CORONAVIRUS CLINICAL RESEARCH SUBJECTS IN NIGERIA: AN ETHICAL FRAMEWORK

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Abstract

Coronavirus made its way into our world in 2019. As the virus began to spread,the World Health Organization, WHO judged it to be a pandemic. Pandemic because it had spread to over 200 countries in a short space of time, leaving in its wake scores of dead persons. A virus is deadly by nature. The only option is to develop a vaccine that will help stem the spread of the deadly virus. Development of vaccine takes a whole lot of time. Besides, efficacy of the vaccine depends on a robust clinical trial enabling the investigator to have a wide range of volunteers as well as patients to participate in the clinical trial. Two things are of paramount value: keeping proper ethical protocols and good data. Good record keeping will be helpful in tracking the progress made in the development of the vaccine, and also noting the reactions of people during the clinical trials. Abuse of the research participants should be minimized as much as possible. There is need for the Institutional Review Board (IRB) to ensure that the ethical principlesare followed; and that research participants-patients and volunteers-are properly informed and so give their informed consent.

Keywords: coronavirus, pandemic, vaccine, clinical trials, research participants, ethical, informed consent

Introduction

Coronavirus, also known as Covid-19 has been ravaging and will continue to ravage the world. Wuhan Province in China was its entry point in the world. At the time it started, like a little insignificant illness, the good Samaritan Chinese physician

cried out for help. He was literally ignored by the Chinese government for reasons undisclosed to the public. Not too long, this medical practitioner, more or less a whistle blower, died having contracted the virus. Looking at his action, one can say that he acted in consonance with the Hippocratic oath he took while in medical school. The Hippocratic oath is attributed to Hippocrates of Cos (460B.C). He seemed to have been attributed with founding the empirically based western medicine. So much is in the credit of this man by way of medical text.[1]Oath is an essential part of medicine that it continues to be part of the ceremony of medical as well as nursing students.[2] The medical texts attest to the nature of the practice of medicine in Greece at the time under discussion. Greece, it must be stated, was known for some of the great minds in philosophy like: Socrates, Plato, Aristotle. Understanding the gradual, but progressive development of philosophy, helps to provide the right frame of mind and disposition to medicine. Greece seems to have been the birth place for scientific medicine. It is not farfetched from the oath as part of the text reads: "…to regard him who has taught me this *techné…"*[3]*Technémeans* 'art and science'. The point to take here is that medicine is an organized body of knowledge specifically directed for the human good. The highlight of this is basically the obligation such term places on the physician. There has to be a correspondence in his moral and professional life.[4] Here it is expected that the physician's life be integral. Implicit is the physician-patient relationship that should be nurtured and safe guarded by the physician.[5] In this way the ground is prepared for trust relationship needed for effective clinical practice and research trials.

The goal of this article is to sensitize the Nigerian populace towards understanding their rights and privileges, in matters regarding clinical trials, in pursuance of manufacturing medication for the treatment of covid-19. For this reason, the author shall simply address in the article the ethical framework for biomedical research. The article will take the following structure:

a. History of clinical research
b. Some ethical practices that enhance respect and fairness in the use of human subjects for research
c. Poverty index of Nigeria
d. Poverty and social inequality in Nigeria
e. Recommendations
f. Conclusion

1. History of Clinical Research

It is quite obvious that the present challenging moment is harassing research biologists, epidemiologists, virologists, research pharmacists to list just a few. Experts in these various fields are looking for a way forward. Laboratories in the world are collecting specimens and titrating chemicals, so that they produce substances that can be used for research. After this has been accomplished, their greatest and most challenging task becomes how, where and when to assemble the human research subjects. This has to be done in a moral, transparent, and accountable manner given the fact that in the past abuses have crept in. History as we know would often repeat itself. Record shows that in the past some horrible things have been done to research participants.

The Nuremberg Code (9th December,1946-20th August,1947) for instance did not only address clinical research issues, rather it also looked into "war crimes, crimes against humanity, and membership in a criminal organization, the S.S."[6] This has been adjudged the most comprehensive, authoritative code "informing all ethical codes on research with humans."[7]

The Helsinki Declaration in 1964 by World Medical Association[8] (WMA) was aimed at monitoring medical practices ensuring that international standards are met with regard to human subjects.[9] The document produced at the Helsinki declaration continue to be updated. The most recent known update was in 2004. Other guidelines include Belmont report (1979); while there are some countries and regional focused guidelines like 45 CFR 46 (1991) specific to the United States, National Health

Council (1996) Brazil, Council of Europe (1997, revised in 2005) for Europe as the titles states, United Kingdom rolled out Medical Research Council Guidelines in 1998, Uganda produced a Guideline for Science and Technology research in 1998, Canada rolled out Tri-Council Working Group for human research in 1998 and has been reviewed and has the most recent cope in 2005. Other countries that deserve a mention include Australia (1999), New Delhi (2000), Tanzania (2001), and South Africa (1997 with a review in 2002). All these are useful guidelines protecting the human person as research subject.

In the face of this pandemic and given the urgent need for a cure either medication[10] or vaccine, experimental research is a *sine qua non* (a necessary pathway). Here the human person must be used if the results are to be helpful in curbing the current health issue. If any lesson is to be learnt from the past, it is the need to reduce the level of abuse that will creep in as the researches are carried out. The author seriously advocates that the World Medical Association (WMA) in collaboration with World Health Organization (WHO) overseen by United Nations Organization (UNO) draw up specific ethical requirements for the research using the human person as subjects. This is not far from the collaborative work of WHO and Council of International Organizations of Medical Sciences (CIOMS) as they produced important guidelines on the use of human subjects for clinical research in the developing countries.[11]The goal is to standardize practice by ensuring that all players are held by the same standard of practice. It is not sufficient to have such wonderful guidelines without a monitoring body. To ensure compliance, there has to be a monitoring body in each country to work with WMA, WHO and UNO. There has to be constant and transparent reporting system. In the same vein, there is need to have a provision for a whistle blower, so that any nation disregarding the rules of the game would have to be called to order. An independent body[12] may have to be set up to look into the cases of abuses. The reason is this, history has shown that there are always people wanting to circumvent the rules. The times are hard and we need to have

stringent norms. It is the only way to achieve the desired goal. Covid-19 is redefining the world. The world as we knew it in 2019 is no longer the same. There is need to have a level playing ground for all. By the way who is speaking a contrary word? Did the United States of America not pull out from funding the World Health Organization? This is a new world. Every nation has to be treated as equal, having equal voice at the decision making table. The days of ascribing the lower level to the developing nations, or even regard them as underdogs are over. This is part of the motivation for this article. There is no doubt in my mind that whenever a vaccine is discovered Nigeria will be attraction point of the western world. It is important therefore that the people are not left in their ignorance while being used as research subjects.

As has been previously mentioned, in the last 80 years or there about, human biomedical research has been suffused with myriad of guidance.[13] In spite of the guidance provided, human research subjects continue to be abused, exploited and denigrated. Each of the guidance provided simply addressed issues raised in a specific research.[14]On the whole, the guidance has to ensure that human rights are respected. To this end, there is the need to have an ethical framework on which human subjects are to be used as research subjects.[15]This will ensure that the researchers respect research principles while recognizing the common humanity they need to protect. Further, one expects such to curb conflict of interest on the part of the researcher so that distrust does not set in between the researcher and the subject. What are some of the fundamental principles that are necessary for a clinical research?

Some ethical practices that enhance respect and fairness in clinical research using the human person as subject

These are collaborative partnership, social value, scientific validity, fair participant selection, healthy risk-benefit ratio, independent review board, proper informed consent, and autonomy and respect of research participants. These are important for a healthy clinical research.

Collaborative partnership

If there has to be a successful research, one cannot cast into the dustbin collaborative partnership. By this principle, the researcher does not assume a superior role and position over the research subjects even though they shall be compensated. It is a win-win situation for both if all goes well at the end of the day. Besides, generally it would also be beneficial for the world at large since it is a common enemy that is fought by all. However, more particularly, it should benefit the community. Nigeria is a peculiar nation. There are lots of issues bordering on mistrust. The society is suspect of things going on with the government. As a matter of principle, government should not get close to such a project if they want it to succeed. It should freely be run by an independent local body but supervised. Further, attention would have to be focused on a check and balancing system for sustainability. Covid-19 is currently in most countries of the world. Any research that is to be carried out in Nigeria must consider a viable community consultation.[16]In this way, the people will feel honored and respected while the exercise lasts. It undeniably calls for a quick response in the production of medication or vaccine to arrest the pandemic.

Social value

Health has a social dimension as well as medicine. Results from such research is not private and personal. One basic question that will come to mind would be, who will benefit from this research? A vast majority would have to be persons who from that region. Say for instance, any research on the production of vaccine against covid-19 has to be done in such a manner that the beneficiaries will have to come from amongst the area the research participants/subjects live. Anything short of this would have been tantamount to exploitation. It goes back into society for its use in the attack of the disease. As has been seen, covid-19 is not restricted to one country or region. Rather, it goes to wherever place its victims move to. Describing it as a

mobile disease would not be out of place. A research seeking for measures to cure or heal the disease will not be out of place. How can adverse impact of conducting the research be minimized?

Scientific validity

Since the research done is for the sake of good health, steps taken to arrive at a given result should be systematically explained and documented. There should not be any form of mystery surrounding the process of this research. It has little to do with the Bible or the Quran or the traditional religion. Any such conversation brings doubt and uncertainty into the entire research mechanism. If the research subjects begin to doubt and suspect the researcher, that will be an appropriate moment to terminate such a research. Conversely if a research participant pulls out a card of doubt and uncertainty, he/she has to be eased out of the process. The reason is that trust is a *sine qua non* if the purpose of the research is to be met. Having dealt with the trust issue, the stages employed in arriving at a given result must be scientifically explainable. It is not about mystery or magic or secrecy. Scientific research cannot be a secret. It is a *techné* (Art and Science)[17] which will lead to knowledge and discovery.[18] Discovery signals the success of the research but at the same time opens the pathway for even deeper research. Nigeria is a country where oversight may not be quite present. It is essential to mention here that profound care should be taken to see that what is performed conforms with known scientific methods universally acceptable and approved. Any trado-medicine that is used in the process of the research as treatment deserve thorough explanation. Dosage, side effects must be clearly stated.

Fair participant selection

This forms the fulcrum of the research because it predisposes the research towards failure or success. Selection of the persons to serve as research subjects is often not quite easy. Here the researcher has to have clarity of mind in terms of what he hopes

to achieve. A number of things come into play here. Determining the target population is quite important. Covid-19 has been identified as having a greater toll on person with underlying medical condition. The researcher may need to assemble a certain percentage of such persons and see how they respond to such materials and from there could work out the best way to manage the health of such persons in a medical facility. No group should be neglected or relegated to the background. Every group and different age brackets are important if the research is to arrive at a robust medical response. Hence, the research is one and the same time valuable to people across the continent. This too has to be put into cognizance.

Health risk-benefit ratio

Researching with patients who have medical precondition leaves one with some concern. You do not want to have a clinical trial with persons whose level of risk is higher than the benefit. The risk must not outweigh the benefit. Consequently Beauchamp and Childress state quite clearly: "in submitting a research protocol involving human subjects to an institutional review board (IRB) for approval, an investigator is expected to array the risks to subjects and probable benefits to both subjects and society, and then to explain why the probable benefits outweigh the risks."[19] These are often arrived at by using judgments of experts who must have had experience in the field for a long time. All of this has to be based on a reliable data and not on guess work. Being a scientific work, a lot of data is important. This will mean good record keeping. Either electronically or through the filing system. Nigeria is one country that these may be difficult to get hold of. Electronic material is near impossible because the infrastructure is very much poorly developed. This is a country whose power supply is functioning at half capacity. She has not even ventured into developing wind and solar energies for its electricity power generation. The filing system stands the risk of going up in flames anytime those in charge decide to hide a few

facts. It is a common place in the country. Recently the office of the Accountant General of the Federation was engulfed by fire. It happened after the office was quizzed about her transparency in accounting for the numerous donations made by locals as well as foreigners in pursuance of assisting persons worse hit economically by the covid-19 pandemic. It was a shock to the nation. Since then some other offices have been gutted by fire. Research of this sort would require great records so that research can grow on a linear progression.

Independent Review Board

It is made up of experts whose job will be to progressively follow the progress made during the research. Nothing is out of its purview. Members of the board will have to sign a non-conflict of interest form. Such a body will help check malpractice in the cause of the research. An independent review board satisfies this concern and curiosity. Its importance cannot be overemphasized. It is one way to check fraud as well as charlatans. Already in a country (Nigeria) that the world does not believe to be transparent in her activities, this is one way to gain the trust and confidence of the international bodies who may examine such research group. As it is, foreign agencies may sponsor such research in Nigeria. If it so be that there are multinational companies demonstrating interest to run a research programme in quest of a vaccine, an independent review board (IRB) will create a lot of trust and confidence.

Proper Informed Consent

This is at the heart of medicine. It is made up of two essential components, first is information and second is the consent itself.[20] What does it mean to provide information to the research participant? What should get into the information? What are the subjects expected to be informed about? The information component is expected to deal with things like complete disclosure of what will take place; recommendation

of what the next plans are; and asking for a feedback to make sure there is a sufficient understanding of the earlier two items. Having had everything explained and understood, the research participant is expected to make decision based on what he has come to know.[21] The decision made bequeaths authority to the research professional in following the plan that is chosen by the research subject. It must be noted that some research may necessitate nondisclosure.[22] Nondisclosure might sometimes be beneficial to the research participants. This is especially expected in therapeutic use of placebos. It supports non-transparency in disclosure to research subjects, incomplete disclosure, and intentional deceit.[23] Nondisclosure posture of researchers is for a good reason. It may be difficult for researchers to conduct a successful research in such fields as epidemiology and virology if they need to obtain consent from research participants for access to their records.[24] A successful disclosure would necessarily require establishment of a robust informed consent procedure. An informed consent form must be signed. It is to be presented in the language that the research participants understand. If need be translation of a similar form in the language of the research participant has to be made available. This does not cancel out the need for an interpreter or an intermediary who may have to explain certain unclear terminologies. This is a necessary step because international ethical standards require it. The Nuremberg Code and the Helsinki Report already allude to this. It is a regular requirement at every patient-physician/care giver encounter. In this way the patient enters into a relationship with the physician and in this case with the researcher. Patient's autonomy is upheld and emphasized. It shows the fact that the patient is making a choice voluntarily.

Autonomy and respect of research participants

This is a way to uphold and restore human dignity in areas where it has been lost. It is important to keep in mind that the research subjects are to be treated as humans and not as

underdogs. The research carried out 50 plus years ago abused the autonomy of the individual. Some researchers without disclosure to their research subjects administered radioactive substances to unsuspecting patients. They justified their action by claiming that dying patients as well as condemned criminals suffer no harm or injury.[25] Such an understanding breached United Nations principle on respect for the equality of all human person. The quest for human autonomy has biblical support and foundation. Hence, the human subject cannot be treated as mere objects without recourse to his spiritual dimension.Spiritual dimension of the human person is the spring board for things like "anger, courage, appetite and sensation…."[26] These are affections of the soul. As a matter of fact, "all the affections of the soul involve a body-passion, gentleness, fear, pity, courage, joy, loving, and hating…."[27] It is abundantly clear that at this point we are dealing with a human person composed of body and soul. Ancient philosophers understood the fact of the composite nature of the human person.[28] This precisely gives the human person such autonomous power that makes everyone relate at a level of equality. In this way Martin Buber's concept of 'I-Thou' makes a lot of sense. Any relationship that is not founded on it becomes exploitative. Hence, the principle of autonomy safeguards and preserves the dignity of the human person.[29] Recognizing the force in each human person saves the world from undermining humanity. Unfortunately, this does not seem to be the case. Sometimes breach of this primary element in the human person symptomizes the world's bewilderment. Human interactions all over the world seemed to be plagued by some sort of misdemeanor. Disregard for autonomy represents a whole wide range of disproportionality in human behaviour. Human subjects who have submitted themselves as willing 'sacrificial lambs' deserve every respect. Indeed, they should be regarded as heroes of our time. Many more would be willing to submit themselves as research participants, if only the treatment meted out to former participants, could be termed wholesome. In other words, proper

ethical conduct shall improve the relationship between research participants and research scientists. The sad thing is that the social inequality and the quest to satisfy the basic need for man has undermined the efforts of individuals and organizations to uphold human autonomy and respect for the individual. The deplorable nature of things in Nigeria and the wide social gap makes human research subject a victim of abuse.

The poverty index of Nigeria

Human research subjects are often the last group in the chain of research which seeks to develop medicine or vaccine that will be used on humans. At the stage of the human trials, it means the research is coming to a concluding stage. Besides, it indicates that some glimmer of hope hangs somewhere. Caution seems to be the word that should be constantly at play once this stage is reached. The poverty index of the country makes it even more mandatory for caution to be used while at this stage of the research. From 2019 statistics, we find the following report as of May 2020. The statistics show that 40.1% of the total population[30] have been classified as poor.[31] This percentage if translated into the ratio has 4 out of every 10 Nigerians as having below per capita expenditure of ₦137,430.00 Naira per annum. This percentage amounts to 82.9 million Nigerians who are considered poor by national standards. The number could be much higher than this since researchers could not get data from some Northern states as a result of insurgency, banditry, kidnapping and it's like. Such a huge number of poor persons in a country like ours means that abuse can easily set in if the government does not set up a functional machinery to monitor activities of persons in different fields. More importantly, the past history of clinical research has indicted research scientists of exploitation and non-professional sharp practices. We should not allow the same repeat itself in this 21st century.

Poverty and Social Inequality in Nigeria

Though Nigeria is the 6th richest oil producing country in the world, and the 3rd in OPEC, unfortunately it is hard to feel the wealth. Compared to other oil producing countries in the world, Nigeria's poverty index is shocking and alarming. The present situation may not be unconnected with poor administrative procedures and the fact of corruption. Even though the Buhari APC-led government got to power by promising waging war against corruption. Many who believed in the campaign days of the government have now lost hope. There is little that the government can do to fight corruption. Most people doubt the capability and ability of the leadership to steer the nation out of corruption. It does appear as though corruption has become part of the national programme. Certainly, the problem of the nation has corruption as its biggest challenge. In a nation where social amenities provided don't get to those who need it the most, one cannot expect improvement in the life of the masses. This is the story of Nigeria. During the #EndSars protest, a lot of discoveries were made. Palliatives provided to cushion the biting effects of the pandemic were traced to private ware houses. It is sad to note that the gap between the rich and poor is so wide. One often hears the expression, it is either you are poor or rich in Nigeria. Middle class does not exist any longer. Any nation without the middle class cannot claim to be doing well economically. This is the sad story of Nigeria.

In a situation like this people are anxious to rake up money from which ever source, legitimate or illegitimate. Countries where the social inequality is reaching alarming rate, there is the fear of exploitation. The rich class will relate with the poor masses in an exploitative manner. Such a relationship places the poor masses at a huge disadvantage. Consequently, one may be right to suspect that scientific investigators may play foul during clinical trials especially with the human research subject. In the face of poverty and hunger humans can be abused. The financially disadvantaged person may yield himself/herself for use just for

pecuniary reasons. On the part of the research investigator, he/she may carry out his/her research amongst such a class of people without due process. Due process here refers to all the protocols that should be observed with a human research participant. These protocols were developed to avoid abuse of the human person. The Helsinki declaration in 1964 provides rich material on this. I have already discussed this at the early part of the paper. It is the dignity of the human person that would require serious care be taken in dealing with the human person in such a research programme. Covid-19 is a serious pandemic. Efforts should be made to arrest its further spread and the cause of death of many people. Developing more vaccines in addition to the ones in use at the moment should be encouraged. In this way, covid-19 variants would have been arrested since more robust research will yield vaccines that can contain the new variant.

RECOMMENDATIONS

This paper has pointed out a few things that should be in place while involving the human person in a scientific clinical trial. For reasons of clarity, I wish to tabulate a few of the things all parties involved (research scientist and human subject) should be aware of.

1. Research investigators must provide free and informed consent to the human subjects (participants). This has to be documented. The document may be presented also in a language[32] other than English. This will ensure free and informed consent on the part of the research participant. Component of true consent include voluntariness, disclosure of required information and determination of sound comprehension.
2. Ethics training for investigators should be mandatory. National Health Institute should have oversight of the activity of such investigators. IRB on its own part should coordinate the events since they give final approval to the application of the research investigator.
3. The research being performed must be beneficial to persons

other than the research subjects. It has to be beneficial to future patients, to the research scientists and the society in general.

4. Vulnerable patients are to be protected so that they are not exploited; while the IRB ensures that the appropriate population is selected for the research trials either randomization or blinding.
5. Research subjects should not be attracted into the clinical trials on pecuniary grounds.
6. The research investigator must declare 'No Conflict of Interest'.
7. Transparency should stand out all through the process.

CONCLUSION

The author of this article has been able to explain the ethics of clinical trials especially as it involves the human subject. Clinical research history has shown that abuses were quite rife/plentiful in the heyday of clinical research as the world of ethics was still in its infantile stages. Today, due to the ugly experiences, codes have been put together. Norms of behavior have been assembled as guide and check for all research scientists. The world of ethics will not tolerate disrespect of human life and dignity. All this has been highlighted in the article. It is to point out the central role the human person continues to play. Clinical research in this time of pandemic is a necessary instrument to curbing the spread of the virus. Developing necessary vaccines should be the moral obligation of all who have been entrusted with leadership. Most importantly during this time is the duty towards the weak and vulnerable. Research should not exploit such people. In fact, the goal of medicine overall is good health for all. Any meaningful research takes up that task and duty of ensuring that good health is provided through the use of adequate research means.

Endnotes

[1]The medical texts include titles like *Ancient Medicine, The Art, On the Sacred Disease*, and The Oath.

[2]Martin S. Pernick. "Bioethics and History" in. *The Cambridge World History of Medical Ethics*, sRobert B. Baker and Laurence B. Mccullough (Eds.). (New York: Cambridge University Press, 2009), p.22. Cf. also Steven H. Miles, The Hippocratic Oath and the Ethics of Medicine. (New York: Oxford University Press, 2004). Hippocrates must have lived around late 5th and early 4th century B.C.

[3]Steven H. Miles, *The Hippocratic Oath and the Ethics of Medicine*. (New York: Oxford University Press, 2004), p.13.

[4]Steven H. Milles p.98

[5]Steven H. Miles p.101. Cf. also Tom L. Beauchamp and James F. Childress. *Principles of Biomedical Ethics*. (New York: Oxford University Press, 2013), pp.331-340.

[6]George J. Annas and Michael A. Grodin. "The Nuremberg Code" in Ezekiel J. Emanuel; Christine Grady; Robert A. Crouch ; Reider K. Lie ; Franklin G. Miller and David Wendler. *The Oxford Textbook of Clinical Research Ethics*. (New York: Oxford University Press, 2010), p.136.

[7]George J. Annas and Michael A. Grodin, p.136.

[8]The World Medical Association (WMA) has its origin in Paris. It was founded in Paris around 1947. Amongst other things the body was established to ensure that medicine was practiced in an utmost ethical, legal and humane way. It is with the overall mission of providing health to all universally.

[9]Richard E. Aschroft."The Declaration of Helsinki" in Ezekiel J. Emanuel; Christine Grady; Robert A. Crouch ; Reider K. Lie ; Franklin G. Miller and David Wendler. *The Oxford Textbook of Clinical Research Ethics*. (New York: Oxford University Press2010), p.141.

[10]It is well known in medical world that viruses are not really treated. The best one can have would be developing a vaccine.

[11]Baruch A. Brody. "International Ethics of Human Subjects Research in the Late Twentieth Century", in The Cambridge World History of Medical EthicsRobert B. Baker and Laurence B. Mc-

cullough. (New York: Cambridge University Press, 2009),p.578.
[12]Supervision is one thing that has to be emphasized. Globalization has turned the world into a village. Movement is quite easy and fast compared to a decade or more ago. The free movement made the spread of covid-19 faster than calculated. For this reason, serious and honest supervision should be emphasized. If this is not done, one will not really trust the transparency of action. Cf. the article by Barbara K. Redman "Research Misconduct and Fraud" in The Penn Center Guide to Bioethics VarditRavitsky, Autumn Fiester and Arthur L. Caplan (Eds.) (New York: Springer Publishing Company, 2009),pp.213-222,which is specifically about researchers requesting for funding on a bloated budget. No one discovers this until after the fact. If there were supervision that would not have occurred. This time there has to be a global supervising machine to ensure compliance at all levels.
[13]Ezekiel J. Emanuel; Christine Grady; Robert A. Crouch ; Reider K. Lie ; Franklin G. Miller and David Wendler. *The Oxford Textbook of Clinical Research Ethics*. (New York: Oxford University Press, 2010), p.123.
[14]Ibidem. p. 123.
[15]Ulrich Tröhler. "The Historical Development of International Codes of Ethics for Human Subjects Research" in *The Cambridge World History of Medical Ethics* Robert B. Baker and Laurence B. Mccullough(Eds.). (New York: Cambridge University Press, 2009), p.570.
[16]Jill M. Baren. "Unique Aspects of Informed Consent in Emergency Research" in *The Penn Center Guide to Bioethics*Vardit-Ravotsky, Autumn Fiester and Arthur L. Caplan. (New York: Springer Publishing Company, 2009), p.238.
[17]Steven H. Miles.*The Hippocratic Oath and the Ethics of Medicine*. (New York: Oxford University Press, 2004),
p.26
[18]The American Presidential Commission for the Study of Bioethical Issues in the work titled *Moral Science: Protecting Participants in Human Subjects Research*(Washington, D.C 2011) speaks about how research of such kind using human subjects are oriented towards bringing about knowledge and new discovery.

These are important for enhancing health and thus prolonging the life of mankind. It is not far removed from the purpose of the search for a vaccine or medication to take care of covid-19 that is currently proving stubborn. The world is seeking for a way to come out of the present difficulty: health care is over stressed and the economy has worldwide collapsed. For more information about the commission look up http://www.bioethics.gov.

[19]Tom L. Beauchamp and James F. Childress. Principles of Biomedical Ethics.p.230.

[20]Tom L. Beauchamp and James F. Childress.p.124.

[21]Ibidem. P.124.

[22]Ibidem. P. 127.

[23]Ibidem. P. 128.

[24]Cf. Tom L. Beauchamp and James F. Childress. p. 130.

[25]Albert Jonsen. p. 127.

[26]Jonathan Barnes,p. 642

[27]*Ibidem*. p. 642

[28]Readers can recourse to the propositions of Pythagoras, Anaxagoras, Democritus, Plato, Diogenes, Heraclitus to mention but a few for further discourse on the Soul. A common trend in these philosophers is the fact that the soul has a locomotive force. It moves and propels the human person. This force individuates and hence becomes life giving force. In other words, each human soul is dynamic but incorporeal. Cf. Jonathan Barnes, p. 644.

[29]Austin Flannery (Ed.). *Vatican Council II, Vol. I. The Conciliar and Post Conciliar Documents.Gaudium et Spes*, Nos. 12-14. (New Delhi: St. Paul's, 2014), pp. 803-805.

[30]Those who carried out the study did consider the sample from Borno state as non-random and non-representative.

[31]Cf. Nigeria poverty rate by State 2019. www.statista.com Accessed on May 1, 2021.

[32]There are over 150 languages in Nigeria with their individual dialects. Experts should be commissioned to translate such important document in the different language of the people especially those participating in the clinical trial.