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PARTICIPATION IN RESEARCH AND THE CRPD

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ABSTRACT

This article discusses the implications of the United Nations' Convention on the Rights of Persons with Disabilities ("CRPD") for domestic policies on research involving persons with disabilities, including those with limited decision-making abilities. It starts with an examination of the protection the Convention affords to persons with disabilities against being enrolled in research projects, and argues that it does offer some such protection, but that the precise extent of this protection depends on conceptual and other matters that are not easily resolved by straightforward treaty interpretation. The article then proceeds with an analysis of whether the CRPD includes a right to participate in research projects on an equal basis with others. It argues that there are good reasons to interpret the CRPD to include such a right and explores its normative content. The article describes how the prohibition on discrimination delineates the scope for lawful exclusion of persons with disabilities in research studies and illustrates how discrimination analysis can be used to distinguish lawful practices from unlawful ones. It stops short, however, of drawing general conclusions about when exclusion is prohibited by the CRPD, arguing that this will depend on unresolved issues about the correct interpretation of the Convention's right to legal capacity, and on an analysis of the rights and interests at stake in any given situation.

I. INTRODUCTION

Human subjects research,[1] in various fields, is clearly important to societal progress. For such research to be possible, individuals obviously have to be provided with opportunities to participate in it. At the same time, participation is not always without risks or burdens. It is against a background of cases of serious harm to, and exploitation of, research subjects[2] that international treaties, declarations and guidelines on research on human subjects have been developed.[3] This fact helps to explain the focus on the *protection* of research participants in these documents, and the central role played by the requirement of free and informed consent.[4] Protection is secured in part by provisions regarding the risks and burdens of research (assessment, monitoring, minimization, acceptability, etc). The requirement of consent is intended to ensure that research participants understand the risks and burdens involved in a project and that they and are nonetheless willing to take part in it. To this end, article 7 of the

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[1] That is, research involving human beings as research subjects and/or research participants.

[2] The term "research subject" is still extensively used, not the least in codes of research ethics. Often, but not always, "research participant" may be more appropriate. In this paper both terms will be used, with no substantive distinction intended unless otherwise indicated.

[3] See e.g. the discussion leading to the prohibition of scientific and medical experimentation without consent (Article 7 ICCPR) in Annotations on the Text of the Draft International Covenants on Human Rights [UN Doc A/2929]A/2929, Ch. VI, para. 14. [1 July 1955]

[4] Teresa Iacono and Rachel Carling-Jenkins, 'The Human Rights Context for Ethical Requirements for Involving People with Intellectual Disability in Medical Research' (2012) 56 (11) Journal of Intellectual Disability Research, 1124-5, [1122].

International Covenant on Civil and Political Rights ("ICCPR") prescribes that "no one shall be subjected without his free consent to medical or scientific experimentation".[5] The Convention on Human Rights and Biomedicine (Oviedo Convention)[6] and its Additional Protocol concerning Biomedical Research (Protocol on Biomedical Research)[7] clarify that participation in research presupposes that the individual has been provided with appropriate information as to the purpose and nature of the intervention, as well as its consequences and risks.[8] They further state that research on persons lacking the ability to make free and informed decisions is only permitted if certain special safeguards are met.[9] The Declaration of Helsinki (DoH), developed by the World Medical Association and having in many contexts acquired the status of soft-law, incorporates similar standards.[10]

As indicated by the research governance just mentioned, ethical concerns have predominantly been raised about medical (or biomedical) research, and the regulatory safeguards put in place still relate, for the most part, only to those kinds of research. It is well-known, however, that ethically unacceptable or controversial research has been conducted outside of medicine, too. Quite a few studies in psychology, for instance, have elicited fear, anxiety, stress, embarrassment and similar effects at levels that cannot be considered innocuous, and have typically been conducted without fully informed consent.[11] In sociology, anthropology and, again, psychology, various studies involving covert (sometimes participatory) observation have been conducted, where the privacy and reasonable expectations of research subjects have been violated in ways that could be questioned from an ethical perspective.[12] And "field experiments" in economics, where researchers test what effects various manipulations of people's resources have on their acquisition and use of utilities they arguably need, have also raised ethical concerns.[13] Accordingly, some legal instruments are broader in scope and, as reflected in the occasional dissatisfaction with the codification of ethical concerns in

[5] International Covenant on Civil and Political Rights (United Nations [UN]) 999 UNTS 171, UN Doc A/6316, UN Doc A/RES/2200(XXI), Annex, UN Reg No I-14668, [Signed] 16th Dec 1966; [Entered into Force] 23rd Mar 1976.

[6] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Council of Europe) ETS No 164, 2137 UNTS 171, UNTS Reg No I-37266 [Opened For Signature] 4th Apr 1997; [Entered into Force] 1st Dec 1999.

[7] (Council of Europe) CETS No 195 [Signed] 25th Jan 2005; [Entered into Force] 1st Sep 2007.

[8] Oviedo Convention, Article 15, and Protocol on Biomedical Research, Article 13.

[9] Oviedo Convention, Article 15, and Protocol on Biomedical Research, Article 17.

[10] World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (adopted June 1964, last revised 2013) paras. 26 and 28.

[11]The Milgram obedience experiment probably being the most well-known one. Stanley Milgram, 'Behavioral Study of Obedience' (1963) 67 Journal of Abnormal and Social Psychology 371. But see e.g. Allan J. Kimmel, *Ethical Issues in Behavioral Research: Basic and Applied Perspectives*, 2nd ed. (Blackwell, 2007), ch. 3-4, for more examples.

[12] Laud Humphrey's infamous study of sexual encounters between males in public restrooms, so called "tearooms", in the 1960s is a case in point. Laud Humphreys*, Tearoom Trade: A Study of Homosexual Encounters in Public Places* (Duckworth, 1970). Other examples are addressed in e.g. Brian Schrag, 'Piercing the Veil: Ethical Issues in Ethnographic Research' (2009) 15 (2) Science and Engineering Ethics 135-60; and Kimmel (fn 11 above), ch. 5. For an overview of the many ethical (and methodological) challenges with participant observation, see Thomas J. Roulet et al., 'Reconsidering the Value of Covert Research: The Role of Ambiguous Consent in Participant Observation' (2017) 20 (3) Organizational Research Methods 487-517.

[13] See e.g. Megan Blomfield, 'Ethics in Economics: Lessons from Human Subjects Research' (2012) 5 (1) Erasmus Journal for Philosophy and Economics, 24-44.

research[14], other fields of research have increasingly had to adjust their practices to protective standards similar to those which researchers in medicine have to abide by. For example, Swedish legislation on research ethics[15] applies not only to medical or biomedical research. It covers all research involving physical interventions, attempts to influence participants (physically or mentally), obvious risks of participants coming to harm (physically or mentally), or the processing of "special categories of" personal data (as defined by the EU General Data Protection Regulation).[16] And while not legally binding, many influential ethics codes recognize the risk of harm and exploitation in those other fields as well, and include specific guidelines aimed to safeguard against various kinds of wrongdoing towards participants.[17]

In 2008, the CRPD came into force.[18] This treaty aims to ensure the full and equal enjoyment of human rights by persons with disabilities,[19] and although it incorporates provisions on the need to protect persons with disabilities from exploitation and harm, other interests are arguably at the forefront of it. These include respect for individual autonomy and participation and inclusion in the community.

Aims

In this article, we discuss some of the implications of the CRPD for domestic policies on research involving adult persons with disabilities, in particular persons with psychosocial, intellectual and cognitive disabilities, including impaired decision-making ability.[20] Such policies could, of course, pertain to research on the subjects' impairments, but they may just as often concern research unrelated to these impairments.

Our aim is to assess the extent to which the CRPD grants persons with disabilities (a) a right to participate in research and; (b) a right to protection against research enrolment. This assessment is timely and important. For one thing, the routine exclusion of certain groups from research projects obviously introduces a significant risk that many of the specific circumstances under which these groups live their lives remain under-

[14] See e.g. Will C. van den Hoonaard and Ann Hamilton (eds.), *The Ethics Rupture* (University of Toronto Press, 2016).
[15] Swedish Act concerning the Ethical Review of Research Involving Humans (SFS 2003:460).
[16] Regulation (EU) 2016/679 [2016] OJ L119/1. The Swedish Act concerning the Ethical Review of Research Involving Humans (fn 15), § 13 requires that, in all of these cases, ethics review is mandatory and in the former three kinds of research, informed consent is required by all adult research participants capable of providing it.
[17] See e.g. The British Psychological Society, 'Code of Human Research Ethics' (2014); American Psychological Association, 'Ethical Principles of Psychologists and Code of Conduct' (amended 2010 and 2016); section 8, American Sociological Association, 'Code of Ethics' (2018), Association of Social Anthropologists of the UK; and the Commonwealth, 'Ethical Guidelines for Good Research Practice' (2011), and the British Society of Criminology, 'Statement of Ethics for Researchers' (2015), section 4.
[18] Convention on the Rights of Persons with Disabilities, (United Nations [UN]) 2515 UNTS 3, UN Doc A/RES/61/106, Annex, GAOR 61st Session Supp 49, 65 [Adopted] 13th Dec 2006; [Opened for Signature] 30th Mar 2007; [Entered into Force] 3rd May 2008.
[19] CRPD, article 1.
[20] The CRPD does not define disability or any sub-categories thereof, and terms like "mental", "psychosocial", "intellectual" and "cognitive" disabilities are used to refer to slightly different categories of people in human rights law scholarship. We adopt a broad understanding of the relevant terms, recognizing that there may be a certain an overlap between these categories and that persons with multiple impairments can fall under more than one of them.

investigated, limiting the development of new and improved services tailored to meet their needs.[21] States party to the CRPD would then not fulfil their treaty obligations, and, more generally, it goes against the call from representatives of the disability movement for increased respect for personal choices.[22] On the other hand, the treaty's unequivocal condemnation of non-consensual experimentation on human beings reflects an ambition not to undo the hard-won protections of research subjects against harm and exploitation.[23]

Now, the CRPD arguably has implications not only for whether persons with disabilities have a right to participate or not participate in research, but also for states parties' policies on what kinds of research ought to be facilitated, and how, from a methodological standpoint, this research ought to be conducted. For example, there has been discussion within disability research about the value and prospects of participatory research designs.[24] This and similar interesting issues, however, lie beyond of the scope of the present paper.

Outline

The paper proceeds as follows: in Section 2, we ask what protection the CRPD provides for persons with disabilities against enrolment in research. Such protection is afforded by the Convention – explicitly, and sometimes implicitly – but its scope, we shall maintain, hinges on as yet unresolved issues about, inter alia, what counts as valid consent, and on the interpretation of (arguably vague) terms such as "experimentation", "integrity" and "exploitation".

Section 3 discusses the extent to which the CRPD includes a right to participate in research. It contends that while several of the Convention's articles presuppose that persons with disabilities participate in research, they fall short of actually granting a right to such participation. We also argue, however, that the right to equal protection and benefit of the law guaranteed by article 5 amounts to a right to participate in research on an equal basis with others.

Section 4 adds to the preceding and subsequent analysis by considering some of the potential reasons – legitimate or not – why researchers may decline to include persons

[21] The need to conduct research on issues that are important for marginalized groups have been discussed in relation to the right to enjoy the benefits of scientific progress included in the International Covenant on Economic, Social and Cultural Rights, (United Nations [UN]) 993 UNTS 3, CTS 1976/46, S Exec Doc D, 95-2 (1978), GAOR 21st Session Supp 16, 49, UN Doc A/6316, UN Doc A/RES/21/2200, [Adopted] 16th Dec 1966; [Signed] 16th Dec 1966; [Entered Into Force] 3rd Jan 1976; Article 15.1(b). See e.g. Human Rights Council, 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications', A/HRC/20/26, paras. 15, 31, 43-44, (14 May 2012). The Committee on the Economic, Social and Cultural Rights is currently developing a general comment on article 15 that will presumably clarify the scope of states' obligations on this point.

[22] See e.g. Inclusion International, 'Independent but not Alone: A Global Report on the Right to Decide' (2014), World Network of Users and Survivors of Psychiatry (WNUSP); and Center for the Human Rights of Users and Survivors of Psychiatry (CHRUSP) 'Response to Draft General Comment on Article 12' (28 February 2014): wnusp.wordpress.com/advocacy/legal-capacity/ [accessed 14 January 2020].

[23] CRPD, article 15.

[24] See e.g. Mark Priestley, Lisa Waddington and Carlotta Bessozic, 'Towards an Agenda for Disability Research in Europe: Learning from Disabled People's Organisations' (2010) 25 (6) Disability & Society 731-47.

with disabilities in their research, and Section 5 explains how discrimination analysis can be used to distinguish lawful exclusion of persons with disabilities from research studies from discriminatory practices violating the CRPD. Here we argue that a proper discrimination analysis will involve balancing many different considerations, and that analyses will need, ultimately, to be made on a case by case basis. We end, in Section 6, with some concluding remarks.

II. CRPD AND THE RIGHT TO PROTECTION AGAINST RESEARCH ENROLMENT

Several provisions of the CRPD protect persons with disabilities from enrolment in research that is unethical or that they do not wish to participate in. Article 15 (Freedom from torture or cruel, inhuman or degrading treatment or punishment) prohibits cruel, inhuman and degrading treatment in general and medical and scientific experimentation without the free consent of the person concerned in particular. Article 17 (Protecting the integrity of the person) includes a right to respect for the integrity of the person and article 16 (Freedom from exploitation, violence and abuse) obliges states parties to take action to protect persons with disabilities from exploitation and abuse. These provisions target different kinds of misconduct. Article 15 deals with the most flagrant offences. It is modelled on article 7 of the ICCPR, and it is clear from the negotiation records of the CRPD that the drafters foresaw that it would be interpreted in light of the meaning the corresponding article had acquired in the ICCPR.[25]

Under the ICCPR, the prohibition of medical and scientific experimentation without consent has generated relatively little discussion. Rather than referring to a specific methodology, the term "experimentation" arguably denotes trying something out for the purpose of generating new knowledge. Hence, in the context of medicine, it serves to distinguish medical experimentation (or research) from medical treatment, which aims to improve the health of the person concerned.[26] The article makes a distinction between medical and (other) scientific experimentation. What research practices (*non*-medical) scientific experimentation covers is not clear from the text or the preparatory works. Manfred Nowak's commentary suggests, however, that essentially two types of malpractice are at issue: research on human subjects without consent, and research that causes significant harm to individuals or exposes them to great risks.[27] This clearly includes experiments of the kind carried out in the concentration camps during the Nazi regime, for example,[28] but the prohibition goes further; Nowak suggests that research on humans which leads to mutilation or other severe physical and mental suffering are impermissible, and other authors have interpreted the ICCPR in a similar vein.[29]

Precisely how the line should be drawn between research practices which infringe article

[25] Daily Summaries of the Fifth Session of the Ad Hoc Committee related to article 11 Freedom from torture or cruel, inhuman or degrading treatment or punishment (28 January 2005), morning session, see recorded statements by Chile, the Russian Federation and the Coordinator.
[26] Cf. Manfred Nowak, *U.N. Covenant on Civil and Political Rights: CCPR Commentary*, 2nd rev ed. (N.P. Engel, 2005), 190.
[27] Ibid., 190-191.
[28] The *travaux préparatoires* to the ICCPR confirms that the drafters' primary intention was to take a firm stand against the abhorrent experiments of totalitarian regimes conducted during World War II. General Assembly (fn 3 above) Ch. VI, para. 14.
[29] Nowak (fn 26 above), 191; and Sarah Joseph and Melissa Castan, *The international Covenant on Civil and Political Rights: Cases, Materials and Commentary*, 3rd ed. (OUP, 2013), [146].

15 of the CRPD and research practices which do not violate this provision is unclear. Arguably, low risk studies that only cause slight psychological distress to their participants do not constitute 'experimentation' or 'inhuman or degrading treatment' in the specific senses these terms have in international human rights law, even if such studies are undertaken without proper consent from the persons concerned. But the point at which research interventions become invasive or harmful enough to be covered by article 15 may be difficult to determine. From a legal point of view, this issue may not be very important since practices that do not fall within the protective scope of article 15 might nevertheless be prohibited by CRPD article 17, which stipulates that a person with disabilities has "a right to respect for his or her physical and mental integrity on an equal basis with others". Questions can be raised about the scope of article 17 as well, of course; the treaty text provides no information that helps us to decide what kinds of research project interfere with a person's integrity. There is little doubt, however, that research involving some form of physical intervention, such as taking a blood sample or undergoing a physical examination, falls within the scope of article 17.[30] Arguably, studies in which participants are asked to disclose sensitive information about their private lives or are observed in clearly private settings would also fall within the scope of this article.[31]

It may be that some research studies are prohibited by the CRPD because they violate article 16. To what extent the latter article could be used to safeguard persons with disabilities against unethical research enrolment depends in part on its relationship to articles 15 and 17. The main issue here is whether article 16 offers protection which is independent of that offered by these other articles; that is, whether there could be exploitation or abuse in research, in the sense assumed by article 16, without there also being cruel, inhuman or degrading treatment, *or* a violation of a person's integrity. Just how strong protection article 16 offers, in this context, obviously also hinges on the extent to which persons with disabilities are seen as vulnerable to exploitation or abuse. That persons with disabilities are more vulnerable than others, all else being equal, is uncontroversial in the context of the CRPD.[32] Precisely how vulnerable remains, however, an open question, and depends in part on one's views on the *sources* of such vulnerability; in particular, on the extent to which impairments and various social factors, respectively, contribute to it.[33] It also depends on one's views on the "dignity of risk"[34]

[30] Cf. European Court of Human Rights, *Y.F. v. Turkey*, appn 24209/94, 22 July 2003, 39 EHRR 34, paras 33-36. The case concerned a gynaecological examination without consent. The Court held that a person's body concerns the most intimate aspect of "private life", a concept which covers the physical and psychological integrity of a person. Thus, a compulsory medical intervention, even if it is of minor importance, constitutes an interference which must be justified to comply with the European Convention on Human Rights.

[31] It can be discussed whether research projects involving the processing of data from medical records or population-based registries only interfere with the protection of integrity in article 17 or also contravene the protection of privacy in article 22.2 of the CRPD. In human rights law, a clear distinction between the rights to respect for integrity and to privacy is not always upheld.

[32] This position has, however, been challenged in other theoretical and political contexts. The pitfalls of identifying especially "vulnerable groups" are for example brought to the fore by so called vulnerability theory. See e.g. Martha Albertson Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) 20 (1) Yale Journal of Law and Feminism, 1-25.

[33] See for example Amanda Keeling, 'Article 16: Freedom from Exploitation, Violence and Abuse' in Ilias Bantekas, Michael Ashley Stein and Dimitris Anastasiou (eds.) *The UN Convention on the Rights of Persons with Disabilities: A Commentary* (Oxford University Press, 2018), 475ff.

[34] Piers Gooding, 'Supported Decision-Making: A Rights-Based Disability Concept and its Implications for

in relation to exploitation; that is, whether concerns about overprotection of persons with disabilities should be seen as limiting the applicability of article 16.

Taken together, the right not to be subjected to medical and scientific experimentation without consent, the right to equal respect for integrity and privacy, and states parties' obligation to prevent exploitation and abuse, on one level means that persons with disabilities benefit from the same protection against inclusion in unethical research as others. Nothing in the treaty text of the CRPD, or in the *travaux préparatoires*, suggests that these articles are intended to provide persons with disabilities with stronger (or weaker) protection from malpractice within the field of research than that afforded to persons generally. Thus, for example, persons with disabilities, just like everyone else, are protected against clinical research that could have been carried out on animals, that involves risks that are disproportionate to the potential benefits of the study, and that has not been approved by a research ethics committee.[35] And, as already mentioned, persons with disabilities, like everybody else, must be protected from research enrolment without their free and informed consent.[36] The fact the drafters appeared to aim for equal protection in these regards also means, however, that where research subjects are considered to have some particular vulnerability (situational or of another kind) additional safeguards may need to be put in place.[37] For example, and as just mentioned, the "strength" and concrete implications of the protection offered by article 16 depends on what we may legitimately assume about disabled persons' vulnerability to exploitation in the research context; which is a matter for continued discussion. In the next subsection, we shall also address article 12's take on equal protection when it comes to informed consent.

Finally, complementing the specific safeguards in articles 15-17, the general prohibition of discrimination in article 5 (Equality and non-discrimination) protects against discriminatory inclusion of persons with disabilities in research studies. For example, to selectively enroll persons with intellectual disabilities in a potentially harmful or burdensome nutrition study for reasons related to researchers' convenience is not only wrong because it may expose the research participants to unacceptable risks, or risks that they may find difficult to assess. It also concentrates the harms and burdens of such research to persons with disabilities in a discriminatory manner. One could also imagine cases where articles 15-17 may not come into play, but where the prohibition of discrimination in article 5 nonetheless applies; cases, for example, where selective inclusion of persons with disabilities in a study will reinforce public prejudice against this group, and may cause stigma.

Mental Health Law' (2013) 20 (3) Psychiatry, Psychology and Law 431, 435f.

[35] Cf. Oviedo Convention, Article 16, and its Protocol on Biomedical Research, Articles 5-7, and DoH, paras. 16 and 23.

[36] Cf. Oviedo Convention, Article 16(v), and its Protocol on Biomedical Research, Article 14, and DoH, para. 25.

[37] Cf. UNESCO, Universal Declaration on Bioethics and Human Rights, 33 C/Res 74; [Adopted] 19th Oct 2005, Article 8 (UDBHR); and DoH, para. 19. Examples of persons considered to be in need of additional safeguards include: prisoners and others deprived of their liberty; pregnant women; economically disadvantaged groups and persons suffering from ailments for which there is no satisfactory standard treatment. See Protocol on Biomedical Research, articles 12, 18 and 20, its explanatory report 'Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research', Strasbourg, 25 January 2005, para. 69.

A. Protection against enrolment without consent

As explained above, participation in research involving at least some kind of interference with integrity requires the free and informed agreement of the individuals concerned. What constitutes valid consent to research is not defined in the treaty text of the CRPD.[38] The negotiation records indicate that the appropriate formulation of the consent requirement was discussed during the drafting procedure, and that the phrase "free and informed consent" was chosen because it has an accepted meaning within human rights law.[39] In other human rights instruments covering participation in medical research, consent to such participation implies an agreement to take part in a particular research project that was obtained without threats or improper inducements and after disclosure of the aim of the project and the possible risks and benefits involved. In the European context, this understanding of consent is codified in the (legally binding) Oviedo Convention and its Protocol on Biomedical Research.[40] At the global level, it is embodied in the (not legally binding) UNESCO Declaration on Bioethics and Human Rights (UDBHR) and in bioethical declarations and guidelines developed by medical professionals and bioethicists, such as the DoH and the CIOMS guidelines.[41] These documents further clarify that research participants should be informed of their rights, in particular the right to withdraw consent at any time without reprisals.[42] Information should be provided in a comprehensible format to research participants.[43] Before obtaining consent, researchers must also ensure that research subjects have understood the information provided,[44] and in cases of doubt about an individual's ability to understand the relevant information, arrangements must be in place to verify whether or not the person has such ability.[45] Similar standards covering other fields of research can be found in various ethical guidelines.[46]

Notably, many codes distinguish between persons who are able to provide consent and those who are not. Where persons considered to fall within the latter category are

[38] References to consent occur in several provisions of the treaty, i.e. in article 15 in relation to medical and scientific experimentation, in article 25(d) with regard to provision of health care and in article 23.1(a) in relation to marriage. None of these provisions, however, define the term.

[39] General Assembly, 'Report of the Coordinator to the Ad Hoc Committee at its fifth session', Annex II to the Fifth Session Report of the Ad Hoc Committee, 25 February 2005, A/AC.265/2005/2, para. 39 and Daily Summaries of the Fifth Session (fn 25) recorded statements by the Russian Federation, New Zealand, Jordan, Australia, Luxembourg (on behalf of the EU), the Coordinator and the Office of the High Commissioner for Human Rights.

[40] Oviedo Convention, Articles 5, 15 and16(iv), and its Protocol concerning Biomedical Research, Articles 12-14. It should be noted that the Convention is ratified by 29 of the 47 Council of Europe Member States and that its Protocol is ratified by 11 States only.

[41] UDBHR, Article 6.2. See also DoH, paras. 25-26, and International Ethical Guidelines for Health-related Research Involving Humans, prepared by Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), guideline 9 (CIOMS guidelines).

[42] UDBHR, Article 6.2, Oviedo Convention, Article 5 and 16(iv-v), and its Protocol on Biomedical Research, Article 13.1 and 13.3, DoH, para 26, and CIOMS guidelines, guideline 9.

[43] UDBHR, Article 6.2, Protocol on Biomedical Research, Article 13.1, DoH, para. 26, and CIOMS guidelines, commentary to guideline 9.

[44] DoH, para. 26 and CIOMS guidelines, commentary to guideline 9.

[45] Protocol on Biomedical Research, Article 14.3 and CIOMS guidelines, commentary to guideline 16.

[46] Cf. The British Psychological Society, 'Code of Human Research Ethics' (fn 17 above), section 4, American Psychological Association (fn 17), 'Ethical Principles of Psychologists and Code of Conduct' (amended 2010 and 2016), section 8, and American Sociological Association, 'Code of Ethics' (fn 17), section 11.

concerned, these instruments permits exceptions to the rule that consent to research must be given by the research subject him- or herself. Persons who cannot consent may be enrolled in research projects if certain criteria are met. These are, roughly: the project has the potential to directly benefit the research subject; research of comparable effectiveness cannot be carried out on individuals capable of giving consent; and authorization has been given by a suitable third party (i.e. a legal representative or an authority).[47] In addition, potential research subjects lacking the ability to consent must nevertheless be informed about the research and what participation involves, so that they are involved as much as possible in the decision-making procedure. Also, the person must not object to participation.[48] Many clinical research projects cannot be expected to produce direct health benefits for the participants, so it follows from the above that persons who cannot provide free and informed consent should as a rule be excluded from such projects. There is one exception to this rule, however, as enrolment is permitted if the project aims to benefit other persons with the same disease, disorder or condition and the research involves minimal risks and burdens for those involved.[49]

The CRPD does not include standards at this level of detail, and questions about research participation received little attention during its negotiation.[50] It is possible to interpret the CRPD in light of the above standards, and to construe it so that it allows for the enrolment of persons with limited decision-making skills if and only if the criteria outlined above are met; and certainly this approach has been taken by some states parties to the CRPD in their interpretative declarations.[51] It is not entirely convincing, however. The protection package included in the Oviedo Convention, the DoH and several other codes is based on two assumptions: that some people – as a result of, for example, an impairment or a disease – lack the abilities necessary to provide *legally valid* consent to research, and that authorisation by a *third party* can compensate for such inability.[52]

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[47] UDBHR, Article 7(b), Oviedo Convention, Article 17.1(ii-1v), Protocol on Biomedical Research, Article 15.1(i-iii) and DoH, para. 28. Similar requirements are incorporated in the CIOMS guidelines, guideline 16, and national regulations, such as the Swedish Act Concerning the Ethical Review of Research Involving Humans (fn 15 above) §§ 20-22.

[48] UDBHR, Article 7(b), Oviedo Convention, Article 17.1(v), Protocol on Biomedical Research, Article 15.1(v) and DoH, para. 29.

[49] Oviedo Convention, Article 17.2, and Protocol on Biomedical Research, Article 15.2. UDBHR includes a similar limitation (in Article 7(b)), as does the DoH (paras. 28 and 30). A critical discussion of this provision can be found in Mats Johansson and Linus Broström, 'Does Peer Benefit Justify Research on Incompetent Individuals? The Same-population Condition in Codes of Research Ethics' (2012) 15 (3) Medicine, Health Care and Philosophy 287-94.

[50] The legitimacy of systems such as those envisaged in the Oviedo Convention was briefly discussed by a few states during the seventh session and then as part of a much broader discussion concerning the legitimacy of health interventions without the consent of the person concerned. Daily Summaries of the Seventh Session of the Ad Hoc Committee (19 January 2006), e.g. recorded statements by Norway and Yemen.

[51] France and the Netherlands have made interpretative declarations to the CRPD stating that they interpret the CRPD to permit enrolment of persons who are not able to consent in biomedical research if such enrolment is authorised by their representative or an authority or body provided and after the other protective measures included in human rights instruments have been undertaken. Full declarations available at: treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=iv-15&chapter=4&lang=en [accessed 14 January 2020]

[52] See e.g. Oviedo Convention, Article 17.1(iv), and its explanatory report 'The Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine' Oviedo, 4 April 1997,

These assumptions are difficult to square with article 12 of the CRPD (Equal recognition before the law), at least under some influential interpretations of this article. Article 12.2 protects the right of persons with disabilities to enjoy legal capacity (i.e. to make decisions and have them respected by the domestic legal order) on an equal basis with others in "all aspects of life". The treaty text does not specify what this means in relation to persons with diminished capacity for understanding and reasoning, but the Committee on the Rights of Persons with Disabilities (CRPD Committee) has insisted that the possession of certain decision-making abilities is not a prerequisite of the right to enjoy legal capacity under the CRPD.[53] Article 12.3 of the Convention does oblige states to ensure that persons with disabilities have access to the *support* they may require in exercising their legal capacity. Nothing in the treaty text, however, appears to imply that states parties are permitted to disqualify decisions made without such support. Accordingly, the Committee submits that article 12.2 obliges states to recognize the choices of persons with disabilities as legally valid also in situations where there is doubt about an individual's ability to understand and weigh the relevant information and to appreciate the consequences of his or her decision.[54]

While this interpretation can be contested, it certainly harmonises with the CRPD's emphasis, in article 3, on respect for autonomy and individual self-determination. Applying this line of argument to the subject matter discussed here, the implication is that consent to research that would not have qualified as sufficiently informed under, for example, the Oviedo Convention and the DoH, is legally valid under the CRPD. Clearly, if this is correct, the CRPD affords weaker protection against research enrolment than those other instruments in this respect. Moreover, the CRPD contains no specific rules limiting the scope for research enrolment of persons who cannot provide legally valid consent. Whereas the Oviedo Convention, the DoH, and several other codes prohibit research involving those with certain intellectual or cognitive disabilities whenever the relevant study could be conducted with those with no disabilities instead, the CRPD does not. Likewise, whilst those codes of research ethics limit the participation of a person who lacks the ability to consent to situations where he or she may directly benefit or is not exposed to more than minimal risks and burdens, the CRPD contains no such additional requirements for research participants with impaired decision-making ability. This is another respect, then, in which the CRPD affords weaker protection against research enrolment for persons with cognitive and intellectual disabilities. With the exception of situations where discrimination, exploitation or abuse is involved, the CRPD treaty text, for example, provides no rules preventing persons with disabilities who (with or without support) do not understand what's at stake from participating in risky research. In part this may be explained by the fact that the CRPD has a broad scope and is less specific on matters concerning research ethics, but it is also in line with the CRPD Committee's refusal to hold some people to lack legal capacity.

B. Protection through legal representation

An intriguing question is whether the CRPD is compatible with domestic systems in which

paras. 41, 43 and 105. See also the explanatory report to the Protocol on Biomedical Research (fn 37) paras. 69 and 85, and DoH para. 28 and 30.

[53] CRPD Committee, *'General comment No. 1: Art 12: Equal recognition before the law'*, adopted 11 April 2014, CRPD/GC/1, paras. 13-15.

[54] Ibid.

a third party, often called a "legal representative", is mandated to decide on participation in research by persons who are believed to lack decision-making skills and who do not oppose such participation.[55] The treaty text offers no clear-cut answer to this question; it neither authorises nor prohibits such systems *per se*. As alluded to above, the debate over the correct interpretation of the CRPD on matters concerning legal capacity is ongoing. According to the CRPD Committee, the Convention prescribes that all forms of scientific and medical research on persons with disabilities must be based on the consent of those concerned, and argues that "such consent cannot be given via substituted decision-making".[56] In using the phrase "substituted decision-making", the Committee is referring to systems in which legal capacity is removed from the potential research participant and transferred to a third party who has not been selected (or at least accepted) by the person concerned, or in which a third party is authorised to make decisions based on what is believed to be in the potential participant's "objective best interest" as opposed to his or her "will and preferences".[57] It appears, then that the CRPD accepts support systems only where the third party is someone the potential participant has accepted or appointed (e.g. through power of attorney), and where the representative bases his or her decisions on the will and preferences of the person he or she represents.[58] As noted above, some state parties have interpreted the convention differently, however.[59]

The CRPD further prescribes that all measures relating to the exercise of legal capacity should provide for appropriate and effective safeguards to prevent abuse.[60] This includes regular review of the system by a competent, independent and impartial authority or judicial body to ensure that any "legal representatives" or support persons respect the rights, will and preferences of the person with disabilities, and that the relationship between that person and his or her representative/supporter is free of conflict of interest and undue influence.[61] Applied in the research context, this prohibits researchers from enrolling a person with disabilities in studies where this does not respect the latter's will and preferences. It also prevents persons with an interest in a research project from representing or supporting prospective research subjects in the same project. Furthermore, article 12.4 disqualifies unethical representatives who seek to achieve a certain outcome by means of threats, deception or manipulation.[62] Such safeguards are not explicitly mentioned in the previously discussed regulations focusing on research

[55] Persons who oppose participation in a research project must never be enrolled, regardless of their decision-making abilities, see fn 48 above.
[56] CRPD Committee, *'Concluding observations on the initial report of Montenegro'*, adopted 22 September 2017, CRPD/C/MNE/CO/1, paras 34-35, *'Concluding observations on the initial report of Costa Rica'*, adopted 12 May 2014, CRPD/C/CRI/CO/1, paras 31-32, and *'Concluding observations on the initial report of Italy'*, adopted 6 October 2016, CRPD/C/ITA/CO/1, paras 39-40.
[57] CRPD Committee, *'General comment No. 1'*, para. 27.
[58] In cases where the person's will and preferences cannot be determined, even though significant efforts have been made, the Committee prescribes that a decision is made based on the "best interpretation of will and preferences". Ibid., para 21.
[59] See fn 51 above. See also declarations made by Australia, Canada, Estonia, Ireland and Norway regarding the lawfulness so called substitute decision-making.
[60] CRPD, Article 12.4.
[61] Ibid.
[62] CRPD Committee, *'General comment No. 1'*, para. 22. Precisely where the line between due and undue influence is to be drawn in the context of the support paradigm is an intricate question Cf. Lucy Series, 'Relationships, Autonomy and Legal Capacity: Mental Capacity and Support Paradigms' (2015) 40 International Journal of Law and Psychiatry 80-91, [88].

ethics, for example the Oviedo convention or the DoH.[63]

Comparison of the support system advocated by the CRPD Committee and that foreseen in, for example, the Oviedo Convention reveals significant differences. Under the Oviedo Convention, third-party authorisation is a prerequisite of the inclusion of persons who wish to participate in a research project (or do not object to such participation) but are deemed to lack the ability to make free and informed decisions on the matter.[64] Without such authorisation, research on persons who cannot consent is unlawful. The CRPD contains no such authorisation requirement. Indeed, the support system envisaged by the CRPD Committee is a voluntary one, meaning that support must be made available to anyone who needs and wants it, but must never be imposed.[65] Another set of differences revolve around the fact that the Oviedo Convention accepts (but does not prescribe) domestic systems of legal representation in which the person or body responsible for authorizing research participation is not selected by individual concerned and may not even be accepted by him or her. It also accepts systems in which legal representatives are permitted to base their decisions on what they believe to be in the individual's best interest.[66] According to the CRPD Committee, such systems violate article 12 of the CRPD.[67] Last, but not least, the CRPD prescribes that support systems must be subject to regular review and strengthened by appropriate and effective safeguards.[68] The Oviedo Convention does not explicitly require monitoring of that kind.

The differences listed above affect the circumstances under which the respective systems prescribe, or accept, the exclusion, from research, of persons who lack ability to consent to that research. Inclusion is permissible under the CRPD in some situations where it would not be permitted under the safeguards imposed by most codes of research ethics, but it is also prohibited by the Convention under some circumstances where those codes would permit inclusion. Whether these differences, with respect to legal representation, imply that one of the systems provides stronger protection than the other will depend, in part, on what one believes prospective research subjects ought to be protected against. The primary purpose of the CRPD support system is to ensure that persons with disabilities are not enrolled in research studies or provided with certain legal representation when this can be said to conflict with their will and preferences. The systems endorsed by the Oviedo Convention, the DoH, etc. have a different focus, aiming to protect persons with limited decision-making abilities from harms, risks and burdens of research participation even in situations where the individual appears to be willing to bear these burdens. How well the systems meet their aims in practice will depend, of course, on empirical issues – issues including the availability of decision-making support and legal representation, and the quality of the services provided under the relevant arrangements.

Although it remains an open question whether a support system or a system of legal

[63] Protocol on Biomedical Research, Article 12, however, obliges ethics committee to ensure that no undue influence is exerted on persons to participate in research.
[64] Oviedo Convention, Article 17(iv).
[65] CRPD Committee, *'General comment No. 1'*, paras. 18 and 29(b) and (g).
[66] The Oviedo Convention provide states with a fair amount of discretion when designing their systems in this regard. See the explanatory report to the Oviedo Convention (fn 52), para. 42.
[67] CRPD Committee, *'General comment No. 1'*, paras. 27, 29(b) and (g).
[68] CRPD, article 12.4.

representatives provides the most effective protection against enrolment in research studies, the discussion in Section 2.1 shows that many codes of research ethics impose stricter limits on research inclusion than those defined by the CRPD. On the other hand, the CRPD arguably provides persons with disabilities with a stronger right to contribute to research. Indeed, the CRPD Committee has expressed concern over the fact that some states parties have not taken appropriate action to ensure that persons with disabilities are permitted and enabled to consent to research.[69]

To summarise, the CRPD protects persons with disabilities against unethical research enrolment. Article 5 protects against discriminatory enrolment. In addition, articles 15-17 prohibit non-consensual experimentation, exploitative or abusive research practices, and studies that violate a person's integrity. The strength of this protection package depends on several factors, most notably on the interpretation of terms such as "experimentation", "exploitation" and "integrity". It also depends on how, in view of article 12, we conceptualise valid consent and on the design of the system for support or legal representation in place in the domestic context. The next section will discuss whether, and to what extent, the CRPD not only safeguards against involuntary enrolment, but creates an individual right to participate in research.

III. CRPD AND THE RIGHT TO PARTICIPATE IN RESEARCH

The first thing to note is that the Convention contains no explicit right to research participation. However, it sets out several rights and obligations which presuppose that persons with disabilities participate, in one way or another, in research. Article 31 (Statistics and data collection), for example, insists that states parties collect information, including statistical and research data, to enable the formulation of adequate policies giving effect to the CRPD. Compliance with that article will, at a minimum, involve the processing of data on persons with disabilities, but in many cases it will also require persons with disabilities to be personally engaged, observed and/or exposed to interventions, and the like. Article 4 (General obligations) requires states parties to undertake or promote research on universally designed goods and services and to develop accessible information and communications technologies.[70] Article 24 (Education) requires states to set up inclusive education systems that maximize the academic and social development of disabled pupils and students.[71] Similarly, articles 25 (Health), 26 (Habilitation and rehabilitation), and 27 (Work and employment) oblige states to ensure that persons with disabilities have equal access to health care services,[72] to comprehensive rehabilitation and habilitation programmes,[73] and to suitable vocational guidance and training programmes, respectively.[74] To meet these obligations, states will need to develop an understanding of how best to ensure inclusive teaching,

[69] CRPD Committee, 'Concluding observations on the initial report of Uganda', adopted 12 May 2016, CRPD/C/UGA/CO/1, para. 28 and 'Concluding observations on the initial report of Kenya', adopted 30 September 2015, CRPD/C/KEN/CO/1, paras. 29-30.
[70] CRPD, Articles 4.1 (f) and (g).
[71] CRPD, Article 24.1 and 24.2 (e).
[72] Article 25(a) and (b) obliges states parties to provide persons with disabilities with "*the same range, quality and standard* of free or affordable health care and programmes as provided to other persons" [our italics] and ensure that persons with disabilities have access to any health services they may need because of their impairment/ disability.
[73] CRPD, Article 26.1.
[74] CRPD, Article 27.1(d).

promote employment, secure equal access to adequate health interventions, etc., and there is little prospect of their doing so, with sufficient reliability, unless research involving persons with disabilities is conducted. Having said that, an obligation for states parties to conduct research on persons with disabilities will at most support a right for this group of persons to be involved in research: it does not ground any individual right.

Article 9 (Accessibility) also has implications for the right to research participation. While it does not grant persons with disabilities a right to such participation *per se*, it obliges states parties to take steps to remove obstacles to whatever participation opportunities there would otherwise be. For example, states parties are obliged to put in place appropriate measures ensuring that research studies will – when necessary, and to the extent possible – make information material accessible to persons with disabilities, so that this group will not be excluded as the result of insufficient accessibility efforts being made by the state. Moreover, failure to take reasonable action to accommodate impairment or disability-related needs in individual cases violates the prohibition of discrimination: article 2 (Definitions) makes it clear that the denial of reasonable accommodation is a form of discrimination akin to direct and indirect discrimination; and article 5 paragraph 3 obliges states to ensure that reasonable accommodation is provided whenever it is needed.[75]

Moreover, as has already been discussed, article 12.2 of the CRPD protects the right of persons with disabilities to exercise legal capacity on an equal basis with others. This includes the right to decide whether or not to participate in research; should an opportunity to be enrolled in a study present itself. Paragraph 3 entitles prospective research participants to the support they may need and want to express legally recognized consent. However, this provision does not imply a right to be invited to, or enrolled in, a particular research study; it merely ensures that whatever research opportunities are offered, the person with disabilities is to choose whether or not to take them. In the remainder of this section, however, we will argue that there are good reasons for interpreting the Convention to include, also, a stronger right – a right to participation in the development of new knowledge *on an equal basis with others*. This, if correct, implies that when research studies are being conducted they must be open to prospective participants with disabilities, if they are open to others.

A. The right to participate on an equal basis with others

Article 5 of the CRPD obliges states parties to ensure that persons with disabilities are entitled to equal protection and benefit of the law. To this end, states shall prohibit all discrimination on the basis of disability.[76] The Convention defines disability-based discrimination as follows:

> any distinction, exclusion or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any

[75] Article 2 in CRPD defines reasonable accommodation as the "necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms".
[76] CRPD, Article 5.2.

other field.[77]

A literal interpretation of this definition suggests that a practice must aim at, or have, a negative impact on the enjoyment or exercise of a human right in order for it to be discriminatory. As discussed above, the "right to participate in research" appears in neither the CRPD nor any other human rights treaty. This does not mean that the exclusion of persons with disabilities from research falls outside the scope of the Convention's protection against discrimination, however. Article 5 of the CRPD is modelled on article 26 of the ICCPR,[78] and since the late 1980s the Human Rights Committee has interpreted the latter as a freestanding prohibition on discriminatory domestic legislation and practices in any field regulated and protected by public authorities.[79] The CRPD Committee has affirmed that article 5 must be interpreted in the same vein.[80] In view of the purpose of the CRPD – which is to ensure that persons with disabilities enjoy the same level of protection of human rights as others – this seems reasonable.[81]

If it is assumed that article 5 of the CRPD applies to research participation, the question becomes: would the exclusion of persons with disabilities from research participation constitute discrimination as defined in article 2? The answer appears to be that it would, if two criteria are met. First, the relevant exclusion must be based on reasons that are related to disability/impairment.[82] The presence of a disability does not have to be the sole reason for exclusion, however. The prohibition of discrimination has been interpreted to cover also disadvantageous treatment based on reasons which appear to be neutral but have a disproportionate impact on persons with disabilities; this is often called indirect discrimination.[83] A situation where ostensibly disability-neutral legal requirements make the inclusion of those with disabilities so cumbersome or costly that researchers avoid enrolling such persons would be a case in point (more examples will be given in the next section).

Secondly, the exclusion must have a negative impact on those concerned.[84] It can, of course, be questioned whether exclusion from research participation harms or disadvantages those excluded. The main purpose of research, after all, is to generate

[77] CRPD, Article 2.

[78] The first two paragraphs of article 5 of the CRPD are almost a carbon copy of article 26 of the ICCPR.

[79] See e.g. Human Rights Committee, 'General comment No. 18: Non-discrimination', adopted 10 November 1989, HRI/GEN/1/Rev.9 (Vol. I), adopted 10 November 1989. In para. 12 the Committee states: "[a]rticle 26 does not merely duplicate the guarantee already provided for in article 2 but provides in itself an autonomous right. It prohibits discrimination in law or in fact in any field regulated and protected by public authorities. […] In other words, the application of the principle of non-discrimination contained in article 26 is not limited to those rights which are provided for in the Covenant."

[80] CRPD Committee, *'General comment No. 6 on equality and non-discrimination'*, adopted 26 April 2018, CRPD/C/GC/6, para. 13.

[81] Vienna Convention on the Law of Treaties (1969), 1155 UNTS 331 [Adopted] 23rd May 1969; [Opened for Signature] 23rd May 1969; [Entered into Force] 27th Jan 1980, article 31.1. This provision affirms that treaty-based norms are to be interpreted in accordance with the "ordinary meaning" of the terms "in their context and in the light of its object and purpose".

[82] In article 2 the CRPD defines discrimination as "any distinction, exclusion or restriction *on the basis of disability"* [our italics].

[83] CRPD Committee, *'General comment No. 6'* (fn 80), para. 18(b).

[84] Article 2 in the Convention speaks of state practice that "has the purpose or effect of *impairing or nullifying* the recognition, enjoyment or exercise […] of human rights and fundamental freedoms" [our italics].

new knowledge, not to promote the well-being or serve the interests of the individual participating in the study. Participating individuals devote time and effort to the projects in which they are involved, but those projects cannot be expected to yield any direct personal benefits for them, and from that perspective it may be more natural to think of research participation as, if anything, a burden. However, there are situations where enrolment in a study may offer the participant tangible benefits. For example, in medical research participants may be remunerated, receive superior health monitoring, learn more about their condition, and about ways to alleviate or cope with its negative effects, or receive some other "collateral" benefit. Participating in a clinical trial may also, on occasion, be the only way of gaining access to certain treatment, where no other therapeutic intervention is available or where the treatment being tested holds out some special promise. To participate in a pedagogical intervention study will sometimes be the only the way of getting access to a course taught with certain new and promising educational methods, and there might, for example, be no other way of being eligible for a particular program for occupational rehabilitation than to accept being enrolled in a research study of the effects of that program.

A less tangible benefit, but possibly just as important, is that persons with disabilities, like others, may have an interest in contributing to society's pursuit of knowledge, just as they may have an interest in other ways of discharging their (self-perceived) moral obligations towards others.[85] A fairly extensive corpus of literature suggests that participation in at least some kinds of research is indeed often based on altruistic considerations.[86] Even when this is not the case, however, persons with disabilities may have an interest in the opportunity to participate simply because others have this option. That is, whether or not research participation, or pulling one's weight as a member of society, can be regarded as a benefit, arrangements which deny disabled persons opportunities that others have are, in themselves, negative for persons with disabilities.

Finally, the exclusion of disabled persons from research for reasons related to disability/impairment may have wider deleterious effects: it could, for example, reinforce stereotypical images of persons with disabilities as people who are unable to make socially valued contributions to society, and eventually this may contribute to social exclusion.

If we accept that persons with disabilities may benefit from research participation, or at least from having that option, depriving persons with disabilities of an opportunity to participate in research can certainly be viewed as a disadvantage. The next question is whether such disability-related disadvantageous practices can be justified under the CRPD. The treaty text is silent on this matter. So are other human rights treaties

[85] Recent jurisprudence from the Court of Justice of the European Union could be interpreted to support this view. In a case concerning a French regulation banning blood donations by men who have had or currently have sexual relations with other men, the Court held that men covered by the ban were treated "less favourably" than male heterosexual donors. The regulation therefore discriminated among potential donors based on sexual orientation and needed to be justified to not violate the prohibition on discrimination. Court of Justice, *Léger v. Ministre des Affaires sociales, de la Santé et des Droits des femmes*, C-528/13, ECLI: EU:C:2015:288, paras. 49-51.

[86] For a few recent examples, including further references, see Jennifer s. Carrera et al., 'Research Altruism as Motivation for Participation in Community-centered Environmental Health Research' (2018) 196 Social Science & Medicine 175-81, and Deborah Goodman et al., 'Factors that Motivate Participation in Observational Genetic Cancer Research Studies' (2019) 9 (2) Open Journal of Epidemiology 156-72.

developed under the auspices of the UN. Still, these latter treaties have been interpreted so as not to outlaw every action which, strictly speaking, meets the definition of discrimination: practices pursuing a legitimate aim, based on "objective and reasonable criteria", do not violate the prohibition of discrimination they set down.[87] There are good arguments for the view that the CRPD's prohibition of disability discrimination leaves room for a similar possibility of justification. This would accord with the drafter's intentions and with the Convention's purpose of ensuring that persons with disabilities enjoy the same human rights protection as others, and no state party has so far challenged it.[88]

In Section 5 we will illustrate how argumentation about the legitimacy and lawfulness of research protocols that exclude persons with disabilities may play out.

IV. POTENTIAL REASONS FOR EXCLUSION

As a preliminary to the hands-on discrimination analysis to be presented in Section 5, it will be helpful to distinguish between different conceivable reasons why researchers, rightly or wrongly, may decide not to enrol persons with certain psychosocial, intellectual or cognitive disabilities in their studies. The rationale for such exclusions strongly bears on whether or not they can be justified, and hence their compliance with the prohibition on discrimination. Below, four types of rationale, or reason, are considered. In many cases, the exclusion of persons with disabilities for these reasons may well amount to discrimination in the sense prohibited by article 5. However, the goal of the discussion is not to determine whether any of the four reasons considered are discriminatory in this sense. It is rather to describe imaginary scenarios which add flesh to the general analysis of discrimination set out in Section 5.

A. Exclusion based on protection

Persons who might otherwise have been considered for inclusion in a research study could be excluded on grounds of protection. As has already been mentioned, key research ethics guidelines, declarations and conventions guarantee certain protections. Researchers could attempt to justify the exclusion of persons with disabilities by appealing to those safeguards. For example, a person with an intellectual disability may declare an interest in participating in a phase I drug trial, i.e. a trial designed to assess the safety of a drug in healthy volunteers. The person in question, it can be supposed, meets the general eligibility criteria for enrolment, with respect to age, sex, somatic health status, etc., but the researchers nevertheless decide not to include this person. Pointing to the fact a phase I trial involves risks, they determine that the person lacks the ability to provide informed consent and appeal to the prohibition against enrolling persons without decision-making capacity if the relevant research could be conducted with participants who are able to give consent.

[87] Anna Nilsson, 'Article 2: Definitions' in in Ilias Bantekas, Michael Ashley Stein and Dimitris Anastasiou (eds.) *The UN Convention on the Rights of Persons with Disabilities: A Commentary* (Oxford University Press, 2018), 75; and Rachele Cera, 'Article 5 [Equality and Non-Discrimination]' in Valentina Della Fina and Rachele Cera Giuseppe Palmisano (eds.) *The United Nations Convention on the Rights of Persons with Disabilities: A Commentary* (Springer, 2017), [160].

[88] Anna Nilsson, 'Objective and Reasonable? Scrutinising Compulsory Mental Health Interventions from a Non- discrimination Perspective' (2014) 14 (3) Human Rights Law Review 459-85, [463-4].

In another scenario, researchers are recruiting participants for an evacuation study, targeting persons with mid-stage Alzheimer's disease, and with the ultimate aim of designing and marking escape routes in a way adapted to the behaviour of this group and that of those with similar disabilities. In accordance with requirements in the standard codes of research ethics serving to protect research participants from tangible harm and exploitation, participants are enrolled with the consent of their loved-ones, who act as their legal representatives. However, those with no significant others – at all, or available – are excluded, again in line with the consideration not to include unrepresented persons without the ability to consent.[89] Alternatively, the researchers may instead wish to enrol the potential participants under a support paradigm, but note in a particular case that none of the persons that could be asked to provide the relevant support for the person with Alzheimer's is fit to fulfil that role.

B. Exclusion based on methodological concerns

Research is governed by various general scientific norms connected with its aim of generating sound results that can be trusted. Such norms guide researchers when they design their studies, and some of the methodological standards that have to be met relate, directly or indirectly, to participant selection. Researchers could, therefore, decide, on occasion, not to include persons with certain disabilities in order to guarantee the methodological quality of the research. For example, a subpopulation of those with psychosocial disabilities could be excluded if there are reasons to believe that this group runs a greater risk of dropping out from the study, since high attrition rates make it hard to obtain statistically significant results. Individuals could also be excluded on the basis that, with their level of cognitive impairment, they have poor prospects of fully following complex study instructions. Again, the chances of obtaining data which can be correctly interpreted may in some cases be judged slim. That may arise when a research interview would have to be conducted with the help of support (someone interpreting what the person with disabilities expresses). For that reason, or similar reasons, interview responses may be difficult for researchers to assess.

Presumably, many methodological challenges can be met with appropriate training and resources (cf. below), but the possibility of an ineliminable tension between the goals of inclusion and scientific quality cannot be ruled out a priori.

C. Exclusion based on perceived irrelevance to the research question

Researchers' choices to not include persons with a disability in their studies are sometimes best explained by the focus of their research questions. Researchers may be interested in doing human subject research on issues affecting groups which happen not to include persons with disabilities. For example, a study surveying the factors affecting the wellbeing of PhD students at top universities is unlikely to enrol those with significant cognitive disabilities. At times, however, failure to enrol persons with disabilities will be the result of ignorance about, or inattention to, the fact that such

[89] See e.g. the British Psychological Society, 'Code of Human Research Ethics' (fn 17), section 4, and Swedish Act concerning the Ethical Review of Research Involving Humans (fn 15), §22. Cf. also Oviedo Convention, Article 17.1(iv) and its Protocol on Biomedical Research, Article 15(iv).

persons are part of the population one is interested in – and that their experiences, needs, perspectives and so on, may be different from those that persons without disabilities have. These are cases where persons with disabilities may not be deliberately excluded, but where the researchers fail to see that considerations of representativeness dictate that such persons are included.

D. Exclusion based on limited resources

Finally, the involvement of persons with cognitive or psychosocial disabilities in research may be both time consuming and resource intensive, and researchers could for that reason decide to avoid it.[90] In particular, offering potential participants the special protection that their impairments call for may (be believed to) raise costs and/or slow down the project. Adapting and monitoring the consent procedure, finding individuals prepared and able to provide decision-making support, and making thorough risk assessments that take into consideration the specific impairments and situation of those being considered for enrolment, are some of the measures that may (be believed to) present a challenge for researchers with promised or expected deliverables, deadlines and limited project budgets. Any measures requiring extra training, on the part of researchers, will typically tax resources. Additional "hurdles" in the form of tougher scrutiny by research ethics committees may also need to be reckoned with.[91]

V. DISCRIMINATION ANALYSIS

In Section 3, it was argued that the CRPD gives persons with disabilities the right to participate in research on an equal basis with others. This obviously applies to all kinds of research conducted at public universities and other academic institutions. Indirectly, it also applies to research conducted in private settings. According to article 4.1(e), state parties must "take all appropriate measures to eliminate discrimination on the basis of disability by any person, organization or private enterprise". This means that no researchers, public or private, are free to exclude persons with disabilities from research participation in discriminatory ways.[92]

In order to determine whether a concrete case of exclusion from research participation violates or complies with the CRPD, one must consider the reasons for exclusion (cf. section 4). All research that excludes persons with disabilities for disability-related reasons must serve legitimate aims and be based on objective and reasonable criteria to comply with the Convention.[93] Starting with the first of these conditions, the pursuit of a legitimate aim, it can be seen that in all of the imagined scenarios above researchers were motivated by legitimate aims. In the examples, the exclusions were intended to protect research subjects, to secure methodological quality, to pursue a particular research interest or to proceed on limited resources. All of these aims, in themselves, are compatible with the CRPD.

[90] As noted by Iacono and Carling-Jenkins (fn 4), researchers have complained about the over-regulation by ethics committees of research involving people with intellectual disabilities.
[91] Cf. Nancy A. Pachana et al., 'Can We Do Better? Researchers' Experiences with Ethical Review Boards on Projects with Later Life as a Focus' (2015) 43 (3) Journal of Alzheimer's Disease 701-7.
[92] Cf. CRPD Committee, *Bacher v. Austria*, Communication No. 26/2014, adopted 16 February 2018, CRPD/C/19/DR/26/2014, para. 9.3.
[93] Section 3.1.

For exclusion of prospective research participants to be based on "objective" criteria, such exclusion must be relevant to – typically by contributing to – the (legitimate) aim.[94] Exclusion decisions must not be based on ignorance or (negligently) mistaken assumptions about the excluded group. It would, for example, be discriminatory to exclude persons who are blind, or deaf, on the basis of prejudicial assumptions about the cognitive abilities of such persons. Whether a given research protocol contributes to the aims in question is essentially an empirical matter that can only be answered definitively in relation to a concrete case. There is, however, little doubt that the exclusions of persons with disabilities in the examples given above serve the relevant aims in one way or another. Preventing persons with intellectual disabilities from participating in a phase I drug trial will, of course, protect this group from the risks associated with such participation. The same is true for persons with mid-stage Alzheimer's disease who are excluded from research enrolment because they lack legal representation. And in situations where funding for support and accommodation is lacking, excluding persons with certain disabilities can indeed be a way to ensure the methodological quality of the study.

In addition to being (justifiably believed to be) instrumental to the achievement of legitimate aims, exclusions of persons with disabilities need to meet the criterion of reasonableness. This last step of the discrimination analysis serves to ensure that the practices under review are fair and do not produce consequences that are unduly burdensome for those affected.[95]

Judgements on reasonableness take several considerations into account. These include the importance of the interests at stake, and the positive and negative effects of the practice under review.[96] They also include the consideration of alternative ways to proceed meeting the same aims.[97] There is no basis for making unqualified general statements about whether excluding persons with disabilities from research is reasonable. But to illustrate how reasoning about the reasonableness of exclusion can unfold, let us consider the first example provided in previous section. This example involves the exclusion of a person with an intellectual disability from enrolment in a phase I drug trial because he or she is believed to lack the ability to consent. (Similar considerations apply to the other conceivable grounds for excluding persons with disabilities.) The primary interests at stake here are, on the one hand, the interest of those with disabilities in being protected from certain harms, and, on the other hand, the interest of the same people in being considered as prospective research subjects and allowed to make their own choices about whether or not to get involved. Both interests are important, and the reasonableness of the decision to exclude the individual from the study hinges, by and large, on its positive and negative effects in view of alternative ways to achieve the positive outcomes and mitigate the negative consequences.

[94] Anna Nilsson, *Minding Equality: Compulsory Mental Health Interventions and the CRPD* (PhD thesis, Faculty of Law, Lund University, Media Tryck, 2017), [80].
[95] Ibid., [81-85]. The UN treaty bodies have sometimes couched their reasoning about reasonableness in terms of "proportionality". See e.g. CRPD Committee, *H.M. v. Sweden*, Communication No. 3/2011, adopted 19 April 2012, CRPD/C/7/D/3/2011, paras. 8.2 and 8.8.
[96] Nilsson (fn 94) 81f.
[97] Ibid., 82.

As noted above, research protocols excluding any disabled person who does not fully understand the risks involved in research participation arguably protect those with disabilities from harms and burdens associated with research participation. A critical question here is whether a similar level of protection could be achieved by other means. One way to facilitate research participation without compromising the participant's interest in protection is to provide decision-making support. Indeed article 12.3 of the CRPD obliges state parties to ensure that persons with disabilities have access to such support. Whether various support mechanisms could effectively enable free and informed consent in all situations where an individual wishes to participate is, however, an empirical question, one which cannot be settled by stipulation. The development of support mechanisms to aid people in their decision-making has only recently begun and there are good reasons to be optimistic about the future. A growing body of literature discusses the prospects of providing such support in various situations where personal decisions are to be made.[98] But this is an area in which relatively little empirical research has been conducted, and it remains unclear whether the various forms of support being considered will meet the needs of all those currently being excluded from research participation for reasons of cognitive and mental impairment.

In situations where the support provided fails to give the potential participant an adequate understanding of what study participation will involve, we need to balance the costs and benefits of the decision (or policy) under consideration to determine its reasonableness. Turning first to the benefits of exclusion, people vary in their cognitive abilities and decision-making skills. The reasons against including a particular participant in a research study are arguably weightier in situations where he or she does not understand the risks involved, or overestimates the chances of gaining direct health (or other) benefits from the project, than they are in situations where the lack of understanding concerns more peripheral information. In addition, research projects differ in the risks and burdens to which they expose their participants. While it seems fair to exclude persons lacking certain decision-making abilities from high-risk projects, it may be unreasonable to exclude the same group from participation in low-risk, low-burden, studies where participants are, say, expected to answer a set of innocuous questions or will merely have a blood sample taken. The risk of instrumentalising those who do not fully understand what the research is about remains, of course, but the need for protection is arguably less in low-risk, low-burden studies than it is in studies that are more demanding for participants or expose them to more serious risks and burdens.

A closer evaluation of the costs of exclusion would also be necessary. It would be important, for example, to ask whether the relevant study may involve direct benefits for those enrolled. As the Oviedo Convention, its Protocol on Biomedical Research, and the DoH all suggest, it may be unreasonable to exclude persons who cannot consent to research participation from studies that have the potential to produce real and direct

[98] *Ex pluribus* Michael Bach and Lana Kerzner, 'A New Paradigm for Protecting Autonomy and the Right to Legal Capacity - Advancing Substantive Equality for Persons with Disabilities through Law, Policy and Practice', prepared for the Law Commission of Ontario, 2010, 72ff and Piers Gooding, *A New Era for Mental Health Law and Policy: Supported Decision-Making and the UN Convention on the Rights of Persons with Disabilities* (Cambridge University Press, 2017), ch. 6.

health benefits to participants.[99] Other benefits could also be considered. People choose to participate in research for a range of reasons,[100] and whatever benefit a participant can be expected to obtain from his or her participation (clinical, psychological, educational or another sort), if this benefit could be significant, this too would have some bearing on the lawfulness of any exclusions. At the same time, it should be kept in mind that the main positive outcomes of research are not, in general, benefits to the research subjects, but rather benefits to science or society. Including persons with disabilities in research projects facilitates the development of technical aids and new services tailored to meet their needs. It also enables states to create more accessible and inclusive societies and thereby fulfil their treaty obligations under the CRPD.[101] The more important that aim is considered to be, the greater is the probability that leaving persons with disabilities out of research studies will be considered unlawful.

As the points above illustrate, judgements of reasonableness take a variety of considerations into account, among them: the availability of support enabling free and informed consent, the magnitude of the harms and burdens that the person may have to endure in the study, the tangible benefits that he or she may be deprived of if excluded, and the importance of the research project's contribution to society. The fact that it can be very difficult to determine whether the potential participant understands the risks to which he or she will be exposed in a particular research project, or whether a given set of support measures enables free and informed decisions to be made, adds to the complexity of the matter. Similarly, the difficulties involved in determining the probability of the harms, burdens and possible benefits of a particular research project add to the complexity of any assessment of these harms, burdens and benefits. When the different considerations are being balanced, the certainty, or reliability, with which all of these assessments has been made arguably also needs to be taken into account. Where, for example, estimates of the expected benefits of a particular project, or the probability of their occurrence, rest on uncertain data, this will reduce the weight of the reasons in favour of including persons who are unable to consent. Conversely, if such estimates rest on certain information, that will strengthen the case for inclusion.

To summarise, it is difficult, if not impossible, to provide a comprehensive answer to the question: under what circumstances can the exclusion of persons with disabilities from research participation be considered reasonable, and therefore lawful under the CRPD?

Judgements of reasonableness can only be reached in the context of a particular study and a particular group of prospective study participants – where the weight of the reasons for and against participation are balanced against each other. As already mentioned, while the CRPD grants persons with disabilities many different rights, some of which do relate to protection against research enrolment, taken as a whole it can indeed be read as guidance intended to curb, among other things, paternalistic policies and attitudes. That is why special emphasis is given in the Convention to such interests as individual autonomy, and participation and inclusion in the community. Even on that

[99] Oviedo Convention, Article 17.1, and its Protocol on Biomedical Research, Article 15.1. DoH para. 28. A similar argument could be made with regard to other forms of direct benefits such as access to a particular educational method or program for occupational rehabilitation, see section 3.1.
[100] See e.g. Michael C. Soule et al., 'Understanding Motivations to Participate in an Observational Research Study: Why Do Patients Enroll?' (2016) 55 (3) Social Work in Health Care 231-46.
[101] Section 3.

reading, however, it is far from clear that this translates into these interests having decisively greater weight in the balancing of reasons for and against research enrolment – that is something that would have to be argued on a case-by-case basis.

VI. CONCLUDING REMARKS

The nature and scope of the basic rules governing research-based knowledge production and the rights of those who participate in it are critical issues for every society. Such rules must ensure that important research is made possible. They must also safeguard against unethical research: research that is unnecessary, flawed in its design, exploitative, or such that its potential benefits do not compensate for the risk of harm it introduces. The rules also need to be consistent with general norms of fairness, and in particular non-discrimination. How to reconcile these demands is a recalcitrant issue that every society will have to deal with.

Sometimes explicitly, but in the main implicitly, the CRPD addresses all of the above demands. Article 15 outlaws medical and scientific experimentation without consent, and articles 5 and 16-17 prohibit research practices that are discriminatory, exploitative or violate research participants' integrity. As discussed above, the precise scope of this protection will remain unclear until there is agreement over what, in the CRPD, constitutes valid consent, and who can provide it.[102] What is more, the CRPD arguably grants a right for persons with disabilities to participate in research. There is an obligation on states parties to conduct research involving members of this group and a duty to ensure that prospective research participants with disabilities have access to adequate decision-making support.[103] In addition, the right to legal capacity gives persons with disabilities the right to decide whether or not to participate in research should an opportunity present itself.[104]

Last but not least, the prohibition of discrimination embedded in the Convention outlaws research protocols that exclude persons with disabilities unless such exclusion can be justified, and the necessary justification requires careful consideration of a number of interests and considerations, all of which need to be balanced.[105]

As a final note, researchers need to design CRPD-compliant non-discriminatory research protocols. Success in this endeavour will depend on further work on the implications of the CRPD for human subjects research. Additionally, codes of research ethics may need to be reworked, so as to better reflect the Convention's demand for equal treatment of those with and without disabilities while still achieving the codes' key aims, i.e. the facilitation of important research and safeguarding against harm and exploitation. This is no easy task. Understanding these challenges better, and how best to meet them, is a matter for further research.

[102] Section 2.2.
[103] Section 3 and CRPD, Article 12.3.
[104] CRPD, Article 12.2.
[105] Sections 3.1 and 5.