The British Psychological Society

Professional Practice Board

Conducting research with people not having the capacity to consent to their participation

A practical guide for researchers

Prepared by Catherine Dobson on behalf of the Mental Capacity Act Working Party

December 2008

About the Author

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Foreword

I am very pleased to welcome and commend the research guidance as part of the supporting materials for implementation of the Mental Capacity Act (2005).

One concern following on from the Act and its Code of Practice was that researchers might be deterred from conducting research using people who lack capacity as participants, because of the additional requirements. This could deny people who might wish to take part in research projects from being included, going against the spirit of the Act and also potentially limiting fields of enquiry and development. This guidance helps to address these concerns by supplying practical advice and operational procedures.

This material is impressive in that it summarises the implications of the MCA for researchers, highlights procedural changes that need to be introduced, and flags up the ethical issues and responsibilities for researchers being mindful of the underlying principles of the Act. It also identifies areas where further development work is required.

Of particular value are the various forms that the author has developed; these will be an invaluable resource for researchers in helping them to construct a framework for their approach to research and can be tailored to local circumstances.

Julie Jones
Chief Executive Officer, Social Care Institute for Excellence

Introduction

The practical guide is one of a series of documents commissioned by the Social Care Institute for Excellence, addressing different aspects of the implementation of the Mental Capacity Act (2005) and has been prepared for researchers conducting research with human participants in the United Kingdom. The majority of researchers will be members of professional bodies and/or be employed by academic or research organisations. Some researchers may be independent practitioners commissioned to undertake research. The guidance will also be of relevance to members of research ethics committees and service user and carer organisations.

Participants of research projects may be members of the general public or be in receipt of health or social care services.

Professional organisations contributing to the development of the guidance included:

- The British Psychological Society;
- The Royal College of Speech and Language Therapists; and
- The Royal College of Psychiatrists.

Rationale for the preparation of the practical guide

The Mental Capacity Act (MCA) 2005 in England and Wales and the Incapacity Act (ICA) 2000 in Scotland have established legal frameworks within Great Britain for people lacking the capacity to make decisions for themselves.

Sections 30–34 of MCA 2005 and Section 51 of ICA 2000 (Scotland) refer to decisions concerning participation in research. In general, for all research, researchers should assume that a participant or potential participant does have the capacity to decide whether to consent or not to their participation, unless there is evidence that questions the person's capacity to reach this decision. The Acts and relevant Codes of Practice outline safeguards for individual participants, carers and researchers when research projects do involve non-consenting participants. The Code of Practice for the Mental Capacity Act was published by the Department for Constitutional Affairs in 2007. Throughout this guide the Code of Practice will be referred to as the MCA Code of Practice.

This practical guide offers advice and examples of good practice in connection with conducting research with people lacking the capacity to consent to their participation. Reference is made throughout the document to guidance produced by different professional and research organisations within the United Kingdom.

The guidance refers primarily to changes in the research process arising from the MCA (2005), which applies to England and Wales, with some reference to the Adults with Incapacity Act (Scotland). At present the Mental Capacity Act does not apply to research conducted in Northern Ireland, where the legal framework concerning decision-making for or on behalf of people lacking capacity remains within common law and case law.

The practical guide will be disseminated to professional groups, service user and carer groups, research organisations, university and NHS research ethics committees via

publications and conference presentations. The document is also available for download from www.scie.org.uk.

This practical guide is in two parts:

Part 1 is the professional guidance and covers

- modifications to the research process in order that a project can comply with MCA;
- procedures for ethical scrutiny;
- application of the principles of the Mental Capacity Act to assess whether a participant can consent to their participation; and
- safeguards afforded by the Mental Capacity Act, in particular the process of consultation with others and the appraisal of an individual's involvement with a project.

Part 2 provides proformas, sample correspondence and information sheets which could be adapted by researchers as required for specific projects.

The practical guide

- provides a number of flowcharts to assist researchers in deciding between different courses of action when undertaking research with participants who may lack capacity to consent;
- offers suggestions for enhancing the decision-making capability of potential research participants;
- assists researchers in establishing whether a participant can or cannot consent to their participation in research;
- offers suggestions of who researchers can consult, how and under what circumstances, when undertaking research with people not having the capacity to consent; and
- provides sample letters, information sheets and declaration forms.

Section1: Legal requirements for conducting research with people not having the capacity to consent

1.1 The research process

Taking stages of the 'research process' as a starting point (see figure 1), the practical guide works through the detail of necessary modifications in order that projects meet the requirements of the Mental Capacity Act.

In the United Kingdom, the Research Governance Framework for Health and Social Care (DH, 2004b) provides a broad definition of research 'as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods'. The definition is intended to cover different methodologies of research (quantitative and qualitative) conducted in a wide range of settings with people who may be members of the public, recipients of health or social care services or employees of such agencies.

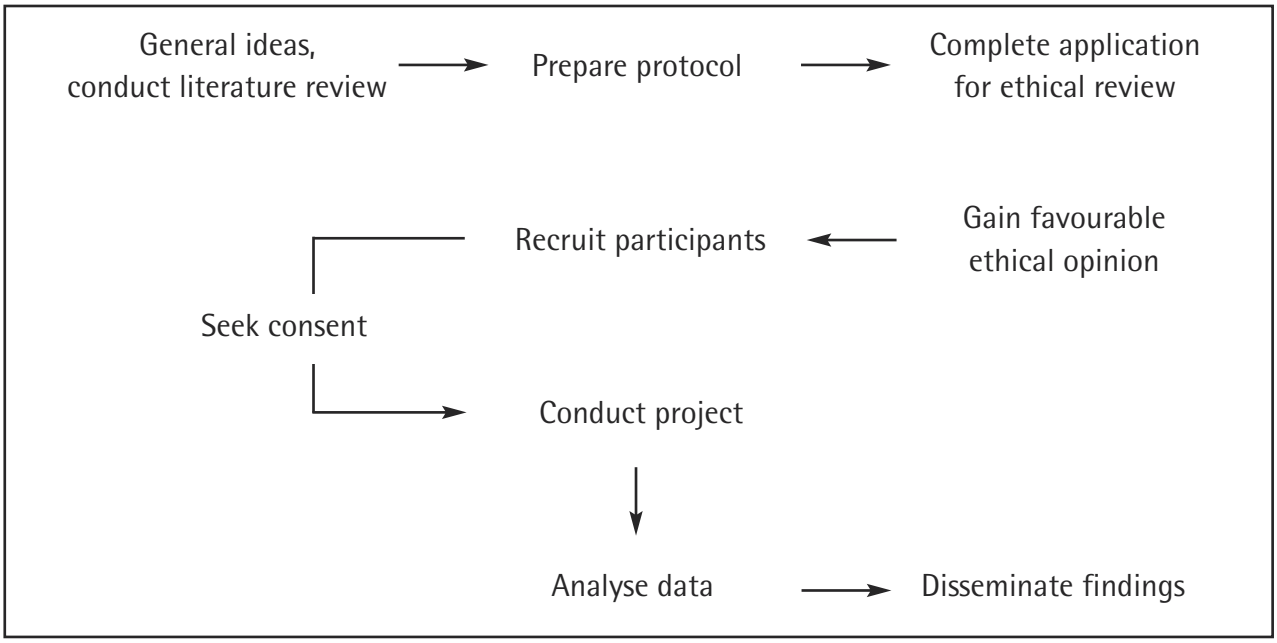


Figure 1: Schematic representation of the research process for conducting research with human participants.

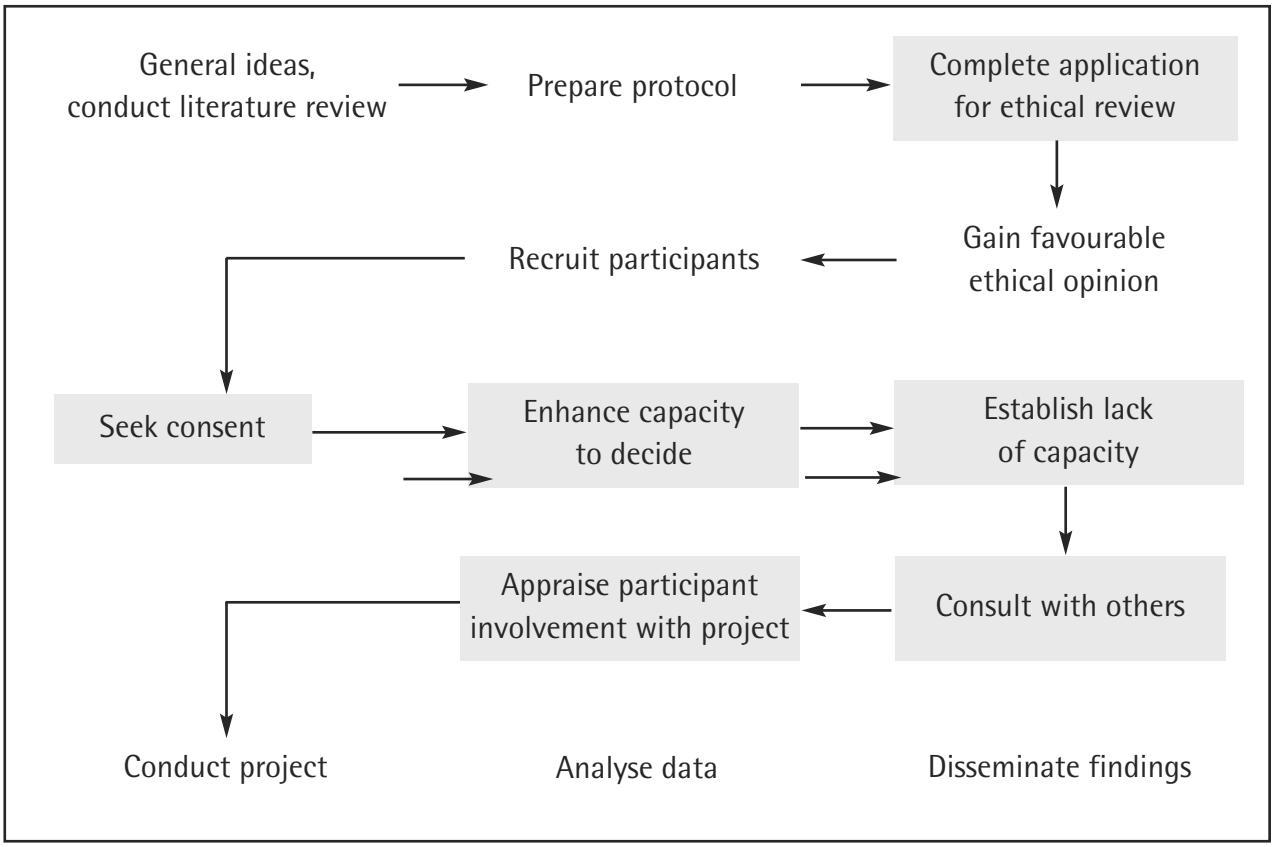
Figure 1 depicts a schematic representation of the 'research process' whilst Figure 2 (page 4) indicates key modifications to that process so that the study meets legal requirements of the Mental Capacity Act (2005), when conducting research with participants not having the capacity to consent to their participation.

Key modifications to the research process entail:

- changes to the process of gaining ethical approval, for example by the completion of supplementary forms and submission to 'flagged' NHS Research Ethics Committees *(see 2.2);*
- explicit assessment of the capacity to consent *(see 3.1–3.7);*

- procedures for ensuring consultation with others *(see 4.1–4.5)*;
- thorough consideration of benefit and risk to the participant; and
- appraisal of an individual participant's involvement with the project *(see 5.1)*.

Figure 2: Modifications to the research process to meet requirements of the Mental Capacity Act.



Shaded areas in Figure 2 represent actions by a researcher which are different from or additional to those required when conducting research with participants who can consent to their participation.

Section 2: Ethical scrutiny

2.1 Principles of ethical scrutiny

Guidance and standards for the ethical conduct of research within medical and health care settings have developed significantly over the past ten to 15 years (DH, 2005). Similar standards of governance have been extended to 'student research', which apply to research conducted as part of educational or professional training (Doyal, 2005; BPS, 2004a). Most universities have established systems for the ethical review of research at departmental, faculty, school or pan-university level. The equivalent systems for scrutiny within social care, until recently, have been less well-developed (DH, 2005). From January 2009 a national Social Care Research Ethics Committee (SCREC) will operate within the framework of the National Research Ethics Service. (See http://www.scie.org.uk/networks/screc/index.asp.)

A fundamental principle underlying ethical practice is 'informed consent'. This principle has been embedded in medical research for some time and has been extended to other kinds of research. The Nuremberg Code and the subsequent World Medical Association Declaration of Helsinki promoted ethical standards for the conduct of medical and biomedical research with human participants. The two most important standards were:

- voluntary informed consent of subjects; and
- scientifically-valid research design that could produce fruitful results for the good of society. (USA DH, 2004; BPS, 2004a, 2004b, 2005, 2008).

Ideally all participants of research projects should be capable of providing well-informed and considered consent. However, the exclusion of participants who cannot decide for themselves could deprive many people of access to the opportunity of active participation in research and potentially of access to innovative interventions and procedures. Herring (2006) in *Medical Law and Ethics* suggests

> *'The Mental Capacity 2005 … establishes the right balance between the need for research to bring benefit or information and the need for protection against exploitation and abuse. It also seeks to ensure that any increased risk of the research, over and above that risk associated with the condition or treatment itself, is either proportionate to the potential benefit to that individual, or, in the case of research to provide knowledge, the risk is minimal.'*

The researcher's role, in addition to reaching a judgement about the ability of a participant to give consent, is also to consider the balance of the benefit of participation with an evaluation of 'proportionate risk'.

The following paragraphs of this practice guide describe how a researcher could begin to ensure these ethical standards are met at the project design phase of the research process.

2.2 Procedure for ethical review

All projects intending to recruit participants lacking capacity to consent must meet the ethical approval of 'appropriate bodies' (MCA, Section 30(4)). As of 2008, projects can be submitted to one of a small number of 'flagged' NHS research ethics committees (NHS RECs). (See Appendix 2 for details and additional information.) The procedure of submission to 'flagged' RECs applies to any project involving patients or clients of health or social care services, and members of the public recruited via university or other research centres. Scrutiny by a 'flagged' NHS REC would be in addition to ethical scrutiny internal to the university or research organisation.

In addition to the standard online application, applicants also need to complete supplementary forms. Supplementary forms can be downloaded from the website of the National Research Ethics Service and are also provided in Part 2 of this practical guide.

There are three key questions on the supplementary forms requiring information additional to that on the standard application form:

- Can the project be as effectively undertaken with participants who have the capacity to consent?
- Is the research about an impairing condition that affects the person?
- Does the research concern treatment or care of that condition?

During the course of conducting a project, researchers may become aware that participants who initially had given valid consent have lost that capability in later stages of the project. In order legally to conduct the research, the usual research process would need to be halted, the protocol revised and ethical opinion re-sought before non-consenting participants could again participate (MCA, Section 34 (2)). The Act makes provision for such research via the Loss of Capacity During Research Project Regulations. The relevant supplementary form is reproduced in Part 2(2) and is available on the NRES website.

2.3 Intrusive research

The Mental Capacity Act (2005) applies in respect of research that is defined as 'intrusive', that is, research that would normally require the consent of a person with capacity. It applies to clinical trials of treatments and procedures but does not apply (at present) to trials, of medicinal products (known as CTiMPs) for which there are separate regulations (The Medicines for Human Use (Clinical Trials) Regulations, 2004).

The MCA Code of Practice, published in 2007, provides examples of research relating mainly to treatment and care. However, the list is followed by the statement

> *'…the Act can cover more than just medical and social care research. Intrusive research which does not meet the requirements of the Act cannot be carried out lawfully in relation to people who lack capacity.'*

The definition of 'intrusive research' in the Mental Capacity Act is deliberately wider than health or medical research as it includes social care research. The following types of research were listed in the Act's Draft Code of Practice (DH, 2006), but omitted from the

published Code of Practice (the primary audience for the Code are those who are under a duty to have regard to its provisions):

- clinical research into new types of treatments (except clinical trials of medicines that are covered by separate regulations);
- health or social care services research to evaluate the effectiveness of a policy intervention or service innovation;
- research in other fields, (e.g. criminal justice, psychological studies, lifestyle or socio-economic surveys);
- research on tissue samples (i.e. blood or spare tissue removed during surgical or diagnostic procedures) – also covered by the Human Tissue Act, 2004;
- research on health and other personal data collected from records; and
- observations, photography or videoing of people without capacity some of which is done covertly so as not to distract the person

The above types of research are examples of 'intrusive research'. Not all of them are invasive, in the sense of physically taking something to or from a person's body.

This meaning of 'intrusive' therefore leads to a broadening of the range of research which would be unlawful if conducted with people who have the capacity to consent, but without their consent (MCA Section 30 (2)). This also potentially applies to research which hitherto may have been considered as not requiring the participant's explicit consent, for example observational studies conducted within care settings or studies using data obtained from internet-based surveys (BPS, 2007).

Where adults lack the capacity to consent, the legal position in England and Wales is that no other person can be authorised to give proxy consent. The sole exception at present concerns research in connection with clinical trials of medicinal products, which require that a legal representative give 'informed consent' (The Medicines for Human Use (Clinical Trials) Regulations, 2004). For all other types of research likely to involve participants not having the capacity to consent, researchers must demonstrate that they have procedures in place to consult others about the involvement of prospective participants.

2.4 Research that does not require consent

Some types of research do not require consent: this applies to all persons whether or not they have the capacity to consent. Section 11.7 of the MCA Code of Practice lists the following types of research:

- Research involving data that has been anonymised and cannot be traced back to individuals.
- Research on human tissue that has been anonymised (Human Tissue Act 2004). The research must have ethical approval.
- Research using confidential patient information (Health Service (Control of Patient Information) Regulations 2002 Section 1.2002/1438). This requires an application to the Patient Information Advisory Group (PIAG), which can

determine 'whether the common law duty of confidentiality can be lifted for activities that fall within defined medical purposes, (including research) where anonymised information will not suffice and consent is not practicable'.

In contrast to healthcare research requiring access to health and clinical records, research using material derived from records held by social care organisations requires the explicit consent of the individual, on the basis of the common law duty of confidentiality. However, supplementary guidance (DH and WAG, 2008) to the MCA Sections 30–34 states:

> *'secondary legislation made under Schedule 3 (Data Protection Act, 1998) permits processing of sensitive data where that is necessary for research, provided that the processing is in the substantial public interest, that it does not support measures or decisions that affect individual's care or treatment and does not and is not likely to cause substantial damage or distress to the subject or anyone else.'*

Whilst access to NHS patient information is covered by the Act and the Code of Practice, use of confidential information from other sources is not. The main issue is how to gain access to partially anonymised records rather than to the full record. One respondent to the consultation phase of this practice guide reported 'records may be released under special licence, the mechanism being specific to government departments/agencies; this does not require the consent of the individual'.

In the course of preparing this practical guide, the author has encountered variation between local authorities in the interpretation of the Data Protection Act, 1998 in relation to the release of material for research purposes.

2.5 Seeking consent to participation in research

A critical step in the research process is the researcher seeking the consent of participants to take part or to refuse. The process of obtaining voluntary and informed consent involves two complementary and reciprocal decisions:

1. The participant makes a decision about whether to take part or to refuse to be involved in a research project.
2. The researcher judges the quality of that decision. If the quality of that decision meets certain ethical standards, the person is considered to have consented to participate or to have refused.

Ethical standards framing this decision are:

- freedom of choice and absence of coercion;
- having general understanding of the research and its intentions; and
- understanding of possible risks and benefits.

In terms of decision-making under the Mental Capacity Act, the key question for the researcher is, does the person have the capacity to consent (or refuse) at the time the decision needs to be made?

The National Research Ethics Service recommends that researchers allow the prospective participant 'sufficient time to reflect on the implication of participation in the study'

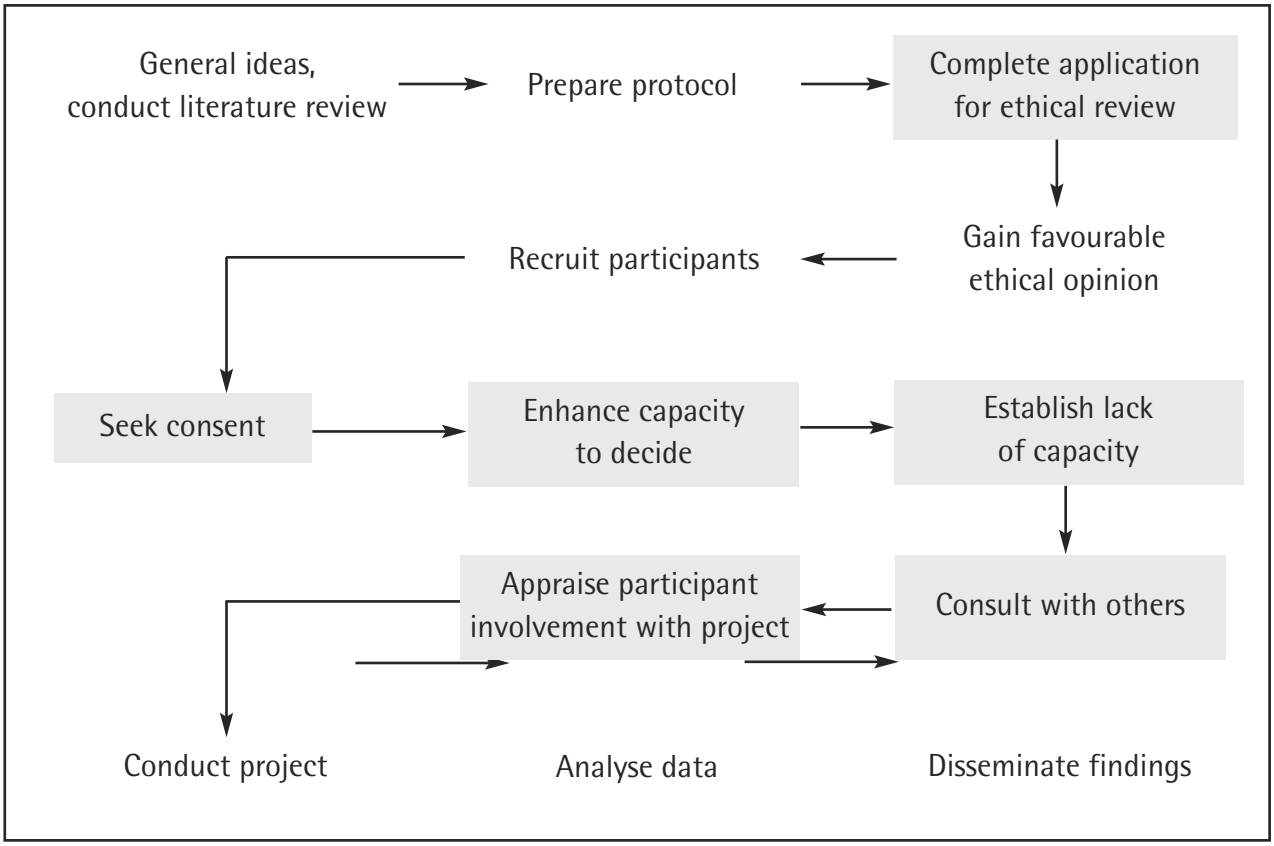
(NRES, 2007). This practical guide suggests that in judging the time lag between providing information about a project and seeking consent, the researcher may need to take heed of the nature of the project and the particular requirements of the project participants.

Section 3: Assessing capacity to consent

3.1 Recruitment of participants

With reference to Figure 2 reproduced below, having secured a favourable ethical opinion, the next stage in the research process is the recruitment of participants.

Figure 2: Modifications (shaded areas) to the research process to meet requirements of the Mental Capacity Act.



In the course of prearing the project protocol the researcher will have specified criteria for inclusion and for exclusion of participants, together with a description of procedures for the recruitment of participants. For prospective participants who lack the capacity to consent, the most likely recruitment methods will be via clinical or care teams, care agencies, or service user and carer organisations. Such 'intermediaries' play a significant role in the research process because of their knowledge of the sample of people from which participants may be selected.

3.2 Assessing capacity to consent to participation in research

What is 'mental capacity'?

Mental capacity is the ability to make a decision (MCA, Code of Practice, 2007). This includes the ability to make a decision that affects daily life as well as the ability to make decisions that may have legal consequences.

What is 'lack of capacity'?

Section 2 (1) Mental Capacity Act 2005 states:

> *'For the purposes of the Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter, because of an impairment of, or disturbance in the functioning of, the mind or brain.'*

Key indicators in judging whether a person lacks capacity are:

- the presence of an impairment or disturbance (disability, condition) that affects the way the person is able to think;
- whether the impairment is permanent, temporary or fluctuating;
- the nature of the decision – the person may be able to make decisions about some things but not others; and
- the timing of the decision – the person may be able to make a decision on the matter in question if the decision is delayed for another time.

In many research projects, the person who seeks consent is also the person who judges whether or not the prospective participant has the capacity to reach this decision themselves. This person is usually the researcher who is directly undertaking the research activity. Researchers may need to assess the capacity of participants at different stages of the project (if the project is to be conducted over a span of time) and possibly in connection with different research questions.

Large-scale projects may involve teams of researchers on different sites with a Chief Investigator taking overall responsibility for the governance of the project. The Chief Investigator may not be the person who routinely seeks participant consent but needs to ensure that systems are in place to safeguard the welfare of all prospective participants, whether or not they have capacity to consent.

Responsibilities of different parties in the research process are outlined in Appendix 3.

3.3 Applying the Five Statutory Principles of the MCA to judge whether a (prospective) participant has the capacity to consent

The Mental Capacity Act provides a decision-making framework that researchers could adopt to enable them to have a 'reasonable belief' that a person lacks capacity to consent to participation in research. In most circumstances, researchers will be able to undertake the assessment of capacity themselves and it is unlikely that an expert professional opinion about capacity will be required.

In the following sections, (3.4–3.7) the five principles of the MCA 2005 are stated, examined in some detail and applied to the research context. The reader may wish to bear in mind the key question or decision: **'Does the person have the capacity to consent, at the time that the decision needs to be made?'**

The process in summary is:

1. The researcher presumes that the participant has the capacity to consent or to refuse.
2. The prospective participant decides whether to participate or to refuse.
3. The researcher judges the quality of that decision and considers whether the participant has agreed or refused to participate on the basis of
   - freedom of choice and absence of coercion;
   - having general understanding of the research and its intentions; and
   - understanding of possible risks and benefits.
4. If the researcher is certain that the decision reached by the participant meets these standards, the researcher can judge that the person has consented to or refused participation.
5. If not certain, the researcher can use the following steps (Sections 3.4–3.7) which are represented diagrammatically (Figure 3) as a flowchart of questions to consider when planning and conducting this phase of the research project. By asking these questions the researcher can reach a judgement about the nature of a participant's consent. A checklist based on these questions is provided in Part 2 of this guide.

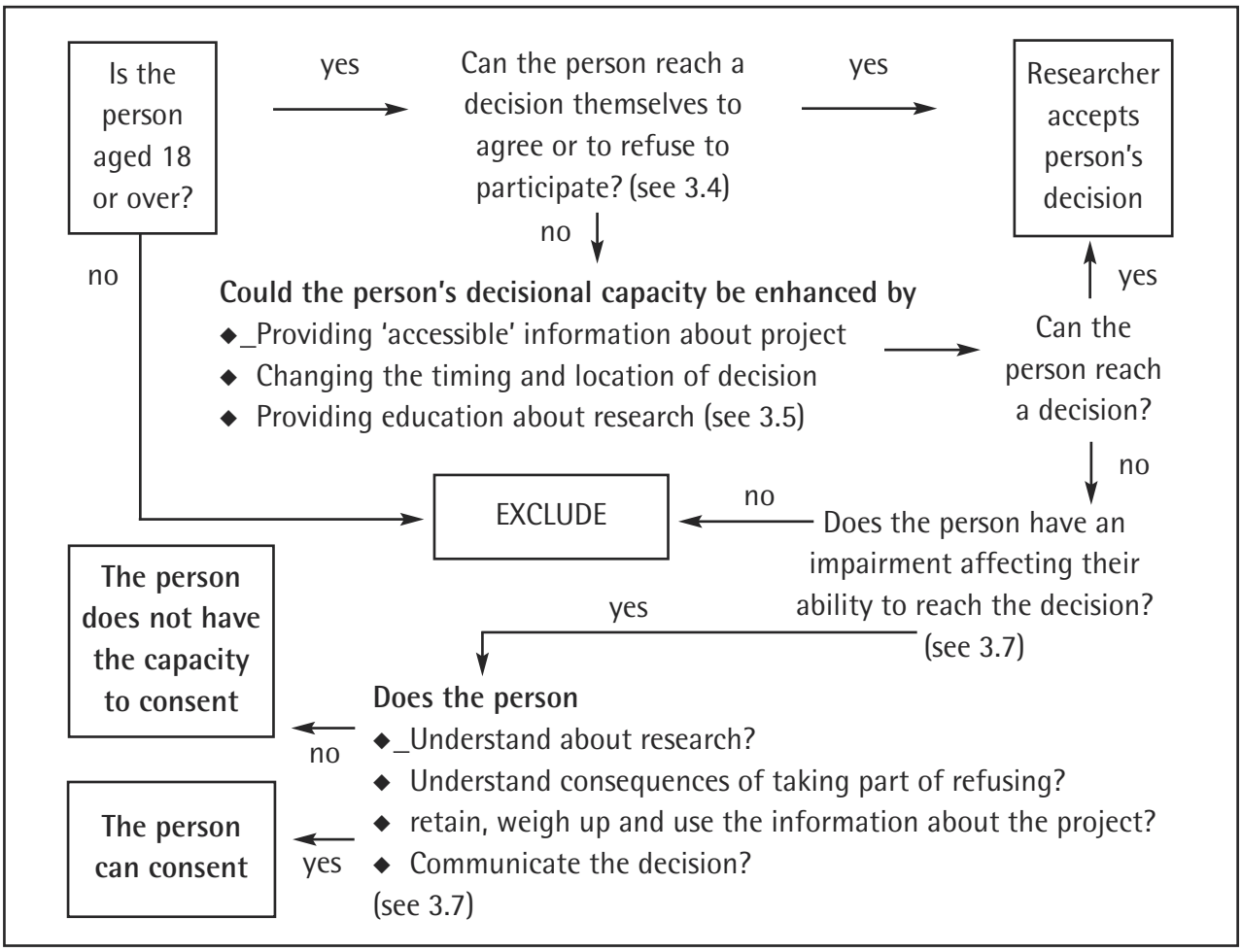


Figure 3: Decision-tree for researchers in assessing capacity to consent to participate in research.

3.4 Principle 1 of the MCA

A person must be assumed to have capacity unless it is established that he lacks capacity.

A researcher must assume that prospective participants for a research study have the capacity to consent, even when they may have a condition that may question that capacity.

The researcher needs to ascertain that the person does not have capacity, and not assume that they don't on the basis of their condition, age, appearance or behaviour.

Proof of lack of capacity: the researcher would need to show that, on the balance of probabilities, the individual lacks the capacity to consent to participation in the research at the time that the consent is required to be made. See 3.7 below for detail of how this judgement is reached.

3.5 Principle 2 of the MCA

A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.

Practical support could enable a potential participant to make their own decision about their involvement in a research project. Some examples of ways of doing this are provided in the box below.

The capability of a prospective participant to reach a decision themselves may be enhanced by:

- Amending the Information Sheet about the project, such as by the use of 'accessible language', using an interpreter or reader of written information, providing only essential information about the project.
- The National Research Ethics Service has provided extensive guidance on improving the language and presentation of information sheets and consent forms in order for them to be better understood by participants. (see http://www.nres.npsa.nhs.uk/rec-community/guidance/#informedConsent).
- Organisations such as Connect and Medicines for Children Research Network have produced suggestions about format and structure of information sheets.
- Providing information in alternative formats, such as aurally for people with visual disabilities, as well as in written formats. Consider conveying information with diagrams and use of colour.
- Breaking down complicated information into smaller points.
- Altering the timing or location that consent is sought – would capacity to consent be improved if the decision were delayed, sought at a different time of day or in a different location?
- Allowing the person time to reach the decision.
- Encouraging discussion with others, such as family or friends about the project.
- Providing education about research. Some people may not have any previous experience of research – would training or discussion about the general idea of research help the person to reach a decision about a particular project?
- Responding to questions about the project.

- Being clear about the possible risks of participation as well as advantages and benefits.
- Being clear about what is actually required of the participant in conducting the research.
- Being clear whether the researcher is seeking consent about research that is about to take place or is due to take place at some time in the future.

Considering systems for communicating with the prospective participant

- Use of augmented communication or symbols or 'talking mats' (Cameron and Murphy 2006)
- Can others assist the person in communicating, whilst at the same time not influencing the person in reaching a decision?

3.6 Principle 3 of the MCA

A person is not to be treated as unable to make a decision merely because he makes an unwise decision.

Consenting to participate in research that, for example, may involve taking risks, may not be an unwise decision even if the research is viewed by many as bizarre or unusual. Potential examples could include studies involving sleep deprivation, extreme cold or the effects of taking financial risks or hallucinogenic substances. Such research should be subject as a matter of course, to ethical scrutiny within university or other research organisations; the greater the degree of risk, the higher the level of scrutiny.

3.7 Reaching a judgment about whether a participant lacks the capacity to consent to research

Proof of lack of capacity: the researcher would need to show that, on the balance of probabilities, the individual lacks the capacity to consent to participation in the research at the time that the consent is required to be made.

The researcher would have to prove that

a) the person has an impairment of the mind or brain that affects how the mind or brain works; and

b) the impairment affects the person's ability to consent at the time the consent is required.

A person is unable to consent to their involvement if they cannot:

1. **Understand information – does the person understand what the research is about?**
   Does the person have a general understanding of the research project?
   Can the person indicate what is expected of them (section 3.5)?
   Have attempts as described above (section 2.2) to enable the participant to make decisions for himself not been successful?

2 **Retain information – can the person hold the information in their mind long enough to use it to make a decision?**
Can the person recall information about the research?
Having a poor memory *per se* is not sufficient grounds for saying that the participant cannot consent.

3 **Use or weigh up the information**
Does the (prospective) participant consider the benefits and risks of taking part in the research?
Can the person identify any consequences of participating or refusing to take part?

4 **Communicate their decision**
Is the person unable to communicate their decision in any way, taking into account any specific language or communication difficulties.

Fluctuating capacity

Can the decision to participate be taken at a time when capacity may have been regained?

If the answers are NO to the first three of the above questions, then, on the balance of probabilities, the person cannot reach a decision themselves and cannot consent to their participation in research.

The researcher will need to document their judgment and consider whether to exclude the person from the study or to include them by taking account of the safeguards provided in the Mental Capacity Act.

A checklist for the researcher is provided in Part 2 of this guide.

3.8 Loss of capacity during a project

Some projects may be designed to include participants who are likely to lose capacity for shorter or longer intervals during the course of a project.

In general, under the Mental Capacity Act 2005 (Loss of Capacity During Research Project) (England) Regulations 2007 (SI2007/679) and The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 (SI2007/837 (W.72), if a person had given consent at some time in the past and that loss of capacity had not been anticipated, the researcher would need to judge:

- whether to make use only of data collected over the period of time that the person had given consent;
- whether to continue to collect data, even though the person no longer can give consent, providing the loss of consent had not been anticipated. In this case, the

researcher would need to seek advice from a personal or nominated consultee and appraise the participant's involvement in the project, as described in Section 4 below. The researcher may need to re-apply for approval from a 'flagged' Research Ethics Committee.

Studies designed since the MCA came into effect, would need to anticipate the possibility of loss of capacity to consent and the researcher would need to take action as described in earlier sections of this guide, such as the completion of supplementary forms as part of the procedure for gaining ethical approval.

Section 4: Consulting with others

4.1 Consulting with others as a way of safeguarding the inclusion of people who lack the capacity to consent to their participation

Principle 4 of the Mental Capacity Act states that decisions made for or on behalf of the person (are) to be made in the person's best interests.

Principle 5 states that before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action

In contrast with many decisions under the remit of the Mental Capacity Act, the decision to participate in research is not an area where consideration of an individual's 'best interests' applies as described in the MCA (MCA Code of Practice, Section 5.4). The reasoning during parliamentary debates on the MCA was that sometimes research may not be of actual benefit to the person. If the principle of 'best interests' were rigorously applied, then persons not having the capacity to consent would be restricted from opportunities for involvement in research. However, if the research is contrary to the interests of the person (such as if it were unduly burdensome, restrictive, etc.) then it would not gain ethical approval and could not legally proceed.

The Mental Capacity Act provides special safeguards for the conduct of research with participants not having the capacity to consent, which include:

- scrutiny by an 'appropriate body' such as NHS Research Ethics Committee that projects meet enhanced standards for ethical approval (as discussed in Section 2);
- consultation with others not involved in the project about the involvement of a person lacking capacity;
- assurance that the interests of the participant are considered as having greater importance than any potential benefit to others; and
- acknowledgement of signs of objection by the participant, or contravention to an advance decision or other form of advance statement.

The above safeguards could be considered as variations of Principle 4, the 'best interests' principle of the MCA and Principle 5, the 'least restrictive' principle.

If considering the inclusion of participants lacking the capacity to consent, the process of consulting with others and reappraising the participant's involvement in the light of that consultation would have been anticipated in the course of seeking approval from a Research Ethics Committee, prior to the recruitment of participants. However, some projects may include participants who lose capacity during later stages of a project. In this case researchers would still need to appraise the individual's involvement and re-apply for ethical approval if the project were to continue with the inclusion of non-consenting participants (The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 (SI2007/679) and The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 (SI2007/837 (W.72)) .

4.2 Role of Research Consultee

The Mental Capacity Act requires that a researcher take 'reasonable steps' to identify others who could be consulted about a prospective participant's involvement in research (MCA para 32 (2)). The researcher is required to identify a person (someone who is interested in that person's welfare) who can be consulted about what the prospective participant's wishes and feelings about participation in the project would be if the person had capacity. In circumstances where the prospective participant has little contact with other than paid or professional carers, the researcher can nominate a person who can be consulted providing they have no direct involvement with the project.

Guidance produced by the Department of Health and Welsh Assembly Government creates roles for 'personal' and 'nominated' consultees as those consulted by the researcher. Of particular importance the research consultee does NOT give consent on behalf of a participant, but rather the researcher seeks advice from the consultee. The researcher, not the consultee, makes the decision about whether to include the person as a participant, though has to abide by information the consultee provides that suggests that the person may object to inclusion in the project.

The following paragraphs provide further description of the roles and responsibilities of consultees, suggest a process by which the researcher seeks advice from consultees and how such advice can be made use of within the overall research process. The roles of personal and nominated consultees in the research process are summarised in Table 1.

Table 1: Roles of personal and nominated consultees in the research process.

	Personal Consultee	Nominated Consultee
What is the consultee's relationship with the (prospective) participant)?	The Personal Consultee is someone the person knows and trusts with important decisions about their welfare and who - is not paid to provide care to the person; - could be a family member, carer, friend; - could be an attorney or a deputy appointed by the Court of Protection.	The Nominated Consultee is someone who - may be known to the person; - may be paid to provide care, such as a member of staff in a care home in which the person lives; - may provide professional services, such as a solicitor or a doctor; - may not be known to the person; - may act as a consultee for several prospective participants. How does the researcher decide who to contact?
How does a researcher decide who to contact?	See flow chart (Figure 4)	See flow chart (Figure 4)

Who initiates contact with a consultee?	The clinical/care team, health or social care agency contact the personal consultee. Contact details are known to the care/clinical team, health or social care agency. See sample letter in Part 2(4b).	The researcher contacts the Nominated Consultee. See sample letter in Part 2(5b) of this guide.
What information does the consultee receive?	The researcher provides information about the project and about the role of a Personal Consultee. See suggested information sheet in Part 2 (4c).	The researcher provides information about the project and about the role of a Nominated Consultee. See suggested information sheet in Part 2 (5c).
What advice does the researcher seek from the Consultee?	Consultee's general understanding of the project. Whether the participant may be interested in taking part in the project or whether they would object. Whether the person may benefit in any way by taking part. Whether the person has previously expressed views about involvement in research, assuming they had such capacity in the past. Whether the person has made any advance statements or has a written advance decision for refusal of life-sustaining treatment. Whether participation would cause any inconvenience or any other difficulty for the person. Whether the person would give any signs, and if so, what these would be, to indicate they were not happy about continuing with the project. Whether the consultee would wish to be approached again for their views. Whether the consultee could suggest an alternative consultee. Whether, from their understanding of the person and the project, on balance the person should or should not take part.	Consultee's general understanding of the project. Whether the consultee has any personal or professional connections with the project or an interest in its outcome. What knowledge of the person, and if so, in what capacity. Whether the consultee has discussed involvement in the project with the person. Consultee's views about whether the participant may benefit from taking part. Consultee's views about whether the person may object, be upset in any way or want to stop being involved, and if so, how this would be shown. Consultee's views about whether participation may cause any problems or inconvenience. Whether, from their understanding of the person and the project, on balance the person should or should not take part.

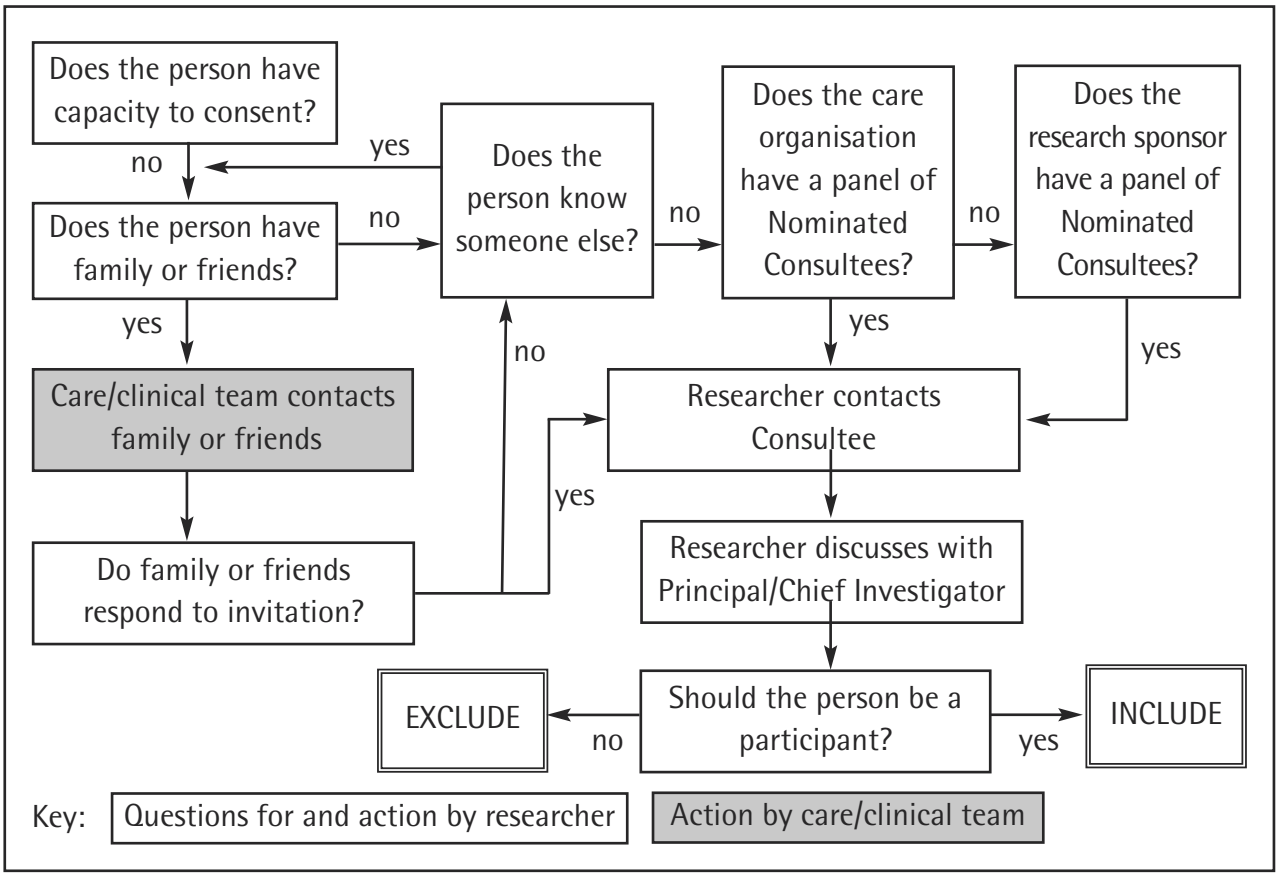
4.3 Consulting with a Research Consultee

The process of consultation starts with the clinical/care team contacting someone known to the prospective participant and inviting them to be consulted about their relatives or friend's involvement in the project (see Figure 4). See Part 2 (4b) for a sample letter together with preliminary information about the project. If the relative or friend accepts the invitation to be a Personal Consultee, the Care/Clinical Team contacts the Personal Consultee to make arrangements to discuss the project with the researcher. The researcher needs to make clear that they are seeking the Personal Consultee's views about whether or not the prospective participant may wish to take part, not their own views about the project. The views and opinion of the consultee will need to be documented by the researcher for later reference. A suggested proforma is provided in Part 2 – Forms.

There is limited research about the extent to which family members are prepared to be consulted. A study in Australia (Iacano & Murray, 2003) demonstrated that 50 per cent of families who were approached declined to offer information about prospective participants.

The researcher may also need to approach the Personal Consultee at later stages in the research process to confirm whether the participant would wish to continue with or to decline taking part in the project.

Figure 4: Seeking advice from a consultee.



4.4 Personal Consultee

The Personal Consultee is someone who the (prospective) participant knows and whom they trust with important decisions about their welfare. The Personal Consultee could be a relative, a friend or someone having a Lasting Power of Attorney for personal welfare (including healthcare and consent to medical treatment) or a deputy appointed by the Court of Protection. The Personal Consultee could NOT be someone who is a paid carer or who has a professional relationship with the prospective participant.

The researcher seeks an opinion from the Personal Consultee about

- whether the person should take part in the research;
- what the person's wishes and feelings would be about such a project;
- whether it is likely that the person would decline to take part, had they the capacity to decide.

If the consultee advises the researcher that the person would not wish to take part, then the person should be withdrawn from the project

Given that Section 32(2) of the Mental Capacity Act (2005) suggests that 'reasonable steps' should be taken to identify a Personal Consultee and has also proposed the appointment of Nominated Consultees, the researcher appears to have a choice about who to approach. A flowchart (Figure 4) is offered as a means of assisting the researcher in deciding whether to seek consultation from a Personal or a Nominated Consultee.

4.5 Nominated Consultee

A Nominated Consultee may be a paid carer or someone who has a professional relationship with the person, such as a solicitor or a doctor, but who has no financial or other interest in the outcome of the project.

Guidance prepared by the Department of Health and the Welsh Assembly Government (2008) suggests that Nominated Consultees could be drawn from a list of potential Consultees, convened by a research active care organisation, such as a NHS Trust, research sponsors, such as the Wellcome Foundation, or universities. Research networks which have evolved as part of the NHS Research Strategy, Best Research for Best Health, may also provide a convenient host for panels of Research Consultees. Alternatively, Independent Mental Capacity Advocates may be in a position to contribute to consultation about the involvement of participants in research, depending on local arrangements.

During the course of discussions for the preparation of this guide, a number of respondents expressed concern about inviting an opinion from consultees who were not known to the prospective participant.

Suggestions for good practice therefore are that a consultee adopts an approach similar to that of an advocate, in which the consultee meets the prospective participant, carers, relatives and friends (if available) in order to gain relevant information on which to base advice to the researcher.

Section 5: Appraising partipant involvement

5.1 Appraising whether to include or exclude a participant

Section 31 of MCA states that the researcher must ensure that the project meets the following five requirements.

1. The research project is associated with the condition which impairs the participant and/or any treatment of the condition. An 'impairing condition' is one which causes or contributes to any disturbance of the mind or brain (and on which the assessment of lack of capacity is based).
2. The research project could not be undertaken as effectively solely with participants who have capacity to consent.
3. The research must be intended to provide **knowledge of the causes, treatment or care** of people affected by the same or similar impairing condition or that it concerns **treatment or care** of the condition.

   The MCA Code of Practice provides further examples of 'similar' conditions or impairments that may not have the same cause, such as cognitive impairment associated with brain injury acquired in adulthood and intellectual impairment consequential to a genetic disorder.
4. The participant is likely to benefit from undertaking the research and that the benefit is not disproportionate to any burden in taking part.
5. If there are no benefits to the person and if the research concerns the gaining of knowledge about the condition, then there should be negligible risk to the participant. In addition, participation in the project should not interfere with the participant's freedom of action or privacy in a significant way, or be unduly invasive or restrictive.

Figure 5 provides a diagrammatic representation of the decisions or judgments the researcher needs to make. Requirements 1–4 above can be debated in principle in the study protocol and in the application for ethical approval (shaded boxes). The fifth requires information about the impact of involvement in the project for the individual participant, information which could only be obtained in the course of consultation with others.

Figure 5: Appraising an individual's involvement in a project.

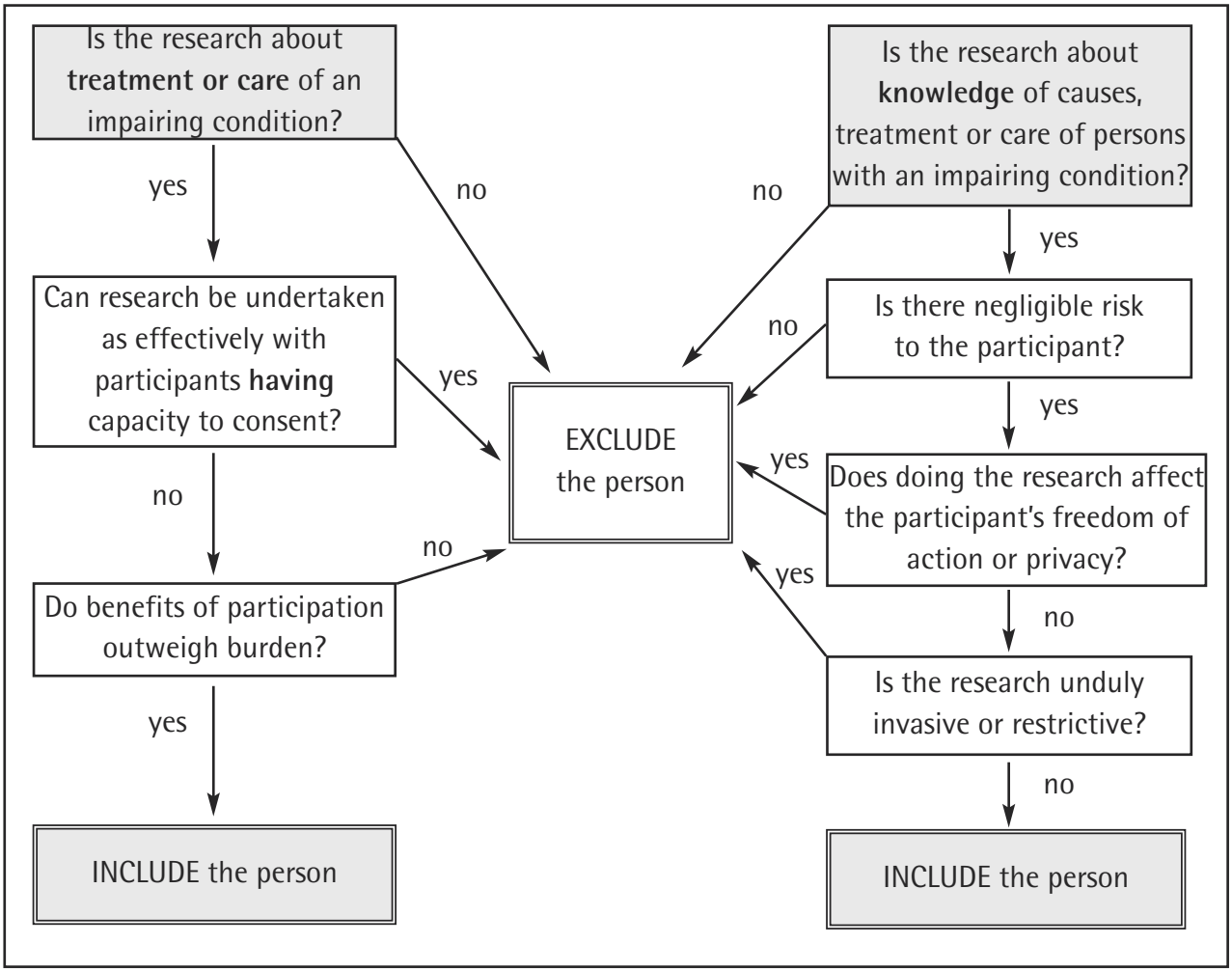


Figure 5 summarises questions the researcher needs to consider. A checklist for researchers is available in Part 2(6) of the practice guide.

5.2 Reviewing continuing participation in a project

A key feature of consent to participate is the freedom to continue or to withdraw from a study. Participants having significant cognitive impairment (language, memory and problem-solving abilities) may be susceptible to influence as a result of pressure from researcher or carer or by merely being in the 'research environment' (Gudjonsson, 2002). Researchers may need to become aware of potential behaviour, both verbal and non-verbal which indicates that the person may wish to withdraw (MCA, Section 33(4) and Code of Practice 11.31). Examples may be that in addition to a clear expression of no longer wishing to participate, the person pushes the equipment away or takes themselves away from the researcher. In research based on observational methods, identifying behaviour that is non-consenting to research may be difficult to distinguish from other behaviour or activities being observed. Such matters would also have been addressed in the application for ethical approval.

If in doubt, the researcher may need to seek additional advice from a Personal or Nominated Consultee. If the consultee advises that the person should be withdrawn, then this must be respected by the researcher (MCA, Section 32 (5)). The researcher may find it helpful to refer to Figure 5 (Appraising an individual's involvement with a project) together with checklist 6 in Part 2 of the Guide

Finally, if any of the requirements of the Act are no longer met, the individual must be withdrawn from the project (Code of Practice, 11.31).

5.3 Recommendations for good practice

1. The researcher appraises the project in relation to each individual participant lacking consent, even though these matters would have been anticipated in principle during the process of gaining ethical approval. The benefits, burdens and risks cannot be assumed to be similar for all participants.
2. Relevant evidence and decisions are documented.
3. The appraisal or re-appraisal of a participant's involvement with the project is conducted by means of a discussion between the researcher (who has collected information from a consultee) and the Principal or Chief Investigator. A major responsibility of the Principal or Chief Investigator is the overall welfare of participants. Documentation recording aspects of the discussion is included in Part 2(6) of the guide.

Section 6: Case studies

Case study 1 demonstrates how a researcher could undertake an assessment of capacity and an appraisal of the involvement of an individual in a study.

Susan, aged 25, married with two children, has been experiencing some mental health problems since the age of 16. She has been experiencing low mood, anxiety and low levels of paranoia but has been able to cope with her problems to date. She has been treated by her GP who has prescribed anxiolytics and anti-depressants and at times she has also been receiving input from the Community Mental Health Team (CMHT) in the area. Susan's marriage recently broke down and her ex-husband has been making threats to take the children away from her because of her mental health condition. Her mother died when she was still very young, her father is an alcoholic, and she has no brothers and sisters. Her friends have rejected her due to her mental health problems and Susan has no one to talk to and feels isolated.

As a result of these experiences her mental health problems have now become unmanageable and Susan has experienced a mental breakdown. She is now on a female ward and her ability to reason and make judgements is significantly impaired. After a detailed assessment of her symptoms by the psychiatrist Susan is diagnosed with a first episode of psychosis. Susan fulfils the necessary criteria to participate in your first episode study. The study involves participation in lengthy questionnaires that could take up to three hours to complete some of which need to be videotaped.

Would Susan participate in the research study?

Questions below offer the researchers a step-by-step examination of Susan's capacity to consent and consideration of whether she should be included in the study. See Figures 3, 4 and 5 and checklists provided in Part 2. (Additional material is provided for purposes of illustration).

Q: Can Susan consent to her participation in research?

If **yes** – Susan can decide whether or not to participate.

If **no** or **unsure** – the researcher needs to assess Susan's capacity to consent.

Whether Susan indicates her willingness to participate is a separate matter from her capacity to consent to participation.

Q: Does Susan have a condition impairing her ability to make decisions?

A: A Susan suffers from psychosis which impairs her capability in making decisions, including about participating in the research study.

Q: Does Susan have the capacity to consent to participation in the 'first episode' study?

A: The researcher determines whether Susan

- can retain information about the study;
- understand the intentions of the project;
- weigh up information about the project and the consequences of participating or not;
- convey her response.

Susan can describe some aspects of what the project is about. She understands she has to answer some questions. Susan cannot describe how taking part or not taking part would affect her.

The researcher kept notes of the discussion with Susan.

In discussion with the Principal Researcher, the Principal Researcher considered that Susan did not have the capacity to consent to her involvement with the research project at the time consent was sought, as she was not able to weigh up information about the project or the consequences of her involvement. Susan was unlikely to regain capacity in relation to making decisions about her involvement with the current project.

A: Susan suffers from psychosis which may impair her capability in making decisions.

The researcher determines whether she can retain and understand the intentions of the project, weigh up that information and the consequences of participating or otherwise and convey her response.

If still no – then Susan does not have the capacity to consent

Whether Susan states her willingness to participate is a separate matter from her capacity to consent.

Q Who can the researcher consult with?

A Susan is described as being isolated from family and friends. Her children are under the age of 18, so no family member may be appropriate to act as a Personal Consultees.

Susan is known to members of the Community Mental Health Team; hence the researcher could contact the team to identify someone who would be willing to act as a Nominated Consultee, providing the team did not have an interest in the outcome of the project. If team members were connected in any way with the project, the researcher would need to contact a different Nominated Consultee who was independent of the project.

Q Is the research about treatment or care or about **knowledge** of a condition, care or treatment?

A The study appears to be about **knowledge** of psychosis or its treatment or care.

Q Does Susan have an advance statement?

A The Nominated Consultee has advised that Susan has not prepared an advance statement.

Q Would participation in the study

a) Be of negligible risk to Susan?

A The researcher uses information gained from the Nominated Consultee about whether the interviews would potentially be of harm to Susan, perhaps, for example, because of the nature of the interview questions.

b) Affect Susan's freedom of action or privacy?

A The interviews could be conducted in a private room; however, the Nominated Consultee advised that Susan participates in therapy sessions which would clash with the intended timing of the interviews with the researcher.

c) Be unduly invasive or restrictive?

A The interviews require in-depth discussions about Susan's family life. The Nominated Consultee has advised that Susan has difficulty in talking about her family life.

A conclusion could be reached that Susan may experience distress in participating in the research interview – hence she should not be included as a participant. Of particular importance is the key distinction between 'research of the treatment' and research which is **knowledge** about the condition, treatment or care of persons'; if the latter, the research may not necessarily be of benefit to the person, but would still need to meet the criterion of 'interests of the person outweighing those of science and society'.

Consideration of whether research is unduly invasive or restrictive may also be different for different people. The MCA Code of Practice suggests that 'unduly invasive' research is that which does not go beyond 'the experience of daily life. Routine medical examination or psychological assessment is considered as not being 'unduly invasive' (MRC, Code of Practice, 11.19).

Case study 2

Case study 2 is an appraisal of the overall ethical stance of a project rather than that of the involvement of individual participants.

In this case study, published in the *Medical Research Council Ethics Guide* (2007), the Blandfordshire REC decided that the health hazard (harm) to participants was equivalent to 'risk' encountered in normal daily life and approved the study. The case study also demonstrates an approach to consultation with others which appraises the participants as a group rather than as individuals.

The Blandfordshire REC was asked to review a proposal to study whether electronic tagging was beneficial to the care of older people with varying degrees of dementia who lived in residential homes. The hypothesis was that the tagging would allow the residents more freedom while minimising their risk of getting lost. There was some discussion about whether the tagging was an invasion of privacy when the individuals concerned were unable to provide informed consent. However, the results of an independent consultation, commissioned by the researchers, of relatives and carers suggested that the benefits to the residents were perceived to outweigh this concern. The tagging device was very small and not noticeable when worn. When the project was reviewed by the REC, it was questioned whether the radio frequencies used constituted a health hazard in this age group. A decision on whether the study might go ahead was deferred until the researchers provided an updated analysis of the literature on this issue, in light of new scientific evidence. This analysis suggested that the radio frequency risk was similar to that of mobile telephones.

Section 7: Concluding comments

The Mental Capacity Act (2005) has opened up the possibilities that people not able to consent should no longer be excluded from participation in research, enabling access to experiences and potential treatments and care for which they may not hitherto have been considered. The MCA has sought to balance such access with safeguards applying at different stages of the research process.

Preparation of the practice guide has brought into focus a number of ethical, philosophical and political matters, such as the nature of 'informed consent', the range of decisions a researcher may need to take at different stages of the research process and stark differences between conducting research in 'health' rather than in 'social care' settings.

The practice guide was originally envisaged as a compendium of resources, references and 'good ideas' for conducting research with people not having the capacity to consent to their participation, prepared from the perspective of different parties in the research process. After much deliberation, the author considered that taking a systemic view of the research process would provide a meaningful structure for materials that a researcher may find useful.

The extent to which researchers find the materials of assistance will depend on whether researchers, sponsors and funders consider the additional safeguards feasible to incorporate within research projects, given tight timescales and restricted budgets. An audit of the use of the guidance materials, together with a review of experience in Scotland and other jurisdictions, may in the future help to identify the kinds of research questions which could not be addressed by other means.

Appendices

Appendix 1

References

Article 17 of the Protocol to the Convention on Human Rights in Biomedicine or Biomedical Research (2005).

British Psychological Society (2004a). *Guidance for the minimum standards of ethical approval for psychological research.* Leicester: Author

British Psychological Society (2004b). *Code of conduct, ethical principles and guidelines.* Leicester: Author.

British Psychological Society (2005). *Good practice guidelines for the conduct of psychological research in the NHS.* Leicester: Author.

British Psychological Society (2008) *Generic Professional Practice Guidelines* (2nd edn.) Leicester: Author.

Cameron, L. & Murphy, J. (2006). Obtaining consent to participate in research: The issues involved in including people with a range of learning and communication disabilities. *British Journal of Learning Disabilities, 35*, 113–120.

British Psychological Society (2007). *Report of the working party on conducting research on the internet: Guidelines for ethical practice in psychological research online.* Leicester: Author.

Department for Constitutional Affairs (2006). *The Mental Capacity Act (2005): Draft Code of Practice.* London. The Stationery Office

Department for Constitutional Affairs (2007). *The Mental Capacity Act (2005): Code of Practice.* London. The Stationery Office.

Department of Health (2004a). *Information about patients: An introduction to the Patient Advisory Group for health professionals and researchers.* Retrieved from http://www.advisorybodies.doh.gov.uk/piag/InformationAboutPatients.pdf.

Department of Health (2004b). *The research governance framework for health and social care – Implementation plan for social care.* London: Department of Health.

Department of Health (2005). *Research governance framework for health and social care.* London: Department of Health. Retrieved 25 November 2008 from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4122427.

Department of Health (2006). Consultation on regulations made under the Mental Capacity Act (2005). Retrieved on 27 November 2008 from http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4138699.

Department of Health and Welsh Assembly Government (2008). *The Mental Capacity Act and consent for research: What research does the Act cover?* . Retrieved on 27 November 2008 from http://new.wales.gov.uk/dhss/publications/health/mentalhealth/mentalcapacityact/2117019/mcaconsente.pdf?lang=en.

Department of Health and Welsh Assembly Government (2008). *Guidance on nominating a consultee for research involving adults who lack capacity to consent.* London: Department of Health.

Doyle, L. (2005). *The ethical governance and regulation of student projects: A proposal.* Retrieved on 25 November 2008 from http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm/DH_4120898.

Gudjonsson, G. (2002). *The psychology of interrogations and confessions: A handbook.* London: Wiley.

Herring, J. (2006). *Medical law and ethics.* OUP

Iacano, T. & Murray, V. (2003). Issues of informed consent in conducting medical research involving persons with intellectual disability. *Journal of Applied Research in Intellectual Disabilities,16*, 41–51.

Medical Research Council (2007). *MRC ethics guide 2007: Medical research involving adults who cannot consent.* London: Author. Retrieved from http://www.mrc.ac.uk/Utilities/Documentrecord?index.htm?d=MRC004446.

The Medicines for Human Use (Clinical Trials) Regulations 2004. London: The Stationery Office.

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007.

Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006. London: The Stationery Office.

Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2006. London: The Stationery Office.

Mental Capacity Act (2005) Chapter 9. London: Office of Public Sector Information.

National Research Ethics Service (2007). Information sheets and consent forms for researchers and reviewers, v.3.2 May 2007. Retrieved on 25 November 2008 from http://www.nres.npsa.nhs.uk/rec-community/Guidance/#PIS.

National Research Ethics Service (2007) Research involving adults unable to consent for themselves v 2 September 2007. Retrieved on 27.11.08 from http://www.nres.npsa.nhs.uk/rec-community/guidance/#consent.

Statutory Instrument 2002 No. 1438 The Health Service (Control of Patient Information) Regulations 2002.

US Department of Health and Human Service. (2004). Research involving human subjects: Research Regulations and ethical guidelines. Quoting from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law 10*(2), pp. 181-182. Washington, DC: US Government Printing Office, 1949.

Appendix 2

NHS Research Ethics Committees which have been 'flagged' to scrutinise projects involving participants who do not have the capacity to consent

The list of 'flagged' RECs which follows is taken from the National Research Ethics Service document *Research involving adults unable to consent for themselves* (version 2, September 2007).

Flagged RECs for research involving adults unable to consent for themselves

England

Barking & Havering REC

Berkshire REC

Bolton REC

Bradford REC

Bromley REC

Cambridgeshire REC 3

Camden & Islington Community REC

Coventry REC

Dorset REC

Ealing and West London Mental Health Trust REC

Essex 2 REC

Frenchay REC

Harrow REC

Leeds West REC

Liverpool Adult REC

National Hospital for Neurology and Neurosurgery and Institute of Neurology REC

Newcastle and North Tyneside REC 2

Norfolk REC

North Staffordshire REC

Northumberland REC

Nottingham REC 1

Sandwell and West Birmingham REC

South East REC

South London and Maudsley and Institute of Psychiatry REC

South Manchester REC

South Sheffield REC

Southampton & South West Hampshire REC 1

York REC

Wales

North East Wales Health Authority Research Ethics Committee

South East Wales Research Ethics Committee Panels B, C and D

Wales Research Ethics Committee

Scotland

Scotland A Research Ethics Committee

Northern Ireland

HSC Research Ethics Committees 1-3

Please note that during 2008, NRES has initiated a Central Allocation System (CAS), whereby researchers intending to submit a project to a 'flagged' REC, can do this via CAS. For further information and relevant 'flagged' RECs, please see http://www.nres.npsa.nhs.uk/news-and-publications/news/important-changes-to-booking-applications-via-the-central-allocation-system. Retrieved on 27 November 2008.

Appendix 3

Roles and responsibilities in the research process

The definitions of roles and responsibilities in the research process were outlined in the *Research Governance Framework for Health and Social Care* (DH, 2005) and have not been updated in response to the Mental Capacity Act.

This practice guide proposes a number of additional responsibilities researchers may have in connection with seeking consent and appraising participant involvement. These new responsibilities are indicated in italics in Table 2.

Table 2: Additional responsibilities researchers may have when seeking consent and appraising participant involvement

Chief Investigator, Investigators, other researchers	• Developing proposals that are scientifically sound and ethical. • Seeking NHS research ethics committee approval. • Conducting research to the agreed protocol (or proposal), in accordance with legal requirements and guidance. • Ensuring participants' welfare while in the study. • Feeding back results of research to participants. • *Assessing capacity to consent.*
Research Ethics Committee	• Providing an independent expert opinion on whether the proposed research is ethical and respects the dignity, rights, safety and well-being of participants.
Sponsor	• Taking overall responsibility for confirming that everything is ready for the research to begin, including: ■ putting and keeping in place arrangements for initiation and management and funding of the study (and, for clinical trials involving medicines, applying for authorisation and making appropriate arrangements for investigational medicinal products for the trial); ■ satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance; ■ satisfying itself the study has ethical approval before it begins; ■ satisfying itself that arrangements will be kept in place for monitoring and reporting on the research, including prompt reporting of suspected serious adverse incidents. ■ Ensuring the research complies with the law. ■ *Convening a panel of Consultees who can be approached by a researcher to advise about the involvement of participants in a project.*
Main funder	• Assessing the scientific quality of the research as proposed. • Establishing the value for money of the research as proposed. • Assessing the quality of the research environment in which the research will be undertaken, and the experience and expertise of the chief investigator, principal investigator(s) and other key researchers involved. • Requiring that a sponsor takes on responsibility before the research begins.

Employing organisation	• Promoting a quality research culture. • Ensuring researchers understand and discharge their responsibilities. • Ensuring the research is properly designed, and that it is well managed, monitored and reported, as agreed with the sponsor. • Taking action if misconduct or fraud is suspected.
Care organisation/ responsible care professional	• Ensuring that research using their patients, service users, carers or staff meets the standard set out in the research governance framework (drawing on the ethical review and sponsor). • Ensuring there is ethical approval for all research for which they have a duty of care. • Retaining responsibility for research participants' care. • *Appointment of Nominated Consultees or a panel of Nominated Consultees.*
Clinical Research Network	• Providing training for researchers. • *Amongst other responsibilities, appointment of Nominated Consultees.*

Appendix 4

Additional questions and ethical implications

I have data about clients obtained as part of my usual practice. Do I have to seek consent from each person to use the data retrospectively? What if individuals are unlikely to understand about research? Do I have to submit a proposal to REC to have results published?

What if the Attorney (LPA for personal welfare) agrees to treatment but doesn't know much about research?

Research with carers or families – does the person have to consent if the basis of the research is about them or a condition the person has?

A carer has raised concerns about actions/activities that participant is expected to undertake in a project

Does service user or carer-led research have to comply with the same ethical standards as professionally organised research?

What are the roles and responsibilities in collaborative research?I have concerns that the MCA (2005) has the potential to stifle important research. For example, case-file studies of 100 per cent samples. This type of research would count as 'intrusive' research and require that the permission of the participants be sought before their records are looked at. This would prove to be an impossible task and thus this type of research method could disappear leaving the field open only to anonymised surveys.

There needs to be at least two separate attempts to get consent, possibly separated by consultation. For example, a person may have capacity or be more amenable on a different day.

Concern is noted regarding the limited number of 'appropriate bodies for ethical review'. This inevitably will lead to increased delays given the number of project proposals that may need to undergo review. More importantly, concern was raised that the 'flagged' RECS may be ill equipped to deal with research that, whilst coming under the scope of the MCA, is not 'medical' in nature.

Whilst, where strong links exist between a university research ethics committee and a local NHS REC, the referral of projects for ethics scrutiny under the MCA, may proceed smoothly and without undue delay for university researchers.

In the absence of such links, however, this requirement is of particular concern to psychologists who are conducting research in accordance with the Society's Code of Ethics and Conduct; and Research Council Research Ethics Frameworks (such as the ESRCs) who do not interact with the NHS, nor do they need to. Most psychological research is subject to ethics scrutiny by university RECs – most of whom have standard operating procedures equivalent to those in the NHS. It may therefore be appropriate for these committees to continue to review low risk research that falls within the provisions of the MCA subject to a clearer definition of what constitutes 'intrusive' research.

However, as 'recognised status' can only be granted by the Secretary of State; and there is little evidence of a willingness on the part of the NHS to extend this status beyond those already 'flagged', researchers in psychology should be very concerned about this development. A considerable joint effort would be needed by a number of relevant organisations (including the Research Councils, the Association of Research Ethics Committees, and learned societies) to lobby the NHS to change its view otherwise.

The definition of 'intrusive' research is so broad that the MCA could potentially impact on all psychological research. This is a matter of considerable concern for psychology researchers in light of the comments outlined in the previous section. Clarification of what is meant by this definition is therefore needed.

Section 11.7 of the Code of Practice states that research involving 'data that has been anonymised and cannot be traced back to individuals' does not require consent (regardless of the capacity of the participants). However, the exact nature of the data to which this relates is ambiguous.

It is unclear whether new research that results in the collection of anonymised data would be excluded from the requirement to obtain consent; or does this just relate to pre-existing anonymised data sets. If the former, then this would allow for a significant amount of psychological research to be conducted under the MCA without the need for approval from a designated REC. If the latter, then again, the concerns outlined above remain.

Clarification should be sought on what exactly is excluded under section 11.7 of the Code of Practice.

Have their been any evaluation of research undertaken in Scotland following the implimentation of the Incapacity Scotland Act (2000)?

Appendix 5

Contributors

Nigel Atter	The British Psychological Society
Dr Elizabeth Baikie	Lothian University Hospitals Trust
Prof Hazel Biggs	Lancaster University
Dr Catherine Dooley	St Georges Hospital, London
Prof Eric Emerson	Lancaster University
Beverley Gibson	Lancashire Care Foundation Trust
Dr John Kincey	Clinical Psychologist
Prof Glynis Murphy	Kent University
Tim Rawcliffe	North West Mental Health Research Network
Dr Suzanne Regan	Independent social care researcher
Debra Rutter	Social Care Institute for Excellence
Dr Bridget Simpson	Stroke Research Network
Jane Simpson	Lancaster University
Dr Louise Shelley	Bangor University
Sue Williams	Kent County Council
Moira Winters	North West Mental Health Research Network
Dr Ann Wakefield	South Manchester REC
Prof Bob Woods	Bangor University
Members of Lancashire Care Trust's Research Governance Service User and Carer Committee	

Part 2: Checklists, sample letters and proformae

(Available in MS Word format)

1. National Research Ethics Service – supplementary form for approval under Sections 30-33 of the Mental Capacity Act.
2. National Research Ethics Service – supplementary forms for approval under Section 34 of the Mental Capacity Act.
3. Checklist – Capacity to consent to participation in research.
4. Consulting with a Personal Consultee.
   a. Checklist for researcher.
   b. Sample letter to partner, family member or friend from clinical/care team.
   c. Sample Information Sheet.
   d. Invitation to act as a Personal Consultee.
   e. Personal Consultee declaration form.
5. Consulting with a Nominated Consultee.
   a. Checklist for researcher.
   b. Sample letter to Nominated Consultee from researcher.
   c. Sample Information Sheet.
   d. Invitation to act as a Nominated Consultee.
   e. Nominated Consultee declaration form.
6. Checklist – appraisal of participant's involvement in the project.

1 National Research Ethics Service: supplementary form for approval under Section 30 of the Mental Capacity act 2005

Section 30 of the Mental Capacity Act 2005: Applications to NHS Research Ethics Committees

Supplementary information

REC reference number:	
Name of main REC:	
Full title of study:	
Name of Chief Investigator:	

This supplementary form should be completed if applying to a NHS Research Ethics Committee in England or Wales for approval under section 30 of the Mental Capacity Act 2005.

Please submit the form together with the on-line REC application form (for new research) or the Notice of Substantial Amendment form (for research already underway with a favourable opinion from a NHS REC), as applicable. For further guidance, see http://www.nres.npsa.nhs.uk/applicants/help/guidance.htm and the Mental Capacity Act Code of Practice.

1. **What impairing condition(s) will the participants have?**

2. **Please justify the inclusion of participants unable to consent for themselves.** *It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.*

3. **How will the capacity of potential participants to consent to the research be assessed? Who in the research team will make the assessment and what knowledge of the participant or relevant training/experience will they have to enable them to undertake it?** *Please see Chapter 4 of the MCA Code of Practice for detailed guidance on this issue.*

4. **Does the research have the potential to benefit participants who are unable to consent for themselves?**

   ☐ Yes ☐ No

   If Yes, please indicate the nature of this benefit:

5. **Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?**

   ☐ Yes ☐ No

If Yes, please explain how the research will achieve this:

6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

☐ Yes ☐ No

If Yes, please give an assessment below. Highlight any risk, burden, restriction or invasion of privacy specific to these participants and say what will be done to minimise it:

7. What arrangements will be made to identify and consult persons ("consultees") able to advise on the inclusion of each individual participant and on their presumed wishes and feelings?

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

8. Is it possible that a participant might need to be treated urgently as part of the research before it is possible to identify and consult a consultee?

☐ Yes ☐ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants:

9. What arrangements will be made to consult consultees during the course of the research where necessary? What burden could this place on consultees?

10. What steps will you take, if appropriate, to provide potential participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

12. What will be the criteria for withdrawal of participants?

13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort)?

14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

2 National Research Ethics Service. Supplementary form for approval under Section 34 of the Mental Capacity Act: loss of capacity during a project

Section 34 of the Mental Capacity Act 2005: Applications to NHS Research Ethics Committees

Supplementary information

REC reference number:	
Name of main REC:	
Full title of study:	
Name of Chief Investigator:	

This supplementary form should be completed if applying to a NHS Research Ethics Committee in England or Wales for approval under the Regulations made under section 34 of the Mental Capacity Act 2005.

Please submit the form together with a Notice of Substantial Amendment form and a copy of the amended protocol, incorporating procedures for complying with the above Regulations.

For further guidance, see http://www.nres.npsa.nhs.uk/applicants/help/guidance.htm and the Mental Capacity Act Code of Practice.

1. What steps would you take to determine that a participant no longer had capacity to consent to the research?

2. Describe the data or material, obtained prior to the loss of capacity by participants, which you plan to retain and use in this research?

3. What further use do you plan to make of the data or material in this research? Justify the need for further research on the data or material following loss of capacity.

4. What arrangements are in place to ensure the confidentiality of any personal data relating to participants who have lost capacity?

5. What arrangements will be made to identify and consult persons ("consultees") able to advise in each case on whether research should be carried out using the participant's data or material and on their presumed wishes and feelings?

Please enclose a copy of the written information to be provided to consultees. This should describe their role under the Regulations made under section 34 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

6. What arrangements will be made to continue to consult consultees during the course of the research?

7. What will be the criteria for discontinuing all further research using the data or material?

8. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

Participant code

3 CHECKLIST for RESEACHERS 1
ASSESSING CAPACITY TO CONSENT TO PARTICIPATION IN RESEARCH

Checklist for researchers to decide whether a prospective participant has the capacity to consent to their participation	
Section A - Enabling capacity: Have you made every effort to enable a prospective participant to make the decision themselves to participate or refuse? Have you used language or methods of communication that the person is most likely to understand? Have you given sufficient time for the person to think about the project? Has the person conferred with others who could help explain the project?	☐ ☐ ☐ ☐
If NO to any item in Section A, return to guidance on 'enabling decision-making'. ***If YES to all items in Section A continue…***	
Section B - Diagnostic assessment Is there evidence to demonstrate impairment of mind or brain? Is there evidence to demonstrate that this is temporary, fluctuating or permanent? Is there evidence to demonstrate that the impairment affects the person's ability to decide about their participation in research?	☐ ☐ ☐
If NO to any item in Section B discuss with Principal Researcher. ***If YES to all items in Section B, continue…***	
Section C - Functional assessment Does the person understand that they can consent to or refuse to participate in research? Does the person understand what the research is about? Does the person understand and weigh-up the benefits and risks of agreeing or refusing to take part? Has the person communicated their decision to you in any way?	☐ ☐ ☐ ☐
If YES to any item in Section C, return to guidance on 'enabling decision-making'. ***If NO to the first three items in Section C – the person DOES NOT have the capacity to consent to or to refuse to take part in the research project.***	
Checklist completed by: **Date:**	

4 Consulting with a PERSONAL CONSULTEE

4a Checklist for Researcher (Personal Consultee)

Project title:	Participant code
Sample letter for partner, friend or relative – sent by care home, care/clinical team	**DONE?** ☐
Information sheet summary, contact information, confidentiality statement sent to partner, friend or carer	☐
Partner, friend or relative response form returned	☐
Personal Consultee declaration completed	☐

4b Sample letter from clinical/care team to partner, family member or friend.

Sample letter

Service/Clinical Team/Care home headed paper
Address
Telephone

Dear Name

The XXXX service/team/home is collaborating with YYYY from (name) Trust/Authority/University/organisation in a research project.
The project is called……

An important aspect of the research project is that all participants have the choice about whether to volunteer or to refuse to take part. However some of the residents/patients may not have the capacity to consent because of a condition/illness they have that affects how they make some decisions.

You have been approached as you are a partner, relative or friend of a resident/patient of this service. The researchers would like to discuss with you your views about whether …….may wish to participate in the research.

I attach some information about the project, the names of the researchers and ways that you can help.

Please have a look at the form and return to (name) at XXX using the stamped-addressed envelope. If you have any queries, please contact (name) on 11111111 to discuss.

Thank you for your interest in the project and taking time to read the information.

(Signed)
Manager/consultant

4c Sample Information Sheet

Attached information for Personal Consultees – provided by researchers

What is the project about?

- Title
- Main aims
- Recruitment of participants
- What participants are required to do
- Potential hazards
- Contact names and addresses
- Complaints
- Use headed paper from university/research organisation

We are intending to recruit participants to his project who may not have the capacity to consent to their participation. This means that they may not be able to judge for themselves whether they should like to take part or refuse. The project includes such participants because we are studying about the (xxx) condition/care and treatment of people having the (xxx) condition. We also consider that it is important for people with the (xxx) condition to have the chance of taking part in the research project.

The project has been approved by a (named) Research Ethics Committee. We shall make sure that the project is safe for each participant and does not cause them undue distress. To help with this, the researchers need information from people who have known the participant for some time.

Why have I been approached?

As a partner, friend or relative of a (prospective) participant in the study, you will have an interest in the person's well-being and welfare. You may have been given a Lasting Power of Attorney to make personal welfare decisions on their behalf when they can't. You may be a deputy appointed by the Court of Protection.

Researcher/s in the project would like to discuss with you whether you think that your friend or relative would like to take part. As you have known them for some time, you may be aware of any views they may have about taking part in such a project or whether they have made an 'Advance Decision'. If your partner, friend or relative has made an 'Advance Decision' this is important as it shows that they have ready made decisions for themselves. The researchers would like to respect the person's wishes.

Secondly, if you think that your partner, friend or relative may be interested in taking part in the project, you may be able to tell us about any possible difficulties they may have. You also may be able to tell us how they may communicate that they wanted to stop being involved.

When thinking about the wishes and interests of your partner, relative or friend, it is important that you should set aside any of your own views about the project.

A 'personal consultee' is a partner, friend or relative of a prospective participant, who provides the researchers with advice. If you would like further information about being a 'personal consultee', please contact xxxxx who has experience in this area.

What do I have to do now?

If you think that your partner, friend or relative would be interested in taking part, please complete the attached form and send this back to XXXX using the stamped-addressed envelope.

If you think that your friend, partner or relative would be interested but you are not sure about whether you would like to talk about this with the researcher, then please suggest who else could be approached.

If you think that your friend, partner or relative would **not** be interested in taking part, then it is important that you still complete the form below.

Will information that I give be kept confidential?

Information about yourself (name, address and telephone number) is in records held by XXX team/care team. XXX care team will contact you, should the researchers wish to speak with you.

Information that you disclose about your partner, friend or relative concerning their participation in the research will be held by the researcher. The researcher will not know your name, address or telephone number. When you meet the researcher, they will talk with you about confidentiality.

What will happen to the forms when I have completed them?

The forms will be looked at by the researcher. The Care Team will contact you by (date) to let you know whether or not the researcher would like to speak with you and arrange a time for a discussion.

If you do not return the form, we shall assume that you do not wish to be contacted about the project.

How can I find out more about the project?

You can contact (person) on (telephone number) to discuss the project further. The project is lead by (person) who can be contacted at (place/number).

Invitation to act as a Personal Consultee

Participant code

Project title

I think that my partner, friend or relative may **NOT** like to take part in the project	Signed…….
I think that my partner friend or relative may be interested in taking part and I would like to discuss this with the researcher.	I agree to being contacted further about the project Signed …….
I think that my partner, friend or relative may like to take part in the project – but I do not wish to be consulted.	I do not agree to being contacted further about the project Signed……..

Thank you for completing the form. Please send in the stamped addressed envelope to XXX care team/care home/clinical team

4e Sample Personal Consultee Declaration

Research centre/sponsor headed paper

Personal Consultee declaration

(Version ……. Date……..)

Project title

Participant code

	Please initial your confirmation/understanding below
1. I confirm that I have read and understood the Information for Consultees (version … dated….) for the study	
2. I confirm that I have had time and opportunity to ask questions about the study or my role as a Personal Consultee	
3. I understand the purpose of the project and what the participant's (my partner, friend or relative's) involvement would be. In my opinion, they would not object to taking part in the study	
4. I understand that participation in the project is voluntary and that my partner, friend or relative would be withdrawn if they do not wish to continue participating and without giving a reason.	
5. I understand that if my partner, friend or relative were withdrawn form the project, this would not affect in any way the care or treatment they receive, or affect their legal rights.	
6. I understand*……(other features relevant to the project, such as that my partner, friend, relative's GP will be informed about their involvement in the study)*	

Name of consultee	date	signature
Name of person who has discussed the study and provided me with information	date	signature
Principal Researcher	date	signature

When completed – one copy to be retained in care/health records, one copy for Consultee, one copy for researcher.

5 Documentation when consulting a NOMINATED CONSULTEE

5a Checklist for Researcher (Nominated Consultee)

Project title:	Participant code
Sample letter for Nominated Consultee – sent by care organisation/Trust/Research organisation	☐
Information sheet summary, contact information, confidentiality statement	☐
Nominated Consultee agreement form returned	☐
Nominated Consultee declaration completed	☐

5b Sample letter from researcher to prospective Nominated Consultee

Sample letter

Care organisation/Trust/Research organisation
Address
Telephone

Dear Name

The XXXX service/team/home is collaborating with YYYY from (name) Trust/Authority/University/organisation in a research project.
The project is called……

An important aspect of the research project is that all participants have the choice about whether to volunteer or to refuse to take part. However some of the residents/patients may not have the capacity to consent because of a condition/illness they have that affects how they make some decisions.

You have been approached as you are have been named by the Care Organisation/Trust/research organisation as someone who can be consulted on such matters. The researchers would like to discuss with you your views about whether...……. may wish to participate in the research project.

I attach some information about the project, who the researchers are and in what ways you can help.

Please write to me or telephone me on (telephone number) to discuss further. When you have decided, please return the form in the stamped-addressed envelope.

Thank you
Signed

5c Sample Information Sheet for Nominated Consultee

Research centre/sponsor headed paper

Information for Nominated Consultees

What is the project about?

- Title
- Main aims
- Recruitment of participants
- What participants are required to do
- Potential hazards
- Contact names and addresses
- Complaints

We are intending to recruit participants to his project who may not have the capacity to consent to their participation. This means that they may not be able to judge for themselves whether they should take part or refuse. The project includes such participants because we are studying about the (xxx) condition/care and treatment of people having the (xxx) condition. We also consider that it is important for people with the (xxx) condition to have the chance of taking part in the research project.

The project has been approved by a (named) Research Ethics Committee. We shall make sure that the project is safe for each participant and does not cause them undue distress. To help with this, the researchers need information from people who have known the participant for some time or those who have agreed to be consulted on such matters.

Why have I been approached?

You may be someone who already knows the prospective participant, working with them as a paid carer or in a professional capacity, such as a doctor or a solicitor. Alternatively, you may already have been approached by a care organisation, Trust or research organisation and agreed to act as a Consultee.

If you do know the prospective participant, you may be able to advise us about any possible difficulties they may have in taking part. You also may be able to tell us how they may communicate that they wanted to cease being involved with the project.

When thinking about the wishes and interests of the prospective participant, it is important that you should set aside any of your own views about the project.

If you would like to seek further information about being a 'nominated consultee', please contact xxxxx who has experience in this area.

What do I have to do now?

If you think that the prospective participant would be interested in taking part, please complete the attached form and send this back to XXXX using the stamped-addressed envelope.

If you think that the prospective participant would be interested but you are not sure about whether you would like to talk about this with the researcher, then please suggest who else could be approached.

If you think that the prospective participant would **not** be interested in taking part, then it is important that you still complete the form below.

Will information that I give be kept confidential?

Information about yourself (name, address and telephone number) will be held by the Care organisation/Trust/Research organisation.

Information that you disclose about the prospective participant will be held by the researcher. The researcher will not know your name, address or telephone number. When you meet the researcher, they will talk with you about confidentiality.

What will happen to the form when I have completed it?

The forms will be looked at by the researcher. The Care organisation/Trust/Research organisation will contact you by (date) to let you know whether or not the researcher would like to speak with you and arrange a time for a discussion.

If you do not return the form, we shall assume that you do not wish to be contacted about the project.

How can I find out more about the project?

You can contact (person) on (telephone number) to discuss the project further. The Principal Researcher is (person) who can be contacted at (place/number).

5d Invitation to act as a Nominated Consultee

Research centre/sponsor headed paper

Agreement to act as a Nominated Consultee

Participant code

Project title

I think that the prospective participant may **NOT** like to take part in the project	I agree with this statement Signed…….
I think that the prospective participant may be interested in taking part and I would like to discuss this with the researcher.	I agree to being contacted further about the project signed …….
I think that the prospective participant may like to take part in the project – but I do not wish to be consulted.	I do not agree to being contacted further about the project Signed……..

Thank you for completing the form. Please send in the stamped addressed envelope to XXX Care organisation/Trust/research organisation

Research centre/sponsor headed paper

5e Nominated Consultee declaration

(Version ……. Date……..)

Project title

Participant code

7.1..I confirm that I have read and understood the Information for Nominated Consultees (version … dated….)	Please initial your confirmation/understanding below
8.2. I confirm that I have had time and opportunity to ask questions about the study or my role as a Nominated Consultee	
9.3. I understand the purpose of the project and what the participant's involvement would be. In my opinion, they would not object to taking part in the study	
10.4.I understand that participation in the project is voluntary and that the participant would be withdrawn if they do not wish to continue participating and without giving a reason.	
11.5.I understand that if the participant were withdrawn from the project, this would not affect in any way the care or treatment they receive, or affect their legal rights.	
12.6.I understand*……(other features relevant to the project, such as the participant's GP being informed about their involvement in the study)*	

Name of consultee	date	signature
Name of person who has discussed the study and provided me with information	date	signature
Principal Researcher	date	signature

When completed – one copy to be retained in care/health records, one copy for Consultee, one copy for researcher.

6 Appraisal of a participant's involvement with a project

Checklist for researchers to appraise the inclusion of a SPECIFIC PARTICIPANT who lacks capacity (for projects other than Clinical Trials of Medicinal Products)	Indicate yes or no
Has a functional assessment of capacity (for consent to research) been done? Is it unlikely that the person would regain capacity to consent?	☐ ☐
If YES to above continue…	
Consulting with others Does the person have an Advanced Statement about refusal of treatment? Has the researcher consulted with a Lasting Power of Attorney for Welfare Decisions (LPA) or a Deputy appointed by the Court of Protection? Has the researcher consulted with family or friends? Has the researcher consulted with a Nominated Consultee?	☐ If YES discuss with Principal Researcher ☐ ☐ ☐
If YES to above, use information gained from consultation with others to complete the following sections	
Is the research about the treatment or care of a person with an impairing condition? Would undertaking the research be of benefit to the participant? Is the participant likely to incur any burden by participating? Does the benefit outweigh the burden of participation?	☐ If NO go to next section ☐ ☐ ☐
If YES, continue… if NO, EXCLUDE the participant	
Is the research about KNOWLEDGE of causes, treatment or care of an impairing condition? Are the risks of taking part negligible?	☐ ☐
If YES continue… If NO, Exclude the participant	
Is participation likely to be invasive or restrictive? Is participation likely to interfere with the participant's freedom or privacy?	☐ ☐
If NO, include the participant. If YES, exclude the participant	
AGREEMENT Have the researcher and Principal/Chief Researcher agreed to **INCLUDE** the participant?	☐

Checklist completed by: **Date completed:**
Principal/Chief Researcher **Date agreed:**