Some time ago, Ian Kennedy asked whether consent was the great bulwark of “patient’s rights”? Is it a necessary nuisance granted as a concession to modish thinking? Is it simply a figment of some lawyer’s (or—awful word—medical ethicist’s) imagination which practitioners know is meaningless in practice? Is it just part of the rhetoric of “patient power”, sent to try doctors’ patience and challenge their authority?1

According to Jackie Cassell and Alisdair Young, for example, it is such a bulwark; indeed, they consider it to be the “ethical touchstone of medical research” that has emerged in the last two decades.2 Nevertheless, at times they also regard the need for consent to be a nuisance—in particular with regard to Health Service Research (HSR)—which is organizational rather than clinical in nature. They can be counted among a recent trend of published papers that are of the opinion that informed consent should not be necessary in all cases.3 This paper argues that this position is not only undesirable, but also untenable when one pauses to consider the spirit of the guidelines that make it a key. To begin to show why this is the case, it is first necessary to reexamine the reasons for the need for informed consent.

As Cassell and Young highlighted, the Nuremberg Code is generally considered to be the birthplace of the principle of informed consent. The very first article of the Code states that

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, 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.4

As can be seen from the extract above, the duty rests with the researchers to inform the volunteer of not only the risks inherent in the research, but also the “nature, duration and purpose of the experiment.”5 In other words, it does not envisage consent as simply being about the disclosure of risks from researcher...
to volunteer. In a similar vein, the World Medical Association’s Declaration of Helsinki states

22. [E]ach potential subject must be adequately informed of the aims, methods, sources of funding, 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.6

Again, it is made clear in the guidance that there is more to consent than just the disclosure of risks. Indeed, paragraph 8 of the Declaration of Helsinki makes this point explicitly when it states that, “Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights.”7 This emphasizes that the interests of the volunteer reach wider than mere physical health. Rather, the key is dignity. That this is the case can be seen from the reasons for the creation and adoption of the Nuremberg Code—the atrocities committed by the Nazis.8 The effect that they had was deep, bringing the concept of unethical research to a new level.9

Dignity and Rights

As David Seedhouse and Ann Gallagher have noted, “dignity” is a word often utilized in declarations and codes of practice, but never actually defined.10 It is similarly left undefined by Cassell and Young. This is perhaps because the concept can be viewed in several different ways.11 This article sees a loss of dignity occurring when a person is not respected as an individual. Everyone has the “right” to be respected, and this integrity covers not only the body, but also the more general “self.” Thus the concept of “dignity” operates in conjunction with other rights, such as the right to autonomy or privacy. To remove any of those rights from a person entails a lack of respect for that person as an individual, which, in turn, leads to a loss of dignity. It may be argued, within the context of HSR, that information pertaining to patients, whether anonymized or not, belongs to those patients. Certainly, it is an intellectual leap to hold that it belongs to the medical practitioners treating them. It therefore follows that, in order to respect that individual, it is necessary to ask for permission before that information is utilized. Once we accept this, a failure to gain this consent will inescapably result in a loss of dignity to that person as she is not being treated with respect.

Yet, to rely on this “right,” it is first necessary to justify that reliance by demonstrating the existence of the right in question. Matti Häyry and Tuija Takala, for example, argue that in the context of genetic privacy and confidentiality, a rights-based analysis leads us to conclude that there are times when disclosure of genetic information can be justified.12 By examining the concepts of rights and duties in some depth, they demonstrate that a thorough analysis leaves philosophical room for maneuver in which the universality of principles such as consent, privacy, and confidentiality may be questioned. Indeed, the inevitability of conflicts between parties with respect to their rights and duties makes it possible to argue that the traditional, “individual-centered, rights-based approach to the matter should be abandoned, and replaced by more communitarian or interpersonal models of medical decision-making.”13

Again, though, such an approach may be resisted. The focus of this questioning of the “right” to privacy and confidentiality is consequentialist in na-
ture. In other words, the justification for the abrogation from such rights is dependant on the fact that to safeguard the privacy and confidentiality of one person will be of detriment to the rights of another (or others) or even to the community as a whole. Alternatively, the benefit to others justifies the (lesser) detriment suffered by the individual. In this way, it becomes “less bad” to remove one person’s rights, as it confers greater benefits on others overall. Even so, this approach relies on three factors: First, it must be demonstrated that the “harm” incurred by the individual is indeed outweighed by the benefits accrued. Second, it must also be shown that the calculations involved in this equation are pure of intention. Finally, but perhaps most importantly, we must also accept that it is justifiable to “trade” the rights of one person in order to benefit others—a moral judgment that is in no way automatically acceptable. If any of these conditions are not met, then there is no justification for the removal of the rights of the individual, and, as such, this would demonstrate a lack of respect being shown to that person. Again, this leads inevitably to a loss of dignity.

It is the first and third of these factors that can be most easily debunked. As Häyry and Takala note, medical treatment has, for a long time, ceased to be its own justification. Rather, the consent of the patient is generally required before any treatment is allowed to proceed. At the heart of this is the principle of autonomy. The view that, as a general principle, it may be permissible to compromise the physical integrity of one person to confer greater benefits onto others is inimical to modern medical ethics. Indeed, very few, if any, ethicists would argue that we may justify the killing of one person to harvest their organs and save the lives of two or more people. This, then, leads to the question: why should such a view be limited only to physical integrity? As mentioned above, it is an intellectual leap to argue that a medical practitioner owns information about her patients. This is similarly the case if we argue that the information belongs to society as a whole. If, therefore, the information belongs to the patient, some justification is needed before her autonomy is compromised. As a simple appeal to consequentialism is inappropriate, then, advocates of the removal of the need for informed consent argue that there is no harm incurred by the individual. Yet, this position is only defensible if one does not accept that the loss of dignity is in itself harm. As noted above, this article argues that it is.

The general tenet of some of the recent arguments seeking to limit the principle of informed consent is that it places too many restrictions on medical practitioners, who are only trying to do their best for their patients or the society in which we live. As correspondence to the *British Medical Journal* in 1998 demonstrates, this can range from compromising the methodological purity of research to a wish not to alarm elderly patients. They share, however, a prioritization of the research over the dignity of the individual. Of course, the Nazi atrocities of the last century are an extreme example. They were almost certainly the worst chapter in the history of medicine. Nevertheless, it must equally be noted that we can learn about the importance of informed consent from a much earlier era—the ancient Greeks.

The Lessons from the Ancient Greeks

A glance at the work of Hippocrates and Plato demonstrates a contrast in views regarding the medical profession and its ethics, but also can be seen as a metaphor of the current debate. In some ways, the Hippocratic Oath is clearly
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 outdated. As Kenneth Vaux, for example, has noted, the increased technologi-
calization of medical practice in the last century has lessened its relevance.\textsuperscript{16} Furthermore, it has also been convincingly argued that the Oath has become outdated due to its emphasis on the relationship between doctors themselves rather than the interaction with patients. For example, it specifically requires the medical practitioner to consider his teacher’s offspring his brother. At other points, the Oath can be (and has been) criticized for promulgating an unduly paternalistic philosophy. For instance, the doctor is advised to perform “all things calmly and adroitly, concealing most things from the patient while you are attending him,” which demonstrates little regard for the principle of consent.\textsuperscript{17}

Nevertheless, what survives of the Oath is not any specific principle but its overall tone. The primary duty of the medical practitioner is to “use treat-
ment to help the sick according to my ability and judgement, but never with a view to injury and wrongdoing.”\textsuperscript{18} Indeed, the emphasis is on the good conscience of the individual medical practitioner. As Edmund Pellegrino has noted, there is little or no evidence of Hippocrates believing in any concept of a medical “profession”:

There is in the Hippocratic corpus little explicit reference to the responsibilities of medicine as a corporate entity with responsibility for its members and duties to the greater human community. The ethic of the profession as a whole is assured largely by the moral behavior of its individual members. There is no explicit delineation of the corporate responsibility of physicians for one another’s ethical behavior. On the whole, the need for maintaining competence is indirectly stated.\textsuperscript{19}

Here, then, is where the Hippocratic Oath can be seen to be a model that is worth following. It can be forgiven some paternalism (particularly as it was prevalent at the time), and its lack of reference to technology (which did not exist at the time) can be forgotten as it idealizes the notion of a doctor acting for the good of her patient. Vaux highlights this fact when he states that “the genius of the oath is that it anchors responsibility in the moral power and ability of man and does not concede to any transcendent moral law or moral arbiter.”\textsuperscript{20} In some ways, therefore, the general principles of the Oath can be seen as rather touching and idealistic. This is because they rely almost entirely on the good conscience of the individual practitioner in order to operate. The inevitable infiltration by doctors of poor moral values into the profession would serve to debunk the myth of the medical utopia perpetuated by Hippocrates.

That such infiltration is inevitable is the central lesson that we can learn from the work of Plato. In particular, Thomas Szasz’s critique of Plato’s work illustrates the points well.\textsuperscript{21} Szasz highlighted the way in which Plato showed that a medical practitioner’s loyalty is not necessarily exclusively directed at her patient. Rather, Plato demonstrated, through his account of a discussion between Socrates and Thrasymachus, how the primary consideration of the medical practitioner is not the patient but the body of the patient. Her concern is for the art of medicine that, through a Hippocratic sense of benevolent altruism as well as respect for the profession, will manifest itself as ensuring that the medical practitioner acts in the best interests of her patient:
[The art of medicine] does not study its own interests, but the needs of the body, just as a groom shows his skill by caring for horses, not for the art of grooming. And so every art seeks, not its own advantage—for it has no deficiencies—but the interest of the subject on which it is exercised.  

It was at this point that Szasz demonstrated how the Platonic ideals highlight the fundamental deficiencies in the Hippocratic utopia. The most telling of these is the way in which a necessary precondition of such benevolent altruism is that the doctor must be in control of the patient’s body, for the good of her art:  

Every art has authority and superior power over its subject.... So the physician, as such, studies only the patient’s interest, not his own. For as we agreed, the business of the physician, in the strict sense, is not to make money for himself, but to exercise his power over the patient’s body.... All that he says and does will be said and done with a view to what is good and proper for the subject for whom he practices his art.  

Of course, this means that, at best, the doctor owes a dual allegiance: to the patient and to the art of medicine. However, as Szasz demonstrated, Plato then went further, arguing that the medical practitioner also owes an allegiance to the state:  

Surely, there could be no worse hindrance than this excessive care of the body.... Treatment.... would be wasted on a man who could not live in his ordinary round of duties and was consequently useless to himself and society.  

The conversation notes that medical treatment should be provided not for the sake of the patient, but the society that the patient belongs to—going so far as to discourage treating those who may “beget children who are likely to be as sickly as himself.” Once we accept such a position, we consequently also accept that the physician is to make moral judgments about the usefulness or otherwise of her patients. Furthermore, the basis upon which such judgments are made rests not on any Hippocratic notion of the patient’s welfare, but on a reading of social utility that has no connection with the patient or her dignity. Indeed, Szasz continued by demonstrating that this has already happened throughout history. He highlighted the fact that the birth of the discipline of public health quickly gave rise to the formation of the “medical police,” which “came into being to serve the absolutist rulers of the seventeenth and eighteenth century Europe.” The purpose of the medical police was to aid the ruler—thus they sought to ensure that, for example, babies were born to provide a population to harvest crops and become soldiers for the king. Needless to say, the individual patient’s needs or wishes were of no relevance at all. In fact, as Szasz noted, “increased power and wealth for the state could often only be obtained at the expense of decreased health and freedom for certain citizens.” Here “we witness a collision between the Platonic and Hippocratic medical ethics—the former easily triumphing over the latter.”  

There are two lessons that we can, and must, derive from Plato. First, the Hippocratic ideal of the doctor of “good conscience” is naïve in the extreme.
Second, physicians are humans, and when they have a conflict of interest, it cannot be taken for granted that the physician will act with the best interests of the patient at heart. History has proved Plato to be correct. The atrocities of the Nazis, sadly, were not the only example of this. Indeed, since the end of the Second World War we have witnessed too many other examples for it to be necessary to list them. In many cases, physicians have acted with government collusion against the interests of their patients—serving their paymasters first.

Those who are now advocating removing the need for informed consent in some cases need to pause for thought and realise exactly what they are arguing for. First, Cassell and Young hold the opinion that “in the context of a socialized health care system such as the NHS, informed consent should not always outweigh other central values in the decision making processes of ethical committees.” This is a dangerous argument, for it allows the physician to give allegiance to the paymaster rather than the patient. Plato, as discussed above, saw that this could lead to problems, and he was proved to be right.

Second, the argument against the need for universal informed consent relies on the idea that no harm will be done to the subject. Cassell and Young, for example, were quick to limit their argument for HSR rather than clinical research. They stated that HSR is mainly concerned with organizational matters, and that in the majority of cases all that is required from the patient is data about them. As a justification for this, they adopted the view of Mary Warnock, who opined that it is of more use to demand that the research process does not exploit the subject, rather than using the blunter instrument that is the requirement for consent. On the face of it, this would satisfy the requirement in Article 8 of the Declaration of Helsinki, discussed earlier in this article, that the fundamental principle is that the dignity of the research subject be respected.

This proviso cannot exist in conjunction with the notion that all is needed is a “lack of harm” to the research subject, as it necessitates a definition of harm that is so narrow as to be counterproductive. “Harm,” as defined by Cassell and Young by implication (as they never actually mention the word), is conceived as being limited to an invasion of the subject’s physical integrity. They argued that the Declaration of Helsinki “presupposes that ethics committees are considering traditional medical research—the effects of individual level interventions on individual patients.” Furthermore,

[Helsinki] divides research into two kinds—therapeutic and non-therapeutic. This widely accepted distinction fits a picture according to which research is carried out on individuals, and in which the brave, the altruistic or the foolhardy who take part in . . . experiments for no possible benefit (non-therapeutic research) deserve special protection.

This leads them to distinguish between HSR and “traditional” research, questioning “whether organisational research is really research at all.” The implication is that if no physical harm can be done to the subject, then it is not exploitative, and there is no loss of dignity. Thus, informed consent should not need to be sought. However, it is disingenuous to conflate the narrow definition of harm with the requirement of the preservation of the subject’s dignity, for there are circumstances where they can be seen to be different. One of these is HSR. Indeed, it is precisely with reference to HSR that the narrowness of the conception of harm used by Cassell and Young can be seen, for, as mentioned above, dignity is not solely dependent on physical integrity. This is because,
even if we only use anonymized information about patients in the abstract, we are still utilizing information that belongs to them, and not the researchers. This argument has been considered in the human rights context by the European Court of Human Rights on two recent occasions, and both times it was accepted by the court that, despite anonymization, unauthorized use of medical information could still constitute an invasion of the patient’s privacy, an affront to their dignity. Furthermore, there are reasons why a patient may want to refuse to divulge information. These may range from moral, rational, or even irrational objections to the proposed research to mere unadulterated selfishness on the part of the owner of the information.

It is the last of these in particular that the opponents of the blanket need for informed consent seize on. Cassell and Young, for example, argued that we all have “membership” of the National Health Service (NHS), and that therefore our “NHS rights as individuals are subject to the need to protect all members.” This is primarily to avoid infringing the Human Rights Act and its prohibition of discrimination. Yet although the goal of eradicating inequality and discrimination is to be applauded, it must be asked whether this should be implemented in this specific context at the expense of another basic human right—that of privacy. Indeed, it is simply not the case that HSR causes no harm, for, as argued above, some might feel a loss of dignity and sense of having been exploited or disrespected. Furthermore, there is a dangerous precedent being set if this line of reasoning is adopted. This is due to the necessary acceptance that there is something, in this case a desire to help as many people as possible within the NHS “membership,” that can trump the rights of the individual. Once this is the case, then we revert back to the situation that Szasz warned about through Plato’s work.

The conceit implied by Cassell and Young is that, because there is no physical “harm” to the patient, there is therefore no consequent loss of dignity. Moreover, they then put forward a utilitarian argument to advance the view that it is morally permissible to use the information to benefit the “membership” that is the NHS. As they noted, “[O]ur NHS rights as individuals are subject to the need to protect the rights of all members.” In this way, benefit is achieved for the community as a whole, without harming anyone. Certainly, this argument is seductive; nevertheless, it cannot be accepted.

Rather, this author argues instead that the “harm” occurs precisely because there is a loss of dignity. Indeed, any approach that limits the rights of the individual for the benefit of a collective ceases to respect that person. By denying the patient an informed choice regarding the use of their information, the position advocated by Cassell and Young treats them as “members” of the NHS collective rather than individuals who happen to belong to it. Furthermore, it is not clear that the patient gains any benefit from the use of their information. Although there are tangible gains for the collective—in the form of better practices leading to more effective future treatments—it is not certain that the individual will need (or want) that treatment in the future. Any benefit gained by that individual is thus tangential at best, in the form of potentially increased resources available for other treatments that the patient may potentially need in the future. In this context, the lack of direct benefit to the patient provides no counterweight to the loss of dignity incurred. Once we look at the situation in this way, the view that no harm occurs becomes effectively untenable.
Conclusion

It might be argued that the medical profession has learned its lessons from the past, and that it should not be forever punished for the sins of doctors who are, for the most part, already dead. Nevertheless, if Plato can teach us one thing, it is that the Hippocratic ideal of the purity of the medical conscience can never be seen as anything but unachievable. There are many examples, even today, of doctors who act without the best interests of their patients at heart. As Pellegrino has noted, history teaches us lessons that we would be very unwise to forget:

Clearly, the lessons of the Nuremberg Trials have not been learnt . . . The integrity of Medical Ethics is important not because it protects the physicians’ prerogatives but because it is a bulwark against the use of medical knowledge for purposes other than for the good of the sick . . . . If medicine becomes . . . the handmaiden of economics, politics or any other force other than that which promotes the good of the patient, it loses its soul and becomes an instrument that justifies oppression and the violation of human rights.38

It is sometimes best not to forget, and for this reason any attempt to limit the requirement for informed consent should be strongly resisted. The consequences of inaction were foreseen by the ancient Greeks, and proved beyond doubt, tragically, in the 20th century. Although this article does not in any way seek to compare HSR to the atrocities of the Holocaust, it does argue that the principle is effectively the same in both scenarios. The principle of informed consent was developed for a reason, and in order to discard it there has to be some sort of justification. The fact that it becomes an obstacle or inconvenience when applied to HSR is not, in itself, such a justification. Something else needs to be brought into the equation. Cassell and Young sought to provide this when they argued that it lies in the absence of harm to the patient. As this article has demonstrated, however, this is not the case, and, furthermore, it cannot be shown to confer any tangible benefits on the patient as an individual. The worst possible reason to dispense with an important principle in medical ethics is that it is too restrictive to medical practitioners. Ethics exist to guide doctors and protect patients, and informed consent is at the heart of this. The dignity of patients can only be assured if this fact is remembered, and the principle adhered to.

Notes

1. Kennedy I. Consent to treatment: The capable person. In: Dyer C, ed. Doctors, Patients and the Law. Oxford: Blackwell; 1992:44–72.
2. Cassell J, Young A. Why we should not seek individual informed consent for participation in health service research. Journal of Medical Ethics 2002;28:313. The full text of this article can be found at: http://jme.bmjournals.com/cgi/content/full/28/5/313–17.
3. See, for example, O’Neill O. Some limits of informed consent. Journal of Medical Ethics 2003; 29:4–7; Tobias J. B.M.J.’s present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. British Medical Journal 1997;314:1111–13; Bhagwanjee S, Muckart D, Jeena PM, Moodley P. Commentary: Why we did not seek informed consent before testing patients for HIV. British Medical Journal 1997;314:1082. Indeed, in 1998 the
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British Medical Journal hosted a debate on the issue with various authors giving their views; Informed Consent In Medical Research. British Medical Journal 1998;316:1000-05.

4. Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington: DC. U.S. G.P.O., 1949–1953.

5. See note 4, Trials of War Criminals 1949-1953.

6. World Medical Association. Declaration of Helsinki, adopted by the WMA's General Assembly in Helsinki in 1964, then amended in 1975, 1983, 1989, 1996 and finally in October 2000, the full text can be found on the WMA’s Web site at: http://www.wma.net.

7. See note 6, World Medical Association 1964.

8. Nicosia F, Huener J, eds. Medicine and Medical Ethics in Nazi Germany: Origins, Practices, Legacies. New York: Bergahn Books; 2002; Annas G. Nazi Doctors and the Nuremberg Code: Human Rights and Human Experimentation. New York: Oxford University Press; 1992.

9. See, generally, Caplan A, ed. When Medicine Went Mad: Bioethics and the Holocaust. Totowa, NJ: Humana Press; 1992.

10. Seedhouse D, Gallagher A. Undignifying institutions. Journal of Medical Ethics 2002;28:368, available at: http://jme.bmjournals.com/cgi/content/full/28/6/368–72.

11. For an excellent analysis of the different origins of dignity, and the consequences of this, see Häyry M. Another look at dignity. Cambridge Quarterly of Healthcare Ethics 2004;13:7–14. The definition of dignity used in this article most closely conforms to the Kantian model described in pp. 8-9, but is a personal one.

12. Häyry M, Takala T. Genetic information, rights, and autonomy. Theoretical Medicine 2001;22:403–14.

13. See note 12, Häyry, Takala 2001:406–7.

14. See note 12, Häyry, Takala 2001:407.

15. See, in particular, Tobias JS. Changing the BMJ’s position on informed consent would be counterproductive. British Medical Journal 1998;316:1001 for a brief précis of the views expressed within the debate on the issue.

16. See Vaux K. Biomedical Ethics—Morality for the New Medicine. New York: Harper and Row; 1968.

17. Jones WHS. Hippocrates, vol. II. Cambridge, Mass.: Harvard University Press; 1923:297.

18. Gelfand M. The Philosophy and Ethics of Medicine. Edinburgh: E&S Livingstone Ltd.; 1968:107.

19. Pellegrino E. Toward an expanded medical ethics: The Hippocratic ethic revisited. In: Veatch R, ed. Cross Cultural Perspectives in Medical Ethics. Boston: Jones and Bartlett Publishers; 1989: 27. Emphasis added.

20. See note 16, Vaux 1968:4.

21. Szasz T. The Theology of Medicine. Oxford: Oxford University Press; 1979.

22. The Republic of Plato, Cornford FM, trans. New York: Oxford University Press; 1945:23.

23. See note 22, The Republic of Plato 1945:23–4.

24. See note 21, Szasz 1979:9. Emphasis added.

25. See note 21, Szasz 1979:9.

26. See note 21, Szasz 1979:12.

27. See note 21, Szasz 1979:13.

28. See note 21, Szasz 1979:13.

29. The most famous being the Tuskegee Syphilis Study and the Swedish Sterilisation Programme. Both lasted into the 1970s. See Jones JH. Bad Blood: The Tuskegee Syphilis Experiment. New York: Free Press; 1993; Armstrong C. Thousands of women sterilised in Sweden without consent. British Medical Journal 1997;315:563, respectively.

30. See note 2, Cassell, Young 2002.

31. Warnock M. Informed consent—A publisher’s duty. In: Doyal L, Tobias JS, eds. Informed Consent in Medical Research. London: BMJ Books; 2001. In Cassell and Young, see note 2.

32. See note 2, Cassell, Young 2002.

33. See note 2, Cassell, Young 2002.

34. See note 2, Cassell, Young 2002.

35. See Z v. Finland (1997) 25 EHRR 371 and MS v. Sweden (1997) 28 EHRR 313.

36. See note 2, Cassell, Young 2002.

37. See note 2, Cassell, Young 2002.

38. Pellegrino E. Nazi doctors and Nuremberg: Some moral lessons revisited. Annals of Internal Medicine 1997;127(4):307–08. The full text can be found at: http://www.acponline.org/journals/annals/15aug97/naziedit.htm.