

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

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## 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.<sup>2</sup> 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.”

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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<sup>3</sup> What is more the late addition and ultimately enactment of a new

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<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> What ambiguity 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<sup>6</sup> 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.<sup>7</sup> 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.”*<sup>8</sup>

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<sup>9</sup> but it does enable the Courts to reach outcomes compliant with convention rights to a greater extent than was previously possible.<sup>10</sup> 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).

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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.’<sup>11</sup> 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.’<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> 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*.<sup>15</sup> 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)<sup>16</sup> 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.<sup>17</sup> 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)<sup>18</sup> 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.’<sup>19</sup> 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

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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."*<sup>20</sup> (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 atomistic, 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 quantum 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."*<sup>21</sup>

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."*<sup>22</sup>

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

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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 interests 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.”*<sup>23</sup>

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<sup>24</sup> and thwart research which is more specifically for their benefit as a class.<sup>25</sup> Solbakk makes a similar point in relation to children.<sup>26</sup>

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<sup>27</sup> 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.<sup>28</sup>

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.<sup>29</sup> 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

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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<sup>30</sup> 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.<sup>31</sup>

Some of these abuses have since been legally remedied,<sup>32</sup> 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<sup>33</sup>) and (above all) the animal kingdom.

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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/sdfiles/vol\\_3/3-1/humanex.html](http://www.ieer.org/sdfiles/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.