

# Regulating Research Involving Humans in Nigeria: Some Recent Improvements

*Cheluchi Onyemelukwe*

## *Introduction*

The ethical conduct of human research has been the subject of many studies and debates. Recently, the debate has focussed to a large extent on ensuring ethical conduct of research involving humans in developing countries. Many developing countries have very limited capacity in the field of scientific research. Thus, they frequently depend on sponsors in developed countries, including multinational pharmaceutical companies, to conduct research in required areas of healthcare, and to a large extent rely on the regulatory processes of developed countries to determine the safety of drugs.<sup>1</sup>

Clinical research conducted by developed country sponsors in developing countries has been criticized on the grounds of failure to meet the ethical standards applicable in developed countries. For example, the debates around the use of placebos in HIV trials in developing countries in the 1990s generated a lot of debate and controversy around standard of care issues.<sup>2</sup> These debates draw attention to the failure to provide the standard treatment in the control arm of a randomized trial and, more broadly, to the difficulty in justifying different ethical standards applicable to research involving humans in developing countries.<sup>3</sup> One result of these debates has been to highlight the need for a closer look at the clinical research undertaken in developing countries.

It is important to examine the ethical standards required of researchers from developed countries when carrying out research in developing countries. However, it is also essential, in my view, to investigate the oversight mechanisms that exist within developing countries to ensure that researchers (whether internal researchers or developed country researchers, including multinational companies) adhere to ethical standards. It would appear that the regulation of research involving humans has received insufficient attention in many developing countries.<sup>4</sup> Studies

have revealed the absence of functional ethics review committees, as well as the inadequacy of the existing ethics review committees in developing countries.<sup>5</sup> In my view, this may be connected, to some degree, with the absence of comprehensive and enforceable regulations and a comprehensive system of ethics review. The existence of international guidelines like the *Helsinki Declaration*<sup>6</sup> is necessary, if only to map the general direction that ethical research must take. But, as has been aptly noted, “such guidelines are no substitute for a substantive system of research governance entrenched at the national level, which most developing countries continue to lack.”<sup>7</sup>

Recently, however, some developing countries have begun to establish domestic regulatory regimes and governance structures to address gaps in the oversight of research. Countries such as Uganda,<sup>8</sup> South Africa,<sup>9</sup> Kenya,<sup>10</sup> Malawi<sup>11</sup> and, more recently, Nigeria have established guidelines and ethics review systems to address existing vacuum in this area. Given the increase in clinical research in the developing world,<sup>12</sup> and allegations of past unethical practices by other researchers in developing countries,<sup>13</sup> it is important to examine the domestic regulatory structures in developing countries. This examination is relevant to scholars, research sponsors and regulators in developed countries who want to understand oversight and regulation in different jurisdictions, and particularly the emergent regulatory regimes of developing countries.

Nigeria, like many developing countries, has a high burden of disease, including HIV/AIDS, and is therefore an attractive venue for research. Its economic and political challenges, evolving legal system, and weak health systems are emblematic of many developing countries, particularly in Africa. Thus, Nigeria makes an interesting and useful case study. In 2006, some steps were taken to improve research oversight in Nigeria. In this article, I describe the

regulatory regime before 2006 and in light of that regime look at the Pfizer case, a 1996 clinical trial of meningitis among children in a poor hospital in Nigeria which drew international attention. Finally, I describe some improvements that have occurred after 2006 and conclude that, while questions may remain about the current regime, the changes are a step in the right direction.

## ***Research in Nigeria***

Nigeria, Africa's most populous country, is a low-income developing country whose health care system has been ranked 187th out of 191 members of the World Health Organization.<sup>14</sup> Although recent by western standards, medical research has been undertaken in Nigeria for many decades, beginning with the research on yellow-fever in 1920 by the Rockefeller Foundation Yellow Fever Commission established in Lagos.<sup>15</sup> Understandably, as with many developing countries, the level of medical research undertaken by locally funded internal researchers is low (at least by comparison to developed countries)<sup>16</sup>, although some commentators have pointed out that the absence of directories of research activities tends to minimize the amount of research that actually takes place.<sup>17</sup> The low level of research is mainly due to lack of government commitment to health research, which has resulted in inadequate facilities and infrastructure, limited resources, little or no policies, and significant brain drain in the medical field.<sup>18</sup> The federal government funds some research through local agencies such as the National Institute for Medical Research (NIMR), which carries out research on parasitic, infective and non-infective diseases.<sup>19</sup>

But, as in most African countries, externally sponsored research forms a substantial part of health research.<sup>20</sup> Multinational pharmaceutical companies may also conduct trials for the purpose of testing new drug interventions, as was the case in the Pfizer incident discussed below. Externally funded research is essential to the growth of knowledge about the prevention and treatment of diseases in Nigeria, and it is important to understand how such research is regulated to ensure ethical conduct.<sup>21</sup>

## ***Research Oversight in Nigeria Prior to 2006***

Nigeria is a federal state, but there is no clear-cut delineation of responsibilities, as regards health, between the federal, state and local governments. Rather, health is on the concurrent legislative list in the Nigerian Constitution.<sup>22</sup> Thus, it is a matter in which the federal and state governments have concurrent powers, with the state subordinate to the federal government in any area of health

in which the federal government has made a generally applicable law. Each tier of government—including the federal, state and local government—establishes, manages and funds its own health facilities, from the monies made available under the national budget, but also frequently with aid from international organizations like the United States Agency for International Development (USAID).

However, the federal government through the National Assembly may make laws to regulate or co-ordinate scientific research, including research involving humans.<sup>23</sup> In addition, matters relating to drugs are within the exclusive powers of the federal legislative body, the National Assembly.<sup>24</sup> This does not prevent the state legislature (the House of Assembly) from establishing institutions or making any arrangements for the purpose of scientific research.<sup>25</sup> Nevertheless, it would appear that the federal government has been more active in the area of regulating research than the states, mainly through the creation of a national regulatory body for new drug approvals and a national ethics review committee.

Prior to 2006, the research oversight mechanisms in Nigeria consisted of a spectrum of formal and informal mechanisms, including regulation by the federal government through agencies created for that purpose, review by ethics review bodies in research institutions, and self-regulation by medical practitioners. There were no general guidelines dealing specifically with the major ethical concerns which arise in relation to research in developing countries. There was also no law or general guidelines requiring the existence of ethics review committees in research institutions, or setting down their structure or composition and functions, or even requiring that research protocols must pass through ethics review. One of the problems highlighted by the controversial trial conducted by Pfizer in Nigeria in 1996 was that Pfizer allegedly obtained no approval by an ethics committee in Nigeria and, as it turned out, had presented a forged and backdated letter from a non-existing ethics review committee.<sup>26</sup>

While not required by law, a number of ethics review committees existed and conducted reviews of research involving humans. These committees monitored research involving humans generally, whether or not involving drug use and production. There are currently ethics review committees in different federal hospitals in Nigeria and in major research centres like the NIMR.<sup>27</sup> The major teaching hospitals, including those situated at the universities in Enugu, Lagos and Ibadan, in which most externally sponsored research take place, have ethics review committees which review research protocols.<sup>28</sup> However, smaller hospitals may not have ethics review committees.<sup>29</sup>

Prior to December 2006, the principal institution in Nigeria for regulating clinical research involving drug trials was the National Agency for Food and Drug Administration and Control (NAFDAC) established by the *National Agency for Food And Drug Administration And Control Act 1993* (the NAFDAC Act).<sup>30</sup> NAFDAC is a parastatal of the Federal Ministry of Health and is responsible for ensuring drug safety and compliance with approved specifications and quality and regulates the importation, exportation, and manufacture of drugs. Its functions also include compiling standard specifications and guidelines for the production of drugs and establishing and maintaining laboratories for carrying out its functions under the Act.<sup>31</sup> NAFDAC has powers to make regulations for carrying into effect its functions under the NAFDAC Act.<sup>32</sup> This is an important power that NAFDAC has exercised in some respects.

In regard to research for pharmaceutical production, NAFDAC drew up a set of guidelines for the purpose of regulating clinical trials of drugs in Nigeria (NAFDAC Guidelines).<sup>33</sup> Under the guidelines “all novel drugs must undergo clinical studies in Nigeria before being granted marketing authorization in Nigeria.”<sup>34</sup> With regard to ethical standards and protection of participants in trial, the guidelines provide that the Helsinki Declaration, as amended, is the basis for clinical trial ethics to be observed by all engaged in research on human beings.<sup>35</sup> Further, the guidelines require independent ethics review of clinical trials by an independent ethics committee. The independent ethics committee is required to review objectively the suitability of investigators, facilities, protocol, the eligibility of trial subject groups, and the adequacy of informed consent and confidentiality.<sup>36</sup>

Informed consent under the NAFDAC Guidelines is to be obtained in accordance with the current revision of the Helsinki Declaration.<sup>37</sup> Apart from informed consent, the Guidelines do not deal with other ethical concerns, such as standard of care or distribution of benefits. They merely require the researcher to state “general ethical considerations” in the trial, describe how participants will be informed, and provide any reasons for not seeking informed consent.<sup>38</sup> Except for the requirement for compensation or treatment in the case of injury or death, the Guidelines do not address issues of what standard of care should be provided to the research participants, or require researchers to explain how the potential benefits of the trial will be made available after the trial is over, or the role of researchers in making such benefits available, issues which have raised controversies in the debate about the conduct of research in developing countries.<sup>39</sup> Ethics review committees are likewise not specifically required to consider these ethical concerns that arise with respect to transnational research. Indeed, the NAFDAC Guidelines deal more with

procedural issues than with substantive ethical issues. New regulations for the approval of drugs have just been released by NAFDAC in 2007.<sup>40</sup> Chief among the requirements are that clinical trials must obtain approval by an ethics review committee and NAFDAC prior to the commencement of such trials.<sup>41</sup> The application of the NAFDAC Guidelines and the newly released *Clinical Trials Regulations* is, however, limited to drug research and does not apply more generally to research involving humans. Thus, neither the *Regulations* nor the Guidelines can be regarded as providing general protections for participants in research in Nigeria, and they do not provide guidance for externally-sponsored research in the specific context of Nigeria.

Although there was no law or guideline requiring the existence of ethics review committees in research institutions, where most of the externally funded research takes place in Nigeria, some of these institutions required review by an ethics review committee located in the institution.<sup>42</sup> But there was no national or general overseeing ethics review committee that formulated general standards to which all ethics review committees had to adhere,<sup>43</sup> and each ethics review committee presumably followed the international guidelines. Ethics review in Nigeria was therefore argued to be less than satisfactory. As some authors noted, “not every research centre has established an ethics review process. Where already established, most of the ethics review committees are grossly underfunded and unequipped for their duties.”<sup>44</sup> Patricia Marshall, in a study commissioned by the United States National Bioethics Advisory Commission, notes that “[t]here is considerable variation in the implementation of the process of ethical review between institutions.”<sup>45</sup> As well, Nwabueze has noted that some of the existing ethics review committees operated not consistently, but on an ad hoc basis.<sup>46</sup>

From the above discussion, it is clear that prior to 2006, there was little formal engagement with the need for regulation of research involving humans or comprehensive oversight of the conduct of research in Nigeria. As the Pfizer case below illustrates, this state of affairs allowed much room for exploitation and unethical practices and left participants with minimal options for legal redress.<sup>47</sup>

### ***The Pfizer Case***

In 1996, allegations of unethical conduct of clinical trials were made against Pfizer, an American multinational pharmaceutical company, over its drug trials conducted in Nigeria following an outbreak of meningitis in several states in Northern Nigeria.<sup>48</sup> Pfizer, on hearing about the epidemic, sent its specialists to test the antibiotic drug Trovafloxacin (commonly called Trovan) in clinical trials at the Kano Infectious Diseases Hospital.<sup>49</sup> The trial was to investigate



whether the oral form of Trovan was more effective and efficient in treating children infected with meningitis than other existing treatments, including Ceftriaxone, the gold standard treatment.<sup>50</sup> Pfizer's Trovan had not been previously tested in children. However, about 200 children infected with meningitis were enrolled in the Kano trials.<sup>51</sup> Sometime after the trial had ended, the *Washington Post* in a series of investigative articles on the conduct of clinical trials by developed country researchers alleged that the trials had been unethical.<sup>52</sup> It was reported that some of the children died, while others suffered seizures, or became paralyzed as a result of the trial.<sup>53</sup>

The allegations made against Pfizer are that there was no informed consent, no follow-up of the children after conclusion of the trial, and no approval of the research protocol by an independent ethics review committee. It was alleged that there was no follow-up of the children partly because many of them did not show up after leaving the hospitals, and also because Pfizer reportedly did not send people to check up on them.<sup>54</sup> The parents of the children alleged that they had not been adequately informed about the trial and would not have subjected their children to it had they been informed.<sup>55</sup> No written consent was obtained, although Pfizer had prepared an informed consent form. It is reported that because of the illiteracy of the parents, only verbal consent was obtained after oral explanations had been made to the parents of the children in English and Hausa (the language of the participants).<sup>56</sup> Further, there was debate about whether or not the trial protocol was reviewed by any ethics review committee.<sup>57</sup> Pfizer stated that it had obtained the necessary approvals, including the approval of an ethics review committee. But there was no ethics committee in the hospital at the time of the trial<sup>58</sup> and no evidence exists that any ethics review committee examined the research protocol before the trial commenced.<sup>59</sup> However, as stated above, there were no regulations or guidelines in Nigeria, at the time of the trials, requiring Pfizer to obtain any such approval.<sup>60</sup>

The Nigerian government opened an inquiry of the incident in 2001. The findings of the panel of inquiry were not made public until the *Washington Post* obtained a leaked copy in May 2006.<sup>61</sup> The panel found, among other things, that Pfizer had not obtained the informed consent of the participants in the trial, since they were not informed that they were engaged in a trial and that no ethics approval was obtained. Consequently, Pfizer's experiment was "an illegal trial of an unregistered drug," and a "clear case of exploitation of the ignorant."<sup>62</sup> In May of 2007, criminal charges were brought against Pfizer in Nigeria, alleging that Pfizer voluntarily caused grievous harm to research participants and seeking two billion dollars as damages from Pfizer.<sup>63</sup>

The Pfizer case depicts the problems which arise with respect to oversight of the activities of multinational pharmaceutical companies and other sponsors of research in many developing countries. A comprehensive regulatory regime is necessary to provide the basic steps that sponsors of research need to take, including the legal requirement for informed consent, an independent ethics review, and possible compensation for research participants. As was made clear in the Pfizer case, lack of such a regime jeopardizes the safety and welfare of vulnerable research participants in developing countries like Nigeria. Fortunately, as I discuss below, Nigeria is taking steps to remedy this problem.

## ***Research Oversight After 2006***

Perhaps taking into consideration the criticisms of the existing state of affairs proffered by international scholars, particularly after the Pfizer incident,<sup>64</sup> as well as a growing awareness in developing countries of the need for proper research oversight, the government of Nigeria has recently established a National Health Research Ethics Committee, as well as a *National Code for Health Research Ethics* designed to provide oversight for research.<sup>65</sup>

The *National Code for Health Research Ethics, 2006* (the Code) applies to "all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria."<sup>66</sup> It therefore provides overarching governance for health research in Nigeria and is not limited to drug research like the NAFDAC Guidelines or the *Clinical Trials Regulations*. However, it may have been better for the Code to provide oversight for not only health research but for all research involving humans, since harm may also be generated in social or other research that involves human participants. The statutory authority for the Code derives from the *National Health Bill, 2004* which is yet to be passed.<sup>67</sup>

The National Health Research Ethics Committee (NHREC) operates at the national level. Health Research Ethics Committees (HRECs) operating at the institutional level in the different states conduct actual reviews of protocol and report to the NHREC.<sup>68</sup> The establishment and authority of the NHREC also derive from section 89 of the *National Health Bill 2004*. The NHREC, consisting of 15 members from different fields of endeavour, has the responsibility for: registering HRECs;<sup>69</sup> updating, revising, editing and modifying the Code;<sup>70</sup> providing oversight of HRECs functions;<sup>71</sup> referring to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider; and meting out penalties against any person found to be in violation of any norms, standards or

guidelines set for the conduct of research under the Act.<sup>72</sup> It also has the responsibility of advising the federal and state ministries of health on any ethical issues concerning research.<sup>73</sup>

As provided by the Code, all institutions that seek to conduct health research must register with the national research ethics committee,<sup>74</sup> and are required to have HRECs.<sup>75</sup> HRECs review research proposals and protocols in order to ensure that research conducted by institutions promote health (i.e., contribute to the prevention of disease or disability or result in cures for disease), and grant approval for research by the institution where research proposals and protocols meet the ethical standards of that HREC.<sup>76</sup>

The Code provides the manner in which registration by the HREC with the NHREC can be done and requires that registration must be renewed after two years.<sup>77</sup> An institution that has no ethics review committee may also enter into an agreement with another institution that has such a committee to provide ethics review of any research which would take place in such an institution.<sup>78</sup> Such agreement may only exist between institutions in the same state or in the same geopolitical zone.<sup>79</sup> Where the research involves more than three sites, the national ethics review committee may review such research or may mandate another research committee to do so on its behalf.<sup>80</sup> In the case of international collaborative research, the HREC may adopt the approval of another HREC or that of any other local or international ethics review committee, provided that such approvals comply with the requirements of the Code and take account of local circumstances.<sup>81</sup> The Code also provides that in international collaborative research, NHREC shall report any findings of misconduct against researchers, sponsors and collaborators to the national ethics regulatory agency of the country of origin of the researcher.<sup>82</sup> This step does not prevent the institution or participants from taking appropriate legal action against such researchers and their representatives in Nigeria, thus allowing room for participants and other interested parties to seek legal redress outside the ethics review system. This is relevant in light of the difficulty that plaintiffs may have in proving that the *Helsinki Declaration* and other such guidelines are not merely aspirational, but create obligations to participants.<sup>83</sup> More generally, the NHREC has powers to undertake other punitive action against researchers found guilty of unethical practices, including barring them from conducting research for variable periods of time depending on the severity of findings of misconduct. The Code also provides that NHREC shall: recommend disciplinary action against researcher(s) to the institutional and legally constituted authorities; report all cases of fraud, deception, infamous conduct, plagiarism, fabrication and falsification to the appropriate regulatory, police and other relevant

authorities; and bar researchers from conducting research for variable periods of time, depending on the severity of findings of misconduct.<sup>84</sup> There are no financial sanctions imposed by the NHREC. It may be argued that the sanctions in the Code are insufficient, especially in relation to external researchers, since these researchers may not face any direct penalties for unethical conduct. This would, however, pose difficulties in any event because of the difficulty in applying extraterritorial sanctions.

Aside from the procedural aspects of ethical review in Nigeria, the Code also provides some substantive ethical principles and guidelines for the ethical conduct of research. According to these: the research must have scientific and social value and be beneficial to the participants, as well as to the wider community; the research must have scientific validity; while minimizing risk, there must be fair selection of participants based on the scientific objective(s) of the research; and there must be valid attempts to minimize risks and maximize health related benefits.<sup>85</sup> Further, research must pass through ethics review,<sup>86</sup> and informed consent is indispensable. Detailed provisions for obtaining informed consent, including the format for an informed consent form, are set out. Where written consent is not obtainable, researchers must propose an alternative process of consent, such as audio recording or signing with thumb prints. All consent activities must be documented.<sup>87</sup> Given the issues raised by the Pfizer case discussed above, these are important principles in the Nigerian context. However, they do not appear to address the socio-cultural factors that may affect the informed consent process in a developing country like Nigeria—factors such as gender issues and issues relating to different understandings of health and disease.<sup>88</sup>

With particular regard to the issue of ensuring benefits to the wider community,<sup>89</sup> it would appear that the obligation to provide benefits is more obligatory than aspirational, given the way the provision is couched. Certainly, HRECs would have to consider what benefits the research would provide to participants and the community in terms of intellectual property and other commercial benefits. There may be a need to be more specific in this regard, however. For instance, different agreements are required to be signed, such as benefit sharing agreements. Who can sign on behalf of research participants and communities? Would this require legal representatives, and who would remunerate these representatives?

Interestingly, the Code does not address the standard of care issue in any significant detail. The standard of care debate has arisen in relation to the use of placebos where an effective treatment exists (as mentioned earlier with regard to the zidovudine trials)<sup>90</sup> and more broadly in relation to the question as to whether the same ethical standards apply across borders, irrespective of different contexts, including

poverty and poor healthcare systems.<sup>91</sup> The Code states only that, “for research to be ethical, it must be conducted in accordance with the principles of good clinical and laboratory practices.”<sup>92</sup> Given the huge debate that has arisen over this in the past, this would appear to be a gap that must be addressed,<sup>93</sup> and perhaps the NHREC will address this issue in further guidance in order to state what constitutes an appropriate standard of care in the Nigerian context.

## Conclusion

While establishing the Code and setting up the NHREC may not necessarily dispose of all unethical practices in research, these steps at least convey concern by the Nigerian government for the safety of research participants and, to some degree, close the existing vacuum in this area. Most importantly, ethics review has now become mandatory for all health research in Nigeria. While it would have been best to have all research involving humans brought under the Code and the authority of the NHREC, establishing the NHREC is surely a step in the right direction. Passing the *National Health Bill, 2004* will give statutory and authoritative backing to these steps and place these improvements on a firm footing. This would also be helpful to research participants, who may want to litigate against research sponsors, as was the case in the Pfizer incident. It is hoped that the Bill will be passed soon. Given that new elections have just been conducted in 2007, it may be that fresh steps are needed to revive and pass the Bill.

It remains to be seen how the rules will work. Certainly, the procedures in the Code and the duties of the ethics review committees need to be executed effectively to achieve the aim for which they are established. There is a need to address in greater detail the peculiar ethical concerns that arise with respect to research in a developing country like Nigeria. Further guidance in dealing with socio-cultural issues in relation to informed consent, and in determining the standard of care required (particularly with respect to randomized clinical trials), is needed.

There may also be issues to be tackled regarding the functionality and feasibility of the rules. For instance, issues of funding ethics review committees and capacity building review still need to be addressed.<sup>94</sup> However, issues of monitoring and implementation, as well as criticism of any rules, can only arise where there exist clear rules and guidelines that take into account the safety of research participants, as well as local circumstances. There is now a set of rules to provide some guidance. The recent steps taken to improve ethics review in Nigeria must therefore be applauded. They should also serve to encourage other developing countries to put in place proper research

oversight systems. This will move the debate from the non-existence of oversight systems for research to the improvements that can be made in domestic settings to better protect research participants. Providing and improving on domestic oversight systems would be an easier task, in my opinion, than regulating from the international stage, although this too has its uses.

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1. See Ileana Dominguez-Urban, “Harmonization in the Regulation of Pharmaceutical Research and Human Right: The Need to Think Globally” (1997) 30 *Cornell Int’l L.J.* 245 at 257; Sonia Shah, “Globalization of Clinical Research by the Pharmaceutical Industry” (2003) 33 *International Journal of Health Services* 29 at 30-31 online: <<http://www.baywood.com/compdf/0020-7314.pdf>>. Research into diseases which may be endemic in developing countries or diseases which are a health concern in both the host country and the sponsoring country may also drive medical research in developing countries. The existence of more treatment-naïve participants and the possibility of getting clearer results than would otherwise be available may also drive research in developing countries. Such clear results would be more difficult to obtain in the western world because it has more ready supplies of, and greater reliance on, drugs —thus making it more complex to determine the efficacy of the treatment being researched due to an increased risk of inaccuracy. Reduced costs, legislative vacuum resulting in fewer delays and requirements, and the strong desire on the part of developing countries to attract researchers from developed countries have also been identified as possible reasons for increased drug research in developing countries. See National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, vol. 1 (Bethesda, Md.: National Bioethics Advisory Commission, 2001) [NBAC] at 1. See also David M. Carr, “Pfizer’s Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries” (2002) 35 *Case W. Res. J. Int’l L.*, online: <[http://lawwww.cwru.edu/student\\_life/journals/jil/Notes/Carr.pdf](http://lawwww.cwru.edu/student_life/journals/jil/Notes/Carr.pdf)>.

2. See e.g. Peter Lurie & Sidney M. Wolfe, "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries" (1997) 337 *New Eng. J. Med.* 853; Harold Varmus & David Satcher, "Ethical Complexities of Conducting Research in Developing Countries" (1997) 337 *New Eng. J. Med.* 1003; Marcia Angell, "The Ethics of Clinical Research in the Third World" (1997) *N. Engl. J. Med.* 847; Marcia Angell, "Investigators' Responsibilities for Human Subjects in Developing Countries" (2000) 342 *New Eng. J. Med.* 967; George J. Annas & Michael A. Grodin, "Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa" (1998) 88 *American Journal of Public Health* 560; Carol Levine, "Placebos and HIV: Lessons Learned" (1998) 28 *Hastings Center Report* 43; Robert A. Crouch & John D. Arras, "AZT Trials and Tribulations" (1998) 28 *Hastings Center Report* 26.

3. See generally Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004).

4. Several questions arise in this respect. For instance, what is the level of awareness within developing countries of the need for ensuring that clinical research is conducted in accordance with international ethical standards? Have adequate steps been taken to ensure that international standards and guidelines are met? How may legislation and regulations aid the maintenance of such standards within developing countries? These questions are compelling in light of the gaps in the regulation of research involving humans in some developing countries. For instance, studies have noted the absence of ethics review committees in some developing countries. See Cheryl Cox Macpherson, "Ethics Committees Research Ethics: Beyond the Guidelines" (2001) 1 *Developing World Bioethics* 57. Many such countries also lack the sophisticated regulatory infrastructure required to evaluate and monitor clinical trials. See U.S., Office of Inspector General, *The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects* (Washington, D.C.: Department of Health and Human Services, 2001), online: <[www.speedupfda.com/Globalization%20of%20Clin%20Trials,%20HHS,%20Sep%2001,%2059pgs.pdf](http://www.speedupfda.com/Globalization%20of%20Clin%20Trials,%20HHS,%20Sep%2001,%2059pgs.pdf)>.

5. A.A. Hyder *et al.*, "Ethical Review of Health Research: A Perspective from Developing Country Researchers" (2004) 30 *Journal of Medical Ethics* 68 at 71. The authors attribute this partly to more experience on the part of developed countries' institutional review boards and to developing countries' lack of set standards for comparison. See also Macpherson, *ibid.* at 57.

6. World Medical Association, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Edinburgh: Canary Publications, 2000).

7. Jolyon Ford & George Tomossy, "Clinical Trials in Developing Countries: the Plaintiff's Challenge," online: (2004) 1 *Law, Social Justice and Global Development* 8 at para. 4 <[http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1](http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1)>.

8. Uganda, National Consensus Conference on Bioethics and Health Research in Uganda, *Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda* (Kampala: National Consensus Conference on Bioethics and Health Research in Uganda, 1997). See Sana Loue & David Okello, "Research Bioethics in the Ugandan Context II: Procedural and Substantive Reform" (2002) 28 *J. L. Med. & Ethics* 165.

9. S. Afr., Department of Health, *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (Pretoria: Department of Health, 2000); see also the *Constitution of the Republic of South Africa 1996*, No. 108 of 1996, s. 12(2)(c), which makes informed consent in research a constitutional requirement, and the *National Health Act 2003*, No. 61 of 2003, which establishes the National Health Research Ethics Council.

10. Kenya, National Council for Science and Technology, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* (Nairobi: National Council for Science and Technology, 2004); Kenya, Ministry of Health, *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (Nairobi: Ministry of Health, 2005); *Science and Technology Act 2001*.

11. Malawi, National Research Council of Malawi, *Procedures and Guidelines for the Conduct of Research in Malawi* (Lilongwe: National Research Council of Malawi, 2002).

12. Office of the Inspector General, *supra* note 4 at 6, where a sixteen-fold increase in foreign research conducted for the approval of drugs in the United States is noted.

13. See SOMO, *SOMO briefing paper on ethics in clinical trials #1: Examples of unethical trials* (Amsterdam: SOMO, 2006), online: <[www.wemos.nl/Documents/clinical\\_%20trials\\_%20report.pdf](http://www.wemos.nl/Documents/clinical_%20trials_%20report.pdf)>.

14. World Health Organization, "The World Health Report 2000 - Health Systems: Improving Performance" (Geneva: World Health Organization, 2000), online: <<http://www.who.int/whr/2000/en/index.html>>. See Samuel Oyandogha, "Minister Ranks Nigeria's Health Sector Among World's Poorest" *Vanguard* (16 December 2003).

15. Olajide O. Ajayi, "Health Research in Nigeria," online: Oxford Research Forum <<http://www.oxfordresearchforum.i12.com/editorials/nigeria.htm>>.

16. See the Nigerian Institute of Medical Research, online: <<http://www.nimr-ng.org/>>, which contains a number of publications by Nigerians which indicate that clinical trials are conducted in that country. Such publications also appear in the database of PubMed and in international journals. As some Nigerian surgeons have pointed out, "unavailability of



modern technology need not make impossible appropriate and relevant research that is subject to excellent study design, proper controls, and scientifically valid interpretations.” Olajide Olaolu Ajayi & Clement Adebayo Ademowo, “Surgery in Nigeria” (1999) 134 Archives of Surgery 206, online: <<http://archsurg.ama-assn.org/cgi/reprint/134/2/206.pdf>>. See Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 1999) at 21-23, describing the substantial difference in the levels of research between developed and developing countries.

17. Temidayo O. Ogundiran, “Enhancing the African bioethics initiative,” online: (2004) 4:21 BMC Medical Education < <http://www.biomedcentral.com/1472-6920/4/21>>.

18. Ajayi, *supra* note 15.

19. Established by the Federal Government by the *Research Institute (Establishment etc) Order 1977*, pursuant to the *National Science and Technology Development Agency Decree* (No 5) of 1977, it succeeded the Medical Research Council of Nigeria created in 1972. The *National Science and Technology Development Agency Decree* repealed the *Medical Research Council Decree of 1972*.

20. See Ogundiran, *supra* note 17. See the Nigerian Institute of Medical Research, *supra* note 16. Among the studies funded by external sources are the NIH-sponsored studies of the social, environmental and genetic determinants of hypertension in African populations, studies in breast cancer genetics, and studies in the genetic and environmental determinants of diabetes type 2. Patricia Marshall, “The Relevance of Culture and Informed Consent in U.S-Funded International Health Research” in National Bioethics Advisory Commission, ed., *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, vol. 2 (Bethesda, Md.: National Bioethics Advisory Commission, 2001) at C-11. Until recently, when the controversial trials were stopped, Family Health International, a not-for-profit public health organization, was conducting clinical trials of Tenofovir, a drug for the prevention of HIV infection, among sex workers in Nigeria. Jon Cohen, “AIDS Clinical Trials: More Woes for Novel HIV Prevention Approach” *Science* 307:5716 (18 March 2005) 1708, online: <<http://www.sciencemag.org/cgi/content/full/307/5716/1708a?ijkey=Ng2Lg1Vjg351w&keytype=ref&siteid=sci>>. The trials had previously been stopped in Cameroon and Cambodia in 2004 for ethical reasons. The organization stopped the Nigerian trials ostensibly for technical reasons. See also Jerome A. Singh & Edward J. Mills, “The Abandoned Trials of Pre-Exposure Prophylaxis for HIV: What Went Wrong?” (2005) 2 PLoS Medicine e234, online: <<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020234>>.

21. In this regard, Ogundiran has noted that:

Collaborative research with colleagues from the developed countries is often externally funded. It includes hospital and community-based trials and mostly involves experimenting with drugs or vaccines. Of particular ethical concern in collaborative research is the fact that external sponsors may differ in their motives for conducting research and there may be limited applicability of research benefits to the country or local community. Moreover, the clinician/researcher and/or institutions are themselves vulnerable to funding pressures.

Ogundiran, *ibid.* at para. 7.

22. See the *Constitution of the Federal Republic of Nigeria 1999*, online: <<http://www.nigeria-law.org/ConstitutionOfTheFederalRepublicOfNigeria.htm>>.

23. *Ibid.* Second Sch., Part II, s. 21.

24. *Ibid.* Second Sch., Part I, s. 26.

25. *Ibid.* Second Sch., Part II, s. 22. The Federal Government has created the Ministry of Science and Technology, which oversees research in Nigeria.

26. Jacqui Wise, “Pfizer accused of testing new drug without ethical approval” (2001) 322 BMJ 194, online: <<http://www.bmj.com/cgi/content/full/bmj%3b322/7280/194>>.

27. See Remigius N. Nwabueze, “Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues” (2003-2004) 14 Ind. Int’l & Comp. L. Rev. 87 at 103.

28. See Marshall, *supra* note 20 at C-11-C-12.

29. Many communities where there may be certain endemic diseases that may be the subject of research have only small hospitals without any ethics review committees to oversee or give approval to research protocols. In a personal communication to the author, the former Chief Medical Director of the University of Nigeria Teaching Hospital in Enugu, Professor Azubuike, expressed doubts as to whether any state hospitals have ethics review committees.

30. *National Agency for Food and Drug Administration and Control Act 1993*, No. 15 of 1993, s. 1 [*NAFDAC Act*]). As mentioned in subsection 2.1 above, the National Assembly (which is the legislative arm of the federal government) has exclusive powers to make laws in regard to food.

31. *Ibid.* s. 5.

32. *Ibid.* s. 29.

33. National Agency for Food and Drug Administration and Control, *Clinical Trials of Drugs in Nigeria: Guidelines, Procedures and Protocols*, online: NAFDAC <[www.nafdac.org](http://www.nafdac.org)> [NAFDAC Guidelines].

34. *Ibid.* at Introduction. This would therefore mean that a drug which is not produced for marketing in Nigeria need not follow the guidelines for clinical trials prescribed by NAFDAC. This is consistent with the functions of NAFDAC, which are principally geared towards protecting

the safety of drugs consumed by people in Nigeria. But it may also leave room for clinical trials for drugs which are not to be marketed in Nigeria. Given that many drugs tested in developing countries like Nigeria by developed country researchers (particularly multinational pharmaceutical companies) are expensive, and may not be tested with the object of sale or use in such countries, this represents a serious danger. The threat is that Nigerians might participate in, but not enjoy the corresponding benefits of, clinical trials. The Pfizer incident, in which the drug tested in the trial could not be used in Nigeria as a result of its non-affordability, presents a good illustration of such a situation. The issue of allowing trials to take place in regard to drugs produced for the foreign market is conceivably addressed by the *Drugs and Related Products (Registration, etc.) Decree 1993*, which provides that clinical trials for the importation, manufacture and supply of a drug sample or product can be undertaken only after a permit has been granted by NAFDAC and a valid clinical trial certificate has been issued. See the *Drugs and Related Products (Registration, etc.) Decree 1993*, No. 19 of 1993, ss. 1(2), 5.

35. NAFDAC Guidelines, *ibid.* at Art. 1.1.

36. *Ibid.* at Art. 1.6.

37. *Ibid.* at Art. 1.8. Comprehensive information is required to be given to subjects, their relatives and, where necessary, their legal representatives. See *ibid.* at Art. 1.9.

38. *Ibid.* at Art. 6.3.

39. See e.g. Annas; Lurie & Wolfe; Varmus & Satcher; and Angell, "The Ethics," *supra* note 2; see also Paul M. McNeill, "Should research ethics change at the border?" (1998) 169 *Medical Journal of Australia* 509; Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, "Fair Benefits for Research in Developing Countries" *Science* 298:5601 (13 December 2002) 2133; and Leonard H. Glantz *et. al.*, "Research in Developing Countries: Taking Benefits Seriously" (1998) 28 *Hastings Center Report* 38.

40. National Agency for Food and Drugs Administration Act as amended, *Clinical Trials Regulations, (2003)* online: <http://nafdacnigeria.net/downloads/DrugProducts/NEWCLINICALTRIALREGULATIONS>

41. *Ibid.* s. 1 (3).

42. Personal communication by Professor Azubuikwe, former Chief Medical Director of the University of Nigeria Teaching Hospital, Enugu, August, 2005. See also Marshall, *supra* note 20 at C-11. There were ethics review committees in different federal hospitals in Nigeria and in major research centres like the NIMR, which conducts clinical research in Nigeria. The major teaching hospitals, including those situated at the universities in Enugu, Lagos and Ibadan—in which most externally sponsored research takes place—have ethics review committees which review research protocols. However, smaller hospitals may not have ethics review committees.

43. Khabir Ahmad, "Developing Countries Need Effective Ethics Review Committees" (2003) 362 *Lancet* 627, online: <http://pdf.thelancet.com/pdfdownload?uid=llan.362.9384.news.26957.1&x=x.pdf>.

44. Ogundiran, *supra* note 17.

45. See Marshall, *supra* note 20 at C-11-12.

46. Nwabueze, *supra* note 27 at 103.

47. *Ibid.* at 110.

48. WHO, "Cerebral meningitis in Nigeria-update," online: World Health Organization <http://www.who.int/disease-outbreak-news/n1996/mar/n7mar1996b.html>. Prior to the meningitis outbreak, there were epidemic outbreaks of measles and cholera. All the victims of these diseases were taken to the Kano Infectious Diseases Hospital for treatment, where local doctors and doctors from Medecins Sans Frontiers treated them. About 15,000 people are alleged to have died from these epidemic outbreaks. The Kano Infectious Diseases Hospital was reportedly a poor, dirty hospital with few beds, poor power supply, and no clean water. The hospital received up to 120 patients everyday for the diseases at the time. Joe Stephens, "The Body Hunters (Part 1): As Drug Testing Spreads, Lives Hang in the Balance" *The Washington Post* (17 December 2000) A01, online: <http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&contentId=A11939-2000Dec15&notFound=true>. See Khabir Ahmad, "Drug company sued over research trial in Nigeria" (2001) 358 *Lancet* 815. "Nigerians Sue Pfizer Over Test Deaths" *BBC News* (30 August 2001), online: <http://news.bbc.co.uk/1/hi/business/1517171.stm>. *The Washington Post* put it at 15, 800.

49. Stephens, *ibid.*

50. Pfizer's main reason for conducting the clinical trials in Kano was to obtain approval from the United States FDA for use in the United States with a large clinical trial. Later, when charges of unethical conduct were made, Pfizer also alleged that another major reason for conducting the trials was to provide humanitarian services to the infected victims who were obviously in need of medical assistance at the time. *Ibid.* See also Nwabueze, *supra* note 27 at 98.

51. One hundred of the children were thus put on the Trovan, while another 100 were put on the Ceftriaxone. Stephens, *ibid.*

52. This was a series of six articles containing stories on clinical trials in developing countries. *Ibid.*

53. *Ibid.* See also Sarah Bosely, "New Drug 'Illegally Tested on Children:' Pfizer Accused of Irregularities During Clinical Trials in Nigeria" *The Guardian* (17 January 2001) 19.

54. As was alleged, many of the affected children were "rural people with no address." Stephens, *ibid.*

55. The parents of the children involved in the trials brought action in the Federal High Court in Nigeria, alleging lack of informed consent and seeking compensation from Pfizer.

This case was dismissed in 2002. *Zango v. Pfizer International, Inc.*, Case No. FHC/K/CS/204/2001. In August, 2001, while the case filed in Nigeria was pending, another suit was filed by thirty families in a District Court in the United States, seeking punitive damages against Pfizer under the United States *Alien Tort Claims Act* and alleging that Pfizer had violated the law of nations in its alleged non-conformity with international ethical standards for research. The suit was later dismissed by the District Court on the grounds of *non forum conveniens*. The plaintiffs appealed. The suit was remanded to the District Court by the Court of Appeals in October, 2003. This suit was also dismissed (in August, 2005) on similar grounds, with the court stating that Nigeria was the proper forum for action. *Abdullahi v. Pfizer, Inc.*, 2002 WL 31082956 (S.D.N.Y.); *Abdullahi v. Pfizer, Inc.*, 2003 WL 22317923 (C.A. 2 (N.Y.)); *Abdullahi v. Pfizer, Inc.*, 2005 WL 1870811 (S.D.N.Y.). The court found that, despite acknowledged problems of corruption and bias, Nigerian law recognizes medical malpractice, negligence and personal injury claims, and Nigerian courts thus afforded an adequate forum for trying the matter. It was noted, moreover, that language used in the instruments relied on by the plaintiffs was merely "aspirational" language which could not be characterized as creating well-defined and universally accepted legal obligations under international law so as to sustain an action under the *Alien Tort Claims Act*. The *Alien Tort Claims Act*, U.S.C. § 1350 empowers the United States District Court to decide on any civilian action brought by a non-citizen on allegations of violation of the law of nations or a treaty of the United States and was famously applied in the case of *Filartiga v. Pen-Irala*, 630 F.2d 876 (2d Cir. 1980). See a history of the *Act* in Marisa Anne Pagnattaro, "Enforcing International Standards: The Potential of the Alien Torts Claim Act" (2004) 37 Vand. J. Transnat'l L. 203 at 211-14. 56. Barnaby Phillips, "Nigeria's Drug Trial Fears" *BBC News* (14 March 2001, online: BBC News <<http://news.bbc.co.uk/1/hi/world/africa/1220032.stm>>. Pfizer also stated, in its defence against allegations of exploitation of extremely vulnerable patients, that it conducted the trials in Nigeria because the drug was produced for a disease particularly found there and the drug would prove useful in treating the disease. Pfizer, "Pfizer's Defence," online: Pfizer U.K. <<http://www.pfizer.co.uk/template4.asp?pageid=198>>. See also Pfizer, "Clinical Trial of Trovan (Trovafoxacin)," online: Pfizer U.K. <<http://www.pfizer.co.uk/template4.asp?pageid=196>>.

57. See Ben Ukwuoma, "Pfizer Official, Others Summoned to Kano over Drug" *The Guardian* (12 January 2001). There are several interesting aspects to the Pfizer incident. The first is the alleged participation of the Nigerian government.

58. See also Phillips, *supra* note 56; Bosely, *supra* note 53.

59. *Supra* note 57.

60. It is unclear if any other approvals were sought or obtained, for instance whether or not the FDA had granted approval for the trial. The drug was approved by the FDA in 1997, a year after the trials in Nigeria. One of the grounds of the approval was the beneficial impact of the drug as manifested in the clinical trials conducted in Kano. Later, in 1999, the FDA issued a public health advisory limiting the use of the drug to certain categories of patients and restricting its use because it was shown to cause fatal liver damage. The EU also withdrew the drug from the market in 1999 because of liver problems. The drug was not registered or marketed in Nigeria since it was too expensive and therefore not affordable. See Shah, *supra* note 1 at 33. See also Center for Drug Evaluation and Research, "Public Health Advisory: Food and Drug Administration: 09 June 1999: Trovan (Trovafoxacin/Alatrofoxacin Mesylate)," online: FDA <<http://www.fda.gov/cder/news/trovan/>>; Tinker Ready, "Pfizer in 'unethical' trial suit" (2001) 7 Nature Medicine 1077, online: <<http://www.nature.com/cgi-taf/DynaPage.taf?file=/nm/journal/v7/n10/full/nm1001-1077c.html&filetype=pdf>>; *ibid*.

61. Joe Stephens, "Panel Faults Pfizer in '96 Clinical Trial In Nigeria: Unapproved Drug Tested on Children" *The Washington Post* (7 May 2006) A01, online: <[http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338_pf.html)>.

62. *Ibid*.

63. Joe Stephens, "Pfizer Faces Criminal Charges in Nigeria" *The Washington Post* (30 May 2007) A10, online: *The Washington Post* <<http://www.washingtonpost.com/wp-dyn/content/article/2007/05/29/AR2007052902107.html>>. See also BBC News, "Nigeria sues drugs giant Pfizer" *BBC News* (5 June 2007), online: BBC News <<http://news.bbc.co.uk/2/hi/africa/6719141.stm>>.

64. See generally Nwabueze, *supra* note 27; Shah, *supra* note 1; and Carr, *supra* note 1. See also Sylvester C. Chima, "Regulation of Biomedical Research in Africa" (2006) 332 *BMJ* 884.

65. National Health Research Ethics Committee, "Home," online: <<http://www.nhrec.net/nhrec/>>; National Health Research Ethics Committee, *National Code for Health Research Ethics* (Garki-Abuja: National Health Research Ethics Committee, 2006), online: <[www.nhrec.net/National\\_Code\\_for\\_Health\\_Research\\_Ethics\\_v2.0.pdf](http://www.nhrec.net/National_Code_for_Health_Research_Ethics_v2.0.pdf)> [*Code*].

66. *Code, ibid.* s. B.

67. It is not clear why the National Health Bill, 2004 has not been passed. Given the current political climate in Nigeria, with elections taking place in 2007, it would appear that this may take some more time.

68. See *Code, supra* note 65 s. C (a). See also National Health Research Ethics Committee, "About NHREC," online: <<http://www.nhrec.net/nhrec/about.html>>.

69. *Code, ibid.* s. C.  
 70. *Ibid.* s. O.  
 71. *Ibid.* s. L.  
 72. *Ibid.* s. N.  
 73. National Health Research Committee, *supra* note 68.  
 74. *Code, supra* note 65 s. C (a).  
 75. *Ibid.*  
 76. National Health Research Ethics Committee, *supra* note 68.  
 77. *Code, supra* note 65 s. C (b).  
 78. *Ibid.* s. C (f).  
 79. *Ibid.* In the absence of an institution that has an ethics review committee in the same state or geopolitical zone, an institution is required to refer to the national ethics review committee for guidance.  
 80. *Ibid.* s. C (n).  
 81. *Ibid.* s. E (3)(b).  
 82. *Ibid.* s. N (f).  
 83. See Ford & Tomossy, *supra* note 7.  
 84. *Code, supra* note 65 ss. N (a)-(f).  
 85. *Ibid.* s. F.  
 86. *Ibid.* s. F (e).  
 87. *Ibid.* s. F (f).  
 88. See Ruth Macklin, "Informed Consent for Research: International Perspectives" (2000) 55 *Journal of the American Medical Women's Association* 290, online: <<http://www.amwa-doc.org/index.cfm?objectid=104E062E-D567-0B25-568B8E306A028F22>>.  
 89. For research to be ethical, the interest of participants, researchers, sponsors and communities must be protected. This will ensure that the research has lasting impact, transfers technology where appropriate, contributes to capacity building and demonstrates respect for socio-cultural and other differences. Risks, benefits and responsibilities of research must be shared during the development, planning, conduct, dissemination of results. Intellectual property, indigenous knowledge and contributions of all parties must be taken into consideration, adequately protected and compensated particularly where research leads to tangible or intangible benefits. Satisfactory parameter(s) that shall determine sharing of commercial and other benefits should be clearly articulated and where indicated, benefit sharing agreements, materials transfer agreements, patent rights, intellectual property and royalties' distribution agreements should be signed before initiation of research.  
*Code, supra* note 65 s. F (i).  
 90. *Supra* note 2.  
 91. McNeill, *supra* note 39.  
 92. *Code, supra* note 65 s. F (j).  
 93. *Supra* note 2; *supra* note 39.  
 94. A new initiative, the West African Bioethics Training Program, has been commenced recently to train members of ethics review committees and medical students in bioethics generally and ethics relating to human research. See West

African Bioethics, "Home," online: West African Bioethics <[http://www.westafricanbioethics.net/wabcms/index.php?option=com\\_frontpage&Itemid=1](http://www.westafricanbioethics.net/wabcms/index.php?option=com_frontpage&Itemid=1)>.



