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Chapter 6 Contextualizing bioethics

The declarations in Kenya and South Africa

In the preface to UNESCO's volume on how the UDHGHR (1997) came into being, then Director-General of UNESCO Federico Mayor wrote, 'It is now the responsibility of States to breathe life into the Declaration, *inter alia*, by reflecting it in their domestic legislation' (UNESCO 1999a: III). Seven years on from the adoption of the third declaration, the UDBHR (2005), this chapter outlines how far all three are reflected in the laws, regulations and policies of two states in particular: Kenya and South Africa. First, though, we look again at the negotiation process for the 2005 bioethics declaration.[1] The analysis takes a step back from the negotiations themselves, to see what, if anything, first happened at national level to enable each country to work out its negotiating position. This is followed by a review of how stakeholders (geneticists, ethicists and so on) in Kenya and South Africa perceive the declarations and whether they see the governance of human cloning as an important issue.

Negotiations at national level

The Director-General of UNESCO reported in 2002, 'Despite the ever greater importance of bioethics worldwide, this discipline is still too often the preserve of a handful of specialists' (UNESCO 2002b: 5). Reflecting this, the UDBHR was drafted as a 'practical application' document rather than an academic one (UNESCO 2005c: 3–4). At the June 2005 IGE session charged with finalising the declaration, the Director-General thanked member states for sending 'strong, quality delegations' (UNESCO 2005m: Annex II, 1). (Williams [2005], by contrast, sardonically refers to those who attended this meeting as 'experts'.) The chief Kenyan delegate, a scientist, was selected as the country's then UNESCO Chair in Bioethics (who later became Chair of the IGBC). They were accompanied to the June meeting by the Kenyan Deputy Permanent Delegate to UNESCO (based in Paris) and to the previous session in April by a member of Kenya's National Council for Science and Technology. The chief South African delegate, a geneticist, was appointed by the Minister of Education and attended only the June meeting, although the South African Deputy Permanent Delegate to UNESCO was at both sessions. The Kenyan IGBC representatives at the January 2005 meetings were both from the National Commission for UNESCO (interviews with K_01 and SA_23; UNESCO 2005e: 1 and 9; UNESCO 2005f: 5; UNESCO 2005o: 1 and 10).

Although the majority of people from Kenya and South Africa interviewed in 2005–6 were unfamiliar with the declarations, several had strong opinions about who should be representing them at international negotiations more generally. A Kenyan civil society actor (K_14) could find no consistency from one meeting to the next: 'The people who represent the government – today it's this person, another month it's somebody completely different from another ministry.' A university researcher (K_26) also saw the appointment process as a capricious one, resulting in ill-informed government officials attending international meetings at short notice, with little time to absorb the relevant facts and statistics. They asked, 'Who is representing my views as a geneticist?' South African participants were also of the opinion that representatives at international negotiations need to have a certain level of expertise, although they differed on where the requisite expertise lay. Some of those who conduct genetic research involving human subjects felt that experience 'at the coalface' was important. This would furnish an understanding of the intricacies of obtaining informed consent, for example (interviews with SA_12, SA_20 and SA_21). One (SA_21) commented, 'I think it's very dangerous to have a group of academics putting it [the UDBHR] together when they don't understand what the issues are on the ground, because they can dream up things that are wonderfully ethically sound, but are totally impractical.' A long-standing member of a research ethics committee also thought that practical experience was important, but in terms of ethical review rather than research. Having seen some registers of those involved in UNESCO's bioethics activities, they expressed concern that very few of the people listed had sat on an ethics committee, remarking, 'I found one South African representative that I know has no bioethics research experience on any committee in this country, but is regarded as an expert – and that worries me' (interview with SA_19). Others thought that those with a background in the philosophy of bioethics had a vital role to play, because they have been trained in the logical construction of arguments. One said of the UDBHR, 'I can't see that there were bioethicists involved in the drafting of that thing. … I think it's unusable' (interviews with SA_08 and SA_16 [quoted]).

The tensions between these different positions were articulated by a prominent actor in South African bioethics:

> So what does it mean to be 'a bioethicist'? Should everybody who calls him or herself a bioethicist be consulted? Bioethics is a contentious field populated by scholars, professionals and others from many disciplines, not all of whom have had an adequate training or experience. So whose voices should be heard?
>
> (interview with SA_09)

Their words mirror what ten Have (2010: 14) has said in the context of the UNESCO Bioethics Programme:

> It is not clear who are experts. As an established discipline, bioethics has a body of knowledge, validated experiences, textbooks, journals, and best practices. In this sense, there is distinctive bioethics expertise. At the same time, as a public and policy-making discourse, bioethics is also a more general approach to particular issues, expressing, for example, political views on moral issues.

On being asked who should have put the declarations together, most participants thought a range of people essential, including scientists, ethics committee members and philosophically trained bioethicists, but also government representatives, legal experts, civil society actors and those with previous experience of international negotiations (interviews with SA_05,08,10,14,21,22,24,30,31, 32,33). One government official (SA_31) who had attended many such negotiations commented, 'The people who are prepared to explore the art of the possible are the people we should have in the room' – the 'art of the possible' signifying compromise. To include at intergovernmental meetings a diverse range of stakeholders from each member state might prove impractical, but governments could seek the advice and opinions of such actors in deciding what views their delegations should take to the negotiating table. For one interviewee, whether there had been wide consultation on the draft UDBHR (2005) was more important than who actually made the final decisions: 'I think the process is key, rather than just the people' (interview with SA_22).

Kenya's role in the negotiation of the declaration was coordinated by the National Commission for UNESCO. In formulating its position, the Commission garnered opinions from various people it considered experts, namely members of its own Natural Sciences and Social and Human Sciences Committees and officials from the Ministry of Justice and Constitutional Affairs, the Kenya Medical Research Institute and the National Council for Science and Technology (interviews with K_02, K_13 and K_16). These expert views were sometimes overruled by the permanent delegates to UNESCO in Paris, who work with their counterparts from other African delegations to form positions on issues as a consolidated African Group (interviews with K_16 and K_30). Nevertheless, the chief Kenyan representative at the IGE meetings in April and June 2005 carried out a similar consultation process to the National Commission, in order to be able to present a 'Kenyan position' (interviews with K_02 and K_16).

The tension between experts and states identified at international level by IBC and IGBC members seems, therefore, to have been mirrored at national level. Two members of the National Council for Science and Technology (NCST) later explained that, because the Permanent Delegation to Paris had only recently been established at the time of the UDBHR negotiations, its connections to other bodies were uncertain. By 2012 the lines of communication with the National Commission were far better established, with Kenya's IGBC representative able to get information to the Delegation quickly and easily if unable to attend a meeting in Paris themselves. Furthermore, the Paris office has proved very useful in strengthening relations (and therefore consensus) with other countries in the African Group, not least because, being on site, they are privy to corridor conversations (interviews with K2_16 and K2_21; informal conversation with African delegates at the IGBC meeting, September 2011).

In both Kenya and South Africa, input into the negotiating positions for the UDBHR (2005) on the part of government officials appears to have been curtailed by lack of communication within and between departments. At the time of fieldwork in 2005, both the Kenya National Commission for UNESCO and NCST fell under the Ministry for Education, Science and Technology. A member of the Commission described those at NCST as 'very close partners' and, indeed, an NCST representative attended the April IGE meeting (interview with K_16). Nevertheless, two members of NCST, who dealt with biotechnology and bioethics respectively, did not know of the declarations. The former (K_20) said that the connection with UNESCO had never been clear, the latter (K_21) that they had never heard of UNESCO engaging in any kind of bioethics activities. (K_21 did know about a proposed regional bioethics centre at a Kenyan university, but had not realized it was a UNESCO initiative.) Equally, the chief delegate to the IGE meetings (K_01) appeared unaware of ethical guidelines NCST had recently produced. It seems, then, that key information was not shared within and between the National Commission for UNESCO and NCST.

South Africa faced a similar problem, but between government units rather than within them, as it has separate departments for education and for science and technology. In 2005 UNESCO headquarters dealt directly with the Department of Education (where the South African National Commission for UNESCO was housed, now the Department of Basic Education), which did not consult with the Department of Science and Technology with regard to the UDBHR. A member of the latter (SA_26) complained, 'Different government departments are not interacting enough, so that there is kind of an information gap between the different ones and not enough collaboration.' The lack of coherence between government departments working on cross-cutting issues was also noted at an expert meeting on biotechnology held in South Africa in 2008 (NBAC 2008: 2).

Some South African government officials working on biotechnology policy in 2006 were unaware of the declarations before being asked for an interview (SA_28 and SA_31). One of them, from South Africa's Department of Science and Technology, corroborated the difficulty highlighted by IBC and IGBC members at their 2010 meeting in ensuring information gets to the right ministries:

> Basically we don't track the UNESCO processes directly from the department, which is something that made me think that we should do more, because the UNESCO relationship is owned by our Department of Education and they hadn't briefed us or asked us for assistance in this particular declaration.
>
> (interview with SA_31)

They deemed the three declarations, as a suite, to be good documents (having read them in preparation for the interview) and judged there was still time for them to contribute to the 'enabling legislative framework' called for in South Africa's 2001 National Biotechnology Strategy, where there were still gaps in legislation or regulations (DACST 2001: 50). The gaps they referred to, however, were with regard to stem cell research and the use of embryonic tissue, to which there are no references in the UNESCO declarations and, moreover, were to be covered in forthcoming national regulation. Another member of the Department of Science and Technology (SA_26) thought that it was perhaps already too late for the declarations to have much impact on South African biotechnology policy:

> Bioethics is obviously a key issue in growing a biotechnology sector, so it's very important. It probably would have been useful if, at an early stage, we could have grappled with these things and taken them on board. Not that we haven't, but we've now developed our own thinking … well, almost in the absence of the UNESCO documents.
>
> (interview with SA_26)

There was little or no broader dialogue with scientists, civil society groups or the general public on what they thought should be in the declaration in either Kenya or South Africa. On this point, the chief Kenyan representative at the IGE meetings said:

> No, there is not such a thing. Actually that's an issue which myself and another colleague who also attended the April meeting raised when we came back, in our report: that before any of those meetings take place, there must be meetings to agree on our stand and formulate our agenda. And that one has not taken place.
>
> (interview with K_01)

Echoing Chasek and Rajamani, they explained that internet access was slow and costly in Kenya, which may have put people off looking at the UNESCO documentation. They surmised, 'So many people are not even interested to know – if you are not directly involved, why should you read about UNESCO?' (Others interviewed in 2005 hoped new communications technologies would facilitate the country's greater involvement in bioethics and genetics. A member of the National Commission [K_16] believed email would enable Kenya to assert itself more strongly on the IGBC, while in regard to capacity development in science and technology, a scientific advisor to the Commission and the Kenyan government [K_13] averred, 'We don't need to build new buildings, we can communicate through the internet.' NCST is cautious in this regard, noting the digital divide as one of the challenges to harnessing the full potential of science and technology for development in its Strategic Plan 2009–13 [NCST 2010c: 19].)

In South Africa, the only input – albeit of a limited fashion – came from the South African Medical Association's Human Rights Law and Ethics Committee (interviews with SA_16 and SA_23). A quote from a senior member of a

university bioethics department (SA_17) serves to illustrate the paucity of consultation: 'You know, UNESCO has never contacted me with anything, so it's basically finding out from our bioethics circles as to what's happening in UNESCO and then looking up things on our own. But I have never been contacted by UNESCO.' Combined with the lack of governmental input, this left the chief delegate to the June IGE meeting with what Chasek and Rajamani would term a 'hollow mandate' as to how they were to represent South Africa. They commented, 'In hindsight, I attended the meeting poorly equipped to voice the opinions of the country' (interview with SA_23).

The declaration will need a wider support base than was evident during its negotiation if it is to be implemented fully at national level. This was recognized by participants in the UDBHR (2005) IGE meetings from both countries. The chief Kenyan delegate (K_01) thought it necessary to share the declarations beyond those few who had attended the international negotiations. 'Otherwise,' they remarked, 'we go to those meetings, we keep quiet, that's the end of it.' When interviewed in 2005, they were planning to hold a meeting to raise awareness about the declaration and to discuss how it might be domesticated, to which they would invite 'the experts, the communities and interested parties'. This they duly did in 2008 (see below). Their South African counterpart (SA_23) likewise commented that the declaration's principles needed to be promoted among the general public:

> We all have a responsibility to ensure – not just as scientists, but as members of the general public – that this sort of best practice is part and parcel of the very core of our moral values. It doesn't matter that you only try to aspire to these when you're doing genetic research, it should be core principles and perhaps we should have some education around it.

To achieve this, they said, the relevant government departments – the Department of Science and Technology, the Department of Health and the Department of Education – would have to work in partnership. Communications between the three departments and the South African National Commission for UNESCO have improved of late. The Commission, based in the Department of Basic Education, has a unit that coordinates its work in relation to 10 different government departments, including Higher Education and Training, Science and Technology and International Relations and Cooperation. The Department of Health is not one of the 10, but liaises with the Department of Science and Technology on ethics matters (email from National Commission, 24 July 2012).

Perceptions of UNESCO in Kenya and South Africa

The declarations

In 2005–6, 53 interviewees in Kenya and South Africa unconnected with UNESCO were asked to what extent they knew the three bioethics and genetics declarations. Thirty had come across them, of whom 18 only peripherally. One geneticist suggested that UNESCO publish the declarations in scientific journals, to heighten awareness among their community (interview with K_05). (Six interviewees did have UNESCO connections. Of these six, three were unaware of the declarations before being invited to become involved with UNESCO activities.) Once informed of the content and purpose of the declarations, interviewees had varying opinions on their potential usefulness. Two South African geneticists said the declarations would need action behind them to move them beyond being merely 'a nice statement' (SA_27) or 'nice platitudes' (SA_20). A Kenyan geneticist (K_29) similarly commented, 'Of course, the implementation is quite different from the declarations themselves.' On this point, speaking in 2011, the former Kenyan Chair in Bioethics regretted that the UDBHR was adopted as a declaration rather than a convention, as this has made implementation difficult. They would have liked states to have had to submit to monitoring and evaluation (interview with K2_01).

The translation to national and local levels was the key determinant for several people. One South African supporter of the declarations (SA_01) said, 'I think that this [the UDBHR] has been a helpful document and now it's just a matter of how it filters down to more of a grassroots level.' Less positively, a South African geneticist (SA_18) ruminated,

> They seem to take the way out always of talking of the regulations in the individual countries or the laws of the individual countries and so on. So it can only be an advisory sort of document and I think that's fine, but it would seem as though they don't have any teeth.

A scientist who advises both UNESCO and the Kenyan government (K_13) believed it would be 'dangerous' to adopt the declarations without translating them into 'what is happening locally'. Several others said that universal principles

should not be embraced unthinkingly; working out their practical application in particular contexts is often the most challenging aspect of implementing international instruments (interviews with K_15,16 and SA_10,17,24,25). One long-standing ethics committee member (SA_19) went further, believing there to be too much variation between countries for universal norms to be useful. They asserted, 'I believe strongly that national, local ethics guidelines are the things to follow.'

Some valued the declarations as benchmarks that could be referred to in lobbying for the introduction of internationally agreed standards at national level (K_16 and SA_13,23,30), or, like UNESCO, saw additional guidelines as necessary in an era of new technologies and scientific developments (K_10,19,29 and SA_32). A member of two Kenyan research ethics committees (RECs) (K_25) was particularly interested in the genetics declarations, because they thought it likely their committees would have to assess a growing number of protocols for research in this area in the future. Writing soon after the adoption of the UDHGHR (1997), Abbing (1998: 157) saw it as having this potential:

> The Declaration, in providing a framework which is based on general consensus, certainly will support developments in those countries where human rights in relation to genetics are not yet sufficiently guaranteed by the law nor applied in practice. It can be called upon in case of practices not in line with the principles layed [sic] down in the declaration.

Several participants welcomed all three declarations as reinforcing and fleshing out important principles of social responsibility, benefit sharing and capacity building (K_17,19 and SA_01,12,24,33). One (SA_11) said that the declarations are important as a 'global signpost', but that people must be given the opportunity to recognize this. A 2012 questionnaire respondent, who had come to know of the declarations through UNESCO's dissemination activities, corroborated this view. They believe the UDBHR (2005) provides important support for the human rights espoused in the South African constitution and being realized in society.

Most 2005–6 participants with an involvement in bioethics did not see the declarations' intergovernmental origins as distinguishing them significantly from other ethics documents. They (and their institutions) referred mainly to the WMA's *Declaration of Helsinki* and the CIOMS guidelines for international level guidance (K_06,07,08,09,17,19 and SA_04,05,10,14,19,24,30). Particularly with regard to the UDBHR (2005), several people saw what to them was simply another international bioethics declaration as unnecessary, or thought that people might become confused as to which guidelines (and the norms contained therein) to follow (interviews with K_07,09,17,28 and SA_04,05,08,10,14,20,22,25,27, 33). One (K_06) lamented, 'There is a plethora of different guidelines that people are trying hard to get to grips with.' Another (SA_17), who sits on several RECs, was of the opinion that there are too many 'talk-shops' coming up with declarations, to the detriment of implementation 'on the ground'. One person (SA_32) opined that, although the declarations might be useful as a reference point, by and large RECs in South Africa were already aware of the principles enshrined in the declarations' articles. Others thought the declarations complementary to preexisting instruments or that it was useful to be able to draw on different perspectives (interviews with SA_06,24,26,30,31). Researchers at the Kilifi KEMRI-Wellcome Trust Collaborative Programme in Kenya and the South African National Bioinformatics Institute, for example, when faced with a particular ethical problem, would look to synthesize all the relevant resources in order to reach the most appropriate solution (interviews with K_07 and SA_02).

The concern about overlap was still present in 2011–12. Although not dismissive of the declarations, a member of KEMRI (K2_17) did not see them as automatically becoming the main reference documents on ethics: 'UNESCO, for many of us, is a new kid on the block … for myself it would just be like any other thing I might be interested in.' A representative of the Regional Documentation Centre at Egerton University (see Chapter 7) recognized that it would be some time before knowledge about the declarations spread beyond those who attend UNESCO-sponsored conferences and workshops (interview with K2_32). Among the small number of people who returned follow-up questionnaires in 2012 (11 from South Africa, four from Kenya, with an even split between scientists and ethicists from both countries), only two used the declarations in their work, with the chief international reference points remaining the *Declaration of Helsinki* (used by 11 people), the CIOMS guidelines (nine) and the US' Belmont Report (seven). One person added, 'It is to some extent a time issue' and suggested that the declarations could be posted on the website of the Southern African Society for Human Genetics, to make them more easily accessible. More encouragingly, although opinions on the significance of (a) the declarations having been agreed by states and (b) the UDBHR addressing bioethics in a broad sense (rather than just research ethics) ranged from 'not at all significant' to

'very significant', there was a positive leaning on both counts, 10 people apiece opting for 'quite significant' or 'very significant'. One person elaborated on their apparently contradictory responses, explaining that, although their institution did not currently use the declarations, they believed them to be potentially important documents. Another will refer to the declarations on an upcoming project establishing a biobank for Africa. (Note that the questionnaire was not sent to members of the Kenyan National Bioethics Committee, as the aim was to see what influence the declarations had had beyond those involved in the ABC programme – see below.)

Human cloning

Views on the governance of human cloning in Kenya and South Africa reflect those of IBC and IGBC members and sub-Saharan National Commissions and Permanent Delegations, in content and diversity. Kenya does not as yet have an official position on whether or not human reproductive cloning should be banned (interview with K2_21). One NCST member (K2_21), interviewed in 2011, felt that the issue is presently only of peripheral importance to Kenya and other developing countries, but as the technology is likely to be developed soon it is important to be ready, as cloning legislation could have a big impact. Another (K2_16) felt that a meeting with politicians was necessary to educate them on the issue, so that they would not take misinformed positions, as some had done on genetically modified organisms (GMOs). A Kenyan scientist and public policy activist (K2_31) was concerned that research would move faster than legislation, leaving responsible researchers without guidance and resources and rogue scientists to do as they please. They thus supported an international convention to regulate cloning. Echoing the comments of Maimets and the Russian Federation delegate about how UNESCO's silence on the issue might be perceived, they went on:

> You know, unless the same international bodies become bold enough and have a convention, based upon which countries can draw their policies and legislations, then you will potentially be leaving very delicate and important research and development, especially in the area of human genetics and reproductive cloning, to decisions by individuals. … So a convention would be a good start. What I'm just wondering is, who are the lead opponents of not having a convention? I mean, why wouldn't we have a convention to regulate activities in reproductive cloning? … they don't have to wait for – what I should say – rogue research, or research that does not intend to be beneficial but commercial. They don't have to wait for certain negative outcomes before they decide that a convention is necessary. I think it would just be good to have a measure in place that researchers in various countries can use to regulate themselves.

Among questionnaire respondents, only four supported an outright ban of human reproductive cloning, while nine thought that research in this area should be carefully regulated (two did not answer the question). A Kenyan scientist (K2_32), interviewed in 2011, displayed a similarly cautious optimism:

> All these technologies have benefits, but they also have risks. …So what I would say is to just take a precautionary approach. We cannot say a complete no, but we can also not say an open yes. It's just a matter of learning from what's going on elsewhere, but also taking precaution.

Thirteen and ten questionnaire respondents respectively thought that therapeutic and reproductive cloning were important issues, warranting UNESCO's attention. They were less sure that cloning technologies have the potential to make an important contribution to addressing development needs, several finding themselves perplexed by this notion. Most supported international dialogue as a means to improve the international governance of human cloning. One geneticist elaborated that this would help to create essential awareness about the difference between therapeutic and reproductive cloning (and thought that cloning could contribute to development 'when used correctly and in a scientifically safe and ethically sound environment'). Another, like the IGBC delegate from Switzerland, reasoned that intense dialogue would raise awareness and thus lead to better regulation and monitoring. Fewer respondents favoured a convention, mirroring the IBC's preference for dialogue.

Adoption of the UNESCO declarations in Kenya and South Africa

Both Kenya and South Africa are upholding the UNESCO declarations to a greater or lesser extent, through their regulatory frameworks for bioethics and genetics. The ethics systems in both countries have developed substantially over the last decade. Both adopted national guidelines on bioethics in 2004: *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* and *Ethics in Health Research: Principles, structures and*

processes (South Africa). Both countries also have more specific guidelines, on HIV/AIDS vaccines and clinical trials: the *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (2005), the *Guidelines on Ethics for Medical Research: HIV preventive vaccine research* (produced by the Medical Research Council of South Africa in 2003 and adopted as national guidelines) and the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (second edition, 2006). As might be expected, these documents articulate well-established bioethical principles such as informed consent, autonomy, privacy and confidentiality and the need for risk/benefit analyses. They also deal to some degree with several of the issues discussed in Chapter 2 around the ethical dilemmas generated by genetics and research in developing country contexts. In this they draw on the *Declaration of Helsinki*, the CIOMS guidelines and other international ethics documents, but not the UNESCO declarations existing at the time of their publication.

Kenya in 2005

Under the 1977 Science and Technology Act, the National Council for Science and Technology was established to advise the government on 'all matters relating to the scientific and technological activities' (NCST 2012b). It was given ultimate control over what research takes place in Kenya and the power to ensure it is conducted ethically. Some of these powers were devolved to institutional ethics committees, such as the Ethical Review Committee of the Kenya Medical Research Institute (KEMRI). The 2004 ethical guidelines (produced by NCST) described this system as 'weak with many loopholes' (NCST 2004: 2). Certainly, the regulatory framework was far from clear in 2005, when the first period of fieldwork in Kenya was conducted. A member of the Council explained that ethics were not a major concern when the Science and Technology Act was promulgated and thus do not feature prominently within it. NCST had been pushing for many years for the Act to be updated to include current ethics issues, but as several acts were awaiting amendment this was likely to take some time (interview with K_21). The KEMRI ethics committee had gone one step further and recommended a 'stand alone' act for biomedical research involving humans, seeing the Science and Technology Act as too generalized (interview with K_19). The KEMRI-Wellcome Trust Collaborative Programme at Kilifi was using the NCST guidelines, but was assuming these were still in draft, having not heard otherwise (interviews with K_06, K_07 and K_09). On being asked whether the guidelines were legally binding, one member (K_06) commented that this 'would be quite a useful thing to know'. A member of NCST (K_21) confirmed that they could not be binding, by their very nature as guidelines.

Fieldwork revealed some ambiguity as to the status and purpose of certain ethics committees in Kenya. The Science and Technology Act (1977) made provision for a medical sciences committee. This became the Health Sciences Specialist Committee in 1983 and took on responsibility for research ethics policy, regulating institutional committees (such as the KEMRI committee) and reviewing proposals from foreign researchers (interview with K_21; NCST 2010a: iii). Several interviewees in 2005 agreed that, in practice, the KEMRI committee functioned as a national ethics committee, as it is mandated to review protocols from researchers based outside KEMRI (K_07,15,19,21,22,25). Indeed, the KEMRI website reads, as it has done for several years, 'The Committee is accepted by the Ministry of Health as a National Ethical Review Committee' (KEMRI 2012). It seems strange, then, that the Ministry decided to set up its own ethics committee. In January 2001, following recommendations in the National Health Sector Strategic Plan, it established a Health Standards and Regulatory Services Department to, among other things, 'provide the priority medical research agenda' and 'review medical research protocols in Kenya' (Ministry of Health, Republic of Kenya 2001: 1–2 [quoted]; interview with K_27).

As noted by Daniel arap Moi, then president of Kenya, the new department's mandate included the launch of a national ethics committee (Ministry of Health, Republic of Kenya 2001: 6). The National Medical Research, Ethics and Traditional Medicine Committee was duly created in 2002, ostensibly including KEMRI and NCST among its membership (Ministry of Health 2003). On the relationship between this new committee and KEMRI, a member of the latter (K_17) said in 2005:

> The Ministry of Health wanted to start their own. It would be a year ago, we all met together, the Director of Medical Services and some visitors from the Walter Reed [a US-based institute] and they said that they wanted to start their own. But, notwithstanding, we decided we would not wait for them. If they started their own, that's fine and they'd tell us how we would relate to them. But we consider ourselves the National Ethical Review Committee.

They also explained that, as a consequence of the proliferation of committees, it was possible that some research went unapproved, because people could plead, 'I got confused, I didn't know where to go, so I decided not to go anywhere.' A Ministry of Health report (2003) similarly acknowledged that stakeholders needed to be educated on the relationships between KEMRI, NCST and its new committee.

Despite the profusion of committees described above, in 2005 the National Commission for UNESCO, with the then Bioethics Chair, was looking to form a National Bioethics Committee (interviews with K_01 and K_16). Their rationale was the same as that behind UNESCO's Assisting Bioethics Committees initiative: they would start with a committee and perhaps push for a bill 'later on' (K_01). (Interestingly, however, the Chair was unaware at the time of UNESCO's guidelines on how to set up just such a committee.) A member of the Commission did not think the new committee would overlap with Kenya's pre-existing ones because it would engage primarily in sensitizing people about bioethics and the three UNESCO declarations in particular, rather than ethical review. They said, 'I don't think there's any other committee that is doing that.' Furthermore, it would include among its membership representatives from the relevant government bodies (interview with K_16). Not everyone was convinced. A member of NCST (K_21) welcomed the idea of working with UNESCO to promote knowledge sharing and capacity building, but thought that a new committee was unnecessary.

As for the declaration being adopted into Kenyan law, those connected with UNESCO explained why it might be a long time before this happened. A member of the National Commission (K_16) outlined the difficulties of first raising the necessary political will: 'How are you going to sell it to your country? How do you advise? Do you wait until there's a problem, then you say, "Okay, let's refer to …"? Or do you need to sensitize people in advance?' Even if this were to be achieved, the legislative process is a slow one, involving negotiations between several ministries. It can also be somewhat capricious. A scientist who was advisor to both UNESCO and the government (K_13) warned that if the desk officer assigned the portfolio for adoption of a declaration was a 'middle of the roader', nothing might happen for several years. The National Commission representative lamented the slow rate of legislation in Kenya, which meant the system was clogged with pending bills. Also, they pointed out, if the government changes, sensitization of ministers has to begin all over again. In spite of such difficulties, they believed the sensitization of policy-makers worth pursuing, to gain backing for the financial support of the Commission's programmes. If policy-makers believe an issue to be important, they said, they will provide the resources to recognize this importance (interview with K_16). A long-standing member of a Kenyan REC (K_19) described what could be achieved by engaging with government: 'Our policy-makers here are fairly open, yes, they are quite open to new ideas. But as I say, you just need to empower them with the information, they need to know what you are talking about.'

Kenya in 2011

There have been significant changes in the research ethics regulatory framework in Kenya since 2005. A National Bioethics Committee (NBC) has indeed been formed, but through NCST rather than the National Commission, replacing the Health Sciences Specialist Committee (HSSC). The Ministry of Health's ethics committee, created in 2002, has also become part of the new NBC. NCST realized that its ethics provision was no longer adequate, as there are several more research institutions in Kenya now than when it was established in 1977. Thus in 2009 the HSSC took on the task of 'transforming itself' into the National Bioethics Committee of Kenya, broadening its mandate in light of the UDBHR of 2005 (UNESCO 2009a: 1; NCST 2010a: iii and 1 [quoted]; interviews with K2_21 and K2_25). Here the declaration's intergovernmental origins played a part; it was felt that, because it sits closer to law than WHO and CIOMS guidelines, it would be easier to domesticate and use in legal activities (interview with K2_21). The committee's new mandate includes advising the government on ethical issues, such as traditional medicine and use of technology; providing a forum for consultation and public debate; ensuring the highest ethical standards in research; training and accrediting institutional ethics committees; publishing guidelines (on materials transfer, for example); and liaising with corresponding bodies in other countries (NCST 2010a: 1–4; interview with K2_21).

The committee has 17 members and is multidisciplinary (in line with article 19 of the UDBHR), to save procedures 'from being mere rhetorical gambits' (NCST 2010a: 1 [quoted]; interview with K2_21; NCST 2012a). By November 2011, when the second period of fieldwork was conducted, it had met six times and its members believed it had achieved a lot in a short period (interviews with K2_21 and K2_25). It had also gone through UNESCO's ABC programme, becoming the first committee to complete all three stages of the training. Like the founding of the new committee, the training was organized through NCST, which had established a direct connection to the UNESCO Bioethics Programme secretariat in Paris. The Memorandum of Understanding was signed with what had become the

Ministry of Higher Education, Science and Technology, NCST's parent ministry (separate from the Ministry of Education, the parent ministry of the National Commission) (UNESCO 2009a: 1; ten Have *et al*. 2011: 385; interview with K2_21).

The first training, held in November 2009, was attended by members of the HSSC, as well as representatives of Kenyatta National Hospital, KEMRI and other universities and research institutions, some of whom were destined to sit on the new committee. As well as discussing ethical issues of particular concern in Kenya (including regulation of traditional healers, use of genetic samples and review of multi-centre research), participants drafted the mission, role, mandate and rules of procedure of the new NBC (UNESCO 2009a: 2–4). As per the ABC model, the third training session in November 2011 dealt with issues of particular relevance to the country, including accreditation of institutional RECs and materials transfer agreements (conversations with participants, November 2011). Over the year 2011–12, the NBC would also be deciding whether ethics committees are needed at provincial level (interview with K2_21).

The NBC has devised a comprehensive system for the accreditation of institutional RECs. The relationship between NCST and these committees was unclear in the past, but has improved (interview with K2_25). As the inaugural edition of *Bioethics Info-Net*, a newsletter produced by the Kenyatta National Hospital-University of Nairobi REC, notes:

> In the past the NCST could only note the existence of committees and several did not inform the NCST of their existence. … Accreditation will reinvigorate ethics review in the country and ensure sustainability as the national research system continues to grow.
>
> (KNH-UoN REC 2011: 4)

The accreditation application form (NCST 2011) asks for information on the genders, qualifications and specializations of committee members and whether they have had ethics training. It also asks for a copy of a committee's standard operating procedures. To pass, a committee must have at least seven members, a variety of expertise, at least one member from outside the institution, a lay member and a gender ratio of no more than 2:1 either way. Accreditation lasts for three years and committees must send in annual reports, to include details of research protocols reviewed and any training, monitoring or difficulties encountered (NCST/NBC 2011: 4–5).

All institutions with RECs were required to apply for accreditation by October 2011, including 'those that have been in existence for a long time' (NCST no date). As of July 2012, 12 RECs had been accredited, from both public and private institutions, out of 15 applications and an estimated 30 to 35 committees in the country in total (NCST 2012a; interview with K2_21). At present there is no absolute legal obligation for committees to apply, but they would have to under a revised law. A member of NCST (K2_21) was confident that more RECs would come forward once the structure was wholly in place, as most have already gained the US Federal Wide Assurance, which is required of any institution receiving research funding from the US federal government. Under the new system, research protocols can be submitted to any accredited committee. It was hoped this would lighten the KEMRI committee's burden, but this effect is yet to materialize. Both national and international applicants have so far stuck with KEMRI, as they are familiar with its processes (interview with K2_17).

Another task the NBC is undertaking is a review of the 2004 ethical research guidelines. This is necessary, states the NCST website, because 'research activities have grown in quantity and the global arena has shifted towards favoring the conduct of research in countries that have weak research infrastructure' (NCST 2012a). (Note also that the guidelines do not specifically cover genetic research.) The review sits alongside the broader effort to revise the Science and Technology Act, which finally progressed, after much 'forwards and backwards', after the adoption of the new constitution of 2010 (interview with K2_21). Several acts are being revisited to ensure they comply with the constitution, particularly with regard to human rights, as well as a more regionalized form of government. The draft of the new science and technology act was formulated by a taskforce and adjusted in light of public comment and debate, before being put before Parliament. NCST members hoped that the new act would be in place by 2013, but once a piece of legislation reaches the political level it is out of their hands. Given the number of acts being deliberated, in function of the new constitution, it may take some time (interviews with K2_16 and K2_21).

There are also plans for an act specifically on ethics and committees, as the current provisions are not well grounded in legal terms. This will draw on the UNESCO declarations (interviews with K2_16, K2_21 and K2_32). They are useful in countries where the requisite ethical structures do not exist, a member of NCST (K2_21) explained, unlike in

Europe and the US, where ethics systems have been developing since the Second World War. The UDBHR (2005) is especially pertinent, said their colleague (K2_16), because Kenya participated in its drafting. Even though it is rather weak, as a non-binding instrument, that active involvement has an impact on a nation. Again, the timeframe is uncertain, but the NBC was to use 2012 to lay the groundwork by talking to the government about how the UDBHR should be understood.

What has seemingly changed little since 2005 is the relationship between NCST and the National Commission for UNESCO. One member of NCST viewed the relationship positively, seeing the work of the two bodies as complementary. For one thing, NCST provides advisors for the Commission's specialist science committees. They explained:

> So you can see the Council and the Commission have no choice other than to work together, because one is a national institution – competent institution – for science issues. KNATCOM, or National Commission, has mandate over those science areas that are handled by UNESCO. … So any committees of KNATCOM, then the Council sits in, depending on the area. So the Council sits on that to provide the advice. Now, when we have issues that cut across a couple of ministries and it's not necessarily a UNESCO issue on its own, then we take it up as a Council.
>
> (interview with K2_16)

Yet this does not appear to be how the relationship works when it comes to bioethics. Another member of NCST (K2_21) said that all three ABC trainings had already taken place and the National Commission had not been involved: 'I think that tells you everything you need to know.' They saw the Commission as a primarily diplomatic rather than 'hands-on' body that focuses mainly on basic education and did not think the imminent reintegration of the education and science and technology ministries would make a difference to the relationship. The former Bioethics Chair (K2_01), who had been peripherally involved with the formation of the NBC and had attended the second ABC training at the invitation of the Bioethics Programme secretariat in Paris, was more hopeful in this regard, but was irked that the Commission had not been invited to join the NBC or attend the training. In his view, the National Commission, as a UNESCO body and therefore broad-ranging, was better placed to deal with cross-cutting bioethics issues than NCST, which falls under a particular ministry. They also felt that the Commission needed a new paradigm of operation that would see it being more proactive as a link between the government and the people.

Given the lack of communication between NCST and the National Commission, it is perhaps not surprising that Kenya's progress report to the 2011 UNESCO General Conference, delivered by the Minister of Education, did not mention the setting up and training of the NBC (Republic of Kenya 2011). But despite their reservations about the Commission, the NCST representative would be happy to work with the Bioethics Chair and Regional Documentation Centre at Egerton University (see Chapter 7) to run training courses for institutional REC members (interview with K2_21). What has improved since 2005 is Kenya's participation in the IGBC, which has become more structured. Whereas before 'consultation was quite narrow and to a few individuals who are in the know', the IGBC representative (a member of NCST) will now be able to refer issues to the NBC. Some issues may also be referred, where relevant, to the new National Biosafety Authority, which is independent but was 'a baby of the Council' (interview with K2_16).

The National Biosafety Authority is an outcome of the National Biosafety Act of 2009. At the time of fieldwork in 2005, Kenya was awaiting the adoption of a Biosafety Bill, which was first promulgated in 2003. Interviewees could see neither the Bill being expanded to cover human genetics, nor a separate bill on the human side being drawn up in the near future (K_01,13,18,21). In 2006 the National Biotechnology Development Policy was published: 'The Government will initiate appropriate steps to nurture platform biotechnologies for the benefit of Kenyans and, ensure that Kenya becomes a key stakeholder in the international biotechnology enterprise within a decade' [sic] (Republic of Kenya 2006: 5). The policy specifies six priority areas, including medical biotechnology (to include molecular diagnostics, but expressly not human cloning or the unethical use of stem cells) (ISAAA 2009).

It is agricultural biotechnology which has received the most attention, both from policy-makers and the public, with the National Biosafety Act being adopted after more than a decade of wrangling about GMOs (Karembu *et al*. 2010). The National Biosafety Authority oversees the handling and use of GMOs, thus implementing the Cartagena Protocol on Biosafety (National Biosafety Authority 2012). Kenya has also been devising a Biosciences Framework, which was due to be finalized by June 2012. The framework will deal with non-human research, promoting biosecurity,

biosafety and the bioeconomy; that is, the safe, sustainable, developmental and fair use of biological materials (NCST 2012c; conversation at NCST, November 2011). Broader still is Vision 2030 ('A Globally Competitive and Prosperous Kenya'), launched in 2007, which seeks to transform Kenya into a middle income country by 2030. 'Science, Technology and Innovation' is one of six foundations of the policy, as reflected in the government's significantly increased funding of research in recent years (Republic of Kenya 2007: i–ii; NCST 2010b: 30; NCST 2010c: 33; interview with K2_31).

South Africa in 2006

The South African bioethics framework was somewhat more coordinated than the Kenyan one in 2005–6. The South African Constitution of 1996 entrenches the rights and dignity of all, including the right 'not to be subjected to medical or scientific experiments without their informed consent' (Cleaton-Jones and Wassenaar 2010: 710; Dhai and McQuoid-Mason 2010: 2). According to the National Health Act of 2003, implemented by the Department of Health, a National Health Research Ethics Council is to carry out a variety of tasks, including writing guidelines for RECs and setting norms and standards for research with humans; disciplining those found to be in violation of these guidelines or norms; registering and auditing RECs and adjudicating complaints about them; and advising the national and provincial departments of health on issues in research ethics (Clause 72 (6)) (Republic of South Africa 2004: 74). The 2004 ethical guidelines, *Ethics in Health Research: principles, structures and processes*, were written by an interim committee, which subsequently disbanded. At the time of fieldwork in early 2006, the permanent council had not yet been appointed (an invitation for nominations had been issued) (Republic of South Africa 2006).

In terms of implementation of the UNESCO declarations, the chief South African IGE delegate (SA_23) acknowledged, 'The translation post the declaration [UDBHR] has been absolutely pathetic and somebody needs to drive it in a forceful sort of way. And I don't believe that the infrastructure is there for that to happen.' On returning from the IGE meeting in June 2005, they recommended in their report to the South African National Commission that the country should have a central committee to deal with ethics. This committee would engage with the various RECs around the country, to bring them under one 'umbrella' within a virtual structure. National guidelines would 'serve as a framing document that's a "one-stop shop" for anyone wanting to apply to ethics committees to conduct research', thus ensuring that people would be following the same rules, whether they were based within a university, an NGO or any other institution. These proposed functions are in fact very similar to those set out in the National Health Act for the planned National Health Research Ethics Council.

South Africa in 2012

The permanent National Health Research Ethics Council (NHREC) was established in October 2006 and met for the first time in January 2007. Its mandate, as set out above, is very similar to that of Kenya's National Bioethics Committee: standard setting, accrediting and monitoring RECs and advising the government. It can also take disciplinary action against anyone contravening the National Health Act (and any related norms, standards or guidelines) and draft or advise on amendments to relevant sections of the Act (namely Chapter 8 on human samples and Chapter 9 on research). The committee has 14 members, appointed by the Minister of Health (the Department of Health provides the committee secretariat). The members, with other appropriate persons, also form various working groups on pertinent topics, such as vulnerable populations and materials transfer (Department of Health 2010; NHREC 2010: 4; NHREC 2010–11: 8–9 and 13; NHREC 2012c).

The composition of the NHREC and its rules of procedure are regulated under the National Health Act. Section 72 specifies aspects such as the number of members (no more than 15) and the nomination process, but regulations published in September 2010 expand on these stipulations. (Draft regulations for public comment were published in February 2007, but appear to have been finalized only several years later, a few months after the committee's second term of office began in 2010 [Republic of South Africa 2007d and 2010a; NHREC 2010–11: 9]. The draft and final regulations for the National Health Research Committee, which decides on and coordinates health research by public bodies, identifies priority areas and advises the Minister on strategy, were published in the same months [Republic of South Africa 2004: 73, 2007c and 2010b].) Under the regulations, NHREC members must include a range of experts in ethics and law, as well as representatives of the community and the pharmaceutical industry. Nominations are to be sought via the Government Gazette and one or more newspapers, 'enjoying circulation in the entire Republic for appointment'. The committee must meet at least four times a year (Republic of South Africa 2010a: 4–5 and 7). Chapter 11 of the Act, 'Regulations', makes provision for the Minister of Health to constitute regulations relating to

any aspect of the Act, after public comment, with any on human subjects research to be made in consultation with the NHREC (Republic of South Africa 2004: 88–90).

The REC accreditation requirements are very similar to those in Kenya. Using language that mirrors strongly article 19 of the UDBHR, the 2004 ethical guidelines stipulate that RECs should be 'independent, multi-disciplinary, multisectoral and pluralistic'. They must have a minimum of nine members, including at least one lay person and neither gender is to have more than 70 per cent of seats. Accreditation will be re-assessed every three years (Department of Health 2004: 13 and 15). The application form (NHREC no date) requires details of stakeholders (organizations) which can submit applications to the REC, number of applications processed, terms of reference and working procedures. All RECs were to register with the NHREC by 30 April 2008, but an evaluation carried out in October 2009 (by which time 22 had registered) showed that the NHREC still had to identify and register some committees, primarily those recently established or in private organizations (NHREC 2008; NHREC 2009: 5 and 13). By July 2012 there were 33 RECs on NHREC's online register (NHREC 2012a). Where the process differs from Kenya's is that accreditation in South Africa is offered at two levels. Level 1 committees can only review research that is likely to be of minimal risk (that is, low budget research not involving drug testing or human tissue), whereas Level 2 committees can review all types of health research, including multicentre studies involving collaboration within South Africa or beyond. Level 1 accreditation is considered a 'stepping stone' towards Level 2, hence committees are encouraged to build the capacity required for the higher level within five years of registration (Department of Health 2004: 12).

As in Kenya, the 2004 guidelines are under review. By 2010–11, the NHREC's Ethics in Health Research Working Group had examined the first four chapters of the guidelines and sent out revisions for wider stakeholder input. The NHREC 2010–11 report (p. 19) reads:

> The guidelines 'Ethics in Health Research: Principles, Structures and Processes' (blue book) was last updated in 2004. Since then numerous changes had occurred in NHREC and the National Health Act prompting a need to review and revise the ethical guidelines. It was also noted that NHREC played a national role in coordinating activities in research ethics and so had a responsibility to debate and deliberate important substantive issues in research ethics with a view to formulating a policy document on these issues. It is on this basis that this working group was constituted.

Section 71 of the National Health Act ('Research on or experimentation with human subjects') came into effect from 1 March 2012. This introduces some new requirements for health research, such as the categorical need for written consent. A statement posted on the NHREC website (NHREC 2012f) acknowledges that the 2004 guidelines are in conflict with these legal requirements and pledges that detailed regulations, including guidelines for RECs, will be issued in due course. In May 2012 the Department of Health issued a policy framework for health research approval, consolidating the basic requirements of the South African Constitution, the Health Act, the 2004 ethics guidelines and the 2006 clinical trials guidelines (Department of Health 2012).

Brief regulations had already been released in 2009 with regard to 'research on human subjects', which contained several of the provisions on consent referred to in the NHREC's 2012 statement, including the need for ministerial consent for non-therapeutic research with minors. These do not appear to have been formally adopted, however, as they are no longer available in the South African Government's online document repository. Draft regulations (which remain in the repository) had first been released for public comment in February 2007 (Republic of South Africa 2007b and 2009). The NHREC's 2006–9 progress report notes the drafting of these regulations as one of the activities of the Human Subjects in Research Working Group. In 2008 the Group was awaiting ministerial approval and translation to the vernacular and in 2009 consolidated the final version in light of public comment (NHREC 2010: 6–7). In the NHREC's second term of office, the Group merged with the Vulnerable Persons Working Group, to form the Regulations Related to Protection of Vulnerable Human Research Participants Working Group. Activities in 2010–11 included 'development of draft amendments to s71 of the National Health Act, and submission to the Legal Unit in the DoH' and a meeting with said Legal Unit to debate the regulations on human subjects (NHREC 2010–11: 13–14). This appears to have been a separate process to the review of the 2004 guidelines. (No further update was available as of July 2012.)

Unlike Kenya's 2004 guidelines, South Africa's contain chapters on human genetic research and the use of human samples. These mirror many of the articles of the IDHGD (2003). The chapter on human genetic research recognizes that individuals share genes with relatives and other members of the population and may be subject to genetic

discrimination or stigmatization. It stipulates, ‘Researchers should consider the social and cultural significance of their research, especially in the areas of complex socially significant characteristics and the genetic characteristics of collectivities’ (Department of Health 2004: 42–5). ‘Collectivities’ are defined as:

> Groups distinguished by: common beliefs, values, social structures and other features that identify them as a separate group; customary collective decisionmaking according to tradition and beliefs; the custom of leaders expressing a collective view; members of the collectivity being aware of common activities and common interests.
>
> (ibid: 28)

Despite these synergies, the UNESCO genetics declarations do not appear to have inspired this chapter, as they are not cited in the guidelines’ list of key international texts. As the guidelines were published in 2004, it is possible that the chapter on genetic research had already been drafted when the IDHGD was adopted in October 2003.

The chapter of the 2004 guidelines on human samples simply repeats section 68 of the National Health Act (‘Regulations relating to tissue, cells, organs, blood, blood products and gametes’), with the added provision that ‘additional ethical issues that arise in genetic research using human tissue need to be addressed in conformity with human genetic research (Reproductive Biology and Genetic Research [MRC Book 2])’ (Department of Health 2004: 38). This book forms part of the Medical Research Council of South Africa’s *Guidelines on Ethics for Medical Research*. Echoing some of the philosophical objections to human reproductive cloning outlined in Chapter 2, the book states, ‘The pre-embryo [the stage from fertilisation to 14 days] should be treated with the utmost respect because it is a genetically unique, viable human entity. … The production of excess embryos for the sole purpose of research should be discouraged’ (MRC 2002: section 2.2). It also recommends that human reproductive cloning through somatic cell nuclear transfer (SCNT) be prohibited, on the grounds that the risks to the potential child outweigh the benefits (ibid: section 3.7.3). The National Health Act prohibits human reproductive cloning by any means (Republic of South Africa 2004: 63).

Since 2006 there has been a whole raft of regulations to further enact the National Health Act, particularly section 68. Some were presented as drafts for public comment in 2007, but never came to fruition. Instead, new drafts on the same section were produced in 2011, with the final versions coming into force on 2 March 2012, as outlined in Table 6.1. The delay in instituting these and other parts of the Act was a cause of concern for scientists and legal experts alike in South Africa, who wrote in the country’s medical and legal journals of their frustration at the lack of up-to-date legislation, the most relevant promulgated act being the Human Tissue Act of 1983 (Pepper 2009: 505; NBAC 2010: 2; Swanepoel 2010: 3; Sithole 2011: 56–7).

In January 2007 the South African government invited comment on proposed ‘Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics’, another adjunct to the National Health Act (Republic of South Africa 2007a). These gave comprehensive instructions on the collection, processing, storage and use of DNA, RNA and so on. The draft regulations relating to research on human subjects of 2007 also contained a chapter on genetic research, but this was dropped from the unadopted 2009 version (Republic of South Africa 2007b and 2009). The 2012 regulations on biological material cover the collection and use of material from living and dead persons, for genetic testing and research, sex selection (prohibited except for medical reasons) and stem cell research and therapy (allowed, including the use, but not creation, of embryonic stem cells), as well as storage and disclosure of genetic information (Republic of South Africa 2012d).

The other 2012 regulations (see Table 6.1) expand on those on biological material. Those on bodies, tissues and so on outline how and for what purposes these can be procured; those on import and export give detailed guidance on the circumstances under which permits will be issued; and those on stem cell and tissue banks deal with donation, handling, storage and record keeping (and, for tissue banks, registration and inspection). All five sets of regulations carry penalties of fines and/or imprisonment for contravention or non-compliance (Republic of South Africa 2012a, 2012b, 2012c, 2012d, 2012e). While all these regulations mean that the whole of Chapter 8 of the National Health Act has now been enacted, the legislation is not sufficient to deal with stem cell tourism or therapies being offered that have not been fully tested (Pepper 2012: 60). The influence of the UNESCO declarations on the formulation of these regulations, if any, is unclear. When interviewed in 2006, one member of the team that drafted the 2007 version (on DNA, RNA and so on) was unfamiliar with the UNESCO instruments, while another said that the 1997 and 2003

declarations had ‘definitely assisted the writing of the regulations for the genetics that’s going to come through soon’ (interviews with SA_04 and SA_17 respectively).

As well as the regulations for genetic research that fall under the National Health Act, South Africa has a National Biotechnology Strategy (2001), administered by the Department of Science and Technology. (The strategy was published by the Department of Arts, Culture, Science and Technology, which split into the Department of Arts and Culture and the Department of Science and Technology in 2002.) The strategy includes a National Biotechnology Advisory Committee, which was in the final stages of composition at the time of fieldwork in May 2006. The proposed function of the committee was to advise the Minister of Science and Technology on the progress of biotechnology development in South Africa, particularly in terms of innovation and commercialization, but also ethics and legislation. Initially a separate bioethics committee was also planned, but after consultation with the South African Medical Research Council, the Department of Health and experts in the field (including a member of the Interim National Health Research Ethics Committee), it was decided that this would only duplicate existing initiatives. Instead, the advisory committee was to include ethicists among its members, to keep it informed of relevant bioethics issues or developments (interviews with SA_28 and SA_31). Solomon Benatar was appointed (NBAC 2006).

The National Biotechnology Advisory Committee met for the first time in November 2006. Since then it has held four workshops, on South Africa’s biotechnology sector (2008), the biotechnology policy environment (2009), the biotechnology pipeline (2010) and bioprospecting for the bioeconomy (2012). The Committee has also produced position statements bemoaning the lack of regulations on stem cells and ‘genomic sovereignty’ (that is, matters of access to and benefit sharing from human genetics, including import and export of materials). The statements are undated, but it seems reasonable to deduce that they played a part in bringing about the regulatory push of 2011–12. At the 2008 workshop, Benatar put forward the view that bioethics should not be seen as a ‘handmaiden’ to biotechnology, to be used as a convenient support for arguments for scientific advancement, but as an opportunity to ask important questions about what research should be done and why, in the context of addressing inequalities of health, poverty and human rights (NBAC 2008: 6–7).

Also under the auspices of the National Biotechnology Strategy, the Department of Science and Technology produced two sets of guidelines (legal and ethical) on biotechnology research in 2006, in partnership with the Health Professionals Council of South Africa (HPCSA). These are still referred to by some researchers, according to 2012 questionnaire respondents, yet are not available on the department’s website, nor can they be found via an internet search. The HPCSA produced a series of booklets in 2008 on a plethora of ethical issues, one of which is on biotechnology research. It does not include the UNESCO declarations in the list of local and international documents used in compiling the guidelines (the *Declaration of Helsinki*, the CIOMS guidelines and the Belmont Report all feature), but article 2 of the UDHGHR (1997) is quoted, which states that everyone’s rights and dignity must be respected, regardless of genetic characteristics. As the booklet was written with funding from LifeLab, one of the Biotechnology Regional Innovation Centres set up under the National Biotechnology Strategy, it appears it has subsumed the 2006 guidelines (HPCSA 2008a: 3). Both it and the one on health research ethics more generally (HPCSA 2008b) are posted on the NHREC website (NHREC 2012g). It seems likely that they will need to be updated in light of the 2012 research regulations.

Stakeholders in ethics and genetics in Kenya and South Africa had minimal input into the negotiation process for the UNESCO declarations, with the knock-on effect that their acceptance of the declarations has been rather slow. Generally, they feel that translation to the national context will be the key test of the declarations’ validity. Both countries have now adopted many of the provisions of the declarations; for instance, they each have a national bioethics committee that accredits RECs, which must be independent and pluralistic (see UDHGHR, article 16; IDHGD, article 6; and UDBHR, article 19). What is interesting is that Kenya has drawn explicitly on the UDBHR in developing its ethics systems, whereas South Africa’s efforts have been independent of UNESCO. As might be expected, given that only a few of the questionnaire respondents from South Africa use them, the declarations do not appear on the webpage where the NHREC makes available copies of several ethics documents, including CIOMS, Helsinki and Belmont (NHREC 2012g). The difference in approach may be due to the fact that Kenya has played a far more prominent role in the UNESCO Bioethics Programme than South Africa. Kenya has held a seat on the IGBC since the committee’s inception in 1999 (and chaired it from 2007 to 2009) and has championed bioethics at the General Conference (interviews with K2_01 and K2_16). Furthermore, a Kenyan medical researcher has been a member of the IBC since 2008. By contrast, no South African has sat on the IBC since 2003 and the country has

never held a seat on the IGBC. Of late, the only involvement it has had with the two committees has been to send a Paris-based Permanent Delegate to some of their meetings as an observer.

Footnotes

1 The chapter focuses particularly on the UDBHR (2005) because more data were available on this declaration than on the previous two, not least because fieldwork was conducted during and immediately after its negotiation, which meant that it was possible to interview some of those who had been involved. The various meetings leading up to its adoption are also better documented by UNESCO.

Tables

Table 6.1 Promulgation of sections 68 and 71 of the National Health Act

Name	Section of Act	Date of draft	Date came into force
Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics	68	5 Jan 07	N/A
Regulations relating to research on human subjects	71	23 Feb 07	N/A
Regulations relating to human stem cells	68	4 May 07	N/A
Regulations relating to the use of human biological material	68	1 Apr 11	2 Mar 12
Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes	68	1 Apr 11	2 Mar 12
Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue,[a] zygotes and gametes	68	1 Apr 11	2 Mar 12
Regulations relating to stem cell banks[b]	68	1 Apr 11	2 Mar 12
Regulations relating to tissue banks	68	1 Apr 11	2 Mar 12

a the words “foetal tissue” did not appear in the title of the draft version of the regulations.

b the draft title was “Regulations relating to stem cell institutions or organizations”.

Bookshelf ID: NBK189519