



Saturday, August 09, 2014

**Statement on the use of innovative or non-validated medical treatment in Nigeria**

In light of the epidemic of Ebola virus infection that has spread to Nigeria and the availability of several experimental treatments that may reduce morbidity and mortality of the condition, the Nigerian National Health Research Ethics Committee, the body mandated to regulate the practice of research ethics in Nigeria and advise government on matters relating to ethical conduct of research wishes to draw the attention of all concerned stakeholders to the relevant section of the Nigerian National Code for Health Research that deals with situations similar to what we are now encountering with the Ebola Virus Disease (EVD).

In Section B, subsection (f), the code states **“Innovative or non-validated medical treatment – treatment that is designed solely for the benefit of the patient but in which the ability of the treatment to provide the desired result is to some degree not proven. Such activities are exempt while recommending that they should be subjected to research in order to generate information about their efficacy as soon as possible”**. The committee considers the use of all such agents such as zMapp and others for treatment of Ebola Virus Disease (EVD). as innovative or non-validated treatments according to established norms of drugs and treatment development and clinical trials which are designed solely for the benefit of the patient. **The committee therefore wishes to state unequivocally that it is ethical to use these treatments in the current situation without first submitting an application to National, State or Institutional Health Research Ethics Committee for prior review and approval.** In addition, the Committee **waives the current requirement that international shipment of any biological samples out of Nigeria should be preceded by the establishment of a Materials Transfer Agreement (MTA), a copy of which must be lodged with the Committee. This waiver is to promote rapid international response to this global emergency.**

Furthermore, the Nigerian National Code for Health Research Ethics emphasizes that all innovative and non-validated treatments should be carefully and adequately documented so that they can form the basis for Clinical Trials of the efficacy and side effects of such treatment as soon as possible and according to established scientific principles. The National for Health Research



## National Health Research Ethics Committee of Nigeria, Federal Ministry of Health.

Promoting Highest Ethical and Scientific Standard for Health Research in Nigeria

Ethics Committee enjoins all agencies, development partners and research scientists to follow this guideline for the rapid resolution of the current emergency, contribution to preparedness in case of future occurrences and contribution to scientific knowledge. It must be noted that all Phase O and Phase I Clinical Trials that may subsequently be designed for treatment of this infection can be approved ONLY by the National Health Research Ethics Committee as the it has not approved any institutional ethics committee to provide ethical oversight of these category of research. Additional information will be provided on the website of the Committee at <http://nhrec.net/nhrec/> where copies of the National Code for Health Research Ethics can also be downloaded.

Signed

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