Introduction

The Limits of Respect for Autonomy

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This book makes an important contribution to ongoing efforts in the fields of medical law and bioethics to answer the challenges posed by the limitations of the principle of respect for autonomy, especially as these pertain to human research ethics. It aims to offer answers to two, related questions:

1. What are the limitations of the principle of respect for autonomy, and associated conceptualisations of autonomy in human research ethics? And,
2. What alternative concepts or ethical approaches are there that can address these limitations, and how are they related to autonomy?

The principle of respect for autonomy seems to have become firmly embedded in human research ethics since its inclusion in the 1947 Nuremberg Code, which was a response to atrocities committed by Nazi doctors. Nonetheless, there is an increasing awareness of the limitations of the principle of respect for autonomy and the underlying conceptualisations of human autonomy.[1] These limitations become more problematic in light of the need to conduct medical research with those who are not competent in legal terms (e.g., infants),[2] who appear to have

[1] Analysis of these anomalies and the inadequacies of the concept of autonomy to deal with them goes back at least to the early 1980s. See, for example, the contributions in the October 1984 issue of *The Hastings Centre Report*. However, it should be noted that the debate, and the search for alternatives, continues. See, for example, A. L. Caplan, 'Why autonomy needs help', *Journal of Medical Ethics*, 40 (2014), 301–2.

[2] See, among others, T. H. Murray, 'Research exceptionalism?: new ways of thinking about the old problem of minimal risk research with children', *Asian Bioethics Review*, 7 (2015), 139–50; T. Pope and B. Richards, 'Who makes the decisions, especially when it concerns minors?' *Journal of Bioethical Inquiry*, 10 (2013), 441–4; K. Dierickx and D. G. Kirchhoffer, 'New medical technologies and the ethical challenges for minors from the perspective of human dignity', in J. C. Joerdan, E. Hilgendorf, N. Petrillo and F. Thiele (eds.), *Menschenwürde und moderne Medizintechnik* (Baden-Baden: Nomos, 2011), pp. 375–92.

diminished autonomy in philosophical terms (e.g., those with addictions or psychopathologies),[3] or whose autonomy is compromised due to their social situation (e.g., those with lower socio-economic status, in poorer countries or with different cultural perspectives on the moral authority of the individual).[4]

Furthermore, developments in bio-banking and data-storage have meant that the traditionally accepted means of applying the principle of respect for autonomy by seeking informed consent has been called into question, not because people cannot consent, but because there are real questions about how informed they can be about the research that might be conducted using their tissue or data. The use for research purposes of organs and tissues removed and stored after surgery raises related questions about how consent could or should be obtained for these other purposes. Or whether it is necessary at all.[5]

Finding solutions to the limitations of the principle of respect for autonomy is important, especially with the rapid advances taking place in medical technology and the identified lack of research taking place in populations for whom it is more difficult to get ethics clearance using the standard emphasis on respect for autonomy and informed consent. These populations, e.g., minors, are often under researched, leading to risky practices such as off-label prescriptions. The development of alternative ethical frameworks to enable such research while still realising the intended ends of respect for autonomy, i.e., the protection of research participants from abuse and exploitation, is vital.

This introduction provides a brief overview of the development of the idea of respect for autonomy in guidelines governing human research as a way of illustrating how respect for autonomy has become embedded as a principle in human research ethics and law. It then considers some of

[3] See, among others, S. Matthews, 'Addiction, competence, and coercion', *Journal of Philosophical Inquiry*, 39 (2014), 199–234; A. Ho, 'The individualist model of autonomy and the challenge of disability', *Journal of Bioethical Inquiry*, 5 (2008), 193–207.

[4] See, among others, R. Vreeman et al., 'A qualitative study using traditional community assemblies to investigate community perspectives on informed consent and research participation in western Kenya', *BMC Medical Ethics*, 13 (2012), 23; D. Zion, L. Briskman, and B. Loff, 'Returning to history: the ethics of researching asylum seeker health in Australia', *The American Journal of Bioethics*, 10 (2010), 48–56.

[5] See, among others, M. Brazier, 'Organ retention and return: problems of consent', *Journal of Medical Ethics*, 29 (2003), 30–3; G. Laurie, 'Evidence of support for biobanking practices', *BMJ*, 337 (2008), a337; D. G. Kirchhoffer and K. Dierickx, 'Human dignity and human tissue: a meaningful ethical relationship?' *Journal of Medical Ethics*, 37 (2011), 552–6.

the limits of a possible overreliance on respect for autonomy when evaluating the morality and legality of a particular research protocol and introduces how the chapters in this volume address some of these issues and offer possible solutions.

Respect for Autonomy in Human Research Ethics Guidelines

Though the legal formulation of informed consent can be traced to American law in the early twentieth century, with philosophical roots in the thought of John Locke,[6] it is arguably the 1947 Nuremberg Code – which arises out of attempts to define the concept of a medical war crime in the trial of Nazi doctors[7] – that seems to cement the requirement for informed consent, and with it the value of autonomy as a seemingly essential principle governing biomedical ethics, be it clinical ethics or research ethics.

The Nuremberg Code states in Article 1, 'The voluntary consent of the human subject is absolutely essential.' This wording indicates a view that research is only permissible where consent is given. *Voluntary consent*, according to the Nuremberg Code, requires that the subject have the legal capacity to give consent, and that the person's situation makes them able to exercise 'free power of choice'. There must be no element of force, fraud, deceit, duress or coercion, and they must have sufficient knowledge and understanding of what is being proposed, including the nature, duration, purpose, risks, and health effects of the experiment to enable an 'enlightened' decision.

Over time, this emphasis on voluntary consent, including the dimension of 'legal capacity', continues to be a central component of other guidelines, policies and declarations, even as these become much more developed than the very concise Nuremberg Code (the 1947 Code makes a mere 10 points in 504 words; the 2007 Australian National Statement on Ethical Conduct in Human Research, by contrast, is over 100 pages long).

For example, the 1966 United Nations International Covenant on Civil and Political Rights – which is legally binding for ratifying countries –

[6] V. Beširević, 'Basic norms of bioethics: informed consent in UNESCO bioethics declarations', *Annals – Belgrade Law Review*, 3 (2008), 257–65.

[7] P. Weindling, 'The origins of informed consent: the international scientific commission on medical war crimes, and the Nuremberg Code', *Bulletin of the History of Medicine*, 75 (2001), 37–71, 38.

states in Article 7, 'In particular, no one shall be subjected without his free consent to medical or scientific experimentation.' Interestingly, this follows a sentence in the same article prohibiting torture: 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.' (The 1985 United Nations Declaration on Human Rights of Individuals Who Are Not Nationals of the Country in which They Live explicitly extends this prohibition to include aliens (Article 6)). The Covenant, thereby, seems to suggest that performing any kind of medical research without the free consent of subjects is tantamount to cruel, inhuman treatment.

In 1964, the World Medical Association adopted the first version of the Declaration of Helsinki, which has arguably become 'the cornerstone of modern research ethics'.[8] This has been amended numerous times. Many of these changes have to do with the importance of the idea of respect for autonomy. The original 1964 Declaration[9] started from the premise that the doctor would always act out of beneficence for the patient: 'It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.' Consequently, it assumes that the first kind of research would be that with potential therapeutic benefits for the patient. Interestingly, because such benefits are in play, the emphasis on consent, i.e., the free choice of the patient, is less strong: 'If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient' (II, 1); the doctor can combine therapy with research 'only to the extent that clinical research is justified by its therapeutic value for the patient' (II, 2). With regard to non-therapeutic clinical research, however, the 1964 wording is stronger: 'Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured,' (III, 3a) and, very importantly, 'At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for

[8] S. S. Fluss, 'The evolution of research ethics: the current international configuration', *Journal of Law, Medicine and Ethics*, 32 (2004), 596–603, 601.

[9] P. P. Rickham, 'Human experimentation: Code of Ethics of the World Medical Association, Declaration of Helsinki', *British Medical Journal*, 2, 5402 (1964), 177.

research to be continued' (III, 4a). The latter represents a development of the thinking about the importance of autonomy over the wording of Article 9 of the 1947 Nuremberg Code, which only saw it as legitimate for the subject to end the experiment 'if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible'.

By the time we get to the 2013 version of the Declaration of Helsinki, the starting premise regarding 'mission of the doctor' remains firmly in place. The General Principles section, however, now includes the requirement to apply ethical standards 'that promote and ensure respect for all human subjects and protect their health and rights' (Article 7). This is given further expression in Article 9, which stipulates that physicians have a duty to protect the 'right to self-determination' of research subjects. In other words, respect for patient autonomy is now central to the General Principles. Moreover, the 2013 document has an extensive section (Articles 25–32) on informed consent. Indeed, it is the longest section of the document. Article 25 states: 'Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.' Most importantly, relative to Nuremberg, respect for autonomy now extends beyond those who have *legal* capacity to consent. Article 29 states, 'When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.'

The Council of Europe's 1997 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, widely known as the Oviedo Convention, stipulates at the outset in its General Provisions, that the parties to the convention must 'guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms' (Article 1). Unsurprisingly, after addressing the General Provisions, the first specific topic dealt with at length is that of consent. The chapter on consent begins with the following 'General Rule': 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate

information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time' (Article 5).

The 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), follows the 1979 Belmont Report in enshrining the Principle of Respect for Persons as a basic ethical tenet.[10] The Belmont report is the result of the deliberations of the United States of America's National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established by the National Research Act 1974. The CIOMS guidelines, under the section entitled General Ethical Principles, state:

> Respect for persons incorporates at least two fundamental ethical considerations, namely:
>
> (a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
> (b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Moreover, its Guideline 4 deals specifically with the requirement to obtain individual informed consent:

> For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorised representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

In the Commentary on Guideline 4, the CIOMS document states that 'Informed consent protects the individual's freedom of choice and respects the individual's autonomy.'

In conclusion to this section, it is reasonably safe to say that since its initial very strong inclusion in the Nuremberg Code, the idea that the autonomy of research subjects should be respected and that this is best done by obtaining free and informed consent seems to have become

[10] Fluss, 'The evolution of research ethics', 601.

firmly embedded as a key criterion or principle governing human biomedical research. One might argue that in CIOMS, the primary principle is respect for persons, rather than autonomy, since respect for autonomy is seen to be one of the two ways in which persons are respected, the other being security against harm or abuse. Note, however, that even in CIOMS, this 'security' is only afforded to 'persons with impaired or diminished autonomy'. In other words, here too, the reasoning seems to start from respect for autonomy by assuming that where there is full autonomy, respecting this will provide the necessary 'security'; only where this autonomy is compromised, and possibly even absent, are additional protective measures necessary to ensure respect for the person. Moreover, the reach of respect for autonomy is even extended, in the 2013 Declaration of Helsinki, to those who can express assent even though they may not have the legal capacity to consent – e.g., minors. This is not present in the Nuremberg Code, where the focus is squarely on those with the legal capacity, i.e., competent adults.

That said, however, this apparent expansion of autonomy can also be interpreted as pointing to a larger problem, namely, what to do in cases where autonomy, understood as the legal capacity to give consent, is diminished or lacking? The inclusion of the requirement for assent seems to be an attempt to continue to solve the problems of diminished autonomy from within the autonomy paradigm itself, presumably in an effort to avoid the kinds of abuses that gave rise to the Nuremberg Code in the first place.

The Limitations of Respect for Autonomy

The development of the codes and guidelines sketched above is important because it points to the efforts to grapple with a problem fundamental to the ethics of human research. Basically, this problem can be summarised as follows. Research is good for human beings, because it leads to new knowledge and in turn to improved health outcomes. This research, however, frequently requires the exposure of research participants to either the risk of harm, or indeed real harms, ranging from inconvenience to severe side effects. So, the question is, when and how can we morally justify potential or real harms to human beings so that the beneficent ends of research can be achieved?

All human research ethics guidelines and law try to deal with that question. In more clinical contexts, where there are clear proportional therapeutic benefits for those participants, it is easier to morally justify

the exposure to the risks. When, however, there are few or no direct benefits for participants, then, justification becomes more difficult, if not impossible. Only a more extreme consequentialist reasoning that accepts the sacrificing of some for the greater good of others could allow it. It is precisely this kind of reasoning that has shocked the world in various human research scandals, from the Nazi experiments to the Tuskegee syphilis studies. And it is arguably in response to such reasoning that the idea of respect for autonomy and obtaining consent has developed. However, respect for autonomy through obtaining informed consent also seems to solve the initial problem; the way to justify research, and with it potential and real harms to participants, whether with or without real benefits, is to ask the participants to consent. If they agree, it would seem, at least within a strongly liberal view, the problem is solved.

Such thinking has two problems. First, surely, we would not want to allow research that has serious harms with no potential benefit, either to the participants or anyone else for that matter, simply because the participants agreed? Second, and herein lies the focus of this book, surely there are cases where we want to be able to conduct important and potentially beneficial research with participants who cannot consent? How can we morally justify such research?

The Structure of the Book

In making a contribution to answering this question, this book is divided into three parts. Part I addresses the fundamental challenges of defining and using the concept of autonomy at law, and then the practical challenges that arise from three different kinds of limitation of autonomy: lack of autonomy, with very young children as an example; diminished autonomy, with addiction as an example; and compromised autonomy, with low social status as an example. The structure of this part is designed to interrogate, using specific examples, the challenges that would be echoed in similar cases. The concerns around research involving children, especially infants, are mirrored in those with severe disability, or who lack competence due to brain injury. The concerns around diminished autonomy that we find in cases of chronic addiction apply also to people with dementia. The concerns around compromised autonomy arising from power imbalances are echoed in other vulnerable populations such as prisoners or asylum seekers. Part II considers concepts that might qualify, complement or indeed provide alternatives to autonomy when considering the moral status of the individual research

participant or researcher. Part III explores a turn to communities, governance and third parties as ways to ensure the protection of research subjects, the reason why we are interested in respecting autonomy in the first place. In other words, the structure of the book moves from an examination of the limitations of autonomy, through explorations of how to address these at the level of the individual and ends with some avenues to address these limitations at the level of the community.

In the first chapter, Bernadette Richards surveys the conceptions of autonomy that seem to underlie the legal decisions in informed consent cases. She argues that there is no consistent conception of autonomy underpinning these decisions, since the test in law is not about the autonomy of the patient, but rather about the amount of information provided. In light of this, Richards proposes dropping the language of respect for autonomy from legal contexts entirely, focusing instead on more testable duties and rights.

In Chapter 2, Thomas H. Murray provides an account, rich in personal experience, of the historical debates in bioethics that arose around the issue of research involving children, especially where there is no direct benefit to the research participant. What is striking in Murray's analysis is how most of the attempts to deal with the problem of children's lack of capacity to give legal consent, and infants' lack of capacity to give any consent, nonetheless seem to take respect for autonomy as their starting point. In light of the realisation of the importance of cases rather than principles in the way moral evaluations of particular medical ethical issues tend to be made, Murray proposes taking the importance of relationship seriously when thinking about research involving children. This approach finds resonance later in the book in Parts II and III.

In some cases, however, it seems one cannot escape the need to focus on individual capacity for consent. One example is in treatments and clinical trials involving people with chronic addictions. That addiction compromises individual autonomy is self-evident. The extent and nature of this limitation, however, is an area of much debate. Steve Matthews and Jeanette Kennett, in Chapter 3, consider the philosophical puzzle presented by compulsory treatment programmes for heroin addicts on the one hand, and voluntary heroin-assisted treatment, on the other. The former assumes no capacity for consent, the latter insists on voluntary consent. Here, the authors take the approach of thickening, rather than thinning or dismissing the concept of respect for autonomy, by making the distinction between decisional and executive autonomy, which combine to become overall autonomy. They argue that while addicts never

lose their decisional autonomy, it is their executive autonomy, i.e., the capacity to visualise and commit to the steps to realising a meaningful future, that is most impeded by addiction. They propose, nonetheless, that this executive autonomy can be restored with the necessary work and guidance.

S. Stewart Braun considers how we should conceive of autonomy in the face of social and economic inequality. In Chapter 4, Braun shows how the assumption that all people are equally free to make choices about their health and well-being is fundamentally incorrect. Drawing on the work of Michael Marmot, Braun argues that inequality of opportunity puts people of lower socio-economic status at a fundamental disadvantage such that their real autonomy is compromised by systemic limits. Braun offers a philosophical defence of a thicker conception of autonomy as self-creation and suggests that real respect for the autonomy of people of lower socio-economic status requires regulators not simply to tell people to make the right choices, but to address the causes of the systemic lack of opportunity for self-creation.

Part I's consideration of different kinds of limitation of autonomy reveals that there is unlikely to be a one-size-fits-all solution. At times, as in the case of Richards, Matthews and Kennett, and Braun's contributions, it seems fruitful to examine and possibly enrich our understanding of autonomy and its implications. At other times, we need to turn to human relationships and the community, as in the case of Murray and Braun. In other words, solutions to the problems of the limitations of autonomy seem to lie in some combination of revisions or thickenings of our understanding of autonomy, and in some dimension of a community duty to protect or facilitate the flourishing of the individual. Consequently, Part II helps us focus on questions of the former, and Part III possible avenues with respect to the latter.

Part II considers alternative concepts surrounding autonomy that may qualify, complement or indeed replace our need to focus so heavily on respect for autonomy.

Garrett Cullity's contribution in Chapter 5 focuses on an important theoretical consideration implicit in Thomas H. Murray's account in Part I, particularly with regard to the relationship of principles to cases, and the difference between medical ethical decisions involving benefits to patients, and research ethical decisions involving no benefits. According to Cullity, contemporary bioethics is heavily influenced by a pluralist moral approach that accepts no principle as primary. Rather, as championed by Thomas Beauchamp and James Childress, competing