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.[2] 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."*[3]

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2 *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.*

3 *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..."*[4]

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)[5] and the Council of Europe's *Convention on Human Rights and Biomedicine* (CHRB, 1997)[6] 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.[7] 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;[8]

   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:

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.'[9] 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.'[10] 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,

9 *European Law and Biomedical Research in Biomedical Research, Council of Europe 2004, 168.*

10 *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."*[11]

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.[12]

11 *Ibid.*

12 *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[13] and, to a lesser extent, incapable people as a whole.[14] A variation on this theme is found in The Law Commission's Report *Mental Incapacity*[15] 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."*[16]

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.[17]

These recommendations were not adopted in the Draft Mental Incapacity Bill 2002.[18] 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.[19] 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.'[20] 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."*[21]

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."*[22]

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.[23]

The report also seemed to uncritically adopt a very restrictive perception of the best interests test in the research context.[24] 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.'[25] 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.'[26]

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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,[27] had four research clauses (30–33) which imposed three types of requirement on the researcher conducting intrusive[28] 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)

27 *The change in emphasis from incapacity to capacity reflected a desire to stress the enabling ethos within the Bill's provisions.*

28 *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.[29] 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.[30] 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."*[31]

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.[32] 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."*[33]

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

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.[34] 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.'[35] 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."*[36]

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."*[37]

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.[38] 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."*[39]

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.*

Vindicating the right to bodily security of the incapable in research – Part 2

Austen Garwood-Gowers[1]

Introduction

The Mental Capacity Act 2005 (MCA) generally exhibits a stronger ethos of protecting the incapable in intrusive research than the last but one version of the Bill. However, sections 31(5) and 6 of the Act replicate clauses 31(4) and 31(5) of that version. As I noted in Part 1 of this article, these clauses are difficult to reconcile with the primary principle. Here I examine what effect, if any, they will have both on the process of authorising research projects involving intrusive research upon the incapable adult and on the ultimate use of the incapable adult in such research. This will involve analysis of the Act's provisions in the light of both ordinary rules of statutory interpretation and the interpretative obligation imposed by section 3 of the Human Rights Act 1998 (HRA).

A role for section 31(5) and section 31(6)?

Section 31 contains the conditions that an appropriate body must be satisfied are met if it is to approve a research project involving intrusion on an incapable adult.[2] Section 31(5) states that:

> "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."

1 *Senior Lecturer in Law, Nottingham Law School, Nottingham Trent University. I am very grateful to Tom Lewis, also Senior Lecturer in Law at Nottingham Law School, for his thoughtful comments and discussion on this article.*

2 *As Paragraph 10.13 of the Draft Code of Practice sent out for consultation on 9 March 2006 (and available at http://www/dca/gov.uk/consult/codepractise/draftcode05 06.pdf) notes, 'The Secretary of State of Health (in respect of England) and the National Assembly for Wales (in respect of Wales) are required to set out in Regulation who is the "appropriate body" to give approval in relation to particular types of research project. It is currently envisaged that "the appropriate body" is likely to be an independent Research Ethics Committee.'*

Section 31(6) states that:

> "If the research falls within paragraph (b) of subsection (5) 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."

These provisions are couched in the kind of restrictive language that, to the unsuspecting or untrained eye, makes them appear to serve an important role in safeguarding the rights of the incapable adult. However, in fact, it is evident that if one takes these provisions in isolation they have the effect of diluting protection. It is only by treating them as superfluous in the light of other provisions that this effect is avoided. On a literal analysis they clearly are superfluous. Section 33(3) requires the interests of the potential subject of intrusive research to be treated as outweighing those of science and society, and by virtue of section 31(7), the appropriate body is required to have reasonable arrangements in place for ensuring that its requirements (along with those in the rest of sections 32 and 33) are met when the research authorisation process is taking place. To authorise a project involving primacy incompatible intrusion on an incapable adult may also amount to making a decision for the purposes of section 1(5), breaching its stipulation that acts and decisions made on behalf of incapable adults should be best interests compatible.

The other crucial point to make is that on a literal reading the MCA treats project authorisation and actual use of an incapable adult in intrusive research as two distinct legal phases. On such a reading, even if the Courts or an appropriate body were to interpret section 31(5) and 31(6) as allowing research projects involving best interests incompatible intrusion on the incapable adult to be authorised, such an intrusion could not be carried out because it would be inconsistent not only with section 1(5) but also section 30(1) in conjunction with section 33(3). Section 30(1) states that:

> "Intrusive research carried out on, or in relation to, a person who lacks capacity to consent to it is unlawful unless it is carried out–
>
> (a) as part of a research project which is for the time being approved by the appropriate body for the purposes of this Act in accordance with section 31, and
>
> (b) in accordance with sections 32 and 33."

Section 33(3) states that '(t)he interests of the person must be assumed to outweigh those of science and society.'

It is evident that, literally understood, sections 31(5) and 31(6) simply impose limited requirements on the appropriate body that are exceeded by other requirements. The question that remains is whether they can be given some effect on a purposive analysis? Some ministerial statements hint at the idea that the Act was intended to facilitate a trade off of the interests of the incapable adult against the need for research. However, the Minister declined a clear opportunity to exclude the use of the section 1(5) best interests principle in the research context when the Bill was at Third Reading in the Commons[3] What is more the late addition and ultimately enactment of a new

3 *14 Dec 2004.*

clause 33(3) requirement to protect the interest of the incapable adult subject over those of science in intrusive research, is very hard to square with an intent to give section 31(5) and 31(6) substantive effect. This is not to say that the legislation unequivocally supports a primacy approach, rather it is somewhat ambiguous.[4] However, under ordinary rules of statutory interpretation a purposive approach cannot be preferred over a literal one where Parliament's intent behind creating the provisions at issue is ambiguous.[5] What amibuity does facilitate is the application of various legislative presumptions. However, if anything, these further damage the arguments that sections 31(5) and 31(6) should be given substantive effect.

The presumption in favour of maintaining the common law position[6] will clearly favour a best interests approach. So too, it can be suggested, would the presumption in favour of protecting the rights of the citizen.[7] Lord Hoffman explained the scope and rationale of this presumption in *R v Secretary for State for the Home Department, Ex parte Simms* [2000] 2 AC 115, HL:

> *"Fundamental rights cannot be overridden by general or ambiguous words. This is because there is too great a risk that the full implications of their unqualified meaning may have passed unnoticed in the democratic process. In the absence of express language or necessary implication to the contrary, the courts therefore presume that even the most general words were intended to be subject to the basic rights of the individual."*[8]

The right to bodily security is widely accepted to be a fundamental right which extends protection to both the capable and incapable. Its freedom from intrusion aspect is implicated in the protection of several other fundamental rights, including: The right to life; freedom from torture, inhuman and degrading treatment or punishment; freedom from slavery and servitude; the right to liberty and security of person; *and* the right to respect for private and family life. These rights are protected in Europe by, respectively, Articles 2–5 and 8 of the *ECHR*. This brings us to the question of whether the HRA section 3 obligation to interpret law compatibly with 'convention rights' so 'far as it is possible to do so' might be an alternate basis on which to argue that sections 31(5)-(6) of the MCA should be treated as superfluous. Section 3 of the HRA does not allow the Courts to go against the express or implied will of Parliament[9] but it does enable the Courts to reach outcomes compliant with convention rights to a greater extent than was previously possible.[10] In any event in a situation such as this where intention is ambiguous there is no barrier to its use. Thus the only question is whether convention rights compliance does preclude a role for section 31(5)-(6).

4 *The ambiguity is also present in the Act's Draft Code of Practice sent out for consultation.*

5 *See further, D. Greenberg, Craies on Legislation. London: Sweet and Maxwell, 8th edition, 2004, 561*

6 *See e.g. Francis and Francis (a firm) v Central Criminal Court [1988] 3 All ER 775.*

7 *This is done, for example, through the presumptions against taking property with compensation (Central Control Board (Liquor Traffic) v Cannon Brewery Co Ltd [1919] AC 742 HL, p752); retrospective effect of legislation (Waddington v Miah [1974] 1 WLR 683); denial of access to the Courts (Raymond v Honey [1983] 1 AC 1 HL); interference with the liberty of the subject (R v Hallstrom ex p W [1986] QB 1090) except in wartime (R v Halliday [1917] AC 260 HL); and non-compliance with international treaty obligations.*

8 *[2000] 2 AC 115, 131, HL*

9 *See, for example, R v Lambert [2002] 2 AC 545, HL.*

10 *See, for example, Brooke LJ in Goode v Martin [2002] 1 ALL ER 620, 629 CA.*

Convention Rights and Intrusive Research on the Incapable

In most cases authorisation of projects involving primacy incompatible intrusive research is not going to constitute a threat to the life of prospective participants, involve detaining them or rise to the threshold for being deemed slavery or servitude. However, it may generally violate Article 8 in its private life aspect and, at least in many cases, Article 3 in its inhuman and degrading treatment aspect. These rights could be used in isolation or in conjunction with Article 14 where the violation of primacy is class selective.

As far as Article 3 is concerned factors relevant to determining whether conduct reaches the minimum level of severity to be classed as inhuman and degrading for the purposes of Article 3 include: Its nature and context; the manner of its execution; its duration; its physical and mental effects, including any impact on health; and its object – for example, whether or not it is intended to humiliate or debase. A key case is *Herczegfalvy v Austria* (10533/83) (1993) 15 EHRR 432 where the European Court of Human Rights stated that as a general rule it would not be inhuman or degrading to subject incapable patients, if necessary by force, to 'a measure which is a therapeutic necessity.'[11] However, it did so with the proviso that, '(t)he Court must nevertheless satisfy itself that the medical necessity has been convincingly shown to exist.'[12] Whilst the Court would doubtless also allow this test to be waived in relation to an intrusion that was necessary to protect the rights of others, to allow it to be waived in order to better meet the mere needs of others would be to undermine its very basis. Thus the only difficulty in showing that Article 3 is violated by a best interests incompatible intrusion on the incapable in the research context, is in showing that the intrusion reaches the minimum severity threshold.

Questions of minimum threshold are not such a significant issue with Article 8. The private life aspect of Article 8 is engaged by compulsory urine testing according to the Court in *Peters v The Netherlands* (1994) 77A DR 75 and by even minor forms of compulsory medical intervention according to the Commission in *X v Austria* (1980) 18 D.R. 154 at 156. The real issue is whether the intrusion can be justified by Article 8(2). This states that:

> *"There shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals or for the protection of the rights and freedoms of others."*

The purpose of the 'in accordance with the law' requirement is to provide the minimum degree of protection against arbitrariness required by the rule of law in a democratic society.[13] To this end measures must firstly have a basis in national law and secondly have the qualities of being accessible and foreseeable in terms of consequences for those affected and compatible with the rule of law.[14] Sections 31(5)-(6) will not change the fact that there is not a clear basis in domestic law on which to subject the incapable adult to best interests incompatible intrusions in the research context.

The 'necessary in a democratic society' requirement within Article 8(2) was interpreted by the

11 *(1993) 15 EHRR 432, para 82*

12 *Ibid.*

13 *Herczegfalvy v Austria (1993) 15 EHRR 432 para 91. See also McLeod v United Kingdom, Case 24755/94, Judgment 23 September 1998 and Hashman and Harrup v United Kingdom, Case 25594/94, Judgment 25 November 1999.*

14 *Ibid at para 88.*

Court in *Olsson v Sweden* (1988) A 130, para 67 as meaning that 'an interference corresponds to a pressing social need and, in particular, that it is proportionate to the legitimate aim pursued.' Restricting the right to bodily security to help meet the needs of others could be said to be connected to the health objective under Article 8(2). However, there are a number of reasons why at the proportionality stage, if not sooner, the Court is likely to find restriction on this basis to fall short of being necessary in a democratic society.

The first of these is that trading off bodily security to meet the perceived needs of others can be construed as counterproductive and intrinsically wrong in the manner described by Mr Justice Flaherty in *McFall*.[15] The second is that existing standards support the absolute position. Drawing on the experience of member states, the Court would find that some continental jurisdictions have a legal duty to rescue in the common accident, danger and emergency situation but that this is limited and is unlikely to justify anything of the order of trespass on the living person. Furthermore it would find the *Declaration of Helsinki* (1964) and, more especially, the *Convention on Human Rights and Biomedicine* (CHRB, 1997)[16] persuasive and, despite their research provisions relating to the incompetent, both of these may be deemed to support absolute protection.

Both of these reasons would bolster the Article 3 argument. Furthermore claims under both Article 3 and 8 might be bolstered by reference to Article 14. Article 14 states that:

> *"The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."*

It is breached where, without objective and reasonable justification persons in relevantly similar situations are treated differently or persons in relevantly dissimilar situations are treated in the same way. It is evident in this sense that Article 14 is concerned with the principle of equality. John Harris has argued in one article that moving away from best interests protection of the incapable adult is necessary to achieve equality.[17] However, having defined equality as the principle 'that each person is entitled to the same concern, *respect* and protection of society as is accorded to any other person in the community' (ital. added)'[18] he proceeds in a subsequent article to suggest that respect entails, 'not just respect for the choices of those competent to make them but also respect for the best interests or welfare of those who are not.'[19] To allow capable people to agree to some research that others may consider not to be in their interests whilst protecting the incapable from the same does not amount to discrimination. It simply affords the capable a choice that respect for their

15 *See reference to this case in the second paragraph of Part I of this Article. For further discussion of the arguments here see Garwood-Gowers, A, 'The Right to Bodily Security Vis-à-Vis the Needs of Others,' Ch 27 in Weisstub, D.N., Pintos, G.D. (eds.), Autonomy and Human Rights in Healthcare, 2006 (forthcoming) Kluwer Academic Publishing.*

16 *See, for example, Glass v UK [2004] 1 FLR 1019 where the Court used the professional standards Articles of the CHRB in order to help it reach the conclusion that a hospital's failure to involve the courts in a dispute about the care of a minor and to proceed with administering diamorphine with the consent of the child's legal representatives (the parents in this case) breached the child's Art 8 right to private life and could not be justified under Art 8(2) because it did not fulfil the necessity requirement. The CHRB is partly designed to elaborate the standards that should underpin assessment of ECHR rights in the context of biology and medicine. See Part I of this Article for further consideration of both the Declaration of Helsinki and the CHRB*

17 *Harris, J, 'The Ethics of Clinical Research with Cognitively Impaired Subjects' (1997) 5 Ital J Neurol Sci Suppl 9–13. See also Harris, J, 'Scientific Research as a Moral Duty' (2005) 31 JME 242-8*

18 *Ibid at 12.*

19 *Harris, J, 'Law and Regulation of Retained Organs: The Ethical Issues' (2002) 22(4) Legal Studies 527 at 529.*

autonomy warrants and denies the incapable that choice out of respect for the fact that, by definition, they lack the capacity to properly construe what is compatible with their interests in the given situation.

Given that selectively diluting protection of the incapable adult would be discriminatory, the remaining question from an Article 14 perspective is whether that discrimination can be objectively and reasonably justified. Much of Harris's attempt to justify diluting protection of the incapable adult is founded on the idea that all people have a moral obligation to participate in research:

> *"It is not plausible to believe that the costs of acting morally fall only on those competent to consent. So long as we ensure that such costs do not fall* more heavily *on those not competent to consent than on others I see no sound argument for exempting them from the demands of morality. They may not be* accountable *in law, if they do wrong, but there is no reason to ensure that they do wrong by exempting them from their moral obligations."*[20] (ital. added)

This idea is appealing to many but simplistic for at least two reasons. Firstly, it assumes that research is a beneficent activity when in fact whether or not it is depends on the context in which one is speaking. And part of the context in the West is the dominance of an atomovistic, mechanistic and deterministic approach to medicine that focuses on suppression of symptoms, surgery and other inherently limited tools. The medical establishment has typically supported and perpetuated this system in preference to one based on holistic prevention and cure partly out of a misguided allegiance to a Newtonian-Cartesian paradigm of hard science that is now a century outmoded in the light of new developments in the hard sciences, especially those in the field of quantam physics. What is more, vested commercial interests have underpinned the current approach not least in the research context where the focus is largely on the development of synthetic – and hence patentable – medicines. These problems link in with a second concern with Harris's approach which is that it fails to assess the merits of pluralism. Protecting individuality, particularly in relation to choices over the body, is important both as an end in its own right and as a function of maintaining a healthy society. What is more to suggest that it should be intruded upon for supposedly beneficent purposes is politically naïve in terms of the degree of reliance it places on the rational exercise of state authority. However, Harris, whilst admitting that it would be better if research could be pursued without the use of incapable adults, suggests that if the current position;

> *"jeopardises our capacity to pursue well founded research then perhaps we should remember that free-riding is not an attractive principle; nor is it a moral principle. We should not ... assume that those incompetent to consent would wish to be free-riders, nor that they be excluded from discharging an obligation of good citizenship which we all share."*[21]

Much the same point has been made by Gunn et al., in this Journal:

> *"If one wishes to gain the benefit of medical research, one has the obligation to offer oneself for participation. Otherwise, the person gaining the benefit of the research is a mere parasite on society, taking only the advantages and undertaking no risks."*[22]

Using terms like 'free-rider' and 'parasite' may serve the implicit purpose of both articles but is

20 *Ibid 12.*

21 *Ibid 13.*

22 *'Medical Research on Incompetent Adults' (2000) Journal of Mental Health Law, 60 at 63.*

pejorative and highly inappropriate even if one assumes that most of the modern research effort is beneficent. Some non-participants may be making good contributions to the world in other ways. What is more, though degrees of contribution may at times be considered a valid basis on which to change the way benefits are distributed it cannot be considered, at least where something as important as the right to bodily security is concerned, a valid basis on which to change the law relating to contribution, let alone to do so selectively with a particular class at the cost of the principle of equality of persons.

Gunn et al. put forward alternative arguments for moving the law away from a best nterests approach all of which are clustered around the idea that such change would be beneficial for incapable adults as a class. Firstly they argue that it would be,

> *"consistent with principles of normalisation and social inclusion. It challenges stereotypes that incompetent adults are a drain on society."*[23]

In response, it may be noted that participation *can* have these effects for incapable adults but will in fact be abnormalising where it is secured on a discriminatory basis. Gunn et al., also argue that not moving away from a best interests approach will limit the ability to generalize research outcomes to incapable adults[24] and thwart research which is more specifically for their benefit as a class.[25] Solbakk makes a similar point in relation to children.[26]

He suggests that by protecting the incapable from being involved in research of no real and direct benefit to them that is greater than minimally risky, the CHRB has encouraged a practice of selecting adults in non-therapeutic research instead of children as participants and of developing new standards for paediatric use on the basis of extrapolation of data from studies on adults. Solbakk notes how critics such as Brody[27] suggest that this leads to the paradoxical situation that children are often exposed to clinical decisions without appropriate guidance from research and that, consequently, diseased children are in danger of becoming therapeutic orphans.[28]

Solbakk uses this as a platform to argue that systematically protecting children from non-therapeutic research with a risk level that is greater than minimal could lead to an infringement of their right to equitable access to healthcare of appropriate quality, which he notes is explicitly protected by Article 3 of the *CHRB*.[29] However, this analysis would seem to be based on a myopic and ultimately biased reading of the CHRB. Article 3 only requires states, 'taking into account health needs and available resources', to take

> *"appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality."*

It would be extremely odd if it were deemed appropriate to provide for research needs in a manner that directly conflicts with Article 2 of the Convention and its sister provision, Article 3 of the Additional Protocol on Biomedical Research. What is more, as I have already argued in Part 1, it

23 *Ibid.*

24 *Ibid.*

25 *Ibid 61.*

26 *Solbakk, J.H., 'Uses and abuses of biomedical research,' p35–50 in Council of Europe Publishing (ed.), Biomedical Research, Council of Europe, October 2004.*

27 *Brody, B, The Ethics of Biomedical Research; An International Perspective, 1998, New York, Oxford University Press 177.*

28 *Ibid at 43.*

29 *Solbakk, J.H., 'Uses and abuses of biomedical research,' p35–50 at 43 in Council of Europe Publishing (ed.), Biomedical Research, October 2004, Council of Europe.*

is difficult to use the needs of a class of people to justify infringement of the rights of individuals who happen to be in that class. The Court of Appeal in Maryland was confronted with the issue in *Grimes and Higgins v Kennedy-Krieger Institute* 782 A2d 807 (2001). The key facts of this case were that a prestigious research institute, associated with John Hopkins University, had created a non-therapeutic research program involving certain classes of homes. Some homes, one with a child resident and others where families with young children were encouraged to reside by landlords complicit with researchers, were deliberately not provided with the full lead paint abatement modifications that had been provided to others. The majority concluded that:

> *"Whatever the interests of a parent, and whatever the interests of the general public in fostering research that might, according to a researcher's hypothesis, be for the good of all children, this Court's concern for the particular child and particular case, over-arches all other interests. It is, simply, and we hope, succinctly put, not in the best interest of any healthy child to be intentionally put in a non-therapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children (para 221)."*

Of course it might in theory be possible to argue that if it is legitimate to trade off the right to bodily security vis-à-vis the needs of others in extreme circumstances then participation of incompetent adults in medical research is one such extreme circumstance. However, for common arguments to the effect that we need to dilute protection to make progress in relation to conditions like Alzheimer's disease, one could substitute the argument that we need to dilute protection of all classes of person to facilitate greater extraction of bodily material to help meet the need for transplantation and general biotechnological advancement. Or, more specifically, we could substitute the argument that we need to dilute protection of insensate dying persons to facilitate the need to prepare their body for use in transplantation, medical research or medical education after their death. Intrusive research on the incapable adult is not a special case at all but simply one example of modern medicine's massive reliance on the body to meet a plethora of medical needs.

Given the above arguments, one may sum up this section by saying that it is extremely likely that Article 8 and, at least in certain circumstances, Article 3 would be violated by treating the right to bodily security as relative vis-à-vis the needs of others. This extreme likelihood rises to the level of virtual certainty when one selects a particular class for such relative treatment.

Nonetheless, no amount of reassurance to the effect that the formal legal position is a primacy protective one can take away from the fact that the Government rather disingenuously sneaked sections 31(5)-(6) into the MCA when they serve no other function than to encourage researchers and the public at large to mistakenly view it as legitimate to deviate from a best interests approach. The Government is on the cusp of colluding with the abuse of incapable adults. Rather than wait for the Courts to pick up the pieces and lay out the *actual* (non) effect of sections 31(5)-(6), it should act to remove them before the Act comes into force.

Conclusion

In his dissenting judgment in *Olmstead v United States*, 277 U.S. 438, 479 (1928) Judge Brandies observed that:

> *"Experience should teach us to be most on guard to protect liberty when the government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."*

The idea of attempting to do something useful for society or science is naturally appealing. However, such attempts are – like wooden horses – not always what they seem. Indeed, one may even conclude that to try and benefit society or science at the cost of the individual is fundamentally flawed from the outset. It is only when science and society are founded on respect that they are worthwhile. Founded on anything else they simply become a mechanism for abuse.

Much of the international community seems to have partially regressed from this realisation in the research context despite having committed itself formally to it in the wake of Nazi research atrocities. And whilst nothing post-World War II has matched the scale of Nazi experimental depravity, there have been serious atrocities. For example, some horrific radiation experiments were carried out on unknowing/uninformed servicemen and members of the public in the United States from the 1940s until the early 1970s[30] and in the UK the Ministry of Defence conducted experiments with chemical warfare agents on servicemen for decades at its Porton Down site, including experiments on at least 349 servicemen with potentially deadly doses of the nerve agent sarin.[31]

Some of these abuses have since been legally remedied,[32] but research continues to be an area ripe for abuses. Many regulators, medical establishments, researchers/research entities and even technically independent voices in the discourse are far too cosy with each other over an agenda which consists of uncritically lauding the benefits of research whilst simultaneously failing to fully respect the individual, even to the point of discrimination. Whilst some of that discrimination is undoubtedly unwitting, it is important to note that research has long been a rich field for opportunists to pick on the vulnerable like vultures at a carcass. It is certainly no coincidence that most research abuses have been targeted against those typically less well equipped to resist them such as the incapable, poor and illiterate people (particularly in developing countries[33]) and (above all) the animal kingdom.

30 *Makhijani, A and Kennedy, E, Human Radiation Experiments in the United States, Institute for Energy and Environmental Research, 1994 available at: http://www.ieer.org/sdafiles/vol_3/3-1/humanex.html*

31 *See further Plomer, A, The Law and Ethics of Medical Research, 2005, Cavendish Publishing, 45–46.*

32 *See, for example, In Re Cincinnati Radiation Litig 874 F Supp 796 (SD Ohio 1995), Re Maddison, Deceased [2002] EWHC 2567 Admin.*

33 *See further Macklin, R, Double Standards in Medical Research in Developing Countries, 2004, Cambridge University Press.*