BELGIAN ADVISORY COMMITTEE ON Bioethics

Opinion no. 54 of 10 December 2012 on consent for the *post mortem* removal of human body material for human medical applications or for scientific research purposes

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The point 1 of the opinion has been partially translated; the points 2 hasn't been been translated. These points are available only in French, Dutch or German on the website of the Committee: www.health.belgium.be/bioeth under the headings 'avis' or 'adviezen' or 'Gutachten'.

Request for an opinion of 12 February 2010 from Mrs L. Onkelinx, Minister of Social Affairs and Public Health, concerning the scope of Article 12 of the Law of 19 December 2008 on the acquisition and use of human body material for human medical applications or for scientific research purposes.

1. Definition of the subject of the Opinion

In a letter dated 12 February 2010, the Minister of Social Affairs and Public Health sought the Committee's opinion on two aspects of organ removal: firstly, Articles 6, § 2, and 7, § 2 , 3 °, of the Law of 13 June 1986 on the removal and transplantation of organs, inserted by the Law of 25 February 2007, together with the deletion of Article 10, § 4, 3, of the said law by the same Law of 25 February 2007; and secondly, the scope of Article 12 of the Law of 19 December 2008 on the acquisition and use of human body material for human medical applications or for scientific research purposes.

The Committee considered that these two aspects are clearly distinct from one another and that each requires specific ethical reflection. It has therefore deemed it appropriate to separate them, and to respond to the Minister's request in two Opinions. The first Opinion (Opinion no. 50 of 9 May 2011) focuses on the *Law of 13 June 1986 on the removal and transplantation of organs*. The present Opinion deals with the *Law of 19 December 2008 on the acquisition and use of human body material for human medical applications or for scientific research purposes*.

A. Scope of the Law of 19 December 2008

This law applies "to the donation, removal, acquisition, testing, handling, preservation, storage, distribution and use of body material intended for human applications or for scientific research purposes" (Article 3, § 1, Paragraph 1). Its scope is therefore very broad and awkward to define. To do so, reference must be made to the definitions contained in Article 2 of the law:

- *human body material*: "any human biological material, including human tissue and cells, gametes, embryos, foetuses and substances extracted from them, regardless of their degree of transformation";
- *cells*: "isolated cells of human origin cells or a group of cells of human origin not linked together by connective tissue"
- *tissue*: "any constituent part of the human body consisting of cells";
- *removal*: "act by which the human body material is extracted from the human body";
- *human medical application*: "use of human body material on or in a human recipient, including extracorporeal application";
- *scientific research*: "any use of human body material for the development of knowledge for the exercise of the health care professions."

The law therefore applies to any removal of human body material intended for human medical applications or for scientific research purposes, in the sense which has just been recapitulated but which is not further specified in the text. Its scope encompasses the removal of and all operations carried out using *stem cells*, regardless of their origin,

including from cord blood, peripheral blood or bone marrow or of mesenchymal origin (Art. 3, § 2). The Law of 19 December 2008 does not apply, however, to:

- what happens after death to the body itself: on this point, reference should be made to the Law of 20 July 1971 on funerals and burials and to the regional decrees on the same subject. These latter do not mention the "donation of the body to science" for educational (and research) purposes, which of course is done on a voluntary basis, as the use of the body in this way can be stipulated by the deceased in his or her will;
- the removal of organs for transplantation, which is the subject of the Law of 13 June 1986 on the removal and transplantation of organs;
- procedures using blood, blood components and blood products of human origin, which are covered by the Law of 5 July 1994 on blood and blood products of human origin;
- the removal of and procedures with human body material for autologous use within a single procedure;
- the removal and procedures performed with body material exclusively for diagnostic purposes for the benefit of the person from whom the material was removed, provided it is not used for any other purpose;
- hair (with the exception of follicles), nails, urine, breast milk, faeces, sweat and tears (Art. 3, § 3).

As the Committee stressed in its Opinion no. 50, it is thus appropriate to make a clear distinction between *organs removed for therapeutic purposes*, referred to by the Law of 13 June 1986 and *tissues and cells removed for any purpose whatsoever*, or *organs removed for scientific research purposes*, referred to by the Law of 19 December 2008. However, this distinction between the scope of the Laws of 13 June 1986 and 19 December 2008 respectively does not always seem to be properly observed in practice.

[…see the French, Dutch or German version of the opinion on www.health.belgium.be/bioeth under the headings avis or adviezen or Gutachten].

[B. ….]

C. Subject of this Opinion

This Opinion does not directly address the *use* of human body material, but considers the conditions under which it is obtained after death. It aims to provide an ethical assessment of Article 12 of the Law of 19 December 2008, which states that Articles 10, 11, 12, 13 and 14 of the Act of 13 June 1986 on the removal and transplantation of organs *apply to any removal of human body material after death*. […].

[2. Legal framework]

3. Ethical considerations

A. Introductory considerations

Various types of human body material are used in an increasing number of contexts with an ever wider spectrum of possible purposes. As Bronwyn Parry vividly puts it:

> *The act of excising and collecting bodily parts and tissues for anatomical analysis or pedagogical use has a long tradition. However, the practice of intentionally harvesting them for re-utilisation … is relatively new. [The perfection of*

transplantation technologies and] advances in molecular biology are together creating an unprecedented demand for human corporeal material ... Whole organs such as kidneys, along with corneas, mitral heart valves, ... ligaments, ... ova, sperm, and embryonic stem cells are now routinely transferred ... for reincorporation in recipient individuals or use in ... research programmes. The exponential increase in demand for biomaterials ... is now culminating in new forms of bio-commerce...[1]

In addition to use for directly *therapeutic purposes* (such as transplantation), human body material is also becoming an increasingly important raw material for *scientific research*. News regularly appears in the specialist literature and the press on breakthroughs in the search for possible treatments for diseases through the study of body material collected from humans. Thus, a recent large-scale British-Canadian study of breast cancer revealed that, based on the examination of nearly 2,000 tumour specimens, ten different tumour types had been identified, each presenting different DNA mutations and patterns of gene expression favouring tumours.[2] It is hoped that such knowledge can be applied in new and more specific treatments.

In addition, it is increasingly common for isolated human body material to form the basis for *product development*. Various products – such as bone paste, diagnostic tests and certain pharmaceutical products – are directly or indirectly derived from human body material.

The demand for human body material is thus intense in the field of modern medicine, whether for direct therapeutic applications addressing life-threatening conditions, the development and production of medical devices that can be implanted in the human body, or the use of certain types of materials in the context of scientific research, sometimes at very fundamental stages. These different types of use thus relate to a variety of contexts, in which the link between the use of human body material and the ultimate therapeutic goal may vary in intensity and immediacy.

This situation was analysed in two different ways by the Committee.

For some members, the *post mortem* use of human body material cannot be justified in an opt-out regime other than in response to a directly life-threatening emergency, as in the case of organ transplantation from a (deceased) donor to a (living) recipient. These members also point out that many of the products mentioned above are being developed in a private context for profit-making purposes (although the development work may be based on fundamental research in the public sector).

In the view of other members, it is neither correct nor justified to suggest that the therapeutic purposes that authorise an opt-out regime for *post mortem* collection of material should be so limited. After all, medical devices contribute to care and the maintenance of quality of life for a growing number of health conditions. As for scientific research in the strict sense of the term, the primary objective of even the most fundamental research must be, once human beings are involved – as is the case where human body material is used, even after death – "to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments) (...)" as stated in the Helsinki Declaration, a cardinal text for research ethics.[3]

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[1] B. Parry, "Entangled exchange: Reconceptualising the characterisation and practice of bodily commodification" *Geoforum* 2008; 39: 1133-1144, 1133-1134.

[2] C. Curtis et al., "The genomic and transcriptomic architecture of 2,000 breast tumours reveals novel subgroups" *Nature* 2012; doi:10.1038/nature10983 (published online on 18 April 2012).

[3] World Medical Association, Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, point 7, available at http://www.wma.net/en/30publications/10policies/b3/.

This implies that, if research meets current fundamental ethical standards[4] and is based on a properly evaluated objective and scientific method, it is in principle never dissociated from a therapeutic purpose (in the broad sense). Its outcome may be unpredictable – this is what makes it research rather than a body of existing knowledge – but its purpose must be part of a causal chain that, in the short, medium or long term, contributes to the understanding of diseases and the improvement of treatment possibilities.

As for the commercialisation of certain devices and applications derived from human body material extracted *post mortem* and the research associated with such activities, this represents a response to existing (therapeutic) needs. It should also be remembered that this profit-making activity is supervised by European and national legislation and that if abuses occur, they are supposed to be punished by the courts. In addition, in the view of the members of this second group within the Committee, it is by no means clear that discontinuing the opt-out regime would reduce the abuses for the sake of financial gain: it would make the sources of available human material scarce, which could well have precisely the opposite effect and further increase the importance of the market in this area.

These viewpoints on the opt-out system lead to differing ethical assessments of the system established by the Law of 19 December 2008.

As indicated in the chapter on the legal aspects of our question, Article 12 of this law implies a highly significant double extension of the regime of "presumed consent" that applies in Belgium to *post mortem* organ transplants:

1) an extension from *post mortem* removal of *organs* to *post mortem* removal of *any human body material* falling within the scope of the 2008 Law, and

2) an extension from *post mortem* extraction for *transplantation* purposes (*i.e. directly therapeutic* purposes) to *post mortem* extraction for *research purposes*.

It is this double extension that is regarded as lacking ethical justification by some members of the Committee. To others, it seems ethically justified, provided the conditions stipulated by the law are reinforced.

No member was in favour of an unconditional opt-out system, which would apply to any removal and any use of human body material. The ethically sensitive nature of this "material" is emphasised by all the Committee members, and is the reason why there is a need for a better legal and ethical framework for its removal and use. All Committee members therefore believe that the system of an opt-out– which in legal terms represents a derogation from the common regime of consent – must always meet certain conditions in order to be justified.

B. Position opposing the opt-out system for *post mortem* removal of human body material

Some Committee members see the extension of the regime of "presumed consent" brought about by the Law of 19 December 2008 as ethically unacceptable.
They argue that: (1) there is no general duty to participate in biomedical research, and such a duty therefore does not apply *post mortem* either, and (2) the collection of body material after death may have disadvantages, possibly for the deceased, but above all for the living and for society as a whole.[5] The arguments for this position are presented below, based on a

[4] Based on the Helsinki Declaration (Seoul 2008) (http://www.wma.net/en/30publications/10policies/b3/), the Guidelines of CIOMS, the Council for International Organisations of Medical Sciences (http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines_nov_2002_blurb.htm) and the Unesco Universal Declaration on Bioethics and Human Rights (http://portal.unesco.org/en).

[5] We will explain later on why, according to these members, the system of *presumed consent* as set out in the 2008 Law amounts in practice to little more than the 'conscription' or automatic

rebuttal of the arguments commonly used by supporters of a regime of "presumed consent" for the *post mortem* collection of human body material.

1. There is no general duty to participate in biomedical research

A supposed general duty to participate in biomedical research is defended by several prominent bioethicists, including Arthur Caplan, John Harris and Rosamond Rhodes.[6] They base this argument on several underlying duties, which are not, however, stressed to the same extent by all these authors, and which we will scrutinise in turn.

- A moral obligation to help others or *duty of beneficence*: When our actions are likely to save others from serious harm and we can reasonably be expected to perform such acts (after assessing the risk and benefit to ourselves and the benefit to others), we should perform such actions. We have a moral obligation to help others in need, and because biomedical research is a necessary means of remedying medical needs, the promotion of biomedical research is a moral duty.[7]

- A moral *duty of fairness*: Following Rawls, some of the above authors stress that people who benefit from participation in cooperative social arrangements have obligations towards one other when they are asked to assume the risks and duties that are often associated with involvement in such cooperative activities.[8] This duty of fairness is in turn sometimes broken down as follows:

    1. A duty not to behave like a *free-rider*: People who refuse to participate in biomedical research while accepting its benefits behave like free-riders towards people who do participate in biomedical research. As we all (at least in industrialised countries) derive benefit from the results of biomedical research, non-participants have a moral debt that entails a duty to support biomedical research.[9]

    2. A duty to *help maintain public goods*: Regardless of whether non-participants are free-riding, everyone has a duty to participate in biomedical research because the knowledge it generates must be regarded as a "public good". A "public good" is a good that can be used by one person without reducing its enjoyment by another person. In addition, everyone (potentially) derives benefit from a "public good", which is why it is impossible to exclude people who do not contribute to it from the enjoyment of it.[10] The problem with "public goods" is that people do not feel called upon to contribute to them, even when the benefits to them of the "public good" outweigh the

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collection of bodily material *post mortem*, whenever a clinician or researcher regards such collection as potentially useful and has access to the body of the deceased.

6 A.L. Caplan, "Is there a duty to serve as a subject in biomedical research?" *IRB: Ethics and Human Research* 1984; 6(5): 1-5; S. Chan & J. Harris, "Free riders and pious sons - why science research remains obligatory" *Bioethics* 2009; 23(3): 161-171; J. Harris, "Scientific research is a moral duty" *Journal of Medical Ethics* 2005; 31: 242-248; R. Rhodes, "In defense of the duty to participate in biomedical research" *American Journal of Bioethics* 2008; 8(10): 37-44. See also e.g. C.D. Herrera, "Universal compulsory service in medical research" *Theoretical Medicine* 2003; 24(3): 215-231.

7 J. Harris, "Scientific research is a moral duty" *Journal of Medical Ethics* 2005; 31: 242-248.

8 J. Rawls, *A theory of justice*. Cambridge: Harvard University Press, 1971.

9 A.L. Caplan, "Is There a Duty to Serve as a Subject in Biomedical Research?" *IRB: Ethics and Human Research* 1984; 6(5): 1-5; H.M. Evans, "Should patients be allowed to veto their participation in clinical research?" *Journal of Medical Ethics* 2004; 30:198-203; D. Orentlicher, "Making research a requirement of treatment: why we should sometimes let doctors pressure patients to participate in research" *Hastings Center Report* 2005; 35(5): 20-28.

10 D. Woodward & R.D. Smith, "Global Public Goods and Health: Concepts and Issues" in R. Smith et al. (Eds). *Global Public Goods for Health: Health Economic and Public Health Perspectives*. Oxford: Oxford University Press, 2003: 3-32.

disadvantages they incur by contributing to it. As biomedical research leads to very important medical knowledge which benefits us all, we have a duty to support the production of such knowledge by participating in biomedical research ourselves.

However, each of these arguments, though plausible at first sight, is open to some fundamental criticisms. We will comment on these criticisms in reverse order (dealing first with criticisms of the alleged duty of fairness and then with criticisms of the alleged duty of beneficence).

a) Criticisms of the idea of a duty to participate in biomedical research due to a moral duty of fairness

1) Criticism of the argument about free-riding behaviour

A first criticism asserts that the charge of *free-riding behaviour* is inappropriate. Such behaviour may be said to exist when a person receives a benefit for which others have paid, but refuses to pay a share of the costs required for this benefit to exist. In fact, though, people do already pay – through taxes and insurance premiums or out of pocket – for virtually every medical benefit they receive.[11] In addition, they often contribute indirectly – through taxes – to the subsidies given to biomedical research projects.

Even if they did not participate at all, it could not be claimed that people who refuse to participate in biomedical research while accepting its benefits behave like free-riders. After all, the costs of participating in biomedical research that are borne by the *current* participants in research will not be reduced if other people also participate. This is because the benefits of new participants' involvement will not be enjoyed by the existing participants, but by those who may benefit from the results in the future without in practice contributing themselves. Although increased participation in biomedical research would probably help society as a whole and future generations, it does not imply a decrease in the costs for those who currently participate in biomedical research.

For these reasons, the idea that an obligation to participate exists on the basis of a duty of reciprocity with regard to the contributions that others have made *previously* to biomedical research and from which we are currently reaping the fruits cannot be accepted as such, since whether or not we reap the fruits today of others' past contributions will neither increase or decrease the moral value or the costs associated with those contributions.

To make the argument that non-participants are free-riders convincing, it would also be necessary to demonstrate that non-participants actually hinder biomedical research significantly by their refusal to participate; yet the right of objection is always maintained, even in the most radical opt-out systems. Although the presumption of consent is justifiable under certain conditions and in some cases, removing the possibility of refuting that presumption would not be, because of the freedom that individuals should always have where their bodies are concerned, the effect of which persists after death.

2) Criticism of the argument concerning the maintaining of public goods

A "public good" is a good that can be used by one person without reducing its enjoyment by another. In addition, everyone (potentially) derives benefit from a "public good", which is why it is impossible to exclude people who do not contribute to it from the enjoyment of it. As biomedical research leads to very important medical knowledge which benefits us all, some argue that we have a duty to support the production of such knowledge by participating in

[11] I. Brassington, "John Harris' argument for a duty to research" *Bioethics* 2007; 21(3): 160-168; I. Brassington, "Defending the duty to research?" *Bioethics* 2011; 25(1): 21-26; I. de Melo-Martin, "Response to Rosamond Rhodes" *Newsletter on Philosophy and Medicine* 2008; 7(2): 13-14.

biomedical research ourselves.

The main problem with this argument is that the claim that biomedical research is a "public good" must itself be qualified. One may legitimately ask to what extent biomedical research does actually give rise to research results which are available to the public, to affordable treatments and to discoveries that are relevant (and at the very least harmless).

The argument that there is a general obligation to participate in biomedical research because we all derive benefit from its results in the industrialised world takes no account of the social context of access to healthcare. In fact, access to the results of biomedical research also depends, in the industrialised world, on factors such as financial opportunity (health insurance), the availability of preventive care and the ability to process the influx of information about medical solutions and developments. This means that any such obligation does not exist or only exists to a much lesser extent on the part of disadvantaged groups.[12]

Many biomedical research projects do not aim – or not primarily – to improve the general welfare, but are (at least in part) driven by greed. Often, the results are not shared with colleagues[13] or even have a counter-productive effect, because part of the research and (especially) of the development of diagnostic and therapeutic methods is restricted for many years by patents that are granted.[14]

In addition, there is no denying that many biomedical research projects, including many studies with human experimental subjects, provide little or no relevant information and therefore cannot contribute to an improvement to the general welfare.[15]

Moreover, the point should not be overlooked that biomedical research projects can also be harmful to the people involved. Those in charge of research can simply exploit the participants, treating them as a mere means to gain prestige and/or wealth (one only has to think, for example, of the late Henrietta Lacks and her family[16], the late John Moore[17] and members of the Havasupai tribe in the United States[18]). We may also add that the results of research, for example in the case of genetic research, can also have discriminatory effects or a stigmatising impact (not just for the participant, but also for the group to which he or she belongs).[19]

In short, even if it were possible to demonstrate that biomedical research as a social concept should be regarded as a "public good", one might ask how we can infer from this a duty to

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[12] I. de Melo-Martin, "Response to Rosamond Rhodes" *Newsletter on Philosophy and Medicine* 2008; 7(2): 13-14.

[13] See Advisory Committee Opinion no. 51 of 12 March 2012 on the publication of the results of experiments conducted on humans.

[14] See for example Sterckx, Sigrid (2009), "Patenting and licensing of university research: Promoting innovation or undermining academic values?", *Science & Engineering Ethics*, published online on 19 September 2009 (doi 10.1007/s11948-009-9168-8), printed version 2011, vol. 17(1), pp. 45-64. Cockbain, Julian & Sterckx, Sigrid (2011), "Something more is necessary – Are genes and genetic diagnostic tests statutory subject matter for US patents?", *Expert Review of Molecular Diagnostics* 11(2), pp. 149-158. Sterckx, Sigrid (2007), "Patents and Access to Drugs in Developing Countries: An Ethical Analysis", in Chadwick, Ruth; Kuhse, Helga; Schüklenk, Udo & Singer, Peter (Eds). *The Bioethics Reader – Editors' Choice*. Oxford: Blackwell, pp. 145-161.

[15] S. Holm, B. Hofmann & J.H. Solbakk, "Conscription to Biobank Research?" in H. Solbakk, S. Holm & B. Hofmann (Eds). *The Ethics of Research Biobanking*. New York: Springer, 2009: 255-262.

[16] Skloot, R. *The Immortal Life of Henrietta Lacks*. New York: Crown, 2010.

[17] *Moore v. Regents of University of California* (51 Cal.3d 120, Supreme Court of California), 9 July 1990.

[18] Van Assche, Kristof & Sterckx, Sigrid (2012), "The protection of human dignity in research involving human body material" in van Beers, B.; Corrias, L. & Werner, W. (Eds). *Probing the Boundaries of Humanity* (submitted, undergoing revision by Cambridge University Press).

[19] *Ibid.*

participate in biomedical research projects. Such research projects must at the very least meet a number of minimum requirements in terms of relevance, social benefits and minimal risk of harm (not just physical harm and infringements of privacy, but also emotional and moral harm – see below). It would therefore be difficult to establish that there is a general duty to participate in biomedical research.[20]

b) Criticisms of the idea of a duty to participate in biomedical research arising from a duty of beneficence

The argument based on a *duty of beneficence* asserts that because biomedical research is a necessary means for remedying medical needs, the promotion of biomedical research is a moral duty.

The attempt to justify the obligation to participate in biomedical research on the grounds of a duty to help others is based on a confusion between what are known as "perfect" and "imperfect" duties in the vocabulary of ethics. Whereas the duty *not to harm others* can be regarded as a perfect duty, the duty to *help* others is merely an imperfect duty.[21] As was convincingly argued by the influential 18th century philosopher Immanuel Kant, it is more serious to harm people that it is not to help them, and the duty of *non-maleficence* should be regarded as more important than the duty of *beneficence.*

The imperfect duty to help others implies that we must consider the happiness of others as an end in itself, but that we have considerable leeway as to how we go about doing this, and can balance it against other objectives (including private ones). This even means that the pursuit of other people's happiness does not always have to be preferred.[22]

To postulate a *perfect* moral duty to help others is untenable for at least the following two reasons.

Firstly, because it imposes too great a demand.[23] Such an obligation would imply that people have a duty not only to participate in research, but also to perform all kinds of other actions that promote the life of the community, but that we normally regard as purely voluntary (e.g. giving surplus food to the hungry or alms to the poor). In addition, the moral duty to help others also implies from a utilitarian viewpoint that participation in biomedical research is obligatory even if a significant risk exists, as long as the expected benefits to society are significant enough.

A *second reason* why postulating a perfect moral duty to help others is indefensible is that such a requirement would undermine our moral integrity and have a profoundly alienating effect. Given that there are very many ways to limit harm to others, we would be required to spend most of our time and energy fighting against poverty, hunger, war and so on, rather than on other projects that reduce the harm to others to a lesser extent. As pointed out

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[20] In the view of other members, research is a "public good" provided it is circumscribed by international ethical standards (such as the Helsinki Declaration or the CIOMS Guidelines) which define what the fundamental objectives of research should be in order for it to be ethically justified. In this context, the minimum standards for the protection of people participating in research or contributing to it by means of samples or personal data should be applied. Assessments by ethics committees, which are required by law, aim to check that ethical and regulatory considerations have been properly taken into account. These members argue that the fact that the outcome of research is unpredictable does not invalidate its justification or discredit its status as a public good. At the same time, they do not hold that the notion of public good *per se* implies an obligation for all individuals to participate in research (see below on how this notion of 'public good' is interpreted, in light of the concept of a 'moral community' which these members apply to society).

[21] S. Shapshay & K. Pringle, "Participation in biomedical research is an imperfect moral duty: A response to John Harris" *Journal of Medical Ethics* 2007; 33(7): 414-417.

[22] T.E. Hill. *Dignity and practical reason in Kant's moral theory*. Ithaca: Cornell University Press, 1992.

[23] L. Murphy, *Moral Demands in Nonideal Theory*. Oxford: Oxford University Press, 2000.

convincingly by Bernard Williams, a person who had such a duty would degenerate into a harm-minimising instrument without personal integrity, because the actions he or she performed would not reflect his or her deepest convictions and life projects.[24]

We could certainly accept, like Kant, that there is an *imperfect* moral duty to help others, but here again we might ask why this duty should result in mandatory participation in biomedical research.[25] The duty of beneficence requires us to benefit our fellow-humans, but there are many ways to do so, some of which are much more relevant than participation in biomedical research.[26] Even if contributing to the fight against disease were regarded as our main task, it is not clear why participating in research would be the only or best way to do this. It may well be that biomedical research (especially as practised today) is not the best way to reduce the global burden of disease. Given the close link between poverty and disease, poverty reduction is probably a far more effective way to combat disease than furthering biomedical research.[27]

We may also add that the fact that biomedical research can only contribute *indirectly* to the welfare and health of human beings after the lapse of a (sometimes lengthy) period of time and without any guarantee of success, whereas other options are direct, much faster if not instantaneous and far more certain (e.g. contributing to food aid or donating organs for a transplant), by definition makes biomedical research less attractive than other possible ways of helping others.

2. The harm resulting from removing body material after death overrides the potential benefits

A second line of argument that might be adopted by the defenders of a system of *presumed consent* for *post mortem* removal of body material is based on the utilitarian argument that the *post mortem* collection and use of biological material are permissible or even obligatory in ethical terms, because they can provide significant benefits to society and do scarcely any harm (the possibility of slight harm to the relatives of the person from whom the material is removed is recognised by the proponents of this view, but they believe that, ultimately, they do not outweigh the potential benefits – see below). Such a view implies that the removal of human body material *post mortem* could become a routine practice.

The system of *presumed consent* as provided for in the Law of 19 December 2008 amounts in practice to the automatic collection (or "conscription") of body material *post mortem*, whenever a clinician or researcher (1) regards such collection as potentially useful, (2) directly or indirectly (via a colleague or a biobank) has access to the body of the deceased, and (3) determines that the person concerned has not indicated any objection to a *post mortem* removal of organs for transplantation purposes.

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[24] B. Williams, "A critique of utilitarianism" in J.J.C. Smart & B. Williams (Eds). *Utilitarianism, for and against*. Cambridge: Cambridge University Press, 1990: 82-117.

[25] S. Shapshay & K. Pringle, "Participation in biomedical research is an imperfect moral duty: A response to John Harris" *Journal of Medical Ethics* 2007; 33(7): 414-417.

[26] I. de Melo-Martin, "Response to Rosamond Rhodes" *Newsletter on Philosophy and Medicine* 2008; 7(2): 13-14.

[27] See e.g. S.H. Woolf et al., "Giving Everyone the Health of the Educated: An Examination of Whether Social Change Would Save More Lives than Medical Advances" *American Journal of Public Health* 2007; 97(4): 679: *"[C]orrecting disparities in education-associated mortality rates would have saved more than a million lives rather than about 178 thousand that were averted by medical advances"*. See also T. Pogge, "Responsibilities for poverty-related ill health" *Ethics International Affairs* 2002; 16: 71: *"[P]overty is far and away the most important factor in explaining health deficits. Because they are poor, 815 million persons are malnourished, 1.1 billion lack access to safe water, 2.4 billion lack access to basic sanitation, more than 880 million lack access to health services, and approximately 1 billion have no adequate shelter"*.

The law stipulates (Art. 12) that the consent of the person concerned is presumed *for any removal of material after death* and is therefore authorised in all cases, *unless* the person has expressed an objection to *post mortem* removal of organs for transplantation. Given that the Belgian population is totally unaware that under the 2008 Law, not objecting to the *post mortem* removal of organs for transplantation is *treated as equivalent* to not objecting to the *post mortem* removal of organs for the purposes of scientific research and of tissue and cells for scientific research or therapeutic purposes, and given, therefore, that citizens who *do not agree* will not express an objection because they are not aware that they need to do so, the 2008 Law has *made access to material from the body of deceased people extremely easy*.

a) Similarities with the debate on *presumed consent* versus *informed consent* for *post mortem* organ transplantation, but a different ethical conclusion

Pleas for as permissive a regime as possible for the *post mortem* removal of body material for therapeutic and research purposes are often based on ethical arguments that we also encounter in the context of discussions on the *post mortem removal of organs for transplantation*, e.g. the arguments cited by various prominent bioethicists to advocate a system of *presumed consent* for organ transplantation after death.

These specific arguments are discussed briefly below, since the distinction between the *post mortem* removal of body material for a therapeutic purpose that will directly benefit a patient and removal for research purposes is seen as a fundamental distinction by those Committee members who oppose the *presumed consent* regime provided for in the law of 19 December 2008. The view of these members does *not* mean they reject the *presumed consent* regime in force in Belgium for *post mortem* removal of *organs for transplantation*. They contend that the problems lie in the *extension* of this regime. They reason that the *benefits* on the basis of which one may opt deliberately for a system of *presumed consent* for posthumous organ donations *are not convincing* in the context of posthumous removal of body material. At this point, the disadvantages that may exist but cannot be regarded as decisive for posthumous organ donation in a system of *presumed consent*, gain in importance in an ethical appraisal, since the advantages expected from the posthumous removal of body material are less certain, and although they do exist, are often less important than in the case of the removal of organs for transplantation purposes.

According to Beauchamp and Childress, there is an *obligation to rescue* if five conditions are all met: (1) a person's life or health of is in serious danger; (2) another person's intervention is required to avert this danger; (3) the intervention has a high probability of success; (4) the intervention does not involve any significant risk, expense or burden to the other person; and (5) the potential benefit to the person in need outweighs the probable risk, expense or burden for the other person.[28] Refusing to help in such circumstances – "the failure to undertake easy rescue" – makes the person a "bad Samaritan" according to Joel Feinberg.[29]

Post mortem organ removal for transplantation purposes satisfies these five conditions and is therefore an example of an *easy rescue* according to this reasoning. This is why ethicists who defend this position hold that we can establish a principle that people have a duty, after their death, to provide their organs for transplantation purposes if doing so may save the lives or substantially improve the health of others. From this point of view, to agree to a *post mortem* organ donation can no longer be regarded as a form of generosity, but must be considered an important morally binding duty.[30] Some authors go even further than postulating a serious moral obligation here, and take the view that the imposition of a *legally binding* obligation to donate is justified (i.e. pure conscription), since the benefits for people

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[28] T.L. Beauchamp & J.F. Childress. *Principles of biomedical ethics*. New York: Oxford University Press, 1994: 264.

[29] J. Feinberg. *Freedom and fulfillment*. Princeton, NJ: Princeton University Press, 1992: 175.

[30] See e.g. D.A Peters, "A unified approach to organ donor recruitment, organ procurement, and distribution" *Journal of Law and Health* 1989-90; 3: 157-187, 168.

experiencing a serious medical condition are very significant (organs can usually save lives) and the disadvantages for the dead, the relatives and society as a whole are very slight.

For the sake of clarity, it should be mentioned that these members of the Committee are *not* proponents of pure conscription (without any possible opt-out) for *post mortem* organ transplants, but think that *presumed consent* is ethically defensible in this context, given the particularly important and direct therapeutic benefits of such *post mortem* organ removal, which normally saves lives.[31] Further, these members believe that if an organ posthumously removed for transplantation proves unsuitable, it should be available for use in scientific research related to transplantation. Except in exceptional circumstances, the family must be informed.

As we shall see, the relative value of the benefits and drawbacks of a system of *presumed consent* for posthumous removal of body material for research purposes is totally different from the relative value of the benefits and drawbacks of a system of *presumed consent* for posthumous removal of organs for transplantation. The balance tips in the latter case on the negative side.

b) Posthumous removal of body material: the benefits are less certain and, although they exist, often less important

The aim of the law – to ensure enough body material can be obtained so that biomedical research can be performed – is less important and urgent than the aim of organ transplantation. The posthumous removal of human body material from a specific deceased person cannot directly save a life.

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[31] Naturally, these members are aware that some people have objections to a system of *presumed consent* for posthumous organ donation. However, they believe that these objections are not decisive. We cannot go into this debate in detail, since it is not essential to the question which this opinion is supposed to answer; however, we will make some brief remarks. Opponents of a system of *presumed consent* for posthumous organ donation often remark that such a system leads to organs sometimes being removed from people who did not wish to be donors, because a certain percentage of people who do not wish to donate organs fail to register their wish not to do so. If organ removal is performed anyway, this constitutes a fundamental breach of their wishes regarding the disposal of their body after death. They hold that in an *opt-in* regime or *informed consent* regime, organ removal is far less likely to be performed on someone who did not want it. On this type of argument, see e.g. R.M. Veatch & J.B. Pitt, "The myth of presumed consent: Ethical problems in organ procurement strategies" *Transplantation Proceedings* 1995; 27: 188-192. However, one could equally well say that in an opt-in system, the organs of people who do wish to donate organs, but have failed to register this wish, will not be removed. It is not clear why this would be regarded as less serious from a moral point of view than the removal of organs from people who did not wish to donate, but had not registered their opposition. Moreover, as numerous opinion polls show that those who are willing to donate their organs easily outnumber those who are not, it seems appropriate, on the basis of a 'fewer mistakes claim', to opt for a system of presumed consent. See e.g. MB Gill, "Presumed Consent, Autonomy, and Organ Donation" *Journal of Medicine and Philosophy* 2004, 29 (1): 37-59. Again, though, the main reason why these members of the Committee are in favour of a system of *presumed consent* in the specific context of the post mortem removal of organs for transplantation is related to its particularly important and direct therapeutic benefits (given that they normally help save lives). Of course, it goes without saying that any authority introducing a system of presumed consent must make constant efforts to give its citizens clear and detailed information. In this area, the Belgian authorities still have a lot of work to do, as already noted by the Advisory Committee in its Opinion no. 50 of 9 May 2011 (especially in point 4.E.2.d.). In a system of *presumed consent* for post mortem organ transplantation, there will certainly be occasional cases in which organs are taken from people who did not wish to donate, but had not registered their opposition and had not told their relatives either. In such cases, the wishes of the deceased will not have been respected. However, the principle that a person's wishes about what will happen to his or her body after death must be respected as far as possible is not an absolute one. In other words, this principle may, in exceptional cases, be overridden by other moral principles, such as when another person's life is at stake and we can reasonably assume that the transplant will save his or her life.

Moreover, the aim of obtaining enough body material to be able to carry out biomedical research, which Committee members opposed to extending the opt-out certainly do not deny is highly laudable in many cases (see below), can be achieved *in another way*, one which is ethically justifiable. A sufficient stock of body material for research can, with some effort, be obtained using a regime of *informed consent* or, more correctly formulated, explicit authorisation (see on this point the specific recommendations in Opinion no. 45 of 19 January 2009 concerning human biological material banks, point VI.1.2.C.; we will return to the details of such a regime later on, in the chapter "Recommendations and conclusions").

However, the system provided for in the 2008 Law is *easier* for those wishing to obtain *post mortem* body material, and is also *cheaper*, as it takes less time than the system proposed by these members. In these members' view, however, this is not sufficient reason to prefer the system established in the 2008 Law.

So much for the point that the benefits of the posthumous removal of body material for research purposes are relatively limited and that there is an alternative way to obtain these benefits, which, although it requires a little more time and resources, poses far fewer ethical problems than the system set up by law. What about the disadvantages? In other words, for what specific reasons do the members of the Committee consider the system provided for by the law to be ethically indefensible?

c) Posthumous removal of body material: the nature and ethical relevance of the possible disadvantages

1) Potential disadvantages for society

When people learn about the system used to obtain body material *post mortem* for research purposes, this could have a direct impact on the number of organs removed *post mortem*, as there is currently no possibility of adopting differing positions in terms of objecting or consenting to the removal of body material and the removal of organs. In other words, a system which is ethically problematic (or perceived as such) for the posthumous removal of body material for research could undermine the system of presumed consent for posthumous organ donation with which we are familiar in Belgium.[32]

More generally, it could even lead to a collapse in the confidence that many citizens have towards the government and biomedical research. While the population remains unaware of what is permitted by the 2008 law in terms of the *post mortem* collection and use of body material, the risk of a strong reaction is probably very slight, but the Alder Hey scandal in the United Kingdom,[33] which still arouses emotion many years after the events concerned, demonstrates the scale of the trauma that can result from a "leak" in a single case.

2) Potential disadvantages for close relatives of the deceased

If we examine the question from the perspective of the close relatives, it is fair to say that the disadvantages of biomedical research on body material from a deceased person may be more severe and are likely to affect a larger number of people than the removal of organs from a deceased person for transplantation. Alongside the *comparable* potential drawbacks – associated with the potential psychological disturbance that some family members may experience from the idea of the body being cut open, material removed, and the dead person's body being exploited – there may also be disadvantages which are *specific* to the context of biomedical research on body material removed *post mortem*.

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[32] See e.g. Nys, H. (2009) "Bloed, zweet en tranen. Kritische ontleding van de wet van 19 december 2008 inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal", *Rechtskundig Weekblad*, 2009-2010, p. 184, n° 26.

[33] Royal Liverpool Children's Inquiry Report (2001), available at http://www.ricinquiry.org.uk/download/index.htm [consulted on 23 August 2012].

3) Potential disadvantages from the point of view of the deceased: harm to posthumous "interests"?

In the literature, it is sometimes assumed rather casually, without many supporting arguments being offered, that what happens to the body of someone who has died has no implications as far as that person is concerned. However, conclusions on this subject ought to be based on an analysis of the possible arguments, rather than on mere suppositions. One of the reasons why such an analysis is far from simple is that terms are sometimes used in this context that cannot be applicable (e.g. the "rights" of the deceased), or that may intuitively seem to be applicable, but require clarification and argumentation (e.g. the "interests" of the deceased), or that clearly can be applicable but have less normative force as a concept and, like any term on which we wish to develop an ethical argument, require explanation (e.g. the "wishes" of the deceased).

The question of whether there are what may be called posthumous "interests" is much discussed and gives rise to differing views. Three positions can be distinguished in this debate.

A *first group* claims that deceased individuals may incur harm from posthumous events. This group is found in the religious community, and associates the corpse's physical intactness with the deceased's interests in the (presumed) afterlife. From this point of view, posthumous interests are significant because the deceased begins a second life after death, of a spiritual nature, and the physical intactness of the body may be a crucial precondition for this. We will not consider this point of view any further in the rest of this Opinion.

A *second group* believes that the dead cannot incur any harm from posthumous events and that it therefore makes no sense to speak of harm to the *ante mortem* person from events occurring *post mortem*. They argue that the dead can no longer have any interests, and hence no interests that can be affected by the posthumous use of their body material.[34]

For example this reasoning is found in a very pronounced form in Jonsen: "*Consent is ethically important because it manifests and protects the moral autonomy of persons … [and] it is a barrier to exploitation and harm. These purposes are no longer relevant to the cadaver, which has no autonomy and cannot be harmed.*"[35] Some people who have similar views on the issue stress that posthumous interests, if they exist, are in any case easily ousted by the interests of the living, who need the body material of the deceased for their health.[36]

The claim that posthumous interests do not exist and that we can do whatever we like with the body of the deceased – at least if we are solely taking the position of the previously living person as our basis and we disregard the possible impact on the relatives and on society – is based on two combined assumptions:

1) *Lack of subject*: After death, there is no longer a subject who has interests and there is therefore no one to be harmed. Partridge, for example, argues that the concept of interests that survive death is totally incoherent, "*as there is no … one who can be harmed at the point that any wrongful setback of interest occurs*".[37] Glannon takes the view that the concept of "harm" involves a comparison between anterior and posterior bodily or mental states, and that an action occurring after death cannot cause a real change because it no longer has any influence on the person's intrinsic

[34] See e.g. A. Spital & C. Erin, "Conscription of cadaveric organs for transplantation: Let's at least talk about it" *American Journal of Kidney Diseases* 2002; 39(3): 611-615; and J.S. Taylor, "The Myth of Posthumous Harm" *American Philosophical Quarterly 2005;* 42(4): 311-322.

[35] A. Jonsen, "Transplantation of fetal tissue: An ethicist's viewpoint" *Clinical Research* 1988; 36: 215.

[36] See e.g. A. Spital & J.S. Taylor, "Routine recovery of cadaveric organs for transplantation: Consistent, fair, and life-saving" *Clinical Journal of the American Society of Nephrology* 2007; 2(2): 302.

[37] E. Partridge, "Posthumous interests and posthumous respect" *Ethics* 1981; 91: 243.

characteristics.[38]

2) *The impossibility of regressive causality:* Even if a person had interests before death that are adversely affected by events occurring after his death, such harm cannot have retrospective effects.[39] In short, whatever happens to the body *post mortem* cannot have any influence on the person *ante mortem*.

A *third group* in the debate on whether posthumous interests exist claims that the dead cannot incur any harm from posthumous events, but that people do have interests that survive death and thus can be harmed when these interests are violated. The existence of such *surviving interests* seems consistent with strong intuitions shared by many people on this subject, and therefore deserves further analysis.

The fact that in our society we show respect for people's wishes about what should happen to their estate after their death and to their body (e.g. funeral preferences; donation of body to science; opt-out from organ donation) shows that there is a widely shared intuition (which is often upheld by the law) that certain personal wishes must be respected after death. Death cannot be regarded as completely destroying all moral traces of the person as he or she was when alive.[40] As we noted earlier, some commentators speak in this regard of "interests". The Law Reform Commission in Canada, for example, held that:

> *The utter disregard of one's burial wishes, or the failure to honour one's express wishes on the post-mortem uses of one's body, lend credence to the claim that people have interests that survive their deaths and that they may be harmed when the interests are violated.*[41]

According to many bioethicists, this feeling is much more than an intuition, and is in fact based on clear ethical principles.[42] They believe that the right to respect *post mortem* for the wishes of the person expressed *ante mortem* derives from the autonomy with which the person took decisions while alive about what should happen after his or her death. It can be argued that the decision about how our mortal remains will be disposed of after death is the expression of our final wishes, and hence perhaps our most fundamental wishes.

In the terminology used by Ronald Dworkin in his analysis, this is a "critical" interest rather than an "experiential" interest. Things are of experiential interest to a person on account of the enjoyment they bring him or her (e.g. playing sport, going out for a meal, gardening). The value of such things is *solely* related to the personal experience that the person in question has of them, and it does not really matter whether other people also consider them important. Conversely, things are of critical interest to a person when they have a critical impact on his or her life goals.[43]

By contrast with when he or she is merely engaged in the pursuit of pleasurable experiences, it is essential for a person setting significant life goals that his or her wishes should be respected and taken into account by others. From this point of view, people have the right to choose independently the fate for their body material after their death that reflects their life,

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[38] W. Glannon, "Persons, lives, and posthumous harms" *Journal of Social Philosophy* 2001; 32(2): 128.

[39] See e.g. W. Waluchow, "Feinberg's theory of preposthumous harm" *Dialogue* 1986; 25: 731.

[40] M. Wicclair, "Ethics and research with deceased patients" *Cambridge Quarterly of Healthcare Ethics* 2008; 17(1): 87-97.

[41] Law Reform Commission of Canada. Procurement and transfer of human tissues and organs, working paper 66, 1992: 45.

[42] For an analysis of these principles, see e.g. D. Price. *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework*. Cambridge: Cambridge University Press, 2010. The summary of the arguments that we present here is largely drawn from this impressive work.

[43] R. Dworkin. *Life's Dominion.* London: Harper Collins, 1993: 199-217.

character and moral values most closely. Unlike experiential interests, critical interests may be harmed after death.[44]

A remark frequently heard regarding the determination of what happens to one's own body material after death is that it may be a matter of critical interest while the person is still alive, but not subsequently, because (as stated earlier), there is no longer a subject and hence no longer the possibility of regressive causality of the negation of this critical interest.

It may be objected to the point on the *lack of a subject* that it is generally recognised in other contexts that individuals' interests may be harmed without their being aware of it at the time or in the future. For example, one may be the victim of theft or defamation without being aware of it, or fall into a coma, meaning that others have to make crucial decisions that fundamentally affect one's welfare. It is therefore wrong to believe that we can only have an interest in things of which we are conscious. In short, the "*mental state account of harm*," i.e. the idea that one must be aware of harm for there to be any harm at all, is inadequate.

Wishes can be fulfilled by events after the death of the person concerned just as they can by events during his or her lifetime. Fulfilment of wishes in the former case is just as positive as in the latter. It is true that the dead may never *know* whether their wishes have actually been fulfilled or have been ignored, but it is not clear why a simple lack of knowledge of what has happened would imply that they have not been harmed by their wishes being ignored.[45]

In short, regardless of whether a person is aware of the fulfilment or non-fulfilment of his or her wishes, harm can be caused simply by non-fulfilment of those wishes. Such a concept of harm that is unrelated to one's experience of it adequately captures the very essence of the problem that arises when prior manifestations of wishes (*advance directives*) are not respected. For example, if the wishes of persons in a persistent vegetative state that have been expressed independently beforehand are ignored, it is the wishes of the previously mentally capable person that are ignored. The principle that such wishes must be respected 'survives' the loss of mental abilities and consciousness of the person concerned.

Of course, it may be objected that in this case, the (legal) person is still alive and that this is a fundamental difference. However, various authors argue that, like a person who has died, a person who is no longer capable has undergone a crucial (though less drastic) change to his or her personal identity, which leads us to conclude that even in the case of a persistent vegetative state, the person who was previously capable is regarded as the person who incurs the harm, rather than the subsequently incapable person.[46]

Joel Feinberg, well known for his analysis of the concept of harm, stresses that:

> *All interests are the interests of some person or other and a person's surviving interests are simply the ones that we identify by naming him, the person whose interests they were. He is of course at that moment dead but that does not prevent us from referring now, in the present tense, to his interests, if they are still capable of being blocked or fulfilled, just as we refer to his outstanding debts or claims, as if they are still capable of being paid.*[47]

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[44] See e.g. R.A. Belliotti. *Posthumous Harm: Why the Dead Are Still Vulnerable.* Lanham, Md.: Lexington Books, 2012.

[45] J. Feinberg. *The Moral Limits of the Criminal Law*, Vol. I, Harm to Others. Oxford University Press, 1984.

[46] See for example A. Buchanan, "Advance directives and the personal identity problem" *Philosophy and Public Affairs* 1988; 17(4): 277-302; H. Kuhse, "Some reflections on the problem of advance directives, personhood and personal identity" Kennedy Institute of Ethics Journal 1999; 9(4): 347-364.

[47] J. Feinberg. *The Moral Limits of the Criminal Law*, Vol. I, *Harm to Others*. Oxford University Press, 1984, 83.

He argues that it is absurd to think that as soon as the person to whom we have promised something dies, an unfulfilled promise which was made while that person was still alive ceases to be a serious injustice to him or her.[48] Such an outlook seems far from counter-intuitive or controversial.

It might be objected that even if the existence of "surviving interests" and "posthumous harm" is conceded, the deceased is in any case no longer able to assert any *rights*, and that surviving interests are thus completely devoid of substance. However, this argument can be countered with the point that the obligation to uphold such interests is based on the rights that the person was able to exercise *ante mortem* and that while the rights themselves may have lapsed, some of the duties associated with them survive *post mortem*. In this light, surviving duties may very well exist without there being any surviving rights.

Wellmann stresses, for example, that although rights cannot survive the death of their holder, certain duties arising from these rights may continue to exist and therefore imply future duties for others. He adds: "*But this need not be to ascribe rights to the dead; it can and should be to assert that the rights of the living continue to impose duties even after the persons who possessed those rights have ceased to exist.*"[49] The same reasoning, incidentally, lies behind the continuation of certain contractual obligations after the death of the other party to the contract.

3. The need to be able to avoid moral complicity with the achievement of goals one finds morally objectionable

A final reason that members of the Committee opposed to the extension of the system of *presumed consent* as provided for in the Law of 19 December 2008 wish to expound relates to the importance of being able to avoid moral complicity with behaviour that we find objectionable.

Each of us has certain moral values that are reflected in life plans. These values may conflict with the methods and/or goals of certain types of biomedical research. Even in the case of *post mortem* research on body material, where health risks and threats to privacy can no longer be a concern for the donor, a risk of non-pecuniary harm nevertheless exists.

According to these Committee members, scientists and clinicians do not have the right to take the decision to use body material *post mortem* for research purposes in lieu of the person concerned. The potential donor must have had the opportunity to make sure that he or she was willing to contribute to biomedical research by donating body material *post mortem*, and, if so, to explain what type of research he or she would regard as acceptable in the light of his or her moral values (see also below).

If this opportunity to give specific authorisation is not provided, and if consent is simply assumed "in the interests of science", it is perfectly conceivable that the body material will be used in a way that is completely incompatible with the person's values, which amounts to *unacceptable exploitation*. Regarding the use of leftover body material for research purposes, this reasoning is developed convincingly by bioethicist Julian Savulescu:

> *Each mature person should be the author of his or her own life. Each person has values, plans, aspirations, and feelings about how that life should go. People have values which may collide with research goals [...]. To ask a person's permission to do something to that person is to involve her actively and to give her the opportunity to make the project a part of her plans. When we involve people in our projects without*

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[48] J. Feinberg. *The Moral Limits of the Criminal Law*, Vol. I, *Harm to Others*. Oxford University Press, 1984, 95. See also D. Price. *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework*. Cambridge: Cambridge University Press, 2010: 61.

[49] C. Wellmann. *Real Rights*. Oxford: Oxford University Press, 1995: 156.

their consent we use them as a means to our own ends.[50]

It should also be noted in passing that making body material anonymous or coding it does not undermine this argument *at all*, as such procedures only provide protection in the area of privacy,[51] but in no way guarantee respect for the values of the deceased.

It should further be borne in mind that a person can be held morally complicit if his or her body material is used for a purpose to which he or she has moral objections. Moral complicity means that we can do something wrong just by being linked to unjust acts committed by others. This is obviously the case where a person has helped cause the injustice, but there can also be moral complicity if a person has made an injustice more likely to occur, even *without* making a strictly causal contribution.[52]

The importance of enabling people to avoid posthumous moral complicity is, in the view of these members of the Committee, an additional reason for not accepting the system of *presumed consent* for the *post mortem* use of body material.

C. Favourable position towards an opt-out system for *post mortem* removal of human body material, with certain requirements in addition to current legislation

Within the Committee, other members support the principle of the opt-out system in connection with the *post mortem* removal of human body material, including when it is intended for human medical applications and for scientific research purposes. They contend that the opt-out regime is entirely ethically justified, provided it meets certain conditions.

1. The ethical foundation of the opt-out system

a) Preliminary points

Proponents of this position first wish to point out that, like the members who are opposed to the opt-out scheme introduced by the Law of 19 December 2008, they are opposed to any form of "conscription" in this respect, and believe it is crucial to keep the possibility to refute the presumption of consent introduced by the opt-out regime. This is why they consider the 2008 Law as satisfactory on this point, since it provides the opportunity to rebut the presumption. However, they consider it regrettable that the population is not more aware of this possibility, and think that this lack of information should be remedied by all appropriate means (see recommendations): citizens have the right to know the arrangements that the legislators have made in this area, which may have a direct impact on their bodies after their

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[50] J. Savulescu, "*For and Against:* No Consent Should Be Needed for Using Leftover Body Material for Scientific Purposes – Against" *British Medical Journal* 2000; 325: 648, 649. A comparable view is found in, for example, R. Rhodes, "Rethinking Research Ethics*" American Journal of Bioethics* 2005; 7: 16-17.

[51] Moreover, various studies have shown that even such protection cannot be guaranteed. See e.g. McGuire, A.L. & Gibbs, R.A. (2006), "Genetics. No longer de-identified", *Science* 312, pp. 370–371. See also Schmidt, H. & Callier, S. (2012), "How anonymous is 'anonymous'? Some suggestions towards a coherent universal coding system for genetic samples", *Journal of Medical Ethics* 38(5), pp. 304-309. See also Lowrance, W.W. & Collins, F.S. (2007), "Identifiability in genomic research", *Science* 317, pp. 600–602.

[52] As examples of the interesting literature on moral complicity, see John Gardner, "Complicity and Causality" *Criminal Law and Philosophy* 2007; 1: 127-141; Ronald M. Green, "Benefiting from 'Evil': An Incipient Moral Problem in Human Stem Cell Research" *Bioethics* 2002; 16: 544-556; Christopher Kutz, *Complicity: Ethics and Law for a Collective Age*. Cambridge: Cambridge University Press, 2000; and Helen Watt, ed., *Cooperation, Complicity & Conscience – Problems in Healthcare, Science, Law and Public Policy*. London: The Linacre Centre, 2006.

death, and to be told the reasons for these measures and the ways of registering an objection to them. They argue that it is under these conditions of clarity, publicity and education that the profoundly ethical significance of this system can be preserved.

These members stress that the opt-out system must involve transparency and honesty with the general public – and hence the repeated provision of comprehensive explanations of its principle, its purpose and how it works. This is required firstly because of the sensitive area to which it relates – the use of body material after death – but also because it reflects a certain climate of trust: in return for the limitation of individual autonomy that the scheme involves, for reasons relating to the public interest and the public good, as will be explained below, the legal regime in this area must be perfectly transparent.

It is true that, in principle, there is nothing exceptional about some limitation of individual autonomy in the field of governance, which has been postulated in theory many times in philosophies of the social contract. But it remains important ethically for members of the public to have the significance of the opt-out regime for the community explained to them, as well as the details of how to refute presumed consent if they wish to. This is the only way to counter the charge of disguised "conscription" that the scheme's detractors sometimes level at it.

In line again with the opponents of the system established by the 2008 Law, proponents of the opt-out system also hold that there is no individual moral obligation to participate in research, and that an individual would not be acting immorally if he or she refused to allow the removal of human body material for human applications or scientific purposes.

At the same time, these members stress that for the community itself, participation in research through *post mortem* donation of material is not a neutral attitude and that it matters whether a society encourages participation in scientific research by an opt-out regime. Moreover, these members believe that legislators and holders of public authority would be behaving unethically towards society if they led us to believe that this issue – the question of whether or not to participate in scientific research by allowing body material to be removed *post mortem* – can be left *entirely* to the discretion of each of us.

This ethical position is based on the following supporting elements: 1) an understanding of society as a moral community, 2) a conception of scientific research as a "common good under certain conditions", 3) considerations about the social significance of the opt-out regime and 4) consideration of its practical effects.

b) Elements of the ethical foundation of the opt-out regime for post mortem removal of material for scientific purposes

1) Society as a moral community

Members of the Committee in favour of this position emphasise that, to assess the issue of the ethical justifiability of opting out, individual freedom cannot be the only support; although this freedom should indeed be respected in any democratic system, we must also consider society as a whole as a *moral community*.

In support of this, they note that in order to function, society lays down certain rules and recommendations which affect the freedom of each of us, and which uphold certain values because of their relevance to the community as such.

These rules and recommendations cannot be analysed solely in terms of the deprivation, diminution or manipulation of individual liberties that they entail. Unless one regards society as a mere accumulation of individual freedoms, it must be recognised that the community of citizens has a strength and legitimacy that go beyond the scope of individuals. Such a position does not amount to postulating the community as a "global" power: it merely means allowing that certain values can only be understood at the specific level of the community.

Thus certain values acquire rectitude and legitimacy at the community level even in the absence of any real moral obligation on the part of individuals.

It is in this respect that, despite the absence of an individual moral duty to participate in scientific research, the opt-out system may be regarded as morally and ethically justified at the social level: the point is to establish collectively a mechanism that makes an essential contribution to citizens' participation in research, without this mechanism removing any freedom on their part or creating any inequality in principle. It is important to stress that the opt-out scheme does not oblige anyone to participate in research posthumously, since it is always possible to object to the scheme and rebut the presumption. On the other hand, it draws attention to the value of participation in research at the collective level and the fact that such research is regarded as a "common good under certain conditions."

2) Scientific research as a "common good under certain conditions"

For the members who support this position, the point is not to engage in smug scientism or to lose sight of reality. Research can, if its regulation is non-existent or insufficient, be an activity with particularly deleterious effects, for those who participate in it (healthy or sick volunteers and those from whom samples and/or personal data are taken) and/or their families, but also for society as a whole[53] when it sees its core values being flouted. To be convinced of this, one only has to consider the many tragedies that marked the 20th century in particular in this context.

Research acquires the status of a common good when it is the subject of scientific and ethical evaluation according to international[54] and local ethical standards. When a research protocol involves clinical research, i.e. when it involves people and/or human samples and/or personal data, such research can be implemented only under strict conditions, which must be adhered to throughout the investigation.

In the view of these members, research involving people, human samples or personal data is only a good when (1) it satisfies the ethical and regulatory requirements of international and local ethical standards, and (2) it leads to an increase in scientific knowledge which (3) in the short, medium or long term produces a better understanding of disease and contributes to the medical care of individuals. When these conditions are met, it is reasonable and justified for legislators to encourage the public to participate in research, because of the benefits that it is likely to bring to the community.

The reason why this is so is that research is the best way – if not the only way – to enable a hypothesis associated with an individual case to be turned into a relevant scientific fact at the level of a population or population group. In other words, the scientific approach makes possible a process of objectivisation and generalisation with which an empirical approach cannot compete. And this twofold transformation of a hypothesis (or an observed fact) into scientific fact (or demonstrated fact) and from an individual level to a collective level has a major impact in the field of public health. In fact, this latter is only possible as an intellectual category and as a form of intervention in the public sphere because we have the intellectual and statistical means of moving from the individual case (which is of course observable in a care provision context, independently of any research) to the cohort, and from the cohort to the population. There is thus a consistency of scale, but also in principle of goals, between the field of research and that of public health. It is for this reason that the Committee

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[53] Thus the Tuskegee scandal can be seen as representing the continuation and reproduction of racial and class violence against Afro-Americans in the United States, despite the development of social structures between the 30s and the 70s.

[54] Derived, it will be recalled, from the Helsinki Declaration (Seoul 2008) (http://www.wma.net/en/30publications/10policies/b3/), the Guidelines of CIOMS, the Council for International Organisations of Medical Sciences. (http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines_nov_2002_blurb.htm), and the Unesco Universal Declaration on Bioethics and Human Rights (http://portal.unesco.org/en).

members who hold this position believe that it is fundamentally justified to encourage individuals to participate in research, and that scientific research is a "common good under certain conditions" which should of course be strictly regulated, but which should also be promoted, in particular through an opt-out system for *post mortem* removal of human body material.

3) The social significance of the opt-out scheme

The opt-out regime serves as a *social signal*. The reason why the legislators wish to encourage research is that it is regarded as a good for society. It is therefore not treated as a neutral activity that it would be inappropriate to promote at the level of society or even, simply, as an activity without any interest to the community. The purpose of the opt-out scheme is not to override the freedom of individuals, but to adjust it in order to *communicate* the fact that research is a social and collective "good", particularly because of its links with public health.

In this view, the regime of "presumed consent" sends a positive signal in favour of participation in scientific research in order to support public health, while respecting the possibility of individual objection.

The restriction that it potentially introduces to individual autonomy does not seem here to be disproportionate in light of the essential importance of public health.

4) Practical effects of the opt-out regime

As well as sending a clear signal about the social significance of participation in research, the opt-out scheme is one of the most direct ways, though not the only one, to ensure that enough body material is removed. This seems entirely ethically justified as a goal on the part of legislators for the following reasons:

The effect of ethical regulation on the sources of human body material

Using legal provisions and social structures in a country to ensure that researchers have enough material available is a way of combating the trafficking and black market practices to which demand for human body material worldwide gives rise, although it is not enough in itself to put a stop to those practices.[55] By creating the conditions for the collection of sufficient (though not unlimited: on this point see the recommendations of the members supporting this position) amounts of material, legislators can ensure, among other things, the *ethical regulation* of the demand for and use of human body material by researchers. When the needs for human body material are met through official channels in a country, there is less risk of "unofficial" circuits controlled by criminal gangs developing to meet those needs. This indirectly protects socially vulnerable categories of people (such as prisoners) who are the regular victims of these networks in some countries.

A simplifying and clarifying effect on rules and structures

The rules for the regulation and control of human body material in an enormous variety of contexts (transplantation, fertilisation, development of treatments, removal, analysis, research, storage, transportation, etc.) are becoming increasingly complex and require multiple regulatory or inspection bodies. This causes delays, increases costs and leads to confusion of responsibilities and categorisation. The current system, which encompasses the *post mortem* donation of organs, tissues and cells for transplantation and/or scientific research in a single model (the opt-out regime), concentrates responsibilities for the issue of human body material within human biomaterial institutions and biobanks and reduces the quantity of records and the number of stages in the process. This constitutes a guarantee of

[55] See the report published in *Le Monde* on 22 July 2012.

safety and practicality.

The clarity of the system is one of the factors that have led to a consensus in France, where the opt-out system for the removal of tissue or organs has existed since 2003, apparently without having caused any particular problems so far. The creation of the National Committee for Biovigilance, whose work is coordinated by the National Agency for Medicines and Health Products Safety (MSNA), has enabled collection and other activities relating to human body material to be controlled, in particular through inspections on the ground. The application of the right to object (the opt-out) was not a subject for further debate during the revision of the bioethics law in 2011[56].

Moreover, it should also be noted that it too is regarded as a solidarity-based system, and one which is not forbidden either by EU directives or the Oviedo Convention.

5) Some important points

It should be recalled that the opt-out system cannot be regarded, under these conditions, as "conscription". Encouraging the donation of a *sufficient volume* of material does not mean that everyone participates (as we can always rebut the presumption), but it does require that *we are all socially encouraged to participate*. To those who cite people's natural tendency, when asked, to say that they would be willing to donate, and claim that it is hence unnecessary to establish a system of "presumption", one may answer that it is precisely because participation in research measures its specific value and legitimacy against the yardstick of society as a whole that it is up to the legislator to *send a message* about its importance and legitimacy, and to encourage participation, rather than allowing the unrestricted exercise of individual freedoms to define what such participation will be. However, the fact that some people are prepared to donate of their own free will ensures that this encouragement is a socially regulated amplification of natural traits within society, rather than a forcible appropriation of the individual by the collective.

Moreover, the proponents of this position take the view that in itself, the use of human body material in the context of research which is properly supervised and assessed scientifically and ethically does not entail treating the body as a mere tool. In their view it cannot be seen as desecrating or disregarding the sacredness of the body, even though its physical integrity is affected. At the symbolic level, moreover, some advocates of keeping the opt-out system point out that removing human body material for research has the effect of delaying the body's natural decay after death, and giving it a potential symbolic "utility". Of course there are differing sensitivities, beliefs and attitudes vis-à-vis the body and the respect due to the mortal remains of the deceased, as well as to family members and to the social groups to which the deceased belonged. The Committee members in favour of retaining the opt-out system believe that, if accompanied by certain guarantees, it is a safe and transparent means of preventing corpses from being tampered with for the sake of research in an unjustified and potentially profane way.

Some of these members also point out that all research, especially that involving human body material, is already regulated by safety, health and ethical rules. Thus any research on human body material must have received approval from a medical ethics committee and must be carried out in approved laboratories on material obtained, stored and transported according to specific rules.

Some opponents of the opt-out system under certain conditions argue that it is not a moral duty for everyone to contribute to research, since not everyone has equal access to healthcare and hence to the benefits of scientific research. While it is unfortunately true that access to healthcare is not equal for all, the solution is to act to dispel this disparity. Non-participation on this ground will do nothing to solve this problem of unfairness. In addition,

[56] However, the French expert who was heard by the select committee was highly critical of French law and the opt-out system.

the knowledge gained through the development of research may help to reduce the cost of certain forms of care and thus make them accessible to a larger number of people.

2. Ethical points concerning the treatment of people's final wishes and critical interests in the context of an opt-out system for post mortem removal of material for scientific purposes

Members who wish to keep the opt-out regime would like to stress the following point: at no time does this scheme, in their view, have the effect of completely negating individuals' autonomy regarding their final wishes for funeral arrangements. When the removal of material is for scientific purposes, we must remember that the entire body is not regarded as having been donated to science (which would require an explicit wish on the part of the deceased, expressed during his or her lifetime, to "donate his or her body to science/medicine/the Faculty"). Only partial removals of material, made in compliance with the rules governing the care for and handling of dead bodies, are allowed. Once these have been performed, the last wishes of the deceased can be fully respected and his or her wishes regarding funeral arrangements complied with.

Concerning the point about not wishing to be complicit with research of which one disapproves, this is entirely understandable, and the opt-out scheme does not completely negate this moral right that each of us has regarding what happens to our body, including when material is removed from it for scientific purposes. Rather than a loss of this moral right, it would be more correct to speak of its limitation and management by means of the opt-out regime. As mentioned earlier, in principle only research that meets international ethical standards should be authorised when that research relates to people and/or human specimens and/or personal data. Such compliance is verified by the medical ethics committees that evaluate research protocols using human body material collected *post mortem* with a view to its use for scientific purposes. It is therefore incorrect to consider, unless there is a flaw in the system of ethical evaluation, that the deceased may end up in a situation of "moral complicity" with fundamentally unethical research. In principle, the current system already ensures that research will at least meet minimum ethical standards.

It is true that in the opt-out system, the "moral" value of research is not assessed directly by the individual: rather, this is done *by the Ethics Committee, which performs this assessment in the public interest*, and therefore at least partially and symbolically represents the deceased. However, it is true that there is no longer any right to determine exactly how the material is used, by contrast with what happens in the case of living donations. *Personal preferences* will no longer be taken into account. But this reduced right to determine how the body material is used does not seem to those Committee members who support the opt-out regime to be out of proportion, given the change in the person's status by reason of his or her death. Although the deceased's critical interests must be taken into consideration, this cannot be done to the same extent or by similar mechanisms as those in place for the living. These members therefore reject the argument that the opt-out regime leads to an intolerable exploitation of the person of the deceased.

3. Summary of the position in favour of keeping the opt-out with the addition of further conditions

The members who support this position therefore take the view that Article 12 of the Law of 19 December 2008, which permits the donation under an opt-out regime of body parts of people who have died for human medical applications or for scientific research purposes can be kept, with the addition of further conditions and the reinforcement of the control systems.

They wish to warn against the risks of discontinuing this provision: it is doubtful whether the same level of participation in research can be achieved by awareness campaigns on this issue and the formalisation of individual wishes by certain channels. Moreover, account should be taken of the difficulty of conveying this kind of message to the public, a message

concerning the body, death and disease. It should also be borne in mind how many different requests and appeals individuals are subject to these days.

For all these reasons, it seems unrealistic to believe that it would be possible to achieve the same degree of availability of human body material by seeking an explicit statement of position from each individual. Yet, as has been stated, there is a proven link between the opt-out system and effective and rigorous research which has the potential to contribute greatly to public health. The members who support this regime therefore believe that it would be ethically irresponsible to recommend that the system be discontinued.

However, they consider it essential to reinforce the degree of control and security regarding the collection of body material, for the following reasons:

1) It is unacceptable for only the *use* of biological material should be subject to the appraisal of a medical ethics committee. The *removal* of the material should also undergo ethical validation in some way.

Of course, the fact that the specific purpose for which human biological material will be used has often not yet been defined at the time of collection (by contrast with the removal of material from living donors) makes a "regular" assessment by medical ethics committees impossible.

This is why these members recommend that an agency – possibly the current Federal Agency for Medicines and Health Products – should, in liaison with the medical ethics committee of the hospital where the material is removed, verify the scientific reasons for doing so, regardless of how the collected material will be used. This would enable an assessment of all research needs for human body material.

2) Arrangements should be made to allow a *differing response* to the opt-out for therapeutic purposes and the opt-out for research purposes, so that if people wish to rebut the presumption of consent to the donation of material for research purposes, they are not therefore obliged to do so for donations for therapeutic purposes at the same time.

3) These members also call for the royal decrees implementing the Law of 19 December 2008 to include provisions specifying the establishment of an effective traceability system ranging from the collection of body material to its storage, transportation and final use, and ensuring that only authorised organisations can perform these tasks, in complete transparency.[57]

4) For the donor or his or her family: even after death, the collection of human body material can expose the donor, and by extension members of the family or genetic group from which he or she comes, to stigmatisation (e.g. in connection with genetic studies). Such a risk may be partially – but only partially – circumscribed by the requirement for material that is collected and studied to be treated anonymously. However, in the field of human genetics, total anonymity seems impossible. It would therefore be prudent to provide other security mechanisms to protect descendants and relatives of potential donors from any such abuses.

[57] On traceability, see already Article 14 of the Law of 19 December 2008 and Article 6 of the Royal Decree of 28 September 2009 setting quality and safety standards for the donation, removal, acquisition, testing, handling, storage and distribution of human body material, which human body material banks, intermediate human body material structures and production facilities must meet.

4. Recommendations and conclusions

A. Recommendations made jointly by all Committee members

The Committee unanimously deplores the lack of any ethical debate prior to the adoption of Article 12 of the Law of 19 December 2008, which extends the opt-out system to all *post mortem* removal of human body material for human medical applications or scientific research purposes. None of its members defends this legal provision *in its present form*.

The Committee unanimously stresses the need to allow citizens the possibility of expressing differing wishes with regard to two possibilities: firstly, the *post mortem* removal of organs for directly therapeutic purposes and in response to a life-threatening condition (the case of transplantation); and secondly, the *post mortem* removal of body material for therapeutic purposes not in response to a life-threatening condition or for scientific purposes. These actions do not have the same moral, ethical and social significance – even though they can all be justified – or the same legitimacy. It would be particularly regrettable and dangerous if the extensive scope of Article 12 of the Law of 19 December 2008 were to lead to a reduction in the number of organs available for transplantation, due to the current impossibility of asserting a differing position (refusal or acceptance) vis-à-vis these three types of collection of body material. This problem can only be solved by creating a separate register to record opt-outs from the *post mortem* removal of body material.

The Committee stresses that at the very least it is necessary for the public to be given more information. It is unacceptable that most citizens are unaware of the options available to them regarding the use of body material liable to be removed after their death, even though the Committee members are aware of the potential difficulties of addressing this kind of subject and choosing the appropriate time and tone.

B. Recommendations and conclusions of members opposed to the opt-out system for *post mortem* removal of human body material

In the view of some members of the Committee, the Belgian Law of 19 December 2008 amounts, *in practice*, to making human body material automatically available *post mortem*. They see this as going too far.

These members wish to stress that they definitely consider it important to inform the public in detail about the importance of scientific research and to *actively encourage* people to contribute in some way to its progress.

Fortunately, it seems that the vast majority of citizens in various countries are not at all opposed in principle to the provision of body material while they are alive for the purposes of biomedical research. However, this does *not* give researchers, clinicians and the public authorities the right to assume that:

- *No one* is opposed, or
- Anyone who agrees with the *ante mortem* use of his or her body material for research purposes by definition agrees with its *post mortem* use for the same purposes, or
- Anyone who agrees with the *post mortem* collection of (some of) his or her organs for transplantation purposes by definition also agrees with the *post mortem* collection of body material, for either therapeutic or research purposes.

Once again, these members regard it as desirable to say the least for the public to be informed about the value of biomedical research and encouraged to contribute to it, by donating body material and/or by other means. They are also aware that it would be unfair to impose a condition of "informed consent" in connection with research on human body material, since it is de facto *impossible* to inform a potential donor of *all* possible uses of his or her body material. As the term "informed consent", which requires the information to be

tailored to the individual, may be misleading in this context and give the false impression that the person concerned will have comprehensive and adapted information and hence an ethical safeguard, these members prefer to use another expression.

The appropriate expression in this context is "explicit authorisation". These members therefore argue that:

- The *explicit authorisation of the person concerned* is necessary for the *post mortem* removal of body material for *human medical applications*, except in the case of an organ transplant within the meaning of the Act of 13 June 1986. In this latter case, presumed consent, together with proper performance of the associated duty of information provision, is sufficient.

- The *explicit authorisation of the person concerned* is required *in all cases* for the *post mortem* removal of body material for *research purposes*.

With regard to the specific arrangements and the implementation of the explicit authorisation referred to above, these members believe that a document along the following lines must be given to everyone:

WHAT DO I WANT TO HAPPEN TO MY BODY MATERIAL AFTER MY DEATH?

This document concerns the collection of body material after death, such as cells, tissue, brain or bones; it therefore does *not* relate to organs such as the heart, lungs, liver or kidneys. Increasing use is made of such body material both for *therapeutic* purposes, i.e. for the benefit of other patients (e.g. skin or bone transplants), and for *scientific* purposes (research with a view to discovering possible treatments for diseases). The question of what you want to happen to your body material after you die therefore deserves some thought.

We invite you to make a choice between the following options and tick one of the four boxes:

I, the undersigned,
(first name and surname:).....
(national register number – see the back of your identity card:).....

(1) agree to the removal of body material after my death:

(a) for therapeutic purposes, i.e. for the benefit of another patient (note that in this case, an independent body will decide which patient will receive the material); ☐

(b) for scientific purposes (in order to find treatments for diseases); in this case, any specific research project in which the body material might be used will be subject to the approval of the hospital's medical ethics committee; this committee will ensure in particular that the rules on the protection of privacy and confidentiality are respected; ☐

(c) for both therapeutic (a) and scientific (b) purposes. ☐

(2) withhold permission for any removal of body material after my death, for any purpose whatsoever. ☐

(date:).....

(signature:).....

If you would like more information in order to make your choice, do not hesitate to contact your

doctor. It is essential to understand that you can change your mind at any time. If you do, you can simply ask for a new form, either from the reception desk at the hospital where you are staying, or from your doctor, and return the completed form to the reception desk or your doctor.

We also wish to emphasise that whatever choice you make, it will not in any way influence the care that you will be given. *However, if you do not specify any choice, the law states that you will be deemed to agree with option 1.c. (i.e. use for therapeutic and scientific purposes).*

Thank you for reading this document.

Each of us has values that are reflected in aspirations and life plans. These values may conflict with the methods and/or goals of certain types of scientific research. If scientists think they have good reasons to use such human body material for research either *ante mortem* or *post mortem*, they have every right to explain to the person concerned, while he or she is alive, why this research is valuable and why his or her participation in it (by providing the material in question) is very important. However, they do not have the right to decide in the person's place whether or not the material can be used. The person must be able to ensure that the way the material is used for research, including posthumously, will be consistent with his or her moral values. If we deprive people of this possibility and decide for them "in the interests of science", we are using them as a means to achieve a goal that is not necessarily theirs and are therefore violating their dignity.

With regard to the material that is *already stored in biobanks* and for which no authorisation regarding use can now be sought, since the people concerned are already dead, these Committee members do not claim that this material should be destroyed, given the massive implications this would have for research projects already in progress. However, they call for the rapid introduction of a new regime of explicit authorisation via an amendment to the Act of 19 December 2008 as outlined above.

In addition, these members believe that if an organ removed *post mortem* for transplantation proves unsuitable, it should be available for use in scientific research purposes related to transplantation. Except in exceptional circumstances, the family must be informed.

C. Recommendations and conclusions of members in favour of the opt-out system for *post mortem* removal of human body material

In the view of these members, the current law can be kept, provided further conditions are added and control systems are reinforced.

These members are in favour of keeping the opt-out regime for *post mortem* collection of human body material and wish to warn about the consequences of abandoning this regime – which they regard as morally and ethically justified – for the public health sector. Accordingly, they argue for the retention of Article 12 of the Law of 19 December 2008, which provides for an opt-out system for *post mortem* collection of human body material for scientific purposes. However, given the ethically sensitive nature of this material, they recommend that additional precautions be taken.

1. Improving public information

It is important for citizens to be better informed about the provisions of the current legal framework and the reasons why this system was introduced. These members therefore recommend that in hospital admission booklets, as well as in the waiting rooms of healthcare facilities, concise and simply worded information should be provided in any medium deemed appropriate, mentioning the opt-out regime with regard to the *post mortem*

collection of body material for therapeutic and scientific purposes, and the possibility of withholding permission for such collection, either completely or on a differentiated basis depending on the purpose (direct therapeutic/scientific purposes).

Example of poster text or wording:
"Under the current law, in the event of death, organs, cells and tissue may be removed from the body of the deceased, in a manner respectful of his or her dignity and that of his or her family. The collection of such organs and body material can save lives or contribute to research and development leading to the creation of new medicines. If you do not want body material to be removed after your death, or if you want material to be removed only to save lives through organ transplantation after your death, but not for use in a research setting, you can register your wishes by contacting ... "

2. Evaluating the ethical and scientific appropriateness of collecting human body material

Under the current legislation, only the *use* of biological material must be approved by an ethics committee. However, *the actual removal of this type of ethically sensitive material* should be the subject of evaluation as to its need and appropriateness. It would be unacceptable for such material to be available in unlimited quantities and for it to be collected indiscriminately, without paying heed to the ethically sensitive nature of this material and without checking that there is a proven scientific need.

It is true that such an evaluation cannot proceed in the same way as those currently performed by ethics committees, on the basis of a protocol and in the context of a specific research purpose. This is not possible for two reasons. Firstly, the material has often been collected in advance of the research and the drafting of a protocol. Secondly, for this evaluation to take place presupposes a comprehensive knowledge of the needs for human body material within each research institution and the country more generally, in order to determine whether, based on the type of material required (e.g. corneas or gastric cells) and the research field concerned, there is a shortage (which would permit more material of this type to be collected), a surplus (which would lead to a reduction in the amount of material collected) or a state of equilibrium.

Given the specific characteristics of this evaluation, the Committee members who wish to keep the opt-out regime recommend that an agency should be created – or that this task should be entrusted to the current Federal Agency for Medicines and Health Products – to allow overall research needs for human body material to be assessed, and guidelines issued on how the collection of material should take place in order to be justified. This agency would first need to be able to draw up an inventory of present and future needs for human body material, in partnership with research institutions and human biobanks, as well as by cross-checking against the registers listing research in progress. Based on this inventory, it should be possible to determine the collection volume that is actually needed and hence justifiable.

3. Increased protection for individuals' genetic material

These members acknowledge that, even after the donor's death, there may be a risk to his or her family if genetic information is disclosed that has been derived from the body material of the deceased, since it could be used for discriminatory or stigmatising purposes. The use of measures to maintain anonymity provides only limited protection in human genetics, because certain genetic information is always identifiable. A specific assessment should therefore be performed by the researchers in the research protocol of the risk of identification and stigmatisation of relatives, depending on the type of genetic investigation planned and the susceptibility to stigmatisation of the disease or physiological characteristic under investigation. The Ethics Committee which evaluates the protocol will need to check that adequate measures have been planned to 1) regulate the use and disclosure of identity-

sensitive data/results in a research context, e.g. by stipulating that the results of these investigations will only be disclosed in databases that are subject to data-sharing policies[58], and 2) prevent any disclosure or use of these results outside the context of the research.

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[58] *OECD principles and guidelines for access to research data from public funding*: document available at the address: http://www.oecd.org/sti/sci-tech/oecdprinciplesandguidelinesforaccesstoresearchdatafrompublicfunding.htm

The opinion was prepared in the select commission 2010/3bis, consisting of:

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The working documents of the select commission 2010/3bis – request for opinion, personal contributions of the members, minutes of the meetings, documents consulted – are stored as Annexes 2010/3bis at the Committee's documentation center, where there may be consulted and copied.

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This opinion is available on the website www.health.belgium.be