Article 5 of the UN Convention on the Rights of the Child: parental guidance and the evolving capacities of the child

Varadan, S.R.

4 The role of parents in the proxy informed consent process in medical research involving children

ABSTRACT

Medical research involving child subjects has led to advances in medicine that have dramatically improved the lives, health and well-being of children. Yet, determining when and under what conditions a child should be enrolled in medical research remains an ethically vexing question in research ethics. At the crux of the issue is the free and informed consent of the child participant. A child, who is presumed legally incompetent, or lacks sufficient understanding to exercise autonomous decision-making, will not be able to express free and informed consent in the research setting. Rather than exclude all such children from medical research, a parent (or legal guardian) is designated as a proxy to consent on the child's behalf. However, the concept of proxy informed consent and the framework for its implementation present practical and ethical challenges for researchers, particularly in navigating the relationship between proxy decision-makers and child subjects in the medical research setting. Article 5 of the CRC may offer guidance on this point: (1) it places boundaries around how parental authority should be exercised; (2) it offers a model for parent-child decision-making that is participatory, collaborative and linked to the child's enjoyment of rights under the CRC; (3) it respects and supports the autonomy of child participants by recognising their evolving capacities to give informed consent. This paper concludes that greater consideration should be given to article 5 as a complementary framework for researchers engaged in medical research involving children.

INTRODUCTION

Children have been called the 'little medical heroes' of science.[1] James Phipps, an eight-year old boy, was among the first human subjects to test the smallpox vaccine.[2] James Greenlees, an eleven-year old boy, was the first human subject to undergo a carbolic acid treatment to prevent wound infection, after suffering a compound leg fracture.[3] Joseph Meister, a ten-year old boy, was the first human subject to receive a rabies vaccination, after being bitten fourteen times by a rabid dog.[4] But, for all of these scientific breakthroughs, there are countless other instances, in which a child was subjected to undignified treatment and unnecessary suffering for the purposes of advancing medical knowledge for the benefit of others.[5]

At the crux of human subject research is the tension it poses between the pursuit of knowledge for the benefit of human progress, and the need to preserve the inviolability and dignity of all persons. Informed consent represents an attempt to negotiate that tension through a process that seeks to respect, as widely as possible, the autonomy of persons, expressed in the voluntary, uncoerced and fully informed consent of the human subject in research. It is likely for this reason that informed consent remains the most important ethical requirement in medical research and the *sine qua non* of all research involving human subjects.[6] However, it is also for this reason that

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1 J. Lentz, 'Little Medical Heroes' (1940) 18 *Hygeia* 888; S. Lederer, and A. Grodin, 'Historic Overview: Pediatric Experimentation' in M. Grodin and L. Glantz (eds.) *Children as Research Subjects: Science, Ethics & Law* (Oxford: Oxford University Press, 1994) 3-28; S. Lederer, 'Children as Guinea Pigs: Historical Perspectives' (2003) 10 *Accountability in Research* 1-16, 2-4.

2 Ibid.

3 Lentz 1940 (n 1); Lederer and Grodin 1994 (n 1); Lederer 2003 (n 1) 2-4.

4 Ibid.

5 Lederer and Grodin 1994 (n 1); A. Jonsen, *A Short History of Medical Ethics* (Oxford: Oxford University Press, 1999); P. Weindling, A. von Villiez, A. Loeweneau and N. Farron, 'The victims of unethical human experiments and coerced research under National Socialism' (2016) 40(1) *Endeavour* 1-6.

6 S. Perley, S. Fluss, Z. Bankowski, and F. Simon, 'The Nuremberg Code: An International Overview' in G. Annas and M. Grodin (eds.) *The Nazi Doctors and the Nuremberg Code* (New York: Oxford University Press, 1992), 149-171; E. Emanuel, D. Wendler, and C. Grady, 'What Makes Clinical Research Ethical?' (2000) 283(30) *JAMA* 2701-2711; E. Emanuel, D. Wendler, J. Killen, and C. Grady, 'What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research' (2004) 189 *Journal of Infectious Diseases* 930-937.

medical research involving a child, who may be unable to give informed consent, presents an ethical dilemma for researchers seeking to further knowledge of child-related illness and disease.[7]

Children stand to benefit significantly from advances made through medical research and experimentation. The exclusion of children from medical research has led to the therapeutic orphaning[8] of paediatric drugs, denying children as a class of persons the collective benefits of medical progress.[9] In practical terms, this means that paediatricians are often forced to rely on data derived from adult clinical trials for the treatment of a child, prescribing untested ('off-label') medications which potentially place an individual child at risk, given the differences in children's pharmacokinetic and pharmacodynamic profiles.[10]

To overcome the ethical impasse, children have been categorised as 'vulnerable' subjects in research with additional ethical protections imposed on research involving them.[11] Amongst these protections, consent by proxy provides the ethical and legal basis to obtain consent for a child in medical research.[12] Because children below 18 years of age are generally presumed incompetent under the law, and a young child may lack sufficient understand-

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7 H. Beecher, 'Experimentation in Man' (1959) 159 *JAMA* 461-478; R. McCormick, 'Proxy consent in the experimentation situation' (1974) 18(12) *Perspectives in Biology and Medicine* 2-20; J. Katz, 'The Consent Principle of the Nuremberg Code: Its Significance Then and Now' in G. Annas and M. Grodin (eds) *The Nazi Doctors and the Nuremberg Code* (New York: Oxford University Press, 1992) 227-239; Perley et al. 1992 (n 6).

8 H. Shirkey, 'Editorial: Therapeutic Orphans – Everybody's Business' (1968) 68(2) *Drug Intelligence* 323; H. Shirkey, 'Therapeutic Orphans' (1970) 121(3) *The Journal of Infectious Diseases* 348-350.

9 Nuffield Council of Bioethics, *Children and clinical research: ethical issues*, London: Nuffield Council, 2015, xvi. Accessed at: https://www.nuffieldbioethics.org/publications/children-and-clinical-research

10 M. Spriggs, and P. Caldwell, 'The ethics of paediatric research' (2011) 47 *Journal of Paediatrics and Child Health* 664-667; Nuffield Council 2015 (n 9), xvi.

11 National Commission for the Protection of Human Subjects and Biomedical And Behavioural Research, *Belmont Report*, Office of the Secretary, Department of Health, Education and Welfare (Baltimore: United States of America, 1979); World Medical Association, *Declaration of Helsinki* (2000), revised by the 52nd WMA General Assembly, Edinburgh, Scotland; World Medical Association, *Declaration of Helsinki* (2004), revised by the 55th WMA General Assembly, Tokyo, Japan; World Medical Association, *Declaration of Helsinki* (2008), revised by the 59th WMA General Assembly, Seoul, Korea; World Medical Association, *Declaration of Helsinki* (2013), revised by the 64th WMA General Assembly, Fortaleza, Brazil.

12 World Medical Association, *Draft Code of Ethics on Human Experimentation* (1962) 2(5312) *British Medical Journal* 1119; World Medical Association, *Declaration of Helsinki* (1964), adopted by the 18th World Medical Assembly, Helsinki, Finland; World Medical Association, *Declaration of Helsinki* (1975), revised by the 29th World Medical Assembly, Tokyo, Japan; World Medical Association, *Declaration of Helsinki* (1983) revised by the 35th World Medical Assembly, Venice, Italy; World Medical Association, *Declaration of Helsinki* (1989), revised by the 41st World Medical Assembly, Hong Kong; World Medical Association, *Declaration of Helsinki* (1996), revised by the 48th General Assembly, Somerset West, Republic of South Africa; World Medical Association, *Declaration of Helsinki* 2000 (n 11); Declaration of Helsinki 2004 (n 11); Declaration of Helsinki 2008 (n 11); Declaration of Helsinki 2013 (n 11).

ing and independence to say 'no' to adult researchers, consent by a parent or legal guardian ('proxy') provides an added layer of protection for the vulnerable child participant, while also serving as the legal basis to authorize the child's enrolment in a study.[13]

However, the concept of proxy consent and the framework for its implementation present significant practical and ethical challenges for researchers. What are the parameters of proxy decision-making authority? What is the role of the child in the informed consent process? To what extent should a child's autonomy be recognised and enabled in the proxy informed consent process? The absence of any standardised regulatory framework for proxy informed consent and the resultant variations that have emerged within ethical guidelines has led to uneven approaches in how children are recognised, supported and enabled in the proxy informed consent process.

There are no straightforward answers to these issues, and this chapter does not attempt to resolve them. What it considers is the extent to which the United Nations Convention on the Rights of the Child (CRC) and more specifically article 5, could offer a different vantage point for researchers navigating the ethical dimensions of proxy informed consent in medical research.

For clarity, and to avoid the use of contested terms such as 'therapeutic' and 'non-therapeutic' research, this chapter defines medical research as follows: a subset of health research that deals specifically with human subject experimentation, undertaken for the primary purpose of acquiring generalizable scientific or medical knowledge to further understanding of the causes, development and effects of human disease and improve preventive, diagnostic and therapeutic interventions.[14]

This chapter does not focus on informed consent in medical treatment or experimental therapeutic interventions for the clinical care of a child. Its aim is to consider the complexities surrounding the proxy decision-making process in informed consent in medical research that does not envisage a direct medical benefit to the child. It contemplates the relevance of the CRC, and article 5, as a complementary framework to navigate the decision-making relationship between a child and her carers in the proxy informed consent process.

What follows is a three-part analysis which expounds upon article 5 and its potential relevance in informed consent in medical research involving children. Part I provides a brief history of informed consent and an overview of proxy informed consent provisions in existing international ethical guidelines and instruments. Part II considers the relevance of the CRC in medical research and the unique vantage point that article 5 may provide in respect of the

13 Belmont Report, 1979 (n 11); Spriggs and Caldwell 2011 (n 10) 665.

14 Declaration of Helsinki 2013 (n 11), principle 6; Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), *International Ethical Guidelines for Health-related Research Involving Humans* (2016), Geneva: Switzerland, Preamble. ('CIOMS 2016')

parent-child relationship in proxy informed consent. Part III examines how article 5 could be used to guide researchers navigating the proxy informed consent process. This paper posits that article 5 and the CRC framework may be useful in three respects. First, it introduces boundaries around how proxy authority should be exercised in the informed consent process. Second, it promotes a model for parent-child decision-making that is participatory, collaborative and linked with the child's enjoyment of rights under the CRC. Third, it fosters respect for children's autonomy by recognising the child's evolving capacities to provide informed consent in medical research. The paper concludes that more consideration should be given to article 5 and the CRC as a complementary framework to navigate the ethical dimensions of proxy informed consent in medical research involving children.

1 Overview of informed consent in medical research ethics

1.1 History of informed consent in human subject medical research

That a human subject should voluntarily consent to participation in medical research was not a widely accepted practice when it was codified under Principle One of the Nuremberg Code.[15] At the time, medical experimentation tended to take place in the context of medical treatment, and as such, the rights and protection of human subjects were viewed through the prism of the physician-patient relationship, as part of the physician's duty to act in the patient's best interest.[16] A participant's consent was seen as more of a practical consideration, to facilitate cooperation, rather than an ethical duty to respect the autonomy of the participant.[17]

The gravity and magnitude of atrocities committed during the Nazi era under the guise of medical experimentation[18] was a reckoning for the medical profession..[19] As the Nazi Doctors' Trial (*United States* v *Karl Brandt*[20]) unfolded, the ethical practices of the international medical community came under scrutiny: the defendants drew attention to the use of prisoners, institu-

15 R. Faden and T. Beauchamp, with N. King, *A History and Theory of Informed Consent* (Oxford: Oxford University Press, 1986) 152; Katz, 1992 (n 7) 229; Jonsen 1999 (n 5); Lederer 2003 (n 1).

16 Faden and Beauchamp 1986 (n 15) 152.

17 H. Beecher, 'Ethics and Clinical Research' (1966) 274(2) *The New England Journal of Medicine* 1354-1360; S. Lederer, 'Chapter 49: The Ethics of Experimenting on Human Subjects' in R. B. Baker and L. B. MuCullough (eds), *The Cambridge World History of Medical Ethics* (Cambridge: Cambridge University Press, 2009); Katz 1992 (n 7); Lederer, 2003 (n 1).

18 Wiendling et al., 2016 (n 5).

19 Perley at al., 1992 (n 6); Faden and Beauchamp, 1986 (n 15); Lederer, 2009 (n 17).

20 *United States of America v Karl Brandt et al.,* 21 November 1946-20 August 1947, judgement reprinted in G. Annas and M. Grodin (eds) *The Nazi Doctors and the Nuremberg Code* (New York: Oxford University Press, 1992) 61 - 144.

tionalized children and the mentally-ill in human experimentation, and challenged the assertion that voluntary participation was a common practice that 'generally occurred' in human subject research.[21] In rejecting these claims, the Tribunal pronounced a set of ten 'basic principles' to 'satisfy moral, ethical and legal aspects' of research, which placed central importance on the voluntary participation of the human subject in research.[22] That the Nuremberg Code focused on experimentation with prisoners (unrelated to medical treatment) did not diminish the universality of its principles or the stature of the Code.[23] The Nuremberg Code represented a watershed moment for the autonomy and dignity of human participants in medical experimentation, and to this day, remains the most influential statement on the rights of human subjects in research.[24]

By the late 1950s, however, concerns began to emerge over the practicability and enforceability of the Code, particularly in a rapidly expanding field of drug development and clinical research.[25] There were fears that strict adherence to the informed consent requirements under the Nuremberg Code would 'effectively cripple' research in mental illness and 'render experimentation on children impossible.'[26] There were also doubts over practicability and enforceability of an absolute requirement of informed consent, after it was found that physician-researchers were not consistently implementing the Code's informed consent requirements in clinical research settings.[27]

In the early 1960s, the World Medical Association (WMA) began a process to develop a code of professional ethics (drafted by physicians for physicians) to provide guidance to physician-researchers across a wider range of clinical research settings.[28] Led by the British Medical Research Council, Harvard Medical School, and the British Medical Association, a draft code was drawn up in 1961. In its first iteration, the draft replicated the structure and aims of the Nuremberg Code.[29] However, the WMA delegates could not agree and a protracted period of revisions ensued between 1962 and 1964.[30] When the draft code was finally adopted at the 18th WMA Assembly in Helsinki, Finland in 1964, its provisions on informed consent had significantly changed.[31]

The Declaration of Helsinki departed from the Nuremberg Code in a number of important respects. It introduced the possibility of conducting

21 Faden and Beauchamp 1986 (n 15) 155; Katz 1992 (n 7).
22 Lederer 2009 (n 17); Faden and Beauchamp 1986 (n 15) 155.
23 Faden and Beauchamp 1986 (n 15) 156; Katz 1992 (n 7).
24 Katz, 1992 (n 7).
25 Beecher 1959 (n7); Perley et al. 1992 (n 6) 157; Faden and Beauchamp 1986 (n 15) 156; Lederer 2003 (n 1).
26 Beecher 1959 (n 7); Lederer 2003 (n 1) 10.
27 Beecher, 1966 (n 17).
28 Lederer 2003 (n 1) 10.
29 Katz 1992 (n 7) 233; Perley et al., 1992 (n 6).
30 Beauchamp and Faden 1986 (n 15); Lederer 2003 (n 1).
31 Katz 1992 (n 7) 232; Ethics of Human Experimentation 1962 (n 14).

research on persons incapable of providing voluntary, free and informed consent, breaking from the absolute requirement under Principle One of the Nuremberg Code.[32] It proposed a concept of 'consent by proxy' for persons incapable of providing informed consent to enable their participation in research.[33] It introduced a distinction between medical research combined with clinical care (therapeutic research), for which informed consent was not strictly required,[34] and medical research undertaken for the purpose of accruing scientific knowledge for the benefit of others (non-therapeutic research) for which free and fully informed consent was required.[35] The upshot of these changes was to introduce a concept of informed consent (by proxy) that departed from the autonomy-based model of consent envisaged under Principle One of the Nuremberg Code.

The Declaration of Helsinki has since been revised eight times – 1975, 1983, 1989, 1996, 2000, 2004, 2008, 2013 – and continues to be recognised as the foundational instrument in medical research ethics, from which all other international guidelines and national regulatory frameworks are based.

1.2 INTERNATIONAL ETHICAL GUIDELINES ON INFORMED CONSENT IN MEDICAL RESEARCH

1.2.1 The ethical dilemma of involving children in medical research

When the Declaration of Helsinki introduced the notion of proxy consent into medical research, it did so without explicating how such an informed consent process would be implemented in the research setting. Who would hold the moral legitimacy to act as the proxy? On what basis did a proxy have moral authority to volunteer a child in research? What were the parameters of proxy decision-making authority? What was the child's role in the proxy informed consent process? To what extent should a child's preferences and views be elicited and prioritised in the proxy informed consent process? The uncertainty surrounding these questions led ethicists to debate the morality of involving children in medical research, particularly where the research did not overlap with the clinical care of the child.[36] Many of these questions remain unanswered, and the concept of proxy informed consent continues to stir unease

32 Declaration of Helsinki 1964 (n 12), part II, principle 1, part III, principle 3a.
33 Declaration of Helsinki 1964 (n 12), part II, principle 1, part III, principle 3a.
34 Declaration of Helsinki 1964 (n 12), part II, principle 1.
35 Declaration of Helsinki 1964 (n 12), part III, principle 3a; Katz 1992 (n 7).
36 A. Jonsen, 'Non-therapeutic research with children: the Ramsey versus McCormick Debate' (2006) *JAMA* S12-S14; McCormick 1974 (n 7); P. Ramsey, 'The enforcement of morals: non-therapeutic research on children' (1976) 6(4) *Hastings Centre Report* 21-30; See also P. Ramsey, *The Patient as person* (New Haven: Yale University Press, 1970).

among ethicists, who characterise it as an 'insoluble dilemma' of human subject research.[37]

1.2.2 *International ethical guidelines on proxy informed consent in medical research*

In the meantime, international ethical guidelines and instruments evolved myriad frameworks for proxy informed consent, conferring wide authority to parents (or legal guardians) to act as decision-makers on behalf of their children in medical research. A brief survey of international ethical guidelines and instruments reveals some notable differences in how children are recognised, supported and enabled in the proxy informed consent process

Table 1: Informed consent under international medical research ethical codes and guidelines

Instrument	*Recognition of the child*	*Disclosure and participation in decision-making*	*Respect for child's agreement ('assent')*	*Respect for child's refusal ('dissent')*	*Weight given to child's preferences / authority of proxy*
Declaration of Helsinki (2013)[38] World Medical Association **Principles 28, 29**	Children identified as persons 'incapable of giving informed consent'	**No.** There is no explicit requirement for engaging or involving children in decision-making	**Yes**. If a child is able to agree to participate, physicians must obtain assent alongside consent	**Yes**. A child's dissent or refusal must be respected	The child's refusal is determinative Assent is required alongside informed consent from a legally authorised representative
***CIOMS Guidelines* (2016)**[39] International Organizations of Medical Sciences **Guidelines 9, 15 and 17**	Children and adolescents recognised as having 'evolving capacities to give informed consent'	**Yes.** Age-appropriate information must be provided to children, and they must be involved in discussions in accordance with their evolving capacities	**Yes.** Agreement must be obtained in keeping with the child's evolving capacities	**Yes.** Refusal must be respected over parents/ guardian permission, unless participation in research is the best medical option for the child	The child's refusal is determinative if it does not interfere with his or her best interests in clinical care Assent is required alongside permission from a parent or legally authorised representative

37 R. Moser, 'An Anti-Intellectual Movement in Medicine?' (1974) 227(4) *JAMA* 432-434, 433; McCormick 1974 (n 7)19; S. McLean, 'Medical Experimentation with Children' in P. Alston, S. Parker and J. Seymour, *Children, Rights and the Law* (Oxford: Clarendon Paperback, 1992) 173-191; Spriggs and Caldwell 2011 (n 10).

38 Declaration of Helsinki 2013 (n 11).

39 CIOMS 2016 (n 14).

Instrument	*Recognition of the child*	*Disclosure and participation in decision-making*	*Respect for child's agreement ('assent')*	*Respect for child's refusal ('dissent')*	*Weight given to child's preferences / authority of proxy*
Good Clinical Practice: Consolidated Guidance **(1995, 2006, 2016)**[40] **Paras. 4.8.12**	Children identified as 'vulnerable subjects'	**Yes.** Children should be informed about the nature of the research to the extent of their understanding	**Yes.** If the child is deemed capable of assenting, he or she may sign the informed consent form	**No.** Only parent or guardian may withdraw a child, and only if she or he appears unduly distressed.	The child's refusal is not recognised and not determinative Informed consent is required from a legally acceptable representative Assent may be obtained if the child is capable.
UNESCO Declaration on Bioethics and Human Rights **(2005)**[41] **Art. 7**	Children identified as 'persons without capacity to consent'	**Yes.** The child should be involved to the greatest extent possible in decision-making	**Not required**	**Yes.** If research does not envisage a direct benefit, a child's refusal must be respected	The child's refusal is determinative Authorisation is required from a parent or legal guardian

40 International Council for Harmonisation (ICH), formerly known as the International Conference on Harmonisation (ICH) established technical guidelines for good clinical practice to harmonise guidelines for global pharmaceutical development. The ICH has issued four sets of guidelines – Quality Guidelines, Safety Guidelines, Efficacy Guidelines and Multidisciplinary Guidelines. Its Efficacy Guidelines (E6) address clinical trials and medical research, see International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 'Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice E6(R2), Current Step 4 Version, 9 November 2016. Accessed at: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf (27 October 2021).

41 Declaration on Bioethics and Human Rights, *UNESCO*, adopted by acclamation at the 33rd session of the General Conference of UNESCO, 19 October 2005. Accessed at: https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights (27 October 2021).

Instrument	*Recognition of the child*	*Disclosure and participation in decision-making*	*Respect for child's agreement ('assent')*	*Respect for child's refusal ('dissent')*	*Weight given to child's preferences / authority of proxy*
Regulation (EU) No 536/ 2014 on clinical trials on medicinal products **(2014)**[42] European Parliament **Art. 32**	Children identified as 'minors' incapable of providing informed consent	**Yes.** The child must be engaged in a way adapted to their age and mental maturity	**Not explicit.** However, deference is given to national laws to determine where and when a child may give 'assent'	**Yes.** If a child refuses to participate or wishes to withdraw, his or her views must be respected	The child's refusal is determinative Informed consent is required from a legally designated representative
Convention on Human Rights and Biomedicine (Oviedo Convention) **(1997)**[43] Council of Europe **Arts. 5, 6, 17**	Children identified as 'minors'	**Yes.** The child must be engaged in discussions and informed of his or her rights as prescribed by law	**Not explicit.** However, the child's views will be afforded increasing weight subject to age and maturity	**Yes.** If the child refuses, her or his wishes must be respected	The child's refusal is determinative Informed consent is required from a parent or legal representative
Add'l Protocol on Biomedical Research **(2005)**[44] Council of Europe **Arts. 14, 15**	Children identified as 'minors'	**Yes.** The child must be engaged in discussions and informed of his or her rights as prescribed by law	**Not explicit.** However, the child's views will be afforded increasing weight subject to age and maturity	**Yes.** If the child refuses, her or his wishes must be respected	The child's refusal is determinative Informed consent is required from a parent or legal representative

42 European Parliament, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, *European Parliament and of the Council*, 16 April 2014. Accessed at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf (27 October 2021).

43 Council of Europe, Convention on Human Rights and Biomedicine (Oviedo Convention), entered into force on 1 December 2009. Accessed at: https://www.coe.int/en/web/bioethics/oviedo-convention (27 October 2021).

44 Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (ETS No. 195), adopted 25 January 2005, entered into force on 1 September 2007. Accessed at: https://rm.coe.int/168008371a#:~:text=Parties%20to%20this%20Protocol%20shall,in%20the%20field%20of%20biomedicine. (27 October 2021).

These differences are further magnified at the national level where an estimated 1,100 laws and regulations inform human subject research across 131 countries.[45] A recent survey of informed consent provisions in 27 European countries revealed significant differences in age requirements, legal definitions for consent and assent, and proxy requirements.[46] What we are left with then, is an uneven ethical and regulatory framework for proxy informed consent that provides little assurance to the child that her rights and autonomy will be respected and supported in the informed consent process in medical research.

2 THE CRC AND INFORMED CONSENT IN MEDICAL RESEARCH

2.1 The role of the CRC in medical research with children

Despite its adoption over 30 years ago, the CRC seldom appears in international ethical guidelines and instruments. The Declaration of Helsinki – revised five times since 1989 – makes no reference to the CRC or the rights of children in its preamble or principles.[47] The technical guidelines for good clinical practice issued by the International Council for Harmonisation (ICH-GCP) also make no reference to the CRC.[48] The Guidelines for the Council of International Organizations of Medical Sciences (CIOMS) developed in collaboration with the WHO in 1982 and subsequently revised in 1993, 2002 and 2016 also make no reference to the CRC, despite mentioning the 'evolving capacities of the child' in its provisions on informed consent.[49]

The Convention on Human Rights and Biomedicine[50] mentions the CRC in its preamble, but the rights of the child are not explicitly referenced in its provisions. The Convention has been criticised for failing to recognise 'children's evolving capacities' and 'right to be heard and participate in decision-making' in the informed consent process.[51]

For its part, the Committee on the Rights of the Child has said the CRC applies in medical research, and '… academics, private companies and others,

45 Office for Human Research Protections, U.S. Department of Health and Human Services, *International Compilation of Human Research Standards*, 2019. Accessed at: https://www.hhs.gov/ohrp/sites/default/files/2019-International-Compilation-of-Human-Research-Standards.pdf (15 October 2019).

46 P. Lepola, A. Needham, J. Mendum, P. Sallabank, D. Neubauer, and S. de Wildt, 'Informed consent for pediatric trials in Europe' (2016) 101 *Arch Dis Child* 1017-1025.

47 Declaration of Helsinki 1996 (n 12); Declaration of Helsinki 2000, 2004, 2008, 2013 (n 11).

48 ICH-GCP 2016 (n 40).

49 CIOMS 2016 (n 14), Guideline 17.

50 Oviedo Convention (n 43).

51 T. Liefaard, A. Hendriks, and D. Zlotnik, *From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine*, Leiden University (The Committee on Bioethics of the Council of Europe: Strasbourg, 2017), 4, 5, 27, 28.

undertaking research involving children [must] *respect the principles and provisions of the Convention*' alongside ethical guidelines and codes (emphasis added).[52]

The CRC Committee has further emphasised the importance of respecting children's rights in the research setting

> Children have been subjected to unnecessary or inappropriately designed research with little or no voice to either refuse or consent to participation. In line with the child's evolving capacities, consent of the child should be sought and consent may be sought from parents or guardians if necessary, but in all cases consent must be based on full disclosure of the risks and benefits of research to the child.[53]

Yet, the CRC does not explicitly address children's right to consent in medical treatment or research. The CRC Working Group considered the issue late in the drafting process during its 1989 Working Group Session.[54] A draft paragraph was tabled during discussions on the right to health (article 24), which stated 'that a child shall not be subject to any medical or scientific experimentation or treatment unless it is with the free and informed consent of the child or where appropriate that of the child's parents'.[55] A number of delegates strongly supported the inclusion of the paragraph. However, as discussions ensued, complex issues emerged, raising concerns about adopting such a provision without further consultation with experts.[56] Given the late stage in the drafting process, it was decided that the proposed paragraph should be rejected.[57]

That the CRC did not address children's consent in medical research has been lamented as a missed opportunity to address the issue of proxy informed consent.[58] In the absence of a specific provision, this chapter contemplates whether article 5 could offer guidance to researchers navigating the ethical dimensions of proxy informed consent in medical research involving children.

52 CRC Committee, General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), 17 April 2013, CRC/C/GC/15, para 85.

53 UN Committee on the Rights of the Child, General Comment No. 3 (2003), HIV/AIDS and the rights of the child, 17 March 2003, CRC/GC/2993/3, para 29.

54 Office of the United Nations High Commissioner for Human Rights, *Legislative History of the Convention on the Rights of the Child*, Volume I and Volume II (Geneva: OHCHR, 2007), Vol. II, 601.

55 OHCHR 2007 (n 54) Vol. II, 601.

56 G. Van Bueren, *The International Law on the Rights of the Child*, (London: Martinus Nijhoff Publishers,1995) 310-312.

57 OHCHR 2007 (n 54) Vol. II, 601.

58 McLean 1992 (n 37) 189.

2.2 Article 5 – a unique and necessary provision of the CRC

Article 5 is unique to the CRC, having no antecedent and no subsequent equivalent in any other international and regional instrument on the rights of the child.[59] When the Working Group began discussing article 5, they were motivated by two equally important concepts: the child as a rights holder with evolving capacities, and the duties, responsibilities and rights of parents, legal guardians, members of extended family and community.[60] The ambition of article 5 was to bring together these two important general concepts under one provision, striking a delicate balance between empowering the child in the exercise of her rights, while also respecting the role of parents and guardians in the upbringing of their children.[61]

An important aspect of article 5 was its recognition of autonomy and rights as relational concepts under the CRC. As Tobin explains

> Rights for children under the CRC are not to be enjoyed in isolation from their parents and family … the realization of children's rights will be deeply connected to, and interdependent with, the exercise of parental rights and responsibilities.[62]

Because children are born in a state of dependency, there will be a period in a child's life, in which she will need to rely on parents and others to provide direction and guidance to enable her realization and enjoyment of rights under the Convention.[63] Respecting a child's autonomy as a rights-holder will thus require giving consideration to the involvement of parents in the child's life, not only to ensure the child's protection, but also to support and enable her exercise of rights under the Convention. Viewed in this way, the CRC introduces a conception of rights that does not abandon children to their autonomy but rather recognises the important role that relationships will play in support-

59 G. Kamchedzera, 'Article 5: The Child's Right to Appropriate Direction and Guidance' in A. Alen, J. Vande Lanotte, E. Verhellen, F. Ang, E. Berghmans, M. Verheyde and B. Abramson (eds) *A Commentary on the United Nations Convention on the Rights of the Child* (Martinus Nijhoff Publishers, 2012); John Tobin and Sheila Varadan, 'Article 5: The Right to Parental Direction and Guidance Consistent with a Child's Evolving Capacities' in John Tobin and Philip Alston (eds), *The UN Convention on the Rights of the Child: a Commentary* (Oxford University Press 2019), 159-185.

60 UN Commission on Human Rights, Report of the Working Group on a draft convention on the rights of the child, 1988, E/CN.4/1988/28, para 28; see also UN Commission on Human Rights, Report of the Working Group on a draft convention on the rights of the child, 1987, E/CN.4/1987/25.

61 Working Report 1988 (n 60), paras 28, 30; Tobin and Varadan 2019 (n 59) 160.

62 J. Tobin, 'Chapter 4: Fixed Concepts but Changing Conceptions: Understanding the Relationship Between Children and Parents under the CRC' in M.D. Ruck, M. Peterson-Badali, and M. Freeman (eds), *Handbook of Children's Rights: Global and Multidisciplinary Perspectives* (London: Routledge Taylor & Francis Group, 2017) 21.

63 Tobin and Varadan 2019 (n 59) 161.

ing and enabling children's autonomy as rights-holders.[64] That said, article 5 does not envisage a role for parents and family that is indeterminate or indefinite. The reference to the 'evolving capacities of the child' recognises that as a child grows, respect for her autonomy should concurrently increase, and a time will come when parental guidance and direction will no longer be needed.[65] In this respect, article 5 should be understood as

> an enabling or scaffolding provision that is designed to protect the rights of the child, *not parents,* by demanding that parents and carers provide the direction and guidance necessary for children to enjoy their rights.[66]

For this reason, article 5 is also somewhat radical. It promotes a model of the parent-child relationship that departs from historical conceptions of the parent-child relationship, which were framed in terms of ownership over the child.[67] It introduces a conception of parenthood, which should be understood as 'a form of stewardship … or trusteeship' that

> perceives [the] child not as an object subject to the control and subjugation of an adult but rather an independent subject with discreet entitlements, the realisation of which is dependent on the assistance of adults.[68]

It promotes a parent-child decision-making relationship that is 'co-operative and interdependent', with emphasis on 'a dialogue of participation and mutual respect.'[69] From the child's perspective, it reframes the role of parents as 'first and foremost duty-bearers expected to fulfil their obligation in the upbringing of the child', rather than 'rights-holders vis-à-vis the child.'[70] Article 5 thus introduces a model for parent-child decision-making that places the child at the centre of the process, with a right to receive appropriate guidance and direction from his or her parents, rather than a right of parents to have their authority respected by the State.[71]

This paper suggests that article 5 could offer guidance to researchers, where ethical guidelines and instruments have been unable. It provides a framework

64 A. Daly, *Autonomy and the Court: Beyond the Right to Be Heard* (Stockholm: Brill, 2017), 190.
65 J. Tobin, 'Justifying Children's Rights' (2013) 21(3) *International Journal of Children's Rights* 395-441. DOI: 10.1163/15718182-02013004; N. Peleg, 'International Children's Rights Law: General Principles' in T. Liefaard and U. Kilkelly (eds.) *International Human Rights of Children* (Singapore: Springer Nature, 2018), 2-19, 18.
66 Tobin and Varadan 2019 (n 59), 177.
67 G. Lansdown, *The Evolving Capacities of the Child* (Florence: UNICEF, 2005); Tobin 2017 (n 54).
68 J. Tobin, 'Parents and Children's Rights under the Convention on the Rights of the Child: Finding Reconciliation in a Misunderstood Relationship' (2005) 7(2) *Australian Journal of Professional and Applied Ethics* 31-46.
69 Ibid, 41
70 Peleg 2018 (n 65) 18.
71 Tobin and Varadan 2019 (n 59) 161; Peleg 2018 (n 65) 18.

that encourages a child's involvement at all stages of decision-making,[72] recognising that as children develop and grow, respect for their autonomy should concurrently increase.[73]

3 ARTICLE 5 AND PROXY INFORMED CONSENT IN MEDICAL RESEARCH

This section examines how article 5 could be applied in the research setting to support researchers navigating the relationship between parents (or legal guardians) child subjects in the proxy informed consent process. It suggests that article 5 may be useful in three respects: (1) it introduces boundaries around how proxy decision-making authority is exercised; (2) it promotes a model for parent-child decision-making that fosters participation, dialogue and collaborative decision-making in the proxy informed consent process; (3) it places an obligation on parents and legal guardians to support and enable a child's autonomy by recognising her evolving capacities for decision-making in the research setting. Each of these aspects of article 5 is considered below.

3.1 Boundaries around proxy decision-making authority

For the most part, research ethical guidelines and instruments do not explicate the boundaries of proxy decision-making authority in informed consent. This was likely a deliberate decision to ensure respect for the authority of parents (or legal guardians) acting on behalf of their child in the research setting. However, situations can arise when a proxy's exercise of decision-making authority is not consistent with a child's enjoyment and exercise of rights in the research setting. For example, Spriggs and Gillam observed a practice, in which parents withheld information from their children in the informed consent process.[74] In some cases, parents misrepresented the purpose of the research to the child. Spriggs and Gillam found that while '[t]hese kinds of situations were … troubling for researchers', '[r]esearch ethics guidelines and regulations in the UK, Australia and the USA [had] nothing specific to say about the deception of children' by their parents.[75]

Article 5 may offer guidance to researchers on this point. While it accords respects to the role of parents and other carers in providing guidance and direction to their children, their authority is not unbounded. The nature of the 'responsibilities, rights and duties of parents' is informed by the other provisions of the CRC, specifically those relating to the responsibilities of

72 Tobin 2017 (n 62).
73 Peleg 2018 (n 65) 18.
74 M. Spriggs and L. Gillam, 'Deception of children in research' (2015) 41 *J Med Ethics* 179-182.
75 Ibid, 179, 180.

parents (articles 18, 27, 14 and 5). Any direction and guidance provided to children must also be 'appropriate', which in the context of the CRC framework, will be understood as consistent with the child's enjoyment of other rights under the Convention.[76] Finally, guidance and direction provided by parents must take into account 'the evolving capacities of the child', recognising that as children grow, the role of a proxy will need to be adjusted to enable more respect for the autonomy and agency of the child subject in the research setting.

3.2 The parent-child relationship in proxy informed consent

Remarkably, ethical guidelines and instruments have struggled to formulate an ethical basis to justify children's participation in the proxy informed consent process that is not linked with the determinative outcome of informed consent. This is due, in part, to individualistic conceptions of autonomy that continue to dominate the discourse on informed consent.[77] However, it is also due to traditional understandings of parent-child relationships, in which parents are accorded wide and unfettered authority to determine how and to what extent their child should be involved in decision-making in informed consent.[78]

The advent of concepts such as 'assent' and 'dissent' which appear in some ethical guidelines and instruments[79] and not others[80] offer a more visible platform for children's participation. Yet the concept of 'assent' has been criticised for introducing more confusion rather than clarity over the question of how to recognise and attribute value to a child's participation in the proxy informed consent process.

The concept of 'assent' and its use in the research setting are problematic for a number of reasons. First, there is no agreed definition for 'assent' in medical research ethics.[81] This has resulted in an uneven understanding of what assent means, and how it should be obtained, which in some cases has

76 Tobin and Varadan 2019 (n 59) 171, 172.

77 P. Ramsey, 'The enforcement of morals: non-therapeutic research on children' (1976) 6(4) *Hastings Centre Report* 21-30; McCormick 1974 (n 7); Faden and Beauchamp 1986 (n 15); Emanuel et al., 2000 (n 6).

78 A. Sibley, A. Pollard, R. Fitzpatrick, and M. Sheehan 'Developing a new justification for assent' (2016) 17(2) *BMC Medical Ethics,* 1-9. DOI: 10.1186/s12910-015-0085-x; W. Gaylin and R. Macklin (eds, *Who Speaks for the Child*: *The Problems of Proxy Consent* (New York: Hastings Center, 1982).

79 Declaration of Helsinki, 2000, 2004, 2008, 2013 (n 11); CIOMS 2016 (n 14); ICH-GCP 2016 (n 40).

80 UNESCO 2005 (n 41); EU Regulations 2014 (n 42); Oviedo 1997 (n 43); Additional Protocol 2005 (n 44).

81 Nuffield Council 2015 (n 9) 60.

led to age restrictions or other barriers on children's participation.[82] Second, variations in the assent process have resulted in disagreements over its role and function, prompting some to question the value of children's participation in the informed consent process.[83] Third, the binary framework of 'assent' and 'dissent' has reduced children's participation to either 'agreement' or 'refusal', overlooking the wide range of perspectives in between, and undermining children's rights to freedom of expression in the proxy decision-making process.

These practical challenges have fed broader debates around the value and weight that should be accorded to children's participation in the proxy informed consent process. These perspectives have yielded a number of ethical approaches, which may be summarised as follows: (1) attributing value to a child's views to support and foster her developing autonomy in decision-making in informed consent;[84] (2) attributing value to a child's views as a pedagogical exercise to nurture moral growth and development;[85] (3) attributing value to a child's views as a show of respect for the individual child and her moral worth in the research setting;[86] (4) attributing value to a child's views as a reflection of the fluidity in the parent-child decision-making process, and the gradual devolvement of decision-making authority from the proxy to the child.[87]

The Nuffield Council on Bioethics, in its 2015 report recognised the importance of involving children in the informed consent process, as a show of respect for the individual child 'regardless of their age or capacity.'[88] Navin

82 D. Wendler, and S. Shah, 'Should Children Decide Whether They are Enrolled in Non-beneficial Research?' (2003) 3(4) *American Journal of Bioethics* 1-7; D. Ungar, S. Joffe, and E. Kodish 'Children are not small adults: Documentation of assent for research involving children' *Journal of Pediatrics* (2006) S31-S33. DOI: 10.1016/j.peds.2006.04.048

83 P. Baines, 'Assent for children's participation in research is incoherent and wrong' (2011) 96 *Arch Dis Child*, 960-962. DOI: 10.1136/adc.2011.211342

84 A. Bartholome, 'Parents, Children, and the Moral Benefits of Research' (1976) *Hastings Center Report* 44-45; V. Miller, and R. Nelson, 'A Developmental Approach to Child Assent for Nontherapeutic Research' (2006) *Journal of Pediatrics* S25-30. DOI:10.1016/j.peds.2006.04.047; C. Navin, and J. Wasserman, 'Capacity for Preferences and Pediatric Assent' (2019) 49(1) *Hastings Center Report* 43-51. DOI: 10.1002/hast.980; Nuffield Council 2015 (n 9); S. Joffe, 'Rethink "Affirmative Agreement", but Abandon "Assent" (2003) 3(4) *American Journal of Bioethics* 9-11; R. Nelson, 'We Should Reject Passive Resignation in Favor of Requiring the Assent of Younger Children for Participation in Nonbeneficial Research' (2003) 3(4) *American Journal of Bioethics* 11-13; D. Diekema, 'Taking Children Seriously: What's so Important about Assent?' (2003) 3(4) *American Journal of Bioethics* 25-26; A. Sibley, M. Sheehan, and A. Pollard, 'Assent is not consent' (2012) 38(1) *Journal of Medical Ethics* 3.

85 Sibley et al., 2016 (n 78); Miller and Nelson 2006 (n 84); Joffe 2003 (n 84).

86 Sibley et al., 2016 (n 78) 6; Nuffield Council 2015 (n 9); Navin and Wasserman 2019 (n 84).

87 C. Fisher, 'A Goodness-of-Fit Ethic for Child Assent to Nonbeneficial Research' (2003) 3(4) *American Journal of Bioethics* 27-28; W. Rossi, W. Reynolds and R. Nelson 'Child Assent and Parental Permission in Pediatric Research' (2003) 24 *Theoretical Medicine* 131-148; Joffe 2003 (n 84); Diekema 2003 (n 84).

88 Nuffield Council 2015 (n 9) 102.

and Wasserman agree with this approach, recognising that there is 'moral value' in involving a child that is 'not reducible to considerations of either autonomy or best interests'.[89] Sibley et al., have put forward an ethical justification for children's participation that is based on the 'moral worth' of the child, recognising the inherent value of involving a child even if she is 'not considered to have the necessary and cognitive capacities to give fully informed consent'.[90]

Article 5 and the CRC framework could offer additional guidance to researchers on these issues. First, the CRC reinforces the notion that the child has moral worth and her participation has inherent value, through its rights-based framework. Articles 5 and 12 together affirm that all children are holders of rights, with voice and agency, which, even if not determinative, must be listened to and respected by those adults, exercising influence over the child.[91]

Second, article 5 introduces a model for parent-child decision-making, which demands that 'parents concede that they are not always the sole arbiters of a child's best interests'.[92] It requires that parents work with their children to create decision-making systems that allow the child's views to be heard, taken into account and treated seriously in decision-making processes.[93] This collaborative decision-making model promotes a relationship that is based on dialogue and participation, in which parents must not only involve the child in decision-making, but also explain to her why certain decisions are made.[94] The article 5 framework thus challenges the traditional proxy-child relationship in research ethics, in which the child is designated as 'vulnerable' and the proxy (parent or guardian) empowered as 'protector'. It replaces it with a framework that recognises the evolving capacities of the child, and importantly, demands that parents (or guardians) support the child to develop her decision-making capacities'.[95]

Third, article 5, article 12 and article 18 provide a framework to guide researchers in how they attribute weight to the child's views in the proxy informed consent process. Article 18 requires that parents make the child's best interests their basic concern, while article 5 requires parents to provide guidance and direction that is appropriate and in a manner consistent with the child's evolving capacities. However, articles 5 and 18 together recognise the importance of respect for the views and preferences of a child in the assessment of her best interests. As the CRC Committee explains,

89 Navin and Wasserman 2019 (n 84) 44.
90 Sibley et al., 2012 (n 84); Sibley et al., 2016 (n 78); Navin and Wasserman 2019 (n 84).
91 D. Archard, *Children, Rights and Childhood*, 2nd edition (London: Routledge, 2004) 54; Tobin 2013 (n 65) 407; Tobin and Varadan 2019 (n 59) 173.
92 Tobin 2017 (n 62) 24.
93 Tobin 2017 (n 62) 24.
94 Tobin 2017 (n 62) 24.
95 J. Tobin, 'Understanding Children's Rights: A Vision Beyond Vulnerability' (2015) 84 *Nordic Journal of International Law* 155-182, 177. DOI: 10.1163/15718107-08402002

> Assessment of a child's best interests must include respect for the child's right to express his or her views freely and due weight given to said views in all matters affecting the child … The two articles have complementary roles: the first aims to realize the child's best interests, and the second provides the methodology for hearing the views of the child … in all matters affecting the child, including the assessment of his or her best interests.[96]

The CRC Committee further adds

> The evolving capacities of the child (art. 5) must be taken into consideration when the child's best interests and right to be heard are at stake … as the child matures, his or her views shall have increasing weight in the assessment of his or her best interests.[97]

Thus, as a child grows and her capacities evolve, greater weight must be attributed to her views and preferences in proxy decision-making setting. In this respect, articles 5, 12 and 18 offer guidance to researchers faced with situations, in which a parent's use of proxy authority does not respect the views and preferences of the child subject in the research setting. Applying articles 5, 12 and 18, if a child has sufficient understanding, capacity and maturity to express free and voluntary consent to participate in medical research, her views should be determinative in an assessment of her best interests.[98] This position aligns with the recommendations of the Nuffield Council which state, that 'where [children] are capable of understanding what is involved in taking part in a particular piece of research … professionals have an ethical obligation to actively seek their consent … regardless of any additional requirements of national legislation.'[99] Thus, while the CRC does not directly resolve the question of whether children hold a right to consent in medical research, articles 5, 12 and 18 provide a framework that, at the very least, assures that the views and preferences of a child will not be overlooked or disregarded in the informed consent process.

3.3 The evolving capacities principle and the autonomy of the child

For the most part, ethical guidelines and instruments have generally presumed that all children under 18 years of age lack capacity to provide informed

96 CRC Committee, General Comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1), 29 May 2013, CRC/C/GC/14, para 43.

97 CRC General Comment No. 14, para 44.

98 J. Tobin 'Article 36: Protection against All Other Forms of Exploitation' in J. Tobin and P. Alston (eds) *The UN Convention on the Rights of the Child: A Commentary*, (Oxford: Oxford University Press, 2019) 1402-1419, 1417.

99 Nuffield Council 2015 (n 9) 150-151.

consent, deferring to national laws and regulations to determine when and under what conditions a child may provide informed consent in medical research.[100] However, because a young child may also lack sufficient understanding and independence to engage in autonomous decision-making, children, as a group, are designated as 'vulnerable subjects' in medical research.[101] This combination of presumed incompetence and vulnerability has essentialised children as 'non-autonomous' beings, in need of protection rather than empowerment in the informed consent process.[102]

Yet, there is an emerging body of qualitative research and empirical data that challenges the notion of children as non-autonomous, incapable and vulnerable in the research setting. Hein et al., suggest that a child may be capable of autonomous decision-making through 'shared' or 'co-consent' as early as 12 years of age.[103] Alderson and others have shown that children are able to engage in various levels of decision making at all ages[104] and are often able to express free and informed consent well before the age of legal competency.[105] Although these perspectives are finding more support in the discourse on research ethics,[106] researchers continue to grapple with how to balance respect for parental authority with recognition of children's autonomy in the informed consent process.

Article 5 may provide guidance on this point. As Peleg observes, '[a]rticle 5 and the evolving-capacities principle is, essentially, a mechanism to achieve balance between autonomy and protection'[107] As the CRC Committee further elaborates, 'parents (and others) have a responsibility to continually adjust the levels of support and guidance they offer to a child' to 'take account of

100 Declaration of Helsinki 2013 (n 11) Principles 28, 29; CIOMS 2016 (n 14), Guideline 15, 17; ICH-GCP 2016 (n 40) para 4.8; UNESCO 2005 (n 41) Article 7; EU Regulations 2014 (n 42) article 32; Oviedo Convention 1997 (n 43) Article 5; Additional Protocol 2005 (n 44) Article 14.

101 Belmont Report 1979 (n 11); Declaration of Helsinki 2000, 2004, 2008, 2013 (n 11); CIOMS 2016 (n 14) Guideline 15.

102 Emanuel et al., 2000 (n 6); Ramsey 1970 (n 36); Ramsey 1976 (n 36) ; McCormick 1974 (n 7).

103 I. Hein, M. De Vries, P. Troost, G. Meynen, J.B. Van Goudoever and R. Lindauer 'Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research' (2015) 16(76) *BMC Medical Ethics*, 1-7. DOI: 10.1186/s12910-015-0067-z

104 P. Alderson, J. Hawthorne, M. Killen 'The Participation Rights of Premature Babies' (2005) 13 *International Journal of Children's Rights* 31-50; P. Alderson, K. Sutcliffe, and K. Curtis 'Children's Competence to Consent to Medical Treatment' (2006) 36(6) *Hastings Center Report* 25-34; P. Alderson, *Choosing for Children: Parents' Consent to Surgery* (Oxford: Oxford University Press, 1990); P. Alderson, *Children's Consent to Surgery* (Buckingham: Open University Press, 1993).

105 Alderson 1993 (n 104); P. Alderson, and J. Montgomery, *Health Care Choices: Making decisions with children* (London: Institute for Public Policy Research, 1996).

106 Nuffield Council 2015 (n 9); Navin and Wasserman 2019 (n 84); Miller and Nelson 2006 (n 84).

107 N. Peleg, *The Child's Right to Development*, (Cambridge: Cambridge University Press, 2019) 207.

a child's interests and wishes as well as the child's capacities for autonomous decision-making and comprehension of his or her best interests.'[108] In other words, as a 'child grows and develops, respect for her autonomy should concurrently increase' and a time will come when the child has sufficient capacity that she will no longer need to rely on her right to parental guidance and direction to secure the enjoyment of her rights under the Convention.[109]

In this respect, article 5 and the evolving-capacities principle are not dissimilar to the often cited judgment of the House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority*,[110] in which reference was made to parental rights as a 'dwindling right' which terminates once a child has achieved sufficient understanding, intelligence and discretion to enable her to make a wise choice in her own interests. Though *Gillick* predated the CRC, it embodied a vision of children's rights that aligns with the CRC, and article 5.[111] It is likely for this reason that it has been cited as a basis to recognise children's right to consent in medical research.[112] However, the decision in *Gillick* focuses on children's consent in medical treatment, and is at best a jurisprudential authority confined to common law jurisdictions; whereas article 5 offers a framework to navigate the proxy-child decision-making relationship that is relevant across all of the 196 State Parties to the CRC.

It is important to emphasise that article 5 does not 'render the involvement of … parents mute or displace their authority'.[113] It requires, and indeed expects parents to provide 'appropriate levels of protection' to prevent the child from being forced to make decisions in circumstances when they themselves do not feel competent or comfortable doing so.[114] In this respect, article 5 adopts a conception of autonomy that is relational. It challenges individualistic notions of autonomy in the discourse on informed consent, which have historically characterised children as incompetent and 'non-autonomous', and in its place, offers a concept of 'supported autonomy' which Daly explains as '[c]hildren [being able] to have their autonomy respected

108 CRC Committee, General Comment No. 7 (2005), Implementing child rights in early childhood, 20 September 2006, CRC/C/GC/7/Rev.1, para 17.

109 Tobin 2013 (n 65); Peleg 2018 (n 65) 18; Tobin and Varadan 2019 (n 59) 177.

110 *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 2 WLR 480.

111 J. Tobin 'Judging the Judges: Are They Adopting the Rights Approach in Matters Involving Children?' (2009) 33 *Melbourne University Law Review* 579-625, 600.

112 P. Alderson 'Children's Consent and "Assent" to Healthcare Research' in M. Freeman (ed) *Law and Childhood Studies* (Oxford: Oxford University Press 2012), 175-189; P. Alderson, 'Giving Children's Views "Due Weight" in Medical Law' (2018) 26(3) *International Journal of Children's Rights* 16-37. DOI:10.1163/15718182-02601001; Alderson 2006 (n 104); Nuffield Council 2015 (n 9).

113 Tobin 2005 (n 68) 32.

114 Tobin and Varadan 2019 (n 59) 174.

without being given the same status as adults and without being abandoned to harmful fates unaided'.[115]

At the same time, the evolving capacities principle is not without concerns for the proxy informed consent process. The question of how a child's 'evolving capacities' will be assessed, and the process by which decision-making authority will devolve from the parent to the child are not addressed within article 5 or practically considered by the CRC Committee. Making a child's exercise of autonomy conditional on her evolving capacities potentially 'opens up adults' discretion to decide who is capable',[116] enabling paternalism through the rhetoric of rights.[117] While there will be legitimate situations where a child's autonomy in decision-making will need to be constrained[118] without further elaboration on how a child's 'evolving' capacities will be recognised and practically enabled, there remains a risk that article 5 could be used to undermine rather than support the autonomy of child subjects in the medical research setting.

Notwithstanding these concerns, article 5 and the evolving-capacities principle may nonetheless offer guidance to researchers, providing a framework that fosters respect for a child's autonomy as she grows and develops,[119] and places responsibility on parents (or legal guardians), to exercise their authority in a manner that supports and enables the child's capacities to engage in autonomous decision-making in the informed consent process.

Conclusion

In the mid-1970s, two leading bioethicists – Paul Ramsey and Richard McCormick – were invited to discuss the morality of involving children in medical research, in what would become the pivotal debate on the ethics and regulation of proxy informed consent. As McCormick and Ramsey laid out their arguments, a remarkably blunt conception of the child was revealed. For Ramsey, the child was not a moral agent.[120] For McCormick, the child was neither legally competent nor factually capable of consent.[121] In essentializing the child as 'vulnerable', 'non-autonomous' and 'incapable', Ramsey and McCormick effectively robbed children of voice and agency in the informed

115 Daly 2017 (n 64) 132.
116 Alderson 2018 (n 112).
117 Tobin, 2009 (n 111); see also M. Freeman 'Rethinking Gillick,' (2005) 13(1-2) *International Journal of Children's Rights* 201-218.
118 Daly 2017 (n 64); Tobin, 2009 (n 111); see also W. Gaylin 'Competence: No Longer All or None' in W. Gaylin and R. Macklin (eds), *Who Speaks for the Child*: *The Problems of Proxy Consent*, (New York: Hastings Center 1982), 27-56.
119 Peleg 2018 (n 65) 18.
120 Ramsey 1976 (n 36) 25.
121 McCormick 1974 (n 7) 2.

consent process, laying the foundation for a proxy consent process that would prioritize protection over empowerment in the research setting.

In the 45 years since Ramsey and McCormick, research with children has challenged this narrow understanding of informed consent. Alderson and others offer evidence that children, from a very young age, are able to engage in various forms of decision-making at varying levels.[122] Increasingly, it is recognised that child acquire capacities over a dynamic and evolving process that encompasses multiple dimensions – psychological, cognitive, emotional, social, cultural and spiritual.

Yet, the ethical framework for proxy informed consent remains unchanged, and the image of the child as vulnerable and non-autonomous continues to influence how children are viewed, recognised and supported in the proxy informed consent process in the medical research.

This paper contemplated how article 5 and the CRC framework could be applied to medical research to recognise, support and enable children's voice and agency in the proxy informed consent process. It is suggested that article 5 may offer guidance to researchers in three broad respects. First, it introduces boundaries around how proxy authority is exercised, ensuring parental decision-making is undertaken in a manner that respects and supports the child's enjoyment of rights in the research setting. More practically, it provides a set of guiding principles to evaluate when and under what circumstances the exercise of proxy decision-making authority should not be deemed appropriate in the proxy informed consent setting. Second, it promotes a model for parent-child decision-making that values participation, dialogue and collaborative decision-making in the proxy informed consent process, ensuring that a child's views and preferences are respected and taken seriously at each stage of the decision-making process. Third, it places an obligation on parents to respect and support children's autonomy by recognising their evolving capacities in the decision-making process in informed consent.

It is undeniable that medical research has yielded advances in medicine that have dramatically improved the health, well-being and life expectancy of all human beings. This is particularly true for children, whose lives have been transformed over the past century as a result of medical progress in the prevention, diagnosis and treatment of child-related illness and disease. Inclusion of children in research has been and will remain essential if further gains are to be made in children's health and well-being. Yet, ethical guidelines and instruments continue to grapple with how to involve children in research, in a manner that respects and supports their autonomy. This chapter did not set out to resolve the ethical dilemmas surrounding children's consent in medical research. What it sought to do is introduce a conception of the child as a rights holder, whose voice and agency, even if not determinative, must

122 Alderson 1993 (n 104); Alderson and Montgomery 1996 (n 105); Alderson, Sutcliffe and Curtis 2006 (n 104); Alderson, Hawthorne and Killen 2005 (n 104).

be listened to and respected by parents and researchers in the proxy informed consent process.