

Letters to the Editor

Dear Sir

Comment on Ogundele S., Falade C. O. Good Clinical Practice in Nigeria – The way forward. *Annals of Ibadan Postgraduate Medicine* 2006; 4 (1) 28 – 32.

Ogundele and Falade wrote to suggest the way forward for Good Clinical Practice in Nigeria, however the essay contained a lot of factual and other errors.

1. The origin of ethical principles in clinical trials predates the 1964 Helsinki Declaration (p.28, paragraph 2).
2. The Code of Federal Regulations binds research funded by U.S. Federal government only (p28, paragraph 3)
3. The Pfizer Trial in Kano was not conducted by Médecin sans frontière (p. 28, paragraph 4)
4. The company says that oral consent was taken but this was not documented (p28, paragraph 4).
5. The research that led to the development of the Nuremberg Code was not conducted in 1946 – 1949 (page 29, paragraph 3)

In Nigeria, the Federal Government has revitalized the ethical oversight of health research by strengthening and re-constituting the National Health Research Ethics Committee (NHREC – <http://www.nhrec.net>) which was first set up in the 1980s. The NHREC has released a Code for Health Research Ethics in Nigeria which supersedes all foreign codes and is the legal basis for ethical conduct of health research in Nigeria. The code is available for download on the website of the Committee. This code incorporates ICH-GCP guidelines and is the most modern code for health research ethics in the world.

In addition, the NHREC provides opportunities for training in health research ethics through a technical agreement with the West African Bioethics Training Program (WAB). Training

programs on health research ethics including GCP is available at the website of the WAB at <http://www.westafricanbioethics.net> and the WAB offers both short and long term training in health research ethics and other aspects of modern international research ethics.

The authors of the article conclude that Nigeria can start now to incorporate these guidelines. I am happy to report to them and other interested biomedical researchers and ethicists that Nigeria has started.

Regards,

Professor Clement Adebamowo B.M., Ch.B. Hons., FWACS, FACS, DSc.

Professor of Surgery and Chairman National Health Research Ethics Committee

Author's Reply:

Good Clinical Practice in Nigeria – The way forward. *Annals of Ibadan Postgraduate Medicine* 2006; 4 (1) 28 – 32.

I am pleased to acknowledge the rejoinder of Prof. Adebamowo to our article titled- Good clinical practice: the way forward, which was recently published in your journal. It is reassuring to know from his rejoinder about the existence and the activities of the National Health Research Ethics Committee (NHREC). The new national ethics code of conduct which he also mentioned is a good start for the country in its quest in ensuring that researches on human subjects are conducted in accordance to good clinical practices.

Regarding the comments on our article, I agree that there are in deed some errors in the article and we regret this. I would however submit that these errors are mainly those of syntax and editing and not mainly factual as suggested.

Our responses are as follows:

1. We did not suggest in the article that ethical

principles in biomedical research have their origin in the Helsinki declaration; the historical background to the development of ethics as contained in the article is a testament to this fact. Our submission is that the Ethical principles contained in many of the existing ethics guidelines today are based on the principles enshrined in the Helsinki's declaration of 1964. This fact may be arguable though and we will just want to leave it as that.

2. We stand by the submission that the Code of Federal Regulations (CFR) is binding on researches other than those funded through the US federal government funds. The CFR is an encompassing code which covers different categories of researches.
3. The official documents from the proceeds of the Federal Government probe into the Pfizer drug trial in Kano is not in the public domain. The Kano trial was cited to point out the fact that the study was conducted in

an unethical manner. This fact can not be disputed. The Pfizer submission that it got verbal consent from participant is half hearted and this is not good enough. The source which was quoted in our article stated that 'Doctors without border' administer the drugs on behalf of Pfizer and we are not able to confirm this fact.

4. We agree that the research that led to the enactment of the Nuremberg code were not conducted between 1946-49. It is actually the trial of the German war criminals who conducted unethical studies that took place between October 1946 to April 1949.

Thank you for giving us the opportunity to response to the rejoinder on our article.

Yours sincerely,

Dr. S.Ogundele FMCP