INTERNATIONAL BIOETHICS AND HUMAN RIGHTS : ETHICAL AND LEGAL PRINCIPLES IN BIOMEDICAL RESEARCH

*Subhash Chandra Singh**

I Introduction

THERE IS an ongoing global debate, especially among members of the medical profession, as to the necessity for jurisdiction, regulation and public control of the biomedical research on human subjects. At present there is a wide variation in norms and laws regulating biomedical research. Some countries have statutory regulations, whilst others rely on softer forms of regulation including administrative or professional ethical rules. In the case of research involving adults and children, the procurement of consent prior to medical intervention is usually a legal requirement, but there is no uniform norm on the level of information that the patients should be given to ensure that consent is adequate or informed. There is also no clear consensus on the circumstances in which consent can be dispensed with. Forms and procedures for obtaining consent vary. So do other control mechanisms, such as the legal status, role and composition of research ethics committees of the concerned nation. In the fast developing field of research involving the application of new bio-technologies such as stem cell research or research on human tissues, the law is lagging behind the science. There is often a legal vacuum, as policy makers strive to reach a consensus on guiding principles for regulation of biomedical research. The conduct of clinical trials by pharmaceutical companies in the developing countries resulting in drugs discovery which are then out of reach of the local populations, has also raised the question of whether universal standards of research can be formulated irrespective of inequality of health resources and wealth.

This paper analyses the evolution and changes in form and content of international instruments regulating the conduct of biological research and highlights some of the most difficult ethical and legal challenges posed by globalisation and the use of new biotechnologies in medical research in

* Reader & Dean, Faculty of Law, Mahatma Gandhi Kashi Vidyapith, Varanasi, UP, India.

the 21st century. The central claim of the paper is that the increasing globalisation of medical research is highlighting the tension between the aspiration to universality of ethics driven regulation and the emerging reality of the diversity of moral cultures and the need to respect plurality and ethical diversity in democratic societies. In this aspect, the international debates on the protection of human subjects in research needs to shift it's focus from the realm of ethics to the realm of legally enforceable human rights in biomedicine. This paper systematically explores the legal frameworks which will safeguard the fundamental rights of the individual in some of the most controversial areas of biomedical research today.

II Origin and development of international bioethics

The origin of modern international bioethics has been traced to the brutal abuse of human lives in the holocaust.[1] At the Nuremberg 'Doctors Trial' (1946-47) medical researchers were convicted of 'crimes against humanity' on the basis of ten ethical principles which were said to be fundamental and universally applicable to all eras and cultures.[2] In the decades that followed, increasing efforts were made to formalise and codify a set of principles which would command international approval.

The World Medical Association (WMA) was founded in 1947 to represent physicians and to promote medical ethics and professional freedom worldwide. In 1948, WMA issued the Declaration of Geneva,[3] the first international document stating the ethical duties of physicians to their patients. The Declaration consists of a physician's oath: 'Not to use my medical knowledge contrary to the laws of humanity and an undertaking to practice my profession with conscience and dignity; the health of my patient will be my first consideration'. The physician needs to give the utmost respect for human life from the time of conception. The Declaration of Geneva was followed by the adoption of the first International Code of Medical Ethics in 1949.[4] The 1949 Code contains a brief statement of doctor's duties, which include an obligation to ensure that 'any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest', 'complete loyalty to the patient', 'absolute

1. See G. Annas and M. Gradin (eds.), *The Nazi Doctors and the Nuremberg Code, Human Rights in Human Experimentation* (1992).

2. *Ibid*.

3. The Declaration was adopted just three months before the UN General Assembly adopted the Universal Declaration of Human Rights (1948).

4. World Medical Association, *International Code of Medical Ethics* 109-111 (1949).

secrecy on all he knows about his patient' and a list of practices relating to conflicts of interest and monetary benefits which are deemed unethical. The International Code was amended twice in 1968 and 1983.[5] The 1983 revision of the Code also introduces a requirement that the rights of patients and colleagues shall be respected. Also, the obligation to preserve human life from conception onwards is replaced by a weaker requirement 'to always bear in mind the obligation of preserving human life'.

There are many international conventions that regulate medical practice globally and India being a member of the international community is a party to many of these conventions. The need for these conventions emerged following the gross violations of medical ethics during the second world war, which include illegal experiments on human beings. The WMA facilitated arrangements for these conventions. Landmark international codes on medical research, such as the Declaration of Helsinki (1964) and the growth of the modern bioethics movement, were prompted by the appalling abuse of human lives. In the last decades, however, it is the pace of scientific advances in the application of biotechnologies which has forced a global and international revision of ethical and legal controls in biomedicine, particularly in the filed of research involving human subjects.[6] The evolution of the Declaration of Helsinki is set against the global growth of the bioethics movement, its impact on public policy and the emergence of national and international bioethics committees to regulate biomedical researches.

However, in terms of practical impact, it is the Declaration of Helsinki, adopted by the WMA in 1964, which has had and continues to have the greatest influence on the international regulation of biomedical research. There are certain norms governing trials enshrined under the Helsinki Declaration on biomedical research involving human subjects. It has undergone several revisions since its inception. These norms state that trials should be carried out only if the 'importance of the objective is in proportion to the inherent risk to the subject', whereby the 'concern for the interests of the subject must always prevail over the interests of science and society'. Ethical committees should be set up to safeguard that the volunteer who is participating in a trial is paid liability costs or is compensated for damages caused by the trial, and that he/she is provided

5. WMA, *International Code of Medical Ethics*, adopted by the 3rd WMA General Assembly, London 1949 and amended by the 22nd WMA General Assembly, Sydney, Australia, 1968 and the 35th WMA General Assembly, Venice, Italy, 1983.

6. A.L. Taylor, "Globalisation and Biotechnology, UNESCO and an International Strategy to Advance Human Rights and Public Health", 25 *American Journal of Law and Medicine* 451-79 (1999).

information about the method or drug to be tried out and gives his/her 'informed consent'. In practice, this is not always the case.[7] Also, worthy of note are the Tokyo Declaration of 1975, the Sydney Declaration of 1968, and the Oslo Declaration of 1970. All these declarations basically deal with ethical issues in the practice of medicine, and provide ethical guidelines for medical practitioners.

III International and regional ethical guidelines on medical research

Medical research is needed in order to uncover the causes of ill health or to discover new ways of treating or alleviating pain or illness. In the fast developing field of research involving the application of new biotechnologies such as stem cell research on human tissues, the formulation of the applicable ethical and legal principles tend to lag behind the science. Currently, medical research on human body is regulated through a combination of administrative and professional rules rather than by statute. There is no case law directly on medical research. Thus, the potential liability to medical researchers has to be surmised from general principles of law and rules in related areas including medical treatment.

Though the Declaration of Helsinki does not define medical research it states the legitimate purposes for which research may be conducted :

> The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic, and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.[8]

As far as the research involving existing human subjects (either children or adults) are concerned, there had hitherto been an international consensus that the aim of scientific research should be to benefit the individual participating in the research as well as yielding knowledge which could benefit others in society by uncovering the causes of ill health or discovering new ways of treating or alleviating pain or illness.[9]

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7. Jyotsna Agnihotri Gupta, *New Reproductive Technologies, Women's Health and Autonomy* 325 (2000).

8. The Declaration of Helsinki, paragraph 6.

9. The main purpose of medical research is to improve diagnostic, therapeutic and prophylactic procedures and understanding of the aetiology and pathogenesis of disease, *Declaration of Helsinki* (2000).

The human rights approach envisages that medical research to be conducted only on human subjects who could directly or personally derive a benefit from the research. Any benefits conferred on others were justified on the grounds that they were incidental to the benefit conferred on the participating individual. The principle of medical and surgical morality, therefore, consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, for instance, to the health of others. But performing experiments and operations exclusively from the point of view of the patient's own advantage does not prevent their turning out profitably to science.[10]

The distinction between experimental treatment and research is particularly significant in respect of the specification of the legal obligations imposed on researchers, with the risk that the categorisation of an intervention or procedure as innovative or experimental treatment, 'therapy' or 'practice' could be used to justify a lower level of legal protection on levels of information and disclosure of risks than those appropriate for research, notwithstanding the fact that the effects and risks of an innovative or experimental procedure by definition are yet to be proven.[11]

The distinction between therapeutic and non-therapeutic research in the Helsinki Declaration was fundamental.[12] As per section II (2) of the 1964 Declaration, the doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient. However, the distinction between therapeutic and non-therapeutic research was removed in the 2000 version, after a protracted debate and amidst concerns from critics that the removal of the distinction would lower the protection of research participants.[13]

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10. C. Bernard, "An Introduction to the Study of Experimental Medicine" (1865), reprinted in Reiser *et al*. (eds.), *Ethics in Medicine* 137-39 (1977).

11. At the same time, what made the procedure *experimental* was the fact that the anticipated benefits and risks had not been tested or proven and, unlike a research programme, the intention did not involve the systematic investigation of and collection of data in order to evaluate the scientific validity of the supposed 'treatment'. See Aurora Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* 47 (2005).

12. In the field of medical research a distinction must be recognised between clinical research in which the aim is essentially therapeutic for a patient and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research. See Declaration of Helsinki (1964).

13. P.R. McGinn, "Painstaking Process of Revising WMA's Declaration of Helsinki", *AM News*, January 8, 2001.

The Declaration of Helsinki — evolution of international norms

The Declaration of Helsinki has often been traced as a core influence on the development of many international codes governing research on human subjects,[14] but where the Declaration has been invoked in legal proceedings, a close analysis of the court rulings reveals that the legal force of the Helsinki Declaration is severely limited by local procedural and substantive rules of law. The Declaration has been invoked in a series of cases heard by U.S. courts where it has been cited along with the International Covenant on Civil and Political Rights (1966) as a guide to international legal principles on the conduct of medical experiments.[15] Like the earlier codes, the Helsinki Declaration is intended as a statement of ethical principles to provide guidance to physicians and others conducting medical research on human subjects. The Declaration has undergone five revisions since it was originally adopted in 1964. The last two revisions (1996 and 2000) in particular have been the subject of fierce international disagreement from within and beyond the medical profession. Although the Declaration of Helsinki lacks the status of a treaty since it is not an agreement between states, the domestic courts of different countries have accepted that it too could be invoked as evidence of well-established principles of international law. The practical contribution of the Declaration of Helsinki lies primarily in the influence that it can carry in the area of professional self-regulation in the elaboration of professional codes of practice or alternatively in the drafting of legal instruments which endorse its principles.

More generally, the Declaration of Helsinki, like other ethical codes and forms of 'soft law', suffers from the absence of procedures for enforcement and penalties for breach. Despite many loopholes, Helsinki Declaration may provide a point of reference or guidance for domestic courts which have jurisdiction over the claims complained of, but it lacks 'direct' legal authority and weight.[16]

From a purely legal perspective, the authority of the Helsinki Declaration is weak and limited. As the language of the Declaration itself makes clear, it is a statement of professional ethical principles of ideals issued by members of the medical profession, to other members of the

14. Annas and Grodin, *supra* note 1.

15. See *Abdullahi* v. *Pfizer Inc*, 2002 WL 3108295 6 (SDNY, September 17, 2002) (NO 01 CIV 8118), *Robertson ex rel Robertson* v. *McGe*e, 2002 WL 535045 (ND Okla, January 28, 2002) (NO 01 CIV 60), *Grimes* v. *Kennedy Krieger Institute Inc*, 366 Md 29, 782 A 2d 807 and *Johnson* v. *Arthur*, 65 Ark App 220, 986 SW 2d 874.

16. Plomer, *supra* note 11 at 7.

medical profession. These principles provide, as it is stated in the Preamble to the original Declaration of 1964, certain standards which would serve as a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries'.[17]

The latest version of the Declaration of Helsinki (2000) replaces the previous requirement that the control group be provided with the best 'proven' diagnostic and therapeutic method with the best 'current' method instead. Paragraph 29 provides that:

> The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

In the immediate aftermath of the 2000 revision, there was concern amongst some critics that the new formulation replacing best 'proven' by best 'current' methods was ambiguous. Does best 'current' denote a universal standard, determined purely by clinical factors, or does the standard denote whatever treatment is currently available locally, in which case the standard may be relative to the local, social and economic conditions which may vary from one locality to another? If the former, the best 'current' standard would prohibit the use of placebo controls in resource poor countries. If the latter, placebo controls could legitimately be used under Helsinki rules in developing countries when participants in the same trial in developed countries would be given whatever state of the art treatment is available locally instead of a placebo.[18]

The Convention on Human Rights and Biomedicine (CHRB)

The Council of Europe's Convention on Human Rights and Biomedicine (CHRB) (1997)[19] is an important step towards the harmonisation of international norms in the field of biomedicine. The Convention's aspiration to achieve fundamental and universal value is clear from the preamble's resolve to such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the

17. See the Preamble to the Helsinki Declaration, 1964.

18 Plomer, *supra* note 11 at 117.

19. On the legal status and legal scope of the Convention, see Aurora Plomer, 'Medical Research, Consent and the ECHRB', in Garwood-Gowers *et al*. (eds.), *Healthcare Law: The Impact of the Human Rights Act, 1998* 313-30 (2001).

application of biology and medicine.[20] The aspiration has to be reconciled with the reality of diversity of forms and norms of regulation of medical research across Europe and the rest of the world. The CHRB safeguards the human individual and the human species from the 'misuse of biology' while ensuring that present and future generations enjoy the benefit of progress in biology and medicine. The purpose of the CHRB is stated in chapter I, article1:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.[21]

The CHRB contains a specific chapter on scientific research (chapter V). Article 15 asserts the freedom to carry out scientific research subject to limitations to ensure protection of the human being contained in articles 16 and 17. Free and informed consent has to be given by the participant subject (or his legal representative) in advance.[22] The participant has to be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks (article 5). The consent has to be given expressly, specifically and be documented (article 16 (v)). Article 16 also details limitations on research to ensure protection of human subjects. There is no alternative of comparable effectiveness to research on humans (article 16 (i)). The risks which may be incurred must not be disproportionate to the potential benefits of the research (article 16 (ii)) and the persons undergoing research must be informed of their rights and the safeguards prescribed by law for their protection (article 16 (iv)). The research must have been approved by a research ethic committee (article 16 (iii)).

In the case of 'persons unable to consent', article 17 draws a distinction between:

1. research which has the 'potential to produce real and direct benefit' to the individual (article 17.19 (ii)); and

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20. CHRB, Preamble.

21 CHRB, chapter I. The overreaching fundamental values asserted in chapter I of the Convention include the protection of dignity and identity of all human beings (art. 1), the primacy of the human being (art. 2), equitable access to health care (art. 3), and the requirement that any intervention in the health field should be carried out in accordance with relevant professional obligations and standards (art. 4).

22. Art. 5 specifically requires consent to be given prior to any medical intervention, but the meaning of the word 'intervention' in art. 5 is not restricted to 'medical treatment' and includes scientific research.

2. research which has the 'aim of contributing… to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition' (article 17.2 (i)).

The Council of Europe adopted an Additional Protocol on Biomedical Research in June 2004 which contains some provisions on research in developing countries. The relevant provisions are contained in article 23 whose heading deceptively, does not specifically refer to research in developing countries but adopts instead the general formulation: 'Non-interference with necessary clinical interventions.' Article 23 states that:

i. research shall not delay nor deprive participants of medically necessary preventive, diagnostic or therapeutic procedures.

ii. in research associated with prevention, diagnosis or treatment, participants assigned to control groups shall be assured of proven methods of prevention, diagnosis or treatment.

iii. the use of placebo is permissible where there are no methods of proven effectiveness, or where withdrawal or withholding of such methods does not present an unacceptable risk or burden.

Under the Additional Protocol, the control group is to receive, if not the best, at least a proven treatment and not a placebo. When read with para 1 which prohibits delay of medically necessary interventions, the natural interpretation is that article 23 prohibits the use of placebos when there is a proven treatment, irrespective of the participants' locality. However, it seems that this reading of the text is at odds with that envisaged by the explanatory report, which explains that as regards 'proven' methods of intervention it is expected that a proven method of treatment that is available in the country or region concerned be utilised. Even when 'region' is given a wide meaning to include neighbouring countries (as suggested by the Explanatory Report), the construction suggested by the report points to a local rather than a universal standard.[23]

IV Fundamental principles applicable to human experimentation

The US Advisory Committee on Human Radiation Experiments (ACHRE, 1996) independently claimed to have identified certain fundamental ethical principles which are valid across all cultures and at all times, and which can

23 Plomer, *supra* note 11 at 130.

be used to judge the ethical soundness of experimentation with humans retroactively, if required. In its claim, the ACHRE identified six basic ethical principles which are mostly binding on medical researchers in all societies across time and space.[24] The principles are:

i. one ought not to treat people as mere means to the ends of others
ii. one ought not to deceive others
iii. one ought not to inflict harm or risk of harm
iv. one ought to promote welfare and prevent harm
v. one ought to treat people fairly and with equal respect
vi. one ought to respect the self-determination of others.

The ACHRE regarded these principles as 'basic' because any minimally acceptable ethical standpoint must include them.[25] The ACHRE claimed that the principles reflect a social consensus about the validity of certain moral norms. Applying the above ethical framework, the ACHRE drew a distinction between non-therapeutic experiments without the subject's consent and therapeutic experiments without the subject's consent. The former were held to be not only a violation of the basic principles listed above but also a violation of the hippocratic principle that was the cornerstone of professional medical ethics at the time.[26] Finally, the ACHRE claims that the principle that one ought to promote the welfare and prevent harm is a basic or fundamental principle for the conduct of research, i.e., the welfare principle. However, as stated above, the principle admits of several interpretations, some of which are controversial. The crucial ambiguity here rests on the absence of the clear indication of whose welfare medical researchers are supposedly under a moral obligation to promote: the individual's welfare or the welfare of society? The two are not necessarily compatible and, whilst the former may be non-contentious, the latter is not.[27] Examples of medical experiments prioritising collective over individual benefits can be found in the ACHRE report itself. In the great majority of cases the experiments reviewed were conducted to advance medical science or national interests in defence or space exploration.[28] The committee also found that the human radiation experiments 'contributed significantly to advances in medicine and thus to the health of the public'.

24. Advisory Committee on Human Radiation Experiments (ACHRE), *Final Report of the Advisory Committee on Human Radiation Experiments*, chapter 4, at 1 (1996).
25. *Id*. at 2.
26. *Id.*, Chapter 4, at 8.
27. Plomer, *supra* note 11 at 35.

V International ethical codes relating to consent

There is a widespread consensus in international ethical codes and human rights instruments that medical researchers must obtain the free and informed consent of the research participant in advance. The rule of consent has been presented in all the versions of the Helsinki Declaration since its original adoption in 1964. The 2000 version states thus:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, source of funding, and possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing, the non-written consent must be formally documented and witnessed.[29]

It has been endorsed by the International Covenant on Civil and Political Rights (ICCPR) (1966) which states that no one should 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.[30] Article 5 of the CHRB, which requires that any intervention in the health field 'may only be carried out after the person concerned has given free and informed consent to it', simply affirms a well-established international rule. The purpose of the rule is to ensure respect for autonomy and the right of the individual to choose whether or not to participate in research. According to the explanatory report, article 5 affirms that:

> …no one may in principle be forced to undergo an intervention without his or her consent. Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person. This rule makes clear patients' autonomy in their relationship with health care professionals and restraints the paternalistic approaches, which might ignore the wish of the patient.

28. ACHRE, *supra* note 24 at 2.
29. Paragraph 22.
30. ICCPR, art. 7.

Accordingly, a breach of artice 5 occurs whenever the individual's consent has been obtained by deceit or misinformation, irrespective of whether the individual has suffered harm or not. The right protected is in effect a right to freedom of choice in respect of participation in a research project.[31] Under the well established principle, a doctor is under an obligation to take the consent of patient before any treatment is started. The doctor's duty to obtain consent for treatment is based on the fundamental principle of respect for the individual's right to self-determination and autonomy. In *R* v. *T*,[32] Lord Donaldson said that the individual has a right 'to live his own life how he wishes, even if it will damage his health or lead to his premature death'.[33] For this it follows that every adult person who is mentally competent has an 'absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered, whether the reason is rational, irrational or there is no reason at all'.[34] This right has since being reaffirmed by the Court of Appeal in a number of cases. *Re MB*[35] involved a refusal of treatment by a pregnant woman when the refusal endangered her life and that of her baby. *Re W*[36] involved a prisoner who refused treatment to a leg wound in full knowledge that septicaemia might result and lead to his death. In *Mrs. B.* v. *An NHS Hospital Trust,*[37] the Court of Appeal affirmed the right of a severely disabled but mentally competent woman to refuse life-saving treatment. In *Halushka* v. *University of Saskatchewan*,[38] the Canadian court of Saskatchewan stated thus:

> In order for consent to be effective, it must be an informed consent, freely given and it is the duty of the doctor to give a fair and reasonable explanation of the proposed treatment including the probable effect thereof and any special unusual risks. Such being the duty owed by a physician to his patient in ordinary medical practice, the duty to inform is at least as great, if not greater in the case of those engaged in medical research to persons who offer themselves as subjects for experimentation because in the latter case, there can be no conception to the requirements of full disclosure whereas it may be necessary to keep certain things from

31. Plomer, *supra* note 11 at 44.
32. (1992) 4 All ER 649.
33. *Id.* at 661 d-f.
34. *Ibid*.
35. (1997) 2 FLR 426.
36. *The Independent*, June 17, 2002; *Lawtel* 2(7) 2002.
37. (2002) 2 All ER 449.
38. (1965) 53 DLR 2d 436.

> the patient, in the interest of peace of mind, when a medical operation is being performed.

Similarly, in *Weiss* v. *Solomon*,[39] the Superior Court of Quebec held that in a purely experimental research programme, the doctor must disclose all known risks, including those which are very rare or remote and a *fortiori* those whose consequences would be grave'. The US cases point to an even stricter standard of disclosure for non-therapeutic experiments. In *Whitlock* v. *Duke University*,[40] the claimant had suffered brain damage after taking part in the Atlantis series of dives conducted by the FG Hall Laboratory of Duke University. The purpose of the experimental stimulated deep dives was to research high pressure nervous syndrome. The district court of North Carolina rejected the claimant's claim that the defendants had concealed risks and failed to obtain informed consent. The court distinguished the standard for informed consent in a medical therapeutic context from that in a research, non-therapeutic context, where 'the policy considerations and balance of interests are different'. In a research context, the court said that the standard should be the 'Nuremberg' standard adopted by the US Military Tribunal in the Nuremberg trials:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
2. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

It is to be noted that the Nuremberg standard is stricter than the medical standard of informed consent, in that the experimenter is put under a duty

39. (1989) Carswell Que 72.
40. 637 F Supp 1463 (NC, 1986).

to disclose all risks which may reasonably be anticipated and not just the usual and most frequent risk. In addition, the standard of disclosure in the Nuremberg Code is subjective and puts the doctor or experimenter under an obligation to disclose to the subject all the risks which may have an adverse effect which the subject may personally suffer as against the risks that a reasonable subject may suffer. In this context, it can be said that the degree of required disclosure of risks is higher in the non-therapeutic context than required under therapeutic context.

In *Wright* v. *The Fred Hutchinson Cancer Research Centre*,[41] the participants in a cancer research programme were informed of the nature of the experiment but alleged that they had not been informed about all the risks. The district court of Washington rejected the relatives of the deceased participants' claim that the doctors' failure to disclose risks amounted to a violation of the participants fundamental and constitutionally protected right to life and liberty. The court said that the therapeutic nature of the trial rendered a remedy in negligence more appropriate. The court opined thus:

> The type of wrongful conduct complained, namely defendants' failure to make disclosures necessary to the informed consent process in a therapeutic experimental setting, does not implicate rights that are so rooted in the tradition and conscience of our people as to be ranked as fundamental. A doctor's tortuous failure to obtain informed consent is not a threat to our citizens' enjoyment of ordered liberty, even when the doctor is employed by the state. Although the failure to obtain informed consent necessarily throws some doubt on the voluntariness of the patient's participation in a research study, such a failure does not raise the specter of the type of involuntary, non-therapeutic experimentation, which shocked the nation after World War II and gave rise to the Nuremberg Code'.[42]

On the other hand, the court noted that 'the judiciary has not hesitated to find that, where the human research subjects were not told that they were participating in an experiment and/or the government conducted the experiments knowing they had no therapeutic value, the subject's constitutionally protected right to life and/or liberty had been violated.[43]

VI Human dignity in international human rights instruments related to biomedicine

Reference to the 'inherent dignity of the human person' in international

41. 206 FRD 679 (2002).
42. Nuremberg Code, at 7.
43 *Ibid.*

human rights instruments are usually found in various preambles to instruments, particularly those in the field of biomedicine. The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) states that 'practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.' The Universal Declaration stipulates that no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.[44] The Declaration further reads that genetic data associated with an identifiable person and stored for the purpose of research or any other purpose must be held confidential under the conditions set by law.[45]

References to 'human dignity' also have a prominent role in the text of the Council of Europe's Convention on Biomedicine.[46] The preamble contains three separate references to human dignity, the parties to the Convention first recognising 'the importance of ensuring the dignity of the human beings', secondly 'conscious that the misuse of biology and medicine may lead to acts endangering human dignity', and thirdly 'resolving to take such measures as are necessary to safeguard human dignity as the fundamental rights and freedoms of the individual with regard to the application of biology and medicine'. In addition, human dignity receives special mention in article 1, which requires parties to the Convention to protect the dignity and identity of all human beings and to guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The parties are obliged to take in their internal laws the necessary measures to give effect to the provisions of the Convention.

Here human dignity appears almost as a distinct right rather than a background value as it does in many other international human rights instruments. Article 1 of the CHRB proclaims the need to protect the dignity and identity of all human beings and guarantee everyone, without discrimination respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. However, despite a prominent reference to human dignity in the CHRB, there remains considerable uncertainty about the precise meaning and scope of the concept

44 See art. 6 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997).

45. *Id.*, art. 7.

46. 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.

and its role as a background value of a distinct right.[47]

VII Ethical and legal principles applicable to research on human embryos

In recent years, the embryonic stem cell research has generated a global controversy. Much of the debate so far has focused on the ethical legitimacy of such research and on the search for an ethical consensus. This section focuses instead on the extent to which ethical arguments about human dignity and the right to life translate into legal protection for the human embryos in biomedical human rights instruments.

There is no consensus among the medical communities as to whether, and in what circumstances, embryonic stem cells may be processed. The processing of stem cells, and in particular the creation of stem cells in cases in which the embryo from which they originate has to be destroyed, is scientifically and ethically controversial and illegal in many countries. The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) states that 'practices which are contrary to human dignity', such as reproductive cloning of human beings, shall not be permitted.

A number of European countries in their Parliament on legislation are debating on the research on human embryos. In 1989 political parties represented in the Second Chamber of the Dutch Parliament agreed that experiments on embryos may only be done for a healthy development of the embryo and for achieving a desired pregnancy. Within IVF as far as possible embryos should be created and experiments be allowed only in exceptional circumstances.[48] The Report Genen en Grenzen (Genes and Limits) of the Scientific Institute of the Christian Democratic Party in the Netherlands proposed limitations on experiments with embryos, and a ban on cloning. It recommended that research on embryos should be allowed only to check for hereditary disorders; if none were found, the embryos should be replaced in the uterus. Research on 'pre-embryos' for clinical purposes is allowed, according to the guidelines of the American Fertility Society.[49]

In England, a Committee of Inquiry into Human Fertilisation and Embryology,[50] consisting of members drawn from various disciplines such

47. For instance, in the Explanatory Report of Charter on Fundamental Rights of the European Union, the right to dignity as protected by art. 1 is expressly assigned only to the 'human person'. On this basis, human dignity could only be attributed to individuals who are already born.

48. Jyotsna Agnihotri Gupta, *supra* note 7 at 421.

49. *Ibid*.

50. Warnock Committee, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984).

as medicine, law, theology, natural and social sciences, was established by the British Government in July 1982 for making various recommendations.[51] Its terms of reference also included consideration of recent and potential development in medicine and science related to human fertilisation and embryology, consideration of policies and safeguards that should be applied and consideration of social, ethical and legal implications of these developments. The results of these deliberations were published as the Warnock Report. Regarding experimentation on embryos developed from women's eggs the recommendation reads: No live human embryo derived from *in vitro* fertilisation, whether frozen or unfrozen, may be kept alive, if not transferred to a woman, beyond fourteen days after fertilization.[52] In 1985, the term 'pre-embryo' was coined by the Voluntary Licensing Authority (VLA)[53] in Britain to refer to the embryo upto fourteen days after fertilisation outside woman's body. It was adopted to make embryo research acceptable. Opponents of embryonic stem cell research allege that research on human embryos constitutes an affront to human dignity and a violation of the human embryo's right to life.

As a result of Warnock Committee Report, the Human Fertilisation and Embryology Act, 1990 was passed in the United Kingdom to safeguard the interest of embryos. In 1991 the Human Fertilisation and Embryology Authority (HFEA) was established. This statutory body regulates the use and storage of embryos and gametes outside the human body and gives advice to the public and to the government on the ethical and scientific issues arising from progress in artificial reproductive technology. The Human Fertilisation and Embryology Act, 1990 is the main reference point for the HFEA. Public information about embryo was the recommendation of the Warnock Committee which, in its report, insisted that the embryo of the human species ought to have a special status,[54] and that this should be enshrined in legislation. In according the embryo a special status, the Committee did not seek to afford the human embryo the same status as a living child or adult. Instead, it aimed to prevent the frivolous or unnecessary use of human embryos. While the Committee did stipulate that some research on embryos should be permitted, it also said that it should only be

51 Marry Warnock, *A Question of Life: The Warnock Report on Human Fetilisation and Embryology,* 4 (1985).

52. *Id*. at 66.

53. The Voluntary Licensing Authority (VLA) was formed in response to the recommendations of the Warnock Report to oversee IVF and embryo research. The 14-days limit on embryo research is recommended in the Report of the Warnock Committee.

54. Warnock Committee Report, para II. 17.

carried out upto fourteen day of development,[55] and that all such research ought to be strictly controlled and monitored. These recommendations were included in the provisions of the Human Fertilisation and Embryology Act, 1990 which states that any research performed on human embryos up to fourteen day of development must conform to certain restrictions and is not lawful unless it has been licensed by the HFEA.[56] In addition, the 1990 Act requires any clinician in deciding whether or not to offer infertility treatment to a patient to take account of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.[57]

In the United Kingdom, embryo creation, which involved nuclear replacement technology would not, by law, be allowed to lead to any foetuses and/or babies be produced. Non-reproductive uses of this technology, as the law stands, may be the only possible ones. An example of the non-reproductive use of this technology is the creation of *in vitro* stem cell types to provide insight into how regeneration of damaged human tissue might be induced without risk of rejection. This sort of potential application of nuclear replacement therapy does raise ethical concerns, but these concerns differ greatly from the ones raised by reproductive cloning.[58]

VIII Medical experimentation on the dead

Scientific research on human tissue or body parts is needed to advance the knowledge of the cause of death and disease. However, the scientific community and the medical profession have to operate within the cultural and moral bounds of society.[59] This section considers the question whether the fundamental principles and rights on biomedical research which are normally attributed only to the living be extended to individuals who are no longer alive, but dead? Utilitarian and welfarist principles of beneficence logically presuppose the primacy of collective welfare over individual rights. In practice, then, utilitarian could justify the instrumental use of human bodies for the collective benefit of society.[60] At the same time, the concept of human dignity is essentially underdetermined and open ended in its application. In the case of disposal of human corpses, the concept of human

55. *Id.*, para II. 30.

56. Human Fetilisation and Embryology Act, 1990, ss. 3 and 15.

57. *Id.*, s. 13(5).

58. The need to distinguish between therapeutic and reproductive uses of cloning technology was affirmed in the Human Fertilisation and Embryology Authority/Human Genetics Advisory Commission Joint Consultation Paper on Cloning (1998).

59. Plomer, *supra* note 11 at 94.

60. *Id.* at 95.

dignity entails that there is a distinctive manner treating human beings which is appropriate and fitting to them (in a way, for instance, which would be different from the appropriate handling of a material object, a mineral, an animal or a plant).[61] What dignity and respect require in the disposal of a human corpse is thus deeply related to social belief about the meaning and value of human life. No such beliefs attach to the handling of physical objects from a scientific perspective.

The Council of Europe's CHRB does not address the issue of removal and the use of human tissue for research purposes from the dead. But the European Convention on Human Rights and Fundamental Freedoms (1950) does contain prohibitions on degrading treatment and privacy which have hither to been presumed to apply to the living human being only but would arguably be extended to the dead.

The human rights approach can best secure adequate legal protection of the dead whilst recognising the public interest and legitimacy of some forms of interference with and research on human corpses and body parts. On this basis, there is no doubt that the rights of the deceased legitimately be balanced against the interests of society in the conduct of scientific research on human tissue or organs. It is precisely such societal interest that many human rights instruments thought were been compromised.[62]

IX Conclusion

The knowledge of law and professional ethics is necessary for the doctors conducting any research on the human subjects. In the light of geographical variations in the regulation of medical research, the adoption of a legally binding treaty which aspires to capture fundamental values as well as bringing 'greater unity between the nations may therefore be an important step toward European and international harmonisation of norms in the field of biomedicine'. The Council of Europe's Convention on Human Rights and Biomedicine may be the ideal legal framework for the United Nations to address the problem.

At the national level, a legal or ethical framework purporting to identify fundamental and universal principles and rights in medical research is needed. The national law must provide adequate justifications for overriding individual autonomy and welfare for the sake of the common good. In addition, there are compelling reasons to doubt that the legal framework of

61. Aristotle, *Nicomachean Ethics* translated by Sir David Ross ((1954).

62. See R. McKie, ''Bill on Removal of Organs Will Paralyse Life-Saving Research'', *The Observer*, February 8, 2004.

national and international guidelines may be sufficient to prevent abuses in practice. One major source of concern is the absence of overarching regulatory mechanisms to monitor and control adherence to the guidelines. At the national level, the Research Ethics Committees (RECs) may be entrusted with the task of scrutinising research projects to weed out those which do not comply with international norms. The universality of human rights demanded that prevailing and dominant cultural and ethical beliefs cannot be invoked in a manner as to circumvent or restrain fundamental human freedoms and rights. Cultural beliefs in some societies or sectors cannot be a valid reason to restrict the benefits of science and technology to millions of people.

It is the need of the time that ethical code pertaining to medical practice need to be revised to keep pace with scientific advances in the application of biomedicine. As the biotechnologies have revolutionised health care in India, it is necessary that laws pertaining to medicine and research need to be enacted and the regulations be framed at the earliest. It is also desirable to have laws at the international level, so that scientific knowledge is not confined to a particular country, but shared by all. While it is true that medical researches on human subjects are capable of and subject to abuse and misuse in many ways; the solution does not lie in dismissing the medical research, but to regulate it for the cause of humanity.