KU LEUVEN

FACULTY OF MEDICINE

Masterpaper

Walk the line

How to balance access to research and protection of the prisoner?

Mathijs van Westendorp

Supervisor: prof. dr. Steven Lierman

June 2017

Table of Contents

I. Introduction

History is marked with unethical research resulting in the abuse and exploitation of prisoners.[1] Several factors contribute to the vulnerability of the prison population for abuse and exploitation, such as the higher prevalence of (mental) health problems,[2] the coerciveness of the prison environment, and penological visions in which prisoners lose (some of) their rights.[3] Because of the historic precedent of abuse, prisoners are often excluded from participating in research, thereby protecting them from abuse and exploitation. However, science and scientific research can lead to benefits for the individual, the community and the public. Consequently, the access to the benefits of science is a human right that is found in several treaties.[4] According to the contemporary penological philosophy of normalization, prisoners retain their (human) rights unless the limitation of a right is justified because limitations are necessary and proportional considering the special circumstances in prison.[5] Therefore, it is not possible to a priori justify the exclusion of prisoners from research, as this will violate their 'right to science'.[6] There has to be a justified balance between the access to research and the protection of the prisoner.

The discussion of the topic of research involving prisoners starts with the historical context for research involving prisoners in section II after which the right to science is discussed in section III. In section IV, the conditions and requirements in the Clinical Trials Regulation for the protection of research subjects are considered in relation to the specific difficulties of research involving prisoners. Specifically, the possibility of an informed consent in prison will be discussed considering the informedness, comprehension and voluntariness. In the discussion of the voluntariness, the case law of the European Court of Human Rights will be analysed empirically to show the importance of the prison conditions for the possibility of a non-coerced informed consent. In section V, the possibilities of a justified balance between access to research and protection of the prisoner will be discussed.

II. Historical context of research involving prisoners

A. Abuse and exploitation throughout history

Over the course of history there have been numerous scandals and incidents concerning research involving prisoners. Although there is some documentation on the use of prisoners in research prior to the Second World War,[7] it was considered that prisoners were not worthy of contributing to research, as the participation was considered to be a special moral privilege.[8] However, the Second World War led to the substantial involvement of prisoners in research. One of the reasons was the war effort in the Pacific War Theatre, which brought the need for research on the indigenous infectious diseases.[9] The Battle of Britain led to the research to establish the most effective way of

[1] In this paper prisoner is defined as a person deprived of liberty who is not legally incapacitated and does not have an illegal status. A broader definition would give rise to additional complexities such as the provision of healthcare to those with an illegal status, which is not within the scope of this paper.
[2] Fazel and Baillargeon, "The Health of Prisoners"; Fazel et al., "Mental Health of Prisoners."
[3] According to the principle of less eligibility, the circumstances in prison should be of a certain minimal overall quality, but not exceed an upper limit defined as the standard of living in a comparable situation in the free society meaning the socio-economic situation of the lower working class.
[4] Art. 27 UDHR, art. 15(1)(b) ICESR, art. 13 Charter of Fundamental Rights of the European Union
[5] Maes, *Van Gevangenisstraf Naar Vrijheidsstraf*, 174.
[6] See part III for the definition and discussion of the right to science.
[7] Unethical research most certainly did take place before the Second World War, see Hornblum, "They Were Cheap and Available," 1438.
[8] McCarthy, "Experimentation on Prisoners: The Inadequacy of Voluntary Consent," 58.
[9] Hornblum, "They Were Cheap and Available," 1438–39.

treating crew members of the German air force who were shot down above the cold waters of the North Sea.[10] After the end of the war the Nazi experiments in the concentration camps resulted in the Nazi Doctor's trials.[11] The goal of these trials was not merely to prosecute the defendants but to demonstrate to the world that sadistic experiments and the ideologies leading thereto are unacceptable.[12] As a consequence the Nuremberg Code was formulated.[13] In addition, the universal declaration of human rights (UDHR) were drawn up, re-emphasizing the rights and dignity of all human beings as a result of the lessons learned from the Second World War. The use of science in technology in the atrocities of the Second World War prompted the active participation of the scientific community in the universal human rights debate, culminating in the inclusion of the right to science in art. 27 UDHR, which is fundamental to human dignity and autonomy.[14]

The Nuremberg code consists of only ten rules but has inspired further legislation on the research involving humans. The most important principles that the Code introduced are the informed consent, the beneficence of the research, minimization of risk and the proportionality of the risk to the benefits. Even though it had no legal force, the Nuremberg Code, in combination with the atrocities of the Second World War, meant that in Europe there was reluctance to allow any human research with prisoners.[15] The effect of the Nuremberg code and the Second World War was different in the USA, where research involving prisoners not only continued but increased significantly. The reasoning was that the Nuremberg code was only applicable in Nazi context as the Code was for barbarians,[16] and not pertinent for research in USA.[17] Therefore, it has never established a foothold in institutions in the USA.[18] Subsequently, there is little mention of the code in case law.[19] In the USA, the pharmaceutical industry relied heavily upon research involving prisoners for its trials. [20] This reliance was partly due to the increased demands on the licensing of medicinal products by FDA,[21] leading to an American reservation on the ban of medical experiments in captive groups.[22] In addition, the Vietnam War spurred the patriotically inspired research participation.[23]

The formulation of the first revision of the declaration of Helsinki in 1964, which was greatly influenced by the Nuremberg Code, exemplifies the different ethical views and cultural influences

[10] Berger, "Nazi Science — The Dachau Hypothermia Experiments," 1435.
[11] "Records of the United States Nuernberg War Crimes Trials United Sates of America v. Karl Brandt et Al. (Case I)," 3.
[12] Telford Taylor, "Opening Statement of the Prosecution, December 9, 1946," reprinted in The Nazi Doctors and the Nuremberg Code, ed. George J. Annas and Michael A. Grodin (Oxford University Press, 1992), p. 68.
[13] "Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.
[14] Report of the special rapporteur in the field of cultural rights on Copyright policy and the right to science and culture, A/HRC/28/57 p. 3.
[15] An example of this is the low number of requests for research involving prisoners in the UK, see Bossuyt, "Categorical Rights and Vulnerable Groups.".
[16] Moreno, "Reassessing the Influence of the Nuremberg Code on American Medical Ethics," 349–50.
[17] Ibid., 357–58; Hornblum, "They Were Cheap and Available," 1438; This is a doubtful claim considering the accusations of similar medical practices, of which the Nazi Doctors were tried, occurring in the USA as well as in Nazi Germany, ibid., 1437.
[18] Moreno, "Reassessing the Influence of the Nuremberg Code on American Medical Ethics," 357.
[19] Ibid., 350.
[20] Lederer, "Research without Borders: The Origins of the Declaration of Helsinki," 24.
[21] DHEW report 1976 p. 1
[22] Lederer, "Research without Borders: The Origins of the Declaration of Helsinki," 16.
[23] Reiter, "Coercion and Access to Health Care," 30.

between the USA and Europe.[24] The American influence led to a more flexible subject's consent in the declaration of Helsinki than the Nuremberg code.[25] After the Second World War, the de facto ban on research involving prisoners resulted in the absence of reported scandals regarding research involving prisoners in Europe. However, the prevalent high use of prisoners in research did lead to issues in the USA.

While there was much research happening in the USA involving prisoners, this was not public knowledge until the public was informed of the Tuskegee syphilis experiment, the Holmesburg prison scandal and other unethical experiments through, among others, the study of Henry Beecher and Jessica Mitford's Kind and Usual Punishment.[26] In the Tuskegee syphilis experiment the subjects were unknowingly withheld treatment for syphilis, which came available during the experiment, in order to study the effect of the disease's progression.[27] The public outcry due to the exploitative research ended prison experimentation in the USA[28] and led to the formulation of the Belmont report on ethics of research involving prisoners by National Commission for the Protection of Human Subjects of Bio-medical and Behavioral Research, established in 1974 under the National Research Act.[29] The Belmont report resulted in the revision of legislation on human experiments involving prisoners in 1978, entailing a Federal ban on research involving prisoners.

B. A reappraisal of the balance of the risks and the benefits of scientific research

History shows a lack of respect for the human dignity leading to a lack of protection against exploitation and abuse and an inequitable distribution of the risk and benefits. For the equitable distribution it is essential to ensure reasonable, non-exploitative, and well-considered procedures that are administered fairly and equally. It is problematic when prisoners bear the grunt of the risks of the research without much prospects of the benefits. Therefore, differences in the distribution of burdens and benefits can only be justifiable when they are based on morally relevant distinctions between persons, i.e. not discriminatory. The inappropriate inclusion into research should be prevented when the legal and ethical requirements for the protection of research subjects are not fulfilled. Concerning inappropriate exclusion, researchers have a duty to only exclude groups or communities when it is justified.[30] Whether limitations of the opportunity to participate in scientific research are justified, depends on the possibility to meet the requirements protecting the research subject in a prison environment, in conformity with the aforementioned principle of normalization.

While these abuses evidently show the risk of research involving prisoners, the de facto ban on research involving prisoners means that the prison population is largely devoid of the benefits of scientific research. Presumably the past exploitation and abuse of prisoners in research have led to an overcorrection towards protection.[31] It is an obligation of the State to ensure an equitable distribution of benefits and risks, which can be achieved by facilitating and promoting ethical, safe and responsible research benefiting vulnerable groups, such as prisoners. Considering the above, a reappraisal of the balance between access and protection in research involving prisoners is desirable.

[24] Lederer, "Research without Borders: The Origins of the Declaration of Helsinki," 11–12 & 19–20.
[25] Moreno, "Reassessing the Influence of the Nuremberg Code on American Medical Ethics," 357.
[26] Lerner, "Subjects or Objects?," 1806.
[27] https://www.cdc.gov/tuskegee/timeline.htm
[28] Hornblum, "They Were Cheap and Available," 1439.
[29] US Public Law 93-348.
[30] CIOMS Guideline 12
[31] Elger, "RESEARCH INVOLVING PRISONERS," 236.

III. The right of prisoners to participate in scientific research

The right to science is recognized as a human right in international law. According to the UDHR everyone has the right to share in scientific advancement and its benefits.[32] The ICESR builds on this stating everyone – not only the scientific community[33] – has the right "[t]o enjoy the benefits of scientific progress and its applications".[34] The scope and requirements for the right to science is not systematically defined by the human rights community, and it is not clear what the exact obligations of States are.[35]

The basis for the right to science is the protection of the dignity of human beings.[36] According to the Charter of Fundamental Rights of the European Union, human dignity is inviolable and must be respected and protected.[37] Prisoners and those deprived of their liberty must be treated with respect for the inherent dignity of the human person.[38] The respect for human dignity protects humans from being treated as an object by the state or fellow citizens.[39]

A clinical trial may be conducted only if the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests.[40] States have the obligation to take the necessary steps to achieve the full realization of the right to science,[41] and respect the freedom indispensable for scientific research.[42] In vulnerable groups there is an increased duty on States as these groups face increased difficulty in effectuating their rights themselves. Therefore, States have to take measures to extend the benefits of science and technology to all strata of the population.[43]

Although the wording of the right in the treaties is ambiguous on whether it pertains to the development of scientific progress, the effectiveness of the right to science requires an interpretation that includes the development of science as well as access to it.[44] According to the special rapporteur of the UN Human Rights Council the normative content of the right to science includes four parts: (a) access by everyone without discrimination to the benefits of science and its applications, including scientific knowledge; (b) opportunities for all to contribute to the scientific

[32] Art. 27 UDHR.
[33] Claude, *Science in the Service of Human Rights*, 35–36.
[34] Art. 15(1)(b) ICESR. In addition, art. 13 of the Charter of Fundamental Rights of the European Union states: "scientific research shall be free of constraint".
[35] Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," 3. This is partly because a human right based approach towards the access to science conflicts with the classic intellectual property law approach. The discussion on this interesting, but difficult, balance between access to science and the right of creators to benefit from their creations, i.e. intellectual property right, is not part of this paper as it is not at stake in relation to the participation of prisoners in scientific research.
[36] Recital 2 Clinical Trials Directive; Report on the right to enjoy the benefits of scientific progress and its applications, A/HRC/20/26, p. 3.
[37] Art. 1 Charter of Fundamental Rights of the European Union.
[38] Art. 10(1) ICCPR
[39] COM(2012) 169; SWD(2012) 85 p8; Art 3 of the charter right to integrity of person
[40] Art. 3 Clinical Trials Regulation.
[41] Art. 15(2) ICESR, considering the lack of a systematic definition of the right to science, the exact meaning of 'full realization' is unclear.
[42] Art. 15(3) ICESR.
[43] Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, resolution 3384 (XXX) of 10 November 1975
[44] Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," 9; Shaver, "The Right to Science and Culture," 171.

enterprise and freedom indispensable for scientific research; (c) participation of individuals and communities in decision-making and the related right to information; and (d) an enabling environment fostering the conservation, development and diffusion of science and technology.[45] Failing to facilitate the opportunity to contribute to, and participate in, science limits its development and its benefits, thereby impairing the right to science. The development of empirical science and scientific research, especially clinical trials, requires research subjects that represent the population under investigation.[46] Representative research subjects are not generic and interchangeable, they have specific characteristics,[47] meaning research on diabetes at one point in the research requires trials involving persons inflicted by diabetes. Therefore, it can be essential for the validity of research that it is conducted in a vulnerable group, e.g. the research on insomnia in the prison environment.

Besides the access component of the right to science, States have the duty to protect the research subjects from abuse, [48] which can limit the access to science especially in vulnerable groups. To respect the human dignity and the right to science of prisoners, an equitable balance has to be found between the respect for the autonomy of humans and the protection against abuse and exploitation.[49] The respect for the autonomy of humans requires that the personal choices of someone with the capacity for self-determination should be respected. Contrarily, the protection against harm and abuse requires that those with an impaired or diminished autonomy are safeguarded from the inappropriate inclusion in research, including the protection against coercion of those in a vulnerable position. These requirements can simultaneously lead to the (moral) duty to provide access to research and the duty to protect from abuse. The dilemma is to find the right balance between self-determination and protection. This culminates in the question what level of protection of prisoners as research subjects can be guaranteed in accordance with relevant rules and legislation.

IV. The protection of prisoners in scientific research

Clinical trials are a type of research that involve researching an active intervention in the human being for the (therapeutic) effects of medicinal products. In general, clinical trials entail higher risks compared to other types of research and, because of the history of abuses in a clinical trials setting, this type of research is the most regulated. The purpose of the regulation of clinical trials is to guarantee the protection of the research subject.[50] The protection of the research subject is essential for all types of research, meaning the requirements for clinical trials are relevant for other types of research as well.

In the European Union there are two important legislative texts regulating clinical trials. The European Directive 2001/20 on Clinical Trials (the Directive) and its successor: the EU Clinical Trials Regulation 536/2014 (the Regulation), which shall apply six months after the Commission has given

[45] Report on the right to enjoy the benefits of scientific progress and its applications, A/HRC/20/26.
[46] Recital 14 of the EU Regulation 536/2014, hereafter: Clinical Trials Regulation.
[47] The science of representative research subject is a science in and of itself. Sampling theory is a sub-discipline of statistics, which is concerned with the selection of a subset that is a representative estimation of the whole population.
[48] Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," 21.
[49] Pont, "Ethics in Research Involving Prisoners," 192; Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," 12.
[50] Art. 3 Clinical Trials Regulation.

notice that it is satisfied that the EU portal and EU database are fully functional.[51] The deliberate choice for a Regulation as the legislative instrument for the harmonization of the rules on clinical trials is in part motivated by the "experience [...] that Member States misused the transposition process in order to introduce additional procedural requirements".[52] The basis of the Regulation is the competency of the EU to regulate the internal market for ensuring a high level of human health protection in the EU.[53] However, some authors warn for the lack of clarity and thoroughness of the Regulation for the adequate protection of vulnerable research participants,[54] such as prisoners.

The Regulation incorporates general conditions that have to be met to guarantee the protection of research subjects in a clinical trial.[55] According to the Regulation the "[i]nterests of the subject should always take priority over all other interests",[56] and contains several general requirements for clinical trials involving humans. It requires that every experiment is in conformance with good clinical practices,[57] i.e. of good ethical and scientific quality, which can be considered as ethical standards or guidelines for conducting research. In addition, the research must be scientifically sound[58] and relevant[59] with a positive benefit to risk ratio, i.e. the risks are reasonable in the light of the expected benefits.[60] The rights, safety, dignity and well-being of the subject prevail above the therapeutic and public health benefits.[61] There may be no alternative where the benefits outweigh the risks compared to the research.[62] The research subjects must participate out of free will and give their informed consent.[63] The research may inflict no harm, which includes the respect for privacy and the physical and psychological integrity of the research subject.[64] There needs to be a positive decision by an ethical committee[65] and the research must be under the supervision of a qualified person/investigator[66] who is compliant with the rules concerning liability and insurance.[67] In the evaluation of the benefits of research the benefit to the individual, but also to the population of which the individual is a member, should be taken into account.[68] The involvement of prisoners in research has significant implications on the informed consent, the assessment of the benefit to risk ratio and the respect for the research subject.

[51] Art. 99 and art. 82 Clinical Trials Regulation.
[52] COM(2012) 369 final para. 3.13.
[53] Art. 168 TFEU.
[54] Gennet, Andorno, and Elger, "Does the New EU Regulation on Clinical Trials Adequately Protect Vulnerable Research Participants?," 929.
[55] Art. 28 Clinical Trials Regulation.
[56] Art. 3 Clinical Trials Regulation.
[57] Art. 47 Clinical Trials Regulation.
[58] Art. 3(b) Clinical Trials Regulation.
[59] Art. 2 Clinical Trials Regulation.
[60] Art. 28(1)(a) Clinical Trials Regulation.
[61] Art. 3 Clinical Trials Regulation.
[62] Art. 28(1)(a & e) Clinical Trials Regulation.
[63] Art. 29 Clinical Trials Regulation.
[64] Art. 28(1)(d) Clinical Trials Regulation.
[65] Art. 4 Clinical Trials Regulation.
[66] Art. 49 & 73 Clinical Trials Regulation.
[67] Art. 76 Clinical Trials Regulation.
[68] Art. 6(1)(b)(i) Clinical Trials Regulation.

Although no provisions in the Regulation apply specifically to prisoners,[69] the Regulation provides that specific considerations shall be given to the assessment of trials in specific groups.[70] However, Member States can "maintain additional national measures" for specific groups including "persons deprived of liberty".[71] The notion 'Maintain' (DE: 'beibehalten', FR: 'maintenir') entails that Member States cannot introduce new measures when the Regulation is in force. Despite the legal form of a Regulation, there remain areas where the regulatory framework at EU level must still be complemented by national law, and where the objectives of the Regulation are limited. While the Regulation has a chapter dedicated to the protection of (vulnerable) research subjects and the requirements of informed consent,[72] it only gives the general requirements that have to be satisfied. The Regulation does not harmonise the details of informed consent, as the details of informed consent are a sensitive ethical subject to be elucidated by the Member States.[73] Therefore, the Regulation does not necessarily prohibit Member States from invalidating the informed consent by prisoners for reasons of ethics. However, this is not a blank cheque to exclude prisoners from participating in research. Because, as a consequence of the right to science, the limitation of the right to participate in scientific research must be justifiable.

A. Informed consent

The informed consent is essential for research and part of the necessary protection of research subjects. From the requirements on the informed consent in the Regulation, three elements can be distilled: (A) informedness, (B) comprehension, and (C) voluntariness. Using these three elements, the relevant aspects of informed consent for prisoners participating in research will be discussed.

(1) Informedness

The informedness is the duty to provide information, an essential aspect of informed consent in regular research, which entails that a certain minimal level of information must be provided to the research subject. The Regulation states the information that a research subject must receive has to be comprehensive, concise, clear and relevant.[74]

As a consequence, it is essential to inform prisoners of the relevant aspects and consequences of conducting the research in the prison environment. Prisoners must be informed on the separation between the research, the prison administration and penitentiary healthcare. The information must be given that participation in research will not lead to preferential treatment, both during the prison sentence and afterwards, and that (a refusal to) participation does not influence the duration and/or quality of the prison sentence.

The prison environment poses specific challenges concerning the privacy and confidentiality of prisoners as research subjects. Concerns over their privacy can be a reason for prisoners to refrain from participating in research.[75] Considering that the facilities must be suitable for conducting a

[69] Amendment 188 introducing article 31b, containing specific provisions for the vulnerable group of prisoners comparable to the articles on minor and pregnant women was not incorporated in the final version of the Regulation.
[70] Art. 10(4) Clinical Trials Regulation. In working documents, persons deprived of liberty are named as a vulnerable groups along with minors, pregnant.
[71] Art. 34 Clinical Trials Regulation.
[72] Chapter V of the Clinical Trials Regulation on the protection of subjects and informed consent.
[73] COM(2012) 369 final p. 13.
[74] Art. 29(2) Clinical Trials Regulation.
[75] Christopher et al., "Enrolling in Clinical Research While Incarcerated," 26.

clinical trial,[76] which includes a sufficient level of privacy and data protection considering the Data Protection Directive,[77] it is important that prisoners are properly informed on the privacy implications and the inherent limitations of providing privacy in a prison environment.

(2) Comprehension

It is essential to the validity of informed consent that the information is sufficiently understood by the research subject. According to the Regulation the given information must enable the subject to understand the relevant aspects concerning the clinical trial, where the information must be understandable to a layperson.[78]

The prison demography makes asserting the comprehension of the information given to prisoners as potential research subject challenging. One of the reasons is the higher prevalence of mental health problems.[79] Although the negative impact of psychiatric symptoms may not be as problematic as would be expected.[80] Additionally, the prison population consists of prisoners with different nationalities, not necessarily proficient in the language of the nation in which they are imprisoned.[81] The limits of the language proficiency, and higher risk of misunderstanding, should lead to increased scrutiny in the assessment of the comprehension of the relevant information by these prisoners. As will be discussed under voluntariness, the prisoner must comprehend that participation in research should not be a means to obtain that which should be provided by the prison administration in the first place.

Prisoners must understand what the goals and aims of a research are, because in prison specifically there is an increased risk of the 'therapeutic misconception'.[82] The therapeutic misconception arises because research subjects are generally also patients, making it difficult for research subjects to differentiate between the therapeutic physician–patient relationship and their relationship to the physician in their role as researcher. This is specifically important for prisoners because the prison environment further complicates relationships because of the dependence of prisoners and the diverging interests of other stakeholders in prison. Despite careful explanation of the research's goals, prisoners may believe that the research they are participating in has therapeutic purpose, as it can be difficult for the research subject to understand that the primary objective of their participation in research is not their individual benefit but to generate new scientific knowledge by answering a specific research question.[83] This problem in comprehension can potentially be a threat to the validity of informed consent.[84]

[76] Recital 45, art. 50 Clinical Trials Regulation.
[77] Art. 28(1)(d) Clinical Trials Regulation referring to Data Protection Directive 95/46/EC.
[78] Art. 29(2) Clinical Trials Regulation.
[79] Fazel and Baillargeon, "The Health of Prisoners"; Fazel et al., "Mental Health of Prisoners."
[80] Moser et al., "Coercion and Informed Consent in Research Involving Prisoners," 8.
[81] According to the World Prison Brief of 2008, 18,9% of the total prison population in the EU were foreign prisoners.
[82] Appelbaum, Roth, and Lidz, "The Therapeutic Misconception," 321.
[83] Christopher et al., "An Exploratory Study of Therapeutic Misconception among Incarcerated Clinical Trial Participants," 24.
[84] Del Carmen and Joffe, "Informed Consent for Medical Treatment and Research," 639.

(3) Voluntariness

Voluntariness, "the quality or state of being free in the exercise of one's will",[85] depends both on the intrinsic capability of the individual and on the coerciveness of the environment.[86] The intrinsic capability of the individual for voluntary informed consent is the subject's decisional capacity, which refers to the capability to protect one's own interests. The coerciveness of the environment consists of circumstances that can impede voluntariness such as a lack of alternative means of obtaining medical care or other necessities, or being a junior or subordinate member of a hierarchical group. The question on voluntariness is especially relevant for prisoners considering both the question on the intrinsic capacity of prisoners to provide informed consent and the question on the coerciveness of the prison environment and its influence on the individual prisoner.

Decisional capacity of prisoners in informed consent

The decisional capacity to provide informed consent is inversely linked with the vulnerability to coercion. While the demography of the prison population with high illiteracy rates, low education, and higher prevalence of mental health problems does lead to a heightened susceptibility of coercion, the a priori exclusion of the prison population as a whole would not be proportional.[87] Prisoners, in principal, are adults with decisional capacity considering that some degree of decisional capacity is a necessary condition to be convicted to a prison sentence. In addition, in the philosophy of normalization, prisoners should be presumed to be able to effectuate their rights unless there are strong indications to the contrary.

It is generally assumed that "persons in custody are in a vulnerable position",[88] meaning that prisoners are in a vulnerable situation, but are not vulnerable subjects, i.e. not inherently vulnerable.[89] Prisoners should be assumed to be able to have decisional capacity, which can be unduly influenced in the prison environment, prohibiting the voluntariness of the informed consent.[90]

Coerciveness of the prison environment

According to the Regulation there may be no undue influence exerted on subjects to participate in clinical trials.[91] For voluntariness it is necessary that autonomous deliberation is possible, meaning there need to be venerable options, which are sometimes perceived as lacking in prison.[92] Therefore, it is important to assess the possible undue influences, and potential coercive effects, of the prison environment.

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[85] Webster dictionary

[86] See also: Gennet, Andorno, and Elger, "Does the New EU Regulation on Clinical Trials Adequately Protect Vulnerable Research Participants?," 926. where vulnerability consists of two elements: exposure to a specific risk and susceptibility of the exposed person to this precise risk.

[87] Elger, "RESEARCH INVOLVING PRISONERS," 235.

[88] ECtHR (GC), Salman v. Turkey, 27 June 2000 (Appl. No. 21986/93).

[89] Pont, "Ethics in Research Involving Prisoners," 190; Gennet, Andorno, and Elger, "Does the New EU Regulation on Clinical Trials Adequately Protect Vulnerable Research Participants?," 927. See also CIOMS p. 65 where prisoners are referred to as a group may also be considered vulnerable. Children, for example, are seen as vulnerable in and of themselves.[89]

[90] Provisions in the Clinical Trials Regulation on incapacitated subjects are equally applicable to incapacitated prisoners.

[91] Art. 28(1)(h) Clinical Trials Regulation.

[92] Christopher et al., "Enrolling in Clinical Research While Incarcerated," 24–25.

The oppressive nature of the prison regime with little absolute rights for prisoners gives rise to a system of favours which induces dependency of the prisoner to the prison administration.[93] In the prison as a 'total institution' all aspects of prison life are under the control of one authority, the prison administration. Prisoners must adhere to the prison schedule, are subject to the prison's rules and should be provided in all their needs by the prison administration.[94] The prison environment is characterized by a lack of distinction between norm and fact,[95] leading to a profound influence of the prison administration on the effective legal position of prisoners.[96] Therefore, research involving prisoners requires the cooperation of the prison administration. This can lead to dual loyalty, a divergence of interests which arises when an actor has simultaneous obligations, express or implied, to a beneficiary and to a third party, often the state.[97] This problem can arise in a prison environment because the prison administration can have other interests, such as the prison's security and order, which can eclipse the interest of the individual prisoner.[98] Researchers can be subject to dual loyalty because they depend on prison administration for access to the prisoners participating in the research. The aforementioned therapeutic misconception can lead to an overestimation by the prisoner of the researchers' concern for his interests, easing the pursuit of other interests. The prison physician should be cautious when obtaining informed consent and should defer obtaining informed consent to an independent physician if the subject is in a dependent relationship with the prison physician.[99] Potential subjects can be dissuaded by correctional officers or medical staff because they can be (perceived as) biased against a research study, because of extra workload or ethical preconceptions, i.e. the opinion that research should not be conducted in prison.[100]

Monetary remuneration

The Regulation forbids the undue influence through the use of financial incentives. [101] One of the problems of monetary remuneration of prisoners is that it is provided as a compensation, to cover the costs made by a research subject to participate in the research.[102] The (monetary) costs of participation is limited for prisoners as they are, or should be, provided in their needs by the prison administration.[103] In addition, the difference between prison economy and non-prison economy makes the fair distribution of remuneration difficult. Providing equal remuneration for both prisoners and non-prisoners may be an undue influence on prisoners to participate and could lead to other problems in prison. Research on the motivation by remuneration is conflicting on the question whether prisoners are more likely to be motivated by compensation than non-prisoners.[104] While Moser et al. found that prisoners were significantly less likely to be motivated by compensation, they still chose not to provide the same direct cash remuneration the members of the control group (non-

[93] Kelk, *Nederlands detentierecht*, 32.
[94] Ibid., 28.
[95] Ibid., 34–35.
[96] Ibid., 33.
[97] Dual loyalty is not only found in a (prison) health care context but also in politics, see Baron, "The Problem of Dual Loyalty.".
[98] Kelk, *Nederlands detentierecht*, 31.
[99] Art. 10 Declaration of Helsinki.
[100] Christopher et al., "Enrolling in Clinical Research While Incarcerated," 26.
[101] Art. 28(1)(h) Regulation.
[102] Art. 31(1)(d), art. 32(1)(d), art. 33(d) Regulation, allow only for compensation for expenses and loss of earnings directly related to the participation in the clinical trial in those vulnerable groups.
[103] Kelk, *Nederlands detentierecht*, 28.
[104] 60% of subjects were motivated by compensation, see Christopher et al., "Enrolling in Clinical Research While Incarcerated," 24. Compared to controls, prisoners were significantly less likely to be motivated by compensation, see Moser et al., "Coercion and Informed Consent in Research Involving Prisoners," 6.

prisoners) received to the participating prisoners for fear of undue influence.[105] The payment of an equal monetary remuneration to prisoners and non-prisoners is conflicting with principle of less eligibly and limits the deterrent effect of prison because prisoners, due to their lower costs of living, would comparatively gain more from the same monetary remuneration.

Prison conditions

The behaviour of prisoners can influence the length of the remainder of their prison sentence.[106] To prevent coercion, it must be clear that participation in research is of no influence on the prison sentence. Otherwise not participating in research could be perceived as a non-venerable option, because it would seem that the prisoner is uncooperative. These forms of non-monetary remuneration can be coercive, especially when it must be used to compensate for subpar prison conditions. To limit the coerciveness of the prison environment, an adequate level of the general prison conditions is essential.[107] Some authors find the prison environment to be inherently coercive even under sufficient quality of living conditions. However, this claim is mainly supported by examples of subpar prison conditions such as the inability to obtain adequate healthcare. [108] The rationale is that if the healthcare provided to prisoners is not adequate, participating in research can be perceived as a possibility to get access to adequate healthcare service from university researchers and other professional healthcare providers. Consequently, prisoners can see proper healthcare provided by researchers as a form of remuneration.[109]

In conclusion, bad prison conditions can increase the dependency of prisoners to third parties and increase the coerciveness of the prison environment when participating in research is the only perceived method of providing in the basic needs. The prison conditions influence the coerciveness of the prison environment and consequently the voluntariness of the informed consent. Therefore, the relevant standards on prison conditions must be met for the possibility of a voluntary informed consent.

B. Empirical analysis of ECtHR case law on the prison conditions in the EU

There are different sources on the standards of prison conditions.[110] The European Prison Rules (EPR) are especially relevant as they are recognized in European Court of Human Rights' (ECtHR) case law as (non-binding) standards of prison conditions.[111] These standards contain rules on the basic prison conditions such as the admission, allocation and accommodation, hygiene, clothing and bedding, nutrition, contact with the outside world, prison regime, and health care.

It is commonly assumed that overcrowding is a contributing factor to the problems concerning the aforementioned aspects of good prison conditions, especially the adequate accommodation, privacy, hygiene and bedding. When prison conditions are subpar, this can entail a violation of the prohibition of torture in art. 3 ECHR on the grounds of degrading punishment, degrading treatment, inhuman

[105] Moser et al., "Coercion and Informed Consent in Research Involving Prisoners," 3.
[106] The so called good conduct time or time off for good behaviour.
[107] Reiter, "Experimentation on Prisoners: Persistent Dilemmas in Rights and Regulations," 534, 546–47.
[108] Wener, "Not Situated to Exercise Free Power of Choice," 380.
[109] Reiter, "Experimentation on Prisoners: Persistent Dilemmas in Rights and Regulations," 530.
[110] ECtHR (grand chamber) CASE OF MURŠIĆ v. CROATIA no. 7334/13 contains an overview of relevant standards that the ECtHR considers.
[111] In 2011 387 cases mention the European prison rules (COM(2011) 327 final p. 12).

punishment, inhuman treatment and torture.[112] An analysis of the ECtHR case law concerning these violations can give an insight into the level of the prison conditions in different European States.

(1) Overcrowding

To assess the degree of overcrowding in the EU, the Council of Europe's Annual Penal Statistics[113] on overcrowding are used. The Annual Penal Statistics contains data provided by the individual European states on their overcrowding percentage from 2000 to 2015. This data is provided by the European states themselves, so to prevent a reporting bias in individual States we consider groups of States. Considering the scope of the Clinical Trials Regulation, our analysis excludes non-EU States and we only include data on whole States, not parts or provinces. The average overcrowding per state over the whole period is used to group them into a high prison density and a low prison density group (see Table 1). The average prison density per group (pd_g) is calculated by summation of the prison density per State (pd_{state}) divided by the total number of States (s) in the group.

$$pd_g = \frac{\sum pd_{state}}{s} \tag{1}$$

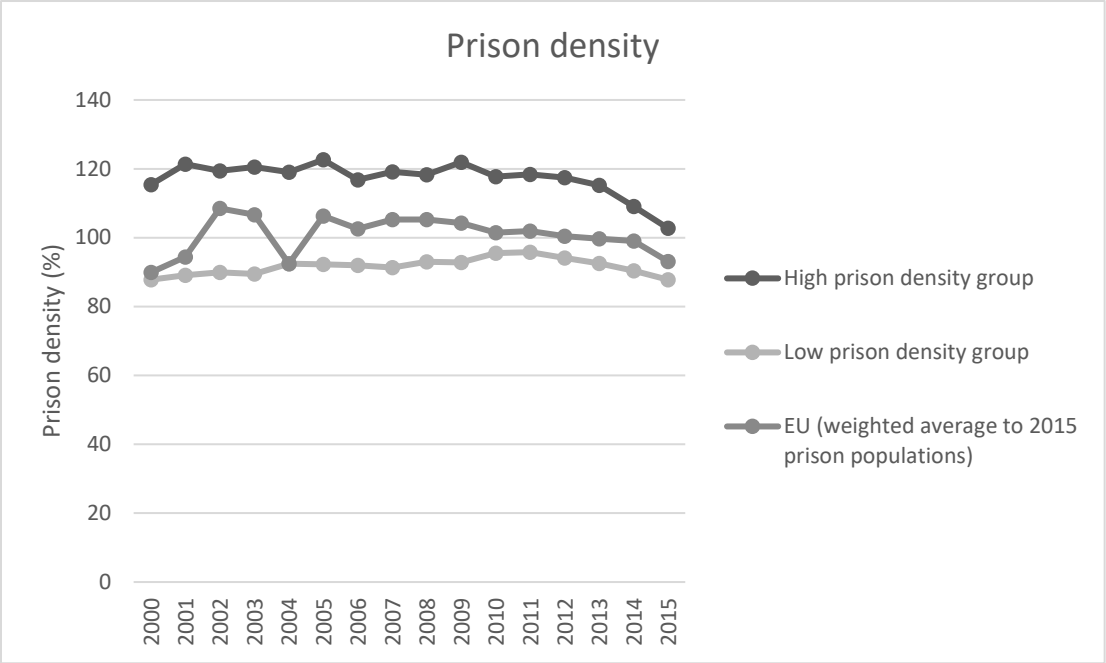
This does not account for the different sizes of the prison populations per State, meaning that the effect of a change in the average density in a State with a large prison population is underestimated and vice versa. Therefore, to account for under- or overestimation, the weighted average (pd_{wa}) for the whole EU is calculated using the prison population sizes per State in 2015 by multiplying the prison density per State with prison population size per state (p_{state}) and dividing by the total prison population size.

$$pd_{wa} = \frac{\sum pd_{state} \times p_{state}}{\sum p_{state}} \tag{2}$$

Group	States	Size of the prison population in 2015
High prison density	Belgium, Croatia, Cyprus, Czech Republic, Finland, France, Greece, Hungary, Italy, Poland, Portugal, Romania, Slovenia, Spain	356.245
Low prison density	Austria, Denmark, England and Wales, Estonia, Germany, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Slovakia, Sweden, Switzerland	219.331

Table 1: prison density groups

[112] Art. 3 ECHR: "No one shall be subjected to torture or to inhuman or degrading treatment or punishment".
[113] Available at http://wp.unil.ch/space/space-i/annual-reports/



Graph 1: Evolution of prison density

The data from the Annual Penal Statistics, plotted in Graph 1, shows that the prison density has been relatively constant both for the high density group, the low density group and consequently the whole EU. A decline in the prison density is visible especially in the high density group after 2012. The dip in 2004 is assumed to be caused by the limited reported data in that year as filling the missing data using a linear interpolation between the prison density in 2003 and 2005 removes the decline.

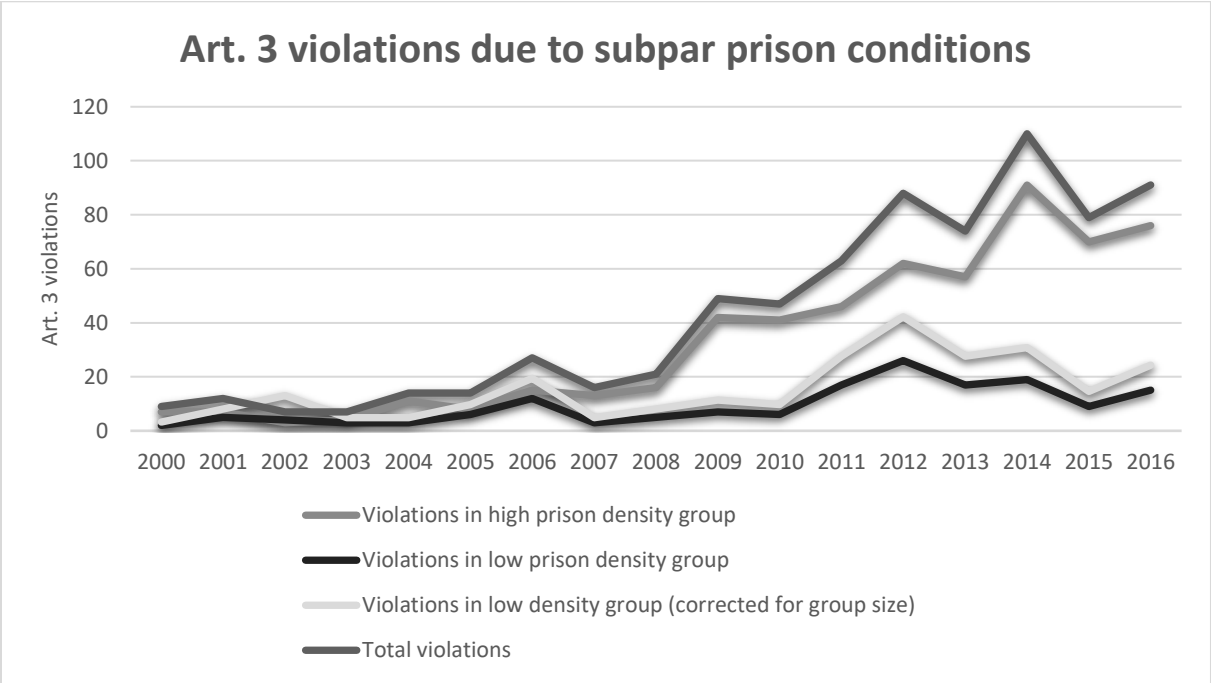
(2) Violations of the prohibition of degrading treatment

The number of violations of art. 3 ECHR can be found in the case law of the ECtHR which is publicly available through the HUDOC database.[114] The case law in the HUDOC database is analysed by using the HUDOC web interface to search the case law text for the words: 'prisoner', 'detainee' and 'détenu', as the primary language of most cases is either in English or French. In addition, only case law concerning violations of art. 3 ECHR were included related to degrading punishment, degrading treatment, inhuman punishment, inhuman treatment and torture. The HUDOC web interface allows the data to be exported as a comma-separated file. This file contains a list of the 'Document Title', 'Application Number', 'Document Type', 'Originating Body', 'Date', 'Conclusion' and 'State' of the case-law that corresponds to the search criteria. Further processing consists of the removal of duplicates based on the Application Number, because some translations are counted as separate cases in the HUDOC database. The data on the number of violations per year per State is shown in Table 3. Because of the different prison population sizes of the high density group (P_{hdg}) and low density group (P_{ldg}), the number of violations in the low density group (V_{ldg}) will be corrected for, giving the number of violations in the low density group corrected for the different group sizes (V_{cg}) by multiplying the number of violations in the low density group with the ratio between the high and low prison density prison populations:

$$V_{cg} = V_{ldg} \times \frac{P_{hdg}}{P_{ldg}} \tag{3}$$

[114] Available at http://hudoc.echr.coe.int/

In the interpretation of the result it should be taken into consideration that the quantity of cases prohibited a manual verification of the reason for a violation leading to the possibility of under- or overestimation of the number of violations.

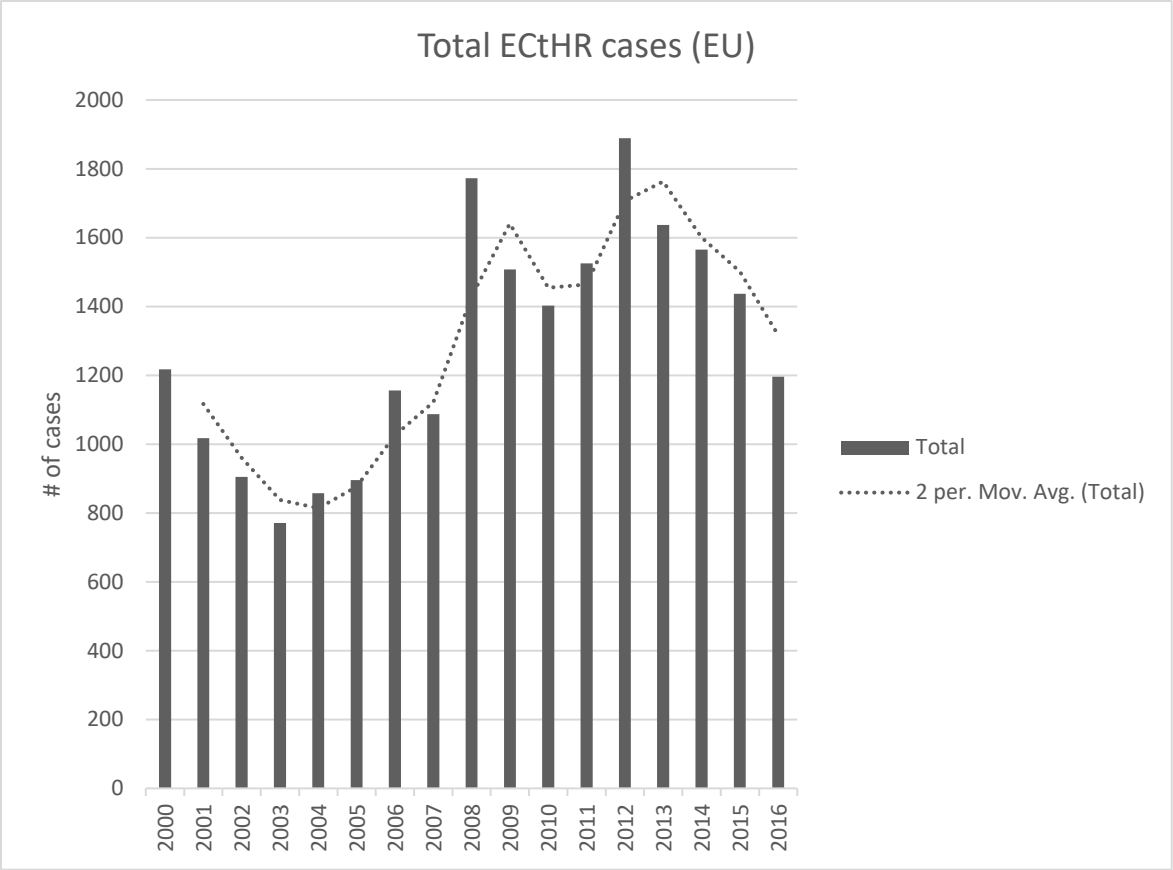


Graph 2: Violations per prison density group

While the prison density has remained relatively unchanged and has even shown a little decline, the number of violations of art. 3 has increased significantly. This rapid increase in the number of violations, is unlikely to be due to worsening prison conditions. A more feasible explanation is the increased attention of the ECtHR for inhumane treatment of prisoners in combination with a small increase in the number of cases from 2000 to 2015, see Graph 3. The precedent in the case law possibly facilitates proceedings as the legal certainty on violations of human rights because of subpar prison conditions increases. The increased attention of the court can be an incentive for States to improve the prison conditions to prevent further convictions.

A comparison between the high density group and the low density groups in Graph 2 shows that the high density group is responsible for most of the increase in the number of violations. This suggests a relation between overcrowding and violations of art. 3 ECHR due to subpar prison conditions, an indication that overcrowding can be a useful measure in assessing prison conditions on the Member State level.

Furthermore, the increase in number of violations found in the low density group is limited. This is an indication that the prison conditions in the low density group are in general above the level that the ECtHR considers a violation. While the case law analysis does not provide a definitive answer of the question whether the prison conditions are of a sufficient level to allow a valid informed consent, it does allow to contemplate on the possibility of a sufficiently uncoerced consent in States in the low density group, while in the high density States there may be a need for more scepticism.



Graph 3: Total number of cases in EU Member States

C. Catch-22

It is evident from the discussion of the requirements of the Regulation that the possibility of providing a valid informed consent is a necessary condition for allowing research involving prisoners. The problem of the voluntariness of the informed consent due to the prison environment constitutes a paradoxical situation in which research is forbidden due to subpar prison conditions, thereby prohibiting research to improve the prison conditions. To assess the possibilities to escape this catch-22, a suggestion for a pragmatic option, consisting of strict control and oversight in combination with a restriction on the research that could potentially be considered as acceptable, will be discussed.

(1) Control and oversight

In all clinical trials, the first step to ensure that the requirements discussed above are fulfilled is the prior authorization of research.[115] The assessment must be done by an appropriate body, organised by the Member States,[116] in which an ethics committee must be involved.[117] After the authorization and start of the research, the research has to be monitored through periodical reporting on safety and adverse events.[118]

Concerning the assessment of research involving prisoners, it is important that the requirements as discussed above are met, meaning that it is required that the researchers and ethics committee

[115] Art. 4 Clinical Trials Regulation.
[116] As is evident from art. 4 of the Regulation the Member States have the freedom determine extend of the tasks of the ethics committee; COM(2012) 369 final para. 92.
[117] Recital 18, art. 6 & 7 Clinical Trials Regulation.
[118] Chapter VI-VII Clinical Trials Regulation.

possess the relevant expertise to accurately assess the different aspects and risks of research involving prisoners, and that special consideration shall be given to the circumstances in which the clinical trial is conducted.[119] The researchers should be familiar with the cultural, social and economic circumstances of the research subjects and their community and must be able to anticipate their needs in any given research.[120] It should be taken into account that when researching in vulnerable groups, the publication of results in certain fields may stigmatize a group or community.[121] While the expertise required could be obtained from prison administrations, members of the ethics committee must be independent and free of undue influences.[122] The role of the ethics committees is especially important as researchers may be biased towards the interest of the success of their research and could for example interpret prison conditions more optimistically to allow inclusion of prisoners in the research.

Ethics committees must necessarily rely on external sources for assessing prison conditions as it cannot be expected in practice that they structurally perform these investigations themselves. Considering that the expertise that the ethics committees can obtain is correlated with the number of cases they assess, it is not unlikely that a central committee will assess research involving prisoners leading to the practical concern whether the committee can time-efficiently assess and control the research taking place in different prisons. This relies on the specific organizations of the ethics committee(s) assessing research involving prisoners in the different Member States. No matter the organisation, research involving prisoners can only be allowed when the ethics committee can make an accurate and effective assessment whether all the requirements on research involving prisoners are fulfilled.

After the prior authorization of a research by the ethics committee, the sponsor must be able to provide monitoring for the well-being of the research subjects,[123] meaning that the sponsor must be able to provide follow up in prison. In addition, it is important that there is sufficient transparency concerning research involving prisoners to reveal abuse and exploitation. The Clinical Trials Regulation provides in centralized data gathering through the uniform EU portal and EU database that should inform stakeholders of ongoing research involving prisoners, increasing transparency of ongoing research. This allows not only research subjects but also interest groups to report problems concerning the research. Suspected unexpected serious adverse reactions (SUSARs) have to be reported by the sponsor according to the Regulation.[124] However, because of the problem of dual loyalty, it may be more difficult for prisoners to report SUSARs. Therefore, it would be desirable that there is a report/complaint procedure that is accessible to prisoners, with regard to privacy, and with the guarantee that reporting will not reflect negatively on the prisoner.

(2) Restrictions on the allowable research

As part of the possibility to escape the aforementioned paradoxical situation it may be necessary to provide additional protection to prisoners by restricting the research that they are allowed to participate in.[125] In other vulnerable groups, such as minors and the pregnant, research is only allowed when it is essential to investigate a condition which only these groups suffer from and can

[119] Art. 10(5) Clinical Trials Regulation.
[120] Elger, "RESEARCH INVOLVING PRISONERS," 235; art. 49 Clinical Trials Regulation.
[121] CIOMS guideline 8 p. 49.
[122] Recital 18 & 19 Clinical Trials Regulation.
[123] Art. 48 Clinical Trials Regulation.
[124] Art. 52 Clinical Trials Regulation.
[125] Elger, "RESEARCH INVOLVING PRISONERS," 236.

only be done in the specific vulnerable group.[126] The higher risk of research and the complexity of the validity of the informed consent justifies this restriction. For research involving prisoners this means that the benefits need to be responsive to health needs of the prisoner and/or entail specific benefits for the prison community. Furthermore, an option that would limit the consequences of an incorrect assessment of the fulfilment of the requirements is to only allow low-risk research. In combination with an adequate feedback system and rigorous oversight, this could allow the different parties to gain the necessary expertise in research involving prisoners and to evaluate the possibility of research involving prisoners in practice.

V. Access versus protection, a balancing act

We have argued that there is a duty for States resulting from the right to science and respect for human dignity to both provide prisoners with the benefits of science through participation in the scientific enterprise and having access to the benefits of science. States simultaneously have the duty to protect prisoners from abuse and exploitation when participating in scientific research, and therefore they must balance the access to the benefits of research with the protection against abuse and exploitation.

Considering the rules for protection of research subjects in the Clinical Trials Regulation, the specific complications that arise in research involving prisoner concern the informed consent, the influence of the prison environment and expertise to accurately assess the former two. If the relevant expertise is not present, an accurate assessment of the relevant risks and benefits is not possible leading to problems in the protection of the research subjects.

The specific expertise in research involving prisoners is likely to be underdeveloped due to a lack of experience in conducting research in this population. Specifically for the ethics committees, it is necessary that it reviews enough relevant cases to build the required experience and expertise to accurately assess research involving prisoners. As the organization of the ethics committees is highly dependent on the Member State, e.g. the topographical distance between prisons and current organization, it is difficult to give general recommendations on this topic. However, possible ways of organising the ethical committee for research with prisoners are (1) embedded in the regular ethics committees or (2) centralized in a specific committee. A potential disadvantage of embedment in the regular committees is that the number of researches is lower compared to those in a central committee. While embedment allows committees to better gauge local circumstances, centralisation has the advantage of gathering expertise and oversight but may have a more administrative character. In the assessment of both researchers and ethics committees, there must be special attention for the informed consent and prison conditions.

For a valid informed consent there needs to be (1) informedness, (2) comprehension and (3) voluntariness. The aspect of voluntariness is the most controversial and complicated in research involving prisoners. The voluntariness is challenging because of the coerciveness of the prison environment due to the susceptibility for coercion of prisoners through subpar prison conditions, the dependency of prisoners to the prison administration and non-equivalent healthcare.

The analysis of the number of violations of art. 3 ECHR, on the grounds of degrading punishment, degrading treatment, inhuman punishment, inhuman treatment and torture, in the case law of the European Court of Human Rights shows that prison overcrowding is an important indicator for subpar prison conditions. The observation that not all States can ensure adequate prison conditions

[126] For minors: art. 32(1)(e-f), and or the pregnant: art. 33(b)(i-ii) Clinical Trials Regulation.

and provide the necessary healthcare to prisoners, complicates and limits the possibility of a voluntary informed consent. Consequently there is catch-22 situation in which prison conditions are limiting the possibility of performing research to improve the prison conditions.

A pragmatic option to escape from this paradoxical situation is to carefully balance the degree of restrictions on the allowable research with the level of prison conditions. This allows a justified balance between access to the benefits of science and protection from unequitable risks. This balance must be vigorously guarded by researchers, ethics committees and sponsors with the required expertise in research involving prisoners.

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VII. Appendix

EU	State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
1995	Austria	86,0	86,0	93,5	97,4		106,3	103,4	103,8	92,4		98,9	101,4	100,3	101,7	101,1	103,3
1957	Belgium	117,0	127,0	113,3	107,4		110,8	117,9	118,5	124,8	128,4	124,8	127,2	131,7	134,2	129,0	127,0
2013	Croatia	58,0	75,0	80,3	84,5	91,3	110,3	121,3	130,6	135,2	139,7	147,5	129,7	120,9	111,0	93,6	83,1
2004	Cyprus		154,0	119,0	156,4	160,6	155,6	108,9	152,7	150,5	147,9	150,8	137,5	140,1	137,7	79,8	97,3
2004	Czech Republic	114,0	105,0	95,6	108,6		101,4	99,9	98,2	105,3	113,6	111,5	113,0	106,3	77,7	93,2	100,4
1973	Denmark	90,0	90,0	94,3	95,6	95,6	96,7	91,6	89,8	90,6	91,1	96,1	95,5	92,9	98,6	91,8	85,2
1973	England and Wales	104,0	94,0	111,1	95,5	95,6	95,9	96,7	96,4	99,9	98,2	97,5	96,6	94,7	95,5	97,5	97,6
2004	Estonia	90,0	96,0	88,9	91,9	95,1	98,6	96,4	90,8	94,2	97,2	94,9	92,4	96,3	100,0	89,8	83,3
1995	Finland	81,0	90,0	106,8	100,5	99,1	112,8	105,5	101,0	101,0	101,2	103,4	105,2	104,6	100,5	99,2	99,5
1957	France	100,0	97,0	111,5	118,2	113,5	112,6	114,8	125,2	131,1	123,3	108,4	113,4	117,0	117,2	114,5	113,4
1957	Germany		103,0	100,8	101,9	100,6	98,4	98,7	97,1	92,8	92,2	91,3	91,3	88,6	87,6	86,3	84,7
1981	Greece	166,0	158,0	156,8	153,2		171,7	168,0	141,9	129,6		123,0	151,7		133,9	121,4	97,6
2004	Hungary	161,0	156,0	159,6	150,6	144,9	145,7	137,0	132,3	119,8	133,4	133,4	138,2	138,8	144,9	142,0	129,4
1973	Ireland	103,0	82,0	86,8	90,1			91,5	91,9	95,6	97,8	101,7	93,5	98,0	91,2	90,6	89,6
1957	Italy	125,0	129,0	134,5	134,2	131,5	138,9	88,6	105,2	129,9	148,2	153,2	147,0	145,4	148,4	109,8	105,6
2004	Latvia	80,0	90,0	85,8	90,4	85,0	78,9	71,3	70,4	71,4	87,8	85,0	82,3	77,7	65,3	75,9	75,2
2004	Lithuania	89,0	108,0	114,1	102,5	80,5	84,3	84,4	86,5	85,5	91,5	94,6	101,1	106,7	102,4	95,5	85,3
1957	Luxembourg		76,0	48,6	64,0	80,2	88,6	96,7	95,3	95,9	96,9	97,0	90,6	92,7	100,8	92,3	93,8
2004	Malta		86,0	94,3	62,6		62,1	77,3		120,2	102,9				85,5	84,6	
1957	Netherlands	90,0	97,0	97,3	95,0	92,6	98,6	93,0	80,8	79,9	79,2	94,9	93,8	85,8	84,8	82,0	76,9
1973	Northern Ireland	45,0	60,0	65,3	65,9	87,0	91,5	99,7	96,1	95,5	82,0	83,1		98,1	93,3	94,8	91,8
*	Norway	90,0	92,0	90,9	98,3	95,4	97,5	95,0	93,8	91,4	91,7	95,1	92,2	93,4	96,3	97,8	89,6
2004	Poland	101,0	117,0	116,7	116,8	114,0	118,3	117,3	118,5	100,0	99,4	94,6	94,5	96,8	81,2	88,2	81,1
1986	Portugal		119,0	120,7	117,5		101,5	104,3	93,3	87,9	93,1	97,4	105,0	112,7	117,4	111,2	113,0
2007	Romania	148,0	143,0	139,1	122,8	104,0	100,8	94,6	84,5	78,5	79,0	82,6	89,3	118,9	116,3	109,1	101,3
2004	Slovakia	80,0	84,0	83,2	92,5	99,0	88,5	82,8	77,9	80,0	88,6	92,0	100,8	102,6	89,8	89,9	90,2
2004	Slovenia	108,0	108,0	105,9	103,0	102,1	102,6	116,6	122,1	120,0	124,3	121,2	114,2	105,2	105,2	117,7	105,8
1986	Spain State Adm.	106,0		112,5	114,1	129,5	133,7	140,0	143,2	141,9	153,0	96,9	91,8	88,9	86,9	118,5	83,9
1995	Sweden	100,5	105,0	107,5	106,9	103,3	104,1	106,2	97,5	98,7	103,4	102,8	96,6	91,3	89,1	91,3	90,9
*	Switzerland	94,0	76,0	76,2	80,9	91,4	93,4	87,3	85,9	85,8	91,0	92,5	88,3	94,6	100,3	95,7	93,7

Table 2: prison densities

State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Austria								1		1			2	2	1			1
Belgium			1				1		1		1	2	3	1	6	4	3	2
Croatia			1				1	3	1	1		2	3	1	3	3	1	1
Cyprus	1	1							1		1			1		2	1	1
Czech Republic												1	2	2				
Denmark						1						5			1			
England and Wales	1	4	2	1			2		3	1	1	3	3	3		1		
Estonia						1				1			1	2	2		1	
Finland						1									1			
France	1	1	1	1	5	1	5	3	1	3	5	8	4	7	3	4	7	
Germany							1		1			2	1			1	1	
Greece		2			2	1	2	2	2	6	4	6	12	8	18	16	19	10
Hungary	0	1			1						1	2	2	2	1	7	7	
Ireland			1												1			
Italy	2	1				2	2		3	12	1	2	3	2	6	1	2	
Latvia					1		4	1		2	1	2	11	4	5		3	1
Lithuania			1				1								1			
Luxembourg		1				1			1				2			2	1	1
Malta														2		2	3	
Netherlands	1			2	2	2	3	1			2						4	
Northern Ireland															1	2		
Norway																		
Poland	2	1		2		1		1		6	3	3	7	4	5	3	11	2
Portugal									1									
Romania				1	2	2	3	3	6	13	24	17	24	29	31	26	24	10
Slovakia										1		1	2		1		1	
Slovenia	1							1		1		2	1		14	3		
Spain					1		1				1	1	1		3	1	1	
Sweden						1				1	2	3	4	3	2		1	
Switzerland							1					1		1	4	1		3

Table 3: violations per state per year