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EXPLORING THE LEGAL REGIME THAT GOVERN PROXY CONSENT IN BIOMEDICAL RESEARCH IN ETHIOPIA

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Abstract

It has become a trend throughout the world for biomedical researchers to rely on proxy consent. Many countries have specific legislation dealing with proxy consent which is not, however, the case in Ethiopia as the Ethiopian law recognizes only two types of consent: implicit consent and explicit consent. These types of consent are not suitable for biomedical research since they can only be made by patients who are competent enough to understand the legal consequences of their decision. Biomedical researchers who want to do clinical trial/research on incompetent patients normally rely on proxy consent. If a person cannot make a decision by himself due to lack of capacity, there must be someone (a proxy/surrogate) who is legally empowered to make a decision for him. The proxy should rely on advance directives/living wills for making a decision. In the absence of advance directive, the proxy needs to have a legal backing while making medical and care decisions on behalf of an incapacitated person. If there is no such legal protection, the proxy and the researcher will obviously face uncertainty. This Article aims at exploring the Ethiopian law on proxy consent and the possibility of introducing new legislation on the same subject matter. To this end, the pertinent domestic and international laws as well as relevant literature are analyzed. It is argued that the current legal system of Ethiopia is deficient in many respects when it comes to the issue of patient-proxy relationship. Therefore, a comprehensive legislation should be introduced for the purpose of regulating proxy consent and other matters that would affect the health and well-being of incapacitated persons.

Keywords: *advance directive, biomedical research, Ethiopian legal system, incompetent patient, proxy consent*

I. INTRODUCTION

The Ethiopian law on best interest of a person mainly covers issues that are related to finance and property matters though best interest decisions can also be associated with medical treatments or participation of a patient in clinical trial. The later one can involve decisions over the life or death of an incapacitated person, which cannot be treated lightly. If a person cannot

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make a decision by himself due to incapacity, there must be someone (a proxy/surrogate) who is legally empowered to make a decision on behalf of the incapacitated person. The proxy should rely on advance directives/living wills for making a decision. In the absence of such directives, the proxy needs to have a legal backing when he makes medical and care decisions on behalf of another person. Otherwise, the proxy will face uncertainty.

A related concern is regarding how the proxy would reconcile his personal beliefs and opinions with that of the incapacitated person. In a deeply religiously conservative society such as Ethiopia, one should not wonder if a proxy refuses certain treatment for incapacitated person for cultural or religious reasons. Thus, one can pose a question: can the proxy refuse medical treatment of the patient because the treatment is contrary to the belief and religion of the proxy or the patient himself? In other words, what if a medical team believes that it is in the best interest of the patient to receive some sort of treatment, but the treatment is contrary to the belief of the person receiving the treatment or the proxy? Still, unanswered question in Ethiopia is the status of advance directives on medical treatment and care of an incompetent patient. It is well recognized in Ethiopia that a person's advance directive on his financial and property matters would be given the priority when it comes to the issue of inheritance and other related matters. However, proxy decisions based on advance directives on health matters have not been given enforceable status and are not specifically addressed in Ethiopia's legal system.

More importantly, when a person appoints a proxy for health related decisions, the type of agreement that needs to be made, the formalities that need to be satisfied, and the court that has jurisdiction to decide on proxy-patient agreement are not settled. This paper will, therefore, examine Ethiopian laws on these issues and it would recommend the type of legislation that needs to be introduced in Ethiopia.

Before discussing about 'best interest' and 'substituted judgment', it may make sense to discuss the meaning of an interest. It would not be a far-fetched idea to argue that a person's interest is a fluid concept that may imply different things at different times and space. A person's wish to live may completely change due to an accident, mental and physical situations, financial situations, family matters or other reasons that can tremendously affect his decision making process. Thus, he may not be in a position to decide in his interest. "Consequently, other persons may at times be better judges of what best promotes our interests than we are."[1] A proxy/surrogate in any legal system cannot, therefore, be unobserved. If a country fails to have a clear law that deals with the interest of an incapacitated person by a proxy, it would certainly fail to fulfill its obligation of protecting its citizens from abuses that threaten their well-being. This is especially true when incapacitated patients are subjected to take part in clinical trials without their prior consent. Every law must clearly show the process of appointing a proxy, the formalities to be satisfied, and the type of factors to be considered by the proxy when he decides. For this reason, understanding the two important principles, i.e. best interest vis-a-vis a substituted judgment, is crucial before adopting any law on this matter. The differences between

[1]DAN W. BROCK, LIFE AND DEATH: PHILOSOPHICAL ESSAYS IN BIOMEDICAL ETHICS 105(Cambridge University Press) (1993).

the two principles and the approach Ethiopia should take in enacting legislation on proxy consent will be discussed in detail below.

The rest of this paper is organized into four sections. Section II discusses the binding and non-binding international instruments on proxy consent. Section III deals with the approaches to proxy consent and the debates surrounding them. Under section IV, the paper examines the place of consent in general and proxy consent in particular by consulting pertinent Ethiopian legislation. It also discusses the legal status of advance ruling, the approaches to proxy consent in Ethiopia, the need to adhere to the legal requirements while entertaining the needs of incapable persons and the relevance of the National Research Ethics Review Guideline in relation to proxy consent. Finally, section V concludes and provides recommendations.

II. INTERNATIONAL HUMAN RIGHTS INSTRUMENTS AND OTHER GUIDING PRINCIPLES ON PROXY CONSENT

The indescribable suffering of prisoners under the Nazi regime in the name of medical research helped adopt the Nuremberg Code[2], which paved the way for the development of international human rights instruments such as the International Covenant on Civil and Political Rights (ICCPR).[3] Under the Nuremberg Code, it is underscored that any scientific research could not be conducted if 'voluntary consent of the human subject' is not obtained.[4] This was reaffirmed by the Helsinki Declaration, which was developed by the World Medical Association.[5] In addition, the Declaration sets out several conditions for conducting scientific research over patients who are incapable of giving informed consent.[6] One of these conditions is the requirement to obtain proxy consent from 'legally authorized representative.'[7] Besides the above instruments, there are also other documents that were adopted in response to unethical scientific research conducted in the last decades.[8]It has to be borne in mind, however, that all of the above instruments are non-binding.

On the other hand, there are many international human rights instruments that make it a crime to conduct a biomedical research without informed consent. Proxy consent for the purpose of biomedical research is not recognized under international human rights instruments as many international human rights instruments require the free will of the incompetent person. The

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[2]Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law. No. 10", Vol. 2, at 181-182. Washington, D.C.: U.S. Government Printing Office, 1949 (Hereinafter, Nuremberg Code). It contains 10 set of principles for human experiment. It was formulated in 1947 in Germany. It is available at https://history.nih.gov/research/downloads/nuremberg.pdf.

[3] Michael A. Grodin, Historical Origins of the Nuremberg Code, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION(George J. Annas and Michael A. Grodin eds., Oxford University Press, 1992).

[4] Nuremberg Code, *supra note* 2, Principle 1.

[5]World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. Bulletin of the World Health Organization, 79 (4), 373 - 374. https://apps.who.int/iris/handle/10665/268312. It was originally adopted in 1964 and revised several times since then. (Herein after Helsinki Declaration).

[6]*Id* , at principles 25-30 of the Declaration.

[7]*Id*, at principle 28.

[8]See Bernard A Fischer, *A Summary of Important Documents in the Field of Research Ethics*, 32(1) SCHIZOPHR BULL69 (2006).

typical example for this is the ICCPR. Article 7 of ICCPR states that "no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment."In particular, "no one shall be subjected without his free consent to medical or scientific experimentation."[9] The second sentence was not present under Article 5 of the Universal Declaration on Human Rights (UDHR). Its inclusion under ICCPR was considered a milestone by legal commentators.[10]

However, Article 7 of ICCPR, on the requirement of informed consent, is absolute, which reflects the disagreement amongst countries on 'the list of permissible exceptions.'[11] 'Free consent', as conceived under Article 7 of ICCPR, will only be guaranteed through informed consent of the person who participates in a biomedical research. Any treatment or participation of a patient in biomedical research without obtaining his informed consent would be considered as a grave violation of that person's fundamental rights. With regard to some category of people who are incapable of giving their 'free will', a commentary to Article 7 of the ICCPR drew attention to the need for "special protection."[12] Be that as it may, "in view of highly personal nature of the right to personal integrity, it appears doubtful whether the consent of the statutory guardian suffices in case of persons not in possession of full mental capacity."[13]

Despite the above misgivings of international human rights instruments, as will be discussed below, proxy consent is designed by many countries as a substitute for 'free will' i.e. informed consent. In addition to the adoption of proxy consent by many countries, informed consent is adopted as binding principle by the International Ethical Guidelines for Biomedical Research Involving Human Subjects (IEGBRIHS).[14] However, in exceptional circumstances, as stipulated under guideline 6 of IEGBRIHS, incompetent patients can participate in biomedical research provided that the participation 'would hold out the prospect of direct benefit' to the patient and proxy consent is obtained.

On the other hand, UN resolution,[15] under principle 11, has upheld similar approaches to the above instruments by insisting on the requirement of informed consent for any type of treatment involving incapable patients. This resolution defines informed consent as a "consent obtained freely, without threats or improper inducements, after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient ..."[16] However, the free will of the patient can be put aside when the exceptional conditions stipulated

[9]Similar messages are also incorporated under Art 15 of Convention on the Rights of Persons with Disabilities (CRPD) Dec. 13, 2006, A/RES/61/106.

[10]MANFRED NOWAK, U.N. COVENANT ON CIVIL AND POLITICAL RIGHTS: CCPR COMMENTARY 188 (N.P. Engel, Germany) (2nd Revised ed., 2005).

[11]*Id*, at 189-91.

[12] CCPR General Comment No 7: Art 7 (Prohibition of Torture or Cruel, Inhuman or Degrading Treatment or Punishment) Adopted at the Sixteenth Session of the Human Rights Committee, on 30 May 1982.and CCPR General Comment No 20: Art 7 (Prohibition of Torture, or Other Cruel, Inhuman or Degrading Treatment or Punishment) Adopted at the Forty-fourth Session of the Human Rights Committee, on 10 March 1992

[13]MANFRED, *supra note* 10, at 190.

[14]COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Geneva, 1993).

[15] Principles for The Protection of Persons With Mental Illness and the Improvement of Mental Health Care Adopted By General Assembly Resolution 46/119 of 17 December 1991.

[16]*Id*, principle 11 (2).

in the resolution are satisfied. Some of the exceptional grounds that are relevant to this article are stipulated under paragraphs 15 and 16 of principle 11. Accordingly, it is possible to involve incompetent patients in biomedical research without obtaining their informed consent "only with the approval of a competent, independent review body specifically constituted for this purpose."[17]

Moreover, if the patient and/or his/her representative are not happy with the decision of the reviewing body, they are given "the right to appeal to a judicial or other independent authority."[18] In general, under IEGBRIHS and the UN resolution, informed consent can be disregarded if: "i) the research is necessary to promote the health of the population represented; ii) this research cannot instead be performed on persons who have the capacity to consent; and iii) adequate procedural safeguards are followed."[19]

III. APPROACHES TO PROXY CONSENT: BEST INTEREST PRINCIPLE AND SUBSTITUTED JUDGMENT PRINCIPLE

A debate on 'best interest' and 'substituted judgment' is based on philosophical[20] and legal foundations. The fundamental difference between the two principles is that while in substituted judgment, "the proxy uses his special knowledge of the patient's preferences to make the decision that the patient would have made had he been competent; "the proxy makes an assessment of the patient's best interests and makes a decision based on that assessment" in the case of best interest principle.[21] Be that as it may, it is not always simple to understand the theoretical distinctions when it comes to making a practical decision. This is due to the fact that the principles are not "always in fact understood in medical ethics, the law or health care practice as applying to distinct groups of cases; the treatment of these two principles is rife with confusion."[22]

Moreover, the debate on which principle is best for an incapable patient is not settled yet. Some argued that both "principles are not competing principles for application in the same cases, but alternative principles to be applied in different cases."[23] According to this argument, the substituted-judgment principle will be applied first when information regarding the patient's wishes and needs are unambiguous due to the availability of ample information. In the absence of one, "only then, surrogate decision-makers for the patient are to select the alternative that is in the best interests of the patient, which is usually interpreted to mean the alternative that most reasonable and informed persons would select in the circumstances."[24] For some scholars,

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[17] *Id*, principle 11 (15).

[18] *Id.*, principle 11 (16).

[19] MELVYN FREEMAN & SOUMITRA PATHARE, WHO RESOURCE BOOK ON MENTAL HEALTH, HUMAN RIGHTS AND LEGISLATION67 (2005).

[20] TOM L. BEAUCHAMP & LAURENCE B. MCCULLOUGH, MEDICAL ETHICS: THE MORAL RESPONSIBILITY OF PHYSICIANS (Prentice Hall) (1984).

[21] A Wrigley, *Proxy Consent: Moral Authority Misconceived*, 33(9) J MED ETHICS 527, 527-31 (2007).

[22] DAN W. BROCK, supra *note* 1, at 290.

[23] *Id*, at 291.

[24] *Id*. See also A.E. BUCHANAN & D.W. BROCK, DECIDING FOR OTHERS: THE ETHICS OF SURROGATE DECISION MAKING, 98-112 (Cambridge, Cambridge University Press) (1990).

however, the principle of substituted judgment is based on 'fictitious' or 'presumed' consent and it should not be the binding principle for that matter.[25] In making decisions on behalf of patients, "we must decide, not what they would have wanted, because we cannot know that, but what is in their best interests."[26] This argument totally rejects the idea of proxy consent. Accordingly, a decision will be made based on informed consent. In the absence of informed consent, medical doctors will have the full autonomy to decide what is best for the patient.[27]

A slightly different version of the above argument is associated with the role proxies are going to play when it comes to making critical decisions. Accordingly, the decision of proxies would be acceptable only if it is not against the advice given by medical professionals. This is called the Beneficence Model[28], which is believed to be the dominant principle prior to the emergence of "human rights, individualism, and the questioning of authority" in the 19th century.[29] This argument relies on the fact that medical professionals are in a better position to make a decisions that is best for the patient. According to this argument, the 'special'[30] knowledge medical professionals possess makes them good decision makers. However, this argument can be attacked from different angles. For one thing, it significantly undermines the role of proxies. With the exception of few circumstances, it is always the case that there is a special bond between a proxy and a patient. Appointment of a proxy is usually based on marital or blood affinity. Thus, the advice and opinion of medical professionals should not be preferred to that of the advice and decision of these categories of people.

Second, having 'specialist' knowledge does not always make a person the best decision maker. Besides the availability of 'specialist' knowledge on certain matters, there can be other factors that affect the decision of a person.[31] The best interest of a patient cannot be promoted by relegating the role of proxies to a secondary status. Doing so would be against the autonomy of a patient, which "has been readily adapted to the setting of medical ethics and recently has been more and more expressed in legal decisions."[32]

Other scholars attack the principle of substituted judgment for completely different reasons. For some, this principle is not accurate in predicting the interest of patients.[33] In connection with care and treatment, researchers have shown that it is not always possible for proxies to accurately predict the type of treatment that is appropriate for a patient that lack capacity. It is found that

[25]Harris J., *Consent And End Of Life Decisions*, 29 (1) J MED ETHICS 10-15 (2003).
[26]*Id*, at 12.
[27]*Id*, at 13.
[28] Tom, *supra note* 20, at 27-35 and 42-46.
[29] Paul R. Johnson, *Patient Autonomy In Decision Making: Recent Trends In Medical Ethics*, 53(2) THE LINACRE QUARTERLY 37, 37-46 (1986).
[30] Mark Komrad, *A Defence of Medical Paternalism: Maximizing Patients' Autonomy*, 9 (I) J MED ETHICS38-44 (1983).
[31]Allen Buchanan, The Physician's Knowledge and the Patient's Best Interest, *in* ETHICS, TRUST, AND THE PROFESSIONS: PHILOSOPHICAL AND CULTURAL ASPECTS, 93-113 (Edmund D. Pellegrino, Robert M. Veatch, and John Langan eds., 1991).
[32] Paul, *supra note* 29, at 38.
[33] D.I. Shalowitz, E. Garrett-Mayer & D. Wendler, The *Accuracy of Surrogate Decision Makers: A Systematic Review*, 166 ARCH INTERN MED 493, 493–497 (2006).

proxies can "predict patients' treatment preferences with only 68% accuracy."[34] Moreover, it was shown that "both patient designation of surrogates and prior surrogate-patient failed to improve surrogate's accuracy".[35] Moreover, the principle is also criticized for being:

> …indeterminate in content and thus offers the surrogate little or no guidance. What the standard does not specify is just how competent one should imagine the patient to be, and what else one ought to envision about the patient's hypothetical outlook and the circumstances surrounding his or her decision-making.[36]

Some researchers have also shown that the lack of clarity of content has forced "many surrogates rely on other factors such as their own best interests or mutual interests of themselves and of the patient …"[37]

To conclude, the two options available to a proxy when there is no advance directive are the best interest standard and the substituted judgment standard. However, as we have seen above, the arguments and counter-arguments are too much to comprehend. It is not easy to generalize them into a couple of categories. One line of argument as advocated by some scholars is whether there is a hierarchical order between the two standards.[38] Despite these controversies, it could be safely concluded that though both principles are not perfect, they help "extend the patient's controls over his or her own health care. This rationale has numbers of important practical implications."[39] That is why the lack of consensus among scholars did not deter countries from adopting either the best interest principle or the substituted judgment standard to determine proxy-patient relationship.

A distinction has already been made between countries that follow 'guardianship model' and others that require 'best interest' of an incapacitated person.[40] The guardianship model requires a court appointed guardian that makes decisions on behalf of the incapacitated person if the decision benefits the incapacitate person.[41] The decisions could relate to "the management of property, healthcare, and personal assistance services."[42]For the 'best interest' model, mostly applied in England and Wales, "the identity of the decision-maker is entirely dependent on the nature of the health and welfare decision to be made and no guardian is appointed with a general authority to make a set of defined decisions."[43]This is because the Mental Capacity Act 2005 makes distinctions between two types of lasting power of attorney: those appointed to make decisions regarding 'acts in connection with care and treatment' and those to make decisions

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[34] *Id.*

[35] *Id.*

[36] L. Broström, M. Johansson & M.K. Nielsen, *What the Patient Would Have Decided: A Fundamental Problem With The Substituted judgment standard*, 10 MEDICINE, HEALTH CARE AND PHILOSOPHY 265, 265–278 (2007).

[37] Elizabeth K. Vig*etal*, Beyond Substituted Judgment: How Surrogates Navigate End-of-Life Decision-Making, 54(11) J AM GERIATRSOC 1688, 1688-1693 (2006).

[38] DAN W. BROCK, *supra note* 1.

[39] Neil M. Lazar, *etal*, *Bioethics for Clinicians: 5. Substitute Decision-Making*, 155(10) CMAJ 1436, 1435-1437 (1996).

[40] Michael C. Dunn, *etal*, *Constructing and Reconstructing 'Best Interests': An Interpretative Examination of Substitute Decision-Making under the Mental Capacity Act 2005*, 29(2) J SOCWELFFAM LAW 118, 177- 133 (2007).

[41] *Id.*

[42] *Id.*

[43] *Id.*

regarding property and financial matters.[44] When proxies make decisions regarding care and treatment, they are required to take into account "the person's past and present" wishes and feelings, and his beliefs and values that are likely to influence his decision. This assessment of best interests looks to what the person lacking capacity would have wanted which will clearly take account of non-medical issues."[45]

In addition to the above factors, a proxy's view of what a patient's wishes might be would not be sufficient to allow her to make a whole range of decisions that would run counter to those the professional care team have already deemed to be the best course of action. Therefore, such factors should be taken into account only if they do not diverge significantly from the factors determining the course of treatment to be taken.[46] All of the above factors are recognized in the Mental Capacity Act 2005 of the UK.

Generally, the above arguments have shown us the difficulty of making decisions on behalf of an incapable person. However, they give additional inputs for the argument that there needs to be a clear legal regime that governs proxy-patient relationship. Otherwise, the 'best interest' of patients can be overlooked by zealous researchers and by proxies who are less interested in the survival of the patient. This is especially true if the proxies are going to benefit financially as a result of the demise of the patient.

IV. EXAMINING ETHIOPIAN LAWS ON CONSENT IN GENERAL AND PROXY CONSENT IN PARTICULAR

A. Consent and Proxy Consent under the Criminal Code and Civil Code of Ethiopia

Prohibition against torture, inhuman and other forms of degrading treatment are incorporated under Articles 18 and 28 of the Federal Democratic Republic of Ethiopia Constitution (FDRE Constitution). Although torture is considered as a crime against humanity, neither the elements constituting torture nor is the definition of the term explicitly provided in the FDRE Constitution. Moreover, the FDRE Constitution does not provide similar provision to that of the second sentence of Article 7 of the ICCPR that deals with the requirement of informed consent for biomedical research.

The intentional/unintentional absence of the second sentence of Article 7 in the FDRE Constitution may be viewed from two angles. On one hand, as it is evident from the many court decisions that are rendered every day, Ethiopian judges rarely refer to international instruments in domestic court decisions. Thus, it would make sense to argue that Ethiopian judges are not in a position to consider the full consequences of violations of Article 7 of the ICCPR. Thus, the Ethiopian legislature erred in leaving out the second sentence of Article 7 of the ICCPR. However, it could also be argued that the legislature's failure to include a similar sentence to that of the second sentence of Article 7 of the ICCPR should not be considered as an excuse for not directly applying the provisions of the ICCPR. This is due to the fact that the ICCPR is one of

[44]Mental Capacity Act 2005 (c.9) UK, See section 5 and section 9 (herein after Mental Capacity Act 2005).

[45] Carolyn Johnston and Jane Liddle, *The Mental Capacity Act 2005: A New Framework For Healthcare Decision Making,* 33 (2) J MED ETHICS 95, 94-97 (2007).

[46] A Wrigley, *supra note* 21, at 531.

the international human rights instruments that are ratified by Ethiopia. Consequently, by virtue of Article 9 of the FDRE Constitution, Article 7 of the ICCPR is directly applicable in Ethiopia. Thus, a biomedical researcher who engages in scientific research without obtaining an informed consent or proxy consent of incapable patients would be held liable.

Moreover, consent is incorporated in different codes of the country. For example, Article 70 of the Criminal Code of Ethiopia[47] states the following:

> a recipient is not liable when any person, having entered into a contract of his own free will without any commercial purposes, donates while alive or causes to be donated after his death, his body, a part of his body or one of his organs to another person for personal use or to a juridical person for appropriate and necessary scientific research or experiment.

Interestingly enough, the above provision deals with the liability of a 'recipient'. But it is not difficult to construe that the donor is not also criminally liable provided that the donation is not for 'commercial purpose'[48] and the 'free will' of the donor is unambiguous. In addition, the provision covers not only donation of a body organ, but also donation of 'his body'. One can argue that a person cannot donate 'his body' that would take effect while the person is alive, and that the only possibility this can happen is if a person participates in biomedical research (that is in a clinical trial).

However the above provision of the Criminal Code contains some constraints for a clinical trial. First, the only consent it recognizes is a contract concluded with the explicit consent of the participant (donor) in a clinical trial. This is because 'free will' of the participant cannot be obtained through implicit consent or proxy consent. Second, it does not enumerate the form of contract that is required for this purpose. Ethiopian law recognizes the validity of a contract that is concluded orally, in written form or through conduct. The provision does not make it clear if medical researchers should require a written contract of a participant in a clinical trial.

To make matters complex, Article 573 (4) of the Criminal Code states that a researcher could face imprisonment from 1up to 10 years if he "carries out scientific or medical examination, research or experiments on a person's body… without his consent or knowledge, or discloses or gives under any conditions to another person such information obtained in this manner". What degree of 'knowledge' of the participant would spare the researcher from a criminal liability? How could we reconcile this requirement with that of the 'free will' under Article 70 of the Criminal Code? In other words, when a clinical trial goes wrong, how could a researcher or his lawyer overcome the proof that the participant has the required 'knowledge' of the clinical trial and its associated consequences? The law does not give us the answer to these questions.

Moreover, the construction of Article 70 and 573 (4) with regard to the requirement of consent is different. In the former one, the 'free will' of the donor or a person that participates in scientific research is required. But Article 573 simply says 'his consent'. 'Free will' is quite

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[47] THE CRIMINAL CODE OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA, Proclamation No.414/2004, 9th of May 2005, Addis Ababa (herein after, CRIMINAL CODE).

[48] Art. 573 (2) (endangering the human body) of the Criminal Code of Ethiopia forbids the selling of body organs for 'money'.

specific and very narrow in its scope as it requires an explicit willingness to participate in a research. Accordingly, "the person concerned must himself or herself declare that he or she consents and consent must be rendered without impermissible external pressure (threat, extortion, etc)."[49] Moreover, this definition implies that "it is not sufficient when the person merely remains passive."[50] Therefore, 'free will' cannot be expressed implicitly for the purpose of Article 70 of the Criminal Code. On the other hand, Article 573 (4) of the Code can be interpreted quite broadly since it simply says 'his consent' which can be implicit or expressed. Moreover, 'his consent' can also be given by his guardian or a person who is legally authorized to make decisions on behalf of an incompetent person. This is technically and legally termed as proxy consent, which is the main focus of this article. To conclude, Article 70 does not allow proxy consent while Article 573(4) can be interpreted broadly to include proxy consent. The question would then be as to how we can reconcile the very different implications and legal consequences of the provisions.

Apart from the above contradictions, the Criminal Code does not explicitly deal with the participation of an incompetent person or a person rendered incapable due to the administration of a drug in a clinical trial. These persons cannot give their 'free will' and they are not expected to have 'knowledge' of the experiment due to their mental condition. As it currently stands, the Criminal Code seems to deny the participation of these groups of people in a clinical experiment that can have tremendous effect on their well-being. Moreover, the current constructions of Article 70 and Article 573 (4) of the Criminal Code would discourage scientific research involving the above persons as researchers could lose their liberty if they are found administering a drug in a clinical trial. Therefore, the possibility of obtaining a valid contract from these persons for the purpose of conducting clinical trial will remain to be the question. In other countries, such as the UK, it is shown that the 'free will' of an incapable person;

> …….must be written, witnessed and lodged with the Office of the Public Guardian. It must also include a certificate stating that the donor understands the purpose … and that no undue pressure has been used to persuade the donor ... This is completed by an independent third party.[51]

The Ethiopian law does not have such kind of stringent requirement nor does it seem to recognize the necessity of similar procedural steps. The current construction of Ethiopian law would face the same criticism as that of the UK law as it has the possibility of encouraging decisions that are "paternalistic, risk averse, subjective, and not wholly incorporating what the person's wishes may be" to be made[52]

Moreover, the law does not specify the court of law having jurisdiction on health matters of incompetent persons although the Criminal Code recognizes the necessity of 'free will' for participation in a clinical trial or donation of body organs. For example, under the Mental Capacity Act of the UK, a court of protection, which has similar power to that of the high court

[49] Manfred, *supra note* 10, at 190.
[50] *Id.*
[51] Carolyn Johnston, *supra note* 45, at 96.
[52] Marshall H, and Sprung S., *The Mental Capacity Act: 10 Years On – The Key Learning Areas For Healthcare Professionals*, 8 DOVE PRESS 29, 29-38 (2018).

of the UK, is empowered to deal with matters related to the health of an incapable person. Thus, the Ethiopia legal system must establish either a specially designated bench or give jurisdiction to the high court of either the state or federal level to entertain similar matters. The researcher prefers the establishment of a separately designated court at state or federal level that deals with health matters of incompetent persons. There is a practice in Ethiopia for the establishment of court benches that deal with certain matters of the law. For example, Ethiopia allows the establishment of regional consumer protection judicial organs and appellate tribunal.[53]As health matters and scientific research on incapacitated persons are very serious issues, they need to be given proper attention and the health and safety of patients must be given utmost priority in any scientific research. The establishment of a designated bench would play an important role in protecting the well-being of incapacitated persons by discouraging unethical scientific researches.

Another very important point that is addressed under Ethiopian law, with a slightly different approach to that of the jurisdiction of other countries, is the definition of an incompetent person. This should be the first thing that needs to be addressed before talking about the relevance of introducing a new legislation on proxy consent. A cursory look into the experience of other countries tells us that any piece of legislation that deals with consent to treatment must begin with the definition of incompetent person. For example, in UK, a person is considered incompetent if he "lacks capacity in relation to a matter if, at the material time, he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of the mind or brain."[54] This definition does not take into account the age, appearance or the current condition and nature of the incompetence (temporary or permanent).[55]The application of Articles 70 and 573 of the Criminal Code would also make it very difficult if biomedical researchers or judges are uncertain with regard to the legal definition of a person's mental status (competence or incompetence).In this regard, it is important to note that the Civil Code of Ethiopia incorporates definition of an incompetent person.

According to Article 339 of the Civil Code, an insane person is defined as one who, as a consequence of his being insufficiently developed or as a consequence of a mental disease or of his senility, is not capable to understand the importance of his actions. The law also stipulates that persons who are feeble minded, drunkards or habitually intoxicated and persons who are prodigals shall, in appropriate cases, be assimilated to insane persons.[56] The later stipulation of the Civil Code is, however, absent in the UK's Mental Capacity Act. For the purpose of biomedical research or a clinical trial, the stipulation in the Civil Code would be controversial since drunkards and habitually intoxicated persons are capable "to understand the information relevant to the decision, to retain that information, to use or weigh that information as part of the process of making the decision, or to communicate his decision (whether by talking, using sign

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[53]*Trade Competition and Consumer Protection of Ethiopia*, Proclamation No. 813/2013, FED. NEGARIT GAZETA, 20th Year No. 28, 21st March 2014, Art 34.

[54] Mental Capacity Act, *supra note* 44, Section 2.

[55]*Id.*

[56]CIVIL CODE OF THE EMPIRE OF ETHIOPIA, Proclamation No. 165/1960, NEGARIT GAZETA, 19th Year No. 2, 5th May 1960, (herein after CIVIL CODE), Art 339. See also Arts 193 and 340 of the same code.

language or any other means)."[57] Thus, any biomedical researcher should not generally assume that these categories of people do not need to be consulted and, in most cases, obtaining an informed consent should be mandatory.

Be the above as they may, conducting assessment on the formation of medical contracts in Ethiopia would give us a different picture from the legal provisions discussed above. Article 2639 of the Civil Code defines medical contract as "a contract whereby a physician undertakes to provide a person with medical care and to do his best to maintain him in good health or cure him, in consideration of payment of a fee." It is vivid from this definition that Article 2639 will not apply to biomedical research. Medical contract can be made "directly between the person in need of medical care and the physician or the medical institution."[58] This Article will be applicable if the patient has the capacity not only to make the contract, but also understand the consequences of the contract as well as the treatment he is going to receive. In fact, the Civil Code also recognizes medical contracts that are "made with the physician or medical institution by a third party, on behalf of the person in need of treatment."[59]Article 2642(2) recognizes the formation of medical contract on behalf of an incompetent person (due to mental or brain illness) or minors.

One line of argument that could be made is that the Civil Code recognizes proxy consent for the purpose of formation of medical contract. This is particularly true if we consider Article 2643 of the Civil Code which deals with the obligation of a patient on whose behalf a medical contract is made by a third party. It imposes an obligation on the patient to pay the medical fees provided that the contract was made by the patient's "father, mother or some other person bound by law or a contract to care for his health."[60] The phrase "some other person bound by law or a contract to care for his health" is interesting for the purpose of this article. It could be argued that this phrase seems to give the impression that a person, other than his next of kin, could be assigned by law or contract to look after the medical needs of an incompetent person. Based on this assessment, we could argue that proxy consent is acknowledged under Ethiopian law. But we could also counter argue that the application of the above phrase is limited to the obligation of a child adopter or institutions that take the obligation to rehabilitate offenders (prisoners) as health matters of minors and protection of interdicted persons are specifically addressed under Article 257 of the Family Code and Article 358 of the Civil Code. Adopters and correctional facilities are obliged by law or contract to take care for persons under their supervision. Both lines of arguments would remain valid until promulgation of a specific legislation or the Cassation bench of the Federal Supreme Court of Ethiopia gives a binding interpretation on this matter.

Moreover, Article 2643 (b) of the Civil Code also imposes an obligation on the patient to pay the medical bills even if the contract was made by any person provided that the patient "was not capable at the time of the contract of expressing his wishes and it was at that moment essential to provide him with treatment." This Article seems to deal with providing treatment during emergencies. Thus, it is not directly relevant to the subject matter of this article.

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[57] Mental Capacity Act 2005, *supra note* 44, Section 3.
[58] See CIVIL CODE, *supra note* 56, Art 2642 (1).
[59] *Id.,* Art 2642(2).
[60] *Id.*, Art 2643 (a).

One thing is, however, certain from the above discussion on the provisions of the Civil Code. This is that the provisions are not relevant to participation of a patient through proxy consent in clinical trial or biomedical research since medical contract is defined as a contract for the provision of medical services by a physician or medical institution.

B. Legal Status of Advance Directives (Living Wills) on Health Matters in Ethiopia

In Ethiopia, there is no specific provision of law that deals with the legal status of advance directives on health matters. The law simply contains general provisions on the status of wills.[61] Moreover, the provisions that deal with the wills made by minors[62] and interdicted persons[63] do not specifically address the issue of advance directives on health matters. They generally deal with the conditions on which minors and legally interdicted persons can make wills. The conditions of a will as provided under Article 857 of the Civil Code make it difficult to conceive the idea that the provisions of the Civil Code dealing with wills would be applicable to health matters. This is due to the fact that Article 857 of the Civil Code deals with wills that are made by deceased persons, and advance directives given by individuals in the context of wills are enforced after the death of the will giver. Hence, such wills are not relevant to the point at issue and certainly not the scope of this research. Therefore, advance directives regarding health matters of incompetent persons are not currently given legal recognition in Ethiopia.

C. Ethiopia's Approach: Best Interest or Substituted Judgment Principle?

The principle in Ethiopia, similar to many other countries, is that "every physical person is capable of performing all the acts of civil life unless he is declared incapable by the law."[64] Exceptionally, a person may be considered incapable due to his age, nationality, mental condition or sentence passed upon him.[65] When it comes to protecting the interest of minors, the Revised Family Code of Ethiopia makes a distinction between a guardian and a tutor. The Civil Code also makes the same distinction with regard to judicially interdicted persons. While minors and judicially interdicted persons should be placed under guardianship for their proper care, they should be placed under a tutor[66] for their financial and property interests.[67] Generally, the father and the mother of a minor are jointly guardian and tutors of their children.[68] They are obliged by law to take care of the physical and mental health of the minor. On the other hand, a tutor's powers are restricted to representation and exercise of the civil rights of a child. Unless there is a contrary decision of a court, parents of a minor are also given the right to represent a child in the exercise of his civil rights.[69] Moreover, as discussed above, insane persons are considered

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[61] *Id*, Art. 857 and the following

[62] CIVIL CODE, *supra note* 56, Art 308. See also REVISED FAMILY CODE, *infra not* 66, Art 295.

[63] *Id*, Art. 368

[64] *Id*, Art. 192 and 196

[65] *Id*, Art. 193-194

[66] FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA THE REVISED FAMILY CODE, Proclamation No. 213/2000, FED NEGARIT GAZETTA, Extra Ordinary Issue No. 1/2000 , 4th July 2000, Addis Ababa (herein after REVISED FAMILY CODE), Art. 216 (1).

[67] *Id.*, Art. 216 (2).

[68] *Id.*, Art. 219 and 231.

[69] *Id*, Art. 219 and 231.

incompetent persons.[70] Persons in this category require a guardian and a tutor appointed by court and any kind of contract concluded by insane persons themselves would be null and void.[71] Moreover, it is stated that the principles applicable to minors are also applicable to incompetent persons (interdicted persons).[72]

As discussed in this Article, Ethiopian law does not seem to follow the 'guardianship model'.[73] The construction of the Civil Code rather resembles that of the UK's Mental Capacity Act 2005 as both make distinctions between two types of representation: those appointed to make decisions regarding 'acts in connection with care and treatment' and those to make decision regarding property and financial matters.[74] Moreover, the overriding principle in many cases regarding family matters and other issues has been 'best interest' of the person concerned. The following table summarizes the application of best interest in the Ethiopian legal system.

Area of Law	Scope	Requirement of Best Interest	Specific article
Criminal Liability	Organ donation	None	Art 70 of the Criminal Code
Criminal Liability	Scientific research	None	Art 573 of the Criminal Code
Family Law	Adoption	Yes	Art 194 (2) of the Revised Family Code
Family Law	Guardianship of a child	Yes	Art 266 of the Revised Family Code
Family Law	Emancipation of a minor	Yes	Art 312 of the Revised Family Code
Contract Law	Hiring of intellectual work	Yes	Art 2636 of the Civil Code

It is also shown above how consent is incorporated regarding the donation of body organs after death. When it comes to proxy consent of incompetent patients, it is discussed in section three that there are two approaches: the best interest and substituted judgment. However, these are concepts that have never been examined in Ethiopia. There is no judicial or legal guide that could help how biomedical researchers need to address the interest of an incompetent person. As discussed above, the only thing the law states is that a person would be legally interdicted and a guardian and a tutor would be appointed by a court when the person is insane. However, the law does not tell us whether the judges need to take into account the best interest or the substituted judgment principle while making guardianship and tutorship decisions. For example, Articles 351 and 354 of the Civil Code state that a judge must consider the interest of the incompetent

[70] CIVIL CODE, Art. 339.
[71] *Id.* Art. 359 and 344.
[72] *Id.,* Art. 358.
[73] Michael, *supra note* 40.
[74] Mental Capacity Act 2005, *supra note* 44, sections 5 and section 9. See also REVISED FAMILY CODE, *supra note* 66, Art. 255-298.

person or that of his/her presumptive heirs when he pronounces judicial interdiction and he must make sure that taking 'such measure is necessary'. Some important issues may arise here. There is no clear rule as to how the judge should evaluate the interest of the interdicted person or that of his/her heirs. There is also no indication of the factors the judge should consider in making the decisions. These are among the vague issues requiring specific rules for their proper implementation.

D. The Need for Strict Adherence to the Law while Looking after the Needs of Incompetent Persons

Legally speaking, the existing laws of Ethiopia do not automatically allow next of akin to make critical decisions regarding health matters of incompetent family member. Thus, both the physicians and the family members of an incompetent person may be held responsible if, for example, a problem occurs during a surgery. The same argument goes to the practice of permitting incompetent person to participate in a biomedical research or a clinical trial. As discussed above, the incompetent person must be legally interdicted by a court before any decision is taken on his behalf. Therefore, physicians and family members should take all the necessary precautions when dealing with proxy consent. The flip side of the argument is that researchers and physicians should not also be held responsible if they refuse to treat a person or allow him to participate in a clinical research that could be beneficial to his health for lack of an informed consent, proxy consent or an advance directive.

The number of people affected by 'non-communicable disease' (such as dementia) is on the rise in developing countries.[75] This number is expected to be 'the most common cause of death by 2030' in Africa.[76] Ethiopia's demographic situation is not going to be any different from the rest of Africa as research indicated that "there was little variation" between countries.[77] Moreover, it can be imagined that there are hundreds of people in Ethiopia that are considered incapable of making decisions for different reasons. Some of them are categorized as minors while the rest are considered incapable due to mental illness (Alzheimer/dementia), old age (senility), terminally ill or in a vegetative state. Except minors, the above categories of people are considered to fall within the definition of insane people according to Article 339 of the Civil Code. For example, in 2017, the World Health Organization reported that many people die every year due to Alzheimer. Alzheimer, which is "listed as the underlying cause of death, accounts for nearly 5,986 deaths in Ethiopia which is about 1 of every 106 deaths in Ethiopia. About 17 people die of Alzheimer each day, an average of 1 death every 88 minutes."[78] This is a significant number and its impact should not be underestimated. Moreover, there is significant

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[75]Rhinnon George-Carey *etal*, *An Estimate of the Prevalence Of Dementia in Africa: A Systematic Analysis*, 2(2) J GLOB HEALTH 1-13 (2012); See also Dementia in sub-Saharan Africa Challenges and opportunities, *available at*https://www.alzheimereurope.org/var/plain_site/storage/original/application/4899128da3f3520aa3024ccbfe0540a0.pdf (Accessed on 6th September, 2019).

[76]*Id.* at 2.

[77]*Id.*, at 1.

[78]Alzheimers/Dementia in Ethiopia, *available at* http://causesofdeathin.com/alzheimers-dementia-in-ethiopia/ (Accessed on 6th September, 2019).

number of people who are terminally ill and bedridden.[79] "In Ethiopia, 80% of the patients were looked after by either their spouse or a child, and 20% of these caregivers had no education or only a primary education."[80] Therefore, their close families provide care and, at the same time, make health related decision on behalf the terminally ill persons.

It has to be noted here that the focus of this research is not on causes of death in Ethiopia. The above data was presented to merely show that a significant number of people cannot make decisions by themselves due to conditions associated with their mental or other severe illness. For any critical decisions with regard to their health matters, they will depend on the help of close families. Their next of kin generally assume that they have the legal and moral authority to make decisions on behalf of their incompetent family member. This is the traditional believe and assumption. Strictly speaking, the current Ethiopian law does not recognize such a general assumption as this can be understood from the close reading of Articles of the Criminal Code, Civil Code and Revised Family Code of Ethiopia. Moreover, let alone a specific law that recognizes proxy consent, there is no law "that establish a default hierarchy of decision makers in the absence of a prior appointment."[81]In some countries, the decision making regarding healthcare of incompetent patients is made by court-appointed guardians.[82]According to the UK's Health Act, as already discussed, guardians may or may not be close relatives of the incompetent person. As far as the guardian is 'a natural person'[83], he could be appointed by a court to look after the well-being of an incompetent person. This approach is very similar to that of the provisions of the Civil Code.[84]Therefore, any attempt of assuming decision making on behalf of an incompetent patient without strictly adhering to the strict procedures specified in the Civil Code would be wrong.[85] In the absence of a strict observation of the law, it would be difficult to see how Ethiopia would meet its international obligation to protect individuals from scientific researches that could end up costing the lives of incompetent persons.

E. The Relevance of the "National Research Ethics Review Guideline"

The FDRE Ministry of Science and Technology (now Ministry of Innovation and Technology) adopted its fifth "National Research Ethics Review Guideline" in 2014.[86] This document serves as guideline for "all types of research that involves human participants."[87]Unlike the Ethiopian laws discussed, the guideline recognizes proxy consent as one form of consent which may be considered as a positive step. The guideline states that "research participants or persons giving proxy consent cannot give full informed consent unless the consent process/form contains adequate information. All such information shall be expressed

[79] Cecilia Sepulveda *etal*, *Quality Care at the End of Life in Africa*, 327(7408) BMJ 209–213 (2003).
[80] *Id,* at 211.
[81] Jennifer Moye*etal*, *Evaluation of the Capacity to Appoint A Healthcare Proxy*, 21(4) AM J GERIATR PSYCHIATRY 327, 326–336 (2013).
[82] See for example, Australia's Guardianship and Administration Act 1993-1.3.2018.
[83] *Id*, section 29.
[84] CIVIL CODE, *supra note* 56, Arts 341-359.
[85] *Id,* Arts 341-359.
[86] NATIONAL RESEARCH ETHICS REVIEW GUIDELINE (5th ed.,2014).
[87] *Id.*, at 19.

in a language that is understandable to the participant."[88] The guideline further cautions "Careful consideration should be made where proxy consent is to be used"[89] for people who have mental or physical disability.

However, it needs to be noted that the guideline is simply a 'guideline' and it cannot be directly enforced by courts. Though the guideline has not received a statutory backing, its relevance to a research involving human beings could not, however, be over-looked.

Moreover, though the guideline recognizes proxy consent, it does not provide any definition of the term at all. In addition, the guideline does not tell us whether researchers need to take into account the best interest or the substituted judgment principle when they employ proxy consent. As it is discussed, a person cannot be considered incompetent unless he is legally interdicted. Therefore, biomedical researchers would be in trouble if they employ proxy consent without following the legal procedure. Nevertheless, this is not addressed in the guideline. It simply says "when informed consent is that of a third party (proxy; parent, next-of-kin, legally authorized representative), the reasons for the indirect approach shall be stated and become part of the protocol."[90] Legally speaking, the current law of Ethiopia does not automatically allow next of kin to make critical decisions regarding health matters of incompetent family member. As a result, researchers and family members could be held legally responsible if they fail to follow the requirement for obtaining an indirect consent. To conclude, the national research ethics review guideline has many loopholes that need to be addressed when it comes to making use of proxy consent in biomedical research.

V. CONCLUSION AND RECOMMENDATIONS

The discussions in this Article have showed that the current Ethiopian legal system does not have a specific law dealing with the issue of proxy consent. Therefore, Ethiopia needs a new and comprehensive legislation that deals with proxy consent and other matters that affect the health and well- being of incapacitated persons. The provisions of the Civil Code, the Family Code and the Criminal Code discussed in this paper are too general and they do not specifically deal with proxy consent. Moreover, none of them incorporate either best interest principle or substitute judgment principle. Advance directives regarding health matters of a patient must be given an enforceable status. As it currently stands, it is not clear if a proxy would refuse or allow certain treatments/participation in a clinical trial based on an advance directive. The researcher believes that there is no moral or legal ground to deny an incompetent person's wishes. As we would enforce the wishes of a deceased person regarding succession matters, we should equally give a legal recognition to the wishes of an incompetent person when it comes to health related issues. For this reason, any new legislation on proxy consent must clearly address this issue. Besides giving an enforceable status, the awareness level of the public regarding making advance directives need to be improved. The government should make use of the main stream media and social medial to increase the level of awareness on the relevance of making advance directives.

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[88] *Id.,* at section 6.13.2.
[89] *Id.,* at section 8.3.5.5
[90] See NATIONAL RESEARCH ETHICS REVIEW GUIDELINE2014,*supra note* 86, section 3.1.2.

The presence of an advance directive could help solve the headache of making health related decisions when one is no longer able to make a decision by himself/herself.

In the absence of an advance directive, the question as to which standard would fit into the Ethiopian legal system needs to be settled in the new legislation. As shown above, the best interest principle is the dominant standard in Ethiopia for family and some contractual matters. Thus, it is tempting to make a hasty conclusion that the same standard should also be adopted with regard to proxy-patient relationship. However, the experiences from other countries show that none of them follow a standard that is purely based on 'best interest' principle or substituted judgment principle. The UK's Mental Capacity Act is a typical example for this as the Act's "pragmatic and holistic approach imposes a rigid, yet rigorous, framework."[91] Moreover, similar approaches are followed in other countries.[92] These laws generally take into account not only an assessment of the patient's best interests and makes a decision based on that assessment (best interest model), but also consideration of the person's present and past wishes, beliefs, values or other factors that may influence his decision if he were a competent person (substituted decision making model). Therefore, Ethiopia's new legislation should closely resemble the practice in other parts of the world. The new legislation must specifically address the vague requirements under Articles 351 and 354 of the Civil Code of Ethiopia. Furthermore, the new legislation must establish a specially designated bench at regional and federal level to entertain proxy-patient relationships.

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[91] Michael, *supra note 40*, at 128.

[92] Guardianship and Administration Act, *supra note* 82, section 5. See also Adults with Incapacity (Scotland) Act 2000, Acts of the Scottish Government (200 asp 4), section 1(4).