

VITENSKAPELIG PUBLIKASJON

# Prohibition on research involving psychiatric patients subject to coercion

AV SØREN BIRKELAND

*Associate Professor, LLM MD PhD (Corresponding author),*

*Department of Clinical Medicine (OPEN)*

*University of Southern Denmark*

*sbirkeland@health.sdu.dk*

KATHRYN BERZINS

*Dr., PhD, School of Healthcare*

*University of Leeds*

JOHN BAKER

*Professor, PhD, School of Healthcare*

*University of Leeds*

TITTI MATTSSON

*Professor, PhD, Department of Law*

*Lund University*

KARL HARALD SØVIG

*Professor, PhD, Department of Law*

*Bergen University*

FREDERIK GILDBERG

*Associate Professor, PhD, Center for Psykiatrisk Sygepleje- og Sundhedsforskning (CPS)*

*University of Southern Denmark*

**ABSTRACT** This paper compares legislation on clinical research conducted on patients subject to coercion in the Scandinavian countries and the UK, examines it from a human rights perspective, and problematizes the Danish legal model as the only one

employing a total ban on this kind of research. Reference is made to the consequences to evidence-based psychiatric care improvements and international ethical principle statements generally entitling psychiatric patients to treatment under similar ethical and scientific conditions as patients with other illnesses, given the absolute premise that the patient does not object to research participation and always retains the right to withdraw.

**KEYWORDS** Coercive measures, Coercion, Psychiatry, Human Rights, Research, Ethics

## 1 Introduction

According to Danish law, patients who are subjected to coercive measures may not participate in ‘experimental treatment’ (Danish: [Forsøgsbehandling]).<sup>1</sup> The current interpretation of this prohibition has many consequences for Danish psychiatric research and may block important initiatives to investigate better means of treating a significant group of patients. *In this paper, we compare Danish legislation to regulation in other Scandinavian countries and the UK and examine it through the lens of international human rights.* By way of introduction, we describe general legal principles regarding coercion in psychiatry. Likewise, requirements for consent to research participation are described with reference to different codes of practice and international soft law instruments. Subsequently, legislation on clinical research conducted in patients subject to coercion in Sweden, Norway and the UK is described followed by a description of the situation in Denmark. Finally, the topic is discussed in the light of theory regarding the capacity to consent in psychotic patients and individuals subject to involuntary commitment.

### 1.1 Coercion in psychiatry – introductory remarks

Psychiatric coercive measures constitute a serious break with common health law principles about patient autonomy. They represent one of the most significant exemptions from the general requirement for obtaining informed consent and for patient involvement in healthcare decision-making.<sup>2,3</sup> However, the necessity for coercion in some special clinical situations is widely acknowledged. The Oviedo Convention states that ‘a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is

- 
1. ACMP. Danish Act on Coercive Measures in Psychiatry, [Bekendtgørelse af lov om anvendelse af tvang i psykiatrien], 1160 (2015), Para 23.
  2. DHA. The Danish Healthcare Act [Sundhedsloven], 191 (2018).
  3. Søren Birkeland and Frederik A Gildberg, ‘Mental Health Nursing, Mechanical Restraint Measures and Patients’ Legal Rights’ (2016) 10 (8) Open Nursing Journal 8. DOI: <https://doi.org/10.2174/1874434601610010008>.

likely to result to his or her health' (Section 7).<sup>4</sup> Similarly, interventions against 'persons of unsound mind' may in some situations be consistent with the European Convention on Human Rights (Article 5).<sup>5</sup> According to Danish law, coercion in terms of involuntary admission to psychiatric hospital, forced treatment, and physical restraints can be used if certain criteria are met.<sup>6</sup> As a point of departure, however, efforts always must be exercised to obtain the patient's consent.<sup>7</sup>

### *1.2 Consent to research – general principles*

Following the Second World War, the Nuremberg Code in 1947 was established as a set of research ethics principles for human experimentation.<sup>89</sup> As a major point, the code states that 'voluntary consent [...] is absolutely essential [...] the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion [...]' (1<sup>st</sup> Para).<sup>10</sup> Furthermore, the code maintains that experiments should aim at results that cannot be procured in any other way (2<sup>nd</sup> Para), and they should be set up in a way that ensures that unnecessary physical and mental suffering and injuries are avoided (4<sup>th</sup> Para). Additionally, they may not imply any risk of death or disabling injury (5<sup>th</sup> Para). Likewise, it is crucial that human subjects are free to immediately quit any experiment at any point and medical staff similarly must stop the experiment if they observe that continuation would be dangerous (9<sup>th</sup> and 10<sup>th</sup> Paras).

Nonetheless, unethical practices continued beyond WWII. One example of infamous and unethical research is the U.S. Public Health Service Syphilis Study at Tuskegee conducted between 1932 and 1972, in which the natural history of syphilis was followed by officials in a cohort of black men without offering medical treatment, even once antibiotic treatment became available. By way of example the Tuskegee study resulted in numerous African American men dying from syphilis,

---

4. Oviedo Convention. 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, (1997). DOI: <https://doi.org/10.1093/humrep/12.9.2076>.

5. Cf. European Convention on Human Rights (ECHR). The Convention for the Protection of Human Rights and Fundamental Freedoms (4 November 1950), Article 5 § 1 (e). DOI: <https://doi.org/10.1093/law:epil/9780199231690/e790>.

6. ACMP (n 1).

7. Oviedo Convention (n 4); ACMP (n 1).

8. Tribunals NM. The Nuremberg Code. 1947. Nuremberg Military Tribunals. DOI: [https://doi.org/10.1007/springerreference\\_300986](https://doi.org/10.1007/springerreference_300986).

9. Bernard A. Fischer, 'A summary of important documents in the field of research ethics' (2006) 32 (1) *Schizophrenia Bulletin* 69. DOI: <https://doi.org/10.1093/schbul/sbj005>.

10. Tribunals (n 8).

women contracting the disease, and children born with congenital syphilis. Similarly, from 1922–1953 medical doctors used marginalized patients as reservoirs to facilitate malarial fever therapy for syphilitic patients by deliberately inoculating them with malaria.<sup>11</sup> Furthermore, other examples of unethical research outside Nazi experiments have been described, among others, by Henry Beecher.<sup>12</sup>

### 1.3 Consent to research in psychiatry – codes of practices

Examples from history of unethical biomedical research conduct over time led to codes of practices being agreed upon. The Nuremberg Code has been already mentioned. Codes often are not legally binding instruments, but, rather, draw authority from the codification in national legislation and from being generally accepted standards in scientific communities, including international journals etc.

#### 1.3.1 The Declaration of Helsinki<sup>13</sup>

The first version of this declaration was adopted in 1964 in Helsinki, Finland. Afterwards, it has undergone several revisions. According to its Para 25, 'Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary [...]'.<sup>14</sup> Furthermore, according to Para 30, research involving patients who are 'mentally incapable of giving consent [...] may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group'. In such situations, informed consent must be obtained from a *legally authorised representative* (LAR).

#### 1.3.2 Hawaii-declaration<sup>15</sup>

The prime declaration was adopted in 1977 at the 6th World Congress of Psychiatry. A revised version was approved by the General Assembly of the World Psychiatric Association in 1983.<sup>16</sup> The declaration explicitly stresses the necessity for

---

11. Matthew Gambino, 'Fevered Decisions: Race, Ethics, and Clinical Vulnerability in the Malarial Treatment of Neurosyphilis, 1922-1953' (2015) 45 (4) *The Hastings Center Report* 39. DOI: <https://doi.org/10.1002/hast.451>.

12. Henry Beecher, 'Ethics and clinical research' (1966) 274 (24) *The New England Journal of Medicine* 1354. DOI: <https://doi.org/10.4324/9781315244426-2>.

13. Helsinki Declaration. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310(20):2191-4. DOI: <https://doi.org/10.1002/047086947x.oth1>.

14. Helsinki Declaration (n 13).

15. Declaration of Hawaii. World Psychiatric Association 'Declaration adopted unanimously by the General Assembly of the World Psychiatric Association at the Sixth World Congress of Psychiatry' (1977) 2 (6096) *British Medical Journal* 1204. DOI: <https://doi.org/10.1136/bmj.2.6096.1204>.

16. Declaration of Hawaii / II (approved by the General Assembly of the World Psychiatric Association in Vienna, Austria, on 10th July 1983).

continuous research. At the same time, the declaration upholds that ‘No procedure shall be performed nor treatment given against or independent of a patient’s own will, unless because of mental illness, the patient cannot form a judgement as to what is in his or her own best interest and without which treatment serious impairment is likely to occur to the patient or others’ (Section 5).<sup>17</sup> Importantly, the declaration’s Section 9 declares that ‘To increase and propagate psychiatric knowledge and skill requires [research] participation of the patients [...]’ but ‘participation must be voluntary, after full information [...] and there must always be a reasonable relationship between calculated risks or inconveniences and the benefit of the study [...]’. In situations where a patient cannot give informed consent, it should be obtained from ‘the legal next-of kin’ and, in case of withdrawal from participation, the psychiatrist’s efforts to help the patient or subject may not be influenced by this decision.

### 1.3.3 Belmont<sup>18</sup>

The Belmont report was issued in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and prompted in part by the Tuskegee Syphilis Study. The report identifies three core principles (respect for persons, beneficence, and justice) and three primary areas of application (informed consent, assessment of risks and benefits, and research subject selection).<sup>19</sup> Specifically, about ‘Voluntariness’ the report maintains that an agreement to participate in research only constitutes a valid consent if it is voluntarily given thereby requiring ‘*conditions free of coercion and undue influence*’. Coercion is narrowly defined in terms of overt and intentional threat of harm in order to get compliance.<sup>20</sup> Regarding research in vulnerable populations, the report upholds the principle that ‘other less burdened classes of persons should be called upon first [...] except where the research is directly related to the specific conditions of the class involved [...]’. Similarly, it is crucial that ‘very sick, and the institutionalized’ patients who frequently lack capacity for free consent should not be involved

---

17. Declaration of Hawaii / II (n 16).

18. Belmont Report. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). Belmont Conference Center, Elkrige, Maryland: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; 1979. DOI: [https://doi.org/10.1007/978-1-4020-5614-7\\_233](https://doi.org/10.1007/978-1-4020-5614-7_233).

19. Justin C. Strickland and William W. Stoops ‘Perceptions of research risk and undue influence: Implications for ethics of research conducted with cocaine users’ (2015) 156 *Drug and Alcohol Dependence* 304. DOI: <https://doi.org/10.1016/j.drugalcdep.2015.09.029>.

20. Belmont Report (n 18).

in research because they are easy to manipulate as a result of, e.g., illness or for administrative convenience.

### 1.3.4 The Oviedo Convention<sup>21</sup>

This international treaty, issued by the Council of Europe, is an international legally binding instrument in the field of biology and medicine. Basically, it draws on the principles established by the European Convention on Human Rights and aims at protecting the dignity and identity of all human beings and at guaranteeing that everyone, without discrimination, should have respect for their integrity and other rights and fundamental freedoms. It deals specifically with biomedical research, genetics and transplantation but also sets out fundamental patients' rights applicable to daily medical practice.<sup>22</sup> The convention is signed and ratified by Denmark and Norway. Sweden has signed the convention, but not ratified it, while it is not signed by the UK.<sup>23</sup> The convention maintains the 'General rule' that 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it [...] The person concerned may freely withdraw consent at any time' (Article 5). Regarding 'Protection of persons not able to consent', it should be noted that the convention allows for intervention if it is '*for his or her direct benefit*' (Article 6). Likewise, if incapacity for consent is caused by mental disability or for similar reasons, 'the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law [...].'<sup>24</sup>

Specifically, regarding 'Scientific research', the convention's article 16 sets forth criteria for protecting persons undergoing research.<sup>25</sup> Hence, it is stated that research involving human beings may only be conducted if a number of conditions are met. First, it is a requirement that there is no alternative of comparable effectiveness to conducting the study in humans (*i*). Second, the risks are not disproportionate to the potential benefits of the study (*ii*). The research project must also be approved by a competent body after independent examination of the project's scientific merit, the importance of the research project, and its ethical acceptability from a multidisciplinary perspective (*iii*). Furthermore, individuals included in the study must be informed of their rights and safeguards prescribed by law (*iv*). Finally, it is

---

21. Oviedo Convention (n 4).

22. Bioetikkonventionen. [Bekendtgørelse af Europarådets konvention af 4. april 1997 om menneskerettigheder og biomedicin], (2000).

23. For a chart of signatures and ratifications, see [https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p\\_auth=2wabmvff](https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=2wabmvff).

24. Oviedo Convention (n 4).

25. Oviedo Convention (n 4).

maintained as a requirement that the necessary consent as provided for under Article 5 has been given.

In article 17, about '*Research on a person without the capacity to consent*' it is stated that such research 'may be undertaken only' if the conditions laid down in Article 16, sub-paragraphs *i* to *iv* mentioned above are fulfilled. It is mandatory that 'the results of the research have the potential to produce real and direct benefit to his or her health' (*i*). Also, it is a prerequisite that 'research of comparable effectiveness cannot be carried out on individuals capable of giving consent' (*ii*). Furthermore, the necessary authorisation provided for under Article 6' must have been given specifically and in writing (*iii*) and it also is a precondition that 'the person concerned does not object' (*iv*). However, if 'the research has not the potential to directly benefit the person concerned', it can be authorised only in exceptional circumstances if it aims to contribute 'through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition' (*i*) and there must be only minimal risk and burden for the research individual (*ii*) (cf. Article 17).<sup>26</sup>

### 1.3.5 United Nations' Convention on the Rights of Persons with Disabilities<sup>27</sup>

The UN Convention on the Rights of Persons with Disabilities (CRPD; 13 December) 2006 is ratified by the European Union and is intended as a human rights instrument which reaffirms that persons with all types of disabilities must enjoy all human rights and fundamental freedoms. All states that are part of this study have ratified it. It adopts a broad categorization of persons with disabilities and will include psychiatric patients. In the context of the present analysis, the convention's articles 12 and 14 deserve mention. About '*Equal recognition before the law*', Article 12 declares that 'States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life' (2). The provision in Article 14 about '*Liberty and security of person*' maintains that 'States Parties shall ensure that persons with disabilities, on an equal basis with others: a) Enjoy the right

---

26. Oviedo Convention (n 4).

27. The UN Convention on the Rights of Persons with Disabilities (December 13) 2006. DOI: [https://doi.org/10.1163/9789004220829\\_010](https://doi.org/10.1163/9789004220829_010). Please also see General Comment No.1 (2014) and Guidelines on the right to liberty and security of persons with disabilities (see, e.g., Supplement No. 55 (A/72/55) in Report of the Committee on the Rights of Persons with Disabilities; Sixteenth session, 15 August-2 September 2016). For a critical discussion of Article 12, please see Lile, Hadi. (2019). Paradigmeskifte eller villedende aktivisme?. *Kritisk juss*. 45. 49-56. <https://doi.org/10.18261/issn.2387-4546-2019-02-01>.

to liberty and security of person [...]. The CPRD committee's 'General Comment' regarding Article 12 explicitly states that having a disability (in this context mental disorder) is not a reason to take away persons' right to make their own decisions.

Similarly, reference can be made to the convention's Article 5 protecting equality and non-discrimination. This article maintains states' duty to 'recognize that all persons are equal before and under the law and are entitled without any discrimination to the equal protection and equal benefit of the law'. Furthermore, the convention's Article 25 states that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability.

As it appears above, there appears to be no general prohibition in international instruments regarding research involving patients subject to psychiatric coercive measures. Instruments rather point to the necessity for treatment and research given the premise that the project has been approved by an ethics committee and that the patient does not object to research participation. When patients seem incapable of decision making, instruments recommend obtaining consent from a legally authorised representative. The position mentioned above may, however, be differently reflected in various countries. The law in Norway, Sweden, and UK is described below, followed by a description of the situation in Denmark.

## 2 Case studies – Legislation on coercion and clinical research in neighbouring countries

### 2.1 Norway – Clinical research in psychiatric patients subject to coercive measures

Clinical research within the health care sector is regulated by the Health Research Act.<sup>28</sup> According to Section 9 every research project within the scope of the act must be approved in advance by the regional committee for Medical and Health Research Ethics, (cf. Section 10 of the Ethics and Integrity in Research Act).<sup>29</sup> The legal framework concerning research on patients with limited capacity to consent is based on the Oviedo convention.<sup>30</sup>

---

28. Health Research Act. Act (20 June 2008 No. 44) on Medical and Health Research; Regulations and legal material is accessible at [https://lovdata.no/info/information\\_in\\_Norwegian](https://lovdata.no/info/information_in_Norwegian) (accessed 1 February 2020) and the database is partly free of charge. A selection of legal material translated into English is available at <http://www.ub.uio.no/ujur/ulov/> (accessed 1 February 2020) but note that not all regulations are translated and that they are not always up to date. For an introduction to Norwegian health law in general, see Karl Harald Søvig, *Medical Law – Norway*, suppl. 92, ed. Herman Nys (Wolters Kluwer 2019).

29. Act 28 April 2017 No. 23 on ethics and integrity in research.

30. See the presentation of the Oviedo Convention in the ministry's proposition to the parliament, cf. Ot.prp. No. 74 (2006–2007) p. 89 (this proposal was submitted prior to Norway's ratification of CRPD).



As a general rule, consent must be obtained from participants in medical and health research, unless otherwise laid down in law, cf. Section 13. This general rule also applies to psychiatric patients, even if they are subject to coercive measures. This approach ensures that vulnerable patient groups are not automatically excluded from medical research, although safeguards are present. As for all research participants, consent must be ‘informed, voluntary, express and documented’ (cf. the Health Research Act Section 13, second paragraph).<sup>31</sup> Capacity to consent is regulated by Section 17. According to the first paragraph, all persons above the age of 18 years may give consent, unless they are deprived of legal capacity in private matters according to the Guardian Act Section 22 (the provisions concerning minors are not dealt with here).<sup>32</sup> The competence to consent pursuant to the first paragraph ‘may cease to apply’ in the situations referred to in Section 4-3, second paragraph of the Patient Rights Act.<sup>33</sup> As a result, capacity to give consent does not cease to exist as an automatic consequence of being admitted to a psychiatric ward, even if the hospitalization is involuntary. An assessment of the patient’s ability to understand the consequences of an actual research project is required.

If the person concerned is not able to consent, the person’s next-of-kin has authority to grant consent, cf. Section 17, fifth paragraph of the Health Research Act. In such situations, Section 18 introduces further conditions for medical research. The ‘potential risks or disadvantages for the person’ must be ‘insignificant’ (litra a) and there must be ‘reason to assume that the results of the research may be of use to the person concerned or other people with the same age-specific disorder, disease, injury or condition’ (litra c). Additionally, the individual involved must not be opposed to the intervention (litra b). It is also a requirement that there is no reason to believe that the person concerned ‘would have been averse to participating in the research project if they had had the capacity to give their consent’, and that ‘similar research cannot be done on people who have the capacity to give consent’, cf. Section 18, third paragraph. The responsibility vested both with the ethics committee and the researchers must be emphasised. The regional committee has to make an assessment that the research project has sufficient quality to be carried out on such a vulnerable group and the individual researcher has to evaluate the involvement of each individual patient. If the research participant can be regarded as ‘being in a relationship of dependency with the person requesting consent’, meaning that the research participant might

---

31. Health Research Act (n 28).

32. Guardianship Act. The Act of 26 March 2010 No. 9 relating to Guardianship.

33. Patient Rights Act. The Act of 2 July 1999 No. 63 relating to Patients’ Rights.

feel pressured to give their consent, informed consent must be obtained from another person with whom the research participant does not have this kind of relationship, cf. Section 13 third paragraph.

For some specific situations, special regulations apply. Testing of medical products (including drugs) is governed by a separate regulation that implements EU law, and conditions are similar to those of other medical research.<sup>34</sup> However, the limitations are more detailed. Inter alia, the results of the research must be directly beneficial to the trial person's health. The Health Research Act also contains a provision concerning research in clinical emergencies, (cf. Section 19).<sup>35</sup> Additionally, the Act contains provisions concerning the use for research purposes of health information collected by the health service in connection with diagnosis and treatment, cf. Sections 28 and 35. Here the regional committees can authorize research without the consent of the patient if the research in question is of 'significant interest to society' and the 'participants' welfare and integrity are ensured'. In all these situations, psychiatric patients subject to coercive measures are regarded in the same manner as other patients. However, the fact that they are in an involuntary situation, may impact the assessment. For example, research on blood samples from patients in a locked ward will normally not be authorized since use of data from involuntary patients will violate their integrity.<sup>36</sup> There are few reported court cases regarding research on patients' subject to coercive measures within psychiatric care.<sup>37,38</sup> An expert committee submitted a draft for a new act concerning psychiatric care but the proposal does not include provisions regarding research.<sup>39</sup>

---

34. Regulation relating to clinical trials on medicinal products for human use (*No. 1321, 30 October 2009*) and EU directive 2001/20 (to be repealed by Regulation EU No 536/2014). Norway is not a member of the European Union but is affiliated to the European Union and its member states by the European Economic Area (EEA-agreement). Based on the EEA-agreement, the three EFTA countries (Iceland, Lichtenstein and Norway) participate extensively in the internal market and is bound by the relevant EU legislation. For an in-depth analysis of the EEA agreement, see Finn Arnesen et al., *Agreement on the European Economic Area: A Commentary* (Nomos/Hart 2018).

35. Health Research Act (n 28).

36. Cf. decision by the National Committee for Medical and Health Research Ethics in an appeal case concerning serum concentration of lipids and drugs amongst patients receiving antipsychotic treatment, cf. case 2013/174.

37. The case decided by the Supreme Court in Rt. 1994 p. 691 concerns the use of information from medical records.

38. ECHR (n 5), article 8.

39. NOU 2019:14 Tvangsbegrensingsloven.

## *2.2 Sweden – Clinical research in psychiatric patients subjected to coercive measures (incl. non-voluntary hospitalization).*

In Sweden, the general regulation dealing with vetting the ethics of research involving living persons is the Ethical Review Act (ERA).<sup>40</sup> According to this regulation, such research must meet certain general criteria regarding information and consent to participate. A central starting point is that research should be allowed only if the risks and the discomfort, that research persons may be exposed to, are in reasonable proportion to the knowledge gain that the study is expected to provide.<sup>41</sup> In other words, there must be an acceptable relationship between risk and benefit. The ERA aims to protect the people who in various ways participate in research and seek to ensure protection by requiring that some research must be tested and approved prior to commencement based on certain criteria. The assessment is based on a balancing of interests and does not mean that privacy infringement can be ruled out. A research project can be approved only in those cases where the risk of health, security and privacy violation is outweighed by the scientific value and gains of the project. According to the ERA, research can only be approved if it can be carried out with respect for human dignity.<sup>42</sup> Furthermore, human rights and fundamental freedoms must always be taken into account in the ethical review.<sup>43</sup> According to this legislation, the research person must be informed about the overall plan for the research, the purpose of the research, the methods that will be used, the consequences and risks that the research may entail, the identity of the principal investigator or of the project, and that participation in the research is voluntary, and that the research person can cancel his or her participation at any time.<sup>44</sup> The Act further states that the research project may only be carried out if the research person has agreed to participate and received information about the research.<sup>45</sup>

The regulation also sets certain specific restrictions for conducting research on people with limited decision-making capacity. This kind of research may be carried out only if it can be expected to provide knowledge that cannot be obtained through research in people following consent achieved through usual procedures. Furthermore, research should be expected to directly benefit the participating, individual patient (section 21). Alternatively, according to the same section, the

---

40. Ethical Review Act, ERA (2003:460). The Act concerning the Ethical Review of Research Involving Humans (SFS 2003:460).

41. ERA (n 40), Para 9.

42. ERA (n 40), Para 7.

43. ERA (n 40), Para 8.

44. ERA (n 40), Para 16.

45. ERA (n 40), Para 17.

project can be carried out if a) the purpose is to contribute to a result that can be of benefit to someone else suffering from the same or similar illness or disorder, and b) the research involves an insignificant risk of injury and only a slight discomfort for the research person. However, the Medical Products Act (MPA) puts some further restrictions on clinical trials in psychiatric patients subjected to coercive measures.<sup>46</sup> According to this legislation (*lex specialis*), clinical drug testing *which is not related to a patient's disease treatment* may not be conducted on patients subjected to psychiatric coercive measures under the Compulsory Mental Care Act and the Forensic Mental Care Act.<sup>47</sup>

Thus, there are certain specific restrictions concerning research involving this group of patients *but no absolute ban*. Any intervention tested must have a connection to the disease treatment given to the person in psychiatric coercive care. In addition, the general conditions for doing research in humans stated above must always be assessed by the ethical review boards.<sup>48</sup> Therefore, the extent to which clinical trials, qualitative research, non-drug trials or any other type of participation in research with persons subjected to coercive measures may get approval by the ethical review board is carefully scrutinized on a case by case basis. The only regulated limitation for research persons subjected to psychiatric coercive measures specifically is in the MPA which puts a ban on clinical drug testing which is not related to a patient's disease treatment.

### *2.3 United Kingdom – Clinical research in psychiatric patients subjected to coercive measures*

The United Kingdom consists of England, governed by Westminster and the devolved administrations of Wales, Scotland and Northern Ireland (NI). Most UK law governing compulsory treatment for mental disorder consists of specific mental health legislation (the Mental Health Act in England and Wales, and the Mental Health Care and Treatment Act in Scotland).<sup>49,50</sup> In NI, a different approach has been taken and mental disorder is managed through more general capacity legislation,<sup>51</sup> rather than legislation specifically for mental disorder. The two UK Mental Health Acts have some differences, but their primary intention is to govern the

---

46. Medical Products Act (2015:315).

47. Compulsory Mental Care Act (1991:1128) Chapter 7 Para 5. See also Forensic Mental Care Act (1991:1129).

48. ERA (n 40).

49. Mental Health Act 1983 (c. 20).

50. Mental Health (Care and Treatment) (Scotland) Act 2003 asp 13. Act of the Scottish Parliament to restate and amend the law relating to mentally disordered persons, and for connected purposes.

51. Mental Capacity Act (Northern Ireland) 2016 (c. 18).

assessment, treatment, and rights of people with a mental health disorder. To be detained under the Mental Health Act a person must be deemed to need urgent treatment for a mental health disorder and be at risk of harm to either themselves or others. These Mental Health Acts do not govern *participation in research* as this is generally deemed an issue for *capacity* legislation.

UK law relating to capacity (with exception of NI) is set out in England and Wales by the Mental Capacity Act<sup>52</sup> and in Scotland by the Adults with Incapacity Act.<sup>53</sup> In general, capacity is presumed to exist, unless there is evidence of its absence, and is seen as being task specific. Capacity depends on the decision the individual is making and their cognitive functioning at the time of making the decision; therefore, a person may be detained under a section of the Mental Health Act but still be deemed to have capacity to participate in research. The decision about the capacity of an individual within a mental health inpatient setting to take part in research is determined by the clinical staff and *not* by the study researchers.

The Health Research Authority (HRA) is responsible for regulating health research in England, in partnership with each of the devolved administrations.<sup>54</sup> Part of the HRA is the UK Research Ethics Service, a structure of local Research Ethics Committees in England that provide ethical approval for UK research and clinical trials.<sup>55</sup> It is a UK-wide legal requirement that any research that involves patients must be reviewed by Research Ethics Committees. This review includes ensuring procedures in line with legislation are in place for participants who are deemed to lack capacity. Generally, when an individual lacks capacity, the decision to include them in the research must be informed by the potential risks and benefits of participation, and the potential benefit must outweigh any risks, particularly in the case of clinical trials. If there are no direct benefits, then the risks should also be negligible. If it is at all possible, participation should be discussed with the individual in such a way as to maximise comprehension of the proposed participation.

Participation in research for patients lacking capacity is governed either by capacity legislation or the Medicines for Human Use Regulations 2004, depending on whether the study is a clinical trial or not. In clinical trials in England and Wales, Scotland and NI a legal representative can give consent on behalf of an adult lacking capacity. They can be a 'personal' legal representative (unconnected with the clinical trial who is appropriate to act due to their relationship with the

---

52. Mental Capacity Act 2005 (c. 9).

53. Adults with Incapacity (Scotland) Act 2000 asp 4.

54. UK Policy Framework for Health and Social Care Research.

55. Governance arrangements for research ethics committees: 2018 edition.

adult. If there is not a personal legal representative available, a 'professional' legal representative (e.g. a doctor unconnected with the trial) can give consent. In Scotland a personal legal representative can be a Welfare Guardian, Welfare Attorney (roles within the AWISA) or the Nearest Relative (role under the Mental Health Care and Treatment Scotland Act 2003). If these are not available, then a professional legal representative can give consent. The legal representative must be aware they are consenting, free to make the decision, be given adequate information, and consider what the adult would want before they make a decision. The adult lacking capacity must also be given information about the trial in line with their presumed understanding.

For non-clinical trials in England and Wales the Mental Capacity Act is used and a 'consultee' is asked for an opinion on whether an adult lacking capacity would want to take part in the research. Consultees can be personal or legal. A personal consultee can be an informal carer or someone else with an interest in their welfare in an unpaid role. If there is no personal consultee available, then a nominated consultee can be a professional as long as they are independent of the research. Consultees must be given information about the study, asked what views the person would have, and their decision recorded on a declaration form (rather than a consent form). The participant must also be given information about the study. In Scotland a non-clinical trial still requires a personal legal representative that must be a Welfare Guardian or Welfare Attorney or nearest relative. Again, they must be given information, asked to decide on behalf of the adult (not their own views) including taking into account whether the adult has expressed any view about the research. There is no specific legislation in NI governing the conduct of non-clinical trials although all research must be approved by a research ethics committee and be in line with the principles of common law.

Although there is no automatic bar on people subject to the mental health act taking part in research, the complexity of the UK regulatory framework is thought to have led to researchers avoiding carrying out research with people who are risk of having lost capacity. This risks a lack of research that in turn limits improvements in care and treatment for certain groups of the population.<sup>56</sup>

---

56. Shepherd, V. (2016). Research involving adults lacking capacity to consent: the impact of research regulation on 'evidence biased' medicine. *BMC Medical Ethics*, 17(1), 55. DOI: <https://doi.org/10.1186/s12910-016-0138-9>.

### 3 The Danish situation – Current Danish legislation on coercion and clinical research

#### 3.1 Danish psychiatry law

As a general rule, according to the Danish Health Care Act, ‘No treatment may be commenced or continued without the patient’s informed consent, unless in accordance with law [...]’.<sup>57</sup> Achieving the patient’s informed consent and patient participation (e.g. in connection with a shared decision-making process) mirrors the bioethical principle of respect for *healthcare users’ autonomy*. Informed consent requirements likewise mirror the principle of liberty stated in the *Danish Constitutional Law*.<sup>58</sup> Danish psychiatric law upholds informed consent principles, but in psychiatry, the use of coercive measures in some situations is legalised through the Act on Coercive Measures in Psychiatry (ACMP).<sup>59</sup> ACMP sets forth the legal requirements for involuntary admission to public psychiatric hospitals and the use of coercive measures during admission. Among coercive measures, are, e.g., mechanical restraints in terms of belt, hand, foot straps and gloves, and sedating injections if considered necessary for ‘relieving the state of a very distressed patient.’<sup>60</sup> In any case, there is a requirement for using the least intrusive measure.<sup>62</sup>

A separate statute governs participation in health research. The *Danish Act on Research Ethics Review of Health Research Projects* (DARER) requires health research projects other than register-based studies, or research based on records, interviews, or questionnaires, to be approved by an Ethics committee.<sup>63</sup> However, specifically regarding patients subject to coercive measures, the ACMP sets out specific rules stating that ‘Patients who are subject to coercive measures according to the Act may not be subjected to experimental treatment’ and that ‘Experimental treatment may not be instituted using coercion in voluntarily admitted patients.’<sup>64</sup> This has led to patients subject to coercive measures being excluded from participation in research involving any kind of intervention. The background and legal situation are described in further detail below.

---

57. DHA (n 2), Para 15; Birkeland and Gilberg (n 3).

58. Danish Constitutional Law (Grundloven; Para 71). According to Para 71, restriction of liberty cannot be instigated without a legal basis.

59. ACMP (n 1), Paras 5, 10, 12.

60. ACMP (n 1), Para 14.

61. ACMP (n 1), Para 17.

62. ACMP (n 1), e.g. Paras 3, 4 and 11.

63. DARER. Danish Act on Research Ethics Review of Health Research Projects, [Lov om videnskabs-etisk behandling af sundhedsvidenskabelige forskningsprojekter], (2011), Paras 13 and 14

64. ACMP (n 1), Para 23.

### 3.2 History of the Danish model on coercion and clinical research – the Mental Health Care White Paper (MHCWP).<sup>65</sup>

In the white paper preceding the ACMP,<sup>66</sup> an entire chapter is devoted to the topic of conducting research when patients undergo coercive measures. MHCWP recapitulates that according to the former ‘Act on Mentally Disordered Inpatients’ no specific legislation existed on the issue and, when considering involvement in research, psychiatric patients were equally treated with other patients. Research projects, therefore, needed prior approval from a medical ethics board. Complaints related to research projects were handled by the Danish National Board of Health.

MHCWP initially maintains that there is essentially *no* difference between the need for patient involvement in psychiatric care and other health care. Regarding psychiatric patients under coercion, however, MHCWP maintains that a substantial difference arises when obtaining *valid* informed consent to research participation. MHCWP refers to the European Council Recommendation (ECR) concerning the legal protection of persons suffering from mental disorder.<sup>67</sup> In the ECR’s Article 5 (2), it is stated that: ‘A treatment which is not yet generally recognised by medical science [...] may be given only if the doctor considers it indispensable and if the patient, after being informed, has given his express consent.’ In those situations where a ‘patient is not capable of understanding the nature of the treatment, the doctor should submit the matter for decision to an appropriate independent authority prescribed by law which should consult the patient’s legal representative, if any’. Likewise, ECR maintains that if applying drugs, etc. without the aim of psychiatric treatment, ‘clinical research should not be permitted in psychiatric patients subject to coercive measures. But in case of purpose of psychiatric treatment, every country should decide whether research should be permitted’. Reference then is made to a Swedish white paper stating that ‘treatment provided to patients subject to coercive measures should always come up to at least commonly acknowledged scientific standards.’<sup>68</sup> From the latter, MHCWP makes the remarkable inference that research generally should not be permitted on patients subject to coercion.

---

65. MHCWP. *Mental Health Care White Paper*. Justitsministeriet. Principbetænkning nr. 1068 (1986) om tvang i psykiatrien. Afgivet af det af justitsministeriet nedsatte udvalg vedrørende sindslidendes retsstilling. Copenhagen; 1986.

66. MHCWP (n 65), page 376.

67. ECR. European Council Recommendation N. 2 concerning the legal protection of persons suffering from mental disorder placed as involuntary patients (Adopted by the Committee of Ministers on 22 February 1983 at the 356th meeting of the Ministers’ Deputies).

68. Socialdepartementet. *Psykiatrien, Tvånget och rättssäkerheten – Betänkanda av Socialberedningen*. Stockholm: Socialdepartementet SOU. 1984:64 page 250.



MHCWP underscores that a patient's participation in a research project requires his or her informed consent as well as an adequate proportionality between the project's supposed risk, adverse effects, discomfort, and scientific value.<sup>69</sup> MHCWP naturally upholds that patients in clinical research should be able to refuse to participate in or withdraw from research without any adverse influence on their care and treatment. MHCWP then argues that there is no reason for further defining the concept of experimental treatment although it covers clinical research including drug trials as well as testing other 'new measures' for the entire or partial reason of a research purpose. The MHCWP does not question that 'Such new measures undoubtedly are important and desirable from the point of view of patients as well' but in any case makes the inference that new measures should 'be only given to voluntarily admitted patients following an informed consent and never to individuals subjected to coercion'. The latter is reasoned by the circumstance that patients who are admitted involuntarily 'have a dependency relationship with the senior consultant making it very difficult to establish the voluntariness of any consent'. It is stressed that reflections do not intend to indicate that a senior consultant would put pressure on the psychiatric patient in order to make him or her participate. According to MHCWP, reflections mirror a worry that some patients would falsely believe that consent could accelerate coercive measure termination or discharge from hospital. MHCWP concludes that ensuring against such beliefs would be so difficult that it is generally required to prohibit participation of psychiatric patients subject to involuntary admission in any kind of 'experimental treatment no matter the form of the treatment and its purpose and irrespective of any informed consent stated by the patient'.<sup>70</sup> The argumentation is notable but not necessarily very convincing. At least it is doubtful whether the argument is convincing enough to deter a patient's wish to actually participate in a study where he or she may contribute to better future care for the patient him- or herself and for other patients (see below). It is remarkable that the other contents of the 1983 European Council Recommendation received virtually no attention in MHCWP, including the Recommendation's Article 5, subsection 1, stating that 'A patient put under placement has a right to be treated under the same ethical and scientific conditions as any other sick person [...]'

---

69. MHCWP (n 65).

70. MHCWP (n 65). Please note that in Danish law, although a psychiatric patient is voluntarily admitted, criteria for involuntary admission must be met if, e.g., mechanical restraints are used for hours (Soren Birkeland, 'Iværksættelse af psykiatrisk tvangsfiksering: lovgivning og retspraksis', *Juristen* nr. 6 2015 page 210). Also, if a voluntarily admitted patient demands to be discharged, the patient must be detained if coming up to criteria for involuntary admission (ACMP Paras 5 and 10).

### 3.3 *The Danish Act on Research Ethics Review of Health Research Projects*<sup>71</sup>

It is noteworthy that the major formal legislation relating to biomedical research, DARER, does not itself address research involving patients subject to psychiatric coercive measures. With reference to the latter act, however, Ministerial Orders on Research Ethics Review of Health Research Projects have been issued. In the 2011 Ministerial Order version, it is repeatedly stressed that ‘Persons subject to coercion according to the Act on Psychiatric Coercive Measures cannot participate in biomedical research projects, cf. Para 23 (1)’ thereby referring to the ACMP.<sup>72</sup> The wording of the ACMP Para 23 has been unchanged since its introduction. However, in 2012 DARER replaced the earlier ‘*Danish Act on Research Ethics Review of Biomedical Research Projects*’.<sup>73</sup> As it is clear from its title, a change in terminology from ‘*Biomedical Research Projects*’ to ‘*Health Research Projects*’ was thereby introduced. Even though the former act did not explicitly address research in psychiatric patients, the change in scope to ‘*Health Research Projects*’ was followed by a *revision* of the accompanying Ministerial Order. As of the revision, patients subject to coercion according to ACMP were not only prohibited from participating in *biomedical research*, but generally could not ‘participate in health research projects’ (please see Ministerial order 538, Para § 10, section 2).<sup>74</sup> Hence, projects involving psychosocial and non-pharmaceutical interventions which are beyond the narrow area of biomedical testing became prohibited.<sup>75</sup> In the bill preceding the 2012 revision, it was stated that ‘Persons who are subject to detention or compulsion in psychiatry cannot participate as test subjects, cf. Pare 23 of the [ACMP]’. However, the bill made no distinction between ‘biomedical research projects’ and projects with psychosocial and non-pharmaceutical interventions. Apparently, without any further deliberation, all kinds of health research involving patients subject to coercion as ‘test subjects’ were prohibited through the Ministerial Order’s direct reference to ACMP.

---

71. DARER (n 63).

72. Ministerial Order 2011. Ministerial Order on Research Ethics Review of Biomedical Research Projects [Vejledning om anmeldelse m.v. af et biomedicinsk forskningsprojekt til det videnskabs-etiske komitéssystem], (2011).

73. Danish Act on Research Ethics Review of Biomedical Research Projects (see, e.g., [Bekendtgørelse af lov om et videnskabs-etisk komitéssystem og behandling af biomedicinske forskningsprojekter] nr. 69, dated 08/01/1999).

74. Ministerial Order 538. Ministerial Order on Research Ethics Review of Health Research Projects [Bekendtgørelse om information og samtykke til deltagelse i sundhedsvidenskabelige forskningsprojekter samt om anmeldelse af og tilsyn med sundhedsvidenskabelige forskningsprojekter], (2012).

75. Still, research only involving questionnaires and interviews, or register-based studies would be permitted.

The ban has some wide-ranging consequences. To illustrate this, let us imagine a research project aiming to investigate methods to reduce mechanical restraint (MR) duration through conflict-management that must be considered a non-pharmaceutical intervention. When considering the pros and cons of research participation from a patient's perspective, this kind of project might imply a risk of prolonged restraint, no effect, or shortened restraint. According to law, however, prolonged restraint still should be averted by the legal obligation to MR release when legal criteria are no longer met. Contrarily, an overly shortened MR duration may possibly result in patient retaliation and pose a risk to staff safety. This would be countered by the customary safety procedures following MR use (e.g. intensive patient observation). From the perspective of the Nuremberg code (see above), a major intention was to ensure that scientific experiments on patients would never again be allowed against the patients' will. A total ban on research on patients subject to coercion, of course, will totally prevent the problem from arising. However, by not allowing any healthcare intervention studies even when major ethical pitfalls are addressed, both patients and clinical practice seem deprived of the much-needed potential for evidence-based improvement. In our imagined research project, participants may suffer from psychosis, or the patient's 'free power of choice' potentially can be challenged through 'force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion' (cf. Nuremberg Code). This, however, could be counteracted by mandatory prior evaluation by an independent board and requirement for obtaining consent from a LAR (see above). MR is one of the most intrusive of all psychiatric coercive measures and its use in Denmark has already been repeatedly criticized and referred to as amounting to ill-treatment by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT).<sup>76,77,78</sup> One might provocatively argue that current legislation allows for the continuation of objectionable practices while prohibiting any initiatives towards evidence-based MR use reductions.

Other examples would be clinical trials with patients that are involuntarily admitted but are given a new antipsychotic medication or clinical trials with patients that are subject to involuntary medication. In the first example, many

---

76. Birkeland and Gildberg (n 3).

77. Report to the Government of Denmark on the visit to Denmark carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), Strasbourg, 2008.

78. Report to the Government of Denmark on the visit to Denmark carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), Strasbourg, 2012. The CPT upholds that "The maximum duration of the application of mechanical restraint should ordinarily not exceed 6 hours'.

would argue that such patients should be allowed to participate if they seem of ‘sound mind’ to consent, and research could not be meaningfully carried out without their participation. Contrarily, in the other example, some might be more sceptical, while the patient simply does not consent to medication at all. Examples reflect underlying nuances that current Danish legislation does not address.

Because of the need for evidence-based interventions, clinical practice has found other options. One way is ‘evaluation research.’ While research with interventions is not allowed, clinicians can implement interventions and afterwards ‘may wish to evaluate effects.’ However, this solution is a slippery slope as, e.g., no patient consent is required for this kind of ‘hidden clinical research’ that therefore may also tend to be an unlawful circumvention of ACMP.

## 4 Some fundamental questions

### 4.1 *The problem with voluntariness in non-voluntary settings*

Above, the problem with respecting patients’ right to self-determination in regard to research participation when subject to compulsion has been recurrently described. Taken as a whole, however, the question can be raised whether it makes sense to seek consent to participation from an individual whose presence in the psychiatric hospital is involuntary. The problems with obtaining valid consent, obviously, are accentuated in forensic psychiatry or prison settings etc.<sup>79</sup> Still, the Nuremberg Code and the Belmont report perhaps most specifically address the type of problem with obtaining ‘*voluntary consent*’ in persons potentially unable to exercise free power of choice due to the ‘*element of force*’ or ‘*other ulterior form of constraint or coercion*’ (see above). The question of ‘*voluntariness*’ vs. ‘*non-voluntariness*’ may not be as black and white as it seems, though. Hewlett previously emphasized that all decisions to participate in research ‘are made within the context and influence of people or circumstances.’<sup>80</sup> Thus, she argues that in clinical research, consent by patients must often be only ‘partially voluntary’, as ‘it lies within the context of illness or the doctor/patient relationship.’ As a result, the duty of the health care researcher would be to ensure that this partially voluntary consent is ‘adequately voluntary’ as is the case in usual clinic decision-making, and ensuring that a patient is adequately informed before his or her consent is obtained. Perhaps we may a little provocatively argue that the decision on research

---

79. Paul G. Stiles, Monica Epstein, Norman Poythress, John F. Edens, ‘Protecting people who decline to participate in research: an example from a prison setting’ (12) 34 (2) *IRB Ethics and Human Research* 15.

80. Sarah Hewlett, ‘Consent to clinical research—Adequately voluntary or substantially influenced?’ (1996) 22 (4) *Journal of Medical Ethics* 232. DOI: <https://doi.org/10.1136/jme.22.4.232>.

participation must be free of coercion – but not necessarily of the background setting. In line with soft law recommendations mentioned above, Hewlett proposes a number of ways to ensure that consent is valid; for example, the use of independent, trained, and research ethics committee employed advocates. About the ‘*dual role*’ dilemma (caring for patients while also serving the public good) this problem in many instances can be solved with a rule requiring that the person asking for enrolment in the research project must be other than the person responsible for the treatment. Correspondingly, in their discussion of ‘*The Concept of Voluntary Consent*’, Nelson and colleagues problematize the use of ‘*coercion*’ as a term.<sup>81</sup> The authors point out that patients may sometimes feel fear of losing health care benefits, regardless of their powers of resistance to any such influence and whether there is a genuine threat. They argue that coercion necessitates an intention to coerce. However, irrespective of not being ‘*coerced*’, the authors argue that many patients may feel heavily pressured to enrol in clinical trials and this kind of pressure may be felt as intensely as in truly coerced persons. Similarly, ‘offers of promising “treatments” that are primarily research investigations can leave a person with a sense of having no meaningful choice’. The authors point to the fact that influences may be perceived very differently by patients. Influences that some individuals easily resist, or sometimes perhaps even welcome can be felt by others as heavily constraining.<sup>82</sup> Totally preventing any sense of involuntariness in itself can be difficult and needs thorough consideration of environmental as well as individual factors. In any case, requiring prior and continuous research ethic committee approval and use of LARs may serve to work against unethical research conduct and safeguard the individual patient’s interest when deciding whether or not the patient should participate in a research project.

#### *4.2 Does the presence of psychosis totally preclude a patient from making decisions regarding whether or not to be a participant in a scientific investigation?*

Regarding soundness of mind in consenting to research participation, the decision-making capacity of patients with severe mental disorder was recently investigated by Spencer and colleagues.<sup>83</sup> Their meta-analysis showed that decision-mak-

---

81. Robert M. Nelson, Tom Beauchamp, Victoria A. Miller, William Reynolds, Richard F. Ittenbach, and Mary Frances Luce, ‘The concept of voluntary consent’ (2011) 11 (8) *The American Journal of Bioethics: AJOB* 6. DOI: <https://doi.org/10.1080/15265161.2011.583318>.

82. Nelson et al. (n 80).

83. Benjamin Walter Jack Spencer, Gregory Shields, Tania Gergel, Matthew Hotopf and Gareth S. Owen, ‘Diversity or disarray? A systematic review of decision-making capacity for treatment and research in schizophrenia and other non-affective psychoses’ (2017) 47 (11) *Psychological Medicine* 1906. DOI: <https://doi.org/10.1017/s0033291717000502>.

ing capacity for treatment was present in half of their patients.<sup>84</sup> In a subsequent cross-sectional study of psychiatric patients with psychoses, the same research team found that half of the participants had decision-making capacity for *research* while only a third had decision-making capacity for *treatment*.<sup>85</sup> The authors conclude that people with severe mental disorder commonly retain decision-making capacity for non-therapeutic research. The authors emphasize that we, therefore, should abstain from making assumptions about an individual's decision-making capacity for research based on the decision-making capacity for treatment, the degree of illness, etc. as 'To do so risks the continued exclusion of a patient group that we know has high rates of [decision-making capacity for research] and for whom research is urgently needed to improve care.'<sup>86</sup> In patient groups deemed incapable of consenting to research participation, use of independent LARs would serve to ensure patients' interest in decisions about research participation. Still, the evidence regarding psychotic patients' capacity for making decisions about research participation is scant. It is doubtful whether the legislative bodies can (or should) be convinced to change national legislation on the basis of such scant evidence. In this regard, it must be remembered that according to the research ethical standard this is not only about 'consenting'. A valid consent simultaneously must be free and *informed*. If a patient is psychotic and is subject to coercive treatment, it may be quite difficult to know when he or she is reasonably informed and as it was problematized above, ensuring that a consent is truly free in a coercive setting may make it even more difficult. At the same time, it is unclear how and by who those capable of making 'sound' decisions about research participation can be reliably identified among those only half of patients having this capability.

#### 4.3 Need for reconsideration of Danish legislation regarding research in patients subject to coercion

It is remarkable that in their recommendations for human rights in psychiatry, the Danish Institute for Human Rights does not address research issues in psychiatry settings.<sup>87</sup> The Danish Ethical Council (DEC), however, previously emphasized

---

84. Spencer et al. (n 84).

85. Benjamin Walter Jack Spencer, Tania Gergel, Matthew Hotopf and Gareth S. Owen, 'Unwell in hospital but not incapable: cross-sectional study on the dissociation of decision-making capacity for treatment and research in in-patients with schizophrenia and related psychoses' (2018) *The British Journal of Psychiatry: the Journal of Mental Science* 1-6. DOI: <https://doi.org/10.1192/bjp.2018.85>.

86. Spencer et al. (n 85). Finally, the authors conclude that "We should not view in-patient psychiatric settings as a research no-go area and, with suitable safeguards, our results suggest we should recruit in these settings. Just because someone is in hospital with schizophrenia or related psychoses does not mean they are incapable. If we talk to them about research projects, they may want to – and be able to – participate."

that the acquisition of new knowledge to improve quality of healthcare in psychiatry is highly dependent on research.<sup>88</sup> Such research must address, e.g., whether treatment modalities actually work or could be improved. Thus, the Council states that it is of the greatest importance for ensuring a continuous improvement of mental healthcare that opportunities for investigating interventions are satisfactory, including both medication based interventions as well as other modes of intervention. In this regard, the Council advocates that ‘mental health care users should be heard about their preferences regarding research projects and research designs.’<sup>89</sup> It is noteworthy that the Danish Ethical Council upholds a ‘*principle of equality*’ indicating the important point of view that every patient has a fundamental right to participate in promoting health care through research (compare ECR Article 5, subsection 1). Correspondingly, the question remains to be addressed as to why for example physically restrained patients should not be ‘heard about their preferences regarding research projects’ and to what extent the possibility of ‘*undue influence*’ can entirely cancel out the principle of equality.

Munthe and colleagues, among others, have argued that research aiming at improvements of treatment, etc. is a societal priority.<sup>90</sup> While usual informed consent requirements still apply, the total benefit of studies involving mentally disordered offenders, therefore, must be weighed against the risks for research subjects. The authors furthermore argue that very small risks to research subjects may be considered to be acceptable if special measures are taken to protect integrity, if there is a general benefit of better treatment etc., and if patients retain the right to veto participation in research. Taken together with the codes of practice and regulation in the countries described above, the Danish prohibition on health research involving patients subjected to coercion seems to merit a re-evaluation. This re-evaluation should consider the possible harm of patient participation in this kind of research weighed against benefits, while considering the intentions lying behind the Nuremberg code and other human rights principles.

When turning to the Declaration of Helsinki,<sup>91</sup> it should be recalled that the declaration does not preclude the possibility of conducting research involving psychiatric patients when obtaining valid consent from the patient concerned is

---

87. DIHR. [Menneskerettigheder og Tvang i Psykiatrien – Anbefalinger]. Copenhagen: The Danish Institute for Human Rights; 2013.

88. The Danish Ethical Council, DEC. [Psykiatriske patienters vilkår – en redegørelse]. Copenhagen: [Etisk Raad]; 1997.

89. DEC (n 89).

90. Christian Munthe, Susanna Radovic, and Henrik Anckarsater, ‘*Ethical issues in forensic psychiatric research on mentally disordered offenders*’ (2010) 24 (1) *Bioethics* 35. DOI: <https://doi.org/10.1111/j.1467-8519.2009.01773.x>.

91. Helsinki Declaration (n 13), Para 30.

deemed problematic (see above). Rather, the declaration upholds the principle that research can be done if the ‘condition that prevents giving informed consent is a necessary characteristic of the research group’ and valid informed consent can be obtained from a LAR. The Belmont Report principles, similarly, do not preclude research in coerced patients,<sup>92</sup> but simply emphasize that the less burdened should be called upon first to accept any risks of research, except where the research is directly related to the specific conditions of the class involved. According to the Oviedo convention, when patients for one reason or another lack capacity for consent, an intervention can be carried out with the authorisation of his or her LAR.<sup>93</sup> In the same way, our review of legislation in UK as well as Norway and Sweden reveals that in these countries research can be conducted when coming up to ethical review board (and, if necessary, legal representative requirements), as well as conditions regulating which risks are acceptable in research on persons not able to consent.

## 5 Conclusion

The simultaneous use of coercive measure may make obtaining valid consent difficult. However, according to European Council Recommendations there is no ban on research involving psychiatric patients subject to coercive measures.<sup>94</sup> Rather, it is declared that such patients have ‘a right to be treated under the same ethical and scientific conditions as any other sick person’ and that every country must decide whether research should be permitted (see above). When looking at the UN Convention on the Rights of Persons with Disabilities (CRPD), it emphasizes that parties must recognize that all persons are equal before and under the law and shall prohibit all discrimination on the basis of disability and that having a disability (in this context mental disorder) is not a reason to take away persons’ right to make their own decisions (Articles 5, 12, and 14). Correspondingly, the Danish Ethical Council has upheld the point of view that psychiatric patients have a fundamental right to equally participate in promoting health care through research.<sup>95</sup> Furthermore, existing research suggests that even when psychotic in-patients are severely unwell, they commonly retain decision-making capacity for research participation.<sup>96</sup>

---

92. Belmont Report (n 18).

93. Oviedo Convention (n 4).

94. ECR (n 67).

95. DEC (n 89).

96. Spencer et al. (n 86).



When it comes to research in patients subject to coercion, consideration must be paid to what kind of risk patients are exposed to (either physical or integrity), whether patients have capacity to give informed consent, whether a representative can consent on their behalf, whether it is possible to conduct the investigation without enrolling patients in a vulnerable position, and whether the vulnerable group itself would benefit from the research in question. In any case, an absolute requirement is that the patient does not object to research participation and retains a right to withdraw from participation at any time. While acknowledging the patient's right to veto, both ethical guidelines, 'soft law instruments' and national law in the other studied countries seem to agree on requiring ethics committee review (and in some cases consent from a legal representative) as an alternative, rather than simply prohibiting research.<sup>97</sup> There are many interventions used in psychiatric patients subject to coercion that could be improved through research, including those that seek to reduce the use of restrictive practices such as restraint and seclusion. Instead of issuing a total ban on research, practice in other countries demonstrates that review of potential studies by an ethics committee, and requiring consent from a legal representative when patients are deemed incapable of consenting, but with the patient always having a final power of veto, facilitates research with patients subject to coercion. Patient rights can be further strengthened by requiring continuous board review of ongoing research projects. The restrictions on research in this area under current Danish law may be an unfortunate barrier to service quality improvement.

## References

- ACMP. Danish Act on Coercive Measures in Psychiatry, [Bekendtgørelse af lov om anvendelse af tvang i psykiatrien], 1160 (2015),  
 Act 28 April 2017 No. 23 on ethics and integrity in research.  
 Adults with Incapacity (Scotland) Act 2000 asp 4.  
 Arnesen F et al., Agreement on the European Economic Area: A Commentary (Nomos/Hart 2018).  
 Beecher H, 'Ethics and clinical research' (1966) 274 (24) *The New England Journal of Medicine* 1354. DOI: <https://doi.org/10.4324/9781315244426-2>.  
 Belmont Report. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). Belmont Conference Center, Elkridge, Maryland: The National Commission for the Protection of Human Subjects of

---

97. Particularly when research is directly related to the specific conditions of the class involved. Compare, e.g., Belmont principles (n 18).

- Biomedical and Behavioral Research; 1979. DOI: [https://doi.org/10.1007/978-1-4020-5614-7\\_233](https://doi.org/10.1007/978-1-4020-5614-7_233).
- Bernard A. Fischer, 'A summary of important documents in the field of research ethics' (2006) 32 (1) *Schizophrenia Bulletin* 69. DOI: <https://doi.org/10.1093/schbul/sbj005>.
- Bioetikkonventionen. [Bekendtgørelse af Europarådets konvention af 4. april 1997 om menneskerettigheder og biomedicin], (2000).
- Birkeland S, 'Iværksættelse af psykiatrisk tvangsfiksering: lovgivning og retspraksis', *Juristen* nr. 6, 2015.
- Birkeland S and Gildberg FA, 'Mental Health Nursing, Mechanical Restraint Measures and Patients' Legal Rights' (2016) 10 (8) *Open Nursing Journal* 8. DOI: <https://doi.org/10.2174/1874434601610010008>.
- Compulsory Mental Care Act (1991:1128) Chapter 7 Para 5. See also Forensic Mental Care Act (1991:1129).
- Danish Act on Research Ethics Review of Biomedical Research Projects (see, e.g., [Bekendtgørelse af lov om et videnskabetisk komitéssystem og behandling af biomedicinske forskningsprojekter] nr. 69, dated 08/01/1999).
- Danish Constitutional Law (Grundloven; Para 71).
- DARER. Danish Act on Research Ethics Review of Health Research Projects, [Lov om videnskabetisk behandling af sundhedsvidenskabelige forskningsprojekter], (2011)
- Declaration of Hawaii. World Psychiatric Association 'Declaration adopted unanimously by the General Assembly of the World Psychiatric Association at the Sixth World Congress of Psychiatry' (1977) 2 (6096) *British Medical Journal* 1204. DOI: <https://doi.org/10.1136/bmj.2.6096.1204>.
- Declaration of Hawaii / II (approved by the General Assembly of the World Psychiatric Association in Vienna, Austria, on 10th July 1983).
- DIHR. [Menneskerettigheder og Tvang i Psykiatrien – Anbefalinger]. Copenhagen: The Danish Institute for Human Rights; 2013.
- ECR. European Council Recommendation N. 2 concerning the legal protection of persons suffering from mental disorder placed as involuntary patients (Adopted by the Committee of Ministers on 22 February 1983 at the 356th meeting of the Ministers' Deputies).
- Ethical Review Act, ERA (2003:460). The Act concerning the Ethical Review of Research Involving Humans (SFS 2003:460).
- European Convention on Human Rights (ECHR). The Convention for the Protection of Human Rights and Fundamental Freedoms (4 November 1950), Article 5 § 1 (e). DOI: <https://doi.org/10.1093/law:epil/9780199231690/e790>.
- Gambino M, 'Fevered Decisions: Race, Ethics, and Clinical Vulnerability in the Malarial Treatment of Neurosyphilis, 1922–1953' (2015) 45 (4) *The Hastings Center Report* 39. DOI: <https://doi.org/10.1002/hast.451>.
- Guardianship Act. The Act of 26 March 2010 No. 9 relating to Guardianship.
- Guidelines on the right to liberty and security of persons with disabilities (In Supplement No. 55 (A/72/55) in Report of the Committee on the Rights of Persons with Disabilities; Sixteenth session, 15 August–2 September 2016).

- Health Research Act. Act (20 June 2008 No. 44) on Medical and Health Research (accessible at [https://lovdata.no/info/information\\_in\\_Norwegian](https://lovdata.no/info/information_in_Norwegian), accessed 1 February 2020).
- Helsinki Declaration. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310(20):2191-4. DOI: <https://doi.org/10.1002/047086947x.oth1>.
- Hewlett S, 'Consent to clinical research—Adequately voluntary or substantially influenced?' (1996) 22 (4) *Journal of Medical Ethics* 232. DOI: <https://doi.org/10.1136/jme.22.4.232>.
- Justin C. Strickland and William W. Stoops 'Perceptions of research risk and undue influence: Implications for ethics of research conducted with cocaine users' (2015) 156 *Drug and Alcohol Dependence* 304. DOI: <https://doi.org/10.1016/j.drugalcdep.2015.09.029>.
- Lile, H (2019). Paradigmeskifte eller villedende aktivisme? *Kritisk juss.* 45. 49-56. <https://doi.org/10.18261/issn.2387-4546-2019-02-01>.
- Medical Products Act (2015:315).
- Mental Health (Care and Treatment) (Scotland) Act 2003 asp 13. Act of the Scottish Parliament to restate and amend the law relating to mentally disordered persons, and for connected purposes.
- Mental Health Care White Paper (MHCWP). Justitsministeriet. Principbetænkning nr. 1068 (1986) om tvang i psykiatrien. Afgivet af det af justitsministeriet nedsatte udvalg vedrørende sindslidendes retsstilling. Copenhagen; 1986.
- Ministerial Order 2011. Ministerial Order on Research Ethics Review of Biomedical Research Projects [Vejledning om anmeldelse m.v. af et biomedicinsk forskningsprojekt til det videnskabetiske komitéssystem], (2011).
- Ministerial Order 538. Ministerial Order on Research Ethics Review of Health Research Projects [Bekendtgørelse om information og samtykke til deltagelse i sundhedsvidenskabelige forskningsprojekter samt om anmeldelse af og tilsyn med sundhedsvidenskabelige forskningsprojekter], (2012).
- Munthe C, Radovic S, and Anckarsater H, 'Ethical issues in forensic psychiatric research on mentally disordered offenders' (2010) 24 (1) *Bioethics* 35. DOI: <https://doi.org/10.1111/j.1467-8519.2009.01773.x>.
- Nelson RM, Beauchamp T, Miller VA, Reynolds W, Ittenbach RF, and Luce MF, 'The concept of voluntary consent' (2011) 11 (8) *The American Journal of Bioethics: AJOB* 6. DOI: <https://doi.org/10.1080/15265161.2011.583318>.
- Nuremberg Military Tribunals. The Nuremberg Code. 1947. DOI: [https://doi.org/10.1007/springerreference\\_300986](https://doi.org/10.1007/springerreference_300986).
- Oviedo Convention. 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, (1997). DOI: <https://doi.org/10.1093/humrep/12.9.2076>.
- Patient Rights Act. The Act of 2 July 1999 No. 63 relating to Patients' Rights.

- Report to the Government of Denmark on the visit to Denmark carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), Strasbourg, 2008.
- Report to the Government of Denmark on the visit to Denmark carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), Strasbourg, 2012.
- Shepherd, V. (2016). 'Research involving adults lacking capacity to consent: the impact of research regulation on "evidence biased" medicine.' *BMC Medical Ethics*, 17(1), 55.  
DOI: <https://doi.org/10.1186/s12910-016-0138-9>.
- Socialdepartementet. *Psykiatrien, Tvånget och rättssäkerheten – Betänkanda av Socialberedningen*. Stockholm: Socialdepartementet SOU. 1984:64.
- Spencer BWJ, Shields G, Gergel T, Hotopf M, and Owen GS, 'Diversity or disarray? A systematic review of decision-making capacity for treatment and research in schizophrenia and other non-affective psychoses' (2017) 47 (11) *Psychological Medicine* 1906.  
DOI: <https://doi.org/10.1017/s0033291717000502>.
- Spencer, BWJ, Gergel T, Hotopf M, and Owen GS, 'Unwell in hospital but not incapable: cross-sectional study on the dissociation of decision-making capacity for treatment and research in in-patients with schizophrenia and related psychoses' (2018) *The British Journal of Psychiatry: The Journal of Mental Science* 1–6. DOI: <https://doi.org/10.1192/bjp.2018.85>.
- Stiles PG, Epstein M, Poythress N, and Edens JF, 'Protecting people who decline to participate in research: an example from a prison setting' (2012) 34 (2) *IRB Ethics and Human Research* 15.
- Søvig KH, *Medical Law – Norway*, suppl. 92, ed. Herman Nys (Wolters Kluwer 2019).
- The Danish Ethical Council, DEC. [*Psykiatriske patienters vilkår – en redegørelse*]. Copenhagen: [Etisk Raad]; 1997.
- The Danish Healthcare Act (DHA; da. [Sundhedsloven]), 191 (2018).
- The UN Convention on the Rights of Persons with Disabilities (December 13) 2006.  
DOI: [https://doi.org/10.1163/9789004220829\\_010](https://doi.org/10.1163/9789004220829_010). Please also see General Comment No.1 (2014).