

# Vindicating the right to bodily security of the incapable in research – Part 1

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## **Introduction**

The concept of a right to bodily security centres partly on freedom from being forced to do things with one's body and freedom from intrusion on it. Restriction of this right can be consistent with respecting individuals but seemingly only where its exercise would clash with their own interests or the rights of others. In spite of this, restriction founded on meeting the mere needs of others has been a persistent feature of discourse, law and practice in a number of fields, not least research where it is often targeted at incapable persons.

## **Legal recognition of the right to bodily security vis-à-vis the needs of others**

Civil law jurisdictions impose a legal duty to rescue in the common accident or emergency situation.<sup>2</sup> Such duties will certainly mandate (limited) bodily action but are unlikely to be strong enough to warrant actual bodily intrusion. The common law is opposed to both these forms of restriction of bodily security. The seminal case is *McFall v Shimp* No. 78-17711. 10 Pa D & C (3d) 90 (Pa 1978). Here the Allegheny county court was faced with an application from Robert McFall, an aplastic anaemia sufferer, to force his cousin, David Shimp, to continue testing to see if he was a bone marrow match and, if suitable, donate bone marrow. In rejecting the application his honour, Mr Justice Flaherty, observed that

*“(t)he common law has consistently held to a rule which provides that one human being is under no legal compulsion to give aid or to take action to save another human being or to rescue.”*<sup>3</sup>

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<sup>2</sup> Feldbrugge, ‘Good and bad samaritans: A comparative survey of criminal law provisions concerning failure to rescue’ (1966) 14 *Am. J. Comp. L.* 630, 655–6.

<sup>3</sup> No. 78-17711 at 2.

He went on to assert that:

“...For our law to compel the defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual, and would impose a rule which would know no limits, and one could not imagine where the line would be drawn...For a society, which respects the rights of one individual, to sink its teeth into the jugular vein or neck of one of its members and suck its sustenance for another member, is revolting to our hard-wrought concepts of jurisprudence...”<sup>4</sup>

Generally speaking, relevant international instruments concord with the common law position by emphasising the dignity, security and primacy of the individual. This is true, for example, of the *Universal Declaration of Human Rights* (1948), *European Convention on Human Rights* (1950), the *World Medical Association’s Declaration of Geneva* (1948) *Physicians Oath* and its *International Code of Medical Ethics* (1949). The *World Medical Association’s Declaration of Helsinki* (1964)<sup>5</sup> and the *Council of Europe’s Convention on Human Rights and Biomedicine* (CHRB, 1997)<sup>6</sup> equally have this emphasis, but also contradictorily reflect the opposing ethos in their provisions concerning research on the incapable.

### **The Declaration of Helsinki and the CHRB.**

The *Declaration of Helsinki* built on the principles for ethical conduct of medical experiments on humans that were laid down following the judgments at the Nuremburg Trials for Nazi war criminals, some of whom were doctors who had performed a range of horrific acts on humans in the name of medical experimentation.<sup>7</sup> Principles 24 and 26 of the Declaration are central to the standard of protection of the incapable in research. Principle 24 states that:

“For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.”

Principle 26 adds that:

“Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.”

Whilst both principles are couched in restrictive terms, their effect is to allow some research that

4 Ibid. See also *Butler-Sloss LJ in St George’s Healthcare NHS Trust v S* [1999] Fam 26, 48.

5 Adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964, and amended most recently by 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

6 See further Zilgalvis, P, ‘The European Convention on

*Human Rights and Biomedicine: Its Past, Present and Future* Chapter 3 in Garwood-Gowers, A, Lewis, T, Tingle, J (eds.), *Healthcare Law: The Impact of the Human Rights Act 1998*, Cavendish, 2001.

7 See Katz, J, *Experimentation with Human Beings*, 1972, Bognor Regis: Russell Sage Foundation, 305–6 particularly.

is incompatible with the interests of the incapable person. Admittedly, principle 24 talks about the need for the research to be necessary to promote health but this is a reference to the health of the population. This means, for example, that research could be performed on an incapable sufferer of Alzheimer's disease where it was necessary to promote the health of Alzheimer's sufferers taken as a whole even if it did not benefit the individual sufferer, let alone have benefits that were sufficient to justify it as the optimal choice in terms of his or her interests.

The substantive requirement in the first sentence of Principle 26 may indirectly temper this problem but it does not solve it. However, there are at least two sound reasons why the deviation from best interests envisaged in these principles should not be given effect to. Firstly the Declaration specifically protects the primacy of the individual – Principle 5 stating that '(i)n medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society'. Secondly, Principle 8 of the Declaration endorses an agenda of special, not lesser, treatment of vulnerable classes such as the incapable, stating that:

*“Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.”*

The CHRB falls into the same trap of having provisions concerning research on the incapable that deviate from full protection. Article 17 states that:

- “1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:
  - i. the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;<sup>8</sup>
  - ii. the results of the research have the potential to produce real and direct benefit;
  - iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
  - iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing; and
  - v. the person concerned does not object.
2. Exceptionally and under protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

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8 These conditions relate to there being no alternative of comparable effectiveness to research on humans, the risks incurred by the subject not being disproportionate to the potential benefits of the research, prior approval by the competent body after independent examination of its

scientific merit (including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability) and the subjects being informed of their rights and the safeguards prescribed by law for their protection.

- i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;
- ii. the research entails only minimal risk and minimal burden for the individual concerned."

Article 17(2)(i) is the key provision here because it makes it clear that the research does not have to be aimed at (or presumably have the prospect of resulting in) benefit to its subjects if it has a benefit to other persons in the same age category or afflicted with the same disease or disorder or having the same condition. In other words there are circumstances in which the incapable can be subject to research that is not in their interests, even some that will not convey any benefit on them whatsoever. This is hard to reconcile with Article 2 which states that in interventions on humans in the fields of medicine and biology,

*"(t)he interests and welfare of the human being shall prevail over the sole interest of society or science."*

What is more, the fact that Article 17 targets the incapable for lesser treatments makes it hard to reconcile with Article 1 which requires signatories to,

*"guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."*

How should these internal inconsistencies be dealt with? Article 17, as a specific issue provision, could be read down in the light of Articles 1 and 2 which convey overarching norms. After all, as Zilgalvis notes, the aim of the Convention is 'to protect human rights and dignity and all its articles must be interpreted in this light.'<sup>9</sup> However, the presence of Article 26 complicates the issue. It stipulates that:

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21."

Expressed in the permissive rather than the negative, it is evident that the purpose of this Article is to allow a measure of restriction of certain rights. The question that arises in the immediate context is whether that might include restricting the right to bodily security of the incapable simply to meet a need for research. Dr Elaine Gadd, former Chair of the Council of Europe Steering Committee on Bioethics (1999–2001), has stated Article 2 'means that wherever the interests of society and those of the individual conflict, the interests of the individual should in principle take precedence.'<sup>10</sup> Nonetheless, Article 2 does not appear in the Article 26(2) list and hence it must be read in the light of Article 26. Commenting on the relationship between the two, Dr Gadd has emphasised that,

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<sup>9</sup> *European Law and Biomedical Research in Biomedical Research, Council of Europe 2004*, 168.

<sup>10</sup> Gadd, E, 'General Provisions of the Convention,' (2001) 12(1) *Journal International de Bioethique* 21–49 at 26.

*“(i)t is important to distinguish the concept of society as a whole, and the fact that society is composed of individuals. Sometimes the interests of different individuals conflict and this conflict will need to be resolved.”<sup>11</sup>*

It is implicit in any system recognising individual primacy that where the interests of individuals conflict, they will have to be weighed against one another and an appropriate resolution found in the light of this. Article 26 merely makes that process and the terms on which it is conducted more explicit and precise. However, in considering the scope of both Article 2 and 26 it is imperative to distinguish between rights and mere needs. Neither Article would preclude restricting protection of one person’s right to bodily security where full protection of it conflicted with the rights of another person (consider, for example, a forced paternity test). However, there are a number of reasons why Article 26 should not be interpreted as allowing the right to bodily security to be diluted to protect the mere needs of others.

Firstly, such an interpretation would put Article 26 out of alignment with the very essence of the primacy principle protected in Article 2 and, where done selectively with a particular class, the equality principle protected in Article 1. Secondly, in doing so it would be contrary to the norm of pluralism that underpins democracy and thus unlikely to satisfy the Article 26 requirement of being ‘necessary in a democratic society.’ Thirdly, as will later be demonstrated, it would lead to the CHRB being incompatible with the European Convention on Human Rights.

Finally, it would put the CHRB out of kilter with the *Additional Protocol on Human Rights and Biomedicine, concerning Biomedical Research* (Strasbourg 25/1/05). Article 15 of the Additional Protocol, entitled ‘Protection of persons not able to consent to research,’ elaborates on Article 17 of the Convention and specifically Article 15(2)(i) mirrors the sentiments of Article 17(2)(i). However, this emphasis on allowing the primacy principle to be abandoned in research on persons not able to consent conflicts with the overall tenor of the Additional Protocol. More specifically, the preamble makes it evident that the reasons for agreeing the Additional Protocol included convictions ‘that biomedical research that is contrary to human dignity and human rights should never be carried out,’ that ‘the paramount concern’ is ‘the protection of the human being participating in research’ and ‘that particular protection shall be given to human beings who may be vulnerable in the context of research.’ Furthermore, Article 3 of the Additional Protocol specifically imports the sentiments of Article 2 of the Convention into the research context by stating that,

*“(t)he interests and welfare of the human being participating in research shall prevail over the sole interest of society or science.”*

In the light of these points, the only credible solution is to read down Article 17(2)(i) to the point of it protecting primacy with respect to research on the incapable.

## **The movement to reform English law**

Domestic debate about when to allow intrusive research on the incapable adult has been biased by two common misconceptions: Firstly, that the CHRB and Declaration of Helsinki permit primacy violating research on the incapable adult (ultimately, as seen above, they should not be read as so doing); and secondly overly limited conceptions of what research interventions can be performed on such adults under the best interests standard.<sup>12</sup>

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<sup>11</sup> *Ibid.*

<sup>12</sup> See further, Garwood-Gowers, A, ‘The Proper Limits for Medical Intervention that Harms the Therapeutic

*Interests of Incompetents*, chapter 10 in Garwood-Gowers, A, Wheat, K, Tingle, J, *Contemporary Issues in Healthcare Law and Ethics*, Reed Elsevier, 2005.

Reform suggestions have particularly centred on the idea of using a “not against interests test” in relation to authorising non-therapeutic research on incapable adults<sup>13</sup> and, to a lesser extent, incapable people as a whole.<sup>14</sup> A variation on this theme is found in The Law Commission’s Report *Mental Incapacity*<sup>15</sup> which concluded that research;

*“which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent if (1) the research is into an incapacitating condition with which the participant is or may be affected and (2) certain statutory procedures are complied with.”*<sup>16</sup>

The procedures referred to include approval of the research by a Mental Incapacity Research Committee which, to paraphrase, must, amongst other things, satisfy itself that the research:

- (a) is desirable in order to provide knowledge of the causes or treatment of, or of the care of persons affected by, mental disability;
- (b) has an object which cannot be effectively achieved without the participation of persons who are or may be without capacity to consent; and
- (c) will not expose such a person participating in the research to more than negligible risk and that what is done in relation to such a person for the purposes of the research will not be unduly invasive or restrictive and will not unduly interfere with his freedom of action or privacy.<sup>17</sup>

These recommendations were not adopted in the Draft Mental Incapacity Bill 2002.<sup>18</sup> However, the notion that reform in this area was completely dead and buried was dispelled by the House of Lords, House of Commons Joint Committee Report on the Draft Bill.<sup>19</sup> The Committee took the view that the law relating to research on the incompetent adult should be codified. It was ‘concerned that if research were to take place in the absence of statute or any regulation the opportunity for abuse would be greater.’<sup>20</sup> This concern was deeply ironic given that its proposal for a statutory approach to research was centred on abandoning best interests protection of the incapable adult. That abandonment was something that the Committee, echoing the Law Commission, tried to justify in terms that related back to incapable adults as a class:

*“We are reminded that if legal mechanisms prevented or deterred research with such people, then the development of treatments and the undertaking of treatment trials for disorders such as Alzheimer’s disease would be very problematic. The range of medical research involving people with incapacity was considerable. Other examples include investigating why people with Down’s*

13 See, particularly, Medical Research Council, *The Ethical Conduct of Research on the Mentally Incapacitated*, Medical Research Council, 1991 and Gunn, M, et al., ‘Medical Research and Incompetent Adults’ (2000) *Journal of Mental Health Law* 60 at 66.

14 See, for example, Kennedy, I, *Principles of Medical Law*, 1998, Oxford, para’s 1340–1345.

15 Law Commission, *Mental Incapacity (Law Com No 231)* (London: HMSO, 1995).

16 *Ibid*, para 6.31. The Commission also recommended procedural protections for the individual participant. – see para 6.36.

17 Law Com No 231, para 6.34. The Commission also envisaged the best interests test being abandoned in relation to other interventions that conveyed no direct benefit to the incapable adult but could be of significant benefit to others – see para 6.26.

18 Presented to Parliament in June 2002 by the Secretary of State for Constitutional Affairs. See clause 4 and clauses 26–29.

19 House of Lords, House of Commons Joint Committee on the Draft Mental Incapacity Bill, Session 2002–3 (Vol 1) HL Paper 189–1, HC 1083–1 (HMSO, 28 Nov 2003) para 275–288.

20 *Ibid* para 284.

*Syndrome are at such high risk of Alzheimer’s disease, how best to treat the effects of acute brain injury, how to understand and manage problems such as self-injurious behaviour affecting people with autism...Research goes beyond the medical field and includes investigating factors influencing the quality of life of people with incapacitating disorders, or how they can be best helped to make decisions for themselves. In all these examples, some of the people will have the capacity to consent to research but others may not.”<sup>21</sup>*

The Committee subjected its support for abandoning a best interests approach to a proviso of non-exploitation:

*“When a person lacks the capacity to give consent, they should only be involved with medical research, if it is either in their best interests or if it is the only method of conducting research into their particular condition and everyone involved with the person is satisfied that this is a non-exploitative proposal which will not harm or distress the individual concerned.”<sup>22</sup>*

This view fails to recognise that allowing the incapable to be utilised in interventions that are inconsistent with their interests necessarily constitutes treating them simply as a means to an end and, in this sense, must necessarily also be said to be exploitative and harmful. One could attempt to circumnavigate this problem by pointing out the benefits that might be gained for people who lack capacity as a whole if protection of them was diluted. However, this would be fatally flawed; either an intervention is in the best interests of an incapable individual, taking into account potential future benefit from advances that may be made in the field, or it is not, in which case it remains exploitative irrespective of these benefits.<sup>23</sup>

The report also seemed to uncritically adopt a very restrictive perception of the best interests test in the research context.<sup>24</sup> It particularly emphasised the opinion of the Royal College of Psychiatrists that the ‘common law does not provide authority’ for medical research on the incompetent ‘as it cannot be argued that research is necessarily in that incapacitated person’s best interests.’<sup>25</sup> As is evident from cases authorising living organ and tissue donation by incapable adults under a best interests test, including *Re Y (Mental Incapacity: Organ and Tissue Bone Marrow Transplant)* [1997] Fam 110, the best interests test does not in fact require an intervention to be necessarily in a person’s best interests but simply that it is prospectively the best option for the incapable out of the choices available.

The Government responded by uncritically adopting the Committee’s view, agreeing that the Bill ‘should include provision for strictly controlled research to fill the gap that exists in the current law and the uncertainty and inequity this creates.’<sup>26</sup>

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21 *Ibid* para 279.

22 *Ibid* para 283.

23 These issues are addressed in more detail under the convention rights section of Part 2 of this article.

24 House of Lords, House of Commons Joint Committee on the Draft Mental Incapacity Bill, Session 2002–3

(Vol 1) HL Paper 189–1, HC 1083–1 (HMSO, 28 Nov 2003), para 279.

25 See further Ev 104 MIB 824b para 3.2.

26 The Government Response to The Scrutiny Committee’s Report on the draft Mental Incapacity Bill, Feb 2004. Available at <http://www.dca.gov.uk/pubs/reports/mental-incapacity.htm>

### The Mental Capacity Bill 2004

The Mental Capacity Bill, introduced in the House of Commons on 17 June 2004,<sup>27</sup> had four research clauses (30–33) which imposed three types of requirement on the researcher conducting intrusive<sup>28</sup> research with or in relation to the incompetent adult: Firstly to get the authorisation for the project from the “appropriate body” under Clause 31; secondly, to engage in such consultation of carers as required by Clause 32; and, thirdly, to satisfy certain additional safeguards. Clause 31, entitled ‘Requirements for approval,’ read as follows:

- “(1) The appropriate body may not approve a research project for the purposes of this Act unless it is satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who lacks capacity to consent to taking part in the project (“P”).
- (2) The research must be connected with a condition which –
- (a) affects P, and
  - (b) is attributable to the impairment of, or disturbance in the functioning of, the mind or brain.
- (3) There must be reasonable grounds for believing that the research would not be as effective if carried out only on, or only in relation to, persons who have capacity to consent to taking part in the project.
- (4) The research must –
- (a) have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P, or
  - (b) be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.
- (5) If the research falls within paragraph (b) of subsection (4) but not within paragraph (a), there must be reasonable grounds for believing –
- (a) that the risk to P from taking part in the project is likely to be negligible, and
  - (b) that anything done to, or in relation to, P will not –
    - (i) interfere with P’s freedom of action or privacy in a significant way, or
    - (ii) be unduly invasive or restrictive.
- (6) There must be reasonable arrangements in place for ensuring that the requirements of sections 32 and 33 will be met.”

Interestingly, Clause 31(4) was constructed so loosely as to allow, subject to certain conditions, the “appropriate body” to authorise projects merely when the burden to the incapable adult was not disproportionate to the benefit (Clause 31(4)(a)) and even when there was *no benefit* to them whatsoever (Clause 31(4)(b), subject to further provisos in Clause 31(5)). Whilst Clause 31(6)

<sup>27</sup> The change in emphasis from incapacity to capacity reflected a desire to stress the enabling ethos within the Bill’s provisions.

<sup>28</sup> Intrusive research under the Act means research that has

sufficient implications for bodily security to mean that it would fall foul of relevant legal standards if performed on a competent person without consent – see further section 30(2).



directed the appropriate body to make sure that appropriate arrangements were in place for meeting the requirements in Clause 32 or 33, neither of these clauses in this version of the Bill mandated a best interests approach to the authorising of research projects involving the incapable adult. The Joint Committee on Human Rights (JCHR) missed this key flaw.<sup>29</sup> This was probably because it used the research provisions of the CHRB as its main standards comparator.

### **Parliamentary Discussion**

At the Bill's Third Reading in the Commons on 14 December 2004, Mr Kevin Barron, Labour MP for Rother Valley, tabled a new clause 3 which was designed to expand application of the philosophy of diluting protection of the incapable out from intrusive research to medical and surgical interventions more generally. It stated that:

*“The Secretary of State may by order applying either generally or in cases of a specified description authorise the carrying out of any medical or surgical procedure in relation to a person without capacity to consent which, although not carried out for his benefit, will in the opinion of the Secretary of State not cause him significant harm and be of significant benefit to others.”*

Sir John Butterfill, Conservative MP for Bournemouth West was one of several Parliamentarians to express concern about the breadth of this proposed reform. He recounted how his mother had been told at an NHS hospital that an operation could be performed on her for her benefit when in fact she was terminally ill with pancreatic cancer and the purpose of the operation was one of medical education.<sup>30</sup> Meanwhile, Mr Dominic Grieve, Conservative MP for Beaconsfield, attacked clauses 31(4) and 5:

*“The fact that the research may be for the benefit of a wider section of society is arguably irrelevant. After all, if I am a person of full capacity and a doctor asks me whether I would be prepared to consent to tests, albeit not massively intrusive tests, which are not for my direct benefit but might benefit thousands of other people, as the law in this country currently stands – thank goodness – it is my right to say no. The idea that, if I were incapacitated, someone could make the decision for me is troubling.”<sup>31</sup>*

With his Hon. Friend Mr Boswell, the Member for Daventry, Mr Grieve tabled an amendment adding a part (c) to Clause 31(4) requiring the research to be in the best interests of the incompetent person.<sup>32</sup> Not surprisingly, the Government, represented by Ms Rosie Winterton, the Minister of State for the Department of Health, sought to persuade both sides that the Bill did not need changing in either direction by stating that the proposed new clause 3 was:

*“...unnecessary, because the Bill will allow for acts whose primary purpose is to benefit a third party, provided that those acts are in P's best interests. I reassure the House that the interpretation of best interests could be broader than P's medical best interests. I can confirm that the Bill will not prevent a genetic test for a familial cancer, for example, that might not be essential to P's medical care but would provide considerable benefit to some other family member.”<sup>33</sup>*

However, she went on to fudge the issue of whether the research clauses as they stood were

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29 Joint Committee on Human Rights – Twenty-Third Report (Session 2003–4) paras 2.53–2.66.

30 14 Dec 2004 : Column 1594 available at <http://www.publications.parliament.uk/pa/cm200405/cmhansrd/cm041214/debtext/41214-25.htm>

31 Ibid column 1600.

32 See *ibid*.

33 Ibid column 1602.

compatible with a best interests approach.<sup>34</sup> Attempting to pin her down, Mr Grieve proceeded to enquire whether the Government was ‘comfortable’ with a set of ethical values where ‘research carried out on an individual that has no possible benefit to that individual’ is ‘justified on the ground that it is there for the wider public good.’<sup>35</sup> However, Ms Winterton rather evasively responded that she was;

*“very comfortable that we are introducing a number of safeguards in the Bill. As the hon. Gentleman has said, research already can be carried out, but now safeguards will be introduced. I am confident that, as far as possible, medical ethics committees will ensure that research benefits individuals at the time. It may not always be possible for some research, particularly when it looks into causes, to be of direct benefit immediately, but it could well be in the future. It might also lead to alleviation of current symptoms.”*<sup>36</sup>

Pursuing the matter further, Mr. Boswell noted that:

*“Clause 1(5) makes a commitment that embraces the whole Bill; that acts done or decisions made should be in the best interests of the person involved. Is the Minister saying that that best-interests principle is suspended in the case of the research clauses? Yes or no?”*

Ms Winterton replied by saying that she was ‘not saying that it is suspended’ but that she thought that it would inevitably be:

*“interpreted slightly differently in this part, for the simple reason that it is always extremely difficult to say that research is absolutely in someone’s best interests. It is in the nature of research that it is almost impossible to prove that it would be of direct benefit.”*<sup>37</sup>

The clause 31(4) issue was to crop up again at Day 3 of the Committee stage in the House of Lords with mixed views being expressed on it.<sup>38</sup> As a variation upon the introduction of a new part (c) to Clause 31(4), Lord Alton and Lady Masham proposed Amendment No 127 which stated that:

*“The clinician and health-care workers responsible for the care of P shall remain responsible for protecting the life and health of P and shall, at all times, ensure that P’s life and health are protected during the course of research.*

*At all times, the life, health and well-being of P shall take precedence over the research being carried out on P and, in the event of any danger to P’s life, health or well-being, P must be withdrawn from the project unless his life, health and well-being can be protected by the research being undertaken in a different manner.”*<sup>39</sup>

The final version of the Bill, published on March 24 of 2005, may not have precisely adopted this amendment but it did incorporate its emphasis on primacy of the individual in research in a new clause 33(3) which stated that ‘(t)he interests of the person must be assumed to outweigh those of science and society.’

34 *Ibid* column 1603.

35 *Ibid* column 1604.

36 *Ibid* column 1604–1605.

37 *Ibid*.

38 1 February 2005. Available at <http://www.publications.parliament.uk/pa/ld199900/ldhansrd/pdvn/lds05/text/50201-17.htm>

39 *Ibid* Column 162.