1

Vulnerability

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1.1 INTRODUCTION

Vulnerability is widely accepted as a relevant concept in human research regulation. Reflecting this, influential international research ethics guidelines require identification of, and protections for, participants who are deemed vulnerable.[1] Nonetheless, vulnerability is challenging to conceptualise and define, with ongoing disputes about the nature and extent of moral obligations to the vulnerable. This chapter maps the history of vulnerability in human research ethics guidelines and explores current debates regarding the role of vulnerability in guiding ethical deliberations about research participation.

1.2 VULNERABILITY IN RESEARCH ETHICS GUIDELINES

Concerns about vulnerability are implied rather than explicitly mentioned in some of the first formal research ethics guidelines such as the Guidelines for Human Experimentation (the Guidelines) issued by the German government in 1931, and the Nuremberg Code (the Code).[2] These early documents were concerned about experimentation on non-consenting individuals, especially those susceptible to exploitation due to various hardships. Both emphasised the importance of informed consent. The Code required the decision of the potential participant to be fully informed and 'without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'.[3] Similarly, the Guidelines prohibited exploiting social hardships to secure research participants, as to do so would be 'incompatible with the principles of medical ethics'.[4] Without explicit use of the term vulnerability, these documents pinpointed concerns about exploitation and whether voluntary informed consent could protect participants suffering hardships. In subsequent guidelines, these concerns are conceptualised as indicators of vulnerability.

Vulnerability is first explicitly identified as a characteristic of individuals and groups who thereby require special protections in the 1979 Belmont Report (the Report). The Report

[1] D. Bracken-Roche et al., 'The Concept of "Vulnerability" in Research Ethics: An In-Depth Analysis of Policies and Guidelines' (2017) *Health Research Policy and Systems*, 15(8), 1–18.

[2] R. B. Ghooi, 'The Nuremberg Code – A Critique' (2011) *Perspectives in Clinical Research*, 2(2), 72–76.

[3] 'The Nuremberg Code', in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Volume 2*, (Washington, DC: US Government Printing Office, 1949), pp. 181–182.

[4] Cited in Ghooi, 'The Nuremberg Code – A Critique', 74.

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intended to provide a comprehensive framework for resolving ethical problems arising from human research.[5] Its three principles – respect for persons, beneficence and justice – offer protection to all research participants without exception. In addition to these universal protections, the Report identified three areas where participants may be especially vulnerable. The first, echoing the 1931 Guidelines, concerned the voluntariness of consent in situations where ordinarily acceptable inducements may become undue if the subject is especially vulnerable.[6] The second required increased scrutiny of risks and benefits for research involving vulnerable populations, arguing that their involvement is more or less appropriate depending upon the nature and magnitude of risks, the anticipated benefits and the condition of the population involved.[7] The third concerned the potential injustice of recruiting participants 'solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition'.[8] Here the Report referred to 'racial minorities, the economically disadvantaged, the very sick, and the institutionalized' whose ready availability may lead to their exploitation.

Thus the Report characterised the vulnerable as individuals and groups with potentially limited capacity to give consent and/or those liable to exploitation for various reasons. It required greater justifications for the inclusion of vulnerable participants, and identified exclusion altogether from research as one way of protecting the vulnerable.

Subsequent research ethics guidelines follow the Report in linking vulnerability to consent, exploitation and special protections. For example, the Declaration on Bioethics and Human Rights stipulates the following:

> In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.[9]

The Declaration of Helsinki requires 'specifically considered protection' for all vulnerable individuals and groups.[10] Likewise, the current Council for International Organizations of Medical Sciences (CIOMS) guidelines invoke 'specific protections':

> When vulnerable individuals and groups are considered for recruitment in research, researchers and research ethics committees must ensure that specific protections are in place to safeguard the rights and welfare of these individuals and groups in the conduct of the research.[11]

This brief survey of research ethics guidance demonstrates that for nearly ninety years there have been concerns that some research participants are more vulnerable than others, and that vulnerable participants require special considerations. Despite the agreement that vulnerable participants require something more than routine ethical consideration, there is little consensus as to what characteristics make some participants more vulnerable than others and whether 'special consideration' is the appropriate moral response to vulnerability.

[5] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 'Belmont Report' (Department of Health, Education and Welfare, 1979).
[6] Ibid., 7.
[7] Ibid., 10.
[8] Ibid.
[9] United Nations Educational, Scientific and Cultural Organization, 'Universal Declaration on Bioethics and Human Rights' (UNESCO, 2005), Art. 8.
[10] World Medical Association, 'Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects' (World Medical Association, 2013).
[11] CIOMS, 'International Ethical Guidelines for Health-Related Research Involving Humans' (Council for International Organizations of Medical Sciences, 2016), Guideline 15.

1.3 VULNERABILITY: AN AMBIGUOUS CONCEPT IN HRR

There is an ambiguity about vulnerability running through the heart of research ethics. Prima facie, research ethics guidance provides protections for all participants who are potentially exposed to research-related harms such as deception, coercion, injury, misuse of their data and other harms. Requirements such as informed consent and balancing benefits and risks aim to mitigate this vulnerability. Yet this universal vulnerability to the potential harms of research is not explicitly named. Instead, the category of 'special' vulnerability attributes vulnerability to groups or individuals such as those identified in the Belmont Report: 'racial minorities, the economically disadvantaged, the very sick, and the institutionalized'.[12] This 'special' vulnerability approach reflects ambivalence about overtly acknowledging universal vulnerability and simultaneous recognition that some research participants do bear greater risk of harms than others. Ambivalence about the concept of vulnerability can be traced back to competing philosophical accounts.

The universal account takes vulnerability to be a type of fragility or susceptibility to suffering, linked to human embodiment. According to Fineman, vulnerability is an ontological necessity of our humanity, an 'inevitable, enduring aspect of the human condition'.[13] Understanding vulnerability as a universal feature reflects the shared human capacity for experiencing pain, frailty and other harms of existence and the inevitability of death for all humans. The notion of universal vulnerability underpins ethical concern for all research participants. The requirement for informed consent arises because all participants are potentially vulnerable to deception as they lack relevant skills to distinguish experimentation from accepted treatment. Similarly, requirements for pain relief in pertinent protocols reflect universal vulnerability to suffering pain. But universal vulnerability is not explicitly identified in research ethics guidelines. Instead, there is an assumed 'normal' research participant for whom standard ethical protections are adequate. This baseline normal research participant is characterised by Luna as 'mature, moderately well-educated, clear thinking, literate, [and] self-supporting'.[14] Vulnerable participants are identified against this implicit norm.

In contrast to universal vulnerability, accounts of special vulnerability claim that vulnerability is essentially specific and relational: individuals are vulnerable to particular agents regarding particular threats to their interests.[15] Although everyone has interests that may be threatened, some individuals or groups have little or no capacity to protect themselves. On this account, vulnerable persons have a reduced capacity to safeguard their interests relative to others. Whereas the universal account stresses our common embodied humanity and equal susceptibility to suffering, the special vulnerability account emphasises the ways in which various inequalities make some individuals ('the vulnerable') especially susceptible to harm or exploitation by others.[16]

[12] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 'Belmont Report', 10.

[13] M. A. Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) *Yale Journal of Law & Feminism*, 20(1), 8.

[14] F. Luna, 'Identifying and Evaluating Layers of Vulnerability – A Way Forward' (2018) *Developing World Bioethics*, 19(2), 88.

[15] R. E. Goodin, *Protecting the Vulnerable: A Reanalysis of Our Social Responsibilities* (Chicago: University of Chicago Press, 1985).

[16] W. Rogers et al., 'Vulnerability' in Bruce Jennings (ed.), *Bioethics*, 4th Edition (Farmington Hills, MI: McMillan Reference, 2014), pp. 3149–3153.

Within research ethics, the notion of special vulnerability is dominant. However, despite widespread requirements for special protections for the vulnerable, vulnerability is rarely defined in research ethics guidance. Bracken-Roche and others found that only three of eleven national and international guidelines contained definitions of vulnerability.[17] Both CIOMS and the Canadian Tri-Council Policy Statement define vulnerability in terms of decreased ability to protect one's own interests, secondary to intra-personal factors (e.g. reduced capacity to give informed consent) or contextual factors (e.g. limited access to social goods including rights, opportunities and power). The third guideline, the International Conference on Harmonisation – Good Clinical Practice guideline, does not define vulnerability per se, but defines vulnerable subjects in a glossary entry as those who may be unduly influenced either by expectations of benefit, or due to their subordinate place in a relevant hierarchy.[18]

The common approach in these and other guidelines is to rely upon lists of individuals or groups with characteristics that are taken to be indicators of vulnerability. The eleven guidelines analysed by Bracken-Roche and others list thirty-two characteristics signifying vulnerability. Individual indicators include being a prisoner, homeless person, woman, economically disadvantaged person, person lacking in political or social power, refugee, neonate and so forth. Identified vulnerable groups include very sick persons, children, minors or young persons, pregnant or breastfeeding women, the elderly, persons with mental illnesses, persons with limited capacity to consent and others. This dominant approach of labelling vulnerable participants has been subject to various critiques.

1.4 PROBLEMS WITH THE LABELLING APPROACH TO VULNERABILITY IN RESEARCH

The aim of labelling individuals or groups as vulnerable is to trigger special protections over and above those offered to all research participants, to prevent or decrease the risk of harms triggered by the vulnerability in question. Nevertheless, this approach is problematic as it leads to stereotyping, discrimination and unwarranted exclusion from research. Critics have argued that the labelling approach is both too narrow and too broad.[19]

One effect of the labelling approach is to focus narrowly on questions about capacity, and whether or not vulnerable individuals are able to give competent, informed consent for research participation.[20] This results in ethical review that attempts to identify all possible factors that might render consent less than fully valid, such as cognitive impairment or coercive circumstances. For individuals who lack capacity to provide valid consent, the proposed remedies for this vulnerability are proxy consent or exclusion from research. However, conceptualising vulnerability primarily in terms of incapacity to provide informed consent is ethically inadequate.

First, this approach fails to address the full range of moral issues raised by vulnerability, such as susceptibility to exploitation.[21] Some research participants who are capable of providing

[17] Bracken-Roche et al., 'The Concept of "Vulnerability" in Research Ethics', 3.
[18] Ibid., 4–5.
[19] C. Levine et al., 'The Limitations of "Vulnerability" as a Protection for Human Research Participants' (2004) *American Journal of Bioethics*, 4(3), 44–49; P. J. Nickel, 'Vulnerable Populations in Research: The Case of the Seriously Ill' (2006) *Theoretical Medicine and Bioethics*, 27(30), 245–264; W. Rogers, 'Vulnerability and Bioethics' in C. Mackenzie et al. (eds), *Vulnerability: New Essays in Ethics and Feminist Philosophy* (New York: Oxford University Press, 2014), pp. 60–87.
[20] P. Bielby, *Competence and Vulnerability in Biomedical Research* (New York: Springer, 2008).
[21] R. Macklin, 'Bioethics, Vulnerability and Protection' (2003) *Bioethics*, 17(5–6), 472–486.

informed consent may, nonetheless, be vulnerable to exploitation, due to poverty, power imbalances in the researcher–participant relationship or other circumstances. For example, pregnant women may be vulnerable to exploitation regarding participation in research aimed at benefitting the fetus. In this situation, pro-natalist pressures may unduly exacerbate women's understandable concerns for foetal well-being, thereby creating opportunities for exploitation.[22] Attention to informed consent processes will not necessarily resolve this kind of exploitation. Nor will it protect those who are vulnerable due to a lack of basic human rights.[23] For example, better information about a research protocol fails to mitigate participants' vulnerability to coercion from local power brokers who stand to profit from the research.

Second, the narrow approach 'can divert attention from features of the research itself, the institutional environment, or the social and economic context that can put participants in harm's way'.[24] Informed consent does not provide protections against dangerous protocols, researchers with conflicts of interest or dysfunctional institutions, all of which make participants vulnerable by increasing their risk of harm. External factors such as these contributed to the deaths of Ellen Roche, a healthy volunteer who died in an asthma research trial,[25] and Dan Markingham, who died in an anti-psychotic medication trial.[26] These participants were made vulnerable by deficiencies in the manufacturing standards of the inhalant, poor standards in the research protocol review process by the institutional review board, inadequate oversight, and significant conflicts of interest at researcher and institutional levels. These factors affect the safety of all participants rather than reflecting specific vulnerabilities of these particular participants.

A third problem with a narrow focus arising from the labelling approach is that concentrating on informed consent offers few options for mitigating vulnerability. For individuals who lack capacity – such as unconscious persons, babies, young children or individuals with severe cognitive deficits – it may not be possible to develop valid consent processes, leaving the alternatives of proxy consent or exclusion from research. Exclusion from research results in inadequate information about therapeutics for affected individuals and groups.[27] Rather than exposing a small number of individuals to specific risks within a regulated clinical trial, exclusion from research increases risks for all members of excluded groups who then must rely on off-label prescribing of therapies with unknown effects for their patient cohort.[28]

Despite the labelling approach to vulnerability being criticised for being too narrow, a second critique claims the opposite: that an over-inclusive approach to identifying vulnerability leads to virtually everyone being labelled as vulnerable.[29] Lists compiled from research ethics guidelines by Bracken-Roche and others and Hurst leave few who are *not* classified as vulnerable.[30] This

[22] A. Ballantyne and W. Rogers, 'Pregnancy, Vulnerability and the Risk of Exploitation in Clinical Research', in F. Baylis and A. Ballantyne (eds), *Missed Trials: Clinical Research Involving Pregnant Women* (Switzerland: Springer, 2016), pp. 139–159.

[23] D. Zion et al., 'The Declaration of Helsinki, CIOMS and the Ethics of Research on Vulnerable Populations' (2000) *Nature Medicine*, 6(6), 615.

[24] Levine et al., 'The Limitations of "Vulnerability"', 46.

[25] R. Steinbrook, 'Protecting Research Subjects: The Crisis at Johns Hopkins' (2002) *New England Journal of Medicine*, 346(90), 716–720.

[26] C. Elliott, 'Institutional Pathology and the Death of Dan Markingson' (2017) *Accountability in Research*, 24(2), 65–79.

[27] W. Rogers and A. Ballantyne, 'Justice in Health Research: What Is the Role of Evidence-Based Medicine?' (2009) *Perspectives in Biology and Medicine*, 52(20), 188–202.

[28] R. Dresser, 'Wanted. Single, White Male for Medical Research' (1992) *The Hastings Center Report*, 22(1), 24–29.

[29] F. Luna, 'Elucidating the Concept of Vulnerability: Layers not Labels' (2009) *International Journal of Feminist Approaches to Bioethics*, 2(1), 121–139.

[30] Bracken-Roche et al., 'The Concept of "Vulnerability"', 1–18; S. A. Hurst, 'Vulnerability in Research and Healthcare; Describing the Elephant in the Room?' (2008) *Bioethics*, 22(40), 191–202.

apparently over-inclusive approach to vulnerability labelling renders the notion of vulnerability ineffectual for two reasons. First, despite its breadth, there is no recognition of the features that might underpin a universal conception of vulnerability; the focus remains on special vulnerability. Second, the over-inclusiveness of the labelling limits the utility of invoking protections for special vulnerability, because the context-specific needs of individuals or groups are obscured rather than identified. Vulnerability cannot be a useful marker for providing *extra* protections if all research participants are deemed vulnerable. The concept becomes so broad as to be meaningless, and certainly impractical for mandating specific responses.[31]

Critics of the over-inclusive labelling of vulnerability note that this approach can lead to stereotyping, discrimination and failure to consider the specifics of each case. Stereotyping occurs when whole categories of individuals are labelled vulnerable, in contrast to the rest of the – presumably invulnerable – population. Labelling has a homogenising effect as all members of the group are assumed to be equally vulnerable. But it is unreasonable both to divide the general population into exclusive vulnerable and non-vulnerable categories, and to obliterate relevant differences between those labelled vulnerable. The impacts on individuals of factors associated with special vulnerability such as educational disadvantage, cognitive impairment or dependent relationships vary enormously. For example, young people under sixteen years are usually labelled vulnerable as they are held incapable of giving valid informed consent. However, the capacity to understand complex information and make considered decisions is highly variable in adolescents; some are capable of consenting and some are not. In addition, vulnerability is not a dichotomous state such that individuals are either vulnerable or not. Rather, vulnerability occurs on a spectrum, with different levels or degrees. But this distinction is lost when labels are applied: regarding vulnerability, 'you are either in or you are out'.[32]

Once individuals or groups are labelled vulnerable, this can be a source of discrimination, used to justify unwarranted and unjust paternalistic policies.[33] Such discrimination is evident regarding pregnant women, who have historically been labelled vulnerable and excluded from research notwithstanding their evident capacity to give informed consent. Routine exclusion of pregnant women from research undermines their autonomy by removing the opportunity to make decisions about research participation. Further, exclusion of pregnant women from research is harmful as it results in a lack of information about safe and effective treatments in pregnancy, especially when pregnant women who are given untested treatments mistakenly believe they are receiving a therapeutic intervention.[34] Exclusion from research is especially problematic where access to treatment is premised on evidence of the safety and efficacy of that treatment. Where groups are systematically excluded from research, the evidence base is correspondingly meagre and their treatment options limited.[35]

Given these problems with the labelling approach to vulnerability in research ethics, I now turn to analytic approaches to conceptualising vulnerability.

[31] See e.g. Levine et al., 'The Limitations of "Vulnerability"', 46; Luna, 'Elucidating the Concept of Vulnerability', 127.

[32] Luna, 'Identifying and Evaluating Layers of Vulnerability', 87.

[33] S. Dodds, 'Depending on Care: Recognition of Vulnerability and the Social Contribution of Care Provision' (2007) *Bioethics*, 21(90), 500–510; A. Ho, 'The Individualist Model of Autonomy and the Challenge of Disability' (2008) *Journal of Bioethical Inquiry*, 5(2–3), 193–207.

[34] F. Baylis and R. MacQuarrie, 'Why Physicians Should Want Pregnant Women Included in Clinical Trials', in F. Baylis and A. Ballantyne (eds), *Missed Trials: Clinical Research Involving Pregnant Women* (Switzerland: Springer, 2016), p. 21.

[35] W. Rogers, 'Evidence-Based Medicine and Justice: A Framework for Looking at the Impact of EBM on Vulnerable or Disadvantaged Groups' (2004) *Journal of Medical Ethics*, 30(20), 141–145.

1.5 ANALYTIC APPROACHES TO DEFINING VULNERABILITY

Analytic approaches to vulnerability seek to explain the concept in ways that foster understanding of what vulnerability is, and what moral responses are owed to the vulnerable. One analytic approach to conceptualising vulnerability identifies characteristics that serve as criteria for vulnerability,[36] while a second examines what is owed to the vulnerable.[37] More recently, Luna has proposed the metaphor of layers to explain multiple forms of vulnerability,[38] while Lange and others focus on sources of vulnerability in their taxonomy.[39]

Kipnis takes vulnerability to be 'a certain precariousness' that leaves the individual open to being harmed or taken advantage of by researchers. Rather than labelling, he asks researchers to consider participants' circumstances as sources of vulnerability. His taxonomy focuses on circumstances – medical, cognitive, deferential, juridic, allocational, infrastructural and social – that threaten the validity of consent.[40] Similarly, Rogers and Ballantyne identify extrinsic and intrinsic – to the individual – sources of vulnerability that render participants unable to safeguard their own interests.[41] On their account, extrinsic vulnerability arises from power inequalities in the researcher–participant relationship.

Nickel argues that in addition to consent considerations, vulnerability is a justification for special protections in research for two fairness-related reasons. The first concerns the unfair burden of research participation imposed on disadvantaged or dependent groups who lack the power to refuse participation. The second concerns the unfair distribution of research benefits, especially those arising from exclusion from research. Consent-based and justice-based reasons for special protections can be mutually reinforcing, as, for example, members of dependent groups may be targeted for inclusion in research because they have limited ability to refuse participation, but the research may not address problems relevant to the groups to which they belong. In considering what is owed to those who are especially vulnerable on these grounds, Nickel appeals to the principle of equal respect, asking researchers to engage in empathic consideration of the circumstances of the vulnerable to better understand their viewpoint.[42]

Luna proposes the metaphor of 'layers of vulnerability as an alternative to labelling. She argues that this relational and dynamic conception of vulnerability avoids the stereotyping and essentialism of the labelling approach. Her account is relational in that it identifies each layer of an individual's vulnerability by closely examining the context in which she is situated, and dynamic because it recognises that layers of vulnerability may come and go as the context changes. Since Luna's account assumes that vulnerability is dynamic and inessential, it does not stereotype or stigmatise individuals when describing them as vulnerable, while the complexity of a person's situation can be recognised through considering multiple layers of vulnerability.[43] More recently, Luna specifies that layers of vulnerability may be related to 'physical problems,

[36] K. Kipnis, 'Vulnerability in Research Subjects: A Bioethical Taxonomy', in National Bioethics Advisory Commission (ed.), *Report on Ethical and Policy Issues in Research Involving Human Participants Volume II* (Bethesda: National Bioethics Advisory Commission, 2006), pp. G1–13; W. Rogers and A. Ballantyne, 'Special Populations: Vulnerability and Protection' (2008) *RECIIS: Electronic Journal of Communication, Information and Innovation in Health*, 2 (supplement 1), S30–S40.

[37] Nickel, 'Vulnerable Populations in Research', 245–264.

[38] Luna, 'Elucidating the Concept of Vulnerability', 121–139.

[39] M. Meeke Lange et al., 'Vulnerability in Research Ethics: A Way Forward' (2013) *Bioethics*, 27(6), 333–340.

[40] Kipnis, 'Vulnerability in Research Subjects', ch 7.

[41] Rogers and Ballantyne, 'Special Populations', S30–S40.

[42] Nickel, 'Vulnerable Populations in Research', 245–264.

[43] Luna, 'Elucidating the Concept of Vulnerability', 121–139.

consent, dependency, exploitation, [and] socioeconomic situations', and that these layers should be understood as dispositions for harm or exploitation. Finally, she introduces the notion of cascade vulnerabilities that can trigger a series of events with harmful consequences.[44]

Lange and others propose a taxonomy of vulnerability.[45] Their taxonomy aims to reconcile universal and particular conceptions of vulnerability by postulating inherent and situational sources of vulnerability.[46] Inherent sources include human corporeality, our affective and social natures and neediness, and our dependence on others. These sources of vulnerability are ineliminable features of the human condition. Inherent sources of vulnerability produce variable risk of harm or wrongs depending on age, health, gender and disability, as well as individuals' capacities for resilience and the presence of social supports. Situational sources of vulnerability are context specific and include personal, social, political, economic or environmental features affecting individuals or social groups. As they are context specific, situational sources of vulnerability may be persistent or fluctuate over time. Situational vulnerability has a sub-category of pathogenic vulnerability. Pathogenic vulnerability refers to vulnerability arising from dysfunctional relationships characterised by prejudice, abuse, neglect or disrespect, or from political situations characterised by injustice, persecution or political violence. In addition, pathogenic vulnerabilities arise when policies designed to protect against existing vulnerabilities have the perverse effect of exacerbating existing, or generating new, vulnerabilities. On this account, the exclusion of pregnant women from research creates the pathogenic vulnerability experienced by ill pregnant women for whose conditions there is inadequate evidence about safe and effective treatments. These three types of vulnerability may co-exist, overlap and be occurrent (immediate and present) or dispositional (latent or background).

Like Kipnis's approach, this taxonomy provides a systematic way to identify existing and potential sources of vulnerability in order to put in place mitigating strategies. By identifying different sources of vulnerability, researchers are required to attend to the wider context of the research as well as to the characteristics of participants. Vulnerability considerations are not limited to consent, exploitation, or unduly circumscribed safety assessments, but must take account of a full range of harms that research participation may involve. As well as protecting against harms, Lange and others postulate a positive duty to foster participants' autonomy that is more onerous than seeking informed consent or avoiding unjust paternalism.[47] On their account, the duty to respect autonomy requires engaging with and furthering the interests of participants such that research participation actively supports autonomy and promotes resilience. Finally, the notion of pathogenic vulnerability grounds a duty to ensure that well-intended extra protections do not exacerbate existing or create new vulnerabilities.

1.6 WHAT WORK CAN THE CONCEPT OF VULNERABILITY DO?

To be useful in research ethics, the concept of vulnerability should draw attention to a set of concerns that are distinct from other moral concerns, and which are identifiable in non-stigmatising or stereotyping ways. The first step is to settle on a definition of vulnerability that encompasses both the universal and special conceptualisations, and is not implicitly comparative regarding some unstated norm of invulnerability. That is, we need a definition that

[44] Luna, 'Identifying and Evaluating Layers of Vulnerability', 90.
[45] Meeke Lange et al., 'Vulnerability in Research Ethics', 336.
[46] C. Mackenzie et al., 'Introduction', in C. Mackenzie et al. (eds), *Vulnerability: New Essays in Ethics and Feminist Philosophy* (New York: Oxford University Press), pp. 1–29.
[47] Meeke Lange et al., 'Vulnerability in Research Ethics', 337.

acknowledges a universal capacity to be harmed or wronged in various ways related to our embodiment, shared needs and relationality, but that also recognises that the likelihood of those harms and wrongs does not fall equally on all individuals due to varying capacities and circumstances. Based on this understanding, vulnerability in research can be thought of as a disposition to, or risk of, suffering harms or wrongs arising from a range of inherent and situational factors. As these factors will independently vary across individuals and groups and change over time, vulnerability ascriptions must be specific, contextualised and reviewed.

The question remains as to whether vulnerability raises its own moral concerns, or is merely a marker for existing harms or wrongs. Hurst adopts the latter view, defining vulnerable research participants as those who are especially likely to incur an already defined research-related wrong. On her account, vulnerability does not generate new moral obligations, but rather serves as a heuristic to draw attention to existing obligations. The point of drawing attention to vulnerability is to flag that special steps may be necessary to fulfil existing research obligations for those who are especially vulnerable.[48] However, this does not seem to be a very satisfactory approach as it effectively renders the concept of vulnerability redundant. Despite the difficulty of defining vulnerability, the concept is valuable in highlighting morally salient features of our humanity that are central to everyday practices and notions of obligation.[49] The concept of vulnerability triggers us to think empathetically and humanely about others in a holistic way; to consider their situation, their strengths and weaknesses, and their liability to harm. These are important moral considerations that can readily be obscured by a procedural focus on informed consent or balancing research benefits and burdens.

In the context of research, researchers have a duty to consider the vulnerability of participants in a systematic and comprehensive way. This includes not only identifying specific risks of harm that may arise from experimental interventions, but also investigating the interactions and potentially cumulative effects of different sources or layers of vulnerability. In this process, researchers should be aware of the dangers of stereotyping and discrimination and actively seek to avoid labelling groups or individuals in essentialist ways. In addition, there is a need to consider the potential for protections in research to have counter-intuitive effects and create their own pathogenic vulnerabilities. Often, these may be more visible to participants than researchers, creating an obligation for meaningful consultation with participants and their communities. As being vulnerable implies a lack of power in some regard, this creates a duty for researchers to foster and support autonomy to the extent possible. This is more onerous than respecting autonomous decisions, as it requires investigation on the part of researchers and more comprehensive actions in terms of capacity building.

1.7 CONCLUSION

The recognition that vulnerable research participants should be protected is longstanding. However, difficulties have arisen in conceptualising vulnerability, reconciling universal and special notions of vulnerability, and identifying distinct duties and obligations triggered by vulnerability. The dominant approach of labelling vulnerable participants and groups is subject to increasing critique, because it can lead to stereotyping, discrimination and exclusion, and fail

[48] Hurst, 'Vulnerability in Research and Healthcare', 195–196.

[49] C. Mackenzie, 'Vulnerability, Needs and Moral Obligation', in C. Straehle (ed.), *Vulnerability, Autonomy and Applied Ethics* (New York: Routledge, 2017), pp. 83–100.

to be action-guiding. Newer analytic approaches conceptualise vulnerability as relational and dynamic, and identify multiple potential sources of vulnerability. These approaches offer a more nuanced way of thinking about vulnerability and protections against the risks of research-related harm and wrongs. Further work is needed to bridge the gap between these newer conceptualisations of vulnerability and practical guidance for research.