From Nuremburg to Informed Consent in the 21st Century

Hilary Rose

This paper was presented in Heraklion, Crete, Greece, at a Symposium on *"Human Experimentation with Human Subjects: The Moral Limits of Biomedical Research",* dedicated to 60th Anniversary of the Doctor's Trial and the Nuremberg Code, organised by the Joint Postgraduate Programme *Bioethics* of the University of Crete, on 17th December, 2007.

Abstract
The paper surveys, in impossibly compressed space, not a linear story of progress since the Nuremberg trial and the code, but a story of mess, muddle and conflict. This account is set in the context of the growth of human rights rhetoric following the defeat of the Nazis. It draws on the author's own research on biobanks to explore the key notions of informed consent and autonomy.
None the less its conclusion is one of cautious optimism in that over the six decades the moral agency of the patient/subject, the patient and the subject, has increasingly been recognised and claimed by all three of these categories and their frequent conflations.

Intransigent nationalism and a universal vision

I want to begin with what for me, as English, is a trivial but uncomfortable memory. In the postwar years and even through the sixties, the children's ritualised playground battles, when they weren't cowboys and Indians (a mere matter of genocide) were the British versus the Germans. In these the children celebrating the defeat of Germany by the allies (but above all the heroic British) echoed the self congratulatory nationalism of the victors. The horrors of Nazism were, in the dominant British culture, more or less erased. This was not entirely surprising, as the Nazi period remained mostly untaught in school history lessons until the eighties. But that perhaps that is the fate of school taught history. It is only when the erased, and those who have positioned themselves as their historians, insist on giving voice to the silenced, that history as a subject gets to change - eventually even within the schools[1].
The point of recalling this memory is simply to note that cultural understandings and values are not homogeneous nor universally shared. Thus despite the Nuremberg Code which emerged from the trial of the Nazi doctors and which is so often invoked as the birth of ethics in biomedical research, that story of research ethics over the last sixty years has by no means been one of linear progress. Its development has been uneven, shaped not only by philosophical reason and argumentation but by context in its historically changing multiplicity of dimensions.

[1] Alas the History Programme on British television consistently serves to turn the clock back to a simple celebration of heroic British nationalism. For daytime television viewers that playground culture is far from dead.

Nonetheless out of the devastation came great visionary projects, most of all of the UN Declaration of Human Rights in 1948. A hard journey had to take place before even the idea of human rights could become a meaningful part of our everyday vocabulary, and a right worth fighting for. This widespread acceptance of the non-negotiable value of human rights is an historic achievement of the last half century. That there are both widespread abuses of human rights, documented in all their ugly detail by Amnesty and other Human Rights NGOs, together with abundant examples of the hypocritical use of the language of human rights by the powerful, does not detract from this cultural and political achievement.

The foundational UN Declaration of Human Rights as a moral and political response to the horrors of Nazism was not alone, it was accompanied by two other international affirmations of human rights: these were the Nuremberg code, the focus of our meeting, and the founding of the World Medical Association which took up the issue of the ethics of biomedical research. Together these three sought to construct a new global ethics insisting on the moral agency of all human beings, with the Nuremberg Code and the WMA particularly focussing on recognition of agency of the patient/subject in biomedical research. The texts were written in the language of the Enlightenment, restating for the mid twentieth century the values of universalism against the particularist values, or to put it more bluntly, against the anti-Semitism and racism of Nazism. A Nazism which, along with the systematic murder of millions of human beings had also almost destroyed European culture. These were extraordinarily imaginative and heroic attempts to construct a world moral framework in which those terrible events could never happen again. But even while we salute that magnificent visionary re- instatement of the universalism of the Enlightenment, it was a product of its time.

The subsequent sixty years and the social and cultural conflicts generated by the rise of the new identity movements, of civil rights, gender, sexuality in a context of global capitalism have forcefully demonstrated cracks within that once confidently claimed universalism. Instead I see the development of biomedical ethics as having been continuously and usefully challenged by both old and new social justice movements which have over that self same sixty years insisted that they too have agency, and that they too claim to be subjects not objects in history. Thus it was not the clinicians or ethicists, reflecting on the Code and it origins in Nazi eugenics who terminated the eugenic practice of compulsory sterilisation. It was the rise of the new social movements above all of feminism, which refused to let women continue to be treated as objects with no moral agency. Thus it was three long decades after Nuremberg before the practice of compulsory sterilisation of learning disabled women ceased in the mid seventies in the US and in the

Scandinavian countries[2]. At the same time those countries, like Britain and Holland, which had achieved similar eugenic ends by sexually segregating and incarcerating their learning disabled citizens, freed them. Such challenges have rarely been welcomed by clinicians or by biomedical research, for they impede their power. For that matter in the age of genomics neither big pharma testing drugs in poor counties nor the gene hunters welcome the criticism of their activities as exploitive and as biopiracy[3].

But rather than pursue the problematic inheritance of the Enlightenment, let us return to the Code itself.

The Nuremberg Code

The Nuremberg Code preceded The UN Declaration by just one year. Prior to this first codification of ethical values and procedures to guide biomedical research, the main source of protection of the wellbeing of the patient/subject both in medical care and biomedical research were the professional ethics of the clinician. He, and it almost always was he, was committed to the Hippocratic Oath and its central injunction to at least do no harm. However the interpretation of what constituted harm was - within limits – a purely professional matter. Centrally the Nuremberg Code moves beyond the reliance on protection by the professional ethic – the paternalistic protection offered by the Hippocratic oath - and insists on the moral agency of the subject /patient in biomedical research. The keys to securing this new status for the patient/subject are " voluntary consent" and the "right to withdraw from the research".

Practically there were two unconsidered problems both with long reverberations. First that however much importance we retrospectively give to the Code, at the time it was not disseminated. So just how were biomedical researchers to know about this new moral agency of their subjects and just how were they to include ethical considerations into their research? Unsurprisingly the bioethics of Nuremberg arrived unevenly and, as a routine practice, only relatively recently in biomedical research. The second practical problem, which remains with us, was the lack of thought given to the matter of enforcement on any future breach of the Code- not least if the breach was carried out in any one country with little or no internal professional or strong public opposition. Soviet

[2]Daniel Kevles, *In the Name of Eugenics: Genetics and the Uses of Human Heredity*, New York, Knopf, 1985; Gunnar Broberg and Nils Rolls Hansen (eds), *Eugenics and the Welfare State: Sterilization Policy in Denmark, Sweden, Norway and Finland*, East Lancing, Michigan University Press, 1996. Hilary Rose, "Eugenics and genetics: the conjoint twins?", *New Formations*, 3/22/2007

[3] The failure of the Genetic Diversity Project, part of the HGP, failed in the teeth of strong opposition from indigenous populations.

forensic psychiatry provides one obvious example of this unconsidered problem, but there are many others. Perhaps it is unreasonable to have expected the Nuremberg judges, so intensely pre-occupied with dealing with the past horrific research practices of the Nazi doctors and in conceptualising the Code itself, to have considered what should be done in the case of any future breach. Under what circumstances? and by whom? the Code would be enforced were left hanging in the air.

Given just how much bioethics looks back to Nuremberg as its symbolic foundation the trials were by no means the inevitable outcome of the defeat of Nazi Germany. While sceptics suggest that the trials were simply an example of "victor's justice", a less than pioneering phenomenon, the inevitability of the trials has been questioned recently, not without irony, by the High Court Judge Lord Stephen Sedley. Sedley noted that that while Winston Churchill was all for shooting Nazis, especially the leading Nazis, out of hand, Stalin, who certainly understood the value of a show trial argued for the very public process of a trial. The spectacle of the formal process of prosecution and defence being played out before the world's press, would ensure that the infamous research of the Nazi doctors on their unwilling victims would receive maximum publicity and thus ensure that international opinion was hardened against the Nazis. Additionally the fate of the convicted would serve as a deterrent against further such crimes.

But while Stalin's proposal was adopted, his preferred show trial model with its pre- decided and crudely obvious outcomes, regardless of the guilt or innocence of the charged, was not. It was in the name of the United States, whose entry into the War indisputably made victory possible, that the charges were brought. Thus despite the criticism, never entirely escapable, that the trial was integral to 'victor's justice', the conduct of the Nuremberg trial of the 23 Nazi doctors and scientists was scrupulous. There was both a prosecution and a formally appointed defence team. The defendants by no means denounced themselves, confessing to their crimes as in the classic Stalin show trial model, instead they remained defiant. Despite the difficulty of mounting a defence their defence team showed no sign of being cowed, challenging any easy notion that the trials were merely the enactment of victor's justice.

The lead US military prosecution lawyer, Brigadier Telford Taylor, began with the recognition that the trial was inescapably about murder, and yet sought to make transparent that the research of the Nazi doctors involved 'more than' mere murder. The legal challenge for the prosecution team was to provide an overwhelming case to the court which defined precisely what was this 'more than'. Was what Telford Taylor spoke of as 'thanatology' - the science of producing death- the key, or was it the total

indifference to the suffering of their research subjects, or both? Because of the commitment to legal process this was not simply a pushover. The prosecutors were confronted by the defendants' self-confidence, even in the box and charged with these heinous crimes, not only stemming from their convinced Nazism, but also from their secure self identity as biomedical research scientists. To the doctors their research and its results were unquestionably part of the international production of good science yielding important biomedical knowledge for human benefit. While not a position their victims could be expected to share, the sufferings of the research subjects could be, and were, entirely discounted within an ideology of scientific racism that insisted that Jews and others were 'untermenschen', not human beings, so outside consideration[4].

The distinction made by the Nazi race theorists between the Aryan Supermen and the untermenschen, chiefly but by no means only the Jews, legitimised the Nazi doctors' assumption of the non human status of their research subjects. Their status was much the same as that of research animals - prior to animal welfare regulation. As non-humans the prisoners of Auschwitz were entirely outside the Hippocratic oath, as the injunction to do no harm simply did not apply to untermenschen . Scientific racism also enabled the research laboratories of Mengele and his colleagues to position themselves in the tradition of the great Claude Bernard, the French founder of the new experimental physiology in the mid 19th century. Bernard did not minimise the price of experimentation on his animal subjects but celebrated the scientific knowledge it made possible. This scientific knowledge would he claimed, at last provide a scientific basis to medicine. His metaphor of " a superb and dazzlingly lighted hall which may be reached only by passing through a long and ghastly kitchen"[5] makes clear that he recognised the bloody practices of the laboratories, but that the science thus gained justified it. Nor has this claim entirely receded even sixty years since Nuremberg. Then, leading British biomedical researchers were anxious to keep the knowledge gained through the ghastly kitchen of the Auschwitz experiments; today a leading US bioethicist, Art Caplan, supports this. Science as a cultural value can still be placed higher than human rights.

This explains how it was possible for the defence team at Nuremberg to challenge the argument that the research of the doctors entailed 'more than' murder by pointing to the example of the US malaria study as not

[4] There were 200 Jews, 50 Roma, 500 Poles, 1,000 Russians, Excerpts from *Trial of War Criminals before the Nuremberg Military Tribunals under Control Council Law*. No/10.October 1946 – April 1949 Wash DC: US, GPO, 1949-53

[5] Claude Bernard, *An Introduction to the study of experimental medicine*, 1865, quoted by Bruno Latour, "The costly ghastly kitchen", in Andrew Cunningham and Perry Williams (eds.*), The Laboratory Revolution in Medicine*, Cambridge UP, 1992, p. 295

fundamentally different in terms of the recognition of the moral agency -or rather the lack of it – accorded the US research subjects. The malaria case alone formed a difficult challenge for the American prosecution team, a difficulty reflected in the frequency to which historians of the Code have returned to it. Similarly the defence team might, but did not, point to the Tuskegee syphilis study, where the systematic denial of effective therapy could be argued to have been something close kin to murder. This 40 year project, which started in 1932, was carried out by the US Public Health Service, studying 600 poor African Americans, 400 of whom were with syphilis. The subjects were given no information, no diagnosis and were invasively tested. Even more outrageously, the sick were given no penicillin when that effective therapy became available for use. Why didn't the Nuremberg defence team cite this study as surely it would have made an even better example for their attack on the prosecution? Maybe they just didn't know about it? But ignorance is not entirely accidental; white Americans in the 1940s would almost certainly have shared the racism of the Nazi doctors, hence perhaps the ensuing inability to see the Tuskegee research as ethically problematic let alone criminal. Perhaps the defence team failed to refer to it because they too found that study acceptable medical practice by the standards of the time, at worst merely ill-conceived – as even today the historian of genetics Elof Axel Carlson has argued.[6]

What Telford crucially needed was to be able to point to a precursor ethics code for biomedical research, an ethical code for this fast-growing 20th century practice of biomedical research. At this point the US biomedical researcher Charles Ivy becomes central **–** along with the Jewish neuro-psychiatrist Leo Alexander. Ivy was a distinguished researcher and influential figure within the American Medical Association who had been thinking about the problems of research ethics in his biomedical research practice; 1946 he presented a report on this topic to the AMA. Thus he was well placed to provide evidence that there was a bioethics code which set out the 'more than' that Telford needed prior to the trial in 1947. Ivy became an important expert witness in the trial. Evelyne Schuster, a historian of the Nazi doctor's trial, wrote " the primary objective of Ivy's medical ethics principles was to make human experiments possible in the future. All other issues, like the protection of human and patient rights in medical science, or the role of the informed consent principle, were secondary to this overarching objective[7]. This is

[6] Elof Axel Carlson*, Times of Triumph, Times of Doubt*, 2006

[7] Ivy's pragmatic recognition of the need to defend the experimental project by making politically expedient ethical concessions echoed the situation in 1870s Britain. Then powerful public revolt against the cruelty of animal experimentation threatened the existence of the new physiology. Charles Darwin himself successfully led the campaign to concede welfare restrictions to protect the science. Hilary Rose, "Gendered Reflexions on the Laboratory in Medicine", in Cunningham and Williams 1992, *op cit,* pp. 324-42

consistent with post-war conduct of both Alexander and Ivy. These physicians never viewed the Nuremberg Code as applying to their own research work. After Nuremberg each reverted to pre-war physician-centred Hippocratic ethics. Alexander thought that his Hippocratic view of research coincided with the intent and vision of the Nuremberg Code, and did not distinguish research from treatment in his own practice. Ivy wanted no interference with decisions of Hippocratic physicians, and did not recognize the rights and authority afforded the research subject by the subject-centered Nuremberg Code he helped to articulate."[8] It is not difficult to see how it is that those concerned by the issue of victor's justice are troubled by the roles of both Ivy and Alexander in the trial.

The United Nations Charter and the World Medical Association

The most powerful affirmation of human rights was the preamble to the Universal Declaration of Human Rights at the United Nations General Assembly December 10th 1948. The language was, and is, visionary. For good reason the Assembly urged that it should be publicly displayed, expounded in schools etc …

Whereas recognition of the inherent dignity and of the equal and inalienable rights of the human family is the foundation for freedom justice and peace in the modern world….

This statement did not for a moment pretend to describe the actuality of the world, what it did do was to set out an inspiring vision of what the world might and should become. 2008 will celebrate its sixtieth year and we may well then ask ourselves to reflect on the Declaration as we are doing this year with its predecessor the Nuremberg Code.

The third affirmation of human rights lacked the grandiose vision of the others, instead it focussed on turning the vision into practice in the ethics of biomedical research. This was the objective of the founding of the World Medical Association. Where the WMA's precursor had been preoccupied with medical ethics, the new post-war WMA understood that the ethics of biomedical research could no longer be neglected. The task the WMA set itself was that of institutionalising biomedical research ethics. Two preliminary international meetings in 1945 and 1946 were held, followed by the first international congress in 1947 with 27 national meeting associations affiliated. In addition to research ethics their agenda also included medical ethics, professional education and socio-medical issues.

[8] Evelyne Shuster review of Ulf Schmidt. *Justice at Nuremberg: Leo Alexander and the Nazi doctors' trial,* Basingstoke: Palgrave Macmillan. 2004, *Med Hist*. 2005 October 1; 49(4): 538–539.

Progress in the WMA has shared the uneven development of bioethics. There were a number of problems from the failure to help or protect one of the earliest members to the appointment of a former Nazi as president in the 90s and the failure to tackle the question of Israeli doctors' involvement in the Amnesty-documented torture of Palestinians. There was an early casualty among the national associations that perhaps should have been considered to be a matter of socio-medical concern, but was not. In 1947 both the Palestinian Arab Medical Association and the Jewish Palestinian Medical Association were affiliates. However one year after the State of Israel had been established, when Israel was allocated some 25% of Palestine, only the Israeli Medical Association remained. But while this was a problem of the erased Palestinian Arab national affiliate, there was also the scandal of the election of the former Nazi biomedical researcher, Hans Joachim Sewering, to the WMA presidency in 1992. International protest ensured that he was forced to resign before he could take up office, but as the US Physicians for Human Rights asked, how could a Nazi have been able to be active within the WMA for over twenty years without being exposed? Such successes of former Nazi figures in important international organisations were surpassed only once and that at the level of the UN itself, when the Austrian President Kurt Waldheim, previously Secretary General of the United Nations, was exposed as a former SS officer. Despite the trials, denazification of major institutions and organisations remained problematic until almost the beginning of 21st century, by which time most remaining undetected Nazis had retired or died.

Torture, far from disappearing, was making a comeback. During an interview in 1999 with a delegation from the Medical Foundation for the Victims of Torture based in London, Dr. E Dolev, the then head of Ethics of the Israeli Medical Association commented that ' a couple of broken fingers' during the interrogation of Palestinian prisoners was a price worth paying for information. An account of this interview was sent to the secretary of the International Medical Association, Delon Human. He wrote 'I must come to the defence of the IMA in affirming that they are signatories to the WMA declaration of Tokyo. They have been active collaborators in the WMAs continued struggle to eradiate torture of any kind in prisons all over the world'[9]. Meanwhile Amnesty has documented the torture and the Israeli Physicians for Human Rights continue to protest. Thus at the international level there has been a continuing and serious problem of *quis custiodet ipsos custodies*.

How well did the Code travel?

In the post war world, with its new vision of human rights, how well did the new Code travel? It has clearly not been sufficient to guarantee linear

[9] Derek Summerfield, "Personal Communication", *BMJ* 29 Oct 2001

progress over the ensuing 60 years. Nor indeed am I entirely confident that the concept of 'voluntary consent' which informs the Nuremberg code is quite the same as today's 'informed consent'. Nor has the Code consistently worked to protect patient/subjects rights. One crucial problem is that the language of the Enlightenment which movingly informs the three affirmations of human rights with their generous language of universal humanism, is more universal in language than in actuality. Thus this account sees the challenges to biomedical research ethics made mostly by social groups who find themselves outside the claimed humanistic universalism as critical for the development of bioethics. Conflict and struggle - and not only inside the seminar room - are integral to bioethical debate and progress. Power, I suggest, haunts bioethics and ignoring it is not an adequate response.

Thus, at the international level, above all in Europe where the dark Nazi episode had taken place, there was a profound consciousness that this victory was crucially the defeat of Nazism. Yet de-Nazification was conspicuously uneven. In the academic discipline of genetics which had provided Hitler and his Nazi party with the greatest scientific support the leading theorists of scientific racism, and even many of those who had participated in the camp experiments themselves remained unscathed. Indeed it was not until the German geneticist Benno Muller Hill documented the phoenix-like survival in the postwar period of the Nazi doctors and scientists - those theorists and practitioners of scientific racism, which had defined both the Aryan superman and the untermenchensen, that the limits of denazification became apparent.[10] These key figures did not merely survive; they remained or became directors of leading laboratories. Tissue sections from camp victims were discovered in the museum of a major brain research institute in Frankfort as recently as the 1980s. It was not until 1997 that the gallery in the Austrian National Natural History Museum -known locally as die Rassenhalle -was closed. This immense collection of skulls was little more than an exhibition of scientific racism[11]. Its curators and the state that funded it still claimed that that their collections were part of good science.

In the US, despite the Nuremberg Code being constructed by US biomedical researchers and one US judge, it became incorporated into practice only very slowly, in public health, military and clinical research.

[10] Benno Muller Hill, *Murderous Science: Elimination by Scientific Selection of Jews, Gypsies, and Others - Germany, 1933-45*, 1988

[11] Awareness of the significance of museums' constructions of the history of humanity was brought to wider attention by the Social Studies of Science researchers. Donna Haraway's *Primate Visions: Gender Race and Nature,* Routledge *1989*, being the landmark text. The Vienna case was documented by Merek Kohn, *The Race Gallery: The Return of Racial Science*, Cape, 1995.

There were areas of research, notably radiation research carried out within the Atomic Energy Commission, which did pick up the challenge and where the lead researchers were concerned about wrong-doing in not respecting the moral agency of the subject. But much military research used soldiers who were far from being fully able to give the "voluntary consent" of which the Code spoke, nor were the unsuspecting patients fed LSD by the CIA.[12] The Tuskegee Syphilis Study showed no signs over its long history of being influenced by the Nuremberg code. It was not ethical reflection by the lead researchers nor ethical directives issued from the Public Health Department in the light of the Code that terminated this extended disgrace[13]. It was the rise of the civil rights movement supported by careful historical documentation that led to an explosion of anger by the African American community. The sense of outrage was so deep that many years later Clinton found it necessary to apologize.

These practices were not confined to the US. At Porton Down, the site of the UK's Chemical and Biological Defence establishments, military personnel were the routine subjects of experiments with nerve gases without being told the nature of the substance or the risks entailed (some were deliberately misinformed, being told they were taking part in trials of cold vaccines). Some died, others were severely affected neurologically, but it took years of legal argument before they received any redress. Indeed, only in January 2008 did the UK MoD finally propose a settlement with the remaining survivors of experiments conducted half a century previously – of a mere £8,300[14].

Nor have individuals, even the elite, fared that much better, at least once dead. Einstein's brain was removed by his clinician -so far as the records show without consultation with his family or what was known of his personal wishes - ostensibly to study the site of his genius. With what seems to have been a mark of personal favour rather the pursuit of science, preserved slices of the brain were despatched in various containers, including mayonnaise jars, to important figures. Well before the Code, the brain of the dead Lenin had received much the same treatment, not by his personal clinician but by the state. In this case an entire institute was set up in Moscow to study the genius's brain (slide sections were still being proudly showed to academic visitors to the Institute well into the 1990s.)

[12] Peter Watson, *War on the Mind***:** *The Military Uses and Abuses of Psychology,* Basic Books, 1978

[13] For a rich source of such examples cf. Jonathan Moreno, *Undue Risk: Secret Sate experiments on Humans*, Routledge, 2001

[14] Rob Evans and Owen Bowcott, "Veterans close to MOD deal", *Guardian,* Jan. 18 2008

Much more recently at Alder Hey hospital in the UK a pathologist had, without consulting the parents, removed most of the organs of their dead babies for his personal research. Given that clinicians had long removed pathological material from dead patients for their pathology teaching and research collections there was there was little new in this. To pathologists such material was a of purely scientific interest, the thought that a mere body part – mere human tissue – was sufficiently important to warrant the need for a living will or the consent of relatives did not cross their minds. But this pathologist's activities were on a huge scale, and he had also moved the collection from Alder Hey to his new hospital, hence in breach of a powerful clinical convention. In this convention pathology specimens cannot be owned nor are they at the disposal of the individual researcher, rather they belong to or are at least the exclusive responsibility of the hospital itself. The ensuing massive public revulsion to the scandal, on such a scale as to be indefensible by the biomedical research culture, led to Department of Health personnel scurrying round UK hospital pathology collections, to make sure no further scandals broke to become politically damaging news items. The story of Burke and Hare, the early 19th century grave robbers ('resurrection men') who had stolen bodies to sell them to the hospitals for dissection, had not disappeared from collective memory. Doctors have by no means steadily enjoyed public trust. Surrounded by other examples of the loss of trust in science, from GM food to BSE or 'Mad Cow Disease' , the government swiftly put through legislation to ensure that no similar abuses occurred in the future.

Yet the story is not entirely negative even though the Alder Hey scandal took place almost sixty years after the Code, the scandal revealed that popular understanding of voluntary consent and human rights had been extended - consent was now demanded not only for experimentation in life, but on the body parts of their dead. Professional paternalism faced a new challenge. The practices of biomedical research had not kept up with this popular extension of the spirit rather than the letter of the Code. This was a significant victory from below, as the British political classes, despite the Blair Brown enthusiasm for self regulation, recognised the necessity to institutionalise an unambiguous and legally enforceable right, and thus the need for fresh legislation.

The Helsinki Declaration and bioethics progress

The orthodox view sees the Helsinki Declaration of 1964 as securing a major advance on the Nuremberg Code, as it formed an even more secure base for good biomedical research practice. Certainly following Helsinki, national codes began to be developed, initially self-regulating and very slowly brought under regulations with enforceable penalties for breaches. Those less convinced by the inevitable linear progress view were concerned by what they saw as Nuremberg's key concept of

voluntary consent as significantly weakened – even supplanted by the Helsinki recognition of the centrality of peer review. Peer review was seen by these latter as dangerously opening the door to the claim of the Nazi doctors that what they were doing was scientific research, which could take its place among "good science". The production of such "good science" was for the Nazi doctors the highest goal. But for those who placed Human Rights at the centre of their thinking about biomedical research the inclusion of peer review was a matter of concern. Was it, some asked, a way of rehabilitating the Nazi doctors and their science?

It is not easy to sum up these untidy moves of human rights forwards and sometimes back, sometimes almost retreating into the oblivion. They form the context which frames the struggle for the recognition of the moral agency of the human research subject, and his or her unqualified right to take part and to refuse to take part in a research project . Positively there is an evident growth in public awareness of human rights; in the West the words are routinely in use by most of society. Governments are routinely criticised by civil society for their failure to support the human rights of new social groups. Today patients and research subjects, even for those who like me are distinctly sceptical about whether it is really happening, nonetheless believe that their consent should be genuinely voluntary. Whether it is the Alder Hey parents or the mobilisation of the professionals and citizens against the Icelandic DNA data base, such shared beliefs and collective action can, in a democratic society, compel recognition of their rights.

Yet this is to look at the glass as half full, it can equally be viewed as half empty. Most negatively since 9/11 there has been a weakening of support for human rights particularly at the level of government. Debates which would have been unthinkable a few years ago, concerning the ethics of admitting evidence gained under torture into legal proceedings are today part and parcel of a growing retreat from the generous moral vision of the immediate post war years. The point of bringing such breaches of international law and Hippocratic oath into this discussion, is to underline the retreat from human rights among the political classes, just as the concept seems to have passed into popular consciousness. Nine/11 nourished communitarianism with its particularist approach to values. It is not that abuses did not occur in the past, but that major powers today see no particular need to hide or defend them. Further the international community's failure to challenge human rights abuses fosters the proliferation of more - witness the continued existence of Guantanamo Bay, policies of rendition, outsourcing torture, or the failure of the international community to support the several UN general assembly resolutions which unequivocally condemn Israel's illegal occupation of the West Bank, Gaza and East Jerusalem.

The rise of Bioethics

To give some idea of the slowness by which bioethics were systematically introduced into biomedical research, despite discussion in philosophical circles, it was not until 1974, ten years after Helsinki, that the US Congress charged the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research 'to conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioural research involving human subjects.'[15] It is more or less over this decade that the challenges from Nuremberg and Helsinki begin to be taken seriously by philosophers newly interested in the ethics of research inquiry. The United States was the location of much of this pioneering philosophical work, a context influencing the individualism embedded within the concept of "informed consent". Individualism, as de Toqueville wrote those many years ago, sits at the heart of American society, alongside and part of, its energetic commitment to democracy. Thus the concept of informed consent has two aspects: first, it assumes that information, which places cognitive reasoning at the centre of how human beings make decisions, is sufficient; second, it assumes that making decision of informed consent is the business of autonomous individuals.

One of the earlier and widely used books, by Beauchamp and Childress[16], fuses traditional medical ethics into bioethics where they discuss the ethical problems of patient/subject research. For them both patients as subjects of care and as subjects of research have to be taken into consideration. While their writing is sensitive to the complexity and difficulty of the lives of patients and research subjects, they primarily pursue those basic principles sought by Congress. It was almost certainly not until the launch of the Human Genome Project (HGP), when its director Nobel prize winner Jim Watson announced the accompanying programme studying the ethical, legal and social implications (ELSI) of genetics that bioethics began to grow dramatically. Watson was shrewd enough to recognise tha, unless it was protected by serious acknowledgement of such risks, the HGP was likely to be attacked for its implicit support for eugenics. This spectre of eugenics has never entirely retreated particularly in the US and in Germany. From Germany have stemmed the gravest ethical concerns and the strongest regulation. Within the US, one of the ELSI committee, the African American sociologist Troy Duster carried out an influential study published as *Backdoor to Eugenics.*

[15] National Commission *Report and recommendations: research on the fetus* US Dept of Health Education and Welfare, Washington DC, 1975, p. 66
[16] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, Oxford University Press, 1979

Even though ELSI funding was at an unprecedented level (echoed more modestly in the EU and indeed most researching countries), and despite the rapid growth in the numbers of bioethicists, the ethical problems of research did not get any easier. With the dominance of informed consent, the transmission of reliable and accurate information to the potential patient/subject became increasingly difficult. Genetics (now more commonly spoke of as genomics) was, and is a fast changing field: the sheer volume of money pouring in from government and industry accelerating the rate of change. The confident observation that all living beings are related through the shared stuff of DNA so that our human genetic make up shares more than 98% of its genes with chimpanzees (and 37% with daffodils) does not immediately cast much light on the relationship between non human animal responses and those of human beings. The assumption of genetic determinism which informed genetic thinking in the immense and costly sequencing of the Human Genome had curious contradictory consequences. The molecular biologists made doom laden predictions of morbidity and mortality and at the same time promethean claims about their capacity to intervene affectively against such predictions via genetic engineering. Those molecular biologists for example, who held up CDs to awestruck audiences saying "all your life is here" were working within a not so hidden commitment to genetic determinism. While biologists and philosophers of biology attacked the determinism on theoretical grounds as inadequate, the critique was as usual not as convincing as the challenge from a new powerful theory to replace the old. With the advent of systems biology, first wave genetic determinism began to cede ground, at least at the research frontier[17].

With molecular medical explanation, the biomedical gaze penetrates ever deeper into the human body, yet the complexity of what is seen is only understood with difficulty and the price of not being able to see may be paid by the patient/subject. One dramatic example of the difficulty and worse, was displayed by the research inflicted death of Jesse Gelsinger. Gelsinger, an American 19 year old with a serious genetic condition was invited to take part in gene therapy trial - therefore simultaneously a biomedical experiment. To the horror of his family, as he was reasonably well when he entered the trial, the gene therapy killed him. The presence of an experienced academic bioethicist on the team and the usual procedure of informed consent had given insufficient protection. The subsequent inquiry into this and other gene therapy trials led to increased vigilance and controls being placed over such trials in the future.

[17] For an elegant demonstration of replacement, see: Pierre Robertoux & Michele Carlier, "From DNA to Mind The decline of causality as a general rule for living matter", *EMBO Reports, Special Issue Science and Society, Genes brain/Mind and behaviour*, Vol. 8, July 2007 pp. S7- S11

In these situations there are, to quote the unlikely figure of Donald Rumsfeld, "Both known unknowns and unknown unknowns". The problem of being able to provide adequate information concerning risk, which with such a cognitively driven concept as informed consent is essential, would seem to verge on the impossible. Today there is a greater understanding of the complexity of biological processes, gene interactions and the rise of the 'omics' (proteomics, metabolomics, interactomics…), which destroys the linear model of the relationship between gene and phenotype. Proposals for gene therapy drew from an older model of genes in which they were conceived of as pretty much determinant. Today, after a number of lethal experiments, there is a broad biomedical consensus that, except in a few very rare cases (eg cystic fibrosis) where there is some efficacy, gene therapy has not worked. Neither the risk to the human subjects nor the immense cost and research effort have been justified.

Informed consent and the patient/subject

Informed consent has come under internal criticism from philosophers, particularly but not only feminists. They have criticised informed consent as individualistic and hence inadequate, and seek to replace it with concepts which better reflect the relationality within which the lives of human beings are embedded. Yet despite this debate among philosophers empirical research carried out by anthropology or sociology, which casts light on what happens in the process of research subjects giving their consent, is only slowly developing. In an ethnographic study carried out by Klaus Høyer[18] of the consent process of research subjects of a DNA data base, few of the subjects could recollect the information content of the research proposal, and some, even among those who had given consent, could not even remember doing so. My own work on DNA data bases supports this. Where the research information had arrived in the post, family members could not recollect its arrival, saying slightly embarrassedly that it must have been thrown away along with the junk mail. In my Icelandic case study there had been a furious public row over the ethics of the data base, and most potential research subjects felt they had learnt enough through this media exposure. In other DNA population studies, even though the project was purely research, and this had been made plain in the information, the subjects nonetheless believed that the biomedical data that the researchers gathered would somehow be available and be helpful to them. One of my informants who had experienced sexual abuse by her father welcomed the data-base as it would expose her father and others like him. That this was impossible shows something of the understandings and expectations research

[18] Klaus Høyer, *Biobanks and Informed Consent,* PhD thesis, Umea 2004. Hilary Rose,*The Commodification of bio-information: The Icelandic Health Data Base.* www.wellcome.ac.uk/doc_WTD003280.html

subjects bring with them. Cognition is very evidently not the only process at work, a position increasing shared by neuroscience[19].

Yet what both studies point to very interestingly was that the social scientists' exploration of how their subjects had made their decisions, led subjects to reflect on the ethical and other issues and discuss them with astute sensitivity. There were echoes of the classic example of the Hawthorne experiments in that where people become the subject of social science research, they find the experience stimulating. Social science research had raised, perhaps for the first time, the research subjects' consciousness of and interest in the ethics of the research.

To me this is both problematic and positive in that it suggests that the current understanding - even policy - that bioethics should be the single discipline at work on this issue is insufficient. US American sociologists Raymond Devries and Janardean Subedi[20] though their claim is restricted to sociology similarly recognise the need for a multi-disciplinary approach. For my part I see ethnography, whether carried out by sociologists or anthropologists, as a powerful method method of giving research subjects a voice. This need echoes Paul Weindling speaking of how he saw his discipline, history, as giving voice to his research subjects – especially as those subjects had died in such hideous suffering, silenced so cruelly so that in many cases not even their names are known.

There are interesting attempts in recent years within the UK to approach this project of how best to admit the voice of the public into ethical debate around biotechnology by various consultative exercises – citizen's juries, consensus forums and the like. This participative approach is seen as contributing to the discussion of the social ethical legal and, in the case of biotechnology, the environmental problems . But also it is hoped that the very process will foster trust (widely understood as seriously at issue after the débacle of GM in Europe) in science and technology. Such exercises are often designed by social scientists, in most attempts the consultative process has sought to involve members of the general public, rather than specific sub-groups of the public who through personal experience have already begun thinking about such problems. Some of us take the view that these expert public voices will have more purchase on the discussion. But this is a relatively narrow debate between sociologists as there is general agreement that the voice of the public must enter the debate. While politicians, scientists and the biotech

[19] I do not have space to explore this, but the dominance of cognition as the core of reasoning is under attack within the neurosciences. Antonio Damasio*, Descartes' Error: Reason, and the Human Brain,* Penguin, 2005

[20] Raymond Devries and Janardean Subedi (eds.), *Bioethics and Society: Constructing the Ethical Enterprise*, Prentice Hall, 1998.

industry may be primarily concerned with the restoration of trust, many of the social scientists see these participative projects as a means of re-emerging the struggle to democratize science. Certainly one of the outcomes of any of these consultative exercises is that participants consistently report their pleasure in having taken part in a complex and lengthy discussion of important matter- and that they would like to take part in others. This echoes the ethnographers' observations that it is only when research subjects are given space to reflect, do they become seriously interested. (That our meeting at Heraklion was open to the public is part of a more general feeling among many academics that these matters are too important to be confined to a restricted audience - however technically well qualified or commercially interested).

It is not only research subjects who are stimulated to think hard about the ethical issues when they take part in a citizen's jury or talk with the enthnographers, I was also intrigued to monitor my own responses when invited to participate in a biomedical research study by a joint clinician/ pharmaceutical company. (I have a genetic condition they were interested in.) Unlike my informants, I read the research proposal attached to the invitation very carefully. Although I am a researcher who works on genetics this proved to a tough task. I turned to my partner, a biologist, for help. He confirmed my view the document was opaque and ill-drafted and scarcely capable of providing clear information. Reading it again I realised that it was so loosely drawn that it was entirely possible to have unwittingly given consent to gene fishing. As I am opposed to this on grounds of privacy, I first queried this with the research nurse. He consulted the principal investigator who replied that they (i.e. the commercial firm) didn't usually do this. Unsurprisingly I did not take part, not least because risk had been merely waved away. But how could many potential research subjects have spotted this risk, without knowledge of the usual ELSI risks in genetic research or without a biologist in the house to confirm her hunch. Incidentally this research project had gone through the ethics committee of a London teaching hospital without challenge. While, of course, my experience may have been atypical, it did little to diminish my feeling that, despite the quantities of ink spilt on informed consent, much biomedical research is still carried out in the Hippocratic tradition of mutually trusting paternalistic professionals. Ivy and Alexander have not left the stage.

I want to conclude by, albeit all too briefly, discussing Rayna Rapp's important ten year ethnographic study of women going through, sometimes with help, the reproductive process. In her book *Testing Women Testing the Fetus*,[21] she observes and interviews women from their first tests before and during pregnancy to the systematic testing of

[21] Rayna Rapp, *Testing Women Testing the Fetus*: *The Social Impact of Amniocentis in America,* Routlege, 2000

the fetus and the newborn. The study is not of bioethical research but of medical care, but as many of the tests are at the cutting edge of new medical technologies and therefore biomedical research, it casts considerable light on how women make decisions in such complex circumstances. It is difficult, reading the study, to find these New York women as much like the model of informed consent with its emphasis on the individual cognitively informed patient.

As the women went through difficult decisions, they drew on many resources, not just their doctors, nurses and genetic counsellors, but also their conversations with one another and with the ethnographer. They also understood themselves as situated in a web of social relations, within their families, their particular socioeconomic circumstances and also in the wider context of the levels of provision they saw as available to them and to the potential child. In a moving phrase to convey the complexity of this ethical reasoning and decision making Rapp describes the women as "moral pioneers." But, and this is a significant but, she underlines that at the time of the study the health and wealth provision in New York were the equal of the best European Welfare State. While it would be a mistake to seize on Rapp's swallows as sure predictors of summer – such moral pioneers offer modest hope.