

# **SIXTY YEARS AFTER NUREMBERG: THE FALLACY OF INFORMED CONSENT IN BIOMEDICAL RESEARCH.**

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The question of autonomy of a patient in the doctor-patient relationship has undergone a lot of metamorphosis. Whereas the original Hippocratic Oath provided for a paternalistic attitude towards a patient, more recent developments have sought to accord a patient some autonomy. Previously, the attitude of "doctor knows all" led to a situation of "implied consent."<sup>1</sup> The atrocities of the Nazi regime as well as those related to practices of slavery in the US brought to the fore and strengthened the need for informed consent.

A US Commission on Bioethics, while acknowledging the contribution of scientific research in alleviating disease and human suffering states, that such endeavours need not and should not be carried out at the expense of human rights and human dignity<sup>2</sup>. The doctrine of informed consent was elucidated by the Judges at the Nuremberg Trial in 1946 and 1947. Since then, this concept found its way in to the Universal Declaration of Human Rights of 1948 and in other documents that deal with ethics of clinical practice and biomedical research involving human subjects. It is now generally agreed that "whether testing a new medical treatment, interviewing people about their personal habits, studying how people think and feel, or observing how they live within groups, research seeks to learn something new about the human condition"<sup>3</sup> and hence the need for informed consent in all forms of research involving human subjects. The key question deserving discussion is: what is informed consent?

During the reign of the Nazi regime, Jews and citizens perceived as enemies of the state were subjected to experiments which led either to their deaths or to serious disabilities, apparently without their consent. At the end of the trial, the Judges formulated a code now known as the "Nuremberg Code" in which they outlined major conditions for research on human subjects: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any ...ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon

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<sup>1</sup> Bailey, CP (1978). Informed Consent, in: Wecht, CH (ed). *Legal Medicine Annual*, Appleton-Century-Crofts, New York, pp. 273

<sup>2</sup> National Bioethics Advisory Commission: *Ethical and Policy Issues in Research involving human participants*, Bethesda, Maryland, August 2001

<sup>3</sup> National Bioethics Advisory Commission: *Ethical and Policy Issues in Research involving Human Participants*, Bethesda, Maryland, August 2001, p.2

his health or person which may possibly come from his participation in the experiment". Further, "The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment and ...may not be delegated..."

But what exactly is informed consent made of? Informed consent is said to consist of information, comprehension and voluntariness.<sup>4</sup> The information itself must be relevant, accurate and sufficient to enable the participant make a choice.<sup>5</sup> *Sufficient* meaning information which covers "...the aims and methods of the research, the benefits that might reasonably be expected to result to the research participant or to others as an outcome of the research, any foreseeable risks and discomforts, the extent of the investigators responsibility, confidentiality of participant data and arrangements for compensation."<sup>6</sup> *Comprehension* meaning the researcher has a duty to ensure that the explanations given have been understood<sup>7</sup> and lastly *voluntariness* meaning the decision to participate must be given free of coercion and/or undue influence.

In Kenya, the Science and Technology Act<sup>8</sup> does not give explicit guidelines on the question of informed consent. The Anatomy Act<sup>9</sup> has certain provisions on informed consent. At section 5, the deceased must have given consent before his/her demise for the body to be examined anatomically. Section 6 allows the Minister in certain instances to grant such permission for an anatomical examination of a body. The Act provides for an offence punishable by law. The Human Tissue Act<sup>10</sup> requires consent of the deceased or of a person who is in lawful custody of the body for any tissue to be removed. The HIV and AIDS Prevention and Control Bill has express provisions on informed consent. It prohibits testing for HIV without consent excepting: (i) a person who has committed a sexual offence, (ii) a person who is unconscious, and (iii) if a medical practitioner considers it to be in the best interest of the patient. This last exception echoes the paternalistic attitude that has always chained the rights of individuals.

In as much as the experience arising out of the Nuremberg Trials taught us the essence of informed consent in biomedical research, certain conditions prevailing in the world tend to make the concept a fallacy. This leaves a continuous situation of tension between proponents of biomedical research and clinical care of patients on the one hand, and proponents of human rights on the other. Herein lies the fallacy of informed consent.

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<sup>4</sup> Belmont Report: Ethical Principles and Guidelines for the protection of Human Subjects of Research <http://www.med.umich.edu/irbmed/ethics/belmont/BELMONT.HTM>

<sup>5</sup> The Nuffield Council on Bioethics - Report of the Working Party on the Ethics of Research related to Healthcare in Developing Countries, pp 135-136

<sup>6</sup> Guideline 2 of the Council for International Organizations of Medical Sciences 1993: International Ethical Guidelines for Biomedical Research involving Human Subjects.

<sup>7</sup> Belmont Report, p.8

<sup>8</sup> Cap 250 (Rev. 1980)

<sup>9</sup> Cap 249 (Rev 1968)

<sup>10</sup> Cap 252 (Rev 1967)