# *Governance of Biomedical Research in Singapore and the Challenge of Conflicts of Interest*

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**Abstract:** This article discusses the establishment of a governance framework for biomedical research in Singapore. It focuses on the work of the Bioethics Advisory Committee (BAC), which has been instrumental in institutionalizing a governance framework, through the provision of recommendations to the government, and through the coordination of efforts among government agencies. However, developing capabilities in biomedical sciences presents challenges that are qualitatively different from those of past technologies. The state has a greater role to play in balancing conflicting and potentially irreconcilable economic, social, and political goals. This article analyzes the various ways by which the BAC has facilitated this.

**Keywords:** conflicts of interest; research ethics; institutional review boards; biomedical research; developmental state; Singapore; East Asia; research regulation

## Introduction

At the turn of the century, Singapore identified the biomedical sciences cluster as its fourth economic pillar. Components of this cluster include pharmaceuticals, medical technology, biotechnology, and healthcare services. Following its earlier developmental policies, a sound governance framework for biomedical research was considered necessary, just as the rule of law has often been perceived to be a precondition to economic development. To this end, the Bioethics Advisory Committee (BAC) was established in December 2000 by the Cabinet as an independent expert advisory body composed of men and women with the relevant expertise to provide the government with balanced advice on ethical, legal, and social issues arising from biomedical research. Since then, the BAC has been instrumental in institutionalizing a governance framework for biomedical research, through the provision of recommendations to the Steering Committee on Life Sciences of the Cabinet. The Steering Committee has been responsible for advancing Singapore's biomedical research capability in a number of ways, including the coordination of efforts among government agencies, such as the Ministry of Health (MOH) and the Agri-Food and Veterinary Authority of Singapore. Since 2002, recommendations published by the BAC on human embryonic stem cell research and cloning, human tissue, human subjects protection, and genetics have been reviewed by an international panel of experts and accepted by the government. However, developing capabilities in biomedical sciences have been shown to present challenges that are qualitatively different from those of past technologies. Far from simply defining a regulatory space, the state has a greater role to play in balancing conflicting and potentially irreconcilable economic, social, and political goals. The BAC has facilitated this process in a number of ways, some of which are discussed in this article.

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We have four objectives in writing this article. The first is to explain the transforming role of the state in its establishment of bioethics as an institution in Singapore. The "developmental state" approach—in which the state has a direct involvement in the ethical governance of biomedical research—sets Singapore apart. However, a developmental state account is inadequate, because it does not give sufficient recognition to the more open-ended and high-risk character of a high value-added and knowledge-intensive industry. In the section that follows, we explain how Singapore has sought to transform itself from a developmental state to an innovative state, or a state seeking success in a global knowledge economy. The second objective of the article is to provide a broad overview of the ethics governance framework from the standpoint of an innovative state. The article then highlights an especially difficult balance for the state to attain. This relates to different aspects of conflicts of interest (COIs). While the state has assumed the role of developing technological capabilities and promoting innovation, it has a simultaneous interest in safeguarding the welfare of research participants, as well as public interests more generally. The third objective is to explicate the challenges posed by COIs, and in the context of Singapore. The final objective is concerned with how such a COI could be managed, an issue taken up in the concluding section of the article. To the extent that resolving COIs could be understood as striking an ethically defensible balance of competing interests, the work of the state (through the BAC or some other agency) is not finished, but we hope we have identified a sustainable way forward.

## Setting the Ethical Groundwork for a Knowledge Economy

Policymakers have been especially conscious of Singapore's vulnerability as a tiny nation-state. The trauma of expulsion from the federation of Malaysia in the short space of about two years after achieving independence from colonial rule may have further etched this vulnerability into the national psyche. In an interview with a panel of journalists from the principal English-language newspaper in Singapore, Lee Kuan Yew (the architect of modern Singapore) was asked if the nation-state should be "always living in fear of a catastrophe." Mr. Lee's response is indicative of the mind-set of key policymakers:

> I'm concerned that Singaporeans assume that Singapore is a normal country, that we can be compared to Denmark or New Zealand or even Liechtenstein or Luxembourg. We are in a very turbulent region. If we do not have a government and a people that differentiate themselves from the rest of the neighbourhood in a positive way and can defend ourselves, Singapore will cease to exist.[1]

Through what has been described as a developmental state model, the state-led industrialization of Singapore between the late 1960s and the 1990s capitalized on the nation-state's locational and infrastructural strengths to attract transnational corporations. This strategy has been relatively successful in enabling Singapore's capabilities in back-end manufacturing, consumer electronics, and a variety of financial and distributional services. The economic returns that this strategy generated have in turn been a crucial source of legitimacy for the state. The rule of law has often been regarded as intrinsic to this developmental strategy.

The assurance that the state will stick to the law has been considered to be critical in securing stable relations with transnational corporations and ensuring continued foreign direct investment. By this formulation, the rule of law amounts in effect to the security of persons, property rights, and contract enforcement. Such a conception has attributed to the common law a spontaneous (rather than engineered) origin and a prioritization of the rule of law ahead of development. Reflecting on the development experiences of East Asian nations, Francis Fukuyama takes a different view in arguing that the rule of law is but a distinct dimension of development, and not a precondition.[2] Rather, the state must intentionally and systematically adopt the rule of law. This is perhaps most evident in his argument that the common law was intimately associated with the rise of the early English state and dependent on state power for its eventual dominance.[3]

Bioethics, particularly in its institutional varieties (as public policy, governance framework, and academic discipline), would not have had so prominent a character in Singapore without strong endorsement and support from the state. To understand biotechnology in Asia, Aihwa Ong emphasizes the need to take the role of the state seriously.[4] Although pharmaceutical companies and global health agencies have tremendous influence over biotechnology, nationalist states have increasingly shaped the flow of human tissues and biotech products. Consequently, important scientific breakthroughs in the field of biotechnology and biomedicine have occurred within political environments with robust sovereignty and paternalist rule. East Asian states are drawing on bioethics and biotechnologies, not only to achieve economic ends but also to shape national identity and gain prestige. Bioethics has been employed in the production of shared corporeal needs and vulnerabilities, to trigger a sense of belonging, and to create a blend of the rationalities of market and science with the "irrationalities" of feeling and identity.[5]

Unlike the industrial development of the past, investment in biotechnology—as Joseph Wong observed—involves "different kinds of bets," in view of uncertainties as to technological viability, economic (and, particularly, commercial) value, and temporal range.[6] Singapore recognizes its own vulnerabilities, particularly its small economy and lack of experience with the development and commercialization of technological innovation.[7] Amid these developments, the state has not retreated into obscurity but has adapted its policy strategies to address and manage the uncertainties in the life sciences. This is a development that is inconsistent with neoliberalism, which puts forward the view that it is in the public interest to reduce government intervention and allow the operation of the market to benefit as many "consumers" as possible.[8] A neoliberal agenda directed at creating a "market society" could lead to a failure of public life[9] and is not necessarily consistent with the ideals of democratic society.[10] Neoliberal thinking has been recognized in the policies of Singapore in creating a knowledge economy.[11] Yet a critical feature has been the ability of the state to channel private initiatives into areas of state priority, and to structure and use state power for economic development.[12]

Another important observation advanced by Wong is the emergence of a "multiple stakeholder state," responsible for promoting research and development, on the one hand, but also for the protection of human subjects that are involved in research, on the other.[13] As these competing goals immediately make clear, regulatory policies are contested among different actors, including within the government by different ministries. In moving a policy initiative forward, it is often necessary for the state to function as a mediator and broker by designating a

mechanism toward this end. Quite aside from the presence of multiple stakeholders, the state itself has multiple roles. It functions as both a market and a premarket regulatory gatekeeper, especially because it shapes market access for biotechnological innovations. The state is also the monopsonistic purchaser of care, thereby affecting in some way the price of all healthcare products and services. In addition, it acts as entrepreneur in the provision of a technology infrastructure,[14] when engaging in activities such as establishing joint research ventures and research parks. On a number of key life sciences policies, the BAC served as one such mechanism for mediation, with the Cabinet as the ultimate decisionmaker.[15] Bioethics, at a policy level, has emerged as a means by which the state could perform its very different functions for the purposes of balancing different needs and reconciling competing commitments. The inherent uncertainties of regulatory policies relating to the life sciences, and the challenges of asymmetric information, limit the state's ability to impose a single viewpoint or regulatory stance. Since 2000, the BAC has advanced the interests of the state in reconciling competing interests, values, and perspectives arising from biomedical research, and in establishing a framework for ethical governance more generally.[16]

**Broadening the Governance Framework for Biomedical Research**

Prior to 2000, ethical governance of biomedical research had been mainly confined to clinical trials. For other types of biomedical research, an ad hoc institutional review board (IRB) or similar body might be established within academic and healthcare institutions on a when-necessary basis. Although the systematization of an ethics governance framework was on the agenda of the BAC from the time of its inception, an incident in 2003 required the prioritization of this initiative. This matter concerned Dr. Simon Shorvon, who was appointed as director of the National Neuroscience Institute in 2000, having been recruited from the UK, where he already had a distinguished career as a researcher.[17] The essence of the case against Dr. Shorvon was that he failed to obtain informed consent from several of the subjects of his research, inappropriately obtained the names of potential participants (through bypassing their own doctors and going to pharmacy records), and failed to inform the relevant ethics committees of some of the crucial details of his research. Of particular significance here was a test that involved instructing patients with Parkinson's disease to omit their medication the evening before coming to the clinic (on-off Levodopa testing) and then videotaping them to observe changes in their movements and coordination. It emerged in the disciplinary hearing that neither the patients nor the ethics committees were properly informed of these aspects of the research, and that patients were under the false impression that this was part of treatment. Following complaints from some patients and their doctors, a series of enquiries was launched, culminating in a hearing before the Disciplinary Committee of the Singapore Medical Council (SMC), which found him guilty of thirty charges of professional misconduct. Dr. Shorvon did not contest these charges, and he chose not to appear at the hearing, having requested deregistration from the SMC's register. He returned to the UK, where he remains registered with the General Medical Council (GMC). The GMC considered whether it should also institute a case against Dr. Shorvon but decided not to proceed. A judicial appeal by the SMC against this decision of the GMC was dismissed by an English court.

For the BAC, the incident highlighted the pressure clinician researchers faced to recruit patients and produce research results as a serious ethical challenge. It also illustrated the difficulties of having to promote innovation, on the one hand, and to safeguard the welfare of patients and research subjects, on the other. Following the approach in major scientific jurisdictions, an effective regulatory regime was considered to be critical in striking a publicly acceptable (and ethically defensible) balance among the different stakeholders. Continuing state interest is considered to be important for other social and political objectives not immediately linked to science; state presence also signaled public interest, and that the research was taken up for the common good.[18]

The governance framework that was established has a number of features. First, it created a common normative platform so that all human biomedical research projects in Singapore, including research involving human tissue or medical information, are to be subject to ethics review by IRBs. This was done by building on the existing system of regulations for pharmaceutical trials and human biomedical research conducted by hospitals, private clinics, and other healthcare establishments under supervision of the MOH. The BAC also specified the constitution, accreditation, and operation of IRBs, as well as their roles and responsibilities, in addition to those applicable to research institutions and individual researchers. Here, high standards of ethical governance are regarded as vital to the progress of biomedical sciences in Singapore. Although the governance framework proposed by the BAC does not have any direct regulatory authority, it is in effect implemented by the state through the MOH and by the Agency for Science, Technology and Research (A*STAR), a principal public funder of biomedical research in Singapore. Should an ethical infraction occur, either or both of these government agencies could require initiation of a number of regulatory actions, including the commencement of disciplinary action and/or the cessation of research funding. In this way, the state retains for itself ultimate discretion as to the degree of regulatory control that is appropriate.

Second, a measure of risk is implicit in the framework, so that ultimate oversight by the state (either through the MOH, the A*STAR, and/or other regulatory bodies) is increased proportionately with the risk that the research presents. The notion of risk clearly encompasses potential harm to the physical and mental well-being of a research participant. For certain types of research, such as those relating to the human embryo, risk has been conceptualized to include risk of harm to society. There are at least two categories of research that are regarded as warranting significant regulatory control. Clinical trials continue to require specific regulatory approval. With the systematization of the ethics review process, ethical clearance is now an additional level of safeguard. Researchers must obtain ethical clearance from an IRB. Regulatory approval will also have to be obtained from the Health Sciences Authority before a clinical trial may commence. In contrast, embryonic stem cell research is considered to pose a more abstract, but no less significant, form of potential harm. This category of research will similarly require both regulatory and ethics approval. Interestingly, harm to science as a knowledge discipline, or concerns that are taken to relate to research integrity, are not regarded as immediate concerns of the state.[19] Rather, these are felt to be more appropriately addressed at an institutional level. Consequently, key research institutions in Singapore have policies on research integrity. They incorporate to varying degrees the key principles set out in the Singapore Statement on Research

Integrity—honesty, accountability, professional courtesy, and fairness, and good stewardship of research on behalf of others—while also defining irresponsible research conduct as essentially falsification, fabrication, and plagiarism.[20]

Third, the regulatory reach is incremental in terms of depth and scope, and it is targeted. It is most extensive and comprehensive for research that poses a direct threat of harm to human participants and to particular moral viewpoints. In contrast, there is at best limited regulatory presence on matters of scientific integrity, including concerns over conflicts of interest that do not pose direct or immediate risk of harm to human participants. On the former, existing provisions on ethics governance have either been elaborated on or otherwise supplemented. In 2007, the MOH issued supplementary guidelines on the day-to-day workings of an IRB. These include guidelines on the composition of an IRB, a more elaborate discussion on the informed consent process, meeting requirements, and requirements relating to documentation.[21] In addition, it emphasized the "fundamental" ethical principles as respect for persons (encompassing autonomy), beneficence, and justice, as its primary focus was on research involving patients, rather than healthy individuals.

## Growing Concern over Conflicts of Interest

Although an ethics governance framework for biomedical research is now in place, the work of the BAC is not over. In recent years, there has been renewed concern over COIs as industrial collaboration and translational medicine (which entails the commercialization of research) are being emphasized.[22] At least from a regulatory standpoint, the extent to which scientific advance can be reconciled with the goal of maximizing economic returns is unclear. For instance, is there any research for which industrial collaboration should be ruled out? Or is there any research for which commercialization should never be allowed? Over the years, Singapore has enjoyed strong linkages with multinational firms, including big pharmaceutical companies. Whereas the ethical validity of this relationship has been taken for granted, it is difficult to ignore ethical concerns associated with certain practices in the industry.[23] The nation-state's economic interest in the subject further accentuates COI concerns.

In Singapore, the BAC defines COIs as circumstances that adversely affect impartiality, objectivity, and independence, and it encapsulates both actual and potential conflicts.[24] The independence and ethical integrity of IRBs are identified as fundamental underlying principles, and institutional hosts of IRBs must take reasonable steps to avoid and minimize conflicts. A recommendation put forward by the BAC is for an IRB to prepare a special report on all reviews of research programs in which there is an actual, potential, or apparent COI, for submission directly to the board of directors of its host institution.[25] On the part of researchers, the BAC indicates that it is important for researchers to take special care to avoid any form of COI, whether actual, potential, or merely an appearance of conflict as such. To ensure objectivity in the review process, researchers should not be involved in, or give the appearance of being involved in, the ethics review and approval process of any project in which they are involved.[26] In addition, similar conflicts could arise where a researcher is also the administrative custodian of patients' medical information, or an attending physician. Transparency through disclosure as a means of addressing conflict situations has been emphasized by

the BAC. It says that researchers have a duty to make a declaration of any conflict, to give full disclosure of the facts giving rise to such conflict, and to detail the steps proposed or taken to minimize or avoid the appearance of actual or potential COIs. On financial COIs, the BAC states that potential research subjects may need to be informed of any financial arrangements offered by corporate sponsors to researchers or their institutions (or both). This disclosure is understood as facilitating understanding and advancing the ethical goal of informed consent.

Relying on individual integrity alone is not likely to hold out any great hope of change. Regulatory guidance is only as effective as its commitment to monitoring and pinpointing responsibility for compliance. Even with guidance that identifies for clinician-researchers certain norms of responsible behavior, such as making financial disclosures and receiving only due compensation, there is evidence in social science research that individuals are not always conscious of their motives and often fail to act in ways they believe they would.[27] Expectations of reciprocity operate in powerful and subtle ways that have negative consequences for clinical care.[28] Disclosure may sanitize COIs and lead clinicians to pretend they have disappeared. Otherwise, the effort to avoid disclosure requirements may lead clinicians to be "creative" in their interpretation of what is or is not a COI.[29]

## Achieving an Ethically Sound Balance

It has been argued that academic medical centers, rather than individual clinicians, have a role in leading efforts to address COIs in the current climate of undue influence on medical objectivity.[30] This is because the profession and industry look to academic medical centers for influential and independent advice, because independent research into the impact of new drugs and devices on population health is borne mainly by them, and because they have primary responsibility for training future clinicians in the habits of scientific objectivity and integrity.[31] To a large extent, this rationale appears to underlie the current ethical governance framework on COIs in Singapore. However, many questions that arise cannot be adequately answered at an institutional level. For instance, sustaining an ethical understanding of the relationship between researchers and research participants, as well as the scientific research enterprise, is an ongoing process that must necessarily include stakeholders aside from academic medical centers. In addition, even if investment in research is intended to benefit the public, broader discussion is necessary on what "benefits" mean (and to whom), and on the extent to which market-driven research prioritization (given the emphasis on industrial collaboration) is ethically appropriate.[32]

To be sure, broader measures beyond installing regulatory oversight have been taken up by the state. One such measure relates to capacity development in biomedical ethics. Under a grant from the National Research Foundation, the Centre for Biomedical Ethics (CBmE) in the Yong Loo Lin School of Medicine in the National University of Singapore conducts workshops and seminars for biomedical researchers, IRB members, and clinicians on a number of topics.[33] At the A*STAR, participation in such training workshops conducted by the CBmE has been made mandatory for researchers. The Capacity Building Programme has also engaged in broader public education efforts, through symposia, seminars, workshops, and performing arts for secondary and preuniversity students and their teachers. The CBmE has collaborated with the Singapore Science Centre in the use

of performing arts to promote awareness of biomedical ethics issues and with the BAC and the Science Centre in establishing a bioethics exhibition.

## Conclusion

A relatively distinct feature of Singapore's experience in its transition into the global knowledge economy is the significance that it has attributed to bioethics as a matter of public policy. More recent policy emphasis on generating returns from investment in biomedical sciences, especially economic ones, accentuates some existing ethical concerns. Arguably, COI is among the most pressing of these. In addressing this and other concerns, a close partnership must be sustained between the state and institutions with ethical expertise, like the BAC and the CBmE. In advancing the common good through enabling ethical research practices, these entities have elucidated and should continue to elucidate fundamental questions, such as those relating to "benefits" and "prioritization." Greater regulatory guidance on COIs may well be required, but the effectiveness of this guidance will also depend on a deeper appreciation by all stakeholders of their respective ethical responsibilities. Much remains to be done here, if the innovative state is to sustain its continuing "success" not only through economic gains but through the maintenance and enhancement of shared values and of the public good.

## Notes

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3. See note 2, Fukuyama 2011, at 253, 256–7.
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7. See note 6, Wong 2011, at 15.
8. Funnell W, Jupe R, Andrew J. *In Government We Trust: Market Failure and the Delusions of Privatisation*. London: Pluto Press; 2009, at 17. Neoliberal thinking was traced to the 1970s, when liberal democracies abruptly turned away from what was perceived to be the unchecked growth of the welfare state to public sector reform that forced the retreat of government from the provision of social services. This phenomenon may be further attributed to the inability of Keynesian economics to deal with the "stagflation" of the 1970s (see Funnell et al. 2009, at 12–16).
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10. See note 8, Funnell et al. 2009, at 273–4. They correctly observe that concern over the ability of public servants to influence resource allocation decisions in ways that are detrimental to public interests is not necessarily addressed by reassigning such decisions to the market, for instance.
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12. Kohli A. *State-Directed Development: Political Power and Industrialization in the Global Periphery*. New York: Cambridge University Press; 2004, at 385–6.
13. See note 6, Wong 2011, at 148–50.

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15. The mediatory function of the BAC is perhaps best illustrated in its recommendations for research involving embryonic stem cells. When interviewed, many of the BAC members considered this to be the BAC's principal role. For a more detailed discussion of the functions, responsibilities, and work of the BAC, see Ho C, Lim S. The coming of bioethics to Singapore. In: Elliott JM, Ho C, Lim S, eds. *Bioethics in Singapore: The Ethical Microcosm*. Singapore: World Scientific; 2010:1–29.
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32. Campbell AV. *Bioethics: The Basics*. London and New York: Routledge; 2013, at 131–4.
33. The CBmE was established in 2006 at the Yong Loo Lin School of Medicine of NUS. It publishes the quarterly online journal *Asian Bioethics Review* and undertakes a wide range of bioethics research, much of it in collaboration with overseas institutions.