee (GAIC), a non-statutory advisory public body, closely monitor the situation to ensure that the insurance industry only use genetic test results approved by the GAIC.

6.13 Following the recommendations of the Select Committee, a 5-year moratorium was implemented by agreement between the UK Government and the Association of British Insurers in 2001. The moratorium has since been extended for another five years to 2011.[38] Under the moratorium, a person will not be required to disclose the result of a predictive genetic test unless the test has been approved by the GAIC (to date, only Huntington's Disease has been approved) and is for coverage of more than £500,000 of life insurance or £300,000 of critical illness insurance, or income protection insurance with annual benefits of more than £30,000.

6.14 We are of the view that a similar moratorium on the use of predictive genetic information could be considered in Singapore. This would allow time for both the insurance industry and the government to look into the substantive issues. Both parties should ensure that only relevant and reliable information is used in assessing insurance applications, and that the outcomes of the conditions considered are both serious and predictable, before considering lifting any such moratorium.

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37 House of Commons' Select Committee on Science and Technology, UK, *Fifth Report: Genetics and Insurance*, 2001.

38 Department of Health and Association of British Insurers, UK, *Concordat and Moratorium on Genetics and Insurance*, 2005.

Recommendation 11: We recommend that the government consider implementing a moratorium on the use of predictive genetic information for insurance purposes, consider the long-term implications of the accessibility of predictive genetic test results by employers and the insurance industry, and monitor developments in this area.

Table 1. The relationship between use of personal information or tissue and the consent requirements, as they are now or are proposed in this Report. The relevant Recommendations (Rec) in the Report are also indicated.

Flow-chart reference	Use of personal information or tissue	Consent	Report Rec No.
1	Obtaining information or tissue for specific research, from a research participant, whether a patient or not	Specific	6
2	Research using identified information or tissue (any source)	Specific	6
3	Research into sensitive topics or with information of a sensitive nature (any source)	Specific	6
4	Storing and using reversibly de-identified information for future research not of a sensitive nature	General	6
5	Storing and using reversibly de-identified tissue, including tissue surplus to clinical requirements, for future research not of a sensitive nature	General	6
6	Use of medical records for research with no patient contact	Conditional waiver by IRB[39]	8
7	Public health or epidemiological research with de-identified information	None	7[40]
8	Disclosure of medical information to national disease registries	None	7[41]
-	Research with legacy tissue collections	None if impracticable[42]	-

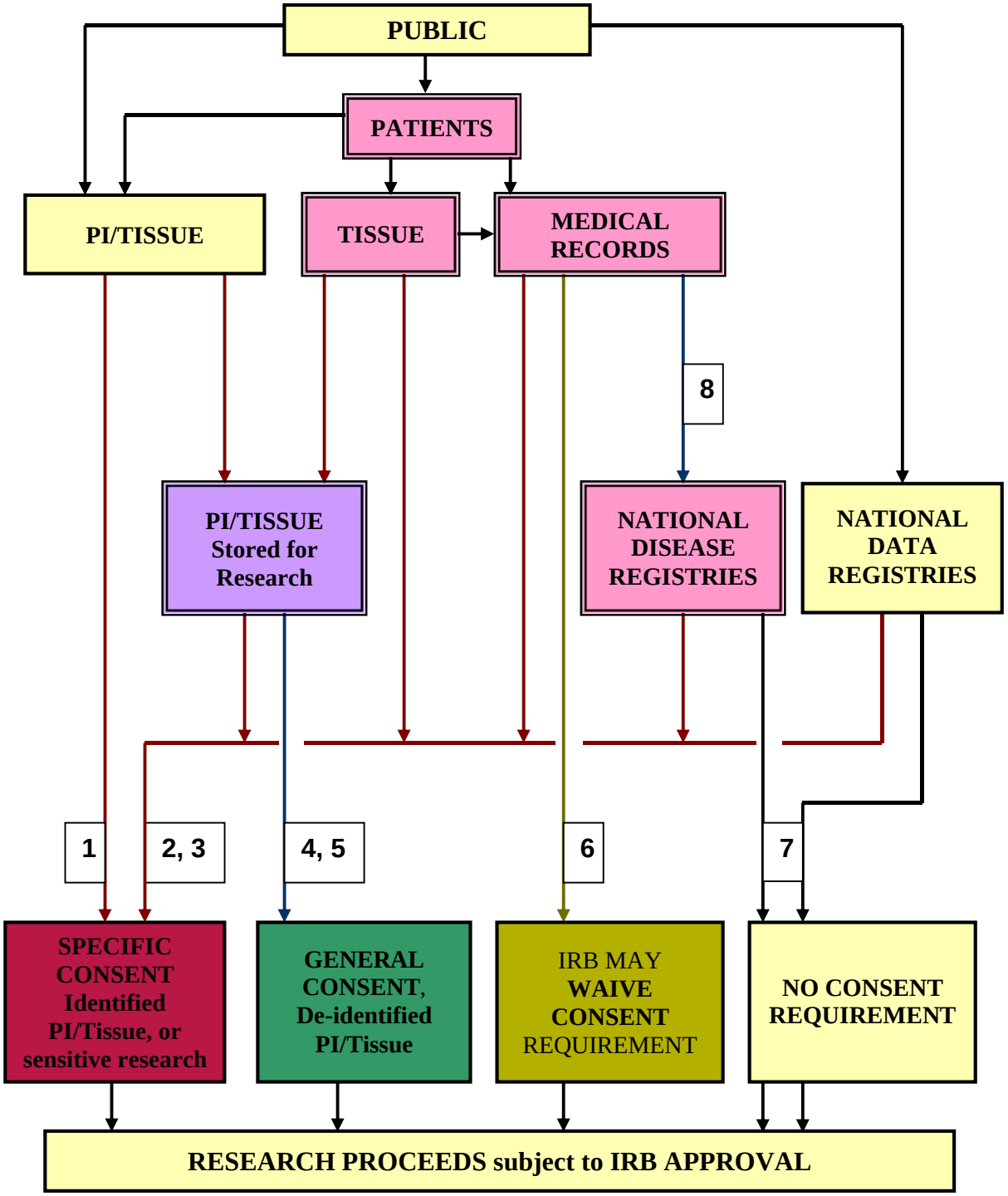
[39] The conditions whereby an IRB may decide to waive the consent requirement are listed in paragraph 5.39 of this Report.

[40] Read with paragraphs 5.22–5.33.

[41] Read with paragraph 5.29.

[42] Recommendation 1B of the BAC *Human Tissue Research* Report (2002) p 34.

Chart 1. Flowchart of personal information (PI) or tissue used in research requiring IRB approval. This Chart is to be read in conjunction with Table 1 which gives the relationship between research use of PI or tissue and the consent requirements, as they exist now or are proposed in this Report. Boxes with double outlines reflect wholly or partly clinical domains.



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