In recent years, Singapore's rapid advancement in the area of biomedical sciences has been attributed to the infrastructure, international connections, legal framework and the human resource pool which is of good quality and well-educated. Singapore is becoming the focal point of biomedical sciences activities in Asia.

In its continuing efforts to further advance Singapore as the biomedical sciences hub in the region, the Singaporean government recognizes the importance of a rational and responsible management of bioethical issues. As such, Singapore is constantly reviewing the ethical, legal and scientific issues relating to matters such as human cloning and genetic testing and research in Singapore.

This article will focus on the recent developments relating to the regulation of human cloning, genetic testing and research in this city-state of Singapore.

**Singapore Prohibits Human Reproductive Cloning**

In Singapore, human reproductive cloning is banned under a recent law which came into effect on 1 October 2004. This piece of legislation is known as the Human Cloning and Other Prohibited Practices Act (the “Act”). The Singaporean government has received the public’s feedback that biomedical research conducted should be done in an ethical manner, and in line with this, Singapore’s Ministry of Health (“MOH”) decided to adopt a graduated approach in regulating biomedical research activities. There was virtually unanimous support for a ban on human reproductive cloning.
The Act is certainly welcomed, as Singapore is fast becoming a science hub for this region. It has also developed the infrastructure to support this industry in the form of the Biopolis, a biomedical campus for biotechnology companies and researchers, from the international and local arena. From a policy perspective, Singapore has taken a more liberal approach to stem cell research. Notwithstanding this, it has decided to take the same line as many other developed countries such as the UK, Australia, Canada, France, Japan and Israel to ban reproductive cloning activities. During the parliamentary debates at the second reading of the Human Cloning and Other Prohibited Practices Bill, it was stated that the bill would “unequivocally make it clear that we (Singapore) prohibit reproductive human cloning,” and that “all these self-promoters (who) want to promote human cloning are not welcomed in Singapore for any activity that is related to human cloning.” However, it was important that a balance be struck between the need to prohibit human cloning and the need to allow therapeutic cloning to enable stem cell research.

The core to the Act is the prohibition of placing of a human embryo clone in the body of a human or an animal, and the fact that the clone did not survive or could not have survived is not a defense. A human embryo is defined as “any live embryo that has a human genome or an altered human genome and that has been developing for less than eight weeks since the appearance of two pro-nuclei or the initiation of its development by other means.” Any period where development of the embryo has been suspended will be disregarded. A human embryo clone is any human embryo that is the genetic copy of another living or dead human but does not include a human embryo created by the fertilization of a human egg by human sperm. Embryo splitting is specifically said not to be created by a process of fertilization.

Certain other practices associated with reproductive technology are also prohibited, as well as the importing and exporting of human embryo clone. In summary, the “other prohibited practices” under the Act are as follows:

- developing of human embryo created other than by fertilization of human egg by human sperm
- developing of human embryo outside body of woman for more than 14 days
- collecting of viable human embryo from body of woman
- certain uses of embryo such as: placing of any human embryo in an animal; placing of any human embryo in the body of a human, other than in a woman’s reproductive tract; or placing of any animal embryo in the body of a human for any period of gestation
- placing of prohibited embryo in body of woman
- importing and exporting of prohibited embryos
- commercial trading in human eggs, human sperm and human embryos

The Act gives certain powers of entry, inspection, and search of premises which are used, or which an enforcement officer has reasonable cause to believe is being used for any prohibited practices. A person having the control or management of the premises can be compelled to furnish information which the enforcement officer may require in relation to the prohibited practices or equipment being used to carry out the same.

Apart from the body corporate committing an offense, an officer will also be guilty of the same where the offense was committed with his consent or connivance or is attributable to any neglect on this part. The same applies to partners in relation to an offense committed by the partnership.
Initially, the proposed penalty for an offender would be a fine not exceeding S$100,000 (US$62,000) or to imprisonment for a term not exceeding five years or to both for the commission of any offense. However, the public response was that a maximum jail term of five years was too low for such a severe offense. As such, the penalty was increased to a maximum jail term of ten years as a greater deterrent.

The coming into force of the Act was timely in view of the InterAcademy Panel’s (the IAP) call for its member groups to lobby their national governments to allow individual countries to legislate on cloning for research or therapeutic purposes. This would pave the way for a convention to be adopted focusing on a ban for human cloning only. The IAP is an umbrella body for national science academies and was launched in 1993. Its primary goal is to help member academies work together to advise citizens and public officials on the scientific aspects of critical global issues.

**Guidelines on Ethics Governance of Research Involving Human Subjects**

In November 2004, the Bioethics Advisory Committee (BAC) released a report setting out guidelines relating to ethics governance of research involving human subjects (the Guidelines). The Guidelines and recommendations set out in the report have been presented to and accepted by the Life Sciences Ministerial Committee.

Established in December 2000 by the Singapore Government, the BAC was tasked to look into the ethical, legal and social issues arising from research on human biology and behavior, and its applications.

Basically, the Guidelines require all institutions (whether private or public), which conduct human biomedical research in Singapore, including research involving human tissue or medical information, to establish institutional review boards (IRBs) to review and supervise such research.

This framework of ethics governance requires all biomedical research involving human subjects to undergo a formal process of ethics review, which may vary from a full formal process to an expedited process, depending on the potential and actual risks that the research under review poses to the human subjects. It covers all biomedical research regardless of whether it is carried out in institutions under the purview of the MOH or not. There may be exemptions in certain special cases, which carry no risk to human subjects or in exceptional situations of national security or emergency health situations.

The Guidelines also set out the roles and responsibilities of institutions, IRBs and researchers. For instance, it is recommended that all IRBs be formally accredited by the MOH and are accountable to their appointing institutions. Furthermore, researchers must comply with all the conditions laid down by the IRB that approved their project. The researchers are also responsible for ensuring that their research complies with all relevant laws and other regulatory obligations and requirements. The institutions have the overall responsibility of ensuring the proper conduct of human biomedical research carried out by their employees on their premises.

The Guidelines do not apply to any human biomedical research in relation to genetically modified organisms, animals and their treatment, and economic, sociological and other studies in the disciplines of the humanities and social sciences.
Report on Genetic Testing and Research in Singapore

The BAC has recently issued a report on genetic testing and genetic research dated November 2005 (the “Report”). The recommendations in the Report were made after examining policies and guidelines from various international and national ethics and professional bodies, and after considering the views of international and local experts, as well as those of professional, religious and civic groups and members of the public. It is hoped that this Report provides ethical guidance to clinicians and researchers when carrying out genetic testing and genetic research, as well as serves as a useful reference for ethics committees reviewing such research.

The Report focuses on three main aspects of human genetics:

• Genetic testing for the detection of specific heritable genetic conditions and susceptibilities
• Quality of genetic information thereby derived
• Research in human genetics

The objectives of the Report are to consider the ethical, legal and social issues arising from the conduct of genetic testing and research, and to provide guidance for the ethical conduct of genetic testing and research. The BAC also hopes that the Report can serve as a useful reference for ethics committee reviewing research.

Essentially, the BAC has made 22 recommendations in the Report under the following categories:

• Genetic information
• General ethical considerations
• Genetic testing of vulnerable persons
• Confidentiality and privacy
• Preimplantation genetic testing
• Germline genetic modification
• Prenatal genetic diagnosis
• Predictive testing
• Genetic screening
• Standards of genetic test providers
• Results interpretation
• Genetic counseling
• Professional diversification and development
• Direct supply of genetic tests to the public

The recommendations in the Report relate to the ethical conduct of clinical genetic testing and genetic testing for research. Genetic testing should be voluntary and the non-consensual or deceitful taking of human tissues for the purpose of genetic testing should be prohibited. The BAC does not recommend the broad use of genetic testing on children and adolescents. However, confirmatory testing and predictive testing for genetic conditions where preventive intervention or treatment is available and beneficial in childhood are recommended. Clinical genetic testing involving vulnerable persons should only be conducted if it is medically beneficial to them and after informed consent has been obtained.
The results from clinical genetic testing should not be disclosed to third parties without the informed consent of the individual unless required to avert serious harm. The Report permits preimplantation genetic screening and diagnosis but subject to licensing and monitoring by a relevant authority. Such screening should be limited to preventing serious genetic conditions. Furthermore, no one shall be under any duty to be involved in preimplantation genetic testing to which he or she has a conscientious objection. The BAC does not recommend the use of preimplantation genetic testing for the selection of desired traits or gender for non-medical reasons. However, preimplantation tissue typing is permissible but should be licensed and evaluated on a case-by-case basis.

Another recommendation by the BAC in the Report is to disallow the clinical practice of germline genetic modification, subject to reassessment in the future. In the case of prenatal genetic diagnosis, the BAC limits its usage to serious medical disorders and not for the selection of desired traits or gender for non-medical reasons. According to the Report, all laboratories conducting clinical genetic tests should be accredited by a body designated by the relevant authority based on standards it considers appropriate. The BAC recommends that only appropriately qualified or sufficiently experienced healthcare professionals may interpret clinical genetic test results.

The BAC emphasizes the importance of sound and effective counseling in the ethical conduct of clinical genetic testing. However, the BAC makes it clear in the Report that genetic information uncovered in the course of standard clinical tests for diagnosis or treatment and the conduct of such clinical tests should be in accordance with accepted medical guidelines, and that its recommendations on consent and counseling would not be applicable unless the analysis of human DNA, RNA, genes and/or chromosomes is involved. The genetic information derived from clinical genetic testing should be treated in the same manner as medical information and its derivation, management and use should be subject to the usual standards in medical ethics.

The Report does not consider issues relating to:
- third party use of genetic information, such as by insurers or from linked medical registries as these would be addressed in a future report
- genetic testing for forensic purposes or solely as a means to ascertain parentage or kinship, and research that involves only history taking such as in the construction of family trees where direct genetic testing is not performed

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