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Heywood, R and Ryan, H and Killett, A and Langdon, Peter E. and Plenderleith, Y and Shiggins, C and Bunning, Karen (2019) Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005. Medical Law International .

DOI

https://doi.org/10.1177/0968533219867365

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Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005

Journal:	*Medical Law International*
Manuscript ID	Draft
Manuscript Type:	Full Article
Keywords:	Mental Capacity Act 2005, Research, Capacity, Best Interests, Consultees

Abstract:	Despite laudable intentions, since its inception, the Mental Capacity Act 2005 of England and Wales (MCA) has proved to be a controversial piece of legislation. The majority of legal scholarship has concentrated on the problems created by the Act in relation to the treatment of incapacitated patients. However, there is an additional and somewhat unexplored dimension to the MCA, that of research. Sections 30 to 33 of the MCA allow intrusive research to be lawfully carried out on, or in relation to, a person who lacks capacity. The legislation does not, therefore, completely prohibit research. Rather, it purports to adopt a permissive approach, seeking to recognise the potential value that incapacitated participants can bring to answering particular research questions. Nonetheless, given that often research may be conducted not for the benefit of an individual, but only for the benefit of others, the MCA remains sensitive to the enhanced vulnerability of incapacitated participants and inserts additional measures of protection. We argue here, however, that the research provisions of the MCA are poorly drafted. We assert that contrasting obligations and expectations are placed on different parties in the approval process, which creates a blurred sense of responsibility and a potential chilling effect.

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Medical Law International Submission

Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005

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A. Introduction

Despite laudable intentions, since its inception, the Mental Capacity Act 2005 of England and Wales (MCA) has proved to be a controversial piece of legislation.[1] Some commentators have criticised the technical legal provisions of the Act, exposing the problems with the legal test for capacity and the interpretational ambiguities associated with best interests.[2] Others have focused on the more philosophical questions underpinning the legislation, exploring the frictions that exist between the concepts of paternalism versus autonomy, and protection versus empowerment[3]. The majority of legal scholarship has concentrated on how these various tensions arise, and are dealt with, in relation to the treatment of incapacitated patients.[4] However, there is an additional and somewhat unexplored dimension to the MCA, that of research.[5] Sections 30 to 33 of the MCA allow intrusive research to be lawfully carried out on, or in relation to, a person who lacks capacity.[6] The legislation does not, therefore, completely prohibit research. Rather, it purports to adopt a permissive approach, seeking to recognise the potential value that incapacitated participants can bring to answering particular research

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[1] See Mary Donnelly, 'Changing Values and Growing Expectations: The Evolution of Capacity Law (2017) 70 *Current Legal Problems* 305; Amel Alghrani *et al.*, 'The Mental Capacity Act 2005—Ten Years On' (2016) 3 *Medical Law Review* 311.

[2] Mary Donnelly, 'Best Interests in the Mental Capacity Act: Time to say Goodbye?' (2016) 24 *Medical Law Review* 318; Mary Donnelly, 'Determining Best Interests Under the Mental Capacity Act 2005' (2011) 19 *Medical Law Review* 304.

[3] Paul Skowron, 'The Relationship between Autonomy and Adult Mental Capacity in the Law of England and Wales' (2018) *Medical Law Review*: doi: https://doi.org/10.1093/medlaw/fwy016; Beverley A Clough, 'New Legal Landscapes: (Re) Constructing the Boundaries of Mental Capacity Law' (2018) 26 *Medical Law Review* 246; Camilla Kong, *Mental Capacity in Relationship: Decision-Making, Dialogue and Autonomy* (CUP 2017); B. Clough, '"People Like That": Realising the Social Model in Mental Capacity Jurisprudence' (2015) 23 *Medical Law Review* 53.

[4] Helen J Taylor,'"What Are "Best Interests"? A Critical Evaluation of "Best Interests" Decision-Making in Clinical Practice' (2016) 24 *Medical Law Review* 176.

[5] Gillian Loomes, 'Researching About Us Without Us: Exploring Research Participation and the Politics of Disability Rights in the Context of the Mental Capacity Act 2005' (2018) 44 *Journal of Medical Ethics* 424; JV McHale, 'Research, Ethics Review and Mental Capacity: Where Now After the Mental Capacity Act 2005?' (2009) 5 *Research Ethics Review* 65.

[6] Mental Capacity Act 2005, s 30 – 33.

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questions. Nonetheless, given that often research may be conducted not for the benefit of an individual, but only for the benefit of others, the MCA remains sensitive to the enhanced vulnerability of incapacitated participants and inserts additional measures of protection. First, a project will only be deemed lawful under the MCA 2005 once an appropriate independent body, which is now defined as an approved MCA Research Ethics Committee (MCA REC), has authorised it.[7] Secondly, before researchers can proceed with MCA REC sanctioned research, a personal or nominated consultee needs to be appointed who must offer an opinion about the willingness and likely wishes of any potential incapacitated participant.[8]

The MCA also imposes a separate set of requirements that have to be satisfied before any research can proceed. In order for the research provisions to be engaged, it must be established that the activities in question fall within the Act's definition of intrusive research, which is narrow in scope.[9] This is accompanied by a requirement that any research must be connected with an impairing condition affecting P, or its treatment.[10] An MCA REC is further obliged to consider from the outset whether or not there are reasonable grounds for believing that research of comparable effectiveness could be carried out on persons who have capacity to consent to taking part in it.[11] Finally, the best interests test, which is used to render lawful an array of other decisions under the broader terms of MCA, does not apply to research.[12] This is replaced by a set of conditions that demand an assessment of the potential benefit to risk ratio that an incapacitated research participant may be exposed to and, in cases where there may be no value whatsoever to that individual, of the potential benefits that may conferred on wider members of society by her involvement.[13] Perhaps due to its perceived sensitive nature, research is thus set apart from other aspects of the legislation, ostensibly with the intention of requiring a higher threshold of protection, while at the same time maintaining some room to enable participant empowerment.[14]

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[7] Mental Capacity Act 2005, s 31 (1); Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006.

[8] Mental Capacity Act 2005, s 32 (1) – (5).

[9] Mental Capacity Act 2005, s 30 (2) (a) – (b).

[10] Mental Capacity Act 2005, s 31 (2) (a) – (b).

[11] Mental Capacity Act 2005, s 31 (4).

[12] Peter Bartlett, *Blackstone's Guide to the Mental Capacity Act 2005* (2nd edn, OUP 2008) at 89.

[13] Mental Capacity Act 2005, s 31 (5) (a) and (b).

[14] HC Deb 18 June 2004, vol 422, cols 67-70W.

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We argue here, however, that the research provisions of the MCA are poorly drafted. It is not entirely clear what type of research should fall within the purview of the Act, and an apparent focus on medically-invasive research causes some key areas to be overlooked. Quite apart from that, in initially calling for some consideration as to whether or not more effective research could be carried out on a capacitous individual, the MCA begins by making a dangerous assumption about the comparative value of an incapacitated participant's involvement in research and thus undermines her societal status. This does not sit comfortably with the growing emphasis on supported decision-making promulgated by Article 12 of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) and so the true extent to which the MCA empowers participants remains a subject of contention.[15] The tailor-made standards for approving research are also deceptive, creating the illusion that extra protection is afforded, when in fact it is not. Finally, difficulties are also encountered because the aspects of the MCA that attempt to guarantee that an incapacitated participant's voice is heard in the approval process, operate under some basic misapprehensions.

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This paper begins by exploring the exact parameters of the MCA in relation to research. It seeks to address the critical question of precisely what is meant by 'intrusive' research and considers what may fall within this definition. We then argue that in demanding an assessment of the comparative effectiveness of incapacitated compared to capacitous participants, the MCA actually sets off on the wrong foot and needs to fundamentally rethink its starting premise. It also needs to reconsider what research needs to be connected with in order to be countenanced. Thereafter, the rationale for abandoning the best interests principle is analysed and we examine whether the new substantive thresholds serve any meaningful purpose. The discussion finally proceeds to investigate the other safeguards introduced by the Act, focusing on the obligations placed on the researcher, the consultee and MCA RECs. We assert that contrasting obligations and expectations are placed on different parties in the approval process, which creates a blurred sense of responsibility and a potential chilling effect.

B. Setting Off on the Wrong Foot

i) Imprecise Parameters

The provisions of the MCA apply only to 'intrusive' research, which is defined as research of a kind that would be unlawful it if was carried out on, or in relation to, a person who had

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[15] Article 12 (2) stresses that States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.

capacity to consent to it, but without his consent.[16] It is only if research falls within this category that the further provisions of the MCA will be engaged. The principal focus of this definition appears to be on invasive medical research, typically involving some physical interference with a participant's body.[17] Thus, if a researcher embarked upon a project which involved some physical manipulation of an incapacitated patient's knee, that would amount to 'intrusive research'. The reason for this is that if identical research were to be performed on a capacitous participant, her consent would be needed for it to be lawful and not characterised as tortious battery.[18] Nevertheless, there is a grey area in the legislation that calls into question certain types of non-invasive research.

Observational research, for example, raises a number of issues and arguably recasts the original scope of the MCA's research provisions. In order for this type of activity to fall within the definition of intrusive research, a rule of law must be identified that would cause the research to be unlawful if it were to be carried out on a non-consenting capacitous patient.[19] Battery would not apply unless there was any unauthorised touching, and this would seldom occur in most types of observational research.[20] Bartlett, however, argues that Article 8 of the European Convention on Human Rights (ECHR) could be engaged to render some observational research unlawful, where a capacitous participant did not consent to it.[21] Article 8 (1) of the ECHR provides that everyone has the right to respect for his private and family life, his home and his correspondence, and section 6 (1) of the Human Rights Act 1998 states that it is unlawful for a public authority, such as an NHS body or a university, to act in a way which is incompatible with a Convention right.[22] Article 8 (1) is qualified and can be legitimately interfered with in certain circumstances under Article 8 (2).[23]

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[16] Mental Capacity Act 2005, s 30 (2) (a) and (b).

[17] See Law Comm 231, draft bill, cl 11 (4) (d). See also Bartlett (n 12) at 88; McHale (n 5) at 66.

[18] See *Wilson v Pringle* [1987] QB 237; *Collins v Wilcock* [1984] 1 WLR 1172.

[19] Above (n 16).

[20] Some methods of observational research may involve a level of hands-on touching. For example, observing blood pressure levels will demand some physical contact with a participant.

[21] Bartlett (n 12) at 88.

[22] Human Rights Act 1998, s 6 (1). See also Article 8 (1) of the European Convention on Human Rights.

[23] Article 8 (2) of the European Convention on Human Rights states that there shall be no interference by a public authority with the exercise of this right except such as is 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,

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The difficulty is that not all observational research is the same and could, potentially, interfere with a participant's privacy to varying degrees. In recognition of this, Bartlett draws a distinction between observational research that may involve a participant undergoing a medical examination in a doctor's surgery, compared to that which may be conducted on a hospital ward.[24] He argues that the former would invoke a 'particularly strong' expectation of privacy, whereas the latter, due to its more public nature, may not do so to the same extent.[25] While we accept that the applicability of Article 8 (1) is very much fact-specific, given the evolving nature of the jurisprudence, we suggest that nowadays a strong argument could be advanced in favour of Article 8 (1) of the ECHR being engaged in both of the above scenarios, and indeed in many more observational research settings.[26] The fact that any observation takes place in a more public environment, in our view, would not automatically render Article 8 (1) redundant. It has been recognised that 'there is a zone of interaction of a person with others, even in a public context, which may fall within the scope of "private life"'.[27] Expanding upon this, Bartlett alludes to common examples of observational research in healthcare settings that could invoke a reasonable expectation of privacy, such as observations in hospital wards, care homes, surgeries and a patient's own home.[28] This list is not exhaustive and could be developed to include observations of focus group discussions, behaviour of inhabitants of specific communities, and communications between individuals in institutions and places of work. These are all environments in which a 'zone of interaction' of a person with others could be present, causing notions of what is public and private to intersect.

It thus seems likely that a certain amount of observational research conducted by an NHS body would at least engage the Article 8 (1) rights of a capacitous participant if it were to be conducted without her consent and would, therefore, *prima facie* fall within the MCA's definition of intrusive research if the same were to be performed on an incapacitated

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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.

[24] Bartlett (n 12) at 88.

[25] Ibid.

[26] See *Peck v United Kingdom* App No 4464/98 (ECtHR 28th January 2003); *Perry v United Kingdom* App No 63737/00 (ECtHR 17th July 2003).

[27] See *P.G. and J.H. v United Kingdom App No* 44787/98 (ECtHR 25th September 2001) at [56]. For discussion see Nicole V Moreham, 'The Right to Respect for Private Life in the European Convention on Human Rights: A Re-examination.' (2008) *European Human Rights Law Review* 44.

[28] Bartlett (n 12) at 88.

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participant.[29] To make a final determination on breach, the question of whether any interference with her right was legitimate under Article 8 (2) would then need to be addressed. It is conceivable that some observational healthcare research could be justified on the grounds that is necessary in a democratic society for public safety or to protect health and morals and that, provided it was done in accordance with the law, any interference with the right could be justified under Article 8 (2).[30] If this held sway, the research would not be unlawful and so would fall outside the definition of intrusive research for the purposes of the MCA. However, it will not be possible to justify all research on these grounds, especially where it is a smaller and more concentrated project that does not have the scope to benefit society more widely. Where interference is incapable of such justification, the research would be unlawful and thus correspond with the MCA's definition of intrusive research. Considering matters through the lens of Article 8 then, the overall conclusion as to which types of observational research would be caught by the definition is far from straightforward. Yet, it does appear that some of it would, which may well be beyond the initial contemplation of the MCA's research-targeted provisions.[31]

Further methods of research that remain contentious are interviews and questionnaires. Where, for instance, a university researcher wishes to involve incapacitated participants in her project, would her work fall within the MCA's definition of intrusive research and thus require her to comply with the additional regulatory requirements by gaining specific MCA REC approval? Where is the rule of law that would deem such activity unlawful should it be performed on a capacitous participant, without her consent? If a participant was interviewed and the conversation then taped and transcribed, if any findings were published and it became possible to identify her as a result, assuming she had not consented, it seems likely that her Article 8 (1) rights would be engaged.[32] However, this overlooks the fact that interview research is often not conducted in this way and that transcriptions are, not infrequently,

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[29] Above (n 26) and (n 27).

[30] See, for discussion, *Uzun v Germany* App No 35623/05 (ECtHR 2nd September 2010).

[31] Above (n 17).

[32] See *Smith and Grady v United Kingdom* App Nos 33985/96 and 33986/96 (ECtHR 27th December 1999). In this case it was held that were detailed investigations took place, including interviews of a sensitive and intimate nature, where any findings were then made public and individuals could subsequently be identified, a violation of Article 8 occurred.

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anonymised.[33] The same is true of the majority of data collected in questionnaires.[34] It is stretching things to suggest that privacy is threatened by interview or questionnaire findings that are not linked in any way to one particular individual, and which safeguard participant anonymity throughout. To conduct either an anonymous interview or a questionnaire on a capacitous participant without her consent may well be unethical, but to say that it would be unlawful on the basis of an infringement of Article 8 seems much less convincing. It is therefore less likely that this would fall within the definition of intrusive research for the purposes of the MCA 2005.

It is important to acknowledge as well that developments in data protection law may provoke arguments about the lawfulness of research on non-consenting capacitous participants which sit distinct from any Article 8 considerations. If, say, research data was gathered and processed from a capacitous participant as part of an observational or questionnaire study, under data protection legislation would it be unlawful for that to happen without her consent? If so, arguably, it could then fall within the meaning of intrusive research for the purposes of the MCA, if it were to be performed on an incapacitated participant. While we have insufficient space here to provide a thorough analysis of the impact of the General Data Protection Regulation (GDPR), for the present purposes it suffices to say that, while consent is one potential ground for lawful processing of data, it is not the only one.[35] Some research data could potentially be lawfully processed without consent on the basis that it is necessary for the purposes of a legitimate interest.[36] This particular ground is the most flexible, and thus provided any research data collected and used was then processed in accordance with the data protection principles, it would not automatically be unlawful by virtue of the absence of

For Peer Review

[33] Barbara DiCicco-Bloom and Benjamin F Crabtree, 'The Qualitative Research Interview' (2006) 40 *Medical Education* 314.

[34] Ann Bowling and Shah Ebrahim (eds), *Handbook of Health Research Methods: Investigation, Measurement and Analysis* (1st edn, OUP 2005).

[35] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of person data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), [2016] OJ L 119/1. See also Data Protection Act 2018.

[36] Above (n 35). Article 6 (1) (f). It should be noted that if any research data related to health, it would be classed as 'special category data'. Alongside the legitimate expectation ground, a further justification would also be needed for the lawful processing of this data. In a research context, this is most likely to be founded under Article 9, (j), in which processing is necessary for achieving purposes in the public interest, and scientific or historical research.

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consent.[37] As such, it should not be assumed that data protection laws will impact upon the MCA's definition of intrusive research in every case, particularly in the context of methods which anonymise data, because the relevant legislation then no longer applies.[38] Ambiguities are undoubtedly rife, but nonetheless in our view the majority of research involving incapacitated participants seeking to employ interview and/or questionnaire methods would fall outside the MCA's definition of intrusive research, meaning that strictly speaking researchers should not be bound to follow the rest of the authorisation provisions. It is at this stage that a disconnect becomes evident between the substantive law on the one hand, and professional regulatory guidance on the other.

Regardless of the correct position of the lawfulness or otherwise of certain types of observational, interview and questionnaire research without consent, the MCA Code of Practice (COP), and other associated professional regulatory guidelines, have taken the lead on this question, stating that observational and interview research is included within the MCA's definition of intrusive research.[39] Thus, the further requirements of the Act must be complied with, and approval sought from a MCA REC, before any non-invasive type of project involving incapacitated participants can be authorised. It is not unusual for Codes of Practice and professional regulatory guidelines to flesh out primary legislation,[40] but it is rare to see such a significant leap being made from what a statute appears to have been initially intended to cover in theory, to what it has actually been interpreted to include in practice. In attempting to clarify the ambiguity surrounding the definition of intrusive research, however well-intentioned the motive, the COP and related guidance have arguably overstepped the original parameters of the primary legislation, without reference to any legal authority to substantiate that position. Addressing the uncertainties associated with the central definition of intrusive research, which is crucial to how the remainder to the MCA research provisions operate, is a matter that should be resolved by the legislature. A further practical problem is created by including interviews

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[37] For the data protection principles, see (n 35), Article 5 (1) (a) – (f). For information on the wide interpretation of the legitimate interest ground, see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/legitimate-interests/ <accessed 22nd Feb 2019>.

[38] Anonymised data falls outside the definition of 'personal data', contained in (n 35) Article 4 (1). For older English authority on this point, see *R v Department of Health, ex p Source Informatics Ltd (No.1)* [2001] QB 424.

[39] Mental Capacity Act 2005: Code of Practice, para [11.5] and [11.15]; NHS Health Research Authority, Mental Capacity Act: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/. <Accessed 21st February 2019>.

[40] See, for example, Human Fertilisation and Embryology Authority: Code of Practice (v9 2018).

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and questionnaires within the definition of intrusive research. Insisting that MCA RECs review and approve *every* project that adopts such methods may be an unnecessary drain on already scarce resources.[41] Consider, for example, a university researcher who wishes to conduct interview or questionnaire research involving incapacitated participants who are not NHS patients, but who are drawn from a wider cross-section of society. In this scenario, McHale suggests that 'an alternative approach would be to allow some forms of research concerning persons lacking capacity to be referred for approval to committees other than NHS research ethics committees, such as university research ethics committees'.[42] This argument has merit, for often a university research ethics committee may be better placed to review certain projects. In some areas, such as social sciences, they may have a wider and more localised pool of expertise to conveniently draw on. Whatever the solution, as things stand, the contours of the MCA remain poorly defined and this is something that needs to be rectified.

ii) Operating from the Wrong Basis

Alongside the scope of the legislation remaining poorly defined, there are further aspects of the requirements for approval that provide cause for concern. As a corollary of its apparent emphasis on medically-invasive research, the MCA also adopts a limited view of what research has to be connected with when dealing with incapacitated participants.

In order to meet the requirements for approval, the research must be connected with an impairing condition affecting the participant, or its treatment.[43] An impairing condition is one that is attributable to, or which causes or contributes to, the impairment of, or disturbance in the functioning of, the mind or brain.[44] It thus portrays a heavily medicalised model of what is deemed valuable in research, which is wedded to the belief that an incapacitated participant should only be permitted to be involved in activities that are directly related to improving knowledge of the causes or treatment of the condition that *she* is suffering from, which is impinging on *her* capacity. This neglects to consider that, provided there is adequate support to help her, an incapacitated participant may remain capable of not only adding value to certain types of research that may be wholly unconnected to her medical condition, but also of

[41] A key component of the ASSENT Project at xxx is to assess how many applications MCA REC actually receive in respect of incapacitated participants.

[42] McHale (n 5) at 67. McHale's reference to 'NHS research ethics committees' is what we have labelled MCA RECs throughout this piece.

[43] Mental Capacity Act 2005, s 31 (2) (a) and (b).

[44] Mental Capacity Act 2005, s 31 (3)

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communicating a desire to become involved in such work.[45] By way of illustration, a general research project conducted by local government aimed at exploring society's perceptions of how local amenities could be improved would almost certainly benefit, to the extent that it is possible, from input from an incapacitated participant. However, a creative interpretation of the legislative provisions would be required to justify her inclusion, which jars with any notion of empowerment.

It is left to the COP to clarify that treatment is not confined purely to medical treatment, but even so it still states that research can only be authorised if it is linked in some way to the condition affecting an incapacitated participant herself, or to others who suffer from the same or a similar condition.[46] This misses the point; the hypothetical research project we discuss above should not have to be justified on the basis that the contribution of an incapacitated participant may improve matters from her perspective as the sufferer of a mental impairment, or indeed that it may help others with similar or related conditions. It should be justified by recognition that she is a member of the public herself, who may be capable of communicating valid input into any research for the benefit of other individuals in society whose capacity is not compromised. Ignoring these important considerations paves the way for an overly restrictive outlook to take shape, which permeates throughout the remainder of the MCA's research framework.

A similar attitude is fostered in relation to the ground for approval that requires consideration as to whether research of comparable effectiveness could be carried out on a capacitous person.[47] This stems from a wider ethical concern that incapacitated participants should not be used in research simply out of a matter of convenience, which is an admirable position to adopt in one sense.[48] Nevertheless, its phrasing may cause a researcher to always begin by asking herself the question: 'can I answer this research question without involving

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[45] Mabel Stevenson and Brian J Taylor, 'Involving Individuals with Dementia as Co-Researchers in Analysis of Findings from a Qualitative Study' (2019) 18 *Dementia* 701; Julie Calveley, 'Including Adults with Intellectual Disabilities who Lack Capacity to Consent in Research' (2012) 19 *Nursing Ethics* 558; Ruth Bartlett, 'Modifying the Diary Interview Method to Research the Lives of People With Dementia' (2012) 22 *Qualitative Health Research* 1717.

[46] Mental Capacity Act 2005: Code of Practice, para [11.16].

[47] Mental Capacity Act 2005, s 31 (4).

[48] Bartlett (n 12) at 89; George F Tomossy and David N Weisstub, *Revival: Human Experimentation and Research* (1st edn, Routledge: Taylor and Francis 2003). For an interesting historical account of the enduring ethical issues see Rebecca Dresser, 'Mentally Disabled Research Subjects: The Enduring Policy Issues' (1996) 276 *Journal of American Medical Association* 67.

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incapacitated participants?' As a starting premise, this tends to create a presumption that research will produce more effective results where the use of capacitous participants is prioritised over those who lack capacity. It may then encourage a researcher to err on the side of exclusion and if this attitude gains traction it creates a distorted impression of the value that an incapacitated participant may be able to bring to research in her own right. Just because more effective results may be capable of being achieved by using only capacitous participants, it does not automatically mean that incapacitated participants should be prevented taking part. The sensible view is to recognise that both sets of participants may be capable of contributing something of equal worth to research and, if this goes unnoticed, the legislative provisions diminish the position of incapacitated participants when they should be aspiring to produce the opposite effect.

It has been argued by some that the more general terms of MCA conflict with the renewed emphasis on supported decision-making endorsed by the UNCRPD.[49] The particular demand for a comparative assessment of capacitated versus incapacitated participants in the sphere of research is a paradigm example of the MCA failing to recognise what supported decision-making is actually about.[50] Rather than promoting an attitude of exclusion, the legislation should aim not only to focus on the ways in which it can recognise the valid contribution that incapacitated participants bring to research, but also on how its provisions could effectively accommodate and facilitate their involvement in the process. It should seek to maximise avenues of support for a participant in research and, where possible, to assist her in making her own decision about participation. While it is desirable to assume that the interests of an incapacitated participant should outweigh the interests of science and society, to view the two interests as always being diametrically opposed may lead to a propensity to overprotect, when the direction of travel should be to place greater emphasis on collaboration between a researcher and a participant to engender empowerment.[51] The research provisions

For Peer Review

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[49] Clough (n 3); Donnelly (n 1); Donnelly (n 2).

[50] Loomes (n 5); Clough (n 3). See also Ciara Shiggins *et al.*, 'Towards an ASSET-Based Approach to Promoting and Sustaining Well-Being for People with Aphasia and their Families: An International Exploratory Study' (2018) *Aphasiology* 1. doi: https://doi.org/10.1080/02687038.2018.1548690; Natalie Joseph-Williams *et al.*, 'Implementing Shared Decision Making in the NHS: Lessons from the MAGIC Programme' (2017) 357 *BMJ* 1744; Treena Jingree, 'Duty of Care, Safety, Normalisation and the Mental Capacity Act: A Discourse Analysis of Staff Arguments about Facilitating Choices for People with Learning Disabilities in UK Services' (2015) 25 *Journal of Community and Applied Social Psychology* 138.

[51] Mental Capacity Act 2005, s 33 (3). On the point of collaboration, see ibid, and also NICE Guidelines: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making.

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are ripe for an overhaul of how they visualise the position of incapacitated participants and, based on the excellent recent work of Clough, this may entail a complete reconsideration of how notions of incapacity and its affect upon individuals are thought about.[52]

At present, the opening sections of the MCA in regard to research begin by asking the wrong questions, which sets a narrow and restrictive tone for the remainder of the provisions. As we will now proceed to discuss, the further additional requirements for approval also miss their target.

C. An Illusionary Higher Threshold for Approving Research?

Best interests occupies a central role in the MCA, providing the lawful basis upon which certain decisions can be made for those who cannot decide for themselves. In theory the test remains objective, yet section 4 of the MCA provides a non-exhaustive list of both objective and subjective factors that must be considered by any decision-maker in the process of deciding what is in an incapacitated person's best interests.[53] One interesting question surrounds its absence in the arena of research, and there was some early confusion on this point.

In his first edition of *Blackstone's Guide to the Mental Capacity Act 2005*, Bartlett argued that the guiding principles of best interests should apply to research in the same way that they should apply to treatment.[54] In the later edition, he then changes his position, accurately identifying that the best interests test is not referred to and that the research sections of the MCA 'introduce their own substantive thresholds'.[55] It would seem that the omission of best interests was deliberate, because its inclusion in the context of research was perceived by some as being problematic on the basis that research is seldom intended to benefit individual participants *per se*.[56] Consequently, it was perhaps thought that endorsing a separate approach may well have afforded extra protection, but whether or not any is provided is disputable.[57] At the same time, a further aim may have been to create a regime that could still facilitate inclusive

For Peer Review

[52] Clough, (n 3).

[53] Mental Capacity Act 2005, s 4; Donnelly (n 2); Taylor (n 4).

[54] Peter Bartlett, *Blackstone's Guide to the Mental Capacity Act 2005* (1st edn, OUP 2005) at 66.

[55] Bartlett (n 12).

[56] HL Deb 01 February 2005, vol 669, cols 130 – 131. https://api.parliament.uk/historic-hansard/lords/2005/feb/01/mental-capacity-bill-37-pm#S5LV0669P0_20050201_HOL_123. <Accessed 26th February 2019>.

[57] HL Deb 01 February 2005, vol 669, col WA102-77.

research, but, once again, it is not obvious that removing reference to best interests accomplishes it. As we examine in more detail below, the tailored thresholds for research require consideration of a range of factors that are not altogether dissimilar to those which must be considered under a best interests assessment, so little if anything is gained by their insertion. For the purposes of the following analysis, the provisions which we are principally concerned with are sections 31 (5) (a) and 31 (5) (b) of the MCA.[58]

i) Benefits to Burdens Ratio: Considering the Position of the Participant (Section 31 (5) (a))

Under section 31 (5) (a), a MCA REC may not approve a research project unless it is satisfied that the research has the potential to benefit a participant without imposing on her a burden that is disproportionate to the potential benefit.[59] One fallout from the MCA's apparent emphasis on medically invasive research, is that any analysis of the notion of 'benefit' may naturally gravitate towards identification of medical advantages.[60] Medical benefits are frequently considered from an objective evidence-based perspective, yet to confine any examination under section 31 (5) (a) of the MCA purely to this is too restrictive.[61] This is one area in which the COP is helpful as it elaborates on the potential meaning of 'benefit', embracing a more expansive approach. Section 11.14 of the COP states that alongside developing more effective ways of treating or managing a participant's condition, benefit could also mean improving the quality of health or social care that a participant may have access to, discovering the cause of the participant's condition if she would benefit from that knowledge, and reducing the risk of the participant being harmed excluded or disadvantaged.[62] The adoption of this broader interpretation is undoubtedly sensible, but it is equally important to acknowledge that these considerations must be targeted at procuring some *direct* benefit to the individual participant *herself*. The subjective circumstances of an individual participant must therefore be considered

[58] Mental Capacity Act 2005, s 31 (5) (a) and (b).

[59] Mental Capacity Act 2005, s 31 (5) (a).

[60] Above n 17.

[61] Matthew J Leach, 'Evidence Based Practice in Traditional & Complementary Medicine: An Agenda for Policy, Practice, Education and Research' (2018) 31 *Complementary Therapies in Clinical Practice* 38; Matthew J Leach, 'Evidence-Based Practice: A Framework for Clinical Practice and Research Design (2006) 12 *International Journal of Nursing Practice* 248; Andrew Miles *et al.*, 'Evidence-Based Healthcare, Clinical Knowledge and the Rise of Personalised Medicine' (2008) 14 *Journal of Evaluation in Clinical Practice* 621.

[62] Mental Capacity Act 2005: Code of Practice, para [11.14].

For Peer Review

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carefully. Remaining cognisant of this becomes even more important when thinking about potential *indirect* benefits under section 31 (5) (a) of the MCA.

If understood correctly, benefits should encompass social, psychological and emotional factors, which may be specific to the individual position of an incapacitated participant.[63] There may be some situations in which she may only receive a tangentially-related benefit from any involvement in research, but the fact that this may be of a marginal, non-physical nature should not prevent it from being classified as something that may be of worth to *her*. The COP also usefully recognises this in stating that where 'the research involves interviews and the person has the opportunity to express their views, this could be considered a real benefit to a particular individual'.[64] The broader potential benefit of allowing an incapacitated research participant to have her voice heard is, therefore, explicitly recognised. It follows that in order to encourage wider participation and inclusiveness, an expansive meaning must be ascribed to the notion of benefit, which considers a range of both objective and subjective factors. At this point, it becomes evident that the test articulated under section 31 (5) (a) of the MCA does not represent as radical a departure from the best interests test as some may have envisaged.[65] The threshold for approval is not in reality raised, because it does not demand proof of a higher objective level of benefit to be present. It simply requires that a balancing exercise is undertaken which necessitates a comparative weighing of benefits versus burdens.[66] Provided there is some potential benefit to a participant, and provided any associated burden is not disproportionate to that benefit, the standard will be satisfied.[67] The correct approach is, thus, to consider both objective and subjective considerations in this assessment and, where this is acknowledged, the balancing exercise performed in the assessment of research under section 31 (5) (a), and the factors that should be included therein, is closely aligned to the manner in which best interests assessments should be performed.[68]

For Peer Review

[63] In *Re A (Mental Patient: Sterilisation)* [1999] 12 WLUK 657; [2000] 1 FLR 549, Dame Elizabeth Butler-Sloss P recognised that considering these factors was crucial to any assessment of best interests, at p.10 of the Official Transcript.

[64] Mental Capacity Act 2005: Code of Practice, para [11.15].

[65] Bartlett (n 12).

[66] Mental Capacity Act 2005, s 31 (5) (a) and (b).

[67] Ibid.

[68] *Re A* (n 63); *Re J (A Minor) (Wardship: Medical Treatment)* [1991] Fam. 33, 55.

ii) Recognition of Wider Societal Benefits (Section 31 (5) (b))

Where a research project will not confer either a direct or indirect benefit on an incapacitated participant under section 31 (5) (a) of the MCA, it may still nonetheless be approved under section 31 (5) (b).[69] Under this section, the emphasis switches to an assessment of whether or not the research is intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition to that of the participant.[70] On the basis that this provision invites some consideration of the impact of the research on individuals other than the incapacitated participant herself, a more visible departure from best interests may initially be apparent here.

A conventional best interests decision must be made by reference to what is in the best interests of a particular individual, but section 31 (5) (b) actually requires quite the opposite.[71] It distances itself from analysing matters from the subjective perspective of a would-be participant and instructs an assessor to turn her attention to any potential knowledge that could be gained from research that may be useful to wider members of society.[72] A different mode of thinking is, at first blush, required than that which would typically be expected of a decision-maker under a standard best interests examination. Casting the net wider in this way has the capacity to facilitate a more inclusive and permissive approach, but where any inquiry must look beyond individual benefits, and where a participant is particularly vulnerable, it would not be unreasonable to expect a more stringent test in order to justify any research. Section 31 (5) (b) does not actually provide this. Given that under this section the research must be intended to provide knowledge of causes, treatment or care of a condition, there may be an inclination to think that it should be judged against a higher level evidence-based criteria, but its wording is prone to mislead. Section 31 (5) (b) only demands that the research must be *intended* to provide knowledge; there is no requirement for it to be objectively proved that any research *will actually* produce such knowledge. As most credible research projects will be underpinned by at least an intention to develop a deeper understanding of a particular problem to help society in a broader sense, the reality is that the test under section 31 (5) (b) may be easier to meet than

For Peer Review

[69] Mental Capacity Act 2005, s 31 (5) (a) and (b).

[70] Mental Capacity Act 2005, s 31 (5) (b).

[71] Per Holman J in *An NHS Trust v MB and Others* [2006] EWHC 507 (Fam); [2006] 2 FLR 319 at [16] [v].

[72] Mental Capacity Act 2005, s 31 (5) (b).

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some may imagine. To mitigate against this, the legislation attempts to provide a protective counterbalance.

Where section 31 (5) (b) is engaged, section 31 (6) states that there must also be reasonable grounds for believing that the risk to the participant from taking part in the project will be negligible, and that anything done to, or in relation to the participant, will not interfere with her freedom of action or privacy in a significant way, or be unduly restrictive.[73] This directs the examination away from balancing out the risks and benefits, towards ensuring that an incapacitated participant is prevented from being exposed to anything greater than a low-level risk when partaking in research designed solely to benefit of others. Those who believe that the definition of a negligible risk is something that can be calculated with precision though are operating under a misapprehension. Any categorisation of a risk as being beyond negligible may depend on a number of factors; emphasis could be given to percentage rates of occurrence, whereas elsewhere it may be placed on the severity of consequence should that risk materialise. Equally, it is subject to differing interpretations. For some, the mere existence of a remote risk, no matter how slight, may be sufficient to classify it as something beyond negligible, thereby ruling out any authorisation of the research. This could lead to a problematic situation in which certain participants may be prevented from taking part in some research projects because of problematic risk appraisals associated with vague definitions. The CoP, for example, equates 'negligible' with 'minimal' and proceeds to state that a participant should suffer 'no harm or distress by taking part'.[74] Properly understood, minimal risk should not be taken to mean no risk at all and so perhaps the COP is too restrictive on this point. It is certainly possible to interpret the meaning of negligible more liberally in order to recognise that certain incapacitated participants may be capable of withstanding a greater level of risk in order to foster their involvement in research.

This feeds into a further important point; any examination of the magnitude of a risk associated with a project needs at least some consideration of how a prospective participant may view it.[75] It is therefore sensible to be explicit about the fact subjective considerations also

For Peer Review

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[73] Mental Capacity Act 2005, s 31 (6). As Brazier and Cave note, this is a less onerous test than is applied under the Medicines for Human Use (Clinical Trials) Regulations 2004. Under Sch 1, Part 5, para 9 of the Clinical Trials Regulations, the research must either benefit the patient or produce *no risk at all*. See Margaret Brazier and Emma Cave, *Medicine, Patients and the Law* (6th edn, Manchester University Press 2016) at 490. Analysis of the Clinical Trials Regulations is beyond the scope of this piece.

[74] Mental Capacity Act 2005: Code of Practice, para [11.18].

[75] See J Richard Eiser *et al.*, 'Risk Interpretation and Action: A Conceptual Framework for Responses to Natural Hazards (2012) 1 *International Journal of Disaster Risk Reduction* 5.

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have a role to play in the assessment of research justified on the grounds of wider societal benefits. Where a participant is able to express enthusiasm for involvement in a project, it may colour any assessment of what amounts to a negligible risk; a risk may exist which to some would appear more than negligible, but from the perspective of a potential participant it may not be viewed in the same way.

The other protective measures under section 31 (6) are also plagued by ambiguous phrases, that are very much dependant on an individual. Ensuring that anything done will not amount to a 'significant' interference with privacy needs at least some evaluation of a participant's position and personal circumstances, because what amounts to a significant interference may vary greatly.[76] Similar complications are associated with the requirement not to do anything that is unduly invasive or restrictive. The meaning of 'unduly' is subject to the specifics of the type of research in question and how it may impact upon a range of participants in potentially different ways.[77] Accordingly, a pattern emerges which belies the notion that section 31 (5) (b) demands a wholly objective examination when assessing any potential wider societal benefits stemming from research. Operating in tandem with the additional protective mechanisms under section 31 (6), it is clear that both objective and subjective factors need to be considered in a manner that is again not entirely inconsistent with the section 4 best interests approach.

iii) The Bespoke Research Provisions: Justified Abandonment of Best Interests?

While the requirements for approval of research under sections 31 (5) (a) and (b) of the MCA are phrased differently, in reality they operate in much the same way as the best interests standard. There is a significant amount of replication between the nature of the factors that must be considered under both approaches, so it is difficult to discern where any added protection in a research context derives from. On the contrary, the research provisions are so opaque in places that they become difficult to translate into a working model of assessment and therefore frustrate, rather than facilitate, research. Arguably the only thing they have accomplished is to create a sense of confusion amongst those who have to apply them, and a

[76] Recently, the Supreme Court stressed the importance of the need to consider things from the *particular* patient's perspective. What amounts to a significant invasion of privacy could, for example, depend on cultural beliefs and different perceptions of privacy. See *Montgomery v Lanarkshire* [2015] UKSC 11; [2015] AC 1430.

[77] See Victoria Shepherd, 'Research Involving Adults Lacking Capacity to Consent: The Impact of Research Regulation on 'Evidence *Biased'* Medicine (2016) *BMC Medical Ethics* https://doi.org/10.1186/s12910-016-0138-9; Herbert C Kelman, 'Privacy and Research with Human Beings' (1977) 33 *Journal of Social Issues* 177.

For Peer Review

lack of consistency between different aspects of the MCA, where it may have been more effective for the legislation to remain more streamlined across all areas of treatment, finances and research.

Instead of incorporating a separate set of substantive thresholds, it may have been simpler and more effective to require both researchers and MCA RECs to undertake a best interests assessment when assessing the validity of participation in research. First, those involved in working with individuals who lack capacity – whatever type of decision is at stake – may be more accustomed to the best interests test. Applied to research, it may therefore be more easily understood, because the minds of consultees and MCA REC member assessors may be more attuned to considering the wider range of factors that are now commonly accepted as having to form part of a holistic balancing process, which may make evaluations more rounded.[78] Secondly, interpreted in an expansive manner, the concept of best interests is sufficiently malleable so as to be capable of achieving a fairer balance between protection and empowerment in research. It would still allow the specific interests of a participant to be prioritised, while at the same time remaining able to consider, and accommodate, the wider interests of society. Insofar as the latter is concerned, some will no doubt point out a problem we alluded to earlier; what is in the best interest of an individual can never be answered by considerations pertaining to what is in the best interests of others. A radical departure would accordingly be required to allow research to proceed where it would only benefit society. Where a broader view is adopted, this is not necessarily the case, particularly if the question is asked: how would an incapacitated feel about her involvement in research that may not necessarily help her, but which could help others?

This is where best interests' explicit endorsement of the need to consider things from the subjective perspective of an incapacitated individual under section 4 of the MCA sends a much stronger and important message than is currently conveyed by sections 31 (5) (a) and (b). When determining the question of best interests, section 4 (6) of the MCA instructs a decision maker to consider, so far as is reasonably ascertainable, the person's past and present wishes and feelings (and, in particular, any relevant written statement made by him when he had capacity),[79] the beliefs and values that would be likely to influence his decision if he had

[78] Donnelly (n 1); Donnelly (n 2).

[79] Mental Capacity Act 2005, s 4 (6) (a).

For Peer Review

capacity,[80] and the other factors that he would be likely to consider if he were able to do so.[81] Under section 4 (7), provided it is practicable and appropriate to consult them, the views of anyone named by the person as someone to be consulted on the matter in question or on matters of that kind should also be taken into account,[82] as should the views of anyone engaged in caring for the person or interested in his welfare.[83] While best interests does not in a general sense provide a complete panacea to English law's current incompatibly with the notion of supported-decision making, these sections do help to give an incapacitated person a voice and could be particularly useful if applied to research.

It is often assumed that an incapacitated participant will be unable to communicate her preferences for any involvement in research, but that is often not so.[84] There will be circumstances where she remains capable of expressing a desire to become involved and so it will be possible to identify a benefit to her own personal development and sense of worth, from contributing to something that may be of value to others.[85] Even where she cannot communicate a preference, she ought not to be automatically precluded from participating in a project for the wider benefit of society, and the advantage of a best interests approach in the context of research would be explicit recognition from the legislation itself, and not just the COP, [86] of the need to view that question through the lens of the participant. It may be possible to conclude that she would be stimulated and enthused by a desire to contribute to society by helping others, which would induce a sense of happiness in her. Researchers must be clearly encouraged to explore with any incapacitated participant, to the greatest extent possible, how she may feel about her involvement in any research that may not necessarily help her, but which could help others. Naturally this requires complex concepts to be addressed that sometimes

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[80] Mental Capacity Act 2005, s 4 (6) (b).

[81] Mental Capacity Act 2005, s 4 (6) (c).

[82] Mental Capacity Act 2005, s 4 (7) (a).

[83] Mental Capacity Act 2005, s 4 (7) (b).

[84] Benjamin W. J. Spencer *et al*., 'Unwell in Hospital but not Incapable: Cross-Sectional Study on the Dissociation of Decision-Making Capacity for Treatment and Research in In-Patients with Schizophrenia and Related Psychoses' (2018) 213 *The British Journal of Psychiatry* 484; Mark J. Jayes and Rebecca L Palmer, 'Stroke Research Staff's Experiences of Seeking Consent from People with Communication Difficulties: Results of a National Online Survey' (2014) 21 *Topics in Stroke Rehabilitation* 443.

[85] See, for example, Mencap, *Involve Me: Independent Evaluation Report* (Foundation for People with Learning Disabilities 2011).

[86] Mental Capacity Act 2005: Code of Practice, paras [11.20], [11.24] and [11.29].

For Peer Review

may be outside a participant's comprehension. Therefore, how meaning is constructed with potential participants is absolutely crucial and the research sections of the MCA fall short of addressing this, instead leaving it to the COP to emphasise. Making the effort to elicit the views of any potential incapacitated participant may reveal that she has a strong desire to act altruistically and to become involved in a project, a view which has gained traction under best interests reasoning. For instance, it has previously been acknowledged that an incapacitated person's best interests may be served by authorising a bone marrow donation that conferred no direct medical benefit on her, but which would only benefit her sibling. In the long run, however, it was agreed that she would gain some emotional, psychological and social benefit from this procedure as it would allow her sister, and indeed her mother, to spend more time with her in the future.[87] In other words, a clear benefit could be identified from helping someone else. This attitude has recently been reiterated by Morgan J in the Court of Protection, where he confirmed that the best interests test does not confine a court to considering self-interest, but could be extended to consider how the potential altruistic wishes of a person could indicate that a course of action ostensibly designed to help others could in fact be in that person's best interests.[88]

Admittedly, in some instances factors pulling in the opposite direction may be sufficiently compelling to override the above points, but they would also be considered as part of a rounded balancing exercise that is typically performed under best interests. All things being equal, however, where an incapacitated participant is capable of communicating a wish to participate in research in order to help others, it should be highly persuasive in terms of sanctioning her involvement. In order to promote this attitude, greater emphasis needs to be placed on ways in researchers themselves can be encouraged to engage participants with the research concepts and communication process in whatever way each individual is able. At present, the legislation gives the impression that this role should be mainly delegated to a consultee, which carries with it some pitfalls that we explore in more detail below.

We now turn to consider whether other aspects of the MCA could potentially depict the bespoke research provisions in a more favourable light. While a number of other requirements must also be complied with before research can be approved, we argue that these additional measures impose different obligations on different parties. Thus, far from adding clarity, they actually send out mixed messages.

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[87] *Re Y (Mental Patient: Bone Marrow Donation)* [1997] Fam 110.

[88] *Re G* [2010] EWHC 3005; [2010] 11 WLUK 498.

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D. Researchers; Consultees; MCA RECs: Mixed Responsibilities

i) Researchers

The question of capacity is the first issue that must be addressed by a researcher, and she must approach this by reference to the general principles contained in the MCA.[89] The starting point is that capacity should always be presumed, which acts as a safeguard by ensuring that the burden of disproving capacity rests on the person contesting it.[90] To rebut that presumption, it must be proven, on the balance of probabilities, that at the material time, a person is unable to make a decision.[91] Under section 3 (1), a person is unable to make a decision if she is unable to understand the information relevant to the decision, to retain that information, to use or weigh that information as part of the process of making the decision, or to communicate her decision (whether by talking, using sign language or any other means).[92] This is a decision-specific, functional approach that focuses on the ability of a participant to actually make a decision through understanding, remembering, processing and communicating.[93] Where a research participant is deemed to have capacity, her decision about participation remains sacrosanct.[94] If, however, the opposite conclusion is reached, the additional measures of the MCA will be triggered. Where research is concerned, specific difficulties arise not only in relation to who is responsible for performing capacity assessments, but also in respect of the nature of the test itself.

The test for capacity is notoriously difficult to apply in practice, which often leads to inconsistencies in its performance.[95] Where a decision relates to treatment, a perceived

For Peer Review

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[89] Mental Capacity Act 2005: Code of Practice, para [11.4]; NHS Health Research Authority, Mental Capacity Act: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/. <Accessed 21st February 2019>.

[90] Mental Capacity Act 2005, s 1 (2).

[91] Mental Capacity Act 2005, s 2 (1)

[92] Mental Capacity Act 2005, s 3 (1) (a) (b) (c) and (d); See *Re C (Refusal of Medical Treatment)* [1994] 1 WLR 290.

[93] Michael Gunn, 'The Meaning of Incapacity' (1994) 2 *Medical Law Review* 8.

[94] It was stated by Lord Donaldson MR in *Re T (Adult: Refusal of Treatment)* [1993] Fam 95 at 102 that 'an adult who suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered...This right of choice is not limited to decisions which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent.' The same principles would apply to research.

[95] Mark Jayes *et al.*, 'How do Health and Social Care Professionals in England and Wales Assess Mental Capacity? A Literature Review' (2019) *Disability and Rehabilitation* 1. Doi: 10.1080/09638288.2019.157293; Paula Case,

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advantage is that medical professionals will usually be involved in at least some stage of any capacity assessment, yet it is a common misconception that they are all trained in assessing capacity, when often they are not.[96] Research has established that in some instances they do not fully understand what the legal test requires of them.[97] This is mitigated to a degree by the fact that disputes about capacity in certain treatment decisions may be more likely to be referred to court for scrutiny. Where this happens, expert testimony will be presented before a judge of the Court of Protection by professionals who have extensive experience in assessing capacity by reference to the appropriate legal test. It is not a guaranteed safeguard though, because recent evidence has suggested that the same select group of experts are often called upon to give evidence repeatedly, thereby creating the danger of assessments becoming too formulaic an exercise.[98] Nonetheless, an added layer of accountability still exists that has the effect of ensuring that any query surrounding capacity in delicately poised treatment cases is subject to forensic judicial scrutiny and open to challenge. No such safety measures are ever likely to be activated in research. While theoretically it would be possible to ask the Court of Protection to make a declaration concerning the capacity of a potential research participant, it is highly unlikely to happen in practice.[99] Individuals involved in the research approval process will have little incentive to seek such a declaration and, given the extra cost and additional time, the chances are that it will never be pursued. It follows that an important layer of legal scrutiny that exists in regard to certain treatment cases, is effectively lost in the realms of research The only real safeguard that exists in respect of the capacity question is, therefore, grounded in the overall scrutiny that a MCA REC maintains over a project, but we argue later that this may be an inappropriate forum to oversee this issue.

Following on from this, as noted, those involved in capacity-related treatment assessments will often have *some* medical and psychological knowledge, albeit from a variety of different backgrounds. It cannot be assumed in the same way that the majority of researchers will possess that skill set, a difficulty which has been amplified by the scope of the MCA being

‘Negotiating the Domain of Mental Capacity: Clinical Judgement or Judicial Diagnosis?’ (2016) 16 *Medical Law International* 174; Mary Dixon-Woods *et al*., ‘Research Involving Adults who Lack Capacity: How have Research Ethics Committees Interpreted the Requirements?’ (2009) 35 *Journal of Medical Ethics* 377.

[96] Jayes (n 95); Daniel Ratcliff *et al*., ‘Health and Social Care Practitioners’ Experiences of Assessing Mental Capacity in a Community Learning Disability Team’ (2016) 44 *British Journal of Learning Disabilities* 329;

[97] Ibid.

[98] Case (n 95).

[99] Mental Capacity Act 2005, s 15.

For Peer Review

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extended to cover a whole range of research, some of which will not be undertaken by medical researchers at all.[100] Where a social scientist proposes a research project involving incapacitated individuals, presuming she has no medical background, what assurances are there that she will possess the skills needed to make an accurate assessment of prospective participants' capacity? A lack of expertise and experience in assessing capacity is not exclusive to researchers, for there are other professional people who are not medically qualified and who may find themselves having to make similar assessments, such as social workers, or those making financial decisions on behalf of others.[101] The difficulties are more pronounced in relation to researchers, however, because the nature of their job may cause them to have less exposure to dealing with incapacitated participants who may exhibit difficulty with understanding, problems with speech and language, and poor memory and recall. Where a researcher perceives that she may be confronted with such individuals, she may be inclined to avoid any challenging capacity-related questions by simply altering the parameters of her investigation. This option will not be open to other professionals who may still have to perform capacity assessments as a core function of their job. If there is a propensity to avoid rather than confront these difficult questions, the problem becomes self-perpetuating as researchers will never gain enough experience to become more proficient in assessing capacity and valued participants may continue to be excluded.

In research, a 'grey area' will also often exist. Some projects will be a one-off, but others may necessitate more prolonged involvement from a participant. It is thus possible that if a participant is asked to take part in a project over a sustained period of time, that she may experience fluctuating capacity at various junctures.[102] Moreover, as capacity is technically decision-specific, there may be some components of a research project that a participant may have capacity to agree to, and others which she may not.[103] While there is some legal

For Peer Review

[100] See discussion above at (n 42).

[101] Marcus Jepson *et al.*, 'Indirect Payments: When the Mental Capacity Act Interacts with the Personalisation Agenda' (2016) 24 *Health and Social Care in the Community* 623; Marie Poole *et al.*, 'Going Home?: An Ethnographic Study of Assessment of Capacity and Best Interests in People with Dementia being Discharged from Hospital' (2014) 14 *BMC Geriatrics* 56; Jill Manthorpe *et al.*, 'Early Days: Knowledge and Use of the Mental Capacity Act 2005 by Care Home Managers and Staff' (2011) 10 *Dementia* 283.

[102] In *Re MB (Caesarean Section)* [1997] 2 WLUK 313; [1997] 2 FLR 426 it was confirmed that a person could be rendered 'temporarily' incapacitated. See also Barton W Palmer *et al.*, 'Changes in Capacity to Consent over time in Patients Involved in Psychiatric Research' (2013) 202 *The British Journal of Psychiatry* 454.

[103] *An NHS Trust v MB and Others* (n 71).

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recognition of the possibility of a 'temporary' loss of capacity,[104] untrained researchers may be unaware of it and hence be more inclined to view the question of capacity as absolute instead of relative. Therefore, if capacity cannot be evidenced securely, exclusion may follow, which may be unnecessary. If capacity also appears to fluctuate during the course of a project, there may be a greater inclination from a researcher to think that a participant has lost capacity while the research is ongoing, when that assessment may be inaccurate. If a participant is then withdrawn on this mistaken belief, her exclusion from a project may be overly premature and needlessly damaging to the research.[105] Alternatively, the opposite problem may occur in which a mistaken belief that a participant has capacity causes her involvement in the study to continue, where it may be inappropriate and perhaps even harmful to allow it to happen.[106] The flip side to this is to acknowledge that capacity related concerns may be only one reason for exclusion. A researcher may operate cautiously because of a perceived fear her own legal exposure, or, worse still, for the sake of administrative convenience. Engaging the mechanisms of the MCA and its associated safeguards carries with it cost, time and resource implications which some may wish to avoid. Whatever the reason though, there is a problem if those who actually remain capable of contributing something of value to a project are unnecessarily discounted, and if those whose capacity is compromised are included without thorough review. It follows that clearer and more specific guidance is required for researchers in terms of how they should approach capacity assessments and what should form part of their decision-making processes when addressing the question of participant inclusion.

For Peer Review

ii) The Consultee

A further obligation placed on the researcher by the MCA is the requirement to appoint a consultee. This individual must be prepared to be consulted by a researcher about whether or not an incapacitated participant should be included within a research project, and to offer her opinion as to what a participant's wishes and feeling would be likely to be about taking part in the project if she had capacity.[107] Two different types of consultee are recognised. A researcher must first seek to appoint a 'personal' consultee, which is defined as a person who otherwise

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[104] Above (n 102).

[105] The MCA makes provisions for loss of capacity during a project. Should this happen, it would seem that immediate exclusion would not automatically be necessary. See Mental Capacity Act 2005, s 34.

[106] Mental Capacity Act 2005, s 33 (4) and (5).

[107] Mental Capacity Act 2005, s 32 (4) (a) and (b).

than in a professional capacity or for remuneration, is engaged in caring for the participant or is interested in her welfare.[108] If no such person can be identified, the researcher, in agreement with a MCA REC, must then appoint a 'nominated' consultee. This is someone who has no connection with the research, but who is still prepared to be consulted about the potential involvement of an incapacitated participant.[109] The rationale behind this system is to ensure that an incapacitated participant is represented by an independent advocate who has no vested interest in the research, and to maximise the potential for her subjective views and beliefs to be heard and respected in decisions about research. This is the archetypal example of the MCA seeking to balance out the aims of protection and empowerment, but whether or not the consultee requirement serves either purpose effectively is open to question.

First, there are some pragmatic difficulties. The system begins by placing an obligation on a researcher to find an appropriate person who has some type of pre-existing personal relationship with a potential participant. Depending on the circumstances, it may actually be very difficult to locate such an individual. The extent of a researcher's duty is to 'take reasonable steps' to locate a personal consultee, but this is ambiguous.[110] One advantage is that it provides a degree of flexibility, so that where any proposed research is scheduled to take place in, say, Norwich, it may be deemed unreasonable to impose on a researcher an obligation to make extensive efforts to contact a participant's distant relative in a remote part of Australia. The drawback is that determining what may amount to taking reasonable steps is open to interpretation. The question will be scrutinised by a MCA REC, so the potential for differing interpretations across the spectrum may add to increased anxiety among researchers. An even greater predicament unfolds where it is not possible to identify a personal consultee. A researcher must then clearly address any arrangements for appointing a nominated consultee when seeking approval from a MCA REC.[111] This enables the latter to assess whether or not there is a convincing reason for not appointing a personal consultee, and for it to advise on the suitability of the arrangements that have been installed for appointing a nominated consultee. A MCA REC may recommend a person who could suitably act in this capacity, and in some

[108] Mental Capacity Act 2005, s 32 (2) (a).

[109] Mental Capacity Act 2005, s 32 (3) (a) and (b)

[110] Mental Capacity Act 2005, s 32 (2).

[111] Mental Capacity Act 2005, s 32 (4) (a) and (b).

For Peer Review

instances direction on this question may be helpful, yet any guidance may still not remedy the array of problems connected with the notion of a nominated consultee.

Not infrequently, a researcher may have to approach a nominated consultee who is involved in providing professional care or support for a potential research participant.[112] Provided they are not connected to the project, this is permissible, but the problem is that a researcher is reliant on the good will of that professional person.[113] Professional people, whatever their discipline, will often not have the time to devote to acting as a consultee for an incapacitated participant whose circumstances they may not be hugely familiar with. A number of potential candidates may decline the invitation, not necessarily because they lack altruistic tendencies, but simply because they may be unable to devote suitable time to get to know a participant and her wishes and thus be incapable of discharging the relevant duty appropriately, especially if it becomes an ongoing obligation. It is too gross a generalisation to suggest that all potential nominated consultees will respond in the negative, for there may be some willing volunteers who will make the time for what they perceive to be a valuable social function. However, the greater number of nominated consultees that refuse to participate at the first time of asking, the further removed the eventual appointed person may become from an incapacitated participant. A risk is also apparent as in some cases no one will agree to act as a consultee, which would effectively block the involvement of some potential participants. If researchers consistently encounter complications insofar as identifying and appointing consultees, then this may chill their enthusiasm for conducting research involving incapacitated individuals, especially if it is perceived to be an excessively burdensome obstacle that is capable of causing significant harm to time-sensitive research.

The system is also predicated on a misconception that a consultee will always be able to offer a convincing opinion about the values, wishes, and beliefs of an incapacitated participant. A personal consultee, as someone who already knows the participant, may be better placed to advise on these considerations than any researcher or nominated consultee, but it is by no means certain that they will be able to do this effectively in every case. In terms of a nominated consultee, the more remote the relationship between her and a participant, the less chance she has of being able to comment accurately on any personal views that participant may hold. Some proposed nominated consultees may recognise this danger and where they have

For Peer Review

[112] See Department of Health, *Guidance on Nominating a Consultee for Research Involving Adults Who Lack Capacity to Consent* (DOH London 2008) at 8.

[113] Ibid.

little or no knowledge of a participant may simply decline to become involved, for proceeding on this basis may cause the system to become artificial, and perhaps even harmful. A natural concomitant of this, however, is that the problems of recruitment identified earlier become amplified.

The notion that the consultee system will promote empowerment by attempting to accommodate the subjective position of an incapacitated participant is, in any event, misleading. Placing emphasis on the personal values, wishes and beliefs of incapacitated individuals is sometimes said to be an autonomy-enhancing type of substitute decision-making, but it will not operate as such in every case.[114] A consultee must only offer *her opinion* to the researcher about what she considers would be the likely wishes and feelings of an incapacitated participant about involvement in a project, but it is crucial to note that it often may not be the actual wishes and feelings of the participant herself that are conveyed, but simply a consultee's interpretation of them. The more serious the impairment affecting capacity, and the more detached a consultee is from knowing a participant personally, the more likely it is that the consultee's advice to the researcher will not closely reflect the wishes and feelings of a potential participant. Given these difficulties, it is a challenge for a consultee to identify the precise scope of her duty and what steps she must take to discharge it. Absent any clearer guidance, she may be hesitant to recommend participation. This may sometimes be sensible, but if over-cautious thinking from an untrained consultee prevails, it may lead to her misinterpreting certain signals from an incapacitated participant as objections, when they are actually not. If this happens, it has potentially far-reaching consequences for encouraging wider participation as a consultee effectively enjoys a power of veto if they advise that participation should not go ahead.[115]

The lack of clarity may also cause consultees to think that they can actually make a decision for an incapacitated participant by attempting to step into her shoes.[116] This view is misguided, for an opinion cannot be legitimately justified by a claim that it is what a participant would have wanted to happen if she had capacity, when in fact she may never have had it in the first place.[117] Signs of a confused sense of responsibility begin to emerge here. The

[114] See *Wye Valley NHS Trust v B* [2015] EWCOP 60; Skowron (n 3); Lucy Series 'The Place of Wishes and Feelings in Best Interests Decisions: Wye Valley NHS Trust v Mr B' (2016) 79 *Modern Law Review* 1101.

[115] Mental Capacity Act 2005, s 32 (5).

[116] In legal terms, this is known as the substituted judgment approach. It has not been endorsed in England, but has been used in some American cases. See *Strunk v Strunk* [1969] 445 S.W.2d 145.

[117] For an interesting discussion on this point see Shaun D Pattinson, *Medical Law and Ethics* (5th edn, Sweet & Maxwell, 2017) at 149 and 455.

For Peer Review

consultee does not provide consent for an incapacitated participant, she simply advises. It is actually a researcher who should make a final decision about inclusion, but whether or not this is recognised as being the correct legal position by the various parties involved in the authorisation process is the subject of doubt.[118] Technically speaking it is correct to recognise that a consultee has no legal power to consent, but if she is still given the power to advise that participation may be inappropriate, which is then viewed by both researchers and MCA RECs as being determinative, the difference between the power to decide and the mere power to advise effectively evaporates.[119] The upshot is that consultees may frequently play a defining role in the authorisation of research and this accords to them powers which exceed those initially contemplated by the Act.[120]

The drafting of the MCA adds a further layer of confusion in terms of the obligations it creates. While it is incumbent on a consultee to offer an opinion on an incapacitated participant's wishes and feelings, the Act itself does not specifically direct a researcher to consider things from that perspective.[121] It is left to the COP to clarify that researchers have a continuing obligation to consider the person's wishes and feelings, but we have already highlighted that is inappropriate where the matter is of such crucial importance.[122] From the wording of the MCA, it may appear to researchers that they have no specific duty to consider things from the perspective of the participant as this is a role that is to be performed exclusively by the consultee. It would be regrettable if this misunderstanding become widespread, because it is dangerous to rely on the consultee system to fill this void. If researchers inadvertently lose sight of these key elements, or at least attach less importance to them, this is problematic due to the fact that, more often than not, it is a researcher and not a consultee who may be best placed to consider how aspects of a particular project may impact upon the personal circumstances of an individual. The system needs to place greater emphasis on researchers and incapacitated participants working together to provide support for the latter to make their own decision about any involvement in research.

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[118] Mental Capacity Act 2005, s 32 (4) (a) and (b); Mental Capacity Act 2005: Code of Practice, para [11.27]. It should be noted here that the researcher does not 'consent' for the participant either.

[119] Above (n 115).

[120] Mental Capacity Act 2005, s 32 (4) (a) and (b).

[121] Mental Capacity Act 2005, s 32 (2) – (6).

[122] Above (n 86).

The final question we now address is whether the additional requirement of needing to gain approval from an MCA REC adds anything more of value to the approval process.

iii) MCA RECs

A MCA REC retains overall responsibility for the final authorisation of any project involving incapacitated participants and its seal of approval is needed to render any research lawful.[123] This oversight serves multiple functions, such as promoting integrity in research, maintaining high standards of ethical practice and assessing whether or not a researcher has discharged all her obligations under the legislation. A MCA REC may also review any considerations pertaining to capacity, and on occasion provide advice to a researcher on arrangements for appointing a consultee. Given the enhanced vulnerability of incapacitated participants, the need for specialist MCA REC supervision was introduced to inject an enhanced layer of independent objective scrutiny to the approval process.[124] In theory, this may seem like a sensible attitude, but its effectiveness should not go unchallenged. It has been common practice for some time now to obtain approval from an appropriate ethics committee before any type of research involving human participants takes place, whether capacitous or not.[125] The NHS has its own ethics committees, so too have other organisations.[126] With this in mind, imagine hypothetically that the specific provisions of the MCA were not enacted; if that were the case, a university social science researcher proposing a project involving the use of incapacitated participants would still be obliged by her institution to seek approval from one of its own ethics committees before any work commenced, so a natural question to ask is: what extra, if anything, is gained by the MCA's insertion of mandated MCA REC authorisation?

One advantage resides in the nature of the obligation created. While there are some exceptions, the majority of more mainstream research on human participants is referred to ethics committees on the basis of good practice, rather than being a specific legal

[123] Mental Capacity Act 2005, s 31.

[124] HL Deb 18 June 2004, vol 422, cols 69 - 70: https://api.parliament.uk/historic-hansard/written-statements/2004/jun/18/mental-capacity-bill#S6CV0422P2_20040618_CWS_5. <Accessed 26th February 2019>.

[125] See UK Research Integrity Office, *Code of Practice for Research: Promoting Good Practice and Preventing Misconduct* (UK Research Integrity Office 2009).

[126] See, amongst others, the Health Research Authority: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/; the British Psychological Society: https://www.bps.org.uk/news-and-policy/bps-code-ethics-and-conduct.

For Peer Review

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requirement.[127] Thus, in the hypothetical scenario presented above, without any legal direction from the MCA, a university researcher wishing to use incapacitated participants in a routine project would only be bound by a professional obligation to seek ethical approval, not a legal one. Admittedly, if she proceeded without it, she may well be subject to a professional sanction for misconduct in research, but that is different than characterising her conduct as being unlawful. It is here where the benefit of the MCA's insistence on specific approval from a MCA REC becomes apparent, for it sends out a powerful symbolic message in identifying that research involving vulnerable incapacitated participants is deserved of a special legal status. A possible deterrent effect is as well brought to the fore because the consequences of failing to gain ethical approval are potentially more serious where that omission would lead to not only unprofessional, but also to unlawful, activity. Where a researcher is aware of this, it is perhaps likely to induce a greater incentive to comply with the legal requirement imposed by the MCA, thereby ensuring that projects will be subject to a greater degree of specialist scrutiny. Accordingly, it seems plausible to suggest that the obligation to gain approval from a MCA REC has the potential to positively influence the way people think about research and incapacitated participants, particularly because it signifies that especial measures must be adhered to in the approval process. The theory behind its inclusion therefore may have some merit, but nonetheless there are other concerns.

For Peer Review

The insistence upon approval from a specific MCA REC, instead of a more general ethics committee, is presumably based on the fact that the former will have the opportunity to develop specialist expertise in dealing with proposals that seek to involve incapacitated participants. MCA REC members will receive customised training that will assist them in assessing whether the requirements for approval have been adequately met. Nevertheless, the composition of a particular committee may impact upon outcomes. Membership of a MCA REC should include a range of individuals from a variety of different backgrounds, including both professional people and lay representatives.[128] This inevitably means though that they will have varying degrees of expertise across different fields, depending on the experience of the individuals sitting on them. Experts who have worked in psychiatry and mental health will naturally have an important role to play in sitting on such a specialist committee, but the extent

[127] For a list of the types of research that require ethical approval by law, see Health Research Authority, Governance Arrangements for Research Ethics Committees (HRA 2018) at [2.3]. It should be noted that most reputable academic journals require proof of ethical approval where human participants have been involved.

[128] See HRA Guidance: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/become-rec-member/. <accessed 26th March 2019>.

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to which each separate committee will include members with significant expertise in assessing capacity by reference to the legal test is somewhat unknown. There is no assurance that this important question will receive the same amount of rigorous scrutiny as it would do in a formal court setting.[129] This problem is not confined to the question of capacity, because if a particular MCA REC happens to have an experienced lawyer well versed in interpreting statutes amongst its membership, there may well be closer examination of the myriad of different meanings that could be ascribed to the thresholds for approval than would be present in other MCA RECs that do not possess the same personnel.

The logistics of the approval process may also frustrate matters. There are circumstances in which an on-going project will be the subject of periodic review from a MCA REC, but more often than not the approval process is anticipatory and forward-looking in nature. Researchers are not supposed to recruit participants beforehand, so any inquiry by a MCA REC is somewhat limited to exploring the procedures that have been put in place for ensuring that capacity assessments are carried out appropriately, and for securing the appointment of consultees. Within this, a MCA REC will probably want to check a researcher's experience and understanding of assessing such things as capacity, but it is unlikely to be able to assess individually the capacity of each participant for itself. This means that a MCA REC has to put significant faith in a researcher's ability, and we have already demonstrated that some will experience difficulty in dealing with complex issues such as capacity, not through any fault of their own, but because it is a nebulous and participant-specific concept.[130] The disadvantage of forward-looking scrutiny is not exclusive to capacity, but also plagues the further conditions for approval. We have illuminated that many of the factors that fall to be examined under those provisions are inherently subjective questions. The potential effect that a project may have on an incapacitated participant must, therefore, be considered from the angle of that individual. Nonetheless, the precise individual is often unidentified at the approval stage and it follows that a MCA REC is precluded from engaging in any rigorous subjective scrutiny.[131] Based on this, the dichotomy of responsibility between a researcher and a MCA REC becomes even more pronounced.

For Peer Review

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[129] Case (n 95).

[130] Gunn (n 93); Palmer (n 102).

[131] Bartlett (n 12) at 90.

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The legislation dictates that the ultimate responsibility for ascertaining whether the requirements under section 31 have been met rests with a MCA REC, but prospective researchers would be well advised to carry these requirements in mind when initially designing any project. However, throughout this piece we have demonstrated the multitude of interpretations that could, potentially, attach to the approval requirements and there is no certainty that a researcher and a MCA REC will think about these issues in the same way. Some members of a MCA REC could, for example, treat certain research requirements as being analogous to a best interests standard and review them with that in mind. A researcher, on the other hand, could view them in an alternative way, with more exclusive focus on mitigating risk rather than seeking to highlight any benefits. The potential for inconsistency between the various levels of decision-maker is thereby exacerbated. Similarly, certain MCA RECs may adopt a lenient approach to assessing the criteria for approval, whereas others may embrace a more hard-line stance. This may tempt a researcher to identify what are perceived to be more sympathetic MCA RECs when deciding where to send a project for approval, but if such cherry-picking becomes commonplace it would be unfortunate, as it could undermine the very need to gain ethical approval in the first place.

Very little is actually known about how MCA RECs operate, both in terms of the volume and type of research that they are asked to approve, and of the actual dynamics of their decision-making processes. In the light of this, McHale's assertion is undoubtedly accurate that this is an area in which further empirical research is required to gain a better understanding of how MCA RECs actually function in practice.[132]

E. Conclusions

The fact that the MCA sought to address the issue of research involving incapacitated participants is commendable. Had it overlooked the issue entirely, which was not beyond the realms of possibility, a considerable gap would have continued to exist in the law of England and Wales.[133] However, some of the problems that we have alluded to may have derived from the main thrust of the MCA being focused on treatment, welfare and financial decisions as opposed to research.[134] The research provisions operate from the wrong standpoint and

[132] McHale (n 5); Dixon-Woods (n 95). See also the details of the ASSENT Project @ xxx, above (n 41).

[133] HL Deb 10 January 2005, vol 668, cols 17 – 18. https://api.parliament.uk/historic-hansard/lords/2005/jan/10/mental-capacity-bill. <Accessed 26th February 2019>.

[134] See literature above (n 4) and (n 101).

For Peer Review

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arguably continue along a skewed trajectory, perhaps betraying the fact that research was very much an afterthought. Insufficient time seems to have been devoted to identifying clear aims and objectives and to creating an effective regime that would adequately meet them.[135] Certainly, the research sections do not appear to sit comfortably with the other aspects of the MCA and, in places, appear to have been rather clumsily drafted.

Establishing a separate set of substantive tests that must be met in order to gain approval does not, in reality, provide any greater degree of protection for incapacitated participants in research than that which could be achieved by assessing the existing objective and subjective factors that must be considered under a traditional section 4 best interests assessment. The additional measures introduced that require the appointment of a consultee and the final approval from a MCA REC are also of questionable effectiveness. The idea that a third-party consultee can act as an effective advocate and thus empower an incapacitated participant by ensuring that her voice is heard is frustrated by its impracticalities. A system that promotes co-operation between a researcher and a participant, with a renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making.[136] Similarly, very little is known about how a MCA REC actually forms its opinion, and about what is at the forefront of the minds of its members when making a decision on a given project. Significant variation in interpretation of the requirements for approval could lead to a pattern of inconsistency between MCA RECs, which has the potential to undermine the perceived value of the system. What is clear, however, is that the manner in which the research requirements have been drafted creates the impression that the researcher, the consultee and the MCA REC are subjective to differing obligations which all potentially overlap, but which may not necessarily be viewed in that way. This sense of confusion may cause researchers to become disillusioned with the system of approval and therefore reluctant to consider incapacitated participants in the future. If the research provisions of the MCA are having this effect, they are arguably impeding the very type of activity that they should be seeking to promote and this ought to be recognised as a problem that needs redressing.

For Peer Review

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[135] HL Deb 18 June 2004, vol 422, cols 67-70: https://api.parliament.uk/historic-hansard/written-statements/2004/jun/18/mental-capacity-bill#S6CV0422P2_20040618_CWS_5. <Accessed 26th February 2019>. This Hansard debate discusses the aims of the MCA 2005. Research is only mentioned sparingly.

[136] Shiggins (n 50); Amanda Sibley *et al.*, 'Developing a New Justification for Assent' (2016) 17 *BMC Medical Ethics* 1. DOI 10.1186/s12910-015-0085-x; Amanda Sibley *et al.*, 'Assent is not Consent' (2012) 38 *Journal of Medical Ethics* 3; Susan Slaughter *et al.*, 'Consent and Assent to Participate in Research from People with Dementia' (2007) 14 *Nursing Ethics* 27.