

Ethics in public domain: biomedical research and beyond¹

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I am concerned with “ethics in public domain: biomedical research and beyond” highlighting complex issues which are being faced by mankind. Ethics in public domain, *the frontier of all the frontiers of research and its applications*, as the author describes it, is faced with the

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challenging task of protecting life and human dignity. Taking the case of biomedical/biogenetic/biotechnological research as one of the frontiers, the paper develops an argument for full participation in the debate by all the stakeholders, among them the professional philosophers and legal luminaries who can impart not just rigor but teeth to ethics in public domain by coming out with universally binding regulations and enforcement mechanisms. In the absence of such regulations, mankind will be groping in the dark while asking how to cope with the situation where the world is divided against itself even on commonly shared vital issues of moral progress. All the steps taken until now at the UN and at the national legislatures fall short not only of full participation by all the stakeholders but of legally and ethically binding regulations, failing to recognize the complexities and the implications of the challenge. Ethics committees have, no doubt, cropped up world-wide in some fields. The fear of proliferation of unregulated research and its applications leading to undesirable, even unintended consequences, on the one hand, and the paradox of moral progress being excluded by scientific and technological progress, on the other hand, haunt the public policy makers everywhere. Unfortunately, ethics committees have had only a limited role and success (in and outside their institutional boundaries) marked by fragmented approaches to guidelines being formulated in individual countries or regions of the world. In the opinion of the author, the real breakthrough that has yet to come will have to pass the test of moral progress at the frontier defending life and human dignity.

Basic Considerations

§1. The crises of knowledge-production without wisdom: My presentation may be broadly viewed from the perspective of *ethics in public domain* which I like to describe as the frontier of all frontiers of research and its applications. Fierce debates on issues like biotechnology, stem cell research and cloning have shown that the rapid scientific and technological progress can give rise to serious ethical questions. These concerns must be addressed by individuals, policy makers and the scientific community alike (i) to take into

account public fears and (ii) to avoid alienating citizens and creating an environment hostile to scientific and technological innovations. Moreover, in the light of efforts to develop in a sustainable way, implications of new technologies for future generations must be thoroughly considered. Thus, the present and future tasks at the greatest frontier before humanity have to do with issues of economic, scientific, technological and moral progress [1, 2]. *The past and present institutional failure universally in almost all fields gives rise to the dilemmas of promoting: knowledge with or without wisdom; scientific progress with or without moral progress; economic and technological progress with or without proliferating forms of exclusion; economic prosperity and political freedom with or without structural violence; biomedical research with or without informed access to new technologies and mechanisms; education with or without literacy; democracy with or without participation; human rights with or without access to them; development with or without environmental damage and climate change; and Earth as a family with or without the human species Homo sapiens and so on.*

Faced with the challenging task of protecting life, human dignity and values, *ethics in public domain* invites our attention, *first of all*, to the paradox of moral progress being excluded by scientific, technological and economic progress every where in the world. Indeed it invites our attention to the universality of this paradox. One of the basic issues, here, is how far the interdisciplinary courses of studies at the universities worldwide could help in fighting exclusive images of knowledge and value which still dominate our lives and activities. How far could these help in overcoming the menace of forms of exclusion proliferating everywhere and in all fields? *Secondly*, whether we are willing to pursue a model of education and a style of living where besides intelligence, professional success, personal attainments, we also learn to value *wisdom*? In a nutshell, I am referring here to the value of bringing moral progress to bear upon all other forms of human progress so that (i) the universality of the crises of *knowledge without wisdom* can be avoided and (ii) forms of exclusion do not proliferate with

progress in knowledge-production, with scientific, technological and economic development. In my view, these questions bring us face to face with future generations as *stakeholders*. Thus, they bring us face to face with the task of interrogating our present policies on education, on societal and state responsibility for the upkeep of health, on quality of life, on environment, on science, technology and development. If we are guided by multiple images of knowledge and value, we can prepare all the *stakeholders* for a future which is open. Since the future is unpredictable, critical reflection on such challenging questions and open problems remains our best guide to possible directions for seeking improvements. And, in any discourse on educational policies at various levels, philosophy and ethics in public domain must assume a fundamental role.

§2. Stakeholders in moral progress: I will begin by asking certain fundamental questions in order to indicate why, and to what extent, mankind depends upon moral progress for regulating the investments which the state, the individual, the institution, the civil society and corporate industry, each as a *stakeholder*, makes where progress in the production and the uses of scientific knowledge is concerned. First, can moral progress in public domain co-evolve with public policy on investment, on planning, on development, on the beneficial uses of the fruits of scientific progress? In fulfilling the tasks of reaping the fruits of the tree of knowledge in diverse fields, when can we say that we are making moral progress which is commensurate with human dignity and human freedom? Since the United Nations adopted the Universal Declaration of Human Rights (UDHR) in 1948, their enforcement and protection as instruments for protecting human agencies and human beings against cruelty, oppression, abuse and degradation has assumed unquestionable priority and importance among the members of the UNO, in their conduct of international relations and in their treatment of their citizens and in their public policy on development. Yet, their universal recognition, their successes, their prospects and the failures of their universal enforcement tell a story not only of moral progress but of moral failure of mankind at the most difficult frontier of improving

the human condition of individual dignity and individual freedom. In terms of the UDHR alone, we can claim, with Michael Ignatieff [3], that the moral intuition that “our species is one, and each of the individuals who compose it is entitled to equal moral consideration” and that “Human rights is the language that systematically embodies this intuition, and to the degree that this intuition gains influence over the conduct of individuals and states, we can say that we are making moral progress”. But in the absence of an enforcement mechanism which is commensurate with the UDHR, an ever widening gap between the word and the deed tells how difficult it is to guard all that which is at stake at the frontier of human rights.

In scientific journals and in conferences devoted to discussions on human rights, bioethics, medical ethics and environmental ethics we are not even surprised to find how frequently references are made (i) to ethical dilemmas, but none to the question of how we might make and judge moral progress, given scientific and technological advance; (ii) to contexts of participation, but none to the environment for participation; and (iii) to rules for participation, but none to the social indicators of participation. I think that this kind of situation is not fundamentally different from those talk-shows in which we find people speaking of (a) education as if it was about everything else except education; (b) UDHR as if it was about everything else except human rights and access to them; and (c) science as if it was about everything else except the question of its being in charge of its own progress and its many uses. As to education, let me quote John Raven (1994) who argues “that the areas in which research and innovation are *most* badly needed in our society do *not* have to do with finding better ways of producing goods of one kind or another but with finding better ways of running society itself” [3]. Building up his detailed arguments in his book on how to manage education for effective schooling, he concludes: “In essence, what we have seen in this book is that the failure of the educational system to achieve its main goals is multiply determined and that that failure contributes to the perpetuation of a society which, at least in the short

term, requires its educational system to perform functions which are in sharp tension with the educational activities it manifestly needs to undertake” [5].

More specifically, take the example of schools failing to teach poor children to read within their 1st two or three years of schooling. Even when they complete the schooling, they are found functionally illiterate. Thus, at a recent *World Bank Conference on Aid Effectiveness for Human and Social Development*, participants showed conclusively that completing school is a very practical and often irrelevant achievement. The most likely explanation for this is institutional failure, given children’s diverse backgrounds at the school entry point. While better-off children, whose reading habits begin to develop already at home, enter school with a vocabulary of 2000 to 4000 words, poor children entering school, without any such background, have barely a vocabulary of only 600. This raises the question whether schools are meant to churn out students who are without any improvement in learning outcomes on the completion of school. What do the schools then invest on, be it the developed or developing countries? Why does it take a few right thinking and questioning men and women to ask paradoxical questions such as these: Whether schools are not meant for teachers instead of children? Whether hospitals are not meant for doctors instead of patients? Whether Parliaments are not meant for their members instead of their constituencies where people with votes belong? Why does our world have to churn out institutions which breed forms of exclusion and collective crime? Today, there is an urgency to seriously address the questions of moral progress and forms of exclusion. This task assumes increasing importance in our highly globalized world which has made scientific, technological and economic progress but which is torn by structural violence, terrorism, human rights violations, poverty, hunger, refugee problems and so on. So long as moral progress not only lags behind but is even excluded by scientific, technological and economic progress, the two kinds of progress will never be synonymous. As a result, everywhere in society there will be forms of exclusion and structural violence. In many dark areas, the future generations too will have to

pay the price on our behalf. This is particularly true in case of environmental damage caused by the present and past human activities. The question is why moral progress of mankind lags far behind scientific and technological progress, always showing a negative correlation.

What I find equally paradoxical is that most of the troubles in our modern world lie in those areas of experience where people already feel strongly connected. Take for example religious fundamentalism which is responsible for terrorism and massive structural violence in many parts of the world. The only explanation for strong connections on which it thrives could be this. Like (the political discourse on) education, or human rights awareness campaigns, or science and technology, fundamentalism too is about everything else except the cause for which the fundamentalists and their known and unknown sponsors seem to fight. Is this kind of situation not really highly paradoxical? Is it not quite reasonable, therefore, to propose the following general systems theoretical strategy? *Participate and reconnect, or participate and rediscover the connections*. This alone should allow us to discover more and more participants, more and more stakeholders, to be empowered and more and more connections than we have thought there are to the situation which we so proudly celebrate as our achievement, or as an object of scientific study. If used as an epistemological strategy, it should allow us to test improvements in the human condition by testing the correlations between the conditions of human dignity, human freedom and human knowledge. Thus, the task here is to engage in those research strategies and developmental models with which we can expect to bring about improvements in the human condition. But at this very level, the most challenging question still remains with us: When can we say that we are on our way to moral recovery and moral progress or on our way to controlling technological progress before we are controlled by it? Is there not a rationality of connecting the conditions of human dignity, human freedom, human knowledge and moral progress, which we can no longer ignore? We can answer this question in the affirmative, because without such rationality it

would not be possible to improve even our causal knowledge of a whole diversity of forms of exclusion in society.

§3. Why ethics in public domain? Negligence and breach of duty of care have become a matter of everyday experience for patients being admitted in hospitals for treatment of disease. There are serious *issues* of medical practice relating to standard and quality of health care, informed access to medical care, ethics consultation service, complementary and alternative medicine, medical reform, informed consent, medical malpractice, assisted reproductive technologies, reproductive health technologies. Take the case of biomedical/biogenetic/biotechnological research as one of the *frontiers*. One of the serious issues is how to promote full participation, in the debate on fundamental issues of policy and implementation, by all the *stakeholders*, among them the professional philosophers and legal luminaries who can impart not just rigor but teeth to ethics in public domain by coming out with universally binding regulations and enforcement mechanisms. In absence of such regulations, mankind will be groping in the dark while asking how to cope with the situation where the world is divided against itself even on commonly shared vital issues of moral progress. All the steps taken until now at the UN and at the national legislatures worldwide fall short not only of full participation by all the *stakeholders* but of legally and ethically binding regulations, failing to recognize the complexities and the implications of the challenge. There is no doubt that ethics committees have cropped up worldwide in some fields. But they have done so under the fear of proliferation of unregulated research and its applications leading to undesirable, even unintended consequences, on the one hand, and under the paradox of moral progress being excluded by scientific and technological progress, on the other hand. In practice, they have had only a limited role and success (in and outside their institutional boundaries) marked by fragmented approaches to guidelines being formulated in individual countries or regions of the world. The real breakthrough that has yet

to come will have to pass the test of moral progress at the frontier defending life, human dignity and values.

Why ethics research committees have cropped up worldwide? How far can they help humanity in facing the present as well as future challenges in science, in technology, in biomedical research and other fields? There is no simple answer. One answer is that it has become imperative to bring issues facing mankind in all fields of knowledge production and its application in full public view for proper and thorough debate, before letting them go before the national legislatures, or parliaments, and UN bodies for policy decisions, particularly where universal legal and ethical regulations are concerned. This is all the more necessary in the context of our aiming at a common sustainable future.

The most important yet neglected aspect of the problem is that with every breakthrough in science and technology, particularly in biomedical research, diseases are invented with the same ease with which their diagnoses, tests and treatments are advertised for doing business with the rich. The invention of **stem-cell/ umbilical cord banking** serves as a good example. These are the banks where rich couples can deposit stem-cell rich cord blood that can be stored and used in the future in case their baby is faced with any serious medical disorder or health problem. If the tests (prenatal and postnatal) reveal that their child is healthy, the cord blood can be donated for scientific research. The charges for registration include enrolment fee and annual storage charges up to two decades or more. Umbilical cord banking is still at a very nascent stage in India. What is true of this example is also true of assisted reproductive technologies.

Leaving out for the moment the specific issues, let me raise those issues which are general and common to several fields at the same time, for example the issues of “informed consent” in varied research contexts. Pre-implant-testing of the artificially-inseminated embryos (before they are implanted in a woman’s body) where couples feel concerned about potential life-threatening genetic or chromosomal defects/diseases in their offspring, stem-

cell banking, human genomics, assisted reproductive technologies and reproductive health technologies in biomedical research, even organ procurement and intensive care for children and surgical patients, *all* raise serious issues not only of “informed consent” but of *informed access*. There are also common issues arising from scientific and technological progress, or those connected with freedom of scientific research. For the moment I shall keep them aside. As the medical technology grows at an incredibly fast speed, the treatment options keep increasing too, though not necessarily in an egalitarian way with equal access to all. In this context, it must be remembered that “informed consent”, an ethically loaded concept, gets inseparably linked with *informed access*, entailing the intervention by ethics consultation service. Without ethics consultation service, “informed consent” loses its meaning and significance in research. Yet most countries in the world have not been able either to institutionalize ethics consultation service at all or to establish a network of such services as a first step to a well-integrated ethics consultation service.

Again, a very serious issue regarding the very access to new technologies such as assisted reproductive technologies or reproductive health technologies arises in the present context. What is it to have, or not to have, *access to new technologies* (**ANT**), be it in medicine or outside medicine? Does **ANT** imply just the ability to pay for them? If yes, then new technologies surely breed new forms of rich-poor divide, since evidently not all who are in need of it can pay for them. The moment we ask who can *afford* to benefit from new technology, the old *rich-poor divide* repeats itself. However, the issue of **ANT** goes much deeper than this. **ANT**, where rational, entails knowledge-based access, allowing one to exercise a dignified rational choice. That is, at a deeper level, “informed consent” is crucial to **ANT**, not just one’s economic status. While choosing a new technology, one should *know* not only the consequences of such a choice but also the reasons *why* one chooses to have the technology at all.

Thus ethically viewed, **ANT** is an issue fundamentally involving decision-making, given sufficient information or knowledge, on the basis of which one may decide to have or not to have the new technology. **ANT** in this sense gets closely reconnected to “informed consent”. The potential beneficiaries must be able to take the right decision whether or not to go for it. Alas! presently, this is universally not the case. This easily results in *medical malpractice*, in manipulation and exploitation. The worst example is the South Korean scandal in which the disgraced scientist unethically procured the eggs for stem-cell research from his own employees.

Universally, what is worse is this: Often, it turns out that the right information about new technologies we are here concerned with is missing just because there is no investment on research on **ANT**, although there is no dearth of investment on producing and selling the new technology to the potential beneficiaries. This raises the question: *Why is it necessary for our world to produce inaccessible technologies?* Is it a step in progress or in regress to do so repeatedly? *The perennial paradox in which we all are involved here is the paradox of producing knowledge and technology without wisdom or moral progress.* Until the present human condition of **ANT** changes, the new technologies will continue to take over, manipulate and exploit human beings at the cost of human dignity and human life. This is particularly true of new technologies connected with bio-medical research.

How does the scenario for ethics in public domain look like in India? In late 1990s, the Indian Council of Medical Research (ICMR) set up a Central Ethics Committee on Human Research (CECHR) with the aim of updating its Ethical Committee’s 1980 “Policy Statement on Ethical Considerations Involved in Research on Human Subjects”. In its September 1996 meeting, the CECHR set up 5 sub-committees identifying major areas of concern, covering (1) Clinical evaluation of drugs/devices/diagnosis/vaccines/herbal remedies; (2) Epidemiological research; (3) Human genetics research; (4) Transplantation research, including foetal tissue transplantation; (5) Assisted reproductive technologies. In

August 1997, the CECHR met to deliberate on their draft guidelines and a Draft Consultative Document. It is difficult to comment how public and interdisciplinary was the public debate intended to be generated region-wise and across the scientific institutions in the country before the final drafting of the guidelines by a drafting committee set up for the purpose. It is difficult to say how many universities, or disciplines, how many professional philosophers of repute, or how many scientists genuinely interested in ethics in public domain were encouraged to participate. Absence of a professional philosopher on all the sub-committees of the CECHR, even on the Sub-Committee for General Principles, is revealing for a people with a civilization rich in moral philosophy going thousands of years back in history. In sharp contrast to this, in Europe, particularly in Germany, ordinary pathways and streets are named after individual scientists and philosophers, celebrating the life of the mind as torch-bearer at the frontier of human life. However, it took CECHR four years to document “Ethical Guidelines for Biomedical Research on Human Subjects” (**EGBRHS**), a publication which ICMR brought out in 2000. The *Foreword* written by the Chairman of the CECHR says: “Biomedical Research has acquired dimensions which are at once exciting and awesome. It raises some delicate and difficult issues of ethics which need to be dealt with sensitivity to human values and with great circumspection. While research which promises to mankind the great blessings of Science should not be stifled by too restrictive an approach, however, great care should be taken to ensure that something does not go out of hand. Therefore, any system of ethical guidelines on research needs to be cognizant of, and informed by, sensitive balance of the risks and benefits”. In the last statement which sounds rather overly utilitarian in restricting itself to the decisive balance of the risks and benefits, it is not possible to miss its sole emphasis on ethical guidelines, raising serious doubts about **EGBRHS** (2000) as an effective instrument of protection of life and dignity. Protection of life and dignity goes far beyond utilitarian rationality. If this is recognized, it entails our ability to distinguish between morally and legally binding regulations on research from mere non-binding guidelines. When

we read through the pages of **EGBRHS** (2000), we merely find statements laying down guidelines to be followed, not even any mention of the need to monitor how they are to be followed.

The debate on a total ban on reproductive and therapeutic cloning divides the world in a manner which makes it clear what is at stake if no consensus on ethical and legal regulations on research is arrived at. A culture of life and its protection is, as some have argued, at stake. At the UN the debate over a ban on reproductive cloning began in 2001 with France and Germany in the lead, with near universal national support. But governments led by the United States and Costa Rica urged the world to back a total ban, including a ban on therapeutic cloning. In all its forms, including the therapeutic embryonic stem cell research in which the human embryos cloned for purpose of obtaining the cells used in the studies are later discarded, human cloning should be banned. The *stakeholders* in this issue seem to be having too many divergent considerations, coming in the way of a universal agreement. On the 18th February 2005, a deeply divided UN General Assembly Committee adopted a nonbinding statement calling on governments to prohibit all forms of human cloning, including techniques used in research on human stem cells, abandoning efforts for stronger action because their divisions were too deep. From the beginning, the debate hinged on whether to outlaw all cloning or permit cloning for research. Nations that sought a total ban always had more votes, but never enough to achieve broad consensus or a binding worldwide treaty. In November 2005, the debate met with failure in arriving at a worldwide treaty to that effect, despite the efforts of the UN legal Committee. The only option left was to work toward the nonbinding political statement, hoping to achieve broad consensus. However, the hope still remains alive at the UN in so far as the present debate is seen as a step toward a universal declaration in the future, provided the national legislatures around the globe work for essential inputs. The declaration adopted in November 2005 also demands that Member states "adopt the measures necessary to prohibit the application of genetic engineering techniques that may

be contrary to human dignity " and to take measures to prevent the exploitation of women in the application of life sciences. The debate on embryonic stem cell research will continue. Stem cells are nascent cells which can develop into replacement cells that researchers believe could help treat damaged organs and illnesses. The embryonic stem cell research aims at designing such cells to treat conditions considered incurable by traditional medical means, such as hearing disorders, nervous system failures, diabetes, Parkinson's disease and glaucoma. Recently news came in that some scientists have developed alternatives like developing stem cells from umbilical cord blood taken from newly born babies, sparing embryonic stem cells. If this should work, it will not only make the morally objectionable embryonic stem cell research avoidable but give the message that it is possible for scientists to learn from ethics in public domain while working harder on safer alternatives for applying the fruits of scientific progress for improving the human condition.

I am here concerned with the question why moral progress of mankind is excluded by scientific and technological progress, always showing a negative correlation. At the global level, state of the art of embryonic stem cell research, of assisted reproductive technologies and reproductive health technologies provide good examples. There are other areas of research and technological development where questions of moral progress arise in so far as investment in areas of development of new and faster technologies is incommensurate with (near absence of) investment on enhanced access not only to new but even to old technologies. As a result, while new technologies reach quickly the privileged few, large masses of people continue to be deprived of even the older and outdated technologies, repeating over and over again the world's oldest divide between the rich and the poor. What is worse is how incommensurate investment on development is with (near absence of) investment on research on the social and other consequences of new technologies. Should scientific, industrial and technological development imitate fashion designing industry in order to reach the chosen few or should it aim at moral progress by improving the human

condition of individual dignity and individual freedom on Earth and minimizing structural violence. If a project investing in development, change or reform breeds forms of exclusion, doing good to some by degrading others, it must be given up in favour of an alternative project which enhances the chances for improving the human condition on Earth. I think that this clearly shows us how mankind may make moral progress in the future while engaging in projects of scientific, technological, industrial and economic development. Let me quote Werner Heisenberg (1989:494), warning us about the new dangers of scientific and technological progress as a challenge calling for our response. Concerned as he was with the ambivalence of science, Werner Heisenberg proposed, as a guiding principle, "to consider any special progress in science or technology as a part of the whole, as something that cannot be separated from the general problems of our way of life, our environment, our political behaviour. This obligation - to keep in mind the unavoidable connection or interplay between *all* actions - will set and should set limits to our blind confidence in science and technology, but not necessarily to science and technology itself" [6]. For detailed, discussion, see references [1, 7]. Similarly, Richard Rhodes [8] reminds us of the deeper truth how "Violence and scarcity are connected. At the end of the 20th century, when the world does not lack resources, scarcity is itself a form of violence – structural violence, as it is termed, meaning violence that results from the way power and wealth are distributed. The fact that African-Americans in the United States have an average 4 years' shorter lifespan than whites quantifies one evident manifestation of structural violence. Hunger, malnutrition, extreme poverty, and preventable disease throughout the world are all manifestations of structural violence" [8]. If we don't stop at some point, we can go on adding challenge after challenge which tells how difficult some human beings make it for others to fight at the frontier, defending human dignity and human freedom. Think of the arrogance of some of us who want to conquer nature where the most urgent task of science and technology is to remove our prejudices, to civilize us and to teach us by example how we can learn from our mistakes.

Think of corruption in public life. Even the media, “the free press”, are not free from it. Particularly in India, the human condition of coastal and rural life as actually lived by poor masses never comes to public attention. Even in times of disaster, whether “natural” such as earthquakes, cyclones or tsunamis or “man-made” such as the uprootment of whole ethnic communities caused by killings and threatenings by organized terrorists, all that we receive are short glimpses only. Why is this so?

§4. Freedom of scientific research: It is not invariably clear in all kinds of contexts of scientific and technological progress, more so in those of biomedical research, whether the scientist’s freedom of scientific research, which civil society more than the state values so much, should automatically extend to their all possible and desirable applications that manifestly aim at the improvement of the human condition. It is as if the freedom of scientific knowledge production was neither synonymous with nor sufficient for the freedom of deciding which *uses* of knowledge to avoid and which to foster for society’s, even future generation’s, long-term interests. Let us admit that the two kinds of freedom are *asymmetrical* with each other. No limits may be set to the scientist’s freedom to search for knowledge, or to fundamental research. But the same does not hold true in the case of society’s search for improvement in the human condition, making use of the fruits of the tree of scientific knowledge. The problem is that scientists and policy makers often do not heed this asymmetry in all its moral and social complexity that involves many stakeholders. *Ethics in public domain strikes at the root of this asymmetry.* It allows us to pause and reflect on our own achievements as soon as these are clouded by our arrogance, uncritically extending freedom of scientific research to its most ambitious and wildest applications. The most spectacular example is provided by advances being made by genetics which raises the prospect of future enhancement and control of human characteristics, even extending enhancement to mind-enhancing drugs, bodybuilding and cosmetic surgery. Biomedical research generally *and* human genetics, human reproductive technologies, human embryonic stem cell research and

human enhancement technologies particularly, pose serious problems of consensus and principled co-operation in the domain of a public policy dispute. The scenario is one in which many stakeholders, representing diverse kinds of interests and epistemic communities, rooted in different moral traditions and values, are sometimes found genuinely interested in overcoming the tensions of a fragmented approach to resolving complex ethical issues which the technologically and market driven scientific research and experimentation pose. But is consensus on values in the public domain attainable? Within the fast developing technology-driven scientific practice itself, how far can the diverse interests of researchers, scientists, human test-subjects, the potential beneficiaries, technocrats, corporations and popular media be integrated with the culturally fostered public ethical concerns? Some of these ethical concerns find expression in our respect for human life, for the embryo, for traditional ways of human procreation, for a properly regulated human subjects research, for human rights of the human subjects participating in research, for their informed consent, for human dignity and human welfare without commercialization, and for improvement of the human condition without commodification. It is no surprise, if the biomedical researchers often find themselves pulled by the forces of (i) technological progress opening up new possibilities of conquering disease and new horizons of controlling human procreation, even enhancing human characteristics, and (ii) moral progress making it imperative to bring more and more of the complexities of scientific practice under principled ethical scrutiny and debate.

In this article, I am arguing that the old images and distinctions regarding scientific knowledge production must be allowed to dissolve, if ethics in public domain is to empower different stakeholders on an equal basis. There may be something to learn from the example of the highly co-operative and highly instrumentalised extended scientific community in fundamental physics and astronomy. Here too scientific knowledge production involves many stakeholders instead of knowledge simply flowing from the university to industry, as was demanded by the older images. If the methodology of inquiry in the natural and social

sciences recognizes *co-operation* at many levels as a necessary condition of knowledge production, we must not forget its role as an important *strategy of inquiry* in this context. Strategies can change over time depending on the complexities of the problem-situation at hand. However, in the social sciences and bio-medical research, strategies of inquiry, of debate and publicity in the media, assume a special significance because the complexities of research cannot be separated from the social responsibility of the stakeholders. Nor can they be separated from the individual interests and rights of those who are being projected as the potential beneficiaries of the new technologies. Thus, they demand situation-to-situation variations in the rules of method. They even demand variations in the priorities of research, in the allocation of funds, in the ethical regulations for obtaining informed consent from the human subjects of research, in the ethical regulations for guaranteeing to all the stakeholders increased access to technologies meant to benefit human beings and in regulating research so that it reflects public values and not just the exclusive interests of researchers and corporations who stand to profit by research. If the methodology lends scientific inquiry its stability, strategy allows it to cope with the increasing complexities of the changing problem-situations and their wider social contexts. While strategies may keep changing with the changes in the researchers` cognitive and practical ends, methodological rules - at least some of them - need not do so over different epochs. However, within one and the same methodology, different, even incompatible strategies may be resorted to if only to realise the cognitive and practical ends of inquiry. If understood as a *strategy of inquiry* in the field of biomedical research, *co-operation* so *internalized* can play a key role in arriving at consensus and in resolving the complex ethical issues and dilemmas in the domain of public policy where there is always a plurality of stakeholders [1, 9-13].

§5. Experimenting with human subjects: How informed can informed consent be? The single page Consent Form for Normal/Control Samples prescribed at most Centres for biochemical technology under the CSIR within the **EGBRHS** (ICMR 2000, pp. 87-88)

provides for a statement of declaration (either signed or thumb impressed) by the Normal Volunteer/Patient, giving his/her consent freely to participate in the (genetic) study aimed at understanding the role of indoor fungi in Asthma/ various disease processes/ and the like, depending on the nature of the experimental project being undertaken. The signatory then adds “that it has been explained to me that all information on medical history and the analysis of my blood samples will be stored anonymously and will be used as Normal (Volunteer)/Patient samples for molecular research of fungal allergy...”. In the same Consent Form the investigator signs, certifying “that the above consent form has been signed in my presence. The purpose for which the sample will be used has been explained to the above named Normal (Volunteer)/Patient. The individual is free to withdraw as and when he/she feels so inclined. All the results of the investigation will be made available to the participants”.

The **EGBRHS** (ICMR 2000, pp. 87-88) are generally rooted in a fairly broad consensus regarding the importance of informed consent, given the correlative expert verbal explanations of the risks involved in experiments on human subjects. In many areas of biomedical/biotechnological/biogenetic research involving human subjects, such as human embryonic research and research in assisted reproductive technology, the ethical guidelines require obtaining informed consent from donors and beneficiaries alike. Generally, each area of research on human subjects demands additional requirements for informed consent, besides the general requirements documented under **EGBRHS**. **EGBRHS** lay down, as a guideline for assisted reproductive technologies, that “After duly counselling the couple/oocyte/semen donor, an informed and written consent should be taken from both the spouses as well as the donor, as the case may be. They should be explained the various risk factors associated with the procedures in simple language and the words that they can understand. These include risks associated with an ovarian hyperstimulation, anaesthetic procedures, and invasive procedures like laparoscopy, aspiration of ovum etc. They should also be explained the possibility of

multiple pregnancies, ectopic gestation, increased rate of spontaneous abortion, premature births, higher prenatal and infant mortality as well as growth and developmental problems. They should also be explained that there is no guarantee on the success/failure of the procedure". The human subjects-research ethical guidelines such as these, which in turn determine the format of biomedical and biotechnological research proposals in various areas, raise serious ethical and legal questions as follows. There are serious problems here in correlating the verbal explanations to be given to the declarations of informed consent to be taken. Notice that the kind of standard these set for the explanation of the risks associated with the procedures involved in assisted reproductive technologies only underlines the fact that the procedures in question are best understood as *experiments on human subjects*. The question arises, *first of all*, how explanatory can such explanations be for the experimental human subject. *Secondly*, on whom should really the onus of the declaration that, in a given case, the informed consent is a properly informed consent rest? Should it rest solely on the donors/patients/subjects themselves, who are required to sign the declarations? In many cases of biomedical research, as the subject of experiments and trials, the human subject is used as the source of samples over a period of time. The same human subject is also used as the source of the information that the informed consent is a properly informed consent. *In the context of scientific inquiry, what is the difference between the two procedures of (i) extracting the samples for the tests/experiments and (ii) extracting the whole truth of the informed consent from the same human subject?* For fulfilling the presupposition that the verbal explanation given to the experimental human subject is properly correlated with the informed consent taken from her/him, the question arises what should be the form and content of those explanations without which no consent can become informed consent. Based on verbal explanations only, when does consent, in writing, become informed consent? When does explanation, even if it is given in writing, allow it to become informed consent, justifying the declarations made by the patient/human subject? Normally, it has been found

that the pattern of verbal explanation remains invariably the same from experiment to experiment, heedless of the background variations among subjects, such as their language, education, literacy, culture, life-style, family life, psychology and the like. Given the asymmetries of information between the scientist-researcher and the experimental human subject (which are similar to the more familiar scenario of doctor-patient asymmetries in all medical practice), ethical dilemmas are bound to proliferate in all biomedical and biotechnological research experimenting with human subjects. Hence the question: How informed can informed consent be qualitatively? When and on what basis can a human subject decide to withdraw from participation in the experiment? Whether she/he should do so just on the basis of verbal explanations which are given at the beginning of research/experiment? Or whether she/he should do so only on the basis of explanations furnished in writing? Or whether she/he should do so only after discovering aspects of research which were being concealed from the outset?

It can be argued that informed consent in the context of experiments on human subjects is a subject far more complex than is generally assumed. Therefore, no simplistic guidelines are going to suffice. Above all, it is an ethically loaded concept. But it is this aspect which has gone unrecognized even in those institutions where ethics committees are in place. I think that declarations of informed consent should have a mandatory provision for relevant explanations in writing. Such declarations should have at least three components. One of these should be signed by the human experimental subjects themselves and the other two by the scientist/researcher and the Ethics Committee who are empowered with the responsibility to clear and monitor the research proposals. But the problem is that at present such committees are generally appointed only to issue clearance of research proposals on the basis of guidelines that are legally and morally non-binding, lacking universal validity, and formally over-simple or ritualistic. In the guidelines, there is no provision requiring the research to be monitored after the clearance has been given. It can be argued that it is imperative to empower

such committees with regulatory, adjudicatory and monitoring authority, going beyond their present bureaucratic advisory role. Moreover, it is imperative at all the levels of decision-making to be properly fed with relevant information based on prior research on what kind of knowledge is helpful to all the stakeholders when it comes to actual decision-making in using a new technology. This raises the most fundamental issue of access to new technologies.

§5.1 Health care reform, Reproductive health technologies and assisted reproductive technologies. First, what are assisted reproductive technologies? Assisted reproductive technologies are those technologies which enable the childless couples, given surrogate mothers, to have children, who if left to themselves would never have a baby either because of infertility or because of treatment for diseases like cancer which could leave a patient infertile or vulnerable even after her full recovery from the disease. Let us take an example. Jennifer Rutansky, a young woman of 26 years, from Jacksonville, Florida, had to go for chemotherapy following surgery and radiotherapy to treat her cancer which was diagnosed in August 1997. Seven years later, having recovered, she got married. But she was warned not to get pregnant. The couple found a surrogate mother. Her own frozen eggs and her husband's sperms were used to produce embryos through the *in vitro fertilization* techniques. The embryos were then transferred into the surrogate mother's womb. The first two experiments, carried out at the Florida Institute for Reproductive Medicine, failed. The third experiment was successful. On October 3, 2005, their biological son was born, thanks to fertility preservation techniques and assisted reproductive technologies. Assisted reproductive technologies go beyond reproductive health technologies that offer reproductive health resources. Reproductive health technologies include drugs, devices, and medical interventions to control reproduction and/or prevent sexually transmitted infection, such as contraceptives and products used to enhance fertility. There has been a race for investing in technologies that are needed to manage the physiological and emotional transitions associated with menopause. But there is hardly any investment in research on how to educate the potential users and

practitioners about the uses of these technologies and proper decision-making. The basic question about any such technology is how accessible it is to those who might be most needy or vulnerable to risk. For example, it is not commensurate with the rights of couples to make ethically and epistemologically responsible decisions regarding the use of the reproductive health technologies merely on the basis of advice about the clinically-proven safety and efficacy of such technologies [13]. A proper investment in research on reproductive health decision-making, sexual practices, and norms and values for childbearing and family formation is needed. In the words of Woodsong and Severy, “The concept of sexual health further affirms the human rights of all individuals to access sexual and reproductive health care services and information related to sexuality, including information that can aid in deciding if, when, and how to have children” [14]. Serious debate and research is needed on answering the question what kind of knowledge is necessary for an individual to influence her use of such technologies or to influence her reproductive health decision-making. There is no doubt about one thing: Whatever information and advice are made accessible to the potential users and practitioners of reproductive health services, these should be more accurate, comprehensive and comprehensible than they are actually. In a nutshell, investment in reproductive health technologies should be accompanied by investment in social and behavioural research on the potential users and practitioners of these technologies [14].

Assisted reproductive technologies, on the other hand, are defined as non-coital methods of conception to overcome infertility problems that involve manipulation of eggs and sperms, the most popular among them being *in vitro fertilization*. Used in 70% of all assisted reproductive technology procedures, *in vitro fertilization* uses drugs to stimulate egg production in a woman. The ripened eggs from the ovary are retrieved, in the laboratory, and fertilized with semen. The resulting embryos are then transferred back into the uterus for implantation. Assisted reproductive technologies are not only highly expensive and therefore not accessible to the ordinary poor people but also time consuming. Moreover, they involve

multiple injections of drugs. What is worse, they have a modest success rate, with less than 25% of cycles involving fresh, non-donor eggs resulting in a live birth. Besides this, there are reproductive health technologies that include drugs, devices, and medical interventions to control reproduction and/or prevent sexually transmitted infections. The **EGBRHS** (ICMR 2000, p. 86) defines “assisted reproduction” as manipulation of the gametes outside the body and transfer of gametes or embryos into the body. Advances in medicine and biomedical research raise important questions which are rarely asked. This is true of the current medical claims to ‘cure’ infertility in couples who are desirous of having a child by accessing the newly available techniques of medically assisted procreation. One of the fundamental questions concerns its inevitable consequence of framing disease, where there may be none, by treating infertility as if it was a disease. It has been rightly argued by some critics that this amounts to confusing “*the survival of the species with that of the individual*” [15]. Infertility is framed as a disease in so far as it is in its name that every attempt is made to publicly defend the medically assisted management and manipulation of women’s bodies for procreation. Again, contrary to their claims, one might ask whether doctors treat sterility at all. The truth is that with artificial insemination, they manipulate male gametes. And with in vitro fertilization and embryo transfers, they produce embryos. Thus, we can look at the medically assisted procreation as a medical takeover and control of the reproduction of the human species. As a worst case scenario, women, who are treated as the suppliers of oocytes, are completely de-humanized (reminding us of the recent scandal in South Korea). Think of the medical control over fertilization. In vitro fertilization makes it possible to control the genetic inheritance of the embryo. This control extends further to the manipulation of the transmission of the genes of the species at the end of the pregnancy.

We can look at assisted reproductive technologies as the medically assisted human procreation by the medical centres which make experimental use of women’s bodies without women themselves having any control over the modalities of assisted reproductive

technology. As experimental subjects, women are here caught between their desire for motherhood, along with their willingness to readily `consent` to their participation in the new practices in which two things are happening simultaneously: The assisted reproductive technology based laboratory experiments extend to their bodies; *and* in this very process they lose their individual rights, their freedom and dignity. This shows the urgency with which the legal and ethical framework of `informed consent` in the context of assisted reproductive technologies, even reproductive health technologies, need to be probed even more deeply and critically than elsewhere in biomedical research.

§5.2. Biomedical research: a question of access to new technologies. In all experimentation using human embryos or foetuses what is at stake is public morality. Hence it is imperative not only to raise ethical questions concerning such research which reflect a diversity of views that must be taken into consideration but to seek consensus through public debate with a view to legislating and, through proper legislation, regulating research wherever it is to be allowed. *It is imperative to arrive at regulations with a legal and moral force instead of mere guidelines which are non-binding and, therefore, not only a waste of time but self-deceit.* In the United Kingdom, it was in 1978 that the world's first baby was born using the technique of *in vitro* fertilization. Until then there was no public debate in sight on the subject of experimentation on fertilization of human eggs in the laboratory simply because most people were ignorant about what was happening in the laboratories. In particular, what attracted attention was (i) the new technique of using couples desirous of having a child as experimental subjects for research, *even extended research* demanded by the new technique trying to understand the very process of fertilization, the structure of the human egg and implantation, while promising to offer them remedial therapy; (ii) the success rate and failure rate of the technique: "removing eggs from a woman's ovary and preparing them for fertilization outside the body, mixing them with male sperm, growing them in a dish for two or three days, in a specially prepared fluid, and finally replacing them in the uterus"; (iii) the

morally most repulsive part of the technique which uses live human embryos for research and then destroys them; (iv) the urgent need for proper legislation, which is based on co-operative consensus on questions of public morality, if such research is to be allowed; and (v) the need to study those factors which restrict women's access to assisted reproductive technologies with a view to understanding what can make them acceptable to them. Availability of assisted reproductive technologies *alone* is not going to matter in women's decision-making whether to use or not to use it. Cultural beliefs and cultural values play an important role. There is also the question whether increased access and choice means enhanced quality of life or enhanced health care, particularly when the partners involved have differences of belief regarding the methods and their impact on the quality of their sexual life or intimacy. Recent studies have suggested that cultural, social and economic barriers to women's access to assisted reproductive technologies vary in different parts of the world [12].

Issues of public morality are not decidable by resort to arguments which are based on a calculus of benefits or utilities, although it is true that business economics, or corporate interests, exercise great influence on public policy, even preventing proper regulation against unethical practices in research and in business. Otherwise public morality would look like morality in private space and lead to trivializations highlighted by the dilemma: either no actions need moral justification in terms of universal moral laws or all actions are justifiable in terms of moral considerations by individuals in private space.

§6. Enforcement mechanisms: What should ethics committees be and do? The role of ethics committees in the field of bio-medical research is well-recognized universally, both at the national and international levels. But this is not the case when we turn our attention to the policies, strategies and solutions where problems of development-planning, sustainable development and management of energy needs in the midst of environmental change or protection of environment are concerned. If it makes sense to think in terms of guidelines for sustainable-development and environment-related problem-posing and

problem-solving, then it also makes sense to widen the scope of environmental discourse by evolving uniform policies with regard to the structure and role of ethics committees in all relevant fields, be it environment-related research and engineering, be it sustainable development-planning, or be it new technologies needed to reduce the risks of environmental/climate change. In the changing relationship between science and its various publics, where criteria other than pure scientific merit have gained acceptance as a basis for the funding of basic research, there is the real but most challenging frontier confronted with the following questions: What is the future of human and ethical values? Who should determine the development of scientific knowledge and its applications? For whom should science be done? Who should be able to tell scientists what methodologies to employ? Whichever way these questions are answered, the structure and role of *ethics committees* at the national and international levels assumes significance in connection with the *enforcement mechanisms* without which all strategies, policies and solutions would have no teeth when it comes to their implementation.

Conclusion

§7. What about informed access to new technologies (IANT)? In a nutshell, let me restate the thesis which I defend in this article and to which all thinking men and women must pay the attention which it deserves. In §3 above, I deliberately introduced the concept of *informed access* in order to develop the argument that “informed consent”, an ethically loaded concept, is inseparable from *informed access*, entailing the intervention by (the nearly absent) *ethics consultation service*. That is to say, without *the ethics consultation service*, “informed consent” loses all its meaning and significance in research. In the biomedical research involving experimentation on human subjects, ethics committees working with ethical guidelines for research emphasize regulations regarding *informed consent* just as a matter of formality. As they stand, these regulations themselves need constantly to be reviewed, if they

are to mean anything to human subjects of biomedical experimentation. What is more serious is this. *Be it biotechnology, genomics, medicine or public health, informed consent without informed access makes no sense, particularly in the context of new technologies cropping up at an amazing speed, even before the older technologies are made fully accessible to people.* They not only crop up, they also extend the laboratory of experimentation to those human beings who willingly participate in research but who have no *informed access* to new technologies. Human beings used as the laboratory extensions under new technologies cannot just be taken for granted. Neither does so-called *informed consent* justify such use of human beings. In my view, therefore, there can be no *informed consent* without *informed access*. As soon as there is debate on *informed consent*, there will be an increasing demand for *informed access* to new technologies. That is to say, without *informed access* to new technologies, there can be no meaningful debate on *informed consent*. And without proper investment on research on *access to new technologies*, any investment on new technologies itself becomes questionable. The concepts of informed consent and informed access are, moreover, ethically loaded concepts. Thus, they entail not only *media advocacy* (16) but *ethical consultation service*, besides an open debate in public domain, more so in the new technologies regime. Once we recognize this, we have to introduce necessary changes in the entire framework governing theory and practice of biomedical research, medicine and public health initiatives world wide. We have to change the very rules of the game governing them as public good.

By bringing a deep human concern to bear upon the ethical problems arising from the implications of (heavy investments on) science and technology, without proper investment on research on their impact and accessibility, I have highlighted, I hope, the biggest challenge before mankind today: *How to foster a strong tradition of interdisciplinary research across different sciences, including the social sciences and humanities, to explore the complex frontier of human and ethical values with a view to inculcate a concern for them in the educational and research institutions world-wide?* Another fundamental question, closely

related to this question, was raised several years ago by Gerard Toulouse, Director of Research at the Ecole Normale Supérieure, Paris, France, as follows: *Given scientific progress, how should the responsibility for raising ethical questions be shared between the individual and the community?* [17]. Toulouse's question is primarily addressed to scientific institutions, such as the Royal Swedish Academy of Sciences, the Royal Society in the UK, the US National Academy of Sciences and the German Research Foundation (Deutsche Forschungsgemeinschaft), which play such an important role in the development of science on the one hand and in building better nations on the other. He cites three examples to bring home to us the need for professional bodies and scientific academies to lead the way in fostering ethical debates about science and protecting those individuals who take risks in upholding the values of scientific freedom and social responsibility. The *three* examples are as follows. *First*, in Soviet dissident scientist Andrei Sakharov's life, which was full of protests against the arms race and in favour of democratic freedom, one already comes across an excellent example of how science and ethics interact. Yet why did the collapse of the Soviet Union lead to the collapse of the scientific establishment there? Moreover, why did the latter fail to protect Sakharov when his life was at great risk? Sakharov was not only ignored, he was indeed exiled to Gorky for seven years. *Secondly*, the American Association for the Advancement of Science (AAAS) has created a prize for scientific freedom and responsibility with the aim of supporting and recognizing courageous individuals as stakeholders in scientific progress. We can say that even more remarkable than this is the fact that as early as 1975, the Report of the Committee on Scientific Freedom and Responsibility of the AAAS initiated a detailed discussion on many of the ethical problems faced by the contemporary society, scientists and engineers [18]. The Report *concluded* by advocating that the AAAS should no longer take a neutral stance with regard to such problems. This step in itself marked a big departure from the dominant tradition of regarding professional scientific institutions as essentially passive organizations which are meant to facilitate communications between

scientists by arranging meetings and publishing journals [19]. Toulouse's *third* example concerns the German Research Council: How the Council has set up in 1997 an international commission on self-regulation in science for promoting good scientific practice.

There is no doubt how much we have to learn from each of these different kinds of examples. To these we must, of course, add those further initiatives such as the Ethics Committees that have been set up across Europe in recent years. Particularly noteworthy is the fact that in December 1997 the European Commission set up the European Group on Ethics in Science and New Technologies (EGE) to succeed the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB 1991-1997). The Group is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects in science and new technologies in connection with the preparation and implementation of Community legislation or policies. During its first mandate the EGE (1998-2000) provided opinions on subjects as diverse as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research. At a specific request of the President of the Commission, Romano Prodi, the Group also wrote the Report on the Charter on Fundamental Rights related to technological innovation. On 24 April 2001 the Commission has appointed the twelve Members for the period 2001-2004 and amended the EGE guidelines in order to strengthen the role of the Group (EGE 2001-2004). The secretariat of the Group is an integral part of the Group of Policy Advisers. A conference entitled "Research Ethics committees in Europe: facing the future together" was to take place in Brussels on 27-28 January 2005. This event was the first of its kind and should have gathered together around 450 representatives of European research ethics committees (RECs), which evaluate, at local or regional level, any type of research protocols involving human beings. The conference was meant to provide a real opportunity to meet one another to share information, best practices and ideas for future recommendations, initiatives and actions.

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