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Langlois A. *Negotiating Bioethics: The Governance of UNESCO's Bioethics Programme*. London and New York: Routledge; 2013.

## Chapter 1 Introduction

The sequencing of the entire human genome has opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries. How competently such dilemmas are managed will dictate whether the fruits of genetic and other biomedical research exacerbate or reduce inequalities of health between North and South. UNESCO, the United Nations Educational, Scientific and Cultural Organization, addresses such issues through its Bioethics Programme, established in 1993. Over the past two decades the Programme has negotiated bioethics in two ways. First, it has navigated the twists and turns of an evolving moral discourse, in tandem with developments in science and technology, particularly in relation to the human body. Second, at the formal intergovernmental level, it has formulated three international declarations on human genetics and bioethics. This book examines how these declarations have come about, their impact on bioethical thinking and practice and the future prospects of the Bioethics Programme.

Although the term 'bioethics' can be used to cover ethical issues across a broad spectrum, UNESCO has focused mainly on the human impact, as the titles of its three declarations demonstrate: the *Universal Declaration on the Human Genome and Human Rights* (1997); the *International Declaration on Human Genetic Data* (2003); and the *Universal Declaration on Bioethics and Human Rights* (2005). Each declaration embraces well-established bioethical principles, such as autonomy and informed consent, as well as newer ideals of knowledge sharing and capacity building between developed and developing countries. These norms and principles are designed to deal with pressing issues in genetics and bioethics. Genetics presents new ethical problems, or at least new perspectives on existing ones. That members of families and communities may share genes poses a challenge to the recognized bioethical principles of privacy and confidentiality, for instance. Relatedly, if the human genome is the common 'heritage of humanity' (as UNESCO terms it), this begs the question how the benefits that might accrue from genetic research should be distributed. At the same time, understandings of what constitutes a bioethical concern are broadening. As inequalities in access to medicine and healthcare between North and South enlarge, what should be the focus of research becomes in itself an ethical question (aside from how it should be carried out). Most recently, UNESCO has been asking this question in the context of whether human reproductive cloning should be banned worldwide.

UNESCO is one of several organizations working in the area of bioethics. This raises another question: is the UNESCO Bioethics Programme an effective forum for (a) decision-making on bioethics issues and (b) ensuring ethical practice? The book seeks to answer this question both theoretically and empirically. Based on original research conducted at UNESCO headquarters and in member states, it draws on international relations theory to assess the efficacy of the Bioethics Programme. International relations theory, in its various forms, seeks to explain world affairs and expound how they might, if possible, be better governed. Governance, in this respect, constitutes decision-making on the management of collective issues and the subsequent implementation of regulations and policies to effect those decisions. At national level, these tasks are often undertaken by governments. At international level, governance is conducted in the absence of a formal world government, partly through institutions such as UNESCO. Effective governance of human genetic and biomedical research would contribute to the protection of individual research participants and, more broadly, the harnessing of this research to tackle global health needs. It would entail, first, high-quality decisions on how these goals could be achieved and, second, comprehensive implementation of those decisions.

Fieldwork data, collected in 2005–6 during doctoral studies and followed up in 2010–12, will shed light on whether the Bioethics Programme provides effective governance. Fieldwork included the following: close observation of meetings of UNESCO's International Bioethics Committee and Intergovernmental Bioethics Committee (which discussed, *inter alia*, the drafting of the 2005 *Universal Declaration on Bioethics and Human Rights* and the possibility of a convention to ban human reproductive cloning); analysis of official records of these and other bioethics meetings within the organization, as well as national policy documents from Kenya and South Africa; 77 interviews with UNESCO staff and delegates, policy-makers in relevant government ministries, geneticists, ethicists, members of civil society organizations and industry professionals; and questionnaires.

2005–6 saw 30 interviews conducted in Kenya, 33 in South Africa, two in the United Kingdom (with people involved in the negotiation of the 2005 declaration) and two in France (at UNESCO headquarters in Paris). Seven further

interviews in Kenya in 2011 augmented the initial findings. Questionnaires sent to former interviewees and other key stakeholders from Kenya and South Africa in 2012 sought to gauge their views on (a) progress in genetics and bioethics at national level (b) UNESCO's capacity-building activities in ethics and (c) human reproductive cloning. Kenya and South Africa were chosen as the major fieldwork destinations because of their significant activities and involvement in bioethics and genetics locally, nationally, regionally and internationally. In Kenya, the Kenya Medical Research Institute carries out vaccine and drug trials for diseases such as HIV/AIDS, malaria and leprosy, while in South Africa geneticists are conducting research of both medical and evolutionary interest. Both countries have a long history of ethical review. The Human Research Ethics Committee of the University of the Witwatersrand (Johannesburg), established in 1966, is one of the oldest in the world. Not far behind, the joint Kenyatta National Hospital and University of Nairobi Ethics and Research Committee was set up in 1974. Questionnaires were also sent to the UNESCO National Commissions and Paris-based Permanent Delegations of 23 English-speaking sub-Saharan African countries. Seven National Commissions and three Permanent Delegations replied.

The book considers two different aspects of the UNESCO Bioethics Programme – deliberation and implementation – at international and national levels. Chapter 4 charts the international negotiation processes for the three declarations, focusing on the power dimensions between (a) developed and developing countries and (b) UNESCO member states and other actors, namely United Nations agencies working in related fields, non-governmental organizations and independent experts in bioethics. Power differentials between North and South surfaced in spite of formal procedures aimed at containing them and several non-state actors felt excluded from the process. Chapter 5 examines the take-up of the declarations around the world and how this has been influenced by their content, their non-binding status (in international law, declarations are by nature non-binding) and UNESCO's efforts to encourage implementation through dissemination and capacity building. It also explores the relationship between UNESCO and other international bodies working in bioethics, particularly the World Health Organization. The choice of non-binding declarations enabled consensus among member states, but the pay-off is that adherence is harder to ensure. Engaging with stakeholders at national level is vital if the declarations are to have meaningful impact.

Chapters 6 and 7 peel back a layer to assess the impact of the declarations in Kenya and South Africa specifically. Chapter 6 asks who decided on each country's negotiating position during the drafting of the declarations, how the declarations are perceived by the respective bioethics and scientific communities and whether they have been incorporated into national laws, regulations and policies. Chapter 7 outlines UNESCO's capacity-building endeavours in Kenya and how these have been received, whether similar activities would be welcome in South Africa and the ethical challenges each country must confront. While the impact of the Bioethics Programme in each has been markedly different – Kenya has embraced it wholeheartedly, whereas in South Africa it barely features – both countries have instituted similar systems to improve ethical review of research. They also face similar challenges, in terms of protecting vulnerable populations, ensuring the benefits of research are shared equitably, training researchers and ethics committee members and educating and engaging with the public in ethical and scientific debate.

In examining deliberation and implementation within the UNESCO Bioethics Programme, from these two different levels, the book addresses the following broad issues: how relations between developed and developing countries can be made more equal; who should be involved in global level decision-making and how this should proceed; how overlap between initiatives can be avoided; what can be done to improve the implementation of international norms by sovereign states; how far universal norms can be contextualized; and what impact the efficacy of national level governance has on that at international level. In this light, Chapter 8 reviews the strengths and weaknesses of the UNESCO Bioethics Programme, drawing on international relations theory to suggest how the latter might be addressed. It also considers the implications of the book's findings for the future of the human cloning debate and makes some practical recommendations on how the Bioethics Programme might move forward. First, though, Chapters 2 and 3 outline the parameters of the analysis to follow. Chapter 2 introduces the fields of bioethics and human genetics, the governance dilemmas they raise and how the UNESCO Bioethics Programme tackles these. Chapter 3 then presents a theoretical framework through which UNESCO's endeavours in bioethics governance can be investigated.

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