

RESEARCH
INVOLVING
HUMAN SUBJECTS
GUIDELINES FOR IRBS

A REPORT BY
THE BIOETHICS ADVISORY COMMITTEE
SINGAPORE

November 2004

FOREWORD

This report, *Research Involving Human Subjects: Guidelines for IRBs*, embodies the third set of recommendations by the BAC, which has been submitted to and accepted by the Life Sciences Ministerial Committee. It follows two earlier reports, the report on *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning* (June 2002), and the report on *Human Tissue Research* (November 2002).

As biomedical science progresses, research involving human subjects will increasingly gain public interest and attention. Concerns regarding the safety and welfare of research participants and measures taken to protect these participants must be addressed adequately.

The recommendations in this report incorporate many of the existing regulatory standards and practice guidelines governing various aspects of biomedical research involving human subjects. It is hoped that these recommendations will help to maintain the standards of practice in human biomedical research in Singapore comparable with the best internationally.

This Report is the product of the Human Genetics Subcommittee (HGS) of the BAC after a thorough process of research and consultation, which began in April 2003. The BAC is much indebted to the parties, which participated in the consultation process and took time to consider and provide thoughtful feedback. We are pleased to append to this Report a complete record of the representations received. The BAC also sought the views of several local and international experts during its deliberations.

Finally, I would like to thank my fellow Committee members, especially the Chairman of the HGS, Associate Professor Terry Kaan, as well as the members of his Subcommittee, for their commitment and dedication to the project and for ensuring that these recommendations remain a considered, fair and sensitive response to the many difficult issues relating to the ethical conduct of research involving human subjects.

Professor Lim Pin
Chairman
Bioethics Advisory Committee
November 2004

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About the Bioethics Advisory Committee

The Bioethics Advisory Committee (BAC) was appointed by the Singapore Cabinet in December 2000. The BAC was directed to „examine the legal, ethical and social issues arising from research on human biology and behaviour and its applications“ and to „develop and recommend policies ... on legal, ethical and social issues, with the aim to protect the rights and welfare of individuals, while allowing the Life Sciences to develop and realise their full potential for the benefit of mankind“.

The BAC reports to the Ministerial Committee for Life Sciences. For further information about the BAC and its work, please visit <http://www.bioethics-singapore.org>

Contacting the Bioethics Advisory Committee

The BAC welcomes views, comments, suggestions and other feedback on the issues raised in this report and on any bioethical issues within the BAC's remit. All feedback should be addressed to:

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