

## Briefing on the Research Provisions of the Mental Capacity Bill

### *Pending Second Reading in the House of Lords*

#### Summary

The Mental Capacity Bill will govern decision making on behalf of adults lacking capacity. As part of that, it will regulate the inclusion of mentally incapacitated adults in research for which consent is legally required, other than clinical trials regulated by the Clinical Trials Regulations 2004. Specific research provisions are included in sections 30-33 of the Bill.

We welcome the Mental Capacity Bill because it provides an opportunity to clarify and enshrine in law the requirements relating to the inclusion in research of adults lacking capacity to consent. We are supportive of the research provisions in the Bill because, on the whole, we consider they take a balanced approach and introduce greater clarity into the requirements in this area. They impose strict safeguards to protect vulnerable individuals whilst, for the most part, ensuring that research of potential benefit to people with mental incapacity can continue.

However, there are aspects of the research provisions that concern us as they may inadvertently:

- prevent some types of research that are of potential importance to patients suffering, or at risk of suffering from mental illness or impairment, whether permanent or temporary (including those in intensive care); and
- be difficult to apply in practice due to a lack of clarity in certain aspects of the requirements.

In order to address this, we recommend a number of amendments and points for clarification. These are set out in the following pages.

#### The need for research including incapacitated adults

Medical research is of vital importance to increasing our understanding of illness and disease and to improving the treatment of patients. The inclusion of individuals with incapacity in research is essential to our understanding and treatment of illnesses and conditions that affect them. This is illustrated by two examples below:

- Untreated **phenylketonuria** (PKU) used to result in profound learning disability. The clinical outcome of this condition has been dramatically altered by studies of adults and children with severe learning disability. These studies have led to the identification of a biochemical disorder in patients suffering with this condition that is treatable via removal of the amino acid phenylalanine from the diet. The biochemical disorder can be detected in newborn babies by the 'Guthrie test' and appropriate treatment can be started immediately. As a result of these studies and the resulting large scale Guthrie screening programme, most people with PKU today do not have a learning disability.
- Studies of incapacitated patients shortly after they suffered serious **head injuries** were necessary to develop and validate scales of impaired consciousness. One trial examined the potential value of steroids in treating head injury and preventing prolonged disability. This

study did not directly benefit those participating in it but the findings of the research were essential for the subsequent 'CRASH' trial, which has improved the treatment and likely outcome of patients suffering from head injuries.

Further examples are set out in Annex A. These examples highlight the potential benefits that research involving adults lacking capacity may bring to patients suffering from similar conditions. They also illustrate that it may be necessary to involve individuals lacking capacity in research notwithstanding that they may not personally benefit from the outcome. This research is essential if other patients suffering from the same condition are to receive better treatment and improved quality of life in the future. With an ageing population, the need for this type of research is likely to increase over time.

## Key Points for Amendment/Clarification

### Clause 2 – People who lack capacity

1. It is unclear to us whether consent to participate in research given when legally competent survives the onset of incapacity. For example, if a patient suffering from manic depression consents to participate in research when he or she is legally competent to do so, does that consent continue to be valid (and outside of the scope of the Bill) if the research is conducted when he or she enters a manic phase at which point capacity is lost? Clause 2(1) of the Bill indicates that capacity is judged “at the material time” but it is not clear to us whether “the material time” is the point at which consent is given (or would, but for the incapacity, generally be sought) or when the event to which it relates occurs. This is particularly relevant to long-term research projects such as the UK Biobank, where consent to use and retain tissue and data is given upfront in relation to research to be conducted for years to come and the onset of incapacity at some stage in the future is highly likely.

*We would like clarification that “the material time” for such purposes is the point at which consent is given or would, but for the incapacity, generally be sought. Of course, any wish expressed by the person to withdraw at the time of the event to which it related would be respected. Clarity on this issue is essential before the Bill is enacted. We would also seek such clarification in the Code of Practice.*

### Clause 30 – Research

2. Clause 30(1)

The use of the words “unlawful unless” in line 28 of Clause 30(1) imply that Clauses 30-33 are not enabling provisions i.e. it cannot be said that: it is *lawful* to include incapacitated adults in research *if* all of the requirements of those Clauses are met. Rather, it would appear Clauses 30-33 impose requirements *additional* to any that may already exist at law, either under the Bill itself or under the existing common law of necessity.

Regrettably, the current law is very unclear. In the majority of cases as things stand at the moment, mentally incapacitated adults cannot be included in intrusive research except under the common law of necessity. Unfortunately, this law lacks clarity and is difficult to apply in a research context. The law of necessity requires that the research is in the best interests of the patient (“P”). This is echoed in Clauses 4 and 5 of the Bill, which permit acts in connection with the care and treatment of P, provided they are in P’s best interests. However, the nature of research is such that it is generally very difficult to say at the outset that its outcomes will benefit those patients participating in it, or indeed other patients. It is that uncertainty that generally makes the research necessary. The purpose of research is predominantly to seek and explore potential opportunities to benefit patients, both present and future. Although it is quite possible to argue that the exploration of such opportunities is in an individual patient’s best interests (whether because of the prospect of some personal benefit to him or her, or through the opportunity to be altruistic by benefiting others), we know from the current law this is by no means beyond doubt.

Given that, we believe the best interests test is inappropriate in a research context and as a consequence could jeopardise valuable research that is of potential importance to those suffering or at risk of suffering from mental illness or impairment. We are therefore very concerned that if Clauses 30-33 are *not* enabling provisions, the best interests test, and the difficulties that brings for research, will continue to apply after the Bill is enacted.

*The Bill presents an opportunity to clarify the law, in particular by replacing the best interests test with the clearer safeguards set out in Clauses 30-33. As we have set out, we do not believe it is certain that this is the effect of Clause 30(1). To address this, we recommend replacing “unlawful unless” with “lawful if” in line 4 of page 17 to clarify that those Clauses are an exhaustive list of the requirements for including incapacitated adults in research. As a minimum, we seek clarification that the safeguards in Clauses 30-33 are exhaustive and that the best interests test will no longer apply to intrusive research.*

## Clause 31 – Requirements for approval

### 3. Clause 31(2)

We welcome the amendments made to this sub-clause in Report Stage in the House of Commons to include research connected with a condition which ‘...causes or contributes to’ the impairment of, or disturbance in the functioning of the mind or brain. This will extend the ambit of the research provisions, including for example, to research into certain types of intensive care research (e.g. research into the treatment of cardiac arrest which is accompanied by unconsciousness) and research into the use of anaesthetics in surgery. However, we believe some ambiguity in the sub-clause remains. As a result, it is not entirely clear to us whether the following would be permitted under the research provisions:

- Research into the possible links between a condition commonly accompanying a mentally incapacitating condition and the incapacitating condition itself (e.g. sexual dysfunction and schizophrenia) – if the possible link is *not* established, will research into the first condition be research ‘connected with...’ the condition causing the incapacity?
- Research into the side-effects of the management and treatment of conditions causing incapacity (e.g. into obesity arising from certain drugs treating schizophrenia) – is such research ‘connected with’ the condition causing the incapacity?

We believe research into both of these types of issues is of potential importance to the care and treatment of those suffering from mentally incapacitating conditions and the improvement of their quality of life. We are therefore concerned to ensure it can continue, subject always to the safeguard at 31(3) that ‘There must be reasonable grounds for believing the research would not be as effective if carried out only on, or only in relation to, persons who have capacity to consent to taking part in the project’.

*We seek clarification that (1) research into the possible links between a condition commonly accompanying a mentally incapacitating condition and the incapacitating condition itself and (2) research into the side-effects of the management and treatment of conditions causing incapacity will, subject to the general safeguards, including at 31(3), continue to be permitted under the Bill.*

### 4. Clause 31(4)(b)

This sub-clause appears to inadvertently prevent some research on ‘diagnostic’ issues.

*To address this, we recommend inserting ‘diagnosis’ after ‘causes’ in line 40 of page 17.*

### 5. Clause 31(5)(a)

We believe the use of the term “risk” in line 27 fails to make clear that it is the extra risk of participating in research that must be minimal, recognising that the patient may already face certain of these risks by virtue of the condition he or she is already in.

*To address this, we recommend inserting “additional” immediately before “risk” in line 1 of page 18.*

6. Clause 31(5)(b)(i)

We are concerned that the term “significant” in line 30 will be difficult to interpret or apply in practice.

*To address this, we recommend deleting “in a significant way” in line 5 of page 18 and inserting “unduly” before “interfere”, also in line 5.*

7. New sub-clause in Clause 31

We consider that the requirements in Clause 31 have been drawn up on the basis of our current understanding of how medical research works and how it benefits individuals. Given that, we believe a regulation-making power is necessary to ensure that the primary legislation can adapt to future scientific developments that cannot be anticipated at the current time.

*Accordingly, we recommend the inclusion of a new sub-clause in Clause 31 as follows:*

*‘The Secretary of State may by order vary, omit or add to any of the requirements set out in Clause 31’.*

## **Clause 32 – Consulting carers etc.**

8. Clauses 32(5), 33(3) and 33(4)

These sub-clauses refer to the obligation to withdraw P in certain circumstances. We have two concerns around this. Firstly, we are concerned that it might be difficult to interpret P’s wishes in practice. Secondly, we are concerned that the term “withdraw” is unclear, particularly where the only involvement of P in the research is to allow the use of his or her data and samples already collected for another purpose, for example, in the course of his or her medical treatment. It is not clear whether withdrawal in this context would mean the disposal of samples or their return to P.

*We seek clarification as to the meaning and interpretation in practice of “withdrawal”, including as a minimum, specific guidance in the Code of Practice.*

9. Clause 32(9)(a)

This sub-clause provides that, in certain emergency situations, a researcher must consult a registered medical practitioner who is not concerned in P’s treatment or care before proceeding. We consider this to be inappropriately restrictive. When such consultation needs to involve a medical practitioner, we believe the interests of P may be better served by consulting a practitioner involved in the clinical care of P. Such an individual is likely to be able to make a better judgement about the appropriateness of involving them in the study. However, we also believe it would be desirable, where possible, to ensure the individual is independent of the research team.

*To address this, we recommend deleting the words “who is not concerned in P’s treatment or care” in lines 4-5 of page 19 and replacing them with “who is not primarily responsible for the organisation or conduct of the research study”.*

**If you would like further information or to discuss any issues arising, please contact:**

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## Annex A

### Further examples of important research involving adults lacking capacity to consent

Several of these examples are concerned with the analytical and preparatory work that needs to be carried out before a clinical trial of a new method of diagnosis or management can be undertaken. Some relate to work to increase understanding of the mechanism of disease so that rational treatment can be developed. The work described is minimally invasive, involving for example taking blood samples (often just a little more blood than needed for diagnostic tests) or assessment of disability.

- Structural imaging (magnetic resonance) investigations of brains of patients with **co-existing learning disability and Schizophrenia** (often very early stage). These have shown that the changes in brain structure resemble those in schizophrenia and not those in learning disability in these patients, suggesting that the primary problem is the schizophrenia – with clear implications for diagnosis and treatment. The learning disability is usually sufficiently advanced that informed consent is not possible.
- Most patients with **Fragile X Syndrome** (the single most common cause of an inherited disability) have substantial intellectual impairment, and **Learning Disability** can also be caused by a wide variety of other genetic disorders, including holoprosencephaly, Williams' syndrome and Prader-Willi syndrome. It is only by studying the individuals suffering from these conditions, many of whom have significant cognitive impairment and so would not be able to give proper informed consent for most research, that researchers can develop the understanding of the mutations and their effect that is necessary to establish the potentially useful points at which a usefully therapeutic intervention could be made, and develop suitable treatments.
- Studies of patients with **Down's syndrome** have shown that this condition is a very common risk factor for developing pre-senile dementia. Studies of the neurobiology, neurochemistry and pathology of the condition have made it possible to establish that, although the onset of dementia in Down's syndrome patients is much earlier than in others, the pathological changes are similar to those of Alzheimer's disease so that similar treatment for memory disorders would be appropriate. As the average IQ of patients with Down's syndrome is around 50, a high proportion of patients would be unable to give informed consent.
- In surgery to treat patients with **subarachnoid haemorrhage** (bleeding into the brain) it is particularly important to know how deeply the patient is anaesthetised. This is to ensure that patients have sufficient anaesthetic to relieve pain but not so much that it might further damage their brain. Current research is investigating which of two EEG monitors will achieve this more effectively in such patients, who are often too confused to give informed consent. Whilst the individual patients will not benefit from being included in this study, future patients with this condition will benefit from more accurate measurement of depth of anaesthesia.
- In the '**IMAGES**' clinical trial on the treatment of strokes; magnesium treatment was shown to be effective in treatment of subcortical strokes, as diagnosed by magnetic imaging. In order to design this trial, the researchers had carried out an observational research study in stroke patients (many of whom were unable to consent for themselves) some years earlier. In that observational research study, they had measured blood pressure and collected blood samples repeatedly over a few days to assess levels of hormones and body salts (including magnesium), and so to help understand something about the natural levels of magnesium in these patients.
- In studying **dementia, especially Alzheimer's disease**, and its genetic inheritance, the use of blood samples and comparing these with the clinical history is vital to further understanding - for example, the extent to which the condition is familial - and to approaches to treatment. Family comparisons, e.g. by studies of sibling pairs – often at different stages of disease – can be particularly important. This needs to include some patients where the disease is too advanced for them to give informed consent.
- **Studies on Creutzfeldt-Jacob Disease**, particularly vCJD, where a significant proportion of patients will not be well enough to give personal consent by the time the diagnosis is made. [Prion

diseases are difficult to diagnose, patients often presenting with depression and then developing instability, sometimes ascribed to anti-depressant side effects.] There is currently no treatment known to aid the patient and, particularly in vCJD, where the time course is swift, currently little time to intervene if there were. Current studies include imaging and neurological studies to determine the pathology, help understanding of the disease process, and work looking for protein and metabolic markers of disease progression and hopefully response to treatment. Although individual participants are unlikely to benefit personally from their involvement in the research in the short term, it is only through studies like these that one can progress to trials of rational forms of treatment that are likely to benefit future patients suffering from CJD.