Informed Consent in Sub-Saharan African Communal Culture: The "Multi-step" Approach

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ABSTRACT

Some scholars argue that the principle of voluntary informed consent is rooted in the Western ethos of liberal individualism; that it would be difficult to implement this requirement in societies where the norms of decision-making emphasize collective rather than individual decision-making (for example, Sub-Saharan Africa); that it would amount to "cultural imperialism" to seek to implement the principle of voluntary informed consent in non-Western societies. This thesis rejects this skepticism about the possibility of implementing the informed consent requirement in non-Western environments and argues that applying the principle of voluntary informed consent in human subjects' research in Sub-Saharan African communal culture could serve as an effective measure to protect vulnerable subjects from possible abuses or exploitations. The thesis proposes the "multi-step" approach to informed consent as the best approach to the implementation of the principle in the African communal setting. The thesis argues that the importance of the "multi-step" approach lies in the fact that it is one that is sensitive to local culture and customs. On the question of whether the principle of voluntary informed consent should be made compulsory in research, the thesis answers that we have no choice in the matter.

Key words: informed consent, Sub-Saharan Africa, communal culture, biomedical/health care research, HIV/AIDS, vaccine trials, "multi-step" approach.

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INTRODUCTION

The principle of voluntary informed consent is an important principle in research ethics. Many national and international ethics guidelines and regulations require that researchers and/or medical professionals obtain voluntary informed consent from participants in research protocol or clinical practice involving human beings. To respect people's voluntary informed consent implies respect for their human dignity and self-worth. It also implies that research subjects be not used as mere "means" to achieve the goal or "ends" of research. Research ethics guidelines are usually written documents specifying or prescribing certain agreed upon standards and values in human subjects research. Interest in ethics guidelines increased tremendously after World War II because of the horrendous experimentations carried out on war prisoners and *unconsenting* research subjects by Nazi researchers and medical scientists. During the trial of the Nazi scientists after the war, the world was alarmed to learn of the inhumane treatment meted out to the helpless victims of the Nazi experimentations. Other cases abound in the literature of abuses of human subjects of research. To minimize or guard against such abuses in the future, ethics guidelines were formulated to regulate biomedical research and scientific experimentations involving human beings.

In other words, the need to protect human rights is one of the propelling factors behind the formulation of the ethics regulations or guidelines. In general, many ethics guidelines either stipulate that the consent information be done in writing or that a consent form be provided which specifies clearly the goal of research and its potential risks and benefits to participants; explains that participation is voluntary and that subjects are free to withdraw at any stage during the research; and provides information about compensation when harm occurs; and states subjects' right to confidentiality.[1] However, an individual-based consent procedure, which it is claimed, is based on "the Western ethos of liberal individualism,"[2] may prove difficult to implement in cultures where the norms of decision-making do not emphasize individual autonomy. A good example is Sub-Saharan Africa where communal cultural values hold sway and where "community" is accepted as the core of the people's life. Besides, many prospective subjects in rural African communities are poor and non-literate peoples who lack

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[1] Onvomaha et al. 2006, p. 1.
[2] Gbadegesin 1998, p. 24.

awareness of the proper goal of research and the meaning of scientific and/or biomedical concepts.

Given the above realities, how would the requirement of voluntary informed consent be applied by researchers in a way that is not only ethically sound but also sensitive to local culture? Or would "Western concepts of informed consent," as some commentators are quoted as saying, be "inappropriate outside the Western world"?[3] And how may we respond to the objections of the scholars who allege that the principle of informed consent is not applicable in non-Western environments? In what ways can research be conducted in local cultures to promote what some scholars call "cultural competence"? "Cultural competence" is defined as "developing sensitivity to the individuality of different cultural groups."[4] We promote "cultural competence" when we respect the cultural values of other people. However, "cultural competence" is not to be confused with ethical relativism — the thesis that there can be "no valid cross-cultural standards for evaluating conduct."[5] On the contrary, like cultural relativism, "cultural competence" is only urging us to accept the fact of cultural differences and respect them. Accordingly, some scholars argue that "we may affirm cultural relativism while we reject ethical relativism."[6] When we apply the issues sketched here to the central issue in the present thesis, the logic of the argument will be to say that while we may urge sensitivity to local customs when conducting biomedical research in local environments, cultural sensitivity does not, however, commit us to skepticism about the possibility of the application of biomedical ethical principles in the conduct of research in such environments.

The issues adumbrated above shall form the basis of the present thesis. For ease of reference and for the purpose of clarity, I have divided the thesis into five chapters. In the first chapter, I discuss the history and development of the principle of informed consent in the context of biomedical research and clinical practice. I highlight and also discuss the factors that gave rise to the informed consent principle in research ethics; show the close link between the principles of voluntary informed consent and respect for autonomy. Also in the chapter, I discuss the different formulations and meaning of the concept of autonomy as well. I conclude the discussion in the chapter by stating the conditions to be met before we can say an individual has made autonomous choice.

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[3] Schuklenk et al. 1998, p. 360.
[4] Seibert et al 2002, pp. 143-146.
[5] Gbadegesin 1998, p. 30.

Chapter two is an analysis of some major research ethics guidelines and the type of importance they accord the informed consent requirement in human subjects' research. The five guidelines I choose for my discussion and analysis are of national, transnational and international significance and concern. My choice of the guidelines is for the reasons of their importance as research ethics documents, their historicity and relevance to the central issues discussed in the thesis. The guidelines harp on the the informed consent requirement as an important safeguard of subjects in research involving human beings. In chapter three, I discuss the nature of African communal culture, showing the influence of "community" and communal values on individual decision-making in Sub-Saharan Africa. The question is: would a culture that emphasizes the value of "community" over individuality affect or influence the way individuals make decisions about major issues in their lives? And what would be the implication of such a culture with regard to ways individuals make their decisions to either participate or refuse to participate in health care or biomedical research?

One way to answer the above questions is to make the glib remark that communal culture has the potential to thwart individual autonomy, or that in such cultures research subjects will not be able give consent that is truly voluntary. But that will be bad logic. Such an answer will also be pat truth, or an answer that is only partially close to the truth. The full-orbed truth is that culture is not static but dynamic. A proper "education" of people in rural communities and providing them with sufficient information regarding the nature and expectations in research is vital in helping them reach considered decisions about whether to be part of a research protocol or not. If freedom is transformative, as Amartya Sen suggests, education too is liberating and enlightening.[7] Freedom and education have the potential to liberate people from hackneyed notions that have become anachronistic in a world that is fast changing and receptive to new and valuable ideas.

In chapter four, I discuss the need for health care and biomedical research in Sub-Saharan Africa. I argue that given the nature, magnitude and catastrophic health care conditions facing Sub-Saharan Africa, and which is exacerbated by the HIV/AIDS pandemic, the scientific community needs to intervene by conducting diagnostic and therapeutic medical research and vaccine trials into new drugs as ways to deal with Africa's desperate health care challenges.

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[6] Ibid.
[7] See Sen 1999, p.3.

Such intervention, I argue, is not only a matter of great urgency, but it is a moral imperative as well. For as one perceptive commentator puts it, "health care is a basic necessity of human beings, no matter the cultural space they inhabit."[8] But bearing in mind that in the communal African society, local customs often emphasize collective rather than individual decision-making, what is the best approach to adopt in conducting health care or biomedical research in such a setting—an approach that is not only ethically sound but also sensitive to local culture? This is the question I address in chapter five, which is also the last chapter of the thesis. In answering the question, I propose the "multi-step" approach to informed consent as the best approach to human subjects' research in the communal African society and in the implementing of the bioethical principle of voluntary informed consent. In the chapter, I outline the process by which the "multi-step" approach to informed consent can be applied in the conduct of research in the African communal setting. The chapter concludes with a restatement of the importance of applying the informed consent requirement in biomedical or health care research involving human subjects. And as to whether the principle of voluntary informed consent should be made compulsory in research, I concur with Beecher's statement that "there is no choice in the matter."[9]

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[8] Frimpong-Mansoh 2007, p. 2.
[9] Beecher 1999, p. 422.

CHAPTER ONE: THE HISTORY AND DEVELOPMENT OF THE PRINCIPLE OF INFORMED   CONSENT

Informed consent is a key ethical requirement in clinical practice involving patients and in health care or biomedical research involving human participants. As P. A. Marshall *et al.* aver, not only is voluntary informed consent universally accepted as a precondition for scientific research involving human beings, but national and international guidelines for ethical conduct in research lay out specific conditions for obtaining such consent.[10] The purpose of these guidelines include among other things, to minimize unethical practice in the conduct of research, to protect research subjects from undue harm and to ensure that the desire for knowledge does not lead to "inhumane, unethical or inconsiderate treatment in experiments on human beings."[11] If the requirement of voluntary informed consent is that crucial, the issue would be to consider what it is. In other words, what is the principle of voluntary *informed consent* all about? How did the principle develop in the context of ethics and biomedical practice as a whole? These are some of the questions that I shall seek to find answers to in this chapter. In the discussion that follows, I shall also briefly consider the historical development of the doctrine of informed consent in the context of biomedical research, clinical practice as well as the ethical underpinnings for the idea of consent itself.

To return to one of the questions posed earlier, what is informed consent? And why is the requirement of voluntary informed consent necessary in research involving human beings and in clinical practice? Before we get into the discussion proper, it is needful to briefly explain what in the context of the present discussion we take research to mean. One definition of research which I find relevant to the issue in the thesis is the one found in the Nigerian National Code of Health Research Ethics (NCHRE) -- the official document that outlines the guidelines for the regulation of research involving human subjects in Nigeria. The definition is, however, in harmony with the ones commonly found in the literature on the subject. According to the NCHRE document, research (in our present context) may be defined as "systematic investigation, including research development, testing and evaluation designed to

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[10] Marshall et al. 2006, p. 1.
[11] McNeill 1998, p. 378.

develop or contribute to generalizable knowledge."[12] Included in this definition of research are the following:

(a) Therapeutic procedures- i.e., interventions administered with the intent of providing direct benefit to the research participant;

(b) Non-therapeutic procedures- i.e., interventions that are not administered with therapeutic intent and that are only intended to answer the scientific question of the study.

However, to be excluded from the above definition are such things as research on the effectiveness of instructional strategies or techniques; clinical audits merely designed or conducted to define or judge only current care, without reference to a standard; studies that are designed to evaluate or assess quality services, programmes and procedures and formative guidelines leading to their environment, etc.[13] The two examples of research given above are the ones relevant to our present discussion. Having defined what research is in our present context, I shall proceed in our discussion of the meaning and historical development of the idea of informed consent.

What is informed consent?

In seeking to answer this question, I should begin by mentioning that the principle of voluntary informed consent is an important principle in biomedical as well as research ethics. Here, I shall be concerned with the idea of consent in the contexts of clinical practice and research ethics. In the first context, consent is said to be informed when a patient approves and authorizes a physician or healthcare professional to undertake medical intervention on her body or person. In the second, research refers to a process by which a prospective research participant indicates his or her willingness to be part of a research involving human subjects. The crucial concepts in these characterizations are "approve," "authorize," and "willingness." To be more specific, informed consent refers to the *knowledgeable* and *voluntary* agreement (or authorization) by a patient to undergo an intervention by a physician (or a health care professional) - and "one that is in accord with the patient's values and preferences."[14] What is true here, in the case of clinical practice is also true about research subjects. National and international guidelines/policies emphasize on the need for investigators to obtain the

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[12] NCHRE 2007, p. 3.
[13] NCHRE 2007, pp. 4-5.

voluntary informed consent of human participants to a research before the research could proceed. Consent is said to be informed and voluntary when, for example, in the context of clinical procedure, a patient approves and authorizes medical intervention regarding her health or in the context of research, when a prospective subject willingly agrees to participate in a research protocol. According to A. M. Capron, the need to develop knowledge about human diseases and possible cures or treatments for them ultimately depends on medical scientists using people as "experimental animals." But as Capron also adds, exposing individuals to risks in the name of science becomes licit only with their informed, voluntary consent.[15] While recognizing the value and importance of individual decision-making, a crucial point needs to be made here: this is that the idea of informed consent also entails the possibility of what Tom Beauchamp and Childress refer to as "informed refusal."[16]

From the above remarks, it is clear that pursuing biomedical research should not only be a priority, but should also be undertaken in an urgent manner. According to the Report of the Nuffield Council on Bioethics titled, "The Ethics of Research Related to Healthcare in Developing Countries," in the particularly case of developing countries, the urgency of biomedical research is based not only on the need to promote scientific knowledge into research but also to deal with cases of the pernicious and fatal ailments ravaging those countries. According to this position, "developing countries urgently need research to help address the enormous burden of disease that they carry."[17] The Nuffield Council Report lists the goals of biomedical as including the following: (1) the need to find new or improved medicines and vaccines to deal with life-threatening diseases; (2) the desire to find better ways of delivering existing products and services to those in the need. Indeed, the benefits to be derived from biomedical research cannot be over-emphasized. Apart from the scientific progress which biomedical research promotes, it also has the added advantage of promoting medical knowledge and human well-being. But as scholars and professional themselves acknowledge, the use of human subjects in research or the use of human beings as experimental subjects often comes at great costs to those who are used. According to Leonardo De Castro, such uses of human beings as research subjects not only expose people to great risks, but also generate ethical concerns.[18] The concerns range from the impact of research on

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[14] Moreno *et al* 1998, p. 687.
[15] Capron 2006, p. 252.
[16] Beauchamp and Childress 2001, p. 80.
[17] Nuffield Council on Bioethics 2002, p. xix.
[18] De Castro 1998, p. 379.

values such as human life, autonomy, dignity, justice as well as happiness. To gauge the costs of research or experimentation on these core values of life, researchers and the public need to carefully assess not only the impact of interventions on persons but also "the consequences arising from the procedures involved" in the interventions themselves.[19]

Apart from the possibility of harm and inconveniences which we have alluded to above-- to research subjects (and sometimes to the researchers themselves)-- human participants in research and clinical experimentations are also vulnerable to exploitation by cunning investigators who may obscure information about some given procedure. As Robert Young points out, the way in which information is framed determines its significance or value for those [here, patients and research participants] to whom it is provided. If information is framed in such a way as to coerce or manipulate people, whatever 'consent' is given under this condition cannot be considered genuine authorization or voluntary, in the true sense of the word.[20] This point needs to be stressed a little more: not only are many research subjects unfamiliar with the technical details and complicated experimental procedures, in resource poor countries burdened with the problems of poverty and disease, local participants are often ignorant about the basic concepts of scientific research to begin with. Given their vulnerabilities, therefore, "human subjects of experimentation are more exposed than they are ordinarily to the possibility of exploitation."[21] It is for these reasons that scholars stress on the need for researchers and medical professionals providing 'full' and uninhibited disclosure or information about research protocols or medical procedure to enable individuals take reasonable decisions about matters involving their lives. We shall discuss more on the issue of disclosure in the section on the conditions of the autonomous choice later on in the chapter.

The importance of transparency on the part of physicians and researchers with regard to the disclosure of information and the obtaining of consent of patients and research subjects is an issue that scholars and experts have harped upon. However, given the importance of these matters-- that is, disclosure and consent-- and given on the other hand, the frailty of human nature which sometimes makes people to act in ways that are devious and ethically inappropriate, the duty to disclose information and obtain the consent of the individual is not merely left to the will of investigators or medical professionals. To leave the matter in the

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[19] Ibid.
[20] Young 1998, p. 444.
[21] De Castro 1998, p. 381.

hands of 'experts' to determine when voluntary consent has been given 'experts' would be to accord it no significance. And to show how significant and important the matter is, virtually all prominent medical and research codes as well as international rules of ethics now demand that "investigators must obtain informed consent of patients and subjects prior to substantial intervention."[22] The most important goal of the informed consent doctrine is to protect the autonomy or self-determination of patients and research subjects.

The historical development of the doctrine

The principle of informed consent is both a revolution and a novelty in medical practice as well as in biomedical research. The rise of informed consent is a revolution for two reasons: (1) it is a reminder that individuals have a part to play in decisions that affect their own lives, and (2) it is a rejection of the old idea of physician paternalism, an idea captured in the attitude that the physician 'knows the best'. With regards to the second reason above, the *revolution* against what is called "physician paternalism" is, due largely, to cases of incidents "involving the perceived abuse of human subjects in clinical research," and also to court litigations that applied legal rights in situations where physicians acted on patients without the latter's consent.[23] The notion of paternalism needs some elaboration here to underscore its meaning in the context of health care and research ethics. Gerald Dworkin describes paternalism as "the interference of a state or an individual with another person, against their will, and justified by a claim that the person interfered with will be better off or protected from harm."[24] For Beauchamp and Childress, it is "the intentional overriding of one person's known preferences or action by another person, whether the person who overrides justifies the action by the goal of benefiting or avoiding harm to the other person whose preferences or actions are overridden."[25]

Conceptually, paternalism derives from the analogy of a father acting (paternally) to "protect" or regulate the life of his children. The analogy with the father, says Beauchamp and Childress, presupposes two features. One is that the father acts beneficently (that is, in accordance with his conception of the interests of his children). The other is that he makes decisions relating to the welfare of his children, rather than letting them make their own

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[22] Beauchamp and Childress 2001, p. 77.
[23] Moreno *et al* 1998, p. 688.
[24] Dworkin 2005, p. 1.
[25] Beauchamp and Childress 2001, p. 178.

decisions.[26] In the context of health care, physicians sometimes withhold information from a patient regarding his or her condition in order not cause harm or worsen the patient's condition. Robert Young argues that this attitude is often motivated by a desire by practitioners to "do the best" for their patients. But Young thinks that withholding information from patients not only denies them the opportunity of making informed choices about their lives, but also places "a person's interest in her health ahead of her interest in deciding for herself what would be best for her, all things considered."[27] Physician paternalism sometimes arises from the idea that a professional has "superior" training, knowledge, and insight and is therefore in an authoritative position to determine what is in a patient's interest.[28] Young thinks, however, that this form of paternalism is to be rejected so long as it denies a competent person the right to make autonomous choice with regards to her medical welfare.

The crucial question here is to ask if paternalism is always wrong or if there are occasions when it may be permissible to act paternalistically. Before answering this question, I should mention that there are different versions of paternalism in the literature. Gerald Dworkin lists four versions of the term as follows: (i) hard vs. soft paternalism, (ii) weak vs. strong paternalism, (iii) pure vs. impure paternalism and, (iv) moral vs. welfare paternalism.[29] Following Joel Feinberg, however, Beauchamp and Childress admit of only two versions as follows: weak (soft) and strong (hard) paternalism. In weak paternalism, an agent intervenes on grounds of beneficence or nonmaleficence to protect persons against their own "substantially nonvoluntary" conduct- that is, actions that are not adequately informed. Strong paternalism on the other hand, involves intervention intended to benefit a person, even when it is the case that "the person's risky choices and actions are informed, voluntarily, and autonomous."[30] The key difference between the two forms of paternalism described above is that in the former, the paternalist's action was undertaken because a person's ability has been compromised one way or the other, whether by severe depression, addiction or sickness that makes rational deliberation difficult. In the latter, a person's wishes and choices are overridden even when her choices are substantially autonomous.[31]

Returning to a question posed earlier, are there occasions when we are justified to act paternalistically? Soren Holm's answer is that whether or not we can justify the overriding of a

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[26] Ibid.
[27] Young 1998, p. 442.
[28] Beauchamp and Childress, p. 178.
[29] Dworkin 2005, p. 1.
[30] Beauchamp and Childress 2001, p. 181.

person's decisions for the benefit of that person will depend on the case in question. He argues that if the justification is consequentialist, and respecting autonomy is seen as a means of creating good consequences, then there will be cases where the consequences of respecting a given autonomous choice will be so bad for the person in question that paternalism is warranted. On the other hand, if the justification for respecting autonomy is nonconsequentialist, Holm says it will depend on the exact premises of the justification as to whether paternalism can be warranted or not.[32] On their part, Beauchamp and Childress argue that beneficence odes sometimes provide justification for paternalism.[33] They posit the following as conditions that may warrant or justify paternalism: (i) sometimes when physicians act not to aggravate a patient's situation, (ii) when a patient is incompetent, and (iii) when disclosure of a disease diagnosis could worsen a person's condition.

The discussion on the issue of paternalism above has been in the context of clinical practice, with particular reference to relationship between patient- physician. Not much is in the literature on whether paternalism can be justified in the context of research- that is, whether researchers or investigators can justifiably withhold information that will enable research subjects make informed decision on whether or not to participate in a research procedure. However, the obvious answer is likely to be that it will be ethically wrong to deceive people into volunteering to be part of a particular research. For as Eleonore Pauwels reminds us, ethics is about telling the truth; and truth itself is central to scientific integrity. In other words, the quality of any research is only enhanced when it is carried out in compliance with fundamental ethical principles.[34] "The measure of ethical sensitivity in a [research] proposal is directly related to the degree of honesty and truthfulness declared."[35] What all these opinions show is that paternalism is never justified except in special circumstances such as the ones I mentioned above. By rejecting paternalism, patients and research subjects try to assert their right to decision making as autonomous individuals.

The principle of informed consent may be described as a revolution in research and biomedical practice. I have already explained the reasons why it is a revolution. On the second score, the importance of the principle lies in the realization by the public that as the power of

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[31] Ibid.
[32] Holm 1998, p. 272.
[33] Beauchamp and Childress 2001, pp. 179- 180.
[34] Pauwels 2007, p. 8.
[35] Ibid, p. 20.

medicine and scientific knowledge increase, so is the need for control over their consequences by those directly affected by them, that is, the public. In other words, "the once unquestioned authority of physicians in clinical decision making has declined as their scientifically grounded expertise has grown, to be replaced by patients' and research subjects' insistence on their right to give an informed consent."[36] Having underscored the revolutionary impact of the principle of informed consent in health care and research practice, the issue still remains to trace its historical roots. In addressing this issue, Robert Young reminds us that though the doctrine of informed consent has featured so prominently in legal cases over the last century, it nevertheless, "rests ultimately on a moral foundation."[37]

The foundations of the principle of voluntary informed consent rest on the ideas of human dignity, freedom, self-determination, autonomy, or individual choice. Long ago, Immanuel Kant made the now famous statement about the autonomy of the will that it is "the property the will has of being a law to itself."[38] What Kant calls the "dignity of man as a rational creature," is based, says Thomas Mappes and David DeGrazia, on "human beings possessing just that property that enables them to govern their own actions in accordance with rules of their own choosing."[39] Unlike Kant, John Stuart Mill provides a utilitarian justification for respecting human liberty of action and thought. For Mill, as for utilitarians generally, respect for the individual has utility value. The argument holds, for example, that a society that fosters or promotes "respect for persons as autonomous agents will be a more progressive and, on balance, a happier society because its citizens will have the opportunities to develop their capacities to act as rational, responsible moral agents."[40] In other words, autonomy is valuable primarily as a means to the creation of that which is intrinsically valuable, such as preference satisfaction, pleasure, human welfare, etc.[41]

The principle of informed consent has become a central element in health care and biomedical ethics. Historically, the classic case which establishes the philosophical basis of the idea of informed consent is said to be a 1914 legal judgment in America: *Schloendorff v. Society of New York Hospitals*. The case is about court findings that surgery ought not to have been performed on a patient who had agreed to an abdominal examination under anaesthesia but

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[36] Moreno *et al*., op. cit., p. 688.
[37] Young 1998, p. 440.
[38] Kant, 1959, p. 65.
[39] Mappes and DeGrazia 2005, p. 45.
[40] Ibid, p. 46.

had declined an operation. In legal terms, this type of action is likened to an assault or battery – an act punishable under the law. In the famous statement which eloquently expressed the view of the right of competent people to self-determination, the Judge demurred, saying:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault.[42]

Apart from the one cited above, numerous other examples or instances abound in history of non-disclosure of full information about medical intervention to patients by physicians. These were all cases of abuse of the trust reposed on physicians by their patients; we shall not go into a detail account of all the other cases here. Suffice it to say that these individual cases of abuse show why the idea of physician paternalism which we alluded to earlier is now largely rejected by everybody, especially in Western societies. But while the individual cases of abuse have featured prominently in the literature and in the development of the idea of informed consent, ethical reflection on the doctrine of informed consent has, however, been due largely to a number of highly publicized cases and revelations involving the abuse of human subjects or the inappropriate use of them in clinical research. Perhaps, the most infamous case of abuse occurred during World War II in Germany where Nazi physicians carried out horrendous experiments on *unconsenting* concentration camp prisoners, subjecting them to horrifying pain, intense suffering, disfigurement and eventual death. At the trial and sentencing of the physicians in Nuremberg, Dr. Andrew Ivy, the American Medical Association's representative remarked that the physicians were not "motivated by the spirit of the true scientist, namely to seek the truth for the good of humanity."[43] But the Nazi atrocities were not an isolated case; the Japanese doctors and bioscientists also conducted bizarre and inhumane experiments on Chinese residents and prisoners during the war. However, the Japanese experimenters were granted immunity from prosecution and their atrocities kept secret by American Occupation Forces "in exchange for information about biological warfare."[44]

In reality, some of the terrible cases of abuse happened in the United States of America, taking place even before the Nazi and Japanese war atrocities. A case in point is the Tuskegee

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[41] Holm 1998, p. 267.
[42] This statement is found in writings on informed consent and individual autonomy. In particular, I am indebted to Moreno J. D. et al., op. cit., for this quotation.
[43] See Moreno et al. 1998, p. 692.

syphilis study (1932 t0 1972) in which 400 poor black sharecroppers diagnosed with syphilis were *used* in an observational study to discover the consequences of untreated syphilis on people. The subjects neither consented to be part of the study nor were they told what the study was all about. They were also not offered any treatment for their disease, but were simply observed as their conditions deteriorated. Over time, many of the victims eventually died of the disease. According to Baruch Brody, this particular case illustrates once more, the need for informed consent and for ensuring that the gains and benefits of a study were commensurate with the risks. It also illustrates the need to protect vulnerable subjects from abuse and exploitation. And because the Tuskegee study was more epidemiological than interventional, Brody says it also "illustrates the need for policies governing that type of human research."[45]

If we were to summarize what we have said so far in a single sentence, it would be to say that the most important goal of informed consent is the need to promote individual choice and self-determination. Similarly, consent[46] is said to be informed and voluntary if the following conditions obtain:

❖ If there is disclosure of information to a patient or research subject about the nature, risks and benefits of a proposed treatment or research
❖ If the patient or subject comprehends what is being disclosed
❖ If he/she is aware of reasonable alternatives to the proposed intervention/investigation
❖ If he/she is competent to give (or withhold) consent
❖ If he/she voluntarily decides (or declines) the said intervention or to be part of the research
❖ If there is an advance authorization permitting a health care provider to act on his/her body

To sum up the above conditions, whether in research or clinical practice, an individual is said to have given an informed consent "if (and perhaps only) if he or she is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention."[47] Without doubt, only free and autonomous individuals can fulfill the conditions enumerated in the foregoing statement. In the section that follows below, we examine the notion of individual autonomy in relation to the doctrine of informed consent.

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[44] McNeill 1998, p. 370.
[45] Brody 1998, p. 33.
[46] Cf. Beauchamp and Childress 2001, pp. 78-79 with Young 1998, p. 422.

Informed consent and the principle of respect for autonomy

It is usual to begin any analysis of the concept, "autonomy" by tracing its etymology to its Greek roots *autos* (meaning, "self") and *nomos* (meaning, "rule," "law," or governance"). In its early appearance in ancient Greek political philosophical thinking, it was a term used to make a distinction between a city-state possessing autarchy (self-rule) or one under the control of some other city-state. In its early usage, therefore, autonomy was used to denote self-rule, self-governance or self-determination. The term was never extended to individual acts but to the freedom of an autarchic state to make laws which were especially suitable to its own specific situation. It was not until the Enlightenment period in Europe that the concept assumed a new meaning and became a buzz word for a philosophy that emphasized on individual choice and self-determination.[48]

In health care as well as applied ethics, the concept of "autonomy", like informed consent, is crucially important. The concepts of autonomy and voluntary informed consent are of basic importance in health care ethics, biomedical research and also in clinical practice involving individual patients and research subjects. Respect for autonomy means showing regard to the choices of individual persons- especially in health care and research, admitting that that they possess the freedom to accept or refuse interventions that affect their life and well-being. Beauchamp and Childress argue that although there is little agreement concerning the nature or scope of autonomy, never the less, the belief that we ought to respect the autonomous choices of persons "runs deep in common morality."[49] But why should we value autonomy or respect persons' choices or freedom? Kant's answer is that it is the basis of our moral standing as rational beings. For him, as free moral agents we have the capacity to choose (or act) according to our own reasons and motives, and without external constraints and manipulative influences. In other words, ideal moral agency requires that our choices be neither constrained externally (by others) nor internally (by some limitations within us). "Actions based on moral principles which are not self-chosen are heteronomous," that is, mere impositions. Kant thinks of autonomy and rationality as co-extensive, and as necessary and sufficient conditions for the ascription of rights to persons. His ethical ideas continue to have great impact on ethical

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[47] Beauchamp and Childress 2001, p. 79.
[48] See Holm 1998, p. 268.
[49] Beauchamp and Childress J. S. 2001, p. 57.

thinking till date. T. A. Mappes and David De Grazia argue that Kant's deontological thinking is relevant to current "argumentation in biomedical ethics" even today.[50]

Conditions of autonomous choice

The concepts of autonomy and informed consent are very closely related. In health care or research ethics, to uphold the importance of obtaining a person's informed consent is to recognize the value of the person's autonomy. A patient or research subject is said to be capable of giving informed consent if she is:

- ❖ Competent
- ❖ Understands the information disclosed to her, and
- ❖ Is able to give (or withhold) her consent freely.[51]

Gerald Dworkin says that there are at least six substantially different ways the concept of moral autonomy is usually defined in philosophical discourse. They are as follows:

1. A person is morally autonomous if and only if he is the author of his moral principles, their originator.
2. A person is morally autonomous if and only if he chooses his moral principles.
3. A person is morally autonomous if and only if the ultimate authority or source of his moral principles is his will.
4. A person is morally autonomous if and only if he decides which moral principles to accept as binding upon him.
5. A person is morally autonomous if and only if he bears the responsibility for the moral theory he accepts and the principles he applies.
6. A person is morally autonomous if and only if he refuses to accept others as moral authorities, that is, he does not accept without independent consideration the judgment of others as to what is morally correct.[52]

In concluding, Beauchamp and Childress argue that while there may be differences as to meaning, however, virtually all theories of autonomy agree that the following are essential for autonomy: (1) *liberty* (independence from controlling influences) and (2) *agency* (capacity for

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[50] Mappes and DeGrazia 2005, p. 18.
[51] Young 1998, p. 442.
[52] Dworkin quoted in Holm 1998, p. 267.

intentional action). In other words, for an action to qualify as autonomous it must not only be intentional, it must also be based on sufficient understanding.[53]

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[53] Beauchamp and Childress 2001, p. 58.

CHAPTER TWO: ETHICAL GUIDELINES ON RESEARCH AND HEALTH CARE PRACTICE

The principle of informed consent is a very important principle in biomedical ethics and discussion. To uphold the value in research or health care of obtaining a person's informed consent is to acknowledge that the person has right to self-determination over his or her life. As I mentioned in chapter one, the principle of informed consent is a key ethical requirement in health care practice involving patients and in biomedical research involving human subjects. J. D. Moreno, A. L. Caplan and P. R. Wolpe argue that, "in the context of biomedical ethical analysis…informed consent gives modern medical ethics its special character."[54] In the same manner, Robert Young makes a point that is crucial to the central issue in this thesis when he reminds us that the informed-consent requirement arose, largely, as a result of various court judgments about the health care provided to specific patients, and through "the establishment of regulatory standards in connection with medical experimentation."[55] It is this last point- the one on the establishment of regulatory standards to guide scientific experimentation- that is the focus of the present chapter.

Guidelines on research ethics have become important all over the world, as there are now many national and international guidelines on research. The development of the guidelines or ethical reflection on them has been greatly influenced by revealed cases of the inappropriate use of human subjects in research and scientific experimentation. Ethical guidelines are also sometimes called "official policies" or "ethical codes" on research ethics. They arose in response to questions about various aspects of research involving subjects- whether human or animal. According to B. A. Brody, these guidelines have identified a large number of issues and have developed "ethically informed responses to them."[56] In this chapter, I shall focus on those aspects of the guidelines that are relevant to the present thesis as well as "ethical responses" to them. What I mean by this is that I will only be discussing here the aspects of the ethics guidelines that deal with research involving human subjects. To be more specific, the guidelines I shall discuss are listed as follows: (i) The Nuremberg Code (1947), (ii) the

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[54] Moreno *et al* 1998, p. 688.
[55] Young 1998, p. 441.
[56] Brody 1998, p. 4.

World Medical Association, Declaration of Helsinki (also known as The Helsinki Declaration), 1964 [latest revision, 2004]; Council of Europe, Recommendation Concerning Medical Research on Human Beings (1990); (iii) Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993); and (iv) Nigeria's National Code of Health Research Ethics (2007).

My choice of the guidelines listed above is based on a number of reasons. For example, my choice of the Nuremberg Code is influenced by its significance as an important historical document and as the first major attempt on the part of governments and medical scientists to guide against the kind of inhumane experimentation carried out by Nazi scientists during the Second World War. My selecting the Helsinki Declaration on the other hand is hinged on its general acceptance by researchers and medical professionals as the key guideline on biomedical research at the international level. It was also the first significant attempt by the medical community to regulate the activities of medical professionals and researchers in the conduct of their duty. More importantly, Helsinki adopted new principles not discussed in Nuremberg. The EU guideline is important as a transnational guideline, straddling between the national and international. It represents as well, the attempt of the European Community to come up with some common view or recommendation on how scientific research involving human subjects should be conducted. The Nigerian National Code of Research Ethics is unique in its history and origin: it represents the position coming from Sub-Saharan Africa on the need to carry out scientific research in an ethically responsible way- in a way that recognizes the rights and dignity of the human person. More importantly is the fact that the code is a legal document which has a binding force on all research efforts as well as on all researchers who wish to carry out scientific investigation in Nigeria.

The need for ethical guidelines: a brief remark

Apart from the few I have listed above, there are other guidelines on research ethics in existence. However, the ones highlighted above will be sufficient for our present purpose. For the purpose of clarity, I shall not discuss all the issues contained in the guidelines but only the ones that are relevant to the overall theme of the thesis, which is the issue of obtaining the voluntary informed consent of research participants. But before getting into the discussion proper, it is important to mention briefly some of the factors that necessitated or gave rise to

the formulation of ethical guidelines in the first place. One major factor that led to the formulation of ethical guidelines, as I indicated above, is the need to deal with ethical problems that arise in research involving subjects. It is generally agreed that basic or scientific research involving human subjects is necessary if we must achieve scientific advances, develop treatments for diseases and make progress in medicine. But experience has shown that such research often gives rise to ethical dilemmas or problems.

In chapter one, I mentioned some cases of abuse of research subjects, such as the one by Nazi physicians of concentration camp inmates during the Second World War, or that of the Tuskegee syphilis study in the United States of America. Without necessarily downplaying the role of theoretical analysis in the issue of the guidelines, I need to remark, however, that these guidelines are, as a matter of fact, more case driven than they are theory driven. For this reason, I provide here a few more examples of cases of unethical conduct in research that made it mandatory to formulate the ethics guidelines. In a 1966 article published in the *New England Journal of Medicine*, Henry Beecher highlighted 22 "examples of unethical or questionably ethical studies" performed on human beings. I will cite just three of the examples provided by Beecher to illustrate the nature of the problem we are dealing with here. One study involved a placebo controlled trial of chloramphenicol for typhoid fever even when the drug's effectiveness in dealing this problem had been recognized. Of the patients placed on the placebo treatment, 22.9% died as opposed to 7.9 % of those who received the active drug. Beecher states that data presented shows that 23 patients who died in the course of the study would have survived if they had received specific therapy. The two other examples I cite involved institutionalized patients, and were equally alarming and ethically questionable. In one (the Willowbrook State School case), disabled and mentally defective children were intentionally infected with hepatitis virus in an attempt to determine the natural history of hepatitis and test the effects of gamma globulin. In the other (the Jewish Chronic Disease case) live cancer cells were injected into human subjects in a study to determine the rate of rejection. The patients were merely told they would receive some "cells"—the word "cancer" was completely omitted in the information conveyed to them.[57] In all the cases mentioned here, not only were the victims unaware of the detail of the study, the research studies were also carried out without their consent.

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[57] Beecher 1999, pp. 423-426.

The cases discussed above are no mere isolated cases of abuse by deviant investigators bent on tarnishing the reputation of decent researchers. On the contrary, numerous examples abound in the literature of other abuses by researchers in many other countries of the world. According to Baruch Brody, these cases of abuse "illustrated the need for appropriate standards for conducting research on human subjects…and they greatly influenced the actual development of official policies" on research.[58] I shall begin the discussion of the guidelines with *The Nuremberg Code*.

(i) The Nuremberg Code

The Nuremberg Code is a series of ten principles that were articulated during the trials, at Nuremberg, of the Nazi physicians that led the research on concentration camp prisoners during the Second World War. The Code begins by acknowledging that certain types of experimentation on human beings are appropriate so long as they are kept within "reasonably well-defined bounds" of the ethics of the medical profession. The ten articles or "basic principles" in the Code are to be observed in order for a research experimentation to be acceptable. I shall summarize below some of the principles that are directly relevant to this thesis.

The first principle is a fairly long one, but I shall summarize it here. The first sentence of the principle reads thus: "The voluntary consent of the human subject is absolutely essential." The code also sets forth other criteria that must be met before any research or experiment involving human beings can be judged as ethically appropriate. These include that investigators minimize any risks research subjects might face, that the degree of risk taken should never exceed the humanitarian importance of the problem to be solved by the experiment, and that research subjects should always be free to withdraw from the research if he or she "has reached the physical or mental state where continuation of the experiment seems to him [her] to be impossible."[59]

The Nuremberg Code emphasizes the centrality of voluntary consent in research. The Code is unique in its history and influence. It was a bold statement that unethical conduct in research by scientists or investigators is something that is unacceptable. It was also a statement that

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[58] Brody 1998, p. 32.
[59] The Nuremberg Code 1947.

"respect for human rights must be considered at every stage of research."[60] The Nuremberg Code helped awaken public interest not only in research but also in the way doctors treat their patients in clinical practice. The Code also served as an impetus in the formulation of other guidelines such as the World Medical Association's, Declaration at Helsinki, Finland, in 1964. I shall briefly highlight some of the essential issues in the Declaration.

World Medical Association Declaration of Helsinki

The World Medical Association's Declaration (popularly known as the *Helsinki Declaration*) is tagged, "Ethical Principles for Medical Research Involving Human Subjects."[61] The Declaration was adopted by the WMA *General Assembly* at Helsinki, Finland, in June 1964, and has undergone several amendments- the last of which was the 2004 amendment. Part of the reason why the Helsinki Declaration is important is that it was the first significant attempt by the medical community to formulate ethical principles to regulate itself. The Declaration adopted many of the principles found in the Nuremberg Code. It however added two important principles not discussed in the Nuremberg Code. First is the suggestion that each investigator must submit his or her research proposal to "an independent committee, for consideration, comment and guidance." Patrick Boleyn-Fitzgerald remarks that this addition or principle was an important step toward the establishment of what later came to be known as "institutional review boards," that is, local committees charged with reviewing research proposals to identify and deal with potential ethical problems.[62]

The second is that Helsinki allowed for the possibility of research on children and other individuals who might not be able to give consent so long as there are people who can give "proxy consent" on their behalf. Boleyn-Fitzgerald remarks further, saying: "if researchers had been required to follow the Nuremberg Code strictly, they would not have conducted research on children since the code states that 'the person involved should have legal capacity to give consent'."[63] The Helsinki Declaration is without doubt, a significant document in the history of history of human research ethics. The Declaration, says Baruch Brody, "remains the fundamental international statement on research involving human subjects."[64] But beyond the

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[60] Pritchard 1998, p. 528.
[61] WMA Declaration of Helsinki 1964 [2004].
[62] Boleyn-Fitzgerald 2003, p.413.
[63] Ibid.
[64] Brody 1998, p. 6.

novelty in the Helsinki document, the statement in the concluding part of the fifth principle of the Declaration is in my thinking, also very significant. The statement reads thus: "Concern for the interests of the subject must always prevail over the interests of science and society"! This emphasis on the welfare of research subjects over, and above, societal or scientific interests is worth noting; for it suggests that individual right is a value worth protecting in research.

There is a thought on *informed consent* expressed in the earlier versions of the Helsinki Declaration, which, though, has been modified in the 2004 version, is worth mentioning here. The idea is found in Principle 9 where it states that research subjects should give their consent to participate in research "preferably in writing." The 2004 version of the Declaration, while reiterating the importance of written consent, however, qualifies it, saying, where "consent cannot be obtained in writing the non-written consent must be formally documented and witnessed." The qualification is important because to insist that information about consent be provided in writing may be difficult in environments where the population have a highly illiteracy rate or where local customs encourage verbal consent.

The Helsinki Declaration, like the Nuremberg Code before it, has had profound impacts not only on official policies on research but also on theories of research ethics in particular.[65] And in fact, the two: the Helsinki Declaration and the Nuremberg Code, have formed the basis of most subsequent documents on research ethics. One other important guideline that followed in their heels is the World Health Organization and the Council for International Organizations of Medical Sciences (CIOMS) guidelines on research involving human subjects. It is to the CIOMS guidelines I turn into in what follows below.

CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects

The Council for International Organizations of Medical Sciences (CIOMS) is an international organization that was established by the World Health Organization and the UNESCO in 1949. The CIOMS guidelines which were first adopted in 1982 has also undergone some revisions. The CIOMS document opens with the following statement: "All research involving human subjects should be conducted in accordance with three basic ethical principles, namely

respect for persons, beneficence and justice." In particular, respect for persons is said to incorporate at least two ethical considerations, namely:

> (a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and (b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.[66]

On consent, the CIOMS guidelines require that investigators obtain voluntary consent of prospective subjects before any research would begin; or, "in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative." I will not go into all the details of the CIOMS document for want of space. But two ideas expressed in the guidelines are worth mentioning because of their relevance to the core issues in the thesis. One is that while the guidelines demand that investigators provide prospective research subjects with necessary information about research, it says this should be done "in language" that the subject "is capable of understanding." This idea is important because of its recognition that in many rural communities, prospective research subjects may not be familiar with technical details or information about biomedical research or the vocabulary with which the information is conveyed. In Sub-Saharan Africa, for example, most rural folks will only appreciate the meaning of research if details are conveyed to them in local dialects by one familiar with the indigenous culture.

The other idea is the special attention the CIOMS guidelines give to "research involving subjects in underdeveloped communities." Here, the guidelines mention that before research could be undertaking, investigators must ensure that: (i) persons in underdeveloped countries will not ordinarily be involved in research that could be carried out reasonably well in developed communities, and (ii) the research is responsive to the health needs and the priorities of the community in which it is to be carried out. What this latter idea seeks to guide against is the possibility of exploitation of vulnerable individuals from poor or underdeveloped communities. The Nuffield Council on Bioethics also stresses the need for researchers not to exploit research subjects from resource poor societies. In it its 2002 Report, "The Ethics of Research Related to Healthcare In Developing Countries," the Council notes that in

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[65] Boleyn-Fitzgerald 2003, p. 413.
[66] CIOMS 1993.

developing countries, the social, cultural as well as economic contexts in which research is conducted often differ from those of developed countries. It, however, argues that notwithstanding the difference, researchers have a "duty not to exploit vulnerable" subjects who volunteer for research in developing societies.[67]

Council of Europe, Recommendation Concerning Medical Research on Human Beings (1990)

The European Union has over the years issued a number of policies or directives on research ethics. Some are directives on the protection of animals used in experimental and other scientific purposes; scientific research on human gametes, embryos and foetuses and donation of human material; research on gene therapy, recommendation on genetic testing and screening for health care purposes, etc. The EU guideline I shall discuss here comes under the title "Principles Concerning Medical Research on Human Beings."[68]

The guideline reiterates most of the issues raised in the other guidelines already discussed in the chapter. It stresses the need for investigators to obtain the "informed, free, express and specific consent" of research subjects; their freedom to withdraw their consent at any stage in the research; the duty of investigators to protect the interests and well-being of subjects; the need to conduct research in ways that will minimize risks and produce benefits for those involved, etc. But Principle 13 is of particular interest because of its requirement that research subjects "not be offered any inducement which may compromise free consent." While they may be compensated for "expenses," "financial loss" or "any inconveniences inherent" in research, they are not to gain any financial benefit for participating in a research. The requirement against financial inducement is meant to guide against people volunteering to be part of a research merely for pecuniary reasons and not out of conviction or willingness. In other words, researchers must provide subjects with clear and unambiguous information to make a choice whether to be part of a research or not. The reason, as some scholars argue, is that "the ability to be autonomous is likely to be restricted by a feeling of obligation to participate because of benefits received."[69] Against this position, however, the Nigerian Code of health ethics research, which is the next guideline I shall examine, maintains a slightly

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[67] Nuffield Council on Bioethics 2002, p. 6.
[68] Council of Europe 1990.
[69] Rashad et al. 2004, p. 395.

different position on the significance of inducement in research. It is to this guideline I now turn in what follows below.

National Code of Health Research Ethics (NCHRE)

The National Code of Health Research Ethics (subsequently referred to as NCHRE) is Nigeria's official policy or guideline on health research ethics. It is the document that sets the norms and standards for the conduct of research on humans, including norms and standards for conducting clinical trials. The NCHRE is a 59- page document on the conduct of biomedical research in Nigeria; it was adopted as an official policy on research in 2007.[70] The NCHRE is unique in its origin and goal. It represents the first serious attempt on the part of the Government and people of Nigeria to regulate biomedical research in the country and to ensure that research involving human beings is carried out in an ethically sound and responsible manner- in a way that will not expose subjects to abuse or exploitation. In his "Foreword" to the Code, the then Minister of Health, Professor Eyitayo Lambo remarked that that the Code "represents the collective concern of the government and people of Nigeria to ensure the protection of human participants in scientific research to the highest ethical standard that is possible."[71]

The NCHRE provides for a National Health Research Ethics Committee (NHREC) - the apex body that regulates research issues and ensures that investigators adhere to the requirements of the research guidelines. Apart from the NHREC, there are also institutional or local health research ethics committees (HRECS) that deal with research matters at the local level. The NHREC is charged among other things, with adjudicating in complaints between researchers and local HRECS; rules on disciplinary actions against persons found to have violated the norms and standards of the ethical guidelines, etc. There are many other issues highlighted in the guideline which I shall not go into in this brief discussion. Suffice it to say that the principle of informed consent occupies a central place in the Nigerian guideline. And since this principle is also central to the present thesis, I shall give some space to discussing it here, albeit briefly.

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[70] See NCHRE 2007, pp. 1- 59.
[71] Lambo 2007, p. iv.

The NCHRE affirms that "informed consent is a *sine qua non* for ethical conduct of research" involving human subjects. It holds that in order for consent to be valid, it must have the following components:

1. Adequate information about the research "at the educational level [not] higher than that of individual with at most 9 years of education in Nigeria."

2. The design of the consent process must be appropriate for the type of research, expected participants, risks anticipated and the research contexts.

3. The consent form must not be too long as to become incomprehensible; must avoid unnecessary verbiage, legalisms, jargons and truth-dumping, etc.[72]

However, the first component above is a little tricky as the condition it prescribes may be somehow difficult to fulfill. The reason is that a vast majority of potential research subjects in Nigeria are non-literate people who do not have any formal education. Therefore, to demand that investigators provide information about consent that will meet the level of persons with "9 years education" would be to deny many potential subjects of the opportunity of participating in research! A de-emphasizing of the education requirement would seem more appropriate for rural folks that investigators hope to involve in research.

There are some important issues addressed in the Nigerian Code that are worthy of note. One is the statement that HREC shall act to safeguard the interests of researchers, subjects and communities participating in research from exploitation. The Nigerian code provides for ethics committees which carry out oversight functions over studies or research protocols to ensure that they are conducted according to ethical standards. Similarly, there are provisions for the review of ongoing research: a research can be modified, suspended, or terminated, as the case maybe.[73] But apart from the supervisory roles undertaken by HRECS, in local communities where studies are carried out, there are also Community Advisory Committees (CAC) that serve to safeguard the welfare of communities. Such Community Advisory Committees are usually made up of representatives of the community where research is going on, professionals who understand research or science issues, and representatives of the research team. Another important idea in the Nigerian guidelines is that which requires that communities "be engaged" and their "consent" sought by researchers before research can be approved or allowed to proceed. "Where applicable, such community assent or engagement efforts shall be

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[72] NCHRE 2007, p. 37.
[73] Ibid, pp. 18-19.

documented and evidence of same submitted to HREC during…research review."[74] The issues I have discussed in this paragraph are important because they help convey the idea that special precautions are required when research is conducted in communities where potential subjects are mostly nonliterate peoples who lack adequate understanding of research matters. They also show that the issue of safeguarding the welfare of researchers and research participants is one that should be taken seriously.

On the matter of inducement which I alluded to above, the Nigerian code states that the informed consent document shall contain not only information about risks and benefits to subjects but also the type of "incentive (inducement) that [accrue] to participants."[75] It is, however, silent on whether inducement would "compromise" the "free consent" of subjects as the EU guidelines suggest. The NCHRE needs to clarify this point to make the matter less ambiguous. In concluding, the National Code of Health Research Ethics, according to Eyitayo Lambo, represents the collective desire of the government and people of Nigeria to ensure that research involving human subjects is carried out to "the highest ethical standard" possible. Accordingly, "a system of ethical regulation of research ensures that research is conducted in a manner that will maximize the benefits of research while limiting its potential harms and exploitation of research participants."[76]

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[74] Ibid, p. 31.
[75] Ibid, pp. 38- 39.
[76] Lambo 2007, p. iv.

CHAPTER THREE: A LOOK AT THE NATURE OF AFRICAN COMMUNAL CULTURE

The last hundred years has witnessed great advancement in medicine and scientific research. Without doubt, advances in research and biomedical technologies have also produced great social benefits, such that we now have cures for hitherto fatal diseases and debilitating ailments. But while progress in medicine and biomedical research has produced social benefits, it has also posed bewildering ethical questions. In the previous chapter, I discussed cases of abuse of human subjects in experimental research, especially during the Second World War-- abuses that alarmed the conscience of humanity and suggested the need for the evolving of policies to help deal with ethical issues in research and human experimentation. The new discipline that emerged to deal with ethical controversies brought about by advances in biomedicine came to be known as *bioethics*.

Historically, bioethics has its roots in Western society; it developed as a response to new technologies in health care system and also as a result of some ethical questions that the development generated. This fact, says Segun Gbadegesin, has led to the feeling by many people from non-Western cultures that bioethics is a "Western phenomenon." The perception is not merely that contemporary bioethics is dominated by Western concerns, but by Western ethos of liberal individualism as well. According to Gbadegesin,

> This perception applies both to the values that make up the ethos of Western liberalism and to the focus of research in bioethics in the West. So far as this issue of focus is concerned, there seems to be a conflict between what is of concern to the West and its technological breakthroughs, and what is of interest to non-Western cultures.[77]

The core values or guiding principles in research ethics and contemporary health care practice are such values as respect for individual autonomy, human dignity and self-determination- values we discussed in the preceding chapter. As Janez Potocnik, European Commissioner for Science and Research remarks, research ethics brings with it obligations. "Issues of protection of identity, privacy, obtaining of informed consent and communicating risks and benefits are

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[77] Gbadegesin 1998, p. 25.

issues researchers need to bear in mind."[78] These issues, as the quotation from Segun Gbadegesin suggests, are considered by many non-Western peoples, as deeply rooted in the individualistic culture of Western societies. But how true is the claim that historically, contemporary bioethics is rooted in the values of Western culture? Even if, for the purpose of argument, we were to accede to the claim about the origin of bioethics, would that commit us to the view that the problems addressed by the discipline are only of value to Western societies? It would be unreasonable to make such a claim. But even if we were to agree-again for the sake of argument- that there is merit in the claim about the origin of bioethics, the crucial issue that we will still be faced with is how to coalesce or blend the principles of individual autonomy/ informed consent (which are said to have their basis in Western liberal culture) with those of a culture that emphasizes the importance of collective decision-making over individual choice. Are the principles of individual autonomy and collective decision-making incompatible? Or, can they be reconciled? How can we resolve the seeming antinomy between these two principles? In dealing with this seeming antinomy, I shall use the African communal culture as the focus of the issues that confront us here.

The nature of African communal culture

Before we get into the discussion on the nature of African communal culture proper, a few remarks on the meaning of culture will be necessary here. Scholars have generally defined the word "culture" in different ways. For example, G.F. Kneller defines it as:

> the totality of ways of life that have evolved through history. A particular culture is the total shared life of a given people - their modes of thinking, acting and feeling, as expressed in religion, law, language, art, technology, child-rearing, and, of course, education.[79]

In his book, *Philosophy and an African Culture*, Kwasi Wiredu tells us that culture goes beyond art, song and dance to include everything that is connected with a people's way of life.[80] Culture, he says, is seen in the way people work or recreate, in their worship, and courtship, in the ways they investigate nature and utilize its possibilities; and in their ways of viewing themselves and interpreting their place in nature. It is also seen in the manner in which people house and clothe themselves; in their system of statecraft, education, rewards

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[78] Potocnik 2007, p. 5.
[79] Kneller 1971, p. 49.
[80] Wiredu 1992, p. 10.

and punishment; in the way they regulate personal relations generally and the ideas underlying these institutions and practices.[81] John Mbiti offers a definition of culture that jells with that of Wiredu above. Writing specifically about African culture, Mbiti says it covers such areas as the social organizations and political systems of the African people- their ethics and morals; their philosophy and laws; their customs and institutions as well as their pattern of economic activity.[82]

While acknowledging the value and similarities in the definitions of culture given above, I shall, however, adopt Wiredu's definition as the one that underscores more, the issues I shall be discussing in what follows in the chapter. The point Wiredu makes in his definition is to say that in a certain sense, human beings are really who they are (or almost who they are) by virtue of their culture. Put differently, culture cannot be separated from human experience since it is that experience that produces and nourishes it. By "human experience," we have in mind the totality of our experiences in life- in politics, in our social relationships, in our use of technology, and even in our encounter with nature. But human experience itself is only possible, or can only be gained within the community. On this last score, it is commonly held that Africans are community conscious. What this means is that community consciousness and solidarity dominates the individual in his thinking and actions. It is in submitting to family or community authority, in being "immersed" in group values and norms that one becomes a true member of the community. Among the Zulu tribe of South Africa, this thought is captured in the following local maxim: "umuntu ngumuntu ngabantu." When translated into English, what the maxim simply means is that "a person is a person through other persons." J. S. Nyasani illustrates this point in a somewhat different manner when he argues that usually, in the African community, the individual is not expected to act outside of his community prescriptions or proscriptions. The will of the individual person is simply dissolved in the collective will of the community. According to Nyasani,

> Everything boils down to the 'me' in the 'we' or rather to the
> survival of the self through the enhancement and consolidation
> of the 'we' as a generic whole…Thus, in Africa, the individual
> will go to all lengths to ascertain the condition of the corporate
> 'we' and to play his part, if necessary, to restore the balance of
> wholeness.[83]

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[81]Ibid.
[82] Mbiti 1975, p. 7.
[83] Nyasani 1997, pp. 81-82.

The few general remarks we have made above go to show the value Africans place on community life. In discussions about the nature of African communal culture, it is often convenient to make a distinction between the traditional and the modern African community. While the former is used to describe African life before the period of European colonialism or the influence of the alien religions of Islam and Christianity, the latter refers to African life after the period of colonization. But we must also add that this distinction is not too clear-cut as much of the practices that go on in the so-called modern African society today predate colonialism itself. However, it is important to mention from the outset that the relationship between the community and the individual in Africa can be likened to that between a mother and her infant baby. Just as the baby depends on her mother for sustenance and well-being, in Africa, community usually looms very large over the individual. Olatunji Oyeshile writes that in its more "primitive" setting, the relationship between community and individual in Africa was very closely-knit; in a metaphoric sense, the community and its members had "similar destiny." And in an allegoric sense, the well-being of the individual depended on the well-being of the community.[84] In the traditional setting here described, the individual was completely "immersed" in the collectivity. It was in submitting himself to the authority of family or community that he derived his personality.

Some scholars have decried what they see as the *over-bearing* nature of the African community which, according to them, interferes with the ability of the individual to act autonomously. Others consider this type of interference as "hegemonic," saying it largely explains the sense of docility and complacency seen in contemporary Africans of today. For example, J. M. Nyasani claims that a great difference is often noticed between an individual brought in the Western liberal environment and one nurtured in the domineering cultural environment of the African setting. According to him, while the former is made to recognize his sense of independence from childhood, the latter usually has his freedom "muzzled right from the outset," and is drilled into an uncritical "submission to authority from above" from very early in life.[85] Similarly, E. K. Ogundowole decries what he calls "a concession to mysticism and uncritical adoption of the dogmas of religion and superstition," which he says have kept Africans in a "metaphysical spell."[86] By "metaphysical spell," Ogundowole is

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[84] Oyeshile 2006, p. 1.
[85] Nyasani 1997, p. 129.
[86] Ogundowole 1983, p. 15.

saying that religion and superstitious beliefs have captivated the minds of Africans, thereby hindering them from making scientific progress like people in other societies of the world. He thinks that it is because of its rejection of religious superstitions and the adoption of scientific reasoning that the West has been able to make substantial progress. Ogundowole advocates liberation of "the African mind from the metaphysical spell of religion" as a major way of social advancement for the African continent.

The opinions expressed in the previous paragraph are indeed very strong. But they only provide a pat answer to why Africans are "uncritical" in their attitude or why they are easily yielding, as these claims go. Some other reasons are also suggested for why the African acts the way he does. It would be needful to consider these other reasons as articulated by the scholars. For the purpose of clarity, and to give the discussion perspective, I shall divide the issues I want to discuss below into three different topics as follows (i) some remarks on the notion of African ontology, (ii) individual and community, and (iii) the nature of decision-making in the African community. I shall begin with the first item on the list and then run through the other items mentioned as well.

Some remarks on the notion of African ontology

Any meaningful discussion of African communal culture must begin with a mention of the nature of "African ontology." By *ontology* here, we have in mind metaphysical belief about the nature of being, existence and creation. It is commonly held that Africans are very religious people. Africans generally believe in a created universe, with a High God at the apex of such a creation. In Africa, the supreme deity is called by various names, depending on the culture or society where such a being is recognized. Among the Igbo and Yoruba people of Nigeria, the High God is called "Chukwu" and "Olodumare" respectively.[87] The Zulu of South Africa call him "Nkulunku" while the Ashanti of Ghana call him "Nyame." However, we are not overtly concerned with the names African call their supreme deity as with the role religion plays in the social life of Africans. Some scholars have argued that in Africa, religion is so pervasive that it becomes difficult to isolate it from the day-to-day living of the people. This is the kind of argument K. A. Baeta makes when he said that in Africa, "religion and life are inseparable, and life is not compacted into sacred and secular."[88] But as adverted to earlier, there are African scholars who see the undue emphasis on religion, especially the alien

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[87] Ilogu 1974, p. 34.
[88] Baeta 1967, p. 9.

religions of Islam and Christianity as contributory factors to Africa's social collapse. Some even argue that these imported religions have blinded Africans to the need to strive to make scientific progress like people in the West. I quoted Ogundowole as one of those African scholars who give vent to this kind of opinion. But we need not over-stress this issue. I only alluded to it as a way of showing the different attitudes that Africans have towards the alien religions that they have had to live with.

African religion is polytheistic, meaning that Africans worshipped different gods or deities. However, in their conception of the supreme deity, Africans consider him as an otiose being, since he does not play any direct role in their lives. The only contact that devotees have with him is through the numerous deities and preternatural forces believed to inhabit the African world. A crucially important aspect of traditional African religion which many scholars fail to emphasize is that behind any act of religious worship is the idea of reciprocity or utility. By this I mean that that people usually pledge allegiance to the gods or deities and worship them, expecting that in turn the gods will reciprocate by offering protection and security to their worshippers. Writing about the nature of religion among the Igbo of Nigeria, Edmund Ilogu says "no god and no act of worship [is] for mere love of the gods. Rather, it is an act either of supplicating for benefits, or pleading for atonement. Utility, therefore, is the most important reason the Iboman can give for the existence of the gods."[89] What is true here about the Igbo is also true of other Africans in general. Among traditional worshippers, religion was a pragmatic affair; people engaged in religion in search for social security and material provision. A god who was seen as irresponsive to the needs of adherents was soon abandoned and another deity sought after who could fulfill the expectations of adherents. In other words, far from being overtly that-worldly or a merely transcendental affair, religion is also a this-worldly affair that is concerned with the social expectations of humans.

Individual and community

As I mentioned earlier in the chapter, the sense of community is a very strong element in African communal culture. Communal culture or simply, *communalism* is, according to Olatunji Oyeshile, a social arrangement or relations that takes the "community" as the primary focus of activities of its individual members. Oyeshile argues that many African intellectuals make the claim that "traditional African societies were largely communalistic and that any

understanding of an African person, "whether at the metaphysical level or socio-political level must be from the communalistic perspective."[90] These claims, says Oyeshile, boil down to a central one that "a man [person] is nothing outside his [her] community."[91] The peculiar characteristics of the African community, we are told, include a sense of commonness among members, mutual dependence, collective action as well as co-operation.[92] Similarly, in a communal culture, the values that regulate social interaction among members are referred to as "communal values"; values, according to Kwame Gyekye, that "express appreciation of the worth and importance of the community."[93] It is these values that define and guide social relations among members of the same community. Oyeshile lists some communal "values" as including such things as sharing of resources, burden and social responsibility, mutual aid, care for others as well as social harmony.[94] However, it is doubtful if some of the things listed here can qualify as "values" in the any sense of the word. We shall not pursue this issue here; suffice it to say that the crucial issue is the claim that community is the receptacle in which communal values flourish. It is also in community that the individual derives not only a sense of security but can ever hope to realize his or her social aspiration. As the opinion goes:

> An individual who is cut off from the community organization is nothing; whereas even the most anti-social idiosyncrasies may be redeemed by renewing the family solidarity.[95]

In other words, in Africa, community is believed to have redeeming features. Indeed, there are scholars who claim that the way community is conceived in Africa differs from the way it is conceived in the West. William Abraham argues, for instance, that while in Western culture, community is merely conceived as a secular institution, in Africa, it "is conceived as having sacral unity, which comprises its living members, its dead (those who live in less substantial form) and its yet unborn children."[96] According to this opinion, in the African world, the living members of the community are said to be in "constant communion with the dead on grounds of kinship."[97] This is the same point Mbiti makes when he says that in Africa, "the

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[89] Ilogu 1974, p. 18.
[90] Oyeshile 2006, p.7.
[91] Ibid.
[92] Ibid, p. 4.
[93] Gyekye 1996, p. 35.
[94] Oyeshile 2006, p. 4.
[95] Taylor 1963, p. 19.
[96] Abraham 1992, p. 25.
[97] Ibid.

individual does not and cannot exist alone except corporately."[98] On the contrary, the individual in the community owes his existence to other people, including those of past generations and those still living. In the same way, whatever happens to a member of the community is believed to happen to the whole community; and whatever happens to the community happens to its individual members. Rene Descartes' popular dictum: "I think, therefore, I am," helps capture the Western idea of individualism and personal autonomy. Mbiti proposes the following as an African counterpoise to the Cartesian dictum: "I am because we are, and since we are, therefore I am." This refrain, says Mbiti, "is a cardinal point in the understanding of the African view of man."[99]

Indeed, in Africa, community has a strong hold on the individual. The common belief is that an individual is *nothing* outside his or her community. E. W. Smith, an English anthropologist who lived most of his life in East Africa during the colonial era captures this point vividly thus:

> Africans have hitherto lived in the collectivist stage: the community has been the unit; every individual interest has been subordinate to the general welfare… There is a solidarity that civilized communities find it hard among their members is but a faint reflection of the brotherhood found within the African clan. The Africans have, it is true, to pay heavily for their collectivism, in the injustice done to personal strivings and aspirations; just as we pay heavily for our individualism, in selfishness and greed.[100]

Even though Smith's comment above may not be wholly salutary, it nevertheless, captures in a very succinct manner, the distinction between the notion of Western individualism and African communalism. The statement also suggests that there are problems inherent in the idea of collectivism- its tendency to "subordinate" individual interest to so-called "general welfare," and the "injustice" it does to "personal strivings and aspirations." We shall examine these problems in the final section of the chapter below. Meanwhile, Mbonu Ojike makes a point similar to Smith's about the nature of community in Africa. Clan, that is, community, says Ojike, is:

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[98] Mbiti 1990, p.106.
[99] Ibid.
[100] Smith 1927, p. 214.

> the bulwark of African society. It is so clearly organized that there is not a single African who does not know his clan ... We are clannish in politics, and clannish in religion; social discipline and social structure follow a clearly distinguishable family structure.[101]

A mere cursory look at what Ojike says above will suggest that his remarks about communal culture are honorific. However, a critical examination of what he says will reveal that it also instantiates the sense of danger that exists when community is portrayed as wielding overweening control over the individual. For whatever it is worth, communal culture is fraught with its own internal contradictions. The problem is that in discussion on the nature of African communal culture, scholars often get carried away in their valorization of communal culture, that they sometimes downplay those aspects of the culture that are destructive of personal freedom and initiatives. In what follows in the concluding part of the chapter, we shall briefly mention a few problems with communalism.

Decision-making in the African community

People make decisions in the various areas of lives, whether in deciding for a choice of a career, in choosing a marriage partner, or in deciding where to reside. In other words, decision-making is something that humans have to make almost on a daily basis. But in the context of the present discussion, I am concerned with decision-making, as it affects research subjects or a patient in a health care situation. How, for example, does communal culture affect the individual in deciding whether to be part of a research protocol or not? Does such a culture hinder or limit personal initiatives in any significant way? These are some of the questions I shall seek to answer in my discussion of decision-making in the context of African culture in this section of the thesis. E. K. Ogundowole, as I mentioned above, charges that Africans are "uncritical" in their acceptance of religious dogma and some aspect of culture, which are "mystical" in nature. This fact, he says, hinders personal initiative and freedom of choice.[102]

The reason for the above charge is that in communal settings, it is often claimed that the elders are the ones who can speak for the whole community. And not only do they claim to speak for

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[101] Ojike 1946, p. 138.
[102] Ogundowole 1985, p. 15.

everybody, but their opinions are usually accepted as binding on every member of the community. What this means, says Oyeshile, is that individual autonomy is not only sacrificed, but also "differing opinions are ruled out."[103] In other words, an added problem with communalism is that it has the tendency to deny the individual his or her liberty, freedom of choice and the human capacity for autonomous action. To deny people their freedom of choice in name of communal agreement is to render them useless as free moral agents. And as Beauchamp and Childress remind us, "respect for autonomous choices of persons runs as deep in common morality as any" other principle.[104] However, it may be objected to saying, emphasis on autonomous choice is rooted in Western individualistic conception of autonomy and that this detracts from the ideal of a culture that values community authority and collective decision-making. But in my opinion, this objection is merely circumlocutory as it fails to point out that so-called "collective decision" in a communal culture is more often than not, the decision of a few elders who have appropriated for themselves authority to legislative rules for other members of the community who have been rendered helpless by the sleight-of-hand methods of the elders. We shall illustrate this point with some examples.

African culture is indeed a very complex mix in that it has been affected by influences coming from within and outside the continent itself. The culture has gone through so much changes and external influences that it becomes difficult to distinguish what is autochthonous to it from what is alien. Such factors as colonialism, Western education and the alien religions of Islam and Christianity have helped transform African culture- for good or for bad. Sometimes, it is difficult also to put a tab on a particular aspect of the culture, or to say of a particular manifestation, that it is truly African or alien. But notwithstanding this difficulty, in the discussion that follows, I hope to make a few remarks about the nature of decision-making in African communal society which in my thinking, are subversive of individual freedom and autonomy. In doing this, I shall focus on three Nigerian cultures and use to generalize or capture totality of African culture as a whole. This type of generalization can be defended on the grounds that the colonial experience, which is common to all African societies, marks some similarities in these cultures as a whole.

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[103] Oyeshile 2006, p. 15.
[104] Beauchamp and Childress 2001, p. 57.

Decision-making among the Hausa-Fulani

The Hausa-Fulani is a nomadic tribe found mostly in Nigeria, but large numbers in other parts of Sub-Saharan Africa. In Nigeria, the Hausa-Fulani inhabit the Northern part of the country. They are mainly Islamic by religion and culture, having embraced as a result Islamic conquests of large parts of Africa which ensured the imposition of the Islamic religion and political authority over conquered territories. The Hausa-Fulani population is largely rural, covering a vast region that stretches beyond the boundaries of contemporary northern Nigeria. The people are also largely engaged in agriculture: many young men are into cattle rearing, while a great number of the adult population are involved in farming, particularly in the cultivation of cereal, which constitutes the staple produce.[105] As with many African groups, the Hausa-Fulani group is highly patriarchal in its norms and social custom, with the male role valued more than the female. The status of women in many African societies has been described as particularly bleak "in view of the social norms that give men 'gatekeeping' roles in households and compounds."[106]

Generally, in a Hausa-Fulani community, family groups live together in a compound (*gida*), with a leader or compound head (*mai gida*)- usually the oldest man- responsible for organizing the group. In the Hausa-Fulani household, it is the responsibility of the husband to provide the economic sustenance of the familial group. With the increasing acceptance of the Islamic practice of purdah (*kulle*), women make limited contribution to the economic wellbeing of the household. They are "primarily involved in housework and childcare," such as cooking and sweeping the compound.[107] However, those who are not in purdah can engage in limited outdoor duties such as petty trading and craftwork.

The role of women in the social setting

Politically, Hausa-Fulani communities are ruled by powerful feudal kings known as *Emirs*. The word "Emir" is the title of a Muslim religious and political leader. An Emir exercises final authority over his subjects on religious, social and political matters. The Emir also has subordinate chiefs and other local rulers who carry out administrative oversights of the local communities on his behalf and help ensure order and social harmony among the people.

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[105] Solivetti 1994, p. 252.
[106] Tidana et al. 2006, p. 2.
[107] Solivetti 1994, p. 253.

Political or administrative authority is exercised solely by men, as women effectively play no public role within the community. According to Luigi Solivetti:

> Public roles are 'automatically' reserved only for those who are recognized as full adults from the economic and social point of view--the (male) heads of domestic units. Furthermore women's presence at public events is limited. Women are excluded, for instance, from communal prayer-- a fundamental occasion of socio-cultural aggregation-- for fear that their presence might disturb male believers.[108]

Marriage in the rural Hausa-Fulani Muslim community is both early and obligatory, as "there are no institutionalized single-person roles, such as bachelor or nun […]. People reluctant to marry, especially women, are at fault and socially penalized."[109] Similarly, when a man dies early (which is common in many parts of Africa because of disease or epidemic) his wife may be ceded to his brother or a near relation who is supposed to continue the duties of a husband with her. Divorcees or widows "who are still fertile have a duty to get married again as soon as possible; if they do not, they are regarded as prostitutes" and made to suffer social scorn.[110] Polygamy is an accepted marriage practice. African culture and the Islamic religion permit it. Many Muslim men in Sub-Saharan Africa are also into polygamous unions, claiming to be following the example of Prophet Mohammed whose marriage followed the same order.

Hausa-Fulani culture like most traditional cultures in Africa is overtly patriarchal and male-oriented. In such male-dominated societies, it is unfortunate, but the painful truth is that the status of women is not only "bleak," but they are oftentimes made to play lowly roles in the social arrangement. This fact is evidenced by the subordinate economic position women occupy in such societies or communities. Similarly, the female matrimonial role or position in such patriarchal societies depicts them as mere *properties* of their husbands or male partners. Some illustration here will help corroborate this claim. Among the Hausa-Fulani, for example, most marriages between young people are usually arranged by their parents-- often without consent of the people getting married, thereby making the family management of the marriage almost inescapable. Islamic marriage rules also restricts a woman's ability to make her own marriage choice by ceding to the father, the "exclusive" right to choose a husband for her

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[108] Solivetti 1994, p. 261.
[109] Ibid, p.256.
[110] Ibid.

daughter even before she has yet to reach the age of puberty.[111] Hausa-Fulani tradition even goes further than this as it gives the father authority over his daughter's first marriage, whatever her age. And he need not consult her before making the decision on her behalf.[112]

In male-oriented societies such as the one I have been discussing here, "decision making is commonly delegated to the most powerful figure… in the [society], such as [a] father" or male adult.[113] The patriarchal basis of African community and the unequal power relationship between men and women means that women are expected to submit to male authority without questioning. This argues Amina Rashad, "impacts on women's autonomy because ultimately both liberty and agency are impaired."[114]

The practice of families arranging marriages for their children has implication on the value of individual autonomy and self-determination. It leaves, says Solivetti, too little room for independent choice of spouse, above all for women. It also leads to constant friction in the home, resulting in the high incidence of divorce and female prostitution found among the Hausa-Fulani. Though this may sound somehow trivial, but in many cases where the couples complain of 'lack of love' between them, "it is made explicit that the woman did not consent to the marriage, in others it is left implicit that there was no real consent."[115]

So much for the discussion of Hausa-Fulani marriage custom. The essential social fact from the discussion is clear: women are seen as the *properties* of their husbands or the men, since they are treated as inferior to them (the men) and are given no freedom to make independent choices in matters that affect their lives and welfare. This is a fearsome truth, but the reality nonetheless. In a study carried out in a rural district in Ghana by P. O. Tidana, Nancy Kass and Patricia Akweongo "to elicit the views of research participants" about the informed procedure in a rural community, "all the female respondents said they consulted their husbands before participating in a study."[116] One particular female respondent said she discussed with her husband, and that it was when he *agreed* for her to participate in the study that she could participate in it.[117] Well, there is nothing wrong with consulting one's spouse as long as the

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[111] Solivetti 1994, p. 258.
[112] Ibid.
[113] See Rashad et al. 2004, p. 396.
[114] Ibid.
[115] Solivetti 1994, p. 266.
[116] Onvomaha et al. 2006, p. 4.
[117] Ibid.

woman can exercise her right to make personal decisions. The fact is that some drastic actions need to be taken in most traditional cultures to accord women more freedom, liberty and equality with their male counterparts. Part of that is to encourage the education of females, to jettison those aspects of traditional culture that have become anachronistic in the light of modernity, and to de-emphasize the role of religion in the daily affairs of society.

Decision-making among the Yoruba

The Yoruba inhabit South-West of Nigeria. They are also found in Togo, in Benin Republic as well as other parts of West Africa. There are millions of Yoruba in Brazil as well, and like other Afro-Brazilians, were descendants of Black slaves who eventually settled in this South-American country. The Yoruba culture or social custom is not too different from those of other African groups: like the latter, it is fiercely patriarchal and male-centred. Why patriarchy occupies such a central place in African culture is a cause for wonderment. Social anthropologists would need to do more to explain why this is the case. Though the point I want to make here is debatable, but it has some merit. I suppose that one explanation why women are accorded a low status in the social arena in African societies is partly religious and partly because of the patriarchal basis of the African culture. In reality, almost all the religious polities of the world seem to suggest that women are inferior to, and should in all things submit to male authority and dominion. A combination of power imbalance between men and women, and the woman's subordination in the domestic context help in perpetuating the myth of male superiority.

The Yoruba practiced a form of government which was monarchical in nature: there were powerful kings, known as "Obas" who ruled over large kingdoms, assisted by tribal or local chiefs who helped in administering and ensuring peace and harmony in villages and local communities. As P. C. Lloyd explains, the Yoruba operated a form of administrative machinery and judicial institutions in which power corresponded with wealth, gender and social status. For example, in each local community, authority was vested in the male head of the community. Similarly, "in each town the lineage was a gerontocratic institution with a large membership, the adult males" having administrative authority over the people. [118] In the administrative structure only adult males or lineage heads were chosen and ultimately decided on issues of public importance among the people. Women effectively played no significant

public role since rank and status depended on wealth and gender considerations, which women effectively lacked.

The Yoruba "Obas" still wield significant power among their subjects even in today's Nigeria. Many Yoruba myths even attribute *divinity* to the "Oba."[119] All this help to accentuate the sense of mythical importance people place on traditional institutions. However, in the enlightened age in which we live, traditional institutions will only hold relevance to modern minds if they help eliminate old prejudices and century-old myths, especially those that define the role of the woman as that of child-rearing and domestic duties. For if they have the right exposure and education, people (African women in this case) would not generally choose to enter into social relations that deny them the resources for accomplishments, and the exercise of responsibility, or that put them in relations of domination or degradation. "From a position of equality, women would not have agreed to a system of social roles that defines" them as "inferior" in the social equation.[120]

Decision-making among the Igbo

The Igbo are one of the major ethnic groups, not only in Nigeria but also in Africa. Like the Yoruba, the Igbo had an early contact with the Europeans through slave trade, colonialism and the Christian religion. The Igbo are mostly Christians; though a handful of traditional religious worshippers still exist in Igbo villages or communities. Traditional Igbo political system was republican in nature. And as we quoted Leith-Ross as saying earlier in the chapter, traditional Igbo democracy was "so…absolute" that it was both a wonder and a marvel to the early European colonialists. Traditional Igbo democracy has been described as "auto-democracy," comparable, says J. O. Oguejiofor, to the democracy of the Greek city-states, "but surpasses ancient Greek democracy in many ways. It gave a certain measure of governmental power to women, and by rejecting hegemony, assured that each community or state had the right to self-government."[121]

Unlike many other African tribal groups, the Igbo had no kings or monarchs. Rather, the clan or community was governed by elected representatives of families. European colonial scholars

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[118] Lloyd 1954, p. 382.
[119] Ibid, p. 367.
[120] Kymlicka 2002, p. 90.
[121] Oguejiofor 1996, p. 23.

were to marvel at the range of Igbo egalitarianism and individualism. A fierce egalitarian attitude is said to be a marked feature of traditional Igbo political organization. To underscore the sense of this egalitarian individualism, Richard Henderson, an American anthropologist who carried out a study on a particular Igbo community in Nigeria, wrote a book about the Igbo and titled it *The King in Every Man*.[122] But notwithstanding the novelty of Igbo political organization, British colonial policy did not help much to preserve a cultural heritage that had its distinctive features and uniqueness. But like most other indigenous cultures, traditional Igbo culture contained some apparent antimony. For while it accorded some measure of recognition to women, it was nevertheless, a highly patriarchal and male-dominated culture. For example, polygamy, a preference of male children over female ones, the regarding of women as inferior to men, etc., were things that thrived much in the traditional Igbo community. In matters of decision-making, women were never called into the assembly of the elders when important decisions were to be made regarding the community or even the welfare of the women themselves. Contemporary Igbo society is still highly patriarchal, but the influence of Christianity and Western education has helped much to moderate the excesses of men in the society.

A Recapitulation

My focus in this chapter has been to consider the nature of community in Africa and to show how communal culture affects individual liberty, freedom and decision-making. I have also looked at the role religion plays in African life and communities. The conclusions I reach from the discussion is that religion and community feeling are strong among Africans and that these two factors influence and help in shaping the way people make decisions in the contemporary African world. But the crucial issue as I conclude the discussion in the chapter is to ask how the issues discussed affect the bioethical principles of autonomy and voluntary informed consent in research and clinical practice, which form the core of the thesis. Do communal values help or limit the human capacity for independent choice and action? Or, do they thwart the development of the human capacity for autonomous choice? In a community-oriented culture like Sub-Saharan Africa, what would be the culturally sensitive way to obtain research subjects voluntary informed consent without compromising the universally accepted standard for the consent process? These are some of the questions I will discuss in the final chapters of the thesis that follow below.

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[122] Henderson 1972.

CHAPTER FOUR: HEALTH CARE AND BIOMEDICAL RESEARCH IN SUB-SAHARAN AFRICA

The World Medical Association Declaration of Helsinki (1996) states as one of the aims of biomedical research the furthering of "scientific knowledge and [the need] to help suffering humanity." International guidelines and regulations on human subjects' research lay down the conditions to be met before a given research can be said to be ethically sound or justified. One such condition is that researchers obtain the voluntary informed consent of subjects before the commencement of any investigation. The informed consent procedure is seen as one important way of protecting subjects' welfare from infringement or abuse. But beyond the issue of promoting or protecting research subjects' welfare and rights, there is also the obligation, according to G ran Hermerén, "to improve our knowledge of the causes of diseases, to prevent, cure and alleviate symptoms."[123] In other words, research or experimentation on human beings (for example, vaccine trials into new drugs) is "essential to scientific progress and the promotion of medical well-being."[124]

The issues adumbrated above will form the basis of the present chapter. In the chapter, I argue that biomedical and/or diagnostic and therapeutic medical research in Sub-Saharan Africa, especially HIV vaccine trials is not only essential but an ethical imperative. The views expressed above jell with the statement of the World Medical Association which holds as follows:

> The primary purpose of medical research involving human subjects
> is to improve prophylactic, diagnostic and therapeutic procedures and
> the understanding of the aetiology and pathogenesis of disease [and]
> even the best proven prophylactic, diagnostic, and therapeutic methods
> must continuously be challenged through research for their
> effectiveness, efficiency, accessibility and quality.[125]

Without doubt, the African continent, more than any other region in the world, is in urgent need of help, particularly research and vaccine trials into diseases factors to help save its population that is threatened with deadly and chronic diseases. The continent is presently faced with a myriad of challenges and problems. This is a decidedly euphemistic way to put the matter; for the truth is that the people of Africa face the risk of total extinction if nothing is

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[123] Hermerén 1996, p. 11.
[124] DeCastro 1998, p. 379.

done urgently to halt the spread of such deadly and obnoxious disease as HIV/AIDS and other chronic ailments. However, there are certain factors that hamper healthcare and biomedical research in developing regions of the world like Sub-Saharan Africa. Some of the constraints include limited resources such as finance, lack of appropriate infrastructure, and expertise.[126] Confronted with the problem of limited resources (both human and material), coupled with the overwhelming nature of the problem of diseases, African nations find it a difficult to handle their health care challenges alone by themselves without the support of rich societies of the world. In this regard, Augustine Frimpong-Mansoh calls for help from "the rich-resources countries in the West, to design and conduct diagnostic and therapeutic interventions and research in Africa," as a way of addressing Africa's desperate health needs.[127] But what actually is the nature of the challenge that necessitates such outside help and intervention in Africa's healthcare problems? And what should be the goal of healthcare research and vaccine trials in developing countries burdened by diseases problems such as the countries of Sub-Saharan Africa? These questions and other relevant issues are what I hope to address in what follows below.

The challenge of Africa's health care problem

I have partly addressed the second question above when I averred that the goals of research include promoting scientific progress and improving our knowledge of the causes of diseases. But other equally important reasons for research are to find new or improved medicines and vaccines for the prevention and cure of disease. Indeed, in its Report titled "The ethics of research related to healthcare in developing countries," the *Nuffield Council on Bioethics* speaks of the need to find effective medicines and vaccines for treatment and prevention of major diseases afflicting people in developing countries. The development of such interventions, it says, "may have the dual effect of directly promoting improved health and leading to further health gains through the impact that such improvements will have on socio-economic development."[128] Here, I suppose, I have provided sufficient answer to the question of the goal of biomedical research in Africa and other diseases that burden developing societies of the world. What remains is to address the question of the nature of disease condition in Sub-Saharan Africa that calls for help and research intervention. I hope to address

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[125] World Medical Association Declaration of Helsinki 2004.
[126] Nuffield Council on Bioethics 2002, p. 22.
[127] Frimpong-Mansoh 2007, p. 2.
[128] Nuffield Council on Bioethics 2002, p. 31.

this issue in an illustrative way, using the examples of some major diseases confronting African peoples. But eventually, I hope to narrow down my illustration to the HIV/AIDS pandemic disease, which undoubtedly is the greatest health care challenge confronting today's African societies.

So, what is the nature of the disease condition in Sub-Saharan Africa? And what are its impact on life and society as a whole? In answering these questions, I need to mention that the traditional fatal diseases that African societies are used to include such diseases as malaria, tuberculosis, cerebro-spinal meningitis, and river blindness. But these disease problems pale to insignificance with the emergence and unabated spread of the human immuno-deficiency virus (HIV) pandemic and the attendant AIDS disease. The HIV/AIDS problem in Sub-Saharan Africa is enormous and terrifying. In the last two decades or so, the disease has been on a rapid increase and remains at the moment the greatest cause of death in Africa, South of the Sahara. HIV/AIDS has had a catastrophic effect particularly on life expectancy in the Sub-Saharan African region. The *Human Development Report* of 2006 shows that over the past three decades, life expectancy gaps between developed and developing countries are closing, with the only exception being Sub-Saharan Africa which has experienced great reversals. Whereas the average life expectancy in North America is 70 years and 80 in Western Europe, in the Arab States it stands at 65 years; 70 years in East Asia and the Pacific; and 75 years in some Latin American and Caribbean countries. The picture coming out of Sub-Sahara is grim: some of the countries have it as low as 13 years. For example, the average life expectancy is 48.1 years in Botswana, 40.9 in Swaziland, 42.6 in Lesotho and 40.5 Zambia.[129] This problem is traceable largely to the HIV/AIDS pandemic which has had a catastrophic effect on life expectancy in the Sub-Saharan African region.

A conservative estimate puts the number of people living with HIV/AIDS worldwide at 40 million as at the year 2002. Of this figure, 28.5 million were living in Sub-Saharan Africa alone.[130] The number has not receded but remains on the increase. The *Human Development Report* describes Sub-Saharan Africa as the "epicenter" of the HIV/AIDS crisis, with infection rate on the increase on a daily basis. A majority of the 3 million people that died of the disease

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[129] Human Development Index 2005. Available at
http://hdrstats.undp.org/countries/country_fact_sheets/cty_fs_BWA.html (accessed on May 17, 2008).
[130] van Liere 2002, p. 1.

in 2005 alone came from the Sub-Saharan African region.[131] But a frightening pattern to the disease is that infection rates are higher among women than men, with the former now accounting "for 57% of HIV infections in the region."[132] In their paper, "AIDS: ethical issues in the developing world," Udo Schuklenk et al. write that in those regions of the world experiencing a rapid spread of HIV/AIDS, an important factor responsible for the spread is "the practice of men having sexual intercourse with sex workers."[133] With particular reference to Africa, Schuklenk and colleagues say "it should be noted that AIDS in Africa…is mostly transmitted through heterosexual contacts, blood transfusion and injection."[134] Early marriages and sexual unions with older men are also factors that increase the risk of infection and death among young women and girls. But there is also a subtle irony about the disease spread: "less visible has been the feminization of the disease and the consequences for gender equity."[135] One of such consequences is that young African women (ages 15-24) are three times more likely to become infected and die from the disease than men. The pandemic is shaping and redefining the demographic structure of several African countries making the probability higher that women would contract the infection than men. They are also more likely to die from the infection than their male counterparts.[136]

As some scholars note, "the ethical issues of AIDS in developing countries are to some degree similar to those in Western countries."[137] The major difference lies in the limited resources available for health care in developing countries, the lack of political will to deal with social problems; and in the case of Africa, ignorance, internecine conflicts as well as corruption among political leaders. But as Marti van Liere observes, many countries in Africa "hardly seem to realize the danger that awaits them."[138] The picture emerging from the continent is ominous and worrisome. The grim reality is that "HIV/AIDS has thrown human development into reverse gear" in many African countries.[139] And the tragic thing about the pandemic is that the population primarily touched by the disease happens to be the socially productive one. Let us take Nigeria as a case in point: even though statistics are not often reliable in the country, figures from the Federal Ministry of Health for the year 2001 put the infection rate for

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[131] Human Development Report 2006, p. 266.
[132] Ibid.
[133] Schuklenk et al. 1998, p. 357.
[134] Ibid.
[135] Human Development Report 2006, p. 266.
[136] Ibid.
[137] Schuklenk et al., p. 355.
[138] van Liere 2002, p. 1.
[139] Human Development Report 2006, p. 266.

HIV at 5.8% for the adult population alone. What this shows is the fact that the country is in the grip of the pandemic.[140] The figure could be higher if there were accurate and reliable statistics. A year earlier, the Ministry of Health had put the overall estimate of Nigerians living with the HIV virus at 3.3 million people- a number which was expected to increase five years later to between 4.9 to 5.5 million.[141] The situation is even worse in other African countries, where the effect of HIV/AIDS have been largely catastrophic. For example, in countries with very high prevalence rates like Botswana, Malawi, or Zambia, to mention but these, the population structure is severely damaged, such that there is "a large gap in the 25-50 age group."[142] In other words, part of the effect of the disease is that a high percentage of Africa's productive work force is lost to HIV/AIDS- a loss, according to van Liere, that "impacts society and economy in multiple ways." Again, "loosing so many young people undermines the fabric of society."[143]

If the claim is true that "people are the real wealth of nations," then Africa is not yet on the track to wealth creation or sustained human progress.[144] The reason is that the nation-states of Africa continue to experience economic reversals because of the catastrophic effect of HIV/AIDS on human capital. By human capital here, I mean not merely labour but also knowledge and skill. The death and the loss of skilled and competent workers resulting from sickness and disease prevent the transfer of knowledge to others. In many nations of the developing world, HIV/AIDS remains a serious hindrance to socio-economic growth and development. In Sub-Saharan Africa, for example, the economic impact of the disease on national economies is great. Not only is the business sector experiencing decline due to the loss of workers, even the healthy ones devote their productive time caring for the sick or attending funerals.[145] This loss of skilled workers in the formal and informal business sectors eventually leads to low productivity, lack of investments and savings by individuals and businesses. In the agrarian sector, the loss of labour results in shortage of food, and in extreme cases, to famine and death. The impact of HIV/AIDS on the national economies in Africa is catastrophic, to put the issue mildly.[146]

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[140] Hilhorst et al 2004, p. 13.
[141] Federal Ministry of Health 2002.
[142] van Liere 2002, p. 1.
[143] Hilhorst et al 2004, p. 99.
[144] Human Development Report 2006, p. 263.
[145] van Liere, op. cit., p. 5.
[146] Ibid, pp. 2-3.

From the discussion so far, it is clear that the disease situation in Africa created by the emergence of HIV/AIDS is tragic. But there is a cruel irony to the tragedy. The irony, as De Zalueta puts it, is that "the poorest regions of the earth"- Sub-Saharan Africa and Southern Asia- are also the ones worst hit by disease and poverty.[147] Stuart Rennie and Frieda Behets lend credence to this view when they remark that of all the continents of the world, Sub-Saharan Africa and Southern Asia are the two with the "greatest HIV/AIDS burdens."[148] This ironic twist to the pandemic is exacerbated by the fact that the continents with the highest prevalence of disease (HIV/AIDS, in particular) are also the ones with "fewest resources to combat the disease."[149] With particular reference to Sub-Saharan Africa, HIV/AIDS is for now the greatest public health challenge confronting the people. It is usual to measure a people's welfare in terms of growth in their country's national production (GDP). But some economists remind us that human welfare and progress should not to be measured in terms of a country's GDP alone, but also in terms of the people's quality of life. Amartya Sen argues, for example, that development can be seen as "a process of expanding the real freedoms that people enjoy."[150] Sen argues further that "freedoms [and human wellbeing] depend also on other determinants, such as social and economic arrangements (for example, facilities for education and health care) as well as political and civil rights (for example, liberty to participate in public discussion and scrutiny)."[151] In other words, human welfare and progress is not to be measured with material wealth alone but also with people's ability to realize their potentials as human beings. According to this opinion:

> Real opportunity is about having real choices- the choices that come with a sufficient income, an education, good health and living in a country that is not governed by tyranny.[152]

It is this "opportunity" to have "real choices" that are denied Africans by the prevalence of disease, poverty and bad governance. There is a need to halt this downward trend by making concerted effort to fight the dreaded HIV virus that has been a major cause of death, misery and pain in Africa. Alongside this battle, is the need to provide illiterate rural Africans with good education, ensure the protection of human rights and good governance for them. These are minimum requirements for a people who desire economic growth and human development.

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[147] Wesley and Peterson 1999, p. 6.
[148] Rennie and Behets 2006, p. 54.
[149] De Zaluta 2001, p. 290.
[150] Sen 1999, p. 3.
[151] Ibid.

These are also factors that have ensured progress and development in Europe and America and some parts of Asia like Japan and South Korea.

The imperative of biomedical research and vaccine trials in dealing with Africa's health care problems

How should the world respond to Africa's healthcare challenges and disease problem? Augustine Frimpong-Mansoh says it is through developing and implementing diagnostic and therapeutic medical research and interventions "to provide the African people with hope and relief from catastrophic diseases, especially the HIV/AIDS pandemic" disease.[153] And not only is such intervention an urgent matter it is also a moral imperative. The reason is that health care is a basic necessity for all human beings, no matter the cultural space they may inhabit in the world.[154] However, the sheer weight of Africa's health care problems is such that African nations cannot bear the burden alone: they would need outside assistance, especially "from the rich-resources countries in the West, to design and conduct diagnostic and therapeutic interventions and research in Africa" to combat the HIV/AIDS disease.[155] Such Western-sponsored health care research has been going on in Africa for a long time; but it needs to be intensified given the new dimension of the disease problem in Africa.

Rennie and Behets make a similar argument as the above when they reminisce; saying, "only a few years ago, the question 'should AIDS treatment programmes be implemented in low-income countries?' was a matter of heated debate among AIDS activists, health economists, bioethicists, and epidemiologists."[156] But given the magnitude of the problem today, the question has been replaced by a daunting new one: "how can the ambitious and costly global AIDS treatment programmes be implemented in ways that are swift, affordable… *and* ethically sound in the resource-poor countries most burdened by HIV/AIDS?"[157] It is a question such as this that has provided the basis for the discussion I have done in this chapter. By way of answer, I have argued among other things that the scientific community needs to respond to Africa's health care problems by carrying out research/vaccine trials as well as diagnostic and therapeutic medical research and interventions in Africa as a way of responding

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[152] Human Development Report 2006, p. 263.
[153] Frimpong-Mansoh 2007, p. 10.
[154] Ibid, p. 2.
[155] Ibid.
[156] Rennie and Behets 2006, p. 52.
[157] Rennie and Behets 2006, p. 52.

to the health care challenges facing contemporary African societies. But given the community-oriented nature of African societies, how would such research be conducted in a way that is "swift," "affordable," and "ethically sound"? This is the question I address in what follows in the next chapter.

CHAPTER FIVE: RESEARCH AND CLINICAL PRACTICE IN SUB-SAHARAN AFRICA: THE "MULTI-STEP" APPROACH TO INFORMED CONSENT

In chapter one, I argued that the notion of voluntary participation in research involving human subjects is pivotal in research ethics. Several international declarations and guidelines make obtaining such voluntary consent essential to any ethically sound research. The principle of voluntary informed consent is also recognized by international human rights instruments as a testing criterion for ethically sound research on human subjects.[158] For example, Article 7 of the International Covenant on Civil and Political Rights requires that "no one shall be subjected without his [her] free consent to medical or scientific experiment."[159] As we saw in the second chapter of the thesis, Nigeria's National Code of Health Research Ethics maintains that "informed consent is a *sine qua non* for ethical conduct of research" involving human subjects.[160] South Africa's Medical Research Council's General Principles also avers that "everyone has the right to bodily and psychological integrity, which includes the right … not to be subjected to medical or scientific experiments without their informed consent."[161] According to Henry Beecher, consent can only be said to be truly informed when adequate information is provided to subjects regarding the nature and risks involved in a given research or experimentation involving human beings. As he explains the matter, "the statement that consent has been obtained has little meaning unless the subject or his [her] guardian is capable of understanding what is to be undertaken and unless all hazards are made clear."[162] What is shown by the foregoing is the importance the principle of voluntary informed consent occupies in research and clinical practice involving human beings.

But how may this principle be applied in a community-oriented culture like Sub-Saharan Africa, in a way that is culturally-sensitive without, however, compromising the universal standard for the application of the principle? This is the question I shall address in this chapter. In the discussion that follows in the chapter, I propose the "multi-step" approach as the best

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[158] Frimpong-Mansoh 2007, p. 3.
[159] Office of the United Nations High Commissioner for Human Rights (OHCHR). 1976. *International Covenant on Civil and Political Rights*. Geneva: OHCHR: Article 7. Available at: http://www2.ohchr.org/english/law/ccpr.htm [Accessed on May 5, 2008].
[160] NCHRE 2007, p. 37.
[161] Quoted by Frimpong-Mansoh, p. 3.
[162] Beecher 1999, p. 428.

approach to adopt in applying the principle of voluntary informed consent in the conduct of biomedical research in the communal African context.[163] In proposing this approach, however, I am not in any way suggesting that the principle of voluntary informed consent is unimportant or cannot be applied in the context of health care research in Africa. On the contrary, I argue that the "multi-step" approach will in fact enhance the principle, and help protect nonliterate and vulnerable research subjects from possible exploitations or abuses. I also dismiss cultural and ethical skepticism concerning the global application of the principle of voluntary informed consent, and argue that the fact that local values and customs require that researchers obtain the permission of local chiefs and leaders before conducting research in local communities, does not in any way hinder or limit the possibility of the individual to give consent that is free or voluntary. On the contrary, the "multi-step" approach will even enhance, solidify and make stronger individual voluntary consent in research.

A "multi-step" approach to informed consent: some illustration

But what is the "multi-step" approach to informed consent all about? How may it be described to capture its real meaning and significance? As a way of answering, the "multi-step" consent approach refers to a process whereby researchers or investigators consult community leaders such as village chiefs, clan or family elders, and obtain their permission before approaching individual members of the community to seek their consent to participate in a research protocol. The "multi-step" approach follows this order: First, researchers or investigators hold meeting or consultation with community leaders and explain to the nature or goal of the research. Second, community leaders deliberate with village elders and household heads about the mission of researchers in the community after which permission is given to researchers to go into the community to discuss with prospective participants. Third, family heads (such as a husbands or a male elder) may also hold a meeting with family members where the family members are informed about the research and the decision or willingness of the community to be part of the research. But while a husband may give permission for his wives or children to be part of a research, he is, however, not the one who gives consent on their behalf. Family members would usually interact with researchers individually. However, an illiterate village elder, father or mother would usually need someone (such as a son or any other educated person) to interpret or explain the details of the research matter to him or her. But in the final

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[163] See Frimpong-Mansoh 2007, p. 6.

analysis, the decision to participate or not participate in a research protocol is that of each individual person concerned.

My discussion of African communal culture in the third chapter of the thesis reveals the strong influence that *community,* local customs and traditions have on the individual in the African world. Whereas Western culture places great importance on the individual member of the community than on the community itself, in Africa, the reverse is usually the case. In the African world, community interest is placed higher than the interest of its individual member. John Mbiti captures this idea vividly when he avers that in Africa "the individual does not and cannot exist alone except corporately," that is, communally.[164] In the same way, the individual is believed to owe his or her existence to the community-- to other people, including those of past generations and those still living. Some scholars describe the African as a "community person;" and hold that the more attached or united to the community an individual is the stronger and more secure he (or she) becomes. According to the argument, those members of community who are assured of social security are only the ones who are "rooted in the [big] *WE* [i.e., community], and [who are] not isolated from it."[165] In other words, the notion of individual autonomy or self-government is not a popular notion among communal Africans. But this is not to suggest that in Africa the individual is not counted as important or that individual liberty is not a valued thing. On the contrary, what it suggests is the idea that it is in community life that the individual finds his/her true freedom and fulfillment. This is the same point that the Nigerian social anthropologist, Mbonu Ojike makes when he declares that community (or clan) is "the bulwark of the African society." [166] Africans, he argues, are "clannish in politics, and clannish in religion." Social discipline and social structure, Ojike says, follows the same pattern.[167] The English anthropologist, J. V. Taylor captures the idea vividly when he argues that in Africa:

> An individual who is cut off from the community organization is nothing; whereas even the most anti-social idiosyncrasies may be redeemed by renewing the family [communal] solidarity.[168]

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[164] Mbiti 1990, p. 106.
[165] See Njoku 2002, p. 278.
[166] Ojike 1946, p. 27.
[167] Ibid.
[168] Taylor 1963, p. 19.

I believe the point is well-made regarding the nature of the relationship between individual and community in the African society. Returning to the issue of consent in a communal setting or culture, some practical examples about community decision-making processes will illustrate the argument I make in the chapter. In a study carried out by P. O. Onvomaha, Nancy Kass, and Patricia Akweongo to evaluate the informed consent process in the Kassena-Nankana District of Northern Ghana, the research team observed that community leaders wielded great influence on local members. All prospective participants who responded to questions said they would only agree to be part of a study if local chiefs gave permission for research to be conducted in the community.[169] In Africa, not only are community leaders influential, they are also seen as "gatekeepers" over the local communities. Local custom requires that such leaders be made aware of any event taking place in the community. Even such private events as a woman having given birth to a new baby need to be made known to the chief or village leader. Local custom also requires that the leader give approval for most big events that have a direct bearing on the community as a whole. This explains why visitors coming into the community (in this case, researcher) must first consult the leaders before a research can be allowed to be conducted in the community. In the example of the Kassena-Nankana District under illustration, Kass and her collaborators report that the process of consulting the village leader would normally follow this order:

> First, the researchers hold a meeting with the chief and elders of the community, where the proposed research is discussed. Once the leaders are satisfied with the proposed research, they give *permission* for the researchers to enter the community and conduct their research.[170]

The protocol of consulting community leaders is akin to what in diplomatic terms is referred as making "courtesy call" on important dignitaries or figures. Sometimes, the protocol of paying homage to local leaders may involve presenting them with gift items such as a bottle of spirit or souvenir. It should be remarked that these are no inducements but mere acts of courtesy, or hospitality, as the case may be. These preliminary events may be followed by the local ruler and his chiefs holding a meeting with their people to inform them about the presence of the researchers in the community. Household heads may also hold similar consultations with those in their compound as well. It is when all this is done that researchers will reach out to individual members of the community to seek their consent.

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[169] Tindana, Kass and Akweongo, pp. 1-6.

Researchers' consulting with community leaders or such leaders giving permission for research to be carried out in the community does not replace the requirement for individual voluntary informed consent in research. At the risk of becoming repetitious about the matter, research ethics guidelines make it mandatory for individual consent to be given. In another collaborative study carried out in South Africa similar to the Ghanaian one discussed above, and which was undertaken to assess informed consent to HIV testing in a perinatal HIV transmission study in a major hospital serving a largely Black population in South Africa (a hospital-based research), the researchers, hospital staff and the volunteer group in the study recognized the need to strengthen the "informed consent" process to protect subjects from possible exploitation, especially "studies undertaken in settings where services are sought by the poor and disadvantaged."[171] The researchers in this study agree with the opinion expressed by Henry Sigerist and Talcott Parsons that patients usually relinquish autonomy to professional authority in the expectation of competence. In this regard, "informed consent is one of the safeguards that provide protection against exploitation when autonomy is relinquished."[172] The South African study reached the conclusion that in study involving human subjects, "it is… important that consent be truly informed and truly voluntary."[173]

The researchers in Kassena-Nankana study conclude that permission given by local chiefs for study to be undertaken in a local community is comparable to an individual or person getting a *visa entry* into a foreign country or territory. The visa merely allows you entry into a country; it does not commit the visa office to act on your behalf while in the country.[174] When we relate the foregoing analyses to the core issue in the chapter, the argument would be to say that the "multi-step" consent approach helps protect illiterate and vulnerable research subjects from exploitation. In many communal settings in Sub-Saharan Africa, a majority of the local inhabitants are poor and nonliterate people who lack little or no awareness of their rights and risks involved in research or clinical trials. The widespread illiteracy problem in Africa raises a concern about research subjects' understanding of medical research concepts and their potential risks for an effective and voluntary informed decision.[175] The "multi-step" approach

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[170] Ibid, p. 3. It should be remarked again that such community assent does not replace the individual's consent; the chief or village elders only serve as a bridge between the people and investigators.
[171] Karim et al. 1998, p. 640.
[172] Ibid.
[173] Ibid.
[174] Tindana, Kass and Akweongo 2006, p.3.
[175] Frimpong-Mansoh 2007, p. 2.

to informed consent helps in the enlightenment of local leaders and those in the community about the meaning and implications of a given research. This is made possible because researchers use the opportunity of consulting local leaders to educate or explain to them about the goal and purpose of the proposed research. The leaders in turn avail their people of the information provided with regard to the goal, benefits as well as risks involved in research. The "multi-step" approach also serves the interest of researchers as it makes their work easier and protects them from any hostility that may have arisen if permission were not sought.

Participants in the study conducted in the Kassena-Nankana district of Northern Ghana who responded to questions expressed some opinions about informed consent and their taking in part in the study. For the sake of brevity, I will consider only four of the responses: from two local chiefs; and two research participants.

Some views from a local community [176]

All respondents to questions agreed that it was necessary to seek the chief's permission before approaching subjects to volunteer for research. The responses as to whether it is necessary to obtain the chief's permission for research in the community go somewhat like this:

First Chief

> It is necessary. I only sit here and give you permission to enter into the community. It is the people who take part in the studies not me.

Second Chief

> Anyone who says he is participating because   of the chief is not telling the truth. People know their rights.

I consider the responses of two participants also: the first, a male, and the second, a female participant.

Male participant

> When the chief informs us and we don't want to participate, we can refuse. If you agree with the chief

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[176] Tindana, Kass and Akweongo 2006, pp. 3- 4.

> then you can participate, that is when you agree but if
> you don't want he won't force you.

Female participant

> I discussed with my husband and he agreed for me to
> participate and that was why I took part in it.

Verbal vs. written consent

In it original formulation, the principle of voluntary informed consent required that subjects give their voluntary informed consent in a "written form." For example, the Helsinki Declaration (the versions from 1964 to 1996) required the physician or researcher to "obtain the subject's freely-given informed consent, preferably in writing." But cultural sensitivity to international collaborative research suggested a re-wording of this aspect of the guideline; hence the 2004 version of Helsinki now reads thus:

> If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

Like the earlier versions of Helsinki, in its wording, the Nuremberg Code also implies that subjects give their consent in writing; but as I have argued above, this is a requirement that has now been discarded by many ethics guidelines. A 2007 European Commission document, *Ethics for Researchers- Facilitating Research Excellence in FP7* (prepared as part of a traineeship in the Governance and Ethics Unit of the Commission, October 2006- February 2007) acknowledges the role that culture plays in obtaining informed consent in research. According to the EU document, the approach to be adopted in obtaining subjects consent in research "depends on the culture and the traditions of the population concerned. In some communities, the notion of individuality is lacking, written agreements do not exist, or women cannot act in autonomy."[177] The document suggests the following as approaches for the obtaining of informed consent from subjects in a local community: (i) Participation of a linguist for the informed consent, (ii) Presentation of the research project using information technologies (video, power-point presentation, play, etc.), and (iii) Interviews conducted with the participants to ensure that they understand the issues at stake in the research project.[178] All these are to be done in the presence of community representatives who are trained by the

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[177] Pauwels 2007, p. 22.

researches or scientific team; and who would witness the oral process of the consent approval. The document states that where possible, these processes be done in the presence of a lawyer.

Whether or not legal representation is required in the informed consent process is a moot point. The reason is that in local communities in Africa legal representation usually conveys the idea of conflict or litigation between warring parties. Unlike in the West where the legal system is viewed in terms of adjudication of dispute between people (not necessarily enemies), in Africa it is viewed differently. For example, to take a person to court is taken as a declaration of war or a sign of enmity. So, the presence of a lawyer during the informed consent process would be to complicate matters as it would send the wrong signals to local people whose participation researchers wish to elicit in their study. Besides, such legal representation could affect in a negative way the sense of trust which local people place on their leaders. I believe the point is well-made here. What is important here is that the EU document lends weight to my proposal about the appropriateness of a "multi-step" approach to informed consent in a community-oriented culture, like in this case, Sub-Saharan Africa. The "multi-step" approach is sensitive to cultural norms and beliefs, and requires that researchers take local custom into consideration when conducting research in local communities. P. S. Seibert *et al*. propose the concept of "cultural competence" as a method of ensuring that researchers are sensitive to the cultural ethos of local communities in the conduct of research.[179] Cultural competence is defined as developing sensitivity to the *individuality* (or uniqueness) of a cultural group- an "individuality" that is "expressed in the behaviour, attitudes and interpretation of life events" by members of that group.[180] In the context of research ethics, it is this sensitivity to the "individuality" of each culture that the "multi-step" approach is advocating. And since a majority of those who get enrolled (and deserve to be enrolled) in research or clinical trials in Africa, are mostly illiterate village people, the "multi-step" approach is not only concerned with researchers respecting the cultural norms of a community but it also aims at ensuring that the rights of research subjects are respected.[181]

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[178] Ibid, p. 21.
[179] Seibert et al 2002, pp. 143-146.
[180] Rashad et al, p. 397.
[181] Some scholars have suggested that a "thicker" or "social model" of the principle of voluntary informd consent (like the "multi-step" approach) is a culturally sensitive method for implementing the principle of voluntary informed consent in Africa because it has a tendency to protect subjects from potential exploitations and abuses. See, for example, Frimpong-Mansoh 2007, p. 3.

Promoting understanding among subjects

Conducting health care or biomedical research in rural communities can be a formidable task. The reason, as I have mentioned in the chapter already is that in such communities, subjects understanding of the goals of research is often limited, shallow, confused, distorted and inadequate. However, this should not pose too difficult a problem for researchers, for even under these difficult situations, the goal of promoting reasonable understanding is still possible. In the spirit of the "multi-step" approach proposed in the chapter, researchers can use symbols, analogies and familiar concepts to promote understanding among illiterate populations or potential subjects. Beauchamp and Childress make the point that persons understand if they have pertinent and sufficient information about events, such as research goals as well as the risks and benefits involved. In other words, grasping the central facts about research is often sufficient to guarantee understanding.[182] This is the same point that the EU document referred to above also mentions. But in practical terms, how can researchers promote understanding among people who have a limited knowledge base about the goals of scientific research and procedures?

While there could be several ways to promote understanding among subjects, there is one particular approach that could prove helpful in this regard. The approach is that in which researchers express to subjects the goals, benefits or risks of research in both numeric and non-numeric terms or probabilities, and assisting them (subjects) to assign meanings to the probabilities through comparing them with things that are familiar in their local environments, such as the risks involved using cattle to plough the field or using a hoe to till the land.[183] It would be strange, for example, to seek to promote understanding among nonliterate people using as types such things as a computer system or a jet fighter—things that local people are not familiar with in their local environments. A crucial point to be made following the discussion in the chapter on "multi-step" approach to informed consent is that the quality of research is enhanced when it is conducted not only in ways that show sensitivity to local customs but also in accordance with fundamental ethical principles or norms. Regarding the question whether biomedical research/vaccine trials for new drugs should continue to be conducted in rural communities in Africa, my answer remains in the affirmative. My answer is based on the realization that health care and biomedical research help advance human knowledge about the aetiology and prognoses of human diseases. But such knowledge not

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[182] Beauchamp and Childress 2001, p. 88.

only improves our understanding about disease remedy; it also helps, says G ran Hermerén, "to improve our Knowledge [on how] "to prevent, cure and alleviate symptoms."[184] It is for reasons such as the above that I have argued in the thesis that diagnostic and therapeutic medical research and vaccine trials for new drugs in Africa are not only essential but also a moral imperative.

Objections and responses

There are some scholars who argue that the principle of voluntary informed consent cannot be applied cross-culturally. As I showed earlier in the thesis, the reasons given for this type of argument range from the claim that bioethics is a Western phenomenon, to the claim that the principle of voluntary informed consent is rooted in the Western ethos of liberal individualism; or that applying the principle globally will create a picture of the "imperialistic" globalization of Western values. Lisa Newton argues, for example, that it will be the worst form of "ethical imperialism" to assume that "the informed consent requirement, which does indeed serve one (only one) moral principle in the Western setting, is in itself such a universal ethical standard."[185] Another, but much more subtle objection is the one coming from a section of the African continent itself. Rennie and Behets report, for example, that Botswana President, Festus Mogae argues that in areas of the world (like Botswana) with a high prevalence of diseases like HIV/AIDS, the policy of compulsory testing be applied to persons without the "rigmarole" of such ethical concerns as obtaining voluntary informed consent from people, respecting autonomy or observing human rights.[186] The argument here is that insistence on ethical considerations in the face of the disease calamity confronting the African people are "trivial" matters in comparison with the urgency and magnitude of the problem at hand.

But what do we make of these types of objections I have mentioned above? A simple response to the first objection would be to say that bioethical issues and questions transcend cultural boundaries. This is the type of answer Segun Gbadegesin gives when he argues that every culture, including the most traditional one, must of necessity develop a response to the new technologies in health-care systems.[187] According to Edmund Pellegrino, "this response may

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[183] Ibid, p. 89.
[184] Hermerén 1996, p. 11.
[185] Newton 1990, p. 11.
[186] See Rennie and Behets 2006, p. 55.
[187] Gbadegesin 1998, p. 25.

be a rejection or an acceptance of these technologies with their consequences."[188] Another way of refuting the objection would be to point out that the benefits that result from biomedical research and vaccine trials for new drugs, for example, do not accrue to Western people alone but to people across cultural boundaries. The other objection that regards as "trivial" ethical concerns about individual rights and autonomy, can be met with the following response: it is never "ethically justifiable to weaken adherence to human rights" while seeking to deal with a nation's health care challenges.[189] The reason is that once we begin on the slippery slope of setting aside some universally recognized ethical principles or norms such as respect for autonomy or human rights, we never will know when we tip over the slope and slip into the abyss of a complete abandonment of those fundamental ethical values that give human life its meaning. For the fact is: the measure of the ethical worth of a research protocol (or proposal) is not to be merely judged by how well it advances scientific knowledge, but it is also directly related to the degree of importance we attach to human rights and " to the degree of honesty and truthfulness declared" by the proposal.[190]

Finally, the objections to the universal application of the principle of voluntary informed consent can be met with the following response: the history of past abuses of human research subjects (some are highlighted in the thesis), requires that we not only guard jealously the principle of informed consent but that any research protocol that circumvents the application of the principle be characterized as an ethical or professional misconduct. For as Henry Beecher says, while consent in any *fully* informed sense may not be completely realizable, "nevertheless, except, possibly, in the most trivial situations, it remains a goal toward which one must strive for sociologic, ethical and clear-cut legal reasons."[191] As to whether the principle of voluntary informed consent should be made compulsory in research, Beecher says that "there is no choice in the matter."[192]

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[188] Pellenigro, quoted by Gbadegesin1998, p. 25.
[189] Rennie and Behets 2006, p. 55.
[190] Pauwels 2007, p. 20.
[191] Beecher 1999, p. 422.
[192] Ibid.

CONCLUSION

In this thesis, I have argued that the principle of informed consent is an important principle in research ethics and in biomedical or health care research involving human subjects. In biomedical ethical analysis, even though the principle of informed consent is by no means the only principle that there is, it is nevertheless the one that gives contemporary health care ethics "its special character."[193] To uphold the importance in research or health care practice of obtaining a person's informed consent is to acknowledge that the person has right over his or her own life. It is also to recognize the value of person's autonomy--that persons have dignity and self-worth. It is often remarked that the principle of informed consent is rooted in the Western ethos of liberal individualism, which emphasizes individual autonomy over collective decision-making. An autonomous being is defined as someone who chooses or devices a plan for his or her life, rather than having one imposed on him or her by "other people or allowing circumstances to dictate one, and proceeds to live in accordance with that plan."[194] Defined this way, some people argue that the principle of individual informed consent cannot be applied in a community-oriented culture like Sub-Saharan Africa where local customs emphasize collective decision-making over individual choice.

In line with the argument above, some scholars remind us that just as societies are different, so are cultures different. They also reminded us of the need to always respect the cultural values of other societies by being sensitive to their local customs or social norms. But how may we respond to these kinds of arguments? Do differences in cultural norms commit us to ethical relativism—the thesis that there can be no valid cross-cultural standards for evaluating moral conduct? In the thesis, I argued against ethical relativism; I adverted that the call is a reasonable one which urges researchers to be sensitive to local cultures and social conditions in the conduct of research. But I denied that cultural sensitivity necessarily justifies skepticism about the possibility of applying bioethical principles in human subjects research in local cultures such as Africa's.

To give vent to the position held in the thesis about the possibility of applying the bioethical principle of voluntary informed consent in the conduct of research in Africa; and indeed, the necessity as well as urgency in conducting such research, I argued among other things that bioethical issues and problems transcend cultural boundaries. This position is underscored by

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[193] Moreno 1998, p. 688.

the weight of evidence provided in the thesis to the effect that the benefits that result from biomedical research and vaccine trials into new drugs do not accrue to Western people alone but to people across cultures. By parity of reasoning also, it it is argued in the thesis that since the benefits that accrue from biomedical research are enjoyed by peoples across cultures, it follows that the burdens and/or investigations to promote human understanding about the aetiology and remedies for human disease conditions should also be shared by people across all cultural spectrum in the world.

In addressing the issues adumbrated above, the thesis discussed the history and development of the principle of informed consent and argued that to uphold the importance in research or health care practice of obtaining a person's informed consent is to recognize that the person has right over his or her own life. It is also to recognize the value of person's autonomy. Indeed, ethical guidelines were formulated not only to protect subjects from possible abuses but also as an acknowledgment of the value of person's autonomy. In relating the issues of voluntary informed consent and individual autonomy in research, the thesis discussed how in a community-oriented culture like Sub-Saharan Africa's, communal values are likely to affect individual decision-making in research. Community is a very strong factor in African life. Similarly, local customs and cultural values affect the way people make decisions in African communities. However, these factors need neither hinder the individual's capacity to make independent choice nor the conduct of health care research in Africa. For given the nature of the health care challenges facing contemporary African socities, the scientific community needs to intervene by conducting, developing and implementing diagnostic and therapeutic health care research as a way of providing African peoples with relief and hope from the catastrophic disease conditions facing them, especially the HIV/AIDS pandemic.[195] Such an intervention, the thesis argued, is not only an urgent matter but also a moral imperative.

But given the nature of the African society in which communal values and local customs hold sway, how may biomedical research be conducted in ways that are culturally sensitive and ethically sound? In answering this question, in the thesis I proposed the "multi-step" approach to informed consent as the best approach to adopt in implementing the informed consent requirement in the conduct of research in the communal African setting. The "multi-step" approach, the thesis argued, is sensitive to local customs and culture. The approach requires

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[194] Young 1998, p. 441.
[195] Frimpong-Mansoh 2007, p.10.

that researchers or investigators first obtain the permission of community leaders before they reach out to local people to seek their participation in research. The approach also affords investigators the opportunity to educate and enlighten local leaders and their people about the meaning and purpose as well as benefits and risks involved in research. But would the "multi-step" approach not compromise the goal of individual voluntary consent eventually? In the thesis, I answered that rather than compromising voluntary consent, the "multi-step" approach would enhance and solidify individual voluntary consent in research. The many "steps" it took investigators to arrive at the consent process would help remind them of the need to be careful in carrying out their study in accordance with acceptable rules. Besides, in the consent process, local people have been sufficiently enlightened already to detect when investigators are not acting according to procedure. More importantly, the presence of representatives from the local community, the scientific community as well as local ethics review committee will also serve to caution investigators not to exploit the ignorance of local people in the conduct of research. To the question whether the principle of voluntary informed consent should be applied in research conducted in a non-Western environment like Sub-Saharan Africa, the thesis answers in the affirmative. And as to whether the principle of voluntary informed consent should be made compulsory in research, I concurred with Henry Beecher's argument that "there is no choice in the matter."[196]

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[196] Beecher 1999, p. 422.

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