CHAPTER 1

Consent: Nuremberg, Helsinki and beyond

INTRODUCTION

Informed consent has a long and distinguished history in liberal political theory and economic thought that goes back to the great debates of the European Enlightenment. The core of the social contract tradition is the claim that freely given consent legitimates action that would otherwise be unacceptable, and in particular the use of coercive power by governments. The basic arguments for market economics appeal to the moral legitimacy of consensual transactions, and contrast them with illegitimate economic transactions based on force, coercion or fraud, such as theft, confiscation and forced labour. These traditional claims have been reworked and reinvigorated in the last thirty years in influential revivals of liberal contractualism in political philosophy and of market thinking in economics.

These debates in politics and economics have been paralleled in biomedical ethics, where informed consent has come to play a larger and larger part, and is now the most discussed theme in Western medical ethics and research ethics.[1] Informed consent procedures

[1] Jeremy Sugarman *et al.*, 'Empirical Research on Informed Consent: An Annotated Bibliography', *Hastings Centre Report*, Special Supplement, January–February 1999, 1–42. The bibliography lists and summarises 377 articles. The torrent continues. A search on the database MedLine reveals that, for example, in the year 2002–3 there were over 300 articles (in English) with 'informed consent' *in the title*, and, even more impressively, over 1,800 with 'informed consent' in the 'subject' field: six new articles *per working day* in the journals cited in MedLine (which covers clinical and medical ethics, but not social sciences, non-medical law, philosophy, political theory, and so on).

have been embedded in clinical and research practice, and in a range of legislative and regulatory regimes that govern the use of personal and medical information and human tissues. Appeals to informed consent and its role in justifying clinical and research practice are now so well entrenched that their presence, indeed their necessity, and their justification are rarely questioned.

In this book we raise a number of questions about standard views of the role of informed consent in biomedical ethics. We begin with an overview of ways in which conceptions of informed consent and its role have developed in biomedicine. In this chapter we sketch changes in received views of the *scope*, the *standards*, the *justification* and the *regulatory use* of informed consent. All four have been transformed over the last thirty years.

These changes are generally seen as improvements. We shall argue that the quest for wider scope, for higher standards, for better justifications and for regulatory reinforcement, which aimed to make consent the lynchpin of biomedical ethics, has created intractable problems. We do not conclude that informed consent is unimportant in biomedicine, or that there is a case for reverting to a paternalistic medical or research culture. Rather we argue that received views of informed consent and of its role in biomedicine need fundamental rethinking.

BEGINNING AT NUREMBERG

The Nuremberg Code of 1947 is generally seen as the first authoritative statement of consent requirements in biomedical ethics. The issues that it was designed to settle were stark and horrifying. Human beings had been callously abused and murdered in the name of medical research, both in pre-war Nazi Germany and subsequently in the concentration camps.[2] During the Nuremberg trials of the

[2] For discussion of the abuses of medical research both in the 1930s and in the death camps see Michael Burleigh, *Death and Deliverance: 'Euthanasia' in Germany, c.1900–1945* (Cambridge: Cambridge University Press, 1994); *Ethics and Extermination: Reflections on Nazi Genocide* (Cambridge: Cambridge University Press, 1997).

doctors charged with these crimes, the defence argued that the Nazi experiments had been no worse than medical research elsewhere. The Code was drafted to help the prosecution by setting out some of the differences. It asserts emphatically that in all research on human beings: 'The voluntary consent of the human subject is absolutely essential.'[3] It glosses the phrase 'voluntary consent' in these words:

> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.[4]

The Nuremberg Code's reasons for requiring 'voluntary consent' echo those traditionally offered by political philosophers for grounding the obligations of citizens in consent. The basic idea of the social contract tradition can be encapsulated in the old tag *volenti non fit iniuria*: no injury is done where the subject is willing. The Nuremberg Code elaborates this thought in a quite traditional way by viewing informed consent as providing assurance and evidence that there has been no 'force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'. Codes don't usually

[3] The Code was initially drafted by Andrew Ivy and Leo Alexander, doctors who worked with the prosecution during the trial. On 17 April 1947, Dr Alexander submitted a memorandum to the US Counsel for War Crimes, outlining six points defining legitimate research, and responding to defence claims that there was no distinction between Nazi practice and medical research elsewhere. The verdict of the Nuremberg Tribunal reiterated these points, and extended six points into ten. Subsequently, the ten points became known as the 'Nuremberg Code'. For the text see http://www.ushmm.org/research/doctors/Nuremberg_Code.htm. The legal status of the Code remained unclear, but it is treated as a landmark document.

[4] *Ibid*, p. 181, principle 1.

offer explicit justifications, but we can find in the text of the Nuremberg Code an appeal to these widely accepted ethical standards, which would form part of virtually any ethical system or outlook. In effect, the Code forbids research that is based on overwhelming or undermining the will, or on forcing the body. Hence it forbids research on those who lack 'sufficient knowledge and comprehension of the elements of the subject matter involved . . . to make an understanding and enlightened decision', and forbids force and duress of all sorts. However, the Code says nothing more explicit about consent, and never mentions information or autonomy.

Contemporary discussions insist that informed consent should play a wider role in biomedicine than was envisaged at the time of the Nuremberg Code. Informed consent requirements have been extended from research to clinical ethics, and standards for seeking and giving informed consent have been made more explicit and more demanding. The justifications given for requiring informed consent have supposedly been strengthened by appeals to various conceptions of autonomy. Finally, informed consent requirements have been extended from medical treatment and research to the secondary use of information and tissues, by incorporating them into the regulation governing data protection, uses of human tissues and genetic technologies. Each of these four developments creates significant problems, which we discuss in the following sections of this chapter.

EXTENDING SCOPE: FROM RESEARCH ETHICS TO CLINICAL ETHICS

Contemporary discussions of informed consent in biomedicine may have started with the Nuremberg focus on research ethics, but they are now taken to apply equally to clinical ethics. The transformation of medical ethics that began in the late 1960s, and has continued since then, seeks to protect patients by requiring their consent for all medical interventions. This was often justified by claiming that it was important not to treat patients paternalistically, on the basis of a

physician's estimate of their best interests, and that informed consent requirements would ensure that the patient rather than the doctor was in control.

The extension of informed consent requirements from research ethics to clinical practice proved highly problematic from the start. The Nuremberg Code demands that research not be done without informed consent: this is a coherent requirement.[5] A parallel demand that medical treatment not be given without the patient's informed consent is clearly unacceptable. Patients who cannot give informed consent can hardly be denied treatment, and medical ethics cannot parallel research ethics by making informed consent a universal, or even a normal, requirement.

This is not a minor problem.[6] Incompetence and impaired competence to consent are more common in medical practice than elsewhere, since impaired cognitive capacities are a common effect of illness and injury. Very many patients are unconscious or too ill, cognitively impaired or mentally confused, too young or too frail to grasp the relevant information, so cannot give informed consent to their medical treatment. Few of them are likely to (re)gain competence in time to consent. Even those 'in the maturity of their faculties'[7] find it hard to grasp information about complex diagnoses or treatments, or severe outcomes. They may ignore or fail to grasp information they are given, mistakenly dismiss important information as routine or trivial, or react to routine information with misplaced or disproportionate dread or fear. Mustering the cognitive grasp and emotional strength to give or refuse informed consent to complex or threatening proposals taxes even the most competent of

[5] However, it is not uncontroversial. Should we forbid all medical research – even research that is minimally intrusive or risky – into conditions that undermine competence to consent, such as severe learning disabilities or dementia? Is it right to do so if these conditions cause great suffering?

[6] Vanessa Raymont *et al.*, 'Prevalence of Mental Incapacity in Medical Inpatients and Associated Risk Factors: Cross Sectional Study', *The Lancet* 364 (2004), 1421–7 argues that incapacity to consent is more common than supposed and under-recognised in the acutely ill.

[7] John Stuart Mill, *On Liberty and Other Writings*, ed. Stefan Collini (Cambridge: Cambridge University Press, 1989), p. 13.

us. These problems have become more intractable as medical interventions have become more complex, thereby adding to the cognitive demands of giving informed consent.

A vast and often repetitive literature, as noted above, has addressed these unpromising realities by using two strategies. Some writers argue that supposedly near alternatives to consent, such as *proxy consent* or *hypothetical consent*, can justify interventions where patients lack (full) competence to consent. In doing so they come close to disregarding or short-changing the very standards to which proponents of consent requirements aspire: actual consent is set aside in favour of somebody else's consent, or of consent that might be given under different conditions, or by somebody with different capacities. Others propose ways of making consenting easier and more user-friendly for marginally competent patients, for example by improving procedures for providing information (e.g., better information leaflets) or by using intermediaries (e.g., counsellors) to help those whose capacities are challenged.[8] Unfortunately gaps between actual cognitive and decision-making capacities and the capacities needed for informed consent to proposed action often cannot be bridged by these methods. Attempts to make informed consent the guiding principle of medical ethics have proved, and are bound to prove, uphill work.

RAISING STANDARDS: EXPLICIT AND SPECIFIC CONSENT

Contemporary discussions of informed consent requirements not only extend their scope from research to medical practice, but seek to raise standards. The Nuremberg standards were open to a range of criticisms. Was it enough to ensure that research subjects – or

[8] For example, there is evidence that *video* presentations may help patients to understand informed consent disclosures: see J. Weston, M. Hannah and J. Downes, 'Evaluating the Benefits of a Patient Information Video During the Informed Consent Process', *Patient Education and Counselling* 30 (1997), 239–5. Others have argued that *written* 'disclosures' are less effective than face-to-face communication: see K. Cox, 'Informed Consent and Decision-making: Patients' Experiences of the Process of Recruitment to Phases I and II Anti-cancer Drug Trial', *Patient Education and Counselling* 46 (2002), 31–8.

for that matter patients – 'have legal capacity to give consent' and are 'so situated as to be able to exercise free power of choice'? Or were these requirements too weak, or too vague? On a natural reading, tacit or implicit consent would meet these standards, provided that those to whom it was ascribed had legal *capacity* and *could* exercise 'free power of choice'. And were the standards clear enough to ensure that those whose consent was sought understood what they were consenting to? The Code requires only that anyone whose consent is sought should have 'sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision'. It does not require that they *actually* make 'an understanding and enlightened decision'. Should adequate standards for informed consent in biomedicine be clearer about the level of information to be provided and understood, and about the quality of the consent *actually* given?

Once again discussions of standards for consent to research interventions led the way. Contemporary discussions of research ethics commonly refer not to the Nuremberg Code but to successive versions of the Declaration of Helsinki, and to a range of congruent conventions and reports.[9] The most recent version of the

[9] The *Declaration of Ethical Principles for Medical Research Involving Human Subjects* was first promulgated in 1964, by the World Medical Association. For the text of the 2004 revision of the Declaration see http://www.wma.net/e/policy/b3.htm. For the history of the Declaration see http://www.wma.net/e/ethicsunit/pdf/chapter_4_decl_of_helsinki.pdf; and Robert V. Carlson, Kenneth M. Boyd and David J. Webb, 'The Revision of the Declaration of Helsinki: Past, Present and Future', *British Journal of Clinical Pharmacology* 57 (2004), 695–713.

Other landmark documents include the *Belmont Report* on *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 1979 (US Department of Health, Education, and Welfare; http://ohsr.od.nih.gov/guidelines/belmont.html) and Article 16 of the *European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, http://conventions.coe.int/treaty/en/Reports/Html/164.htm which prohibits research on human subjects unless 'the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented'.

For secondary literature see B. Brody, *The Ethics of Biomedical Research: An International Perspective* (New York: Oxford University Press, 1998); Sue Eckstein,

Declaration of Helsinki, approved in 2004, sets out strict and strong requirements for (highly) explicit and (fairly) specific consent. Similar demands are often set out in other codes for research ethics.

The relevant articles of the Declaration of Helsinki read:

> 20. The subjects must be volunteers and informed participants in the research project.
> 22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, and any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

Setting aside the Declaration's careless habit of conflating *physicians* with *researchers*, we can see that it promulgates more exacting standards and processes for seeking and obtaining informed consent from research subjects than those set out in the Nuremberg Code. In effect, *Helsinki* 2004 requires researchers to use *explicit* written and documented procedures in requesting and obtaining consent, and to seek *specific* consent to envisaged research projects. It repeatedly emphasises the information that researchers are to provide to research subjects. It goes beyond the Nuremberg demand that research subjects grasp in a general way what is proposed, and its likely effects and risks for them, and requires researchers to inform them about a range of scientific and institutional matters, including 'the aims, methods, sources of funding, and any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study'. Asking research subjects to

ed., *Manual for Research Ethics Committees*, 6th edn (Cambridge: Cambridge University Press, 2003).

grasp this complex of scientific and institutional information is highly demanding, even in the 'best' case where highly competent research subjects are recruited for a prospective study. And some seek to raise the standards even higher.[10]

These standards may demand too much. Many research subjects fail to understand common features of prospective research design, such as the use of randomised trials and placebos.[11] Where they fail, their consent will not meet the Helsinki standards. Does this show that such research should not be done? In other cases, where research is not prospective, but rather based on further analysis of existing data or tissues, it is even harder – indeed often impossible – to see how Helsinki standards could be applied. Research proposals for secondary data analyses, population studies or epidemiological investigations may not be formulated until well after information was recorded or the tissues were removed. The 'research subjects' (if that is how they are best thought of) would have to be recontacted if explicit and specific prior consent were required. Doing so is often impossible. Does this show that retrospective research should not be done, because it cannot meet the Helsinki standards? If it does, and we prohibit all research that does not meet the Helsinki standards, many sorts of medical research will not pass muster and will have to be abandoned.

The quest for higher standards for informed consent has also become vigorous in clinical ethics. In the very years in which some have tried to make consenting *easier* in order to accommodate

[10] For example, one author suggests that 'unless subjects are informed of the researchers' personal characteristics, views, and sponsors whenever they would be likely to consider them significant, their autonomy is being overridden'. T. M. Wilkinson, 'Research, Informed Consent, and the Limits of Disclosure', *Bioethics* 15 (2001), 341–63 (p. 363).

[11] Randomised trials have been in use since the late 1940s. They are commonly required in studies aimed at establishing the relative efficacy of treatments; but there are also persistent criticisms of the method, and queries about its acceptability. On the specific issues of research subjects' consent see Angus Dawson, 'What Should We Do About It? Implications of the Empirical Evidence in Relation to Comprehension and Acceptability of Randomisation?', in S. Holm and M. Jonas, eds., *Engaging the World: The Use of Empirical Research in Bioethics and the Regulation of Biotechnology* (Netherlands: IOS Press, 2004).

patients' cognitive limitations, others have tried to make it *more exacting*. The desire to make consent and consenting rigorous is understandable, but has raised many problems. Even if past standards had been good enough – and there may be reasons to doubt that they were – the growing complexity both of the information relevant to specific clinical interventions and research protocols and of their medical and scientific settings, may now require more exacting procedures.[12] However, simultaneous attempts to make informed consent *easier for patients* and to make it *more exacting* are likely to backfire.

In effect attempts to make informed consent more rigorous argue for two distinct types of improvement. They claim that acts of consenting should be *explicit*, rather than *implied* (*tacit*, *presumed*), and they claim that adequate consent should be *specific* rather than *generic* (*general*). In effect, they generalise the position taken in the Declaration of Helsinki, and extend it from research into clinical practice. Demands for *explicit* and *specific* consent may have started in research ethics, but have now penetrated into clinical practice, into medical ethics and into regulatory requirements. One result has been the development of increasingly complex, lengthy and (at worst) incomprehensible consent forms – and a large literature lamenting the fact!

The distinction between *explicit* and *implied* consent contrasts ways of consenting. Explicit consenting is a two way process. Those who request consent must provide an explicit statement of the nature and purposes of a proposed course of action, its effects, risks and other features, to those whose consent is sought. Those who are asked to consent must show explicitly that they understand

[12] Genetic information, for example, is challenging for many patients and others, who may find the information complex, and the reproductive or clinical risks they face hard to grasp and in some cases threatening. This is particularly likely where patients have to understand the *causal* significance of genetic claims (e.g., base rate fallacy; intuitions of determinism; lack of understanding of penetrance etc.). Indeed, the problems may not lie only with patients. Physicians too may lack an up-to-date grasp of genetics, yet are supposed to inform patients about genetic matters. See J. A. Kegley, 'Genetics Decision-making: a Template for Problems with Informed Consent', *Medical Law* 21 (2002), 459–71.