support such move. The Court did not lay down its previous rulings. Neither did it propound reasons to deviate from them.

Ultimately, therefore, the decision, being a complete departure from established rulings, without sufficient explanation backed by legal basis, the Supreme Court should rethink its ruling and provide sufficient and legally supported reasons for its decision, if not reconsider it altogether. It is essential to recall that the development of the nation rests, in large part, on the assistance provided by the ADB. The *Liang* decision, as it stands, jeopardizes the relations of the Philippines with said international organization, not to mention its relations with other international organizations which play important roles in Philippine development.

Informed Consent in Human Subject Testing: Definition and Status Under International Law

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I. INTRODUCTION

The need to formulate and distribute potentially beneficial drugs to the sick as expeditiously as possible and the need to protect research subjects are competing forces.[1]

Unethical research is possible even when racism, cruelty or greed is absent as motivating factors for the scientists involved in research.[2] *Experience teaches that the "greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."*[3]

A. Background of the Study

Times have changed, but not for the better.

In 1999, nearly 5.6 million people — or over 15,000 a day — became infected with HIV, the virus that causes AIDS. At least 95% of these infections occurred in developing countries. More than 33 million people now live with HIV or AIDS, 23 million of them in Africa. Despite success in pushing back

1. Wendy K. Mariner, *AIDS Research and the Nuremberg Code, in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 286, 294 (George J. Annas & Michael A. Grodin eds., 1992).
2. Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 271 (1997).
3. Olmstead v. United States, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).

the epidemic in some parts of the world, HIV continues its global spread.[4] Not surprisingly, Resolutions from the Security Council[5] and the General Assembly of the United Nations[6] have been issued expressing concern as to the widespread and seemingly uncontainable spread of AIDS.

The race to find a cure for AIDS seems to have no end in sight. Numerous clinical trials are being conducted to test new treatments. In the long term, however, it seems that the best hope for controlling the AIDS epidemic, especially in developing countries, is through the development of vaccines.[7]

The Joint United Nations Programme on HIV/AIDS (UNAIDS) recently released a new set of international ethical guidelines in HIV vaccine research. The "Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research" contains guidance points to be considered in HIV vaccine development activities and vaccine trials. The points are particularly important for developing countries, where many future vaccine trials are expected to take place.[8] These guidelines are an important step towards "our collective responsibility to ensure that all vaccine trials are conducted under the strictest possible ethical and scientific standards."[9]

The guidance document took over two years to formulate. It was based on a series of consultations organized by UNAIDS with representatives from 33 countries. The meetings took place in Brazil, Thailand, and Uganda (countries that participate in HIV vaccine trials), as well as in Geneva and Washington. They involved lawyers, activists, non-governmental organizations, people living with HIV/AIDS, social scientists, ethicists, epidemiologists, health policy specialists, and agencies and institutions involved in vaccine development.[10]

The international ethical guidelines on HIV vaccine research are only one of the numerous ethical guidelines concerning human subject testing which have emerged in the last 50 years, particularly in the last two decades. As international attention has been focused on the abuses that could occur in human experimentation, horrifically highlighted by the Nazi trials conducted in concentration camps,[11] and the Tuskegee syphilis study,[12] different

4. UN AIDS Releases New Guidelines on Ethics of HIV Vaccine Research, *available at* http://www.unaids.org/whatsnew/press/eng/geneva_280200.html (last visited Dec. 28, 1999) [hereinafter Guidelines].
5. U.N. SCOR 4172nd mtg, S/Res/1308 (2000).
6. G.A. Res. 54, U.N. GAOR, 54th Sess., U.N. Doc. A/RES/54/283 (2000).
7. Guidelines, *supra* note 4.
8. *Id.*
9. *Id.*
10. *Id.*
11. *See generally* Alan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, HASTINGS CENTER REPORT (Dec. 21-29, 1978).
12. *Id.*

international organizations have come up with different medical codes and ethical guidelines to govern the conduct of human research.[13]

While there are differences in the ethical principles enunciated in the codes, whether in terms of language or requirements, all the codes are unanimous in at least two requisites. Research involving human subjects is ethical only if: (1) Informed Consent from the subject has been obtained; and (2) the research protocol has been reviewed independently of those who wish to conduct the tests.

Informed Consent lies at the very core of all the ethical principles and guidelines with respect to human subject testing. It is axiomatic that any experiment on a human being should be conducted only after he or she has consented to such. Moreover, this consent must have been obtained *after* the prospective participant has been given information as to what the experiment on him or her would entail. Once both conditions have been met, then Informed Consent has been obtained.

What is Informed Consent, and how did this concept develop? Having evolved from ethical principles, what is its value and status under international law, *i.e.*, is it merely an ethical principle, falling far short of customary norms or international legal standards?

Up until three years ago, some publicists claimed that none of the pertinent documents or instruments on human subject testing embodied a codification of a universal standard, neither did they constitute binding law.[14] However, considering (1) the birth and proliferation of all these ethical principles espousing Informed Consent in human experimentation, and (2) its practice by States, albeit in differing interpretations, can the same conclusion still be reached? Moreover, if Informed Consent *has* attained the status of a custom, how is it defined under international law, *i.e.*, what are the minimum standards?

B. *Significance of the Study*

The pharmaceutical industry is becoming a global enterprise both in marketing prescription drugs and in conducting the human research necessary to establish the safety and efficacy of those drugs.[15] The industry makes a significant

13. *See* discussion Chapter I.A.1, *infra*.

14. *See generally* International Summit Conferences on Bioethics, Towards an International Ethic for Research with Human Being (1987) [hereinafter Towards an International Ethic]. See also *WHO Guidelines on GCP*, Pharmaceutical Bus. News, Feb. 8, 1993, *cited* in Urban, *supra* note 2, at 268.

15. Urban, *supra* note 2, at 245.

contribution to health care, as most important new drugs in the past forty years have come from private pharmaceutical companies.[16]

Human experimentation is a vital aspect of pharmaceuticals research.[17] While new treatments and drugs are usually developed in the laboratory, and then first tested on animals, inevitably, treatments such as vaccines must be tested on humans. There is no other way to ensure their efficacy, for products that work in the test tube and on other animals do not always produce the desired results in the human body.[18]

In the past, medical research on human subjects were conducted in developed countries because of economic and technological resources. Over time this changed. Now research is being conducted in developing countries. Undoubtedly, research in developing countries is necessary due to certain apparent problems: uncontrolled population growth, widespread malnutrition, and the high morbidity and mortality due to communicable diseases.[19] Some of the reasons for the change in venue of testing are laudable, *i.e.*, some health problems are peculiar to certain regions and in order for researchers to understand them, the conditions prevailing must be analyzed; conducting biomedical research in developing countries makes it possible to reduce costs and effectively the price of the treatment itself.[20]

A serious cause for concern, however, is that the move to test in developing nations may have been prompted by the desire to avoid the rules and requirements that are overly complex in the researcher's country of origin. For instance, many Third World countries may not have legal provisions providing for ethical surveillance of biomedical research on human subjects, or if they do, the doctors may not be properly trained.[21] The current regulatory climate in developed nations leaves room for the possibility that pharmaceutical companies and other researchers will be testing drugs on humans in countries

16. SILVERMAN ET. AL., BAD MEDICINE: THE PRESCRIPTION DRUG INDUSTRY IN THE THIRD WORLD 187-88 (1992).

17. Michelle D. Miller, *The Informed-Consent Policy of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Knowledge is the Best Medicine*, 30 CORNELL INT'L L.J. 209, 212 (1997).

18. *Id.*

19. Perla D. Santos Ocampo, *Research on Subjects Incompetent to Consent: Children, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 89 (1974) [hereinafter Ocampo].

20. Diana Serrano La Vertu & Ana Maria Linares, *Ethical Principles of Biomedical Research on Human Subjects: Their Application and Limitations in Latin America and the Caribbean, in* BIOETHICS: ISSUES AND PERSPECTIVES 107 (Susan Schrelle Conner, et al, eds., 1990) [hereinafter La Vertu].

21. *Id.*

where protection for human subjects is non-existent or enforcement is lax.[22] A number of cases suggest that investigators conduct research in developing countries because it is easier to get approval.[23] Another reason why developing countries might be preferred is the decreased exposure to liability, *e.g.*, product liability.[24]

In like manner, the advent of HIV infection and its subsequent dramatic incursion into the sexually active population of countries in both the developed and developing world have provoked many questions that have forced a re-examination of the basic principles and ethical implications of clinical drug assessment. No country in the world has been spared by the AIDS epidemic,[25] and the anxiety to ensure that promising new antiretroviral drugs become accessible to everyone in need of them at the earliest possible opportunity has given rise to pressure for "accelerated approval" by drug regulatory authorities.[26]

The need to determine the status of Informed Consent is further highlighted by the fact that many countries lack domestic regulatory regimes governing human experimentation. Even in countries that have legislation in place, many lack the resources to properly enforce applicable provisions.[27] If Informed Consent is merely an ethical principle, then its status relies predominantly on national regulatory efforts and, on the international level, the enforcement mechanisms created by human rights and humanitarian instruments.[28] On the other hand, if it has attained the status of a custom, then its observance is required regardless of the laws in place in the country where the testing takes place.

The determination of the status of Informed Consent is particularly significant for the Philippines, as it currently has no statute governing the conduct of human experimentation. While the Bureau of Food and Drug requires compliance with the ethical principles enunciated in the International

22. Urban, *supra* note 2, at 270; *See also* Kevin M. King, Note, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 185 (1998).

23. *See* Peter Lurie et al., *Ethical, Behavioral, and Social Aspects of HIV Vaccine Trials in Developing Countries*, 271 JAMA 295, 296 (1994) [hereinafter Lurie]; *See generally* Steven Dickman & Peter Aldhous, *WHO Concern Over New Drug*, 347 SCI. 606 (1990).

24. Lurie, *supra* note 23, at 296.

25. G.A Res. 54, U.N. GAOR, 54th Sess., U.N. Doc. A/RES/54/283 (2000).

26. John Dunne, *Drug and Vaccine Trials: Scientific, Ethical and Legal Considerations*, *in* HIV LAW, ETHICS AND HUMAN RIGHTS 223 (JC Jayasunya, ed., 1995).

27. King, *supra* note 22, at 185.

28. *Id.*

Conference on Harmonization-Good Clinical Practice (ICH-GCP),[29] the requirement merely stems from an administrative regulation. If Informed Consent is a binding obligation under international law, then the Philippines should consider enacting legislation to fully comply with this obligation, as "Government's responsibility for a safe health care environment is undisputed... and [among other things, they have the obligation to ensure the] safety of medical and pharmaceutical technology... which should be in compliance with professional standards."[30]

C. *Theoretical Framework*

The status of Informed Consent under international law can only be determined through a juxtaposition of the principle against Article 38(1) of the Statute of the International Court of Justice (ICJ), the latter being the widely recognized and the most authoritative statement as to the sources of international law.[31] Article 38(1) provides that:

> The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:
>
> (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
>
> (b) international custom, as evidence of a general practice accepted as law;
>
> (c) the general principles of law recognized by civilized nations;
>
> (d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

1. Treaties

The 1969 Vienna Convention on the Law of Treaties defines a treaty as "an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in

29. Nelia P. Cortes-Maramba, *Requirements of Informed Consent of Subjects in the Philippines*, *in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 89 (1974). The ICH-GCP is constituted by members of the drug authorities and the pharmaceutical industry of the European Communities, the USA and Japan, with the aim to harmonize the technical requirements for registration of pharmaceuticals for human use. *See* Chapter I.A.1. *infra*.

30. Other areas of responsibility include quality of health care services and appropriateness of medical care delivery. This responsibility incumbs upon States irrespective whether the healthcare delivery is public or private. Id. at 381-82. Henriette D.C. Roscam Abbing, *The Convention on Human Rights and Biomedicine: An Appraisal of the Council of Europe Convention*, 5 EUR. J. HEALTH L. 5: 377, 381 (1998).

31. *See e.g.*, IAN BROWNLIE, PRINCIPLE OF PUBLIC INTERNATIONAL LAW 3 (4th ed. 1990) *cited in* MALCOLM N. SHAW, INTERNATIONAL LAW (2d ed. 1986).

two or more related instruments and whatever its particular designation."[32] Although no hierarchy was intended by the enumeration of sources in Article 38 (1) of the Statute of the ICJ, the priority given to treaties has been construed to mean that they must be applied to the party at the first instance.[33] Aside from operating as a contract between the State parties, treaties may also create general norms for future conduct of the parties in terms of legal propositions, depending on several factors, including the number of the parties, explicit acceptance of rules of law and the declaratory nature of the provisions.[34]

2. Custom

The Statute of the ICJ defines custom as "evidence of a general practice accepted as law." What is sought is a general recognition among States that a certain practice is obligatory.[35] This phrasing has been criticized because "it is the practice which is evidence of the emergence of a custom."[36] Notwithstanding its phraseology, the definition contains the two most important elements of custom: general practice by States and acceptance as law.[37]

i. State Practice

There are two views on what constitutes State practice. On one hand, State practice may be limited to physical acts.[38] This position finds support in Judge Read's dissenting opinion in the *Anglo-Norwegian Fisheries Case*, in which His Excellency wrote that "[t]he only convincing evidence of State practice is to be found in seizures, where the coastal State asserts its sovereignty over trespassing foreign ships." On the other hand, the more popular view would consider any act, statement, or behavior by a State from which its conscious attitude regarding its recognition of a customary rule can be inferred.[39]

Under the latter view, both the acts and statements or physical and verbal acts of a State constitute state practice. It includes treaties, decisions of

32. Vienna Convention on the Law of Treaties, art. 29, U.K.T.S. No. 58 (1980), Cmnd. 7694; *reprinted in* 1155 U.N.T.S. 331, 8 I.L.M. 679 (1969) [hereinafter Vienna Convention].

33. HENKIN, ET. AL., INTERNATIONAL LAW: CASES AND MATERIALS 679 (1987).

34. BROWNLIE, *supra* note 31, at 12.

35. LAUTERPACHT, THE DEVELOPMENT OF INTERNATIONAL LAW BY THE INTERNATIONAL COURT 368-93 (1958); BROWNLIE, *supra* note 31, at 4.

36. HENKIN, *supra* note 33, at 37.

37. *Id.*

38. D'AMATO, THE CONCEPT OF CUSTOM IN INTERNATIONAL LAW 88 (1971).

39. *See* M. VILLEGER, CUSTOMARY INTERNATIONAL LAW AND TREATIES 4 (1985); Akehurst, *Custom as a Source of International Law*, 47 BRIT. Y.B. INT'L. L. 1, 53 (1974-75) [hereinafter Akehurst].

international and national courts, national legislation,[40] diplomatic correspondence, opinions of national legal advisers, and the practice of international organizations.[41]

State practice as a concept may be further broken down into its three component elements: (1) duration,[42] (2) uniformity or consistency of the practice,[43] and (3) generality.[44]

ii. *Opinio Juris*

State practice, by itself, will not suffice to create a customary rule. It is imperative that the practice stem from a state's belief that there is a legal obligation to do so, and if it were to depart from the practice, it would suffer some form of sanction. In the *North Sea Continental Shelf Cases*, the International Court of Justice expounded on this requirement:

> Not only must the acts concerned amount to a settled practice, but they must also be such, or be carried out in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it... The states concerned must therefore feel that they are conforming to what amounts to a legal obligation. The frequency, or even habitual character of the acts, is not itself enough.[45]

There must be recognition by States of a certain practice as obligatory,[46] or a conception that the practice is required by, or consistent with, prevailing law.[47]

The conviction on the part of States is what is termed *opinio juris sive necessitatis*. It is the presence of this element that distinguishes whether a certain practice is a legal obligation or is merely a product of usage, comity, or morality.[48]

The definition of *opinio juris* depends on the kind of rule created. If the rule, on one hand, imposes a duty, *opinio juris* would be defined as a belief that a certain form of conduct is required by international law. To prove the

40. The term "legislation" was used "in a comprehensive sense.... No form of regulatory disposition effected by a public authority is excluded." 1950 Y.B.I.L.C., II, 368-72.

41. Records of the cumulating practice of international organizations may be regarded as evidence of customary international law with reference to States relations to the organizations. 1950 Y.B.I.L.C., II, 368-72.

42. North Sea Continental Shelf (F.R.G. v. Den.; F.R.G. v. Neth.), 1969 I.C.J. 3 [hereinafter North Sea Cases].

43. Fisheries Jurisdiction Cases (Jurisdiction) (U.K. v. Ire.) 1974 I.C.J. 131.

44. *See* The Paquete Habana, 175 U.S. 677, 700 (1900); North Sea Cases, 1969 I.C.J.

45. North Sea Cases, 1969 I.C.J. at 44.

46. BROWNLIE, *supra* note 31, at 61.

47. *Id.* at 25.

48. *Id.* at 7.

existence of this kind of rule, one must establish the following: (1) that States have acted in a manner required by the alleged rule; (2) that other States have not protested that such acts are illegal; and (3) that States regard the action as obligatory.[49]

In many cases, the Court is willing to assume the existence of *opinio juris* on the basis of evidence of a general practice[50] or a consensus in the literature, or the previous determinations of the Court or other international tribunals.[51] However, in a minority of cases, the Court has adopted a more rigorous approach and has called for more positive evidence of the recognition of the validity of the rules in question in the practice of States.[52]

3. General Principles of Law

Interpretation as to what constitute "general principles of law recognized by civilized nations" has not been unanimous. While some view this provision of the Statute in terms of rules accepted in the domestic law of all civilized States, others see this source as an "intention to authorize the Court to apply the general principles of municipal jurisprudence, in particular of private law, in so far as they are applicable to relations of States."[53] The latter view has been preferred as "it would be incorrect to assume that tribunals have in practice adopted a mechanical system of borrowing from domestic law after a census of domestic systems."[54]

A distinction is also made as to Article 38(1)(c) and "general principles of international law." The latter may refer to the former, but it may also refer to customary law, or to a logical proposition resulting from judicial reasoning on the basis of existing pieces of international law and municipal analogies.[55]

D. Scope and Limitations of the Study

There are numerous issues with respect to Informed Consent in human experimentation; this study will focus on whether populations deemed vulnerable are capable of giving it. Moreover, the issue of Informed Consent as a concept is confined to medical research, *i.e.,* clinical trials and human experimentation rather than medical treatment.

49. Akehurst, *supra* note 39, at 29-30; Lotus case (Fran. v. Turk.), 1927 P.C.I.J. (Merits) (ser. A) No. 10.

50. *See* LAUTERPACHT, *supra* note 35, at 380.

51. *See* Gulf of Maine Case, Judgment of the Chamber, 1984 I.C.J 293-94 ¶ 91-93.

52. BROWNLIE, *supra* note 31, at 7.

53. *Id.* at 16.

54. *Id.*

55. *Id.* at 19.

It has been opined that since experimental drugs are usually taken as part of a treatment protocol, there is often very little practical difference between research and treatment. In medicine, every intervention by a physician can be regarded as an experiment because each person is different, and the exact outcome of medical interventions must therefore remain somewhat uncertain.[56] Further compounding the confusion, the practice of medicine involves a mixture of techniques (the well-proven, the merely historically accepted, and the truly novel) and a mixture of motives (to help the individual, but also to teach the practitioner things of value for future cases).

For purposes of this paper,

> the term *research* designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statement of relationships). Whereas medical practice or treatment uses a proven technique in an attempt to benefit one or more individuals, research studies a (usually novel) technique in an attempt to increase knowledge. It includes clinical trials, which is a carefully designed and executed investigation of the effects of a drug administered to human subjects.[57]

Distinctions between research and therapy are not solely matters of intellectual curiosity; the label "research" carries with it requirements for protocol review.[58] However, patients (and some physicians) see research and participation in human testing as therapy (medical practice designed to benefit individuals).[59]

Research is also further classified into two: therapeutic and non-therapeutic. In non-therapeutic research there may be no apparent benefit for the human subjects, while in therapeutic research at least the experimental group may

56. J. Blumgart, *The Medical Framework for Viewing the Problem of Human Experimentation,* DAEDALUS 98, 248-74 (1969); A.C. Ivy, *The History and Ethics of the Use of Human Subjects in Medical Experiments,* 108 SCIENCE 1-8 (1948).

57. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 341 (15th ed. 1985). Pertinently, the World Health Organization has adopted the following definition of research: "Any proposal relating to human subjects including healthy volunteers that cannot be considered as an element in accepted clinical management or public health practice that involves either: (1) physical or psychological intervention; or (2) collection, storage, and dissemination of information relating to individuals. This definition related not only to planned trials involving human subjects but to research in which environmental factors are manipulated in a way that could place incidentally exposed individuals at undue risk." Frank Gutteridge, et. al., *The Structure and Functioning of Ethical Review Committees, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 206 (1974) [hereinafter Gutteridge].

58. A.M. Capron, *Human Experimentation, in* MEDICAL ETHICS 135, 141 (Robert Veatch, ed., 2nd ed. 1997).

59. Carol Levine, *AIDS and the Ethics of Human Subjects Research, in* AIDS AND ETHICS 90 (Frederic G. Reamer, ed., 1991) [hereinafter C. Levine, *AIDS and Ethics*].

benefit. In therapeutic research, the question arises as to the right of the participant to request placement in the experimental group so that potential benefits may be obtained.[60] For the purpose of this study, Informed Consent is deemed required in both therapeutic and non-therapeutic research as "the line between non-therapeutic research and therapeutic research is a formal distinction lacking substantive support." [61] A person's right to self-determination, and therefore the need for Informed Consent, should not change with the label attached to the bodily invasion, whatever its goal.[62]

E. Organization

This study is divided into five parts. Chapter One is an introduction which provides the theoretical framework for the study. Chapter Two explains Informed Consent: its origins and development, the principles underlying it, and its relation to populations deemed vulnerable and given special protection under international law. Chapter Three consists of a two-pronged analysis: (1) the status of Informed Consent under international law, based on the Sources Doctrine on treaty, custom, and general principles of international law, and the scope of public international law; and (2) how Informed Consent is defined under international law, *i.e.,* what are its minimum standards generally. Chapter Four will contain a summary of the findings and conclusions. Chapter Five contains the author's recommendations.

II. Informed Consent

Ironically, the only Western nation which had a guarantee of research subject's rights before the Nuremberg Code was Germany.[63]

A. Origins and Development

The advances in the field of medical science have not been without its price.

1. History of Informed Consent

i. Development of Ethical Guidelines in Human Research

The Hippocratic Oath is probably the oldest and most universal code of ethics governing the conduct of all doctors all over the world. It states: "I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice..." This is probably the most important line in the Hippocratic Oath. It is thought that many modern

60. James J. Neutens & Laurna Rubinson, Research Techniques for the Health Sciences 30 (2nd ed. 1997).

61. Miller, *supra* note 17, at 210.

62. *Id.*

63. *Id.* at 209.

physicians carry with them the essence of the Hippocratic ethic. They expand it beyond its original literal dietetic application to apply to all forms of medical treatment, in fact, to all behaviors affecting the patient.[64] But while it certainly covers the ethics of basic medical treatment, many believe it inadequate in terms of guiding modern medical research and experimentation. The Hippocratic Oath does not mention consent of the patient as an ethical demand.[65]

The issue of requiring Informed Consent in human experimentation had already appeared as early as the 1930s in the Unites States case of *Fortner v. Koch*,[66] where the Supreme Court of Michigan ruled that doctors could only perform human experimentation with the knowledge and consent of the patient. But it was only in the aftermath of World War II that the legal issues surrounding medical experimentation first came to the attention of the world.[67]

The trials of the Nazi doctors at Nuremberg in 1945 marked a turning point in the modern concern about the ethics of research.[68] The revelation of the experiments performed on concentration camp inmates by Nazi physicians in the name of medical science, dramatically forced the issue of Informed Consent to the attention of the world,[69] and led to the passage of the Nuremberg Code.[70]

The Nuremberg Code is part of the judgment of a U.S. Tribunal against twenty Nazi doctors and three Nazi medical administrators involved in human experimentation in Nazi camps during World War II. The Code details the legal requirements of permissible medical experimentation.[71] The Code

64. Robert M. Veach, *Medical Ethics: An Introduction, in* Medical Ethics 7 (2nd ed. 1997).

65. William J. Curran, *Subject Consent Requirements in clinical Research: An International Perspective for Industrial and Developing Countries, in* Council of International Organizations of Medical Sciences (CIOMS) Protection of Human Rights in the Light of Scientific and Technological Progress in Biology and Medicine, 8th CIOMS Round Table Conference 38 (1974) [hereinafter Curran].

66. Fortner v. Koch, 261 N.W. 762 (Mich. 1935).

67. *See* Carel Ijsselmudein & Ruth Faden, *Research and Informed Consent in Africa—Another Look, in* Health and Human Rights 361 (Jonathan M. Mann, et. al. eds.. 1999).

68. Robert L. Berger, *Nazi Science – The Dachau Hypothermia Experiments,* 322 New Eng. J. Med. 1435-40 (1990) [hereinafter Berger].

69. Maria Woltjen, Note, *Regulation of Informed Consent to Human Experimentation,* 17 Loy. U. Chi. L.J. 507, 509 (1986). Some examples of the experiments conducted include sterilization via irradiation, submersion for hours in ice cold water, injection with malaria or typhus, exposure to mustard gas, and the collection of skulls for racial comparisons.

70. I Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, 181-82 (1950) *reprinted in* Health and Human Rights: A Reader 292 (Jonathan M. Mann et al. eds., 1999) [hereinafter Nuremberg Code].

71. The Code set the absolutely essential prerequisite of a voluntary, competent, informed and comprehending consent for human experiment subjects. Anthony Szczygiel, *Beyond Informed Consent,* 21 Ohio N.U. L. Rev. 171, 194 (1991)

emphasizes the importance of Informed Consent, with the first principle stating that "the voluntary consent of the human subject is absolutely essential."[72] Notwithstanding that the Nuremberg Code has been considered "[t]he most complete and authoritative statement of the law of Informed Consent to human experimentation,"[73] it was not used as a legal standard for medical experimentation in the U.S. until more than twenty five years later.[74]

Highly publicized studies likewise contributed to raising professional and public consciousness of the need to regulate human experimentation. One of the most influential was the Tuskegee syphilis study,[75] where many of the test subjects never had the risks of the study explained to them and hundreds did not know that they were the subjects of an experiment although grave consequences were suffered as a result.[76] Reports of similar ethical violations in other research studies are numerous, as human rights violations in the name of science have been widespread and rampant.[77]

72. Nuremberg Code, *supra* note 70.

73. GEORGE J. ANNAS ET.AL, INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 1 (1977).

74. This delay has been partially attributed to the Tribunal's misunderstanding of the content of standard medical practice relating to human-subjects research. "Although the judges believed that the 'basic principles' of the Nuremberg Code had long been accepted in Western medicine, in actuality the American Medical Association did not fashion guidelines for the conduct of medical research until after the content of the Nazi concentration camp experiments became clear." Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now, in* THE NAZI DOCTORS AND THE NUREMBERG CODE 228 (George J. Annas et.al. eds., 1992) [hereinafter Katz, *Consent Principle*].

75. *See* Brandt, *supra* note 9; The study was conducted by the United States Public Health Service (PHS) in 1932 in Macon County Alabama, to learn more about the natural course of syphilis. The subjects, all black men, were never told that they had syphilis. The doctors only said that they were being treated for "bad blood." In reality, these men were never treated for syphilis. They were given inducements, such as free physical exam, free treatment for minor ailments, and a burial stipend for their survivors, to continue to allow the PHS doctors to draw their blood periodically. As of 1969, at least 28, and as many as 100, of these men has died as a direct result of syphilis, a disease treatable with antibiotics since the 1940s. JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 1-2, 5 (1993).

76. C. Levine, *AIDS and the Ethics, supra* note 59, at 56.

77. For example, placebos were given to 109 military servicemen suffering from streptococcal respiratory infections as a control group, while another group with the disease was treated with Penicillin. In another case, effective treatment for typhoid fever, by administering Chloramphenicol, was withheld from 157 hospital charity patients to determine the relapse rate without such treatment. A third instance of medical experimentation involved institutionalized mentally retarded children who were purposely infected with infectious hepatitis to determine the infectivity of the virus. Other examples include the injecting of "live cancer cells" into twenty-two chronically ill patients without their knowledge; prison inmates testicles' irradiated without their consent; and hospitalized patients injected with plutonium without their knowledge. Henry K. Beecher, *Ethics & Clinical Research,* 274 NEW ENG. J. MED. 1354 (1966), *cited in* Miller, *supra* note 17, at 1.

Since the Nuremberg Code, a great number of international and national rules have been drafted to regulate clinical trials involving human subjects. At the international level reference could be made in particular to Article 7 of the United Nations International Covenant on Civil and Political Rights,[78] the Declaration of Helsinki of the World Medical Association and its subsequent amendments,[79] and the International Guidelines for Biomedical Research Involving Human Subjects adopted in 1993 by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO).[80]

Europe has gone further in terms of regulating clinical research. In 1996, the Council of Europe adopted the Convention on Human Rights and Biomedicine,[81] which entered into force in 1999. This is the first treaty that explicitly sets forth rules for the protection of human subjects in testing. The Commission of the European Union (EU) also proposed in 1997 a European Parliament and Council directive on the approximation of provisions laid down by law, regulation or administrative action relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.[82] Both the Convention and the proposed EU directive were meant to bind the States party to them. They require European countries to adopt specific provisions concerning clinical trials or to adjust their actual legislation.[83]

78. International Covenant on Civil and Political Rights (Dec. 16, 1966), *reprinted in* 6 I.L.M. 368 (1967) [hereinafter ICCPR].

79. World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 and amended in 1975 (Tokyo), 1983 (Venice), 1989 (Hong Kong), and by the 48th General Assembly, Somerset West, Republic of South Africa, Oct. 1996 [hereinafter Declaration of Helsinki].

80. World Health Organization & Council for International Organization of Medical Science, *International Ethical Guidelines for Biomedical Research Involving Human Subjects, reprinted in* ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES 231 (Z. Bankowski & R.J. Levine eds., 1993) [hereinafter CIOMS guidelines].

81. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Council of Europe, European Treaties, *opened for signature* Apr. 4, 1997, *entered into force* October 10, 1999, art. 2, ETS No. 164 [hereinafter CHRB].

82. In 1997, the Commission of the European Union proposed a European Parliament and Council directive on the approximation of provisions laid down by law, regulation or administrative action relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use [Proposed EU Directive on Drug Trials] O.J. 97/C 306/10.

83. Dominique Sprumont, *Legal Protection of Human Research Subjects in Europe,* EUR. J. HEALTH L. 6, 25, 26 (1999).

ii. Pharmaceutical Regulation: the ICH-GCP

The global concern for the protection of human subjects in testing has also branched into the increased and stricter regulation of the pharmaceutical industry. This was a result of the realization that most important new drugs in the past forty years have come from private pharmaceutical companies, [84] and that "the pharmaceutical industry is probably the largest single experimenter with the human subject." [85]

Historically, pharmaceutical regulation was done through national and domestic efforts. As the pharmaceutical industry became a multinational enterprise, and research no longer became a local endeavor but actually crossed boundaries, it became clear that regulation would have to be harmonized. The costs to pharmaceutical companies of duplicative research trials and unnecessary regulation results in higher prices, delays in treatment, or the unavailability of the drug in some markets.[86] But harmonization of regulation, *i.e.*, by adopting a mutual recognition procedure, also creates concern as to the protection of human subjects. It may be the impetus for the conduct of human research in developing countries where protection of human subjects is not so strict, or at the worst, human subjects are not protected at all. Thus, harmonization may result in lower prices and faster availability of the drug, but it should not lead to the exploitation of the populations of developing countries and must ensure the protection of human subjects everywhere.

Good Clinical Practices (GCP) have been established and adopted by different international organizations, as guidelines on good clinical research practice. They are meant to assure that the rights, safety, and well-being of all human research subjects are protected and to enhance the scientific quality of clinical trials and their results. Among the significant ones are the 1995 WHO Guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical product and the 1997 International Conference on Harmonization[87] (ICH)-Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP) between the European Communities, USE and Japan.[88] On this score, it has been noted:

> It is important to realize that the scope of the ICH-GCP goes further than the protection of human research subjects. As stated in its introduction, it implements a thorough system of quality control and quality assurance of clinical trials in order "to facilitate the mutual acceptance of clinical data by the regulatory authorities" in the European Union, Japan, and the United States. One can note that indirectly it also has an influence on the safety and welfare of human research subjects as it prevents the conduct of poorly designed research which could put human research subjects at risk for little or no benefit.[89]

84. SILVERMAN, *supra* note 16, at 188.

85. *See generally* Curran, *supra* note 65.

86. Urban, *supra* note 2, at 245.

87. Sprumont, *supra* note 83, at 27.

88. For an extensive list of the regulation of human research at the international level, *See* "Informal listing of selected international codes, declarations, guidelines, etc. on medical ethics/bioethics/health care ethics/human rights aspects of health," periodically updated by Sev. S. Fluss, c/o CIOMS, WHO, 1211 Geneva 27.

A review of all the documents seeking to guide medical research involving human subjects reveals that the major emphases of the ethics of human subject research are the following: [90]

1. Protecting subjects from risk;
2. Informed consent as a mechanism to ensure voluntary participation;
3. Exclusion of subjects perceived to be particularly vulnerable; and
4. Prior ethical review by a committee including some non-scientists.

Below is a discussion of the principles behind the development of ethical guidelines in research, specifically, that of Informed Consent.

2. Principles of Human Subject Testing: Rights of Test Subjects and Obligations of Researchers.

Medical progress is based on research that necessarily must involve experimentation involving human subjects to improve the management of "diagnostic, therapeutic, and prophylactic" aspects of disease. [91] New forms of treatment rarely lead to dramatic, self-evident advances in medicine. They may be dangerous even if beneficial. Before they can be used with confidence, their value must be adequately established by clinical trials.[92] Almost all, if not all, countries require research on human subjects as a prerequisite to drug approval in an effort to avoid placing potentially harmful products on the market.[93]

The most obvious justifications for any research protocol are its contribution to science and social beneficence, *i.e.*, efficiency and reliability. A review of the documents on human experimentation reveal a consensus that a research protocol must include considerations of the following: (1) respect for persons, (2) beneficence, and (3) justice.[94] Just as it is unethical to place subjects at any risk in a study whose design is so flawed it cannot yield valid data, it is likewise unethical to ignore subjects' welfare and rights to conduct a flawlessly designed study.[95]

89. *Id.* at 28.

90. C. Levine, *AIDS and the Ethics, supra* note 59, at 8.

91. Ocampo, *supra* note 19, at 89.

92. Dunne, *supra* note 26, at 202.

93. Urban, *supra* note 2, at 204.

94. La Vertu, *supra* note 20, at 107.

95. Carol Levine, et. al., *Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS, in* IRB: A REVIEW OF HUMAN SUBJECTS RESEARCH 1 (1991).

i. Respect for Persons: Autonomy and Bodily Integrity[96]

It is significant to note that many of the ethical problems in human subject testing stem from the lack of respect of autonomy (*e.g.*, failure to obtain Informed Consent). Until recently, the idea that individual patients must be respected as autonomous moral decision-makers was foreign to the medical profession.[97] Thus, the different codes of ethics assert that every participant should have sufficient intellectual capacity, give sufficient thought, and know enough about the risks, benefits, and options available.[98]

The principle of Autonomy is premised on the view of an individual as a self-governing being capable of giving shape and meaning to his life. Being autonomous as a person and respecting this autonomy are two different things. It is this principle from which the concept of Informed Consent is primarily based. Generally, it seeks to ensure that each individual participating as a research subject does so with full knowledge and understanding of what is to be done, what are the consequences, and what is the extent of his right to choose not to participate in the research and even to withdraw from it after it has started. It has two categories: (1) elements pertaining to information (communication and understanding of the relevant information); and (2) elements pertaining to consent (voluntary consent and the ability to provide consent).

Respect for persons has two aspects: the respect for the *rights* of the person submitting to the research, and for the *actual person*.[99] It has been argued that individual self-determination should always trump medical progress when the two goals are incompatible. Placing individual autonomy in the ascendant position insures that doctors always respect their patients as people.[100]

ii. Beneficence[101]

This principle demands that the objectives of research should be the promotion of the well-being of human subjects, as provided in the Hippocratic Oath. It implies that in the conduct of research, care must be taken to prevent injury, counteract injury, and otherwise promote the good of the subjects. Corollarily, research must avoid acts that could be harmful or prejudicial. In non-therapeutic research, the researcher focuses upon acquisition of scientific knowledge while therapeutic research concerns itself with the alleviation of

96. *See* La Vertu, *supra* note 20, at 108.

97. Jay Katz, *Informed Consent-Must It Remain a Fairy Tale?,* 10 J. CONTEMP. HEALTH L. & POL'Y 69, 86 (1994) [hereinafter Katz, *Informed Consent*].

98. Nuremberg Code, *supra* note 70, principle 1.

99. La Vertu, *supra* note 20, at 108.

100. Miller, *supra* note 17, at 210.

101. La Vertu, *supra* note 20, at 108.

suffering. Whatever the kind of research, the research subject should not be harmed.

iii. Justice

The principle of justice answers the question of who should receive the benefits of research and suffer its damages.[102] It rests on the premise that equal people should receive equal treatment. There is justice if a person is offered treatment that is fair, due, or deserved; and injustice if there is refusal to offer some benefit to a person entitled to receive it. This principle governs selection of test subjects, *i.e.*, determining whether the real reason for selecting one group of people over another is linked to the type of research itself or to elements that are purely arbitrary or convenient for the investigators.[103]

The justice principle also directs that subjects should be selected "for reasons related to the problem being studied" and not because of their "easy availability, their compromised position, or their manipulability."[104] Thus, the justice principle is of importance to developing countries as it requires a sense of "fairness" in the distribution of the burdens and benefits of research.[105] For example, the preamble of the Convention on Biological Diversity of the United Nations Conference on Environment and Development,[106] signed by 167 countries, promotes the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including... appropriate funding."[107] Further, Article 15 authorizes the signatories to take all necessary steps "to ensure that the benefits of research utilizing genetic resources are shared fairly with the nation of origin."[108]

When a community is called upon to serve as research subjects, the justice principle demands that benefits ought to accrue to that community.[109] But the question has been raised: in countries that have no health care system rich enough or sophisticated enough to distribute an effective vaccine (if one were to be developed) and to monitor the population for efficacy or unknown side

102. *Id.*

103. *Id.*

104. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 5 (1974).

105. Nicholas A. Christakis, *The Ethical Design of an AIDS Vaccine Trial in Africa, in* HASTINGS CENTER REPORT 36 (June-July, 1988) [hereinafter Christakis].

106. 31 I.L.M. 818 (1992).

107. *Id.*

108. *Id.*

109. Rebecca Dresser, *Wanted: Single White Male for Medical Research, in* 22 HASTINGS CENTER REPORT 24, 27 (Jan.-Feb. 1992).

effects, how would the subject populations who tested the vaccine benefit from its development?[110]

3. Minimum Ethical Standards in Vaccine Trials

The application of the above three principles in the conduct of human experimentation has been interpreted to give rise to a reasonable set of minimum ethical standards for vaccine trials regardless of the setting: (1) suitable design and scientific merit; (2) free and, where possible, Informed Consent of the participants; (3) proper counseling regarding avoidance of risky behaviors; (4) the highest standards of risk/benefit analysis; and (5) fair access to any vaccine arising from the research to the populations that participated in its development.[111] These minimum standards may be subsumed under two fundamental requirements to protect the rights and welfare of all subjects:

1. an obligation to present the research protocol to an independent peer review body or ethics review committee for clearance; and
2. a need to obtain freely-given Informed Consent from each person approached to participate in a study, once it has been cleared.

Finally, it should be stressed that the ethical codes are unanimous in asserting the primacy of the welfare of the subject over the interests of science or society.[112] The reason for this non-derogable standard is clear, in light of the numerous violations of human rights that have occurred since the Nuremberg trials, even in developed States,[113] all for the sake of a cure and society's welfare. The fundamental test, therefore, against which all human experimentation should be weighed, is if the rights of each test subject are safeguarded, whatever interest society or science may have in the outcome of the experiment.

C. *Informed Consent as an Ethical principle*

> *The Nuremberg Code and subsequent international codes of ethics concerning scientific research stressed that participation of subjects must be voluntary and informed and that they must be protected against unjustifiable risks.*[114]

110. Christakis, *supra* note 105, at 31-37.

111. *Id.*

112. Declaration of Helsinki, *supra* note 79, art. I(5); CHRB, *supra* note 81; *see also* Nuremberg Code, *supra* note 70, art. 1.

113. *See* United States v. Stanley, 483 U.S. 669, 671 (1987); Jaffee v. United States, 663 F.2d. 1226 (3d Cir. 1981); JONES, BAD BLOOD, *supra* note 75, at 5; Steven Dickman & Peter Aldhous, *WHO Concern Over New Drug,* 347 NATURE 606, 606 (1990); ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT 3 (1995).

114. Berger, *supra* note 68, at 1435-1440.

Informed consent has been defined by the United States Supreme Court as "the giving of information to the patient as to just what would be done and its consequences."[115] It implies a willingness on the part of a prospective subject to take part in a trial after receiving a full description of all proposed interventions, together with an explanation of the objectives, the possible benefits and risks, and assurance of the right to abstain or withdraw from participation at any time without fear or prejudice.[116] The consent requirement is designed to protect the inviolability of the subject[117] and protect his bodily integrity.[118]

Under the Nuremberg Code, Informed Consent is not only the first principle, but it is also one of the few described in absolute terms. "Voluntary consent is .... absolutely essential." As of the Declaration of Helsinki II, Principle 9 states that the requirement of Informed Consent "can be modified in therapeutic clinical research where the subject is also a patient who may receive direct benefit in his or her illness from the experimental treatment or procedure." Principle 5 also provides that if the doctor considers it essential not to obtain Informed Consent, the reasons for this should be stated in the protocol for transmission to the independent committee. Criteria II (3) of the WHO, WMA, CIOMS and other public health groups states, that:

> Potential research subjects should be informed of the objectives of the study including full and clearly intelligible disclosure of the risks of the procedure and the community benefits that may reasonably be expected. Since large field trials pose special problems of communication, appropriate information should be disseminated to communities and to individuals in a variety of ways and well in advance of, as well as during, the trials.

As a principle, Informed Consent involves two significant elements of ethical research. First, Informed Consent is substantive; it is one way to demonstrate respect for the individual's autonomy. Second, Informed Consent is a procedural device for the protection of the subject, which more often than not, tends to promote the interests of the subject.[119]

D. *Informed Consent vis-à-vis Vulnerable Populations*

The principle of Informed Consent in human experimentation raises numerous issues, *e.g.*, what information should be disclosed, what is the level of disclosure, and whether it may be given orally or it should be in writing. The most critical issue involves the question of whether populations deemed vulnerable are

115. Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 67 (1976).

116. Dunne, *supra* note 26, at 214.

117. NEUTENS & RUBINSON, *supra* note 60, at 31.

118. Ian Kennedy, *Patients, Doctors and Human Rights, in* HUMAN RIGHTS FOR THE 1990S: LEGAL POLITICAL AND ETHICAL ISSUES 84 (Robert Blackburn & John Taylor eds., 1991).

119. Urban, *supra* note 2, at 245.

capable of giving it as it has bearing on the status of Informed Consent under international law.

Informed consent requires two things. First, that the research subject possesses the intellectual competence and understanding to provide valid and Informed Consent [CAPACITY].[120] Second, there must be willingness on the part of the prospective subject to take part in the trial after receiving a full description of all proposed interventions, together with an explanation of the objectives, the possible benefits and risks, and most importantly the assurance of the right to abstain or withdraw from participation at any time without fear or prejudice [FREEDOM].[121]

On Capacity. The Nuremberg Code provides that the Informed Consent of the potential test subject is "absolutely essential."[122] Under the Code, individuals lacking the capacity to consent are excluded from the population of potential subjects. But exclusion raises other questions of denial of a potential treatment. Realizing this, the Declarations and the Guidelines, in contrast, attempt to maximize the number of potential subjects. Both instruments discard the unequivocal language of the Code in favor of formulations littered with exceptions, such as proxy consent for those lacking the legal capacity to give their own consent and independent committee permission to conduct therapeutic research without the consent of the subject.[123]

On Freedom. Inherent in the definition of Informed Consent is the principle that the consent of the subject be voluntary.[124] Much discussion about the morality of asking subjects and patients to consent centers not on how informed the subjects are, but on how *free* they are.[125] Freedom here entails freedom of choice – that the subjects are free to choose whether or not to participate and to drop out of the testing at anytime. This choice should only be made by individuals without any overt or subtle coercion.'[126] Informed Consent presupposes *free* consent — that is, prospective test subjects must, in every situation, be able to exercise free power of choice.[127]

120. Dunne, *supra* note 26, at 214.

121. *Id.*

122. The Nuremberg Code, *supra* note 70, art.1.

123. Declaration of Helsinki, *supra* note 79; King, *supra* note 22, at 185.

124. King, *supra* note 22, at 194, *citing* Katz, *The Consent Principle, supra* note 74, at 227.

125. Tom L. Beauchamp, *Informed Consent, in* MEDICAL ETHICS 199 (Robert M. Veatch ed., 1997).

126. F.C. Robbins, *Criteria of Informed Consent in Vaccine Trials, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 212 (1974) [hereinafter Robbins].

127. *See* Nuremberg Code, *supra* note 70.

Based on the above prerequisites of Informed Consent, concern is raised when human subjects are children, prisoners and other individuals defined as vulnerable groups because of the variety of constraints and inducements which effectively remove these individuals' capacity to function autonomously and to make independent choices.[128] Populations that are frequently cited as vulnerable to exploitation include: (i) prison inmates; (ii) the economically and educationally disadvantaged, including tribal and indigenous populations; (iii) military personnel; (iv) children; (v) pregnant women and the unborn; and (vi) the mentally handicapped.[129] These constraints and inducements may be intentionally caused by the physician or the researcher in some situations, but may also be inherent in the situation of illness and economic necessity.[130]

Since International Law itself recognizes the vulnerability of these populations[131] and has provided special consideration and obligations with respect to them, a brief discussion on some of the issues raised in their participation in human testing may be pertinent.

1. Children and Mentally Handicapped Persons

Consistent with the recognition of the fundamental dignity and worth of the child the Convention on the Rights of the Child[132] provides that:

> Article 19
>
> States Parties shall take all appropriate legislative, administrative, social and educational measures to protect the child from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation...
>
> Article 37
>
> States Parties shall ensure that:
>
> No child shall be subjected to torture or other cruel, inhuman or degrading treatment or punishment.

128. Mortimer B. Lipsett, *On the Nature and Ethics of Phase I Clinical Trials of Cancer Chemotherapies*, 248 JAMA 941-42 (1982).

129. King, *supra* note 22, at 194.

130. Beauchamp, *supra* note 125, at 199.

131. E.g. Convention on the Rights of the Child, G.A. Res. 44/25, Annex, U.N. GAOR 44th Sess. Supp. No. 49 at 167, U.N. Doc. A/44/49 (1989), *entered into force* Sept.2 1990 [hereinafter CRC]; Body of Principles for the Protection of All persons under any form of Detention or Imprisonment, U.N. G.A. Res. 43/173, Principle 22 (9 December 1988) [hereinafter Body of Principles]; Declaration on the Protection of All Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452, U.N. GAOR, 30th Sess., Supp. No 34, art 1(2), U.N. Doc A/10034 (1976) adopted December 9, 1975) [hereinafter Declaration from Torture]; Convention on the Elimination of all Forms of Discrimination Against Women, GA Res. 34/180, 1249 U.N.T.S. 13 [hereinafter CEDAW].

132. CRC, *supra* note 131.

As international law treats children as a people warranting extra protection, the use of children as well as those similarly situated, *i.e.*, mentally handicapped persons in human subject experimentation raises some serious concerns. The issue centers on their capacity and freedom to consent. Many believe that children lack the maturity and the capacity to comprehend the testing procedure and to give Informed Consent.[133] In legal terms, they are regarded as incompetent to provide valid consent,[134] and some argue that they should not be subjected to human experimentation absolutely.

2. Women

The growing recognition of the unjust exclusion, oppression, and subordination of women led the General Assembly of the United Nations to adopt the Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW)[135] on 18 December 1979, which entered into force on 3 September 1981. As of 9 December 1999, there were 165 State-parties to the Convention, making it the second most widely accepted international human rights treaty after the CRC. The CEDAW not only recognizes the need for sexual equality, but also notes that "in situations of poverty, women have the least access to food, health, education, training and opportunities for employment and other needs." By Article 12(1), State parties agree that they will "take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning."

Testing on women merits closer inspection to safeguard against discrimination. Pregnant or nursing mothers are also extremely vulnerable test subjects. Not only is it extremely dangerous to test on pregnant women because of the possibility of fetal damage due to testing on the mother,[136] the mother may also be vulnerable to potential coercion due to her physical condition.[137]

3. Prisoners

It has been said that prisoners make up "[a]n ideal cohort of research subjects... They live in standard physical and psychological environment, they have the

133. *See* Ronald Munson, *Intervention and Reflection: Basic Issues, in* MEDICAL ETHICS 249 (Robert Veatch, ed., 2nd ed. 1997).

134. Dunne, *supra* note 26, at 215.

135. GA Res. 34/180, 1249 UNTS 13.

136. J. Farber, *Informed Consent, in* CIOMS PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUNDTABLE CONFERENCE 33 (1974) [hereinafter Farber].

137. C. Levine, *AIDS and the Ethics, supra* note 59, at 89.

flexibility and all the time necessary to participate in long-term experiments, and they can be regularly monitored to ensure compliance with the testing procedure."[138] However, their confinement, coupled with social and economic deprivation, compromise their ability to give consent.[139]

The difficulty with Informed Consent with regard to prisoners was stated by Alvin Bronstein, Director of the National Prison Project, as "[y]ou cannot create ...[a prison] institution in which Informed Consent without coercion is feasible."[140] Likewise, the United States Commission for the Protection of Human Subjects noted that "although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom. The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation."[141] An author observed that subjecting prisoners to testing violates consent standards stating that "how can their consent be 'voluntary' if prisons are inherently coercive institutions?"[142] Thus, one of the Resolutions[143] adopted by the United Nations General Assembly mandates that: "No detained or imprisoned person shall, even with his consent, be subjected to any medical or scientific experimentation which may be detrimental to his health."

III. ANALYSIS

A. Status and Definition of Informed Consent under International Law

1. Sources Doctrine: Classification Under Art. 38 of the Statute of the ICJ

i. Treaty

Half a century has passed since instruments on international human rights, dealing with individual (and social) human rights in general, have been established.[144] To enumerate the more important ones are the United Nations' Universal Declaration of Human Rights,[145] which was passed in 1945, followed five years later by the Council of Europe's European Convention for the Protection of Human Rights and Fundamental Freedoms, as well as the

138. Christakis, *supra* note 105, at 33.

139. National Commission for the Protection of Human Subjects, *Research Involving Prisoners, in* DHEW PUBLICATION NO. (OS) 76-131, 7 (1976) [hereinafter *Research Involving Prisoners*].

140. Alvin Bronstein, *Remarks, in* EXPERIMENTS AND RESEARCH WITH HUMANS: VALUES IN CONFLICT 130-131 (1975).

141. *Research Involving Prisoners, supra* note 139, at 7.

142. Christakis, *supra* note 105, at 33.

143. Body of Principles, *supra* note 131, Principle 22.

144. Abbing, *supra* note 30, at 377.

145. Universal Declaration of Human Rights, G.A. Res. 217, art. 3, U.N. GAOR, 3rd Sess., U.N. Doc. A/810 (1948) [hereinafter UDHR].

UN International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights[146] in 1966.

Concededly, any invocation of the right to health in the above and similar instruments were merely of a general nature and did not explicitly provide for specific rights and obligations with respect to human testing, *i.e.,* the requirement of Informed Consent.[147] Properly viewed, these human rights provisions merely establish the right to bodily integrity.[148] For the most part, they only recognize its general concept, thereby falling short of establishing truly enforceable rights. The provisions are stated in the most general of terms and do not clarify the nonabsolute nature of the right to bodily integrity. They do not establish principles for demarcating legitimate state interests that justify interference with individual bodily integrity. Rather, the effective enforcement of bodily integrity stems from the protections afforded the distinct rights that the concept encompasses, such as the right to life and the right to be free from torture or other forms of cruel, inhuman, or degrading treatment.[149]

As regards the various international codes of ethics for the protection of human subjects in human research,[150] rights of human subjects, including Informed Consent, are actually explicated. But for all its formulation by international organizations, these documents are not treaties and thus, do not have legal force and effect under international law. They remain on the realm of ethical principles and require implementing municipal legislation to make them binding.[151]

It was only on 8 October 1999, when Denmark gave its instrument of ratification, that the first treaty governing human experimentation actually entered into force.[152] The Convention on Human Rights and Biomedicine (CHRB) "is the first internationally-binding legal text designed to protect people against the misuse of biological and medical advances. It aims at preserving human dignity and identity, rights and freedoms, through a series of

146. ICCPR, *supra* note 78.

147. Abbing, *supra* note 30, at 378.

148. *See* African Charter on Human and People's Rights, June 27, 1981, art. 4, Organization of African Unity Doc. CAB/LEG/67/3/Rev.5 (1981), *reprinted in* 21 I.L.M. 59, 60 (1982) [hereinafter African Charter]; American Convention on Human Rights, Nov. 22, 1969, art 5(1), 1144 U.N.T.S. 123, 146 (1978) [hereinafter American Convention]; ICCPR, *supra* note 78; UDHR, *supra* note 145.

149. King, *supra* note 22, at 174-75.

150. *See* Nuremberg Code, *supra* note 70; Declaration of Helsinki, *supra* note 79; CIOMS Guidelines, *supra* note 80.

151. *See* Urban, *supra* note 2, at 273.

152. CHRB, *supra* note 81.

principles and rules,"[153] among them the requirement of Informed Consent that may be freely withdrawn at any time from persons undergoing scientific research in the field of biology and medicine.[154]

The CHRB is the first binding, multilateral Convention dealing squarely with specific substantive and procedural rules governing human experimentation, and "sets out a great number of major principles and rules which signatory States must recognize and incorporate into their domestic law.... [I]t does not, however, prevent a State from giving greater protection vis-à-vis the applications of biology and medicine."[155] But while the CHRB is deemed "a 'universal' instrument, accessible to non-member States of the Council of Europe,"[156] it bears stressing that it is a product of a regional organization, and only those who signed and ratified it are bound. Thus, its impact as a treaty under international law will primarily be only regional.[157]

ii. Custom

Having determined that Informed Consent is not a treaty obligation governing all States, the next step is to look into custom, based on the premise that "[i]nternational law... must be ascertained and administered ... [and w]here there is no treaty and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usage of civilized nations."[158]

The principle of Informed Consent in human experimentation is so axiomatic that proving it as an international customary norm seems unnecessary. That a person must consent, personally or through a representative, to be a subject in any experimentation and that this consent must be based on awareness what it is he is consenting to, appear to be of universal truth. However, it should be noted that not all customs observed by States are deemed as customs under international law. Some of them may actually be just expressions of international morality, comity, or usage, and differentiating these from customary international law requires careful analysis, as:

> It is more difficult to differentiate accurately between international customary law and international morality, international comity and international usage. A possible test is

153. The Convention on Human Rights and Biomedicine Enters Into Force, *available at* http://www.coe.fr/cp/99/419a% 2899%29.html (last visited Apr. 6, 2000) [hereinafter CHRB Enters Into Force].

154. *See* CHRB, *supra* note 81, arts. 5, 15 and 16.

155. CHRB enters into force, *supra* note 153.

156. Abbing, *supra* note 30, at 377.

157. *Id.* at 385; The limited influence of the Convention was explained as partially due to cultural, sociological, and constitutional reasons. *see* Patrick A. Molinari, *The Convention on Human Rights and Biomedicine: A Canadian Perspective,* EUR. J. HEALTH L. 5:349, 352 (1998).

158. *See* The Paquete Habana, 175 U.S. 677, 700 (1900).

> whether, at any specific moment, the subjects of international law who are supposed to be bound by a particular rule of international law, consider the rule in question legally binding or as one which they are prepared to accept merely as a moral duty (international morality), as an act of courtesy (international comity) or as a habit (international usage).[159]
>
> Admittedly, to decide the legal or non-legal character of a rule by reference to the attitude taken towards it by the addressees of the norm is to apply a subjective test. Yet the difficulties arising from this element of uncertainty must not be exaggerated. A fair number of rules of international customary law exist, the legal character of which are not in dispute.[160]

In all instances a legal custom has come into being when it can be demonstrated that States act or fail to act in a certain way because a sense of legally binding obligations has developed.[161] International custom is evidence of a general practice accepted as law, with no requirement or universal acceptance.[162] Thus, it is not the kind of act or omission that determines custom, but the uniformity of practice. If acts or allegations of one State remain isolated or meet strong opposition, or if only a small fraction of the international community exhibits a certain behavior, customary law of universal validity can hardly evolve.[163]

a. State Practice

Between 1980 and 1992, more than 55 countries adopted legislation or took other measures to regulate human experimentation.[164] On the requirement of uniformity, the fact that not all States have actually adopted legislation to regulate human experimentation does not militate against its formation as a custom. Other states which may not have legislation on human experimentation require informed consent in human experimentation. The Philippines, for example, does not have a statute, but the Bureau of Food and Drug requires compliance with the principles enunciated in the ICH-GCP.[165] As established in the *North Sea Cases*, customary law does not need clear and

159. GEORGE SCHWARZENBERGER, A MANUAL OF INTERNATIONAL LAW 4 (5th ed. 1967).

160. *Id.* at 4.

161. *See* The Paquete Habana, 175 U.S. 677, 700 (1900).

162. *Id.*

163. *Id.*

164. Richard J. Kelly et al., *The Regulation of Research on Human Subjects: A Decade of Progress, in* ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES 231 (Z. Bankowski & R.J. Levine eds., 1993).

165. Interview with Dr. Nelia P. Cortes-Maramba, Chairman, Department of Pharmacology, University of the Philippines, in Manila, Philippines (Mar. 13, 2000); Interview with Dr. Sandra Torres, Pfizer Philippines, in Manila Philippines (Mar. 15, 2000).

unequivocal support by all States;[166] a practice does not have to be followed by all States for it to be the basis of a general custom.[167] Only strong opposition to the norm would exclude the formation of new law, as Lauterpacht himself states:

> Assuming that we are confronted with the creation of a new international law by custom, what matters is not so much the number of states participating in its creation and the length of the period within which that change takes place, as the relative importance, in any particular sphere, of states inaugurating the change. In a matter closely related to the principle of the freedom of the seas the conduct of the two principal maritime Powers—such as the Great Britain and the United States—is of special importance. With regard to the continental shelf and submarine areas generally these two states inaugurated the development and their initiative was treated as authoritative almost as a matter of course from the outset.[168]
>
> [Moreover, f]or the purpose of the formation of rules of customary international law, consent [to an emerging norm] is commonly indicated by state practice not in the form of positive statements or other action approving the practice in question, but of acquiescence. This [has been described] as "silence or absence of protest in circumstances which generally call for a positive reaction signifying an objection."[169]

Informed Consent, concededly, has only gained recognition in the last fifty years. But this still fulfills the requirement of duration, as there is no precise length of time during which a practice must exist; the position is simply that it must be followed long enough to show that the other requirements of a custom are met.[170]

b. *Opinio juris sive necessitatis*

As the Court indicates in its judgment in the *North Sea Cases*, the second requirement of custom — acceptance that it is binding in law — is necessary to distinguish it from a rule of international comity, which is a rule based upon a consistent practice in the relations of States which is not accompanied by a feeling of obligation.[171]

The general practice of States, whether through implementing municipal legislation or administrative regulations, clearly shows that States adhere to the principle of Informed Consent.[172] There is also unanimity among publicists that Informed Consent is a precondition to the conduct of human

166. This is more so if only a limited number of States are interested in the matter concerned. D.J. HARRIS, CASES AND MATERIALS ON INTERNATIONAL LAW 411 (5d ed. 1998).

167. *Id.*

168. LAUTERPACHT, *supra* note 35, at 394.

169. *See* HARRIS, *supra* note 166, at 44.

170. *Id.* at 41.

171. *Id.* at 42, *citing* North Sea Cases, *supra* note 42, ¶ 77.

172. *See* Capron, *supra* note 58, at 140; *see* Curran, *supra* note 65, at 12-14; TOWARDS AN INTERNATIONAL ETHIC, *supra* note 14, at 23.

experimentation.[173] While some publicists may argue that Informed Consent has no universal definition and neither are its requirements absolute,[174] no one disputes that it is indispensable in human experimentation.

Even if one or few States should protest such practice, this would still not prevent the Informed Consent from becoming a customary norm. Judge Tanaka, in his dissenting opinion in the *South West Africa Cases, Second Phase*,[175] stated:

> Article 38, paragraph 1(b), of the Statute does not exclude the possibility of a few dissidents for the purpose of the creation of a customary international law and that the contrary view of a particular State or States would result in the permission of obstruction by veto, which could not have been expected by the legislator who drafted said Article.[176]

Treaties also serve as material sources of custom. They can create legal obligations and general norms for the future conduct of the parties.[177]

> In principle they are binding only on the parties, but the number of parties, the explicit acceptance of rules of law, and in some cases, the declaratory nature of the provisions produce a strong law-creating effect at least as great as the general practice considered sufficient to support a customary rule. [178]

The enactment of the CHRB itself may be viewed as a codification of existing norms, or as the latest in a long line of progressive developments in international human rights law regarding human experimentation. That the legal effect of the CHRB is not confined merely to its signatories finds support in the *North Sea Continental Shelf Case*, where Judge Sorensen observed that "a convention adopted as part of the combined process of codification and progressive development of international law may well constitute, or come to constitute the decisive evidence of generally accepted new rules of international law."[179]

Aside from the CHRB, the numerous codes of ethics in human experimentation as well as the United Nations General Assembly Resolutions

173. *See* Urban, *supra* note 2, at 140.

174. Bernard M. Dickens, *Criteria of Adequately Informed Consent, in* MEDICAL EXPERIMENT AND THE PROTECTION OF HUMAN RIGHTS, 12TH CIOMS ROUND TABLE CONFERENCE 220 (1979) [hereinafter Dickens].

175. South West Africa Cases, Second Phase, 1966 I.C.J. 291.

176. *See* HARRIS, *supra* note 166, at 42. On this question of the "persistent objector," the U.S. Restatement reads: "in principle a state that indicates its dissent from a practice while the law is still in the process of development is not bound by that rule even after it matures. Historically, such dissent and consequent exemption from a principle that became a general customary law has been rare." I RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE U.S., ¶ 102, comment 26. (1987).

177. BROWNLIE, *supra* note 31, at 12.

178. *Id.*

179. North Sea Cases, *supra* note 42 (Sorensen, J., dissenting).

on proscriptions of involuntary human experimentation clearly establish the requirement of subjects to give Informed Consent. While these international documents dealing with research trials have been deemed to have little legal effect[180]as they are clearly not treaties, they are still relevant international instruments as they constitute, at the very least, "soft law."[181]

> Although these instruments cannot be considered "full-fledged" rules of international law on the basis of the criteria of the traditional sources, these instruments fulfill at least some, if not a great number, of the criteria required for rules to be considered rules of international law and cannot therefore be simply put aside as non-law.[182]

Specifically, Brownlie opines that the United Nations General Assembly Resolution affirming "the principles of international law recognized by the Charter of the Nuremberg Tribunal and the Judgment of the Tribunal (including the Nuremberg Code)[183] is an example of an important law-making resolution. Though framed as general principles, they provide a basis for the progressive development of the law and the speedy consolidation of customary rules. [184]

Some writers have dismissed the legal significance of the Nuremberg Code, as its principles were said to be largely a reaction to the horrific nature of the crimes against humanity perpetrated by Nazi doctors against Jewish subjects.[185] Admittedly, the Nuremberg Code has never been formally adopted in its entirety as an instrument of international law by the United Nations.[186] The principles were articulated by the military tribunal in absolute terms and this diminished the flexibility and usefulness of the Code's itself as an instrument to govern modern research.[187] Notwithstanding the imperfect nature of the Code's initial formulation of principles, however, its basic principles have had a

180. *See* Urban, *supra* note 2, at 270, *citing* Erwin Deutsch, *Medical Experimentation: International Rules and Practice*, 19 VICTORIA U. WELLINGTON L. REV. 1, 4 (1989).

181. Soft law consists of documents that are not legally binding upon states (and hence are not directly enforceable in courts and tribunals) but that nonetheless may have impact upon international relations, and ultimately, international law, HARRIS, *supra* note 166 at 65. It has been suggested that the main value of international "soft law," which is very important in the field of international economic law, is as a device "to overcome a deadlock in relations between States pursuing conflicting ideological and/or economic aims. They include documents whose legal status under international law is unclear. Seidle-Hohenveldern, 163 HAGUE RECUEIL DES COURS 169, 193 (1979-II).

182. VAN HOOF, RE-THINKING THE SOURCES OF INTERNATIONAL LAW 187-89 (1983).

183. U.N. G. A. Res. No. 95, 2 Dec. 1946 (adopted unanimously), *cited in* BROWNLIE, *supra* note 31, at 15.

184. *Id.*

185. *See* King, *supra* note 22, at 182.

186. *See Id.* at 168; George Annas ,and Michael Grodin, *Medicine and Human Rights: Reflections on the Fiftieth Anniversary of the Doctor's Trial, in* HEALTH AND HUMAN RIGHTS 301 (1999) [hereinafter Annas, *Reflections*].

187. King, *supra* note 22, at 168.

profound impact on the shape and nature of the existing international legal regime concerning human experimentation. That regime consists of humanitarian law (covering issues related to armed conflicts), human rights law (international bill of rights: UDHR, ICCPR, and ICESCR), and ethical standards promulgated by the medical profession.[188]

c. The Link Between Torture and Informed Consent

Bodily integrity is a fundamental right under international human rights law.[189] It refers to an individual's right to exercise sovereignty over his body,[190] and the right to be free from cruel or inhuman treatment.[191] Bodily integrity is intimately linked to an individual's right to self-determination,[192] and these rights are threatened when individuals are denied the right to make free and fully informed decisions regarding whether or not to participate in experimental treatments.[193]

Admittedly the concept of bodily integrity is of a general nature. But its effective enforcement stems from the protections afforded the distinct rights that the concept encompasses,[194] such as the right to life[195] and the right to be free from torture or other forms of cruel, inhuman, or degrading treatment.[196] Thus, while the specific procedural measures embodied in the different ethical guidelines[197] are neither binding nor uniform by themselves,[198] human

188. Annas, *Reflections, supra* note 186, at 302.

189. *See* African Charter, *supra* note 148, art. 4; American Convention, *supra* note 148, art 5(1); UDHR, *supra* note 145, art. 3.

190. King, *supra* note 22, at 174.

191. *See* Kennedy, *supra* note 118, at 84.

192. *See* Katz, *Informed Consent, supra* note 97, at 86.

193. *See* Miller, *supra* note 17, at 244.

194. *See* King, *supra* note 22, at 174-75.

195. *See* African Charter, *supra* note 148, art 4; American Convention, *supra* note 148, art.5; ICCPR, *supra* note 78, art. 6; European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, art. 2, 213 U.N.T.S. 221, 224 [hereinafter European Convention]; UDHR, *supra* note 145, art. 3.

196. *See* Declaration on the Protection of All Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452, U.N. GAOR, 30th Sess., Supp. No. 34, art 1(2), UN Doc. A/10034 (1976) (adopted December 9, 1975) [hereinafter Declaration from Torture]; *see also* African Charter, *supra* note 148, art. 5; American Convention, *supra* note 140, art. 5(2); ICCPR, *supra* note 78, art. 7; European Convention, *supra* note 140, art. 3; UDHR, *supra* note 145, art. 5.

197. *See* Nuremberg Code, *supra* note 70; Declaration of Helsinki, *supra* note 79; CIOMS Guidelines, *supra* note 80.

198. *See* Background Note to U.N. General Assembly Res. No. 37/194: Principles of Medical Ethics, Mar. 9 1983, *reprinted in* PRINCIPLES OF MEDICAL ETHICS 8-9 (CIOMS, Geneva 1983).

experimentation properly falls within the scope of the human rights provisions regarding bodily integrity, the right to life, and the right to be free from cruel, inhuman, or degrading treatment. These principles developed precisely as procedural protections, designed to ensure non-derogation from substantive human rights.[199]

The International Bill of Rights contains a specific prohibition against involuntary human experimentation. Article 7 of the Covenant on Civil and Political Rights[200] provides that "[n]o 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." The importance of the provision stems not only from its explicit prohibition of involuntary human experimentation, but also from its linkage of human experimentation with the concept of bodily integrity, and in particular, the legal protections against cruel, inhuman, or degrading treatment.[201] The drafters of the Covenant probably wished to convey the thought that human experimentation "without his [or her] free consent" constitutes inhuman and degrading treatment akin to "torture," no matter what the motives of the investigator.[202] It is when a doctor disregards a person's bodily integrity that involuntary human experimentation occurs, and with it, some form of torture.

The basic elements of torture include the intentional infliction of severe pain or suffering on an individual by or at the discretion of, public officials in pursuit of some goal.[203] In essence, the proscription against torture treats of the objectification of an individual[204] as an assault on the person's dignity and physical integrity.[205] In this light, involuntary human experimentation is clearly covered by the prohibition against cruel, inhuman, or degrading treatment, for it reduces the individual to nothing more than an object of the researcher or her sponsor.[206]

199. *See generally* Urban, *supra* note 2, at 282.

200. ICCPR, *supra* note 78.

201. King, *supra* note 22, at 173.

202. Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS L.J. 7, 22 (1993).

203. *See* U.N. Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Apr. 18, 1988, S. TREATY DOC. NO. 100-20 (1986), 23 I.L.M. 1027, *amended in* 24 I.L.M. 535 (adopted Dec. 10, 1984); Inter-American Convention to Prevent and Punish Torture, Dec. 9. 1985. Art. 2, AG/RES. 783 (xv-0185), *reprinted in* 25 INT'L LEGAL MATERIALS 519; Declaration from Torture, *supra* note 131, art. 1(1); *see also* PAUL SIEGHART, THE INTERNATIONAL LAW OF HUMAN RIGHTS 162 (1983).

204. Tyrer v. United Kingdom, 26 Eur. Ct. H.R. (ser. A) (1976).

205. *Id.* at 16; *see also* D.J. HARRIS ET AL., LAW OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS 55-89 (1995).

206. King, *supra* note 22, at 178.

It is significant to note that many of the provisions of this Covenant are codifications of existing customary and general principles of international law.[207]

> It is now accepted that respect for a number of the rights protected by the [International Covenant on Civil and Political Rights] has become an international obligation by customary law, for all states, and such obligations are *erga omnes*, obligations to all states. At a minimum, a "state violates international law if, as a matter of state policy, it practices, encourages, or condones" any of the following: genocide; slavery or slave trade; murder or causing the disappearance of a person; *torture or cruel, inhuman, or degrading treatment or punishment;* prolonged arbitrary detention; systematic racial discrimination, or any consistent pattern of gross violations of other human rights. *No government has challenged the existence of a customary law of human rights, or this minimum list.* [208] (emphasis supplied)

Admittedly, the author has doubts whether Article 7 of the ICCPR is a codification of existing customary and general principles, as it was adopted in the early stages of the development of the rights of human subjects. But the link between involuntary human experimentation, *i.e.,* the lack of Informed Consent, to torture and cruel, inhuman and degrading treatment, is now clearly established by the other international documents echoing this link.

> In 1975 the United Nations General Assembly, by consensus, adopted a Declaration on the Protection of All Persons from being subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. The prohibited conduct is "condemned as a denial of the purposes of the Charter of the United Nations and as a violation of human rights and fundamental freedoms proclaimed in the Universal Declaration of Human Rights." In 1984 the General Assembly adopted the text of a Convention on the subject and the Council of Europe has adopted an innovative Convention establishing a European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment...[209]

The different codes of ethical principles passed by various international organizations, as well as the adoption and taking effect of the CHRB strengthens the connection even more. Current international law clearly proscribes torture and other forms of cruel, inhuman, or degrading treatment[210] and the international legal proscriptions create an absolute, non-derogable obligation on the part of governments not to utilize or promote such treatment,[211] *e.g.*, States that are parties to the Convention Against Torture and

207. *See* LOUIS HENKIN, INTERNATIONAL LAW: POLITICS AND VALUES 189-90 (1995) [hereinafter HENKIN, INTERNATIONAL LAW].

208. *Id.* at 189-90.

209. BROWNLIE, *supra* note 31, at 578 (citations omitted).

210. *See id; see also* Andrew McEntee, *Law and Torture, in* A GLIMPSE OF HELL 1, 4 (Duncan Forrest ed., 1996).

211. *See generally* HENKIN, INTERNATIONAL LAW, *supra* note 207, at 189-90.

Other Cruel, Inhuman, or Degrading Treatment, are bound to comply with all obligations that may reasonably arise from that treaty.[212]

iii. General Principles of Law

Consent, at the very least, is undoubtedly an inherent requirement in all contractual obligations, and is deemed as one of the fundamental principles in international law.[213] It is undeniably recognized by all States.[214] Insofar as Informed Consent is derived from the general principle of consent, then the former may be considered as a general principle of international law. The different international instruments and ethical principles serve as evidence of the attitude of States towards customary rules and general principles of law since "law-making treaties, the conclusions of international conferences, resolutions of the United Nations General Assembly, and the drafts adopted by the International Law Commission have a direct influence on the content of the law, an influence the significance of which is not conveyed adequately as material sources."[215]

The general principles of international law can be traced to state practice,[216] and actually overlap with international legal customs. But there is a distinction, as general principles are primarily abstractions from a mass of rules and have been so long and so generally accepted as to be no longer *directly* connected with state practice.[217] Thus, there is justification in declaring Informed Consent as a rule of international law as the principle is found to have been accepted generally based on an examination of the fundamental rule of justice by most nations.[218] "Except for a few controversial areas, there is a fairly wide 'transcultural acceptance' of standards governing ethical research, *i.e.* the need

212. Vienna Convention, art. 26.

213. To rank as a fundamental principle, three conditions are required: (1) they must be exceptionally significant for international law; (2) they must stand out from others by covering a relatively wide range of issues and fall without artificiality under one and the same heading; (3) they must either form an essential part of any known system of international law or be so characteristic of existing international law that if they were ignored we would be in danger of losing sight of a characteristic feature of contemporary international law. If these three tests are applied, seven fundamental principles would emerge, the other six being sovereignty, recognition, good faith, freedom of the seas, international responsibility, and self-defense. SCHWARZENBERGER, *supra* note 159, at 44.

214. BROWNLIE, *supra* note 31, at 19.

215. *Id.* at 11.

216. *Id.*

217. *Id.* at 19.

218. *See* I D.P. O'CONNELL, INTERNATIONAL LAW 10-11 (1965), *citing* In Re Von List, Ann. Dig., 1948 Case No. 215.

for some form of Informed Consent, although many cultural and national differences arise with respect to procedures for their implementation."[219]

2. Public International Law

It may no longer be denied that Informed Consent has characteristics of a customary norm and general principle of law. But does it fall within the scope of public international law? After all, it applies only in human subject testing and other medical interventions, and such have historically been regulated by a State within its domestic jurisdiction.

Article 2, paragraph 7 of the United Nations Charter provides:

> Nothing contained in the present Charter shall authorize the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any State or shall require the Members to submit such matters to settlement under the present Charter; but this principle shall not prejudice the application of enforcement measures under Chapter VII.

This notwithstanding, the domestic jurisdiction of a State is not without restrictions. The legal capacity of every State to control the affairs of its nationals and other persons within its territory is restricted by international law,[220] in view of the international protection of human rights.[221] Organs of the United Nations have taken action on a wide range of topics dealing with the relations of governments to their own people, based on the provision in the charter that "domestic jurisdiction reservation does not apply if the United Nations agency is of the opinion that a breach of a specific legal obligation relating to human rights in the Charter itself has occurred."[222] This domestic reservation has been further reduced by the construction of certain provisions relating to human rights, which are deemed as definite and active legal obligations.[223] Among those resolutions adopted regularly, are resolutions on breaches of human rights, and the right to self-determination under Chapters IX and XI of the Charter.[224]

Issues concerning compliance with international obligations and commitments concerning the rights of persons are matters of legitimate international concern and consequently do not constitute exclusively an

219. Towards an International Ethic, *supra* note 14, at 34.

220. SS Lotus (Fr. v. Tur.) 1927 P.C.I.J. (ser. A) No. 10.

221. RANDELZHOFER, THE UNITED NATIONS CHARTER: A COMMENTARY 76 (Bruno Simma ed., 1994) *see* BROWNLIE, *supra* note 31; Charter of the United Nations, art. 76.

222. BROWNLIE, *supra* note 31, at 554.

223. *Id.* at 294.

224. *Id.* at 554.

internal affair of the respective State.[225] That a State should protect its citizens from testing which does not comply with international standards is an international obligation arising from a fundamental human right enshrined in international conventions.[226]

On another point, the author recognizes that international law has traditionally been regarded as a law made by States principally to govern relations among States.[227] As distinguished from municipal law, international law applies only between entities which can claim international personality, while municipal law is the internal law of States, which regulates the conduct of individuals and other legal entities within their jurisdiction.[228] While there are many domestic concerns that may be of international interest, international law does not address domestic matters.[229] These domestic concerns are deemed within the reserved domain of State activities where the State is not bound by international law.[230] Members of the United Nations are proscribed from intervening in matters within the domestic jurisdiction of other States.[231]

The traditional concept of what properly belongs in public international law has been challenged as unrealistic and unresponsive to the problems facing the international community. "International law in the second half of the twentieth century has been developing in many directions, as the complexities of life in the modern era have multiplied."[232] Events which were once within the exclusive territorial competence of a State, may, as a result of the evolution of international law in human rights and international trade, fall within the jurisdiction of international bodies.[233]

> Perhaps the most important of the revolutions in the dimension of modern international law lies in its steadily expanding scope, in the addition of new subjects to the field of international law. This expansion is due in large measure to the growing number of fields in which all or part of the family of nations cooperate for purposes of international welfare.[234]

225. CSCE Expert Conference on Minorities *reprinted in* HUMAN RIGHTS L. J 332 (1992).

226. *See* Declaration From Torture, *supra* note 131, art 1(2); *see also* African Charter, *supra* note 148, art. 5; American Convention, *supra* note 148, art. 5(2); ICCPR, *supra* note 78, art. 7; European Convention, *supra* note 195, art. 3; UDHR, *supra* note 145, art. 5.

227. HENKIN, *supra* note 33, at xxix.

228. SCHWARZENBERGER, *supra* note 159, at 4.

229. HENKIN, *supra* note 33, at xxix.

230. *See generally* ANNU. DE L'INST. DE DROIT INTERNATIONAL 44, 292 (1952).

231. Charter of the United Nations, art. 2(7).

232. SHAW, *supra* note 31, at 39: "[L]aw reflects the conditions and cultural traditions of the society within it operates... international law is a product of its environment."

233. RANDELZHOFER, *supra* note 221, at 7.

234. HENKIN, *supra* note 33, at 32.

> [W]e must overcome the traditional distinction between public law and private law thinking.... Two of the perspectives in the reordering of international law and understanding of its new dimensions are: (1) the widening of the scope of public international law through inclusion of new subject-matters formerly outside its sphere, and (2) the inclusion, as participants and subjects of international law, of public international organizations and to a less definite extent, of private corporations, and individuals." [235]

The author believes that there are two important reasons why human subject testing in general, and Informed Consent in particular, should properly fall within the ambit of public international law. First, the international community is facing the HIV/AIDS pandemic and other grave and widespread health issues that threaten world population even more than armed conflict. International solutions, cooperation, and regulation are demanded, especially in the conduct of testing. Second, there is a need for international regulation of human experimentation as these serious health issues have led to the increased participation of populations deemed vulnerable, and who are given special protection and status under international law.

i. HIV/AIDS Pandemic

> *A massive study of AIDS in the world begins with three observations: no community or country in the world already affected by AIDS can claim that the spread of HIV has stopped; HIV is spreading and sometimes rapidly spreading to new communities and countries around the world; the epidemic becomes more complex as it matures: the global epidemic is composed of thousands of smaller, complicated epidemics. From these observations, it is clear that the worse is yet to come.*[236]

One of the more recent Resolutions[237] of the United Nations General Assembly on AIDS notes that the epidemic has become such a development crisis in many countries, with devastating consequences for human, social, and economic progress, that the development gains of the past fifty years, including the increase in child survival and in life expectancy, are being reversed.[238] Despite all efforts, the HIV/AIDS epidemic is having a more severe impact than was originally projected. Resources devoted to combating the epidemic at both national and international levels are not commensurate with the magnitude of the problem.

The current global response to AIDS is not enough. Both the Security Council[239] and General Assembly of the United Nations[240] acknowledge that it

235. *Id.* at 32.

236. Peter Söderholm, *AIDS and Multilateral Governance, in* INNOVATION IN MULTILATERALISM 264 (Michael Schechter ed. 1999).

237. G.A. Res. 54/283, 54th Sess., A/RES/54/283 (2000).

238. *Id.*

239. U.N. SCOR 1308 (2000), 4172nd meeting, July 17, 2000.

240. G.A. Res. 54/283, 54th Sess., A/RES/54/283 (2000).

is an international concern requiring coordinated international response. One of the world's most authoritative sources on this epidemic has concluded that the global response to HIV/AIDS has been inadequate and uncoordinated.[241] Inspite of numerous activities on national and international levels to control and prevent the spread of the epidemic, it has been suggested that "relatively little progress has been achieved in terms of preventing the further dispersion of the virus, creating an effective anti-AIDS drug or vaccine, providing basic health care to those already infected, or protecting infected persons from discrimination and persecution."[242]

AIDS has been at the forefront of health issues confronting the international community due to its uniquely devastating impact on all sectors and levels of society. But there are also other diseases that, though not of the same epidemic proportions, are equally serious, *e.g.*, cancer and multiple sclerosis. Clearly, these health issues have such great and widespread impact that transcends borders that they no longer belong within the "exclusive territorial competence of a State." [243]

It is against this backdrop that human experimentation plays such a crucial role and should be deemed to fall under the "steadily expanding scope of modern international law." [244] Testing would not only be a necessary activity in the search for effective treatment, it may also be the only treatment available.

ii. Participation of Vulnerable and Special Populations

A subject of international law is an entity (1) capable of possessing international rights and duties; and (2) which has the capacity to maintain its rights by bringing international claims.[245] If the first condition is not satisfied, the entity concerned may still have legal personality of a restricted kind, dependent on the agreement or acquiescence of recognized legal persons and opposable on the international plane only to those agreeing or acquiescent.[246] Legal persons under this definition, possessing these capacities and immunities, are generally States and, if certain conditions are satisfied, some organizations.[247] While

241. Söderholm, *supra* note 236, at 1, *citing* JONATHAN MANN et. al., AIDS IN THE WORLD 3 (1992).

242. *Id.*

243. RANDELZHOFER, *supra* note 221, at 76.

244. HENKIN, *supra* note 33, at 32.

245. Reparation for Injuries Suffered in the Service of the United Nations 1949 I.C.J. 181; Claim of Mrs. Germaine Mossé (Fr. v. Italy), Commission de Conciliation Franco-Itelliene instituteé en execution del'article 83 du Traite de Paiixavec l'Italie 77 Regles de Droit International Quatriéme fascicule 117, 122-123 (Commission de Conciliation Franco-Itelliene instituteé en execution del'article 83 du Traite de Paiixavec l'Italie Decision Jan. 17, 1953) [hereinafter Reparation for Injuries Case].

246. BROWNLIE, *supra* note 31, at 58.

247. *Id.* at 59.

individuals are traditionally not considered as subjects under international law, there is no general rule that the individual cannot be a subject of international law, and in particular contexts he appears as a legal person on the international plane.[248]

Under international law, children, women, indigenous and cultural minorities, prisoners, and other vulnerable groups who lack autonomy or social power have been granted special protection.[249] Testing on them has traditionally been suspect and sometimes prohibited,[250] as they are perceived to either lack the capacity or the freedom to give Informed Consent. The CHRB for example precludes the use of persons not able to consent to research when research of comparable effectiveness can be carried out on individuals capable of giving consent.[251]

The experience with the AIDS pandemic has forced a reexamination of the traditional ethical thrust to exclude vulnerable persons, as many who were previously considered too vulnerable to be research subjects stand to benefit most from a loosening of reins as to who can participate in clinical trials.[252] Many of those infected with HIV/AIDS are economically disadvantaged, *e.g.*, 90 per cent of the people live in the developing world, particularly Africa,[253] and so participation in clinical trials may be their only chance of treatment. To bar them from participation in research, considering their limited options in treating the disease, is a form of coercion[254]

Another reality is that testing on vulnerable populations is quite practical, efficient, and expedient. The same qualities that render them vulnerable to exploitation, make them "an ideal cohort" of research subjects. They live in standard physical and psychological environments, they have the flexibility and

248. *Id.* at 67.

249. *See* CRC, *supra* note 131, art. 19; African Charter, *supra* note 148; *see also* C. Levine, *AIDS and the Ethics, supra* note 59; Dunne, *supra* note 26, at 215; Farber, *supra* note 136, at 32-33.

250. *E.g., Body of Principles, supra* note 131, Principle 22, which states: "No detained or imprisoned person shall, even with his consent, be subjected to any medical or scientific experimentation which may be detrimental to his health."

251. CHRB, *supra* note 81, art. 17(iii).

252. *See* Robert J. Levine, *The Need to Revise the Declaration of Helsinki: Review of Mother-Infant Transmission Studies on AZT, available at* http://www.med.upenn.edu/%7Ebioethic/Museum/Conway/Ethic2%7E1.HTM (last visited Dec. 30, 1999) [hereinafter Levine, *The Need to Revise*]; C. Levine, *AIDS and the Ethics, supra* note 59 at 79-89.

253. G.A. Res., 54th session, A/RES/54/283, adopted Sept. 14, 2000.

254. Lasagna, *Discussion, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 218 (1974).

all the time necessary to participate in long-term experiments, and they can be regularly monitored to ensure compliance with the testing procedure.[255]

Clearly, these vulnerable populations cannot be excluded from human subject testing. But precisely because they are vulnerable, then the special rights and protections granted to them under international law demand international regulation of human experimentation.

iii. Not an expansion of *Erga Omnes* Obligations

Obligations *erga omnes* are concerned with the enforceability of norms of international law, the violation of which is deemed to be an offense not only against the State directly affected by the breach, but also against all members of the international community.[256] Every State has a legal interest to enforce obligations *erga omnes*[257] a breach of which injures all States.[258] This includes the obligation to respect basic human rights.[259] Consequently, it has been posited that every State possesses the right to bring an action against a violating State.[260]

The majority judgment of the International Court in the Barcelona Traction case (Second Phase),[261] distinguished between obligations of States arising vis-à-vis one another, and the obligations towards the international community as a whole. The Court held that "[S]uch obligations derive, for example, in contemporary international law, from the outlawing of acts of aggression, and of genocide, as also from the principles and rules concerning the basic rights of the human person, including protection from slavery and racial discrimination."

255. Christakis, *supra* note 105, at 33.

256. *See* P. Malanczuk, *Countermeasures and Self-defense in the ILC's Draft Articles on State Responsibility, in* UN CODIFICATION 231; B. Simma, *Does the UN Charter Provide an Adequate Legal Basis for Individual or Collective Responses to Violations of Obligations Erga Omnes? in* THE FUTURE OF INTERNATIONAL LAW ENFORCEMENT: NEW SCENARIOS - NEW LAW 125 (J. Delbruck ed., 1993).

257. Barcelona Traction, Light and Power Company Limited (Belgium v. Spain), 1972 I.C.J. 4 at 32 [hereinafter Barcelona Traction]; American Law Institute, RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES, para. 703 (1987) [hereinafter RESTATEMENT]; L. HANNIKAINEN, PEREMPTORY NORMS (JUS COGENS) IN INTERNATIONAL LAW at 276 (1988); BROWNLIE, *supra* note 31, at 598.

258. *Draft Articles on State Responsibility, Art. 5(2)(e)(iii), in* REPORT OF THE ILC ON ITS 37TH SESSION 1985 Y.B.I.L.C. I, 2; T. MERON, HUMAN RIGHTS AND HUMANITARIAN NORMS AS CUSTOMARY LAW at 191 (1991) [hereinafter MERON].

259. *See Barcelona Traction*, 1972 I.C.J.; S. Schwebel, *Human Rights in the World Court*, 24 VAND. J. TRANS. L. 945 at 965 (1991).

260. *Barcelona Traction*, 1972 I.C.J.; MERON, *supra* note 258.

261. 1970 I.C.J. 3 at 32.

By claiming that Informed Consent is a customary norm and general principle of law that properly falls within the rubric of public international law, it must be stressed that the author does not pretend that Informed Consent is an obligation *erga omnes* or the subject of *actio popularis*. Rather, the author merely asserts that Informed Consent is a customary rule and general principle of law, and that a State may sue another if the national of the first state is being compelled to test by and in the latter country where the standards do not conform to the minimum standards. In such a case, however, the former State takes the latter State to task for violating a customary rule and general principle of law. The former State sues to protect *its* nationals, not the nationals of the latter State.

It is also the author's position that should a suit actually be filed against a State, the determination of whether a standard of consent in human testing already exists or is a developing norm in the international plane would also be within the competence of the ICJ and not the States parties to the action.[262] This finds more force from a consideration that ICJ decisions may either call for the performance of a specific act or acts by the parties[263] or may be declaratory of the law between the parties.[264] In any event, whatever the nature of the measures adopted, domestic jurisdiction loses its hold when action relates to gross and systematic violations of human rights, the question of genocide, or the neglect of non-discrimination.[265]

B. *Definition under International Law: Minimum Standards of Informed Consent*

Defining the minimum standards of Informed Consent is crucial as a survey of State practice. It shows that Informed Consent is something that States adhere to in principle, but in actual practice substantial deviation is the norm.[266] Concretely, Informed Consent has often been applied differently (or not at all) in various countries with differing local conditions and traditions.[267]

262. Northern Cameroons (Preliminary Objections) 1963 I.C.J. 15.

263. Corfu Channel (U.K. v. Alb.) (Merits), 1948 I.C.J. 28; United States Diplomatic and Consular Staff in Tehran (U.S. v. Iran) 1979 ICJ 19.

264. North Sea Cases, *supra* note 42.

265. OSCAR SCHACHTER, INTERNATIONAL LAW IN THEORY AND PRACTICE 332 (1991).

266. *See* Curran, *supra* note 65, at 12-14.

267. *See* Robert J. Levine, *Validity of Consent Procedures in Technologically Developing Countries, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 16 (1974) [hereinafter Levine, *Validity*].

To define Informed Consent, it is necessary to resort to ethical principles formulated specifically for human experimentation,[268] and determine the points of consensus.

A comparative analysis of the international codes and guidelines of human experimentation highlights some fundamental discrepancies between them.[269] For example, while the Nuremberg Code provides that the Informed Consent of the potential test subject is "absolutely essential," [270] the Helsinki Declarations and the CIOMS Guidelines discard the Code's unequivocal language in favor of formulations littered with exceptions.[271] Some of the rules embodied in the Declarations have also been found to frequently conflict, are often ambiguous and of limited application,[272] or difficult to interpret and apply.[273]

> The CIOMS Guidelines are of particular interest in that regard. They recognize that the Declaration of Helsinki is "the fundamental document in the field of ethics in biomedical research" and a copy of the 1989 version of this text can be found in their annex. Nevertheless, they differ on several points, in particular the requirement of informed consent. The situation is rendered even more complicated by the fact that the CIOMS guidelines do not make explicit reference to the Declaration of Helsinki in its latest version (so far 1996). To what extent should the amendments of the Declaration of Helsinki therefore be taken into consideration by someone referring to the CIOMS guidelines? Beside such contradiction, the exact nature of all the norms concerning clinical trials, especially their binding force, also remains uncertain. For instance, should the Nuremberg Code be considered as a set of rules of public international law or merely an ethical code? The answer to this question is not without consequences for the whole regulation of clinical trials. The overall picture of the regulation of clinical research appears therefore as rather complex, if not confusing.[274]

In principle, a consensus emerges from the CHRB, and all the guidelines, codes, declarations, and principles concerning clinical trials on some basic requirements regarding the protection of human research subjects,[275] one of which is Informed Consent.[276] To further analyze these instruments so as to

268. King, *supra* note 22, at 178-79.

269. Sprumont, *supra* note 83, at 25.

270. The Nuremberg Code, *supra* note 70, art.1.

271. King, *supra* note 22, at 185.

272. R. Norman Williams, *Statutory Regulations and Ethical Conduct, in* MEDICAL EXPERIMENT AND THE PROTECTION OF HUMAN RIGHTS, COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 12TH CIOMS ROUND TABLE CONFERENCE 21 (1979).

273. The Evolution of Human Subject Protection Guidelines, at http://www.geocities.com/HotSprings/9190 /guidelines.html (last visited Dec. 2, 1999).

274. Sprumont, *supra* note 83, at 25.

275. *Id.*

276. CHRB, *supra* note 81, arts. 5 & 16(v); *see also* Nuremberg Code, *supra* note 70, art. 1.

derive the minimum standards of Informed Consent, the discussion will be broken down into two areas: (1) information and level of disclosure; and (2) the capacity to give and voluntariness of consent.

1. Information and Level of Disclosure

Determining exactly what information to disclose to a potential test subject is a difficult decision to make. If an overexacting criterion such as full disclosure and complete understanding of the nature and purpose of the experiment is adopted, Informed Consent becomes impossible to obtain.[277] The resulting Informed Consent form would be too thick, and would likely not be understood by the test subjects who are, more often than not, of average and limited knowledge on medical matters. Conversely, if a liberal criterion, such as mere signature of the patient on the form is used, Informed Consent becomes too easy to obtain and the term loses its moral and legal significance. Even in those situations where efforts could be made to provide adequate information, the achievement of understanding would always be difficult because of the lack of scientific and technical background in nearly all subjects.[278]

It is the author's position that the crux of the consent requirement is the freedom of the subject to consent, not that the patient be "fully informed,"[279] considering that the average patient will not fully comprehend the experimental design or therapeutic innovation of the testing[280] and other particularities for its fulfillment.[281] While full disclosure is ideal, information is sufficient if the human subjects are informed of: (1) the purpose and nature of the intervention, (2) the consequences and risks, (3) the safeguards prescribed by law for their protection, and (4) their right to freely withdraw their consent at any time.[282]

> While Informed Consent is an indispensable precondition to the conduct of human experimentation, its requirements are not absolute. The quest is for adequately informed consent rather than "fully" informed consent. Levels of non-disclosure are ethically and legally permissible. It has been seen that such design features as randomization need not be detailed, provided that their consequences for the potential subject are explained. The object of offering and preserving potential subjects' choice is served by disclosure of general data they will want to know, but without requiring them to undertake medical education.[283]

277. Beauchamp, *supra* note 125.

278. *Id.*

279. *See* Curran, *supra* note 65, at 12-14.

280. *See id.*; Dickens, *supra* note 174, at 220; NEUTENS & RUBINSON, *supra* note 60, at 22.

281. Dunne, *supra* note 26, at 211-12.

282. CHRB, *supra* note 81, art. 16.

283. Dickens, *supra* note 174, at 204.

i. Use and Disclosure of Placebos

A placebo is an inert drug preparation devoid of any chemical effect given for mere psychological efficacy, or as a control in evaluating a drug or vaccine believed to have medical effects.[284] Two sets of questions arise about placebos. The first involves the information given to subjects. If a subject were told whether or not he or she was receiving a placebo, the entire point of this design would be lost; on the other hand, failure to disclose is a form of deception.[285]

The second set of issues surrounding placebos is one of risk more than consent; it concerns the circumstances under which a placebo should not be used. It has been argued that when an effective treatment exists, the use of a placebo is unacceptable.[286] This requirement has been the subject of much controversy to date, due to the recent use of placebos in the ACTG 076 Zidovudine protocol in AIDS testing on pregnant women in Africa.[287]

At bottom, the use and non-disclosure of placebos does not violate Informed Consent when there is no proven treatment. The 1996 Declaration of Helsinki itself provides that: "(3) In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method. *This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.*"[288] In addition, the use of placebos in the trials could be justified when vaccine trials involve testing on large populations,[289] or under certain exceptions as when there is scarcity of the experimental drug.[290]

The acceptability of placebo controls was recently illustrated in the AIDS trials of the short-duration regimen of Zidovudine in developing countries, where a WHO panel found that "the choice of a placebo for the control group

284. *Thomas Garrett, Principles of Confidentiality, in* HEALTH CARE ETHICS: PRINCIPLES AND PROBLEMS 109 (1993).

285. It has been asserted that non disclosure of the use of placebos involves deception, in contravention of the person's right to information about his health – he is misled into believing that a possibility of effective treatment exits, as in fact, most subjects consent to experimentation in the hope that the test might help cure them. R.J. Connelly, *Deception and the Placebo Effect in Biomedical Research*, 9 IRB 5-7 (1987).

286. "Ethically, it is justifiable to test a new therapy that promises some advantage over the existing treatment, but not at the cost of withholding the existing treatment from the control group." Capron, *supra* note 58, at 165; *see also* Declaration of Helsinki, *supra* note 79, art. II.3.

287. *See* Annas, *supra* note 73, at 373, *et seq.*; *see generally* REIDAR K. LIE, ETHICAL ISSUES IN CLINICAL TRIAL COLLABORATIONS WITH DEVELOPING COUNTRIES 13-24 (1998).

288. *See* Declaration of Helsinki, *supra* note 79 (italics supplied).

289. *See* Robbins, *supra* note 126, at 212.

290. *See* R. Levine, *Validity*, *supra* note 267; *See also*, C. Levine, AIDS and Ethics, *supra* note 59.

of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women."[291] Subsequently, even leaders in the field of international AIDS research have endorsed the use of placebos under these circumstances, as insisting on equivalency trials and foregoing placebo-controlled studies would make research more expensive and more time-consuming, and many researchers believe that time was of the essence. [292]

2. Capacity to give and Voluntariness of Consent: Testing on Vulnerable Populations

It is not enough that the subject receives adequate information about the nature and purpose of the experimentation. For consent to be valid, a person must also comprehend the disclosed information, be competent to act, and act voluntarily should he consent. [293]

On the one hand, the Nuremberg Code mandates the exclusion of individuals lacking the capacity to consent from the population of potential subjects.[294] Article 17(iii) of the CHRB likewise precludes the use of persons not able to consent to research when research of comparable effectiveness can be carried out on individuals capable of giving consent. On the other hand, the Declarations of Helsinki, the CIOMS Guidelines and even the CHRB allow testing on vulnerable populations,[295] deviating from the rigid principles of the Nuremberg Code by allowing proxy consent for those lacking the legal capacity to give their own consent, and independent committee permission to conduct therapeutic research without the consent of the subject.[296] This deviation from the Code is a recognition by the drafters of the CIOMS Guidelines that "a blanket prohibition against the use of individuals from vulnerable populations, is both overbroad and underinclusive."[297] The CHRB provides that "[t]he opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity."[298]

Certainly, vulnerable groups who lack autonomy or social power are in need of special protection.[299] Not only is it possible that they may not

291. *See* R. Levine, The Need to Revise, *supra* note 252.

292. *Id.*

293. Beauchamp, *supra* note 125, at 135.

294. Declaration of Helsinki, *supra* note 79, *cited in* King, *supra* note 22, at 185.

295. King, *supra* note 22, at 185.

296. Declaration of Helsinki, *supra* note 79, *cited in* King, *supra* note 22, at 185.

297. King, *supra* note 22, at 196.

298. CHRB, *supra* note 81, art. 6(2).

299. *See* CRC, *supra* note 131, art. 19; C. Levine, *AIDS and the Ethics, supra* note 59, at 79; Dunne, *supra* note 26, at 215; Farber, *supra* note 136, at 32-33.

understand what it is they are consenting to,[300] they are also extremely vulnerable to potential coercion due to their physical condition.[301] Their ability to give consent may also be compromised due to their social and economic deprivation.[302] But as previously mentioned, the possibility of exploitation alone cannot and should not prevent these vulnerable populations from participating in human experimentation. It is quite likely that members of these vulnerable populations are economically disadvantaged,[303] hence testing conducted on them might very well be their only opportunity to be treated. All the more when the testing pertains to serious diseases where there is no treatment at all.

3. The Argument of Cultural Relativism

At this point, it should be noted that one of the difficulties in establishing a universal standard of Informed Consent has been the ground of cultural relativism. Ethical guidelines in research, including Informed Consent, have been perceived to essentially reflect the Western view on the nature of persons[304] and were intended to apply in industrial countries and highly urbanized areas of the developing world.[305] All too often, it is claimed, the regulations fail to consider the needs and goals of the particular country where the tests occur[306] and do not reflect their views on the relationship between persons and society.[307] It has been asserted that the State where the testing is to be conducted is in the best position to tailor the standards of testing to accommodate local conditions,[308] including Informed Consent.

There is certainly no denying that some ethical values celebrated in the Western world should not be indiscriminately exported to the rest of the

300. *See* Sharon Perley et al., *The Nuremberg Code: An International Overview, in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 149, 155-56 (George J. Annas & Michael A. Grodin eds., 1992).

301. C. Levine, *AIDS and the Ethics, supra* note 59, at 89.

302. Research Involving Prisoners, *supra* note 139, at 7.

303. *See* R. Levine, *The Need to Revise, supra* note 252; Carlos del Río, Adeeba Kamarulzaman and Udo Schüklenk, *Ethics, Economic Realities and Medical Research in Developing Countries, available at* http://www. arts.monash.edu.au/bioethics/azt/htm (last visited Dec. 30, 1999).

304. R. Levine, Validity, *supra* note 267, at 18; Brian Walsh, *Protecting Citizens from Their Own Countries: How the European Court of Human Affects Domestic Laws and Personal Liberties,* 15 HUM. RTS. 20, 22 (1988) *cited in* Urban, *supra* note 2, at 281.

305. Curran, *supra* note 65, at 57.

306. Craig D. Burnell, *Ethical Issues in Clinical Drug Evaluation: Some Little Considered Aspects, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 281 (1974); La Vertu, *supra* note 20.

307. R. Levine, *Validity, supra* note 267, at 26; La Vertu, *supra* note 20.

308. R. Levine, *The Need to Revise, supra* note 252.

world.[309] For example, while Informed Consent is required to be written in most developed countries and even in some developing ones, *e.g.*, the Philippines, some argue that Informed Consent does not have to be written when the test subjects are illiterate. [310] However, *a contrario*, "sensitivity to the specific practices and beliefs of a community cannot be used [to justify] violating universal human rights."[311] Whatever cultural differences there may be, they cannot be so great that developing nations should be subjected to substantially different consent practices from those accepted in the West.[312] To suggest that Informed Consent is relative to a State's own value system would be to rely on the dangerous and outdated view of cultural relativism.[313] The slogan "African solutions to African problems" has been observed as a thin cover for abusing the basic human rights of citizens.[314]

Any proposal to resist Informed Consent as a requirement must be studied in light of the complex motivations behind human subject testing commonly conducted in developing countries.[315] Research in these societies entails lower costs, lower risks of litigation, less stringent ethical review, the availability of populations prepared to cooperate with almost any study that appears curative in nature, and anticipated under-reporting of side effects due to low consumer awareness.[316] This array of reasons provides further justification to regard with suspicion any suggestion that cultural relativism militates against an international definition of Informed Consent.[317]

309. *See* Christakis, *supra* note 105, at 34-35.

310. R. Levine, The Need to Revise, *supra* note 252.

311. Committee on Human Genome Diversity, Evaluating Human Genetic Diversity 65 (U.S. National Research Council, 1997).

312. Ijsselmudein, *supra* note 67, at 367.

313. Annas, Reflections, *supra* note 186, at 376; *see generally* HARRIS, *supra* note 166, at 626-28.

314. *See* George J. Annas & Michael A. Grodin, *Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa, in* HEALTH AND HUMAN RIGHTS: A READER 373, 376 (Jonathan M. Mann et al eds., 1999).

315. Urban, *supra* note 2 at 282.

316. *See* E.M. Ankrah, *AIDS: Methodological Problems in Studying Its Prevention and Spread*, 29 SOC. SCI. MED. 265-76 (1989); *see also* R. CHAMBERS, RURAL DEVELOPMENT: PUTTING THE LAST FIRST 18-19,133-34,160-67 (4th ed. 1985); P. Kurpooea, J. Rienter, *Unethical Trials of Dipyrone in Thailand*, 2 LANCET 1491 (1988); D. Serwadda, E. Katongole-Mbudde, *AIDS in Africa: Problems for Research and Researchers*, 335 LANCET 842-43 (1990).

317. Ijsselmudein, *supra* note 67, at 367.

IV. SUMMARY AND CONCLUSION

Meaningful, autonomous, Informed Consent is vital to check society's use of the individual for its own ends.[318]

The historical development of law demonstrates the continual process of the cultural enrichment of the legal order by taking into consideration values or interests which have previously been excluded from the sphere of law.[319] It is the role of international human rights law to ensure that government actions are carefully circumscribed, infringing on the rights of the individual only to the extent necessary to achieve legitimate State interests.

One concrete example of the expansion of the scope of international law is in the conduct of human experimentation, specifically, the requirement of Informed Consent. Experimentation on human subjects is more than justified by the valuable information obtained to improve health and alleviate human suffering from disease or ill-health.[320] For as long as human research subjects are protected and not exploited, then the benefits of testing will ultimately outweigh any risk of participation. [321] It has been almost fifty years since the protection and rights of human subjects have been established not only within each State, but also on the international level, through ethical principles and guidelines established by different international organizations, and more recently, the CHRB. But a review of state practice has clearly established that while Informed Consent may have started as an ethical principle, it is now a customary norm and general principle of law. Likewise, the fact that (1) issues of health cut across boundaries and are international concerns; and (2) AIDS has increased the participation of vulnerable populations in clinical research, clearly puts Informed Consent within the realm of international law.

Under international law, Informed Consent demands two things. First, the proposed test subject must be given sufficient information as to have some (not full) understanding of the nature, purpose, consequences and risks, and safeguards for his protection, including the right to freely withdraw consent at any time. Second, consent to the testing must be obtained, whether personally or through a representative.

The development of Informed Consent as a customary legal norm, with definite minimum standards, unquestionably improves the level of protection guaranteed to human research subjects especially in countries where there is no

318. *See* Urban, *supra* note 2, at 282.

319. South West Africa, Second Phase (Eth. v. S. Afr.; Liber. v. S. Afr.), 1966 I.C.J. 6, 252 (Tanaka, J., dissenting).

320. Ocampo, *supra* note 19, at 89.

321. *Id.*

specific regulation of clinical trials.[322] It marks the present shift from ethics to law occurring in the field of biomedicine. [323] Likewise, it should accelerate the movement to harmonize approval of drugs, which will in turn reduce the costs of research, and ultimately, the price of treatment and its availability in the market. [324]

> [T]he dramatic increase in the number of new states and the appearance of many problems in the economic and the social spheres have accounted for many important developments in international law, and greatly increased both its scope and complexity... Perhaps the most significant development of the post-war period... [is] the addition of a new field of international cooperation and organization to the traditional system of the law of nations... the law of nations has passed from the phase in which it was primarily an international law of co-existence... to a phase in which the nations of the world must develop new forms of cooperation and organization to supplement the traditional rules of interstate relations.[325]

V. RECOMMENDATIONS

> *Science has, in the past half-century, enabled a virtual leap of humanity into many new fields of activity which require regulation.*[326]

Having determined that Informed Consent is a recognized obligation under international law with definite minimum standards, the challenge is now to ensure its enforcement among States.

> As the 21ST century approached, the problems facing the international community are many and acute... regimes must be developed for the peaceful accommodation of conflicting uses, the equitable sharing of resources, and the management of pollution. International cooperation is needed to manage massive flows of refugees, to protect human rights, and to curb international terrorism.

A. National Level

Precisely because the world lacks an effective mechanism for enforcing basic medical ethics and human rights principles,[327] individual nations are urged to adopt their own safeguards to protect the human rights of subjects. Consideration is required in both developed and developing countries as to whether prevailing legal provisions and administrative arrangement ensure that the human rights and welfare of subjects involved in medical research are adequately considered and protected. [328] Local or national enforcement

322. Urban, *supra* note 2, at 285.

323. *Id.*

324. *Id.*

325. *See* LOUIS HENKIN, THE INTERNATIONAL BILL OF RIGHTS: THE COVENANT ON CIVIL AND POLITICAL RIGHTS 18-19 (1981).

326. THOMAS M. FRANCK, FAIRNESS IN INTERNATIONAL LAW AND INSTITUTIONS 6 (1995).

327. *See* Annas, Reflections, *supra* note 186, at 309.

328. Declaration of Helsinki, *supra* note 79.

mechanisms need to be implemented in many developing countries and broadened in developed countries.[329]

As a member of the United Nations, the Philippines has a duty under Article 55 and Article 56 of the Charter[330] to promote universal respect for and observance of human rights and fundamental freedoms and to take joint and separate action to achieve these purposes in good faith.[331] With respect to complying with the requirement of Informed Consent, governmental regulations are not enough. The Philippines should enact legislation to regulate the conduct of human experimentation, not only to comply with its international obligations, but more importantly, to increase the level of protection of its vulnerable populations, of which there are many. This legislation could be patterned after the different ethical codes of biomedicine, and at the very least, clearly establish the requirement of obtaining Informed Consent from all test subjects.

Second, since the CHRB is accessible to non-member States of the Council of Europe, the Philippines should consider the possibility of signing the treaty. Among other things, membership would allow it to invoke the provisions of the treaty against other member States, who are incidentally the states conducting most of the research.

Another mechanism to ensure the protection of human subjects in the Philippines is the installation and monitoring of independent/institutional review boards (IRB) or ethical committees within the State,[332] which has been stated to be:

> [t]he most workable approach to protect research subjects.... IRBs primarily serve two functions. First a peer review committee ensures that research protocols are scientifically sound, well-planned, and safe for human experimentation" and that the potential risks to the subjects are outweighed by potential benefits. Second, the IRB acts as the representative of the "broader local community in assessing community acceptance of the particular risk/benefit ratio."[333]

B. International Level

The future will only increase the amount of research that is conducted abroad, particularly in developing nations. Some of that research is necessary for the health

329. Urban, *supra* note 2, at 286.

330. Legal Consequences for States of the Continued Presence of South Africa in Namibia (S. W. Afr.), Advisory Opinion, 1971 I.C.J. Rep. 16; H. LAUTERPACHT, INTERNATIONAL LAW AND HUMAN RIGHTS, 147-49 (1950); Wright, *National Courts and Human Rights – the Fuji Case I*, 45 AM. J. INT'L L. 62, 73 (1951); Schelb, *The International Court of Justice and the Human Rights Clauses of the Charter*, 66 AM. J. INT'L L. 337, 341-50 (1972).

331. Vienna Convention, *supra* note 32, art. 26; LORD MCNAIR, THE LAW OF TREATIES, Chapter XXX (1961).

332. TOWARDS AN INTERNATIONAL ETHIC, *supra* note 14, at 41-43.

333. Urban, *supra* note 2, at 283.

> and well-being of the citizens of developing countries. Some of that research will be performed in developing countries only because regulatory loopholes make it possible. Without international cooperation, without concerted action by both developed and developing countries, these loopholes will remain. A viable and binding international agreement setting minimum standards for the conduct of research is needed now.[334]

Individual State effort is not enough to ensure compliance with Informed Consent. There is a need to accelerate the fundamental change, *i.e.,* the shift from ethics to law, in the regulation of biomedical research and practice. [335] As the consequences of human experimentation affect more than one State, they demand international regulation.[336] The author is aware of the criticisms directed against international regulatory agencies, *i.e.,* lack of resources and funding, problems of monitoring violations, and enforcement of sanctions. But the duty of continuing surveillance over human experimentation is so vast that it demands national and possibly supranational concern and duty.[337]

Interestingly enough, one of the developments of international law is the elaborate system of rules and organizational measures which aims at increasing the protection of human health. At its center is the World Health Organization (WHO).[338]

> In certain instances states have delegated important law-making powers to organization... [and] may make decisions and regulations which are legally effective within the legal system of member states. Other forms of delegation exist involving various procedures for acceptance of the regulations by members. Some organs, for example the World Health Assembly of WHO or the Council of ICAO may make regulations by majority decision, leaving states to contract out by express rejection or by entering reservations.[339]

Thus, if any international organization should be given the awesome task of international regulation of human experimentation, it should be the WHO. Its leadership and essential global directing and coordinating role in AIDS prevention and control, including the task of coordinating scientific research on cures, therapeutics and vaccines has been codified as early as 1987 through a General Assembly Resolution. [340] International Regulation of human experimentation could be effected through the expansion of the current authority of WHO's own ethical review committee, the Secretariat

334. *Id.* at 286.

335. Sprumont, *supra* note 83, at 41.

336. *See generally* Manfred Lachs, *Thoughts on Science, Technology and World Law*, 86 AM. J. INT'L L. 673 (1992).

337. *See* Söderholm, *supra* note 236, at 222.

338. Lachs, *supra* note 336, at 681.

339. BROWNLIE, *supra* note 31, at 700-01.

340. G.A. Res. 42/8, 1987, *cited in* Söderholm, *supra* note 236, at 265.

Committee on Research Involving Human Subjects,[341] to assist and ensure that developed and developing countries have mechanisms that would protect human test subjects [*i.e.,* requiring Informed Consent] in biomedical research.[342]

This role is not only an international imperative that the WHO alone may be able to discharge, but it is also crucial in demonstrating, as the WHO Constitution provides, that "the health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest cooperation of individuals and states."[343]

341. Gutteridge, *supra* note 57, at 207.

342. Violaki, *Discussion, in* COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) PROTECTION OF HUMAN RIGHTS IN THE LIGHT OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS IN BIOLOGY AND MEDICINE, 8TH CIOMS ROUND TABLE CONFERENCE 89 (1974).

343. Jose Alberto Mainetti, *Bioethics: A New Health Philosophy, in* BIOETHICS: ISSUES AND PERSPECTIVES 134 (Susan Schrelle Conner, et al., eds., 1990).