BELGIAN ADVISORY COMMITTEE ON Bioethics

Opinion no. 69 of 13 February 2017 on experiments and other scientific research involving inmates

Contents

Request for an opinion

On 24 June 2013 Prof. Dr. D. Matthys, in his capacity as chairperson of the medical ethics committee of the University Hospital Gent (UZ Gent), asked the following question (in Dutch):

> "The ethics committee of the University Hospital Gent (UZ Gent) recently received a question about the possibility of research involving inmates in Belgian prisons.
>
> We are aware of the restraint involving studies in prisons and the many opinions and guidelines which prohibit this, both national and international. Up until the present time, this ethics committee has shared this opinion and delivered an unfavourable opinion on any research involving inmates.
>
> However, given repeated requests to conduct research with inmates and the recent approval by the Flemish government of the decree of 8 March 2013 regarding the organisation of assistance and services to inmates (published in the official state journal of 11 April 2013), the ethics committee wondered how it should best deal with this question.
>
> Which position should be taken with respect to research relating to healthcare in prison which therefore cannot be conducted elsewhere and which can contribute to an improvement of the medical care in detention conditions? Are there regulations on which research involving inmates is allowed, and which is not?
>
> A forensic psychiatric centre will soon be opened in our region. With the approval of the new decree of 8 March 2013, our ethics committee expects an increase in the number of requests for research involving inmates.
>
> (…)"

On 29 October 2013, Mrs. Laurette Onkelinx, then Minister of Social Affairs and Public Health, made the following similar request for an opinion on "experiments on human subjects involving the specific target population of detainees and those interned" to the Advisory Committee on Bioethics (in Dutch):

> "Research within the framework of the Law of 7 May 2004 on experiments on human subjects poses a fundamental problem for the specific target population of detainees and those interned.
>
> Ethical committees[1] are regularly confronted with this question. Of course, it is obvious that in the case of participation in research, the subjects must be thoroughly informed and free and informed written consent is necessary, but the subjects in question find themselves, given their conviction and/or forced confinement, in circumstances in which they cannot completely autonomously and freely consent.
>
> Nevertheless, it is extremely desirable, in the interests of this target group, that scientific research be made possible; such research can […] have medical […] and also psychological or sociological research aims.

1 The Committee favours the term 'medical ethics committee' over 'ethics committee'.

> Since the Second World War, with the Nuremberg Code, and also on the deontological advice of the Order of Physicians (Orde der Geneesheren)[2], such research has been the subject of much reservation, and to this day no special guidelines exist.
> I would like to ask you for advice on the opportunity for guidelines on this matter and concrete recommendations. It appears to me to be desirable that a framework be formed for scientific research that can be beneficial to these target groups, that can improve the health and detention circumstances, and that can have favourable implications for the development of care and guidance programmes leading to a possible release.
> In particular, I wish to ask you for recommendations on the question of consent, pointing out the possible role of prison staff in a research study and the information given. I also refer to the caution that must be advised if researchers wish to offer a form of reimbursement.
> (…)"

The above requests were declared to be admissible at the plenary meetings of the Committee of 8 July and 16 December 2013.[3] At the start of the Committee's fifth mandate on 8 September 2014, the requests were assigned to the select committee 2014-2 'Experiments on human subjects', which prepared this opinion.

2 Their new title is the "Orde der Artsen" (Order of Doctors).

3 The treatment of this request underwent delay as a consequence of the treatment of a previous request for an opinion (cf. Opinion no. 62) and the transition from the fourth to the fifth mandate (2014-18).

Introduction

As a result of various reports of unethical experiments on human subjects during the Second World War and in the decades since, attention to the ethical quality of medical-scientific research increased greatly and various guidelines for medical-scientific research involving human subjects were drafted, including the Nuremberg Code (1947), the Declaration of Helsinki (1964) and the Belmont Report (1979). Forced or unknowing participation in experiments has been historically strongly condemned, thus raising a great reserve with respect to scientific and medical-scientific research in populations of vulnerable subjects, such as (orphaned) children and inmates. Numerous guidelines, including the Code of Medical Duties (Art. 90), formally prohibit experiments on prisoners. The National Council of the Order of Doctors expressed in a letter from 19 September 2013 its opinion on the conditions[4] under which medical-scientific research involving inmates is admissible.

In the meantime, it has become clear that the lack of scientific research involving vulnerable populations can have important negative consequences for those who belong to these populations. When the specific problems facing these populations are insufficiently researched, these groups are deprived to a great extent of the fruits of scientific progress. As such, these groups can become 'therapeutic orphans', by analogy with the terminology that Shirkey[5] used for the underrepresentation of children in clinical research.

Inmates as a group, and possibly also as individuals, can therefore benefit from participation in scientific research, certainly when this research deals with problems specific to detention. Moreover, there is no fundamental reason to deny them access to the possible fruits of scientific research, and it must be recognised that inmates are in principle competent to grant or refuse free and informed consent. The deprivation of liberty to which inmates are subjected in our democratic society, does not in principle exclude the possibility of free consent to participation in scientific research. However, despite the fact that this objection cannot be made in general, it must be checked that each inmate is capable of granting free and informed consent. Furthermore, a number of specific ethical, juridical and practical issues need to be taken into account when conducting scientific research with this vulnerable population. These additional issues will be dealt with in this opinion.

This opinion restricts itself to scientific research involving inmates, and will not address the very different issue of scientific research involving those who are interned. Internment falls under the domain of care, and is very different from conventional detention, even if

4 "[T]he following principles [can be] derived under which, besides the principles for medical experiments involving non-inmates, extra emphasis should be placed for experiments involving inmates in Belgium:
- the experiment cannot be conducted anywhere else, i.e. outside a prison. The scientific importance of the prison population should be clear as justification to participate in the experiment;
- the results contribute indisputably to an improvement of the medical care in detention circumstances;
- the problem of consent is to be approached with the necessary caution, in order to avoid any form of coercion;
- all relevant information regarding the aims and the course of the experiment is to be shared with the inmates."
(identifying mark of the letter: 102579/BD/TG/fd/CNR 082 13)

5 Shirkey H. Therapeutic orphans. J Pediatr 1968;72(1):119-120.

internees also reside inside prison walls. The rules for scientific research also strongly differ between the two groups. The Committee emphasises that the findings of this opinion do not apply to those who are interned.

This opinion distinguishes between three categories of scientific research. For each of these categories, various juridical considerations are first presented, followed by a clarification of the various ethical issues.

Nature of the scientific research

The desirability and acceptability of scientific research involving inmates depends to a large extent on the nature and purpose of the research. Depending on the recruiting strategy[6] used, such research can concern: (1) studies which do not explicitly aim to recruit inmates as subjects, but which are relevant for an individual inmate due to his/her health problems; (2) studies which explicitly aim to (partly) recruit from the subject population of inmates, with the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose; or (3) studies which explicitly aim to (partly) recruit from the subject population of inmates, without the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose.

1. Scientific research which does not explicitly aim to recruit inmates as subjects, but which is relevant for an individual inmate due to his/her health problems

This includes investigations which are not set up with the intention of including inmates, but for which inmates can be included – before or during their detention – due to a concrete syndrome or care issue. An example is an oncological study in which an inmate as cancer patient wishes to (continue to) participate because of his/her illness. Neither the request to participate nor the research design are in this case related to the detention, but are related to the health problem for which they receive (medical) attention.

2. Scientific research which explicitly aims to recruit (partly) from the subject population of inmates, with the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose

Some problems – medical, psycho(patho)logical, social or criminological – can be related to detention or manifest themselves more frequently amongst inmates than the general population. Research on such problems, with as ultimate goal the improvement of the health of, care for and/or detention circumstances of inmates, is evidently in the best interests of the population in which the research will be conducted. There is also no possibility of

6 This division in three categories is based on the intentions and recruiting strategy of the researchers. This division should therefore be considered from the perspective of the researcher and not that of the participant. Whether the recruitment of inmates as test subjects is ethically permissible for each of the three categories, is discussed in more detail in the ethical considerations (below).

obtaining the same results in another population.

3. Scientific research which explicitly aims to recruit (partly) from the subject population of inmates, without the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose

It is possible that some researchers might see practical and methodological advantages (e.g. less variables, more accurate follow-up) in the inclusion of inmates, simply because of the restricted liberty imposed on inmates. If such studies do not focus on the improvement of the health, care or welfare of inmates, and do not have to be exclusively carried out in the population of inmates, these studies belong to a third category: experiments or other scientific investigations which specifically focus on the target group of inmates, without the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose. In these studies, the recruitment of inmates is explicitly mentioned in the research protocol.

Juridical considerations

The Law of 7 May 2004 on experiments involving human subjects (henceforth: Human Subjects Experiments Law) does not provide specific conditions for experiments involving inmates. The new European Regulation 536/2014 on clinical trials on medicinal products for human use, which will become applicable in the near future, does not change this in any way.[7]

As a consequence, the general conditions under which an experiment can be undertaken or continued according to Article 5 of the Human Subjects Experiments Law are applicable for this category of people (inmates), as well as the requirement of free and informed consent as intended in Article 5 of the same Law. For inmates, particular attention should be given to the voluntary character of the consent to participate in the experiment. This voluntary nature is threatened if the inmate experiences a certain pressure to participate in an experiment. Under Article 1 of the Code of Nuremberg, the test subject must be capable of making a free choice without the intervention of any violence, fraud, deception or any other form of restriction or coercion. This means that the inmates must know before and during their participation that they remain free to cooperate or not, without a refusal on their part having any negative consequences of any sort.[8] It is therefore necessary that the decision to participate or to withdraw from participation be completely independent from the circumstances of the inmate's detention, conviction or sentence. The Convention on Human Rights and Biomedicine from the Council of Europe (henceforth the Oviedo Convention),

7 Regulation (EU) no. 536/2014 from 16 April 2014 concerning clinical trials on medicinal products for human use and repealing Directive 2001/20/EC. This regulation will become applicable under Article 99 when the EU Portal and the EU Database have become fully functional and in particular six months after the European Commission has published a notice in the official Journal of the European Union.

8 Cf. Opinion no. 36, see chapter 3: Current ethical reflection in the human sciences, point d. Situation in Belgium.

which has not been signed or ratified by Belgium, also emphasises the importance of the absence of any pressure or influence, including financial incentive, especially when dealing with those who find themselves in a vulnerable or dependent position such as inmates.

In addition, under Article 4 of the Human Persons Experiments Law, all experiments must be designed, implemented and published according to the ethical and scientific quality requirements that are internationally recognised and that must be respected during the planning, implementation, registration and publication of the experiments, more specifically trials. The Royal Decree of 30 June 2004 in implementing this Law of 7 May 2004 states that clinical trials must be conducted in accordance with the Declaration of Helsinki concerning the ethical principles for medical research involving human subjects, adopted by the general meeting of the World Medical Association, in its last available edition.[9] This Declaration includes general rules for the protection of vulnerable people, without however specifically mentioning inmates. The Declaration considers medical research involving a vulnerable group to be justified only if "the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that results from the research."[10]

The relevant legislation on the prison system and the legal status of inmates does not include specific rules on the participation of inmates in scientific research either.[11] It does provide for the establishment of a Penitentiary Health Council, composed of doctors, dentists and nurses attached to the prison, who advise the Minister in order to promote the quality of healthcare in the best interests of the inmate patient (Art. 98). Under Article 3 of the Royal Decree of 12 December 2005, this Council also provides advice on requests for medical scientific research with due regard for ethical principles and for the possibilities inside prisons (Art. 3, §2, 6°).[12]

In addition to the Human Subjects Experiments Law, there exist a number of international law rules which are not legally binding. The already mentioned Code of Nuremberg[13] is an authoritative source of inspiration for the legislation in many countries. This is also the case for the Oviedo Convention which has not been signed by Belgium, which in Article 20 of its additional protocol on biomedical research includes a specific provision for research on

9 Article 10, as introduced by Article 1 of the Royal Decree of 18 May 2006 amending the Royal Decree of 30 June 2004 setting out implementation measures for the Human Persons Experiments Law, *BS* 26 May 2006, 26727. The principles and detailed guidance on good clinical practices were established in Guideline 2005/28/EU which was implemented in Belgium in the Royal Decree of 18 May 2006.

10 World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects (20), see also https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

11 See in particular the Law of 12 January 2005 on the prison system and the legal status of inmates, including a chapter on healthcare and health protection (chapter VII).

12 Royal Decree of 12 December 2005 which determines the date that Article 98 of the fundamental Law of 12 January 2005 on the prison system and the legal status of inmates and regulating the composition, powers and functioning of the Penitentiary Health Council, will take effect. (*BS* 29 September 2005)

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.

people who have been deprived of their liberty.[14] Other international texts which pay particular attention to the involvement of inmates in research are the recommendation of the Council of Europe on European prison rules from 2006[15], resolution 37-194 from the United Nations adopted by the General Assembly of 18 December 1982[16] and the Council for International Organisations of Medical Sciences (CIOMS) international ethical guidelines for biomedical research involving human subjects from 2003[17]. In addition to the importance of special protection, this last text also highlights explicitly the risk that certain groups be systematically excluded from participation in research.[18]

Ethical considerations

1. Nature of the scientific research

1.1 Scientific research which does not explicitly aim to recruit inmates as subjects, but which is relevant for an individual inmate due to his/her health problems

Inmates already included in an investigation before their detention can, in principle, continue participating during their incarceration, provided that this remains practically feasible. In this case, there are no problems concerning free and informed consent, given that the test subject had already consented at a time when he/she was not deprived of his/her freedom.

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14 Additional protocol of the Convention on Human Rights and Biomedicine, on biomedical research, Strasbourg, 25.01.2005:

Art. 20 – Research on persons deprived of liberty: "*Where the law allows research on persons deprived of liberty, such persons may participate in a research project in which the results do not have the potential to produce direct benefit to their health only if the following additional conditions are met: i. research of comparable effectiveness cannot be carried out without the participation of persons deprived of liberty; ii the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to persons deprived of liberty; iii the research entails only minimal risk and minimal burden.*"

15 Recommendation Rec (2006)2 on European prison rules: *"48.1 Prisoners shall not be subjected to any experiments without their consent. 48.2 Experiments involving prisoners that may result in physical injury, mental distress or other damage to health shall be prohibited."*

16 Resolution 37-194 of the United Nations, adopted by the General Assembly of 18 December 1982, Principles of Medical Ethics relevant to the Role of Health Personnel, particularly Physicians, in the Protection of Prisoners and Detainees against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment: "It is a contravention of medical ethics for health personnel, particularly physicians, to be involved in any professional relationship with prisoners or detainees the purpose of which is not solely to evaluate, protect or improve their physical and mental health." (Principle 3)

17 CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. Guideline 9: Special limitations on risk when research involves individuals who are not capable of giving informed consent. "When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them."

Commentary on Guideline 9: "The low-risk standard: Certain individuals or groups may have limited capacity to give informed consent either because, as in the case of prisoners, their autonomy is limited, or because they have limited cognitive capacity. For research involving persons who are unable to consent, or whose capacity to make an informed choice may not fully meet the standard of informed consent, ethical review committees must distinguish between intervention risks that do not exceed those associated with routing medical or psychological examination of such persons and risks in excess of those."

18 Commentary on Guideline 12: "Members of vulnerable groups also have the same entitlement to access to the benefits of investigational interventions that show promise of therapeutic benefit as persons not considered vulnerable, particularly when no superior or equivalent approaches to therapy are available."

Inmates who wish to participate in scientific research during their incarceration and who are capable of giving free and informed consent can, in principle, participate in the scientific study, just like citizens from the general population. In this case, however (particularly for non-therapeutic experiments), special attention should be paid to the voluntary nature of the consent. In this respect, it is for example important to emphasise during the informed consent procedure that possible participation (or non-participation) in the research will have no effect on the evaluation of the inmate concerned. The Committee also recommends that the (medical) ethics committee responsible for issuing an opinion on the study protocol be informed of the inclusion of an inmate in the study. Another important condition concerns the practical feasibility of making the necessary practical arrangements (such as additional trips to the hospital). On the basis of the testimony given by the experts heard by the Advisory Committee on Bioethics, it appears that there is a strong commitment on the part of the prison system to facilitate participation (or the continuation of participation) in scientific research, where possible.

1.2. Scientific research which explicitly aims to recruit (partly) from the subject population of inmates, with the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose

Some problems, including medical, psycho(patho)logical, social or criminological, which are possibly related to incarceration or which are clearly more common in inmates than in the general population, are relevant for the population of inmates.

As a consequence, there exists sufficient legitimation for such research, which can then receive the approval of an ethics committee provided that the relevant ethical issues are adequately identified and addressed in the submitted research protocol. It goes without saying that written, free and informed consent from each individual participant is essential.

1.3. Scientific research which explicitly aims to recruit (partly) from the subject population of inmates, without the aim of improving the health of, care for and/or detention conditions of inmates or of acquiring the insights necessary for this purpose

The Committee is of the opinion that in the absence of a link between the research and (1) the individual care problem of the inmate (cf. point 1) or (2) an intended improvement of the health of, care for and/or detention conditions of the inmate population or the acquisition of the insights necessary for this purpose (cf. point 2), there are insufficient grounds to justify conducting this research with inmates.

If similar research results can be obtained in a population of less vulnerable test subjects than inmates and if the research aims at no specific or relevant benefit for inmates, research protocols which specifically focus on the inclusion of inmates lack ethical legitimacy.

This does not preclude however, as earlier mentioned, the participation of individual inmates in a trial in the context of care for a health problem, provided that they are able to give free and informed consent and that the necessary practical arrangements can be made.

2. Vulnerable subjects

Inmates are vulnerable test subjects. Not only is their freedom restricted, this population also has a higher concentration of people with serious psychological problems, given the often poor access to (psychiatric) healthcare, the high level of poverty (or disadvantage), social stigmatisation, the problem of illegal residence in Belgium, drug problems and narcotic use, etc.

Given that the behaviour of inmates can have an impact on the length of their sentence (e.g. in the case of conditional release), it must be ensured that inmates do not associate participation in experiments with behaviour that can lead to more favourable evaluations.

It must also be ensured that researchers do not prefer inmates as test subjects because of the simple assumption that this population, due to their restricted freedom, will be better able to comply with the protocol conditions.

3. Free and informed consent

The mere fact of detention does not constitute a principle impediment to the granting of valid free and informed consent, and, consequently, inmates are, in principal, just as capable of giving their free and informed consent as citizens from the general population. Just as in the general population some people are unable to give their consent, so will *some* inmates, due to their personal situation, not be capable of giving free and informed consent, and will be unable to express their will.

With regard to free and informed consent, a number of practical obstacles need to be taken into account when conducting scientific research with inmates. For example, the population of inmates is very heterogeneous, and the knowledge of Dutch, French and/or English cannot be generally assumed.

When inmates are involved in research, particular attention should be paid to informing the test subjects. It is advisable to explicitly mention the fact that participation in the experiment has no influence whatsoever on the assessment of the behaviour of the inmate and his/her sentence, and the protection of privacy deserves special attention (cf. point 5).

4. Reimbursement of expenses in connection with participation in research

The purpose of this reimbursement is to compensate the expenses incurred or the loss of income suffered by the test subject as a result of his/her participation in an experiment or

research study. (Medical) ethics committees are to ensure that this reimbursement of expenses covers realistic expenses, without becoming a reward. This is done in order to prevent financial and/or material incentives corrupting the free consent to participate in an investigation.

As noted by the experts heard by the Advisory Committee on Bioethics, the granting of financial or material compensation or any sort of advantage to inmates is particularly delicate. Firstly, in general inmates do not have to incur any expenses as a result of their participation in an experiment or research study: for example, they do not have to travel anywhere or interrupt paid work in order to participate. Moreover, material and/or financial compensation for inmates is likely to weigh more quickly on the voluntary nature of consent. This is because, on the one hand, inmates have less opportunity to obtain similar advantages and, on the other hand, informal means of payment such as phone cards, cigarettes etc. are used within prison walls. Material rewards that would count as a modest form of compensation outside prison (such as a phone card) can *de facto* have a far greater value within prison walls.

5. Respect for the privacy of the inmates

The restriction of freedom imposed on inmates has obvious implications for participation in scientific research. The cooperation of third parties will be required to enable participation in research, with a consequent risk of a loss of privacy.

This risk of a loss of privacy can however be restricted to a minimum. In the first place, recruitment of test subjects occurs under the supervision of the prison doctor, with respect for professional secrecy. The inmate's consent is required so that, in the context of the recruitment for a research investigation, the prison doctor may consult the inmate's medical file. The Committee recommends that the relevant (medical) ethics committee closely monitors possible conflicts of interest regarding the prison doctor.

6. Evaluation by a(n) (medical) ethics committee

Experiments and other scientific (medical) research in vulnerable populations, in this case inmates, demand a careful evaluation of the particular research protocol by the relevant (medical) ethics committee(s). However, in order to thoroughly evaluate the ethical issues related to the scientific (medical) research, knowledge of the specific context is required. It cannot be assumed that this knowledge will be present in the evaluating (medical) ethics committee(s).

In order to establish whether (1) the study or investigation is relevant for the population of inmates and (2) the ethical issues – taking into account the specific context of research inside prison – are adequately defined and addressed, the Committee recommends calling upon the expertise of the prison system. After all, it must be ascertained whether the researchers, in striving to conduct successful and safe research, sufficiently take into

account the circumstances which can differ inside prison compared to outside. For example, sometimes the continuity of participation should be taken into account: not all inmates reside for a sufficiently long period in (the same) prison, which can have an impact on the practical organisation of the experiment or investigation. This problem can be avoided by including a minimum detention term as inclusion criterion in the protocol.

Based on the consultation of experts conducted by the Advisory Committee on Bioethics, the Penitentiary Health Council appears to be currently the most appropriate contact point for a (medical) ethics committee to seek the abovementioned external expertise. This Council is composed of doctors, psychiatrists, (psychiatric) nurses and representatives from administration.

Such a central advisory body would have the additional advantage that an inventory would be made of all experiments and other scientific research involving prisons. Centrally storing this data would guarantee a uniform approach and prevent the unnecessary organisation of similar experiments.

Finally, the Committee notes the possibility that (medical) ethics committees will have to evaluate research with a particular societal sensitivity, such as genetic research and research involving neuro-imaging.

Recommendations

The Committee unanimously makes the following recommendations. These recommendations only concern inmates, not those interned.

1. **Participation of an inmate in scientific research should be possible for:**

   1.1. **scientific research that does not explicitly aim to recruit inmates as test subjects, but which is relevant to an individual inmate due to his/her health problems:**
   - for inmates who were already included in an experiment or other scientific investigation prior to their detention, there is no problem in the area of free and informed consent, given that consent was given before the inmate was deprived of his/her freedom;
   - for inmates who wish to participate in an experiment or other scientific investigation during their detention and who are capable of giving free and informed consent, the Committee recommends that the (medical) ethics committee responsible for evaluating the research protocol, be informed of the inclusion of an inmate;

   1.2. **scientific research which explicitly aims to recruit (partly) from the population of inmates, <u>with</u> the aim of improving the health of, care for and/or detention circumstances of inmates or of acquiring the insights necessary for this**

purpose.

2. **The Committee considers scientific research which explicitly aims to recruit test subjects (partly) from the population of inmates without the aim of improving the health of, care for and/or detention circumstances of inmates or of acquiring the insights necessary for this purpose, as unethical.**

3. **In the context of scientific research in which inmates participate, attention should be paid to the practical arrangements necessary, and it may be that third parties should be informed of the participation of an inmate in an experiment or investigation. In this case, the privacy of the inmate should be maximally respected at all times. The Committee also recommends that the relevant (medical) ethics committee closely monitors possible conflicts of interest on the part of the third parties involved.**

4. **The Committee requests particular attention for correctly obtaining the free and informed consent of the inmate who is test subject, with special precautions when it comes to non-therapeutic research, i.e. research that does not aim at the direct improvement of the health of and/or the care for the individual inmate. It should also be made clear to the inmate that whether or not he/she participates in a scientific investigation will have neither a favourable nor an unfavourable effect on his/her evaluation or sentence.**

5. **The greatest precaution is recommended when considering granting compensation or reimbursement to inmates.**

6. **It is recommended that an inventory be made of the research data involving inmates in a centralised way, in order to strive for a uniform approach and to prevent the unnecessary duplication of similar research.**

7. **(Medical) ethics committees should ensure that they have sought the necessary expertise when evaluating studies involving inmates. If this expertise is not available amongst the members of the (medical) ethics committee, it is advisable to seek external advice from within the prison system. Support from a new central advisory body, as yet to be set up, for example within the Penitentiary Health Council, is desirable.**

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This opinion was prepared in the select committee 2014/2, consisting of:

Joint chairpersons	Joint reporters	Members	Member of the Bureau
Evelyne Langenaken	Wim Pinxten	André Herchuelz	Paul Schotsmans
Robert Rubens	Steven Lierman	Julien Libbrecht	
		Robert Nailis	
		Stany Wens	

Member of the secretariat
Veerle Weltens
Experts consulted
Dr. Francis Van Mol, Honorary Chief Physician-Director of the Prison Healthcare Service
Dr. Luc Proot, former Chairperson of the Penitentiary Health Council

The working documents of the select committee 2014/2 – request for opinion, personal contributions of the members, minutes of the meetings, documents consulted – are stored as annexes 2014/2 at the Committee's Documentation Centre, where they may be consulted and copied.

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This opinion is available on the website www.health.belgium.be/bioeth, under the "Opinions" section.

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