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Conducting research with people not having the capacity to consent to their participation: A practical guide for researchers

March 2020



This document was updated on behalf of the British Psychological Society by Jahnese Hamilton in 2019 and supersedes the original document prepared by Catherine Dobson in 2008.

ABOUT THE AUTHORS

In 2008 **Catherine Dobson** was a Consultant Clinical Psychologist working with people with learning disabilities in Lancashire, England. She has conducted research about services for people with learning disabilities and mental health problems and was a member of Lancashire Care Foundation Trust's Research Governance Committee. Catherine has contributed to regional implementation of the MCA and has both organised and presented papers on aspects of MCA at conferences.

Jahnese Hamilton is a Clinical Studies Officer working in research with people with mental health conditions, learning disabilities, and autism in Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, England. She leads on the delivery of a large number of NIHR Clinical Research Network Portfolio studies in NHS and Partnership organisations within clinical and care settings, routinely assessing capacity to consent to research. Jahnese works closely with the Autism Research Team at Newcastle University, supporting the translation of research policy and the MCA into protocols for including participants who may lack capacity. She has also conducted research on how researchers assess capacity to consent, and published and presented outcomes of this work in the *British Journal of Learning Disabilities* and at conferences.

ACKNOWLEDGEMENTS

The Society would like to thank Beverley Lowe and members of the Lancashire Care Trust's Research Governance Committee, in particular the Service User and Carer Subcommittee, and members of the BPS Mental Capacity Advisory Group. Thank you also to Ann Le Couteur at Newcastle University for her dedicated encouragement of the pursuit of research questions relevant to people who cannot always represent their own experiences, yet often have the highest levels of health and care needs.

How to cite this guide: British Psychological Society (2020). *Conducting research with people not having the capacity to consent to their participation: A practical guide for researchers*. Leicester: Author.

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Foreword

FOREWORD

Foreword

The purpose of the Health Research Authority, (HRA) is to promote and protect the interests of patients and the public who participate in Health and Care Research. I am therefore delighted to add a few introductory comments to this important updated guidance for researchers conducting research with people not having the capacity to consent.

The 'promote' aspect of our role at the HRA is to ensure that as many people as possible are given the opportunity to get involved in research whilst ensuring that there are appropriate safeguards in place to protect both the participant and the research team. By following the extensive guidance within this document and applying the logical step by step approach, we will all be able to fulfil the ambition of a wider group of people, enabling them to take part in studies, and offering them the same level of hope and empowerment and the opportunity to make a difference.

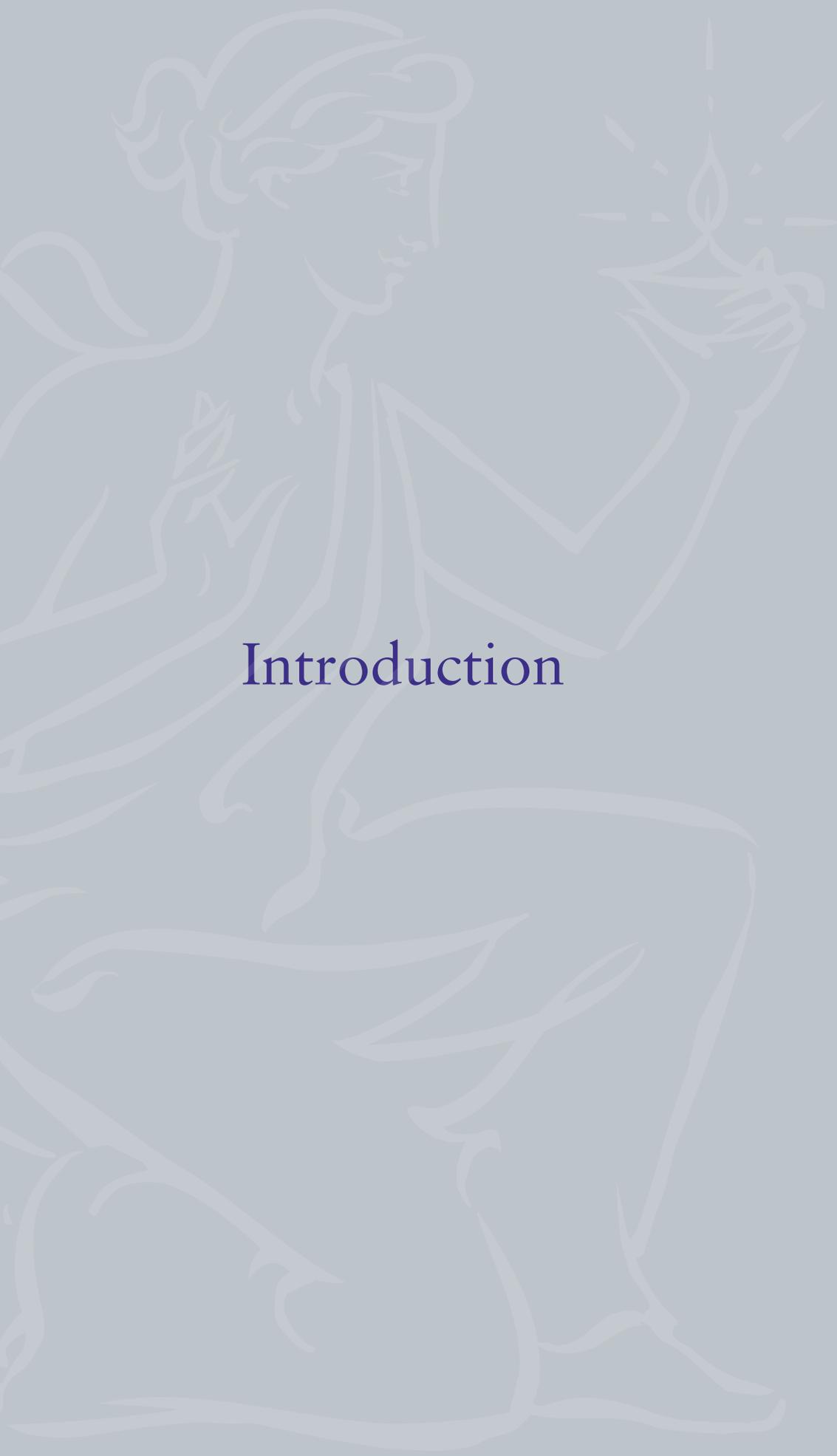
This guidance reminds us that the principle that we should assume is that a participant does have the capacity to decide whether to consent unless there is evidence that would

prevent this. I recently read a statement from a patient who expressed huge frustration that they felt disempowered by over protective healthcare professionals who were not willing to adapt their language or communication style to assist their understanding and left them unable to consent to take part in a study.

Assessing the capacity to consent is a key skill for researchers and this document has been developed by a team of experts who understand patient needs and the regulatory landscape. They have used this understanding and experience drawn from people who want to be included to develop a clearly defined approach which encourages the use of accessible language and communication aids to make research more inclusive.

I am happy to endorse and recommend this guidance.

Teresa Allen
Chief Executive
Health Research Authority



Introduction

INTRODUCTION

Introduction

The practical guide is one of a series of documents originally 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 MCA (2005) in England and Wales, the MCA (Northern Ireland) 2016 and the Adults with Incapacity (Scotland) Act (AWI) 2000 have established legal frameworks within the United Kingdom for people lacking the capacity to make decisions for themselves.

Sections 30–34 of MCA 2005, Sections 132–138 of MCA (Northern Ireland) 2016 and Section 51 of AWI (Scotland) 2000, 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 MCA was first 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 MCA (Northern Ireland) 2016, and the AWI (Scotland) 2000. At the time of updating this guide in 2018–2019 the Scottish Government was consulting on a reform of the AWI, which may bring further changes affecting research processes in Scotland.

The practical guide will be disseminated to professional groups, service user and carer groups, research organisations, university and NHS research ethics committees via publication and conference presentations. The document is also available for download from www.bps.org.uk.

THIS PRACTICAL GUIDE IS IN TWO PARTS

PART 1 IS THE PROFESSIONAL GUIDANCE AND COVER

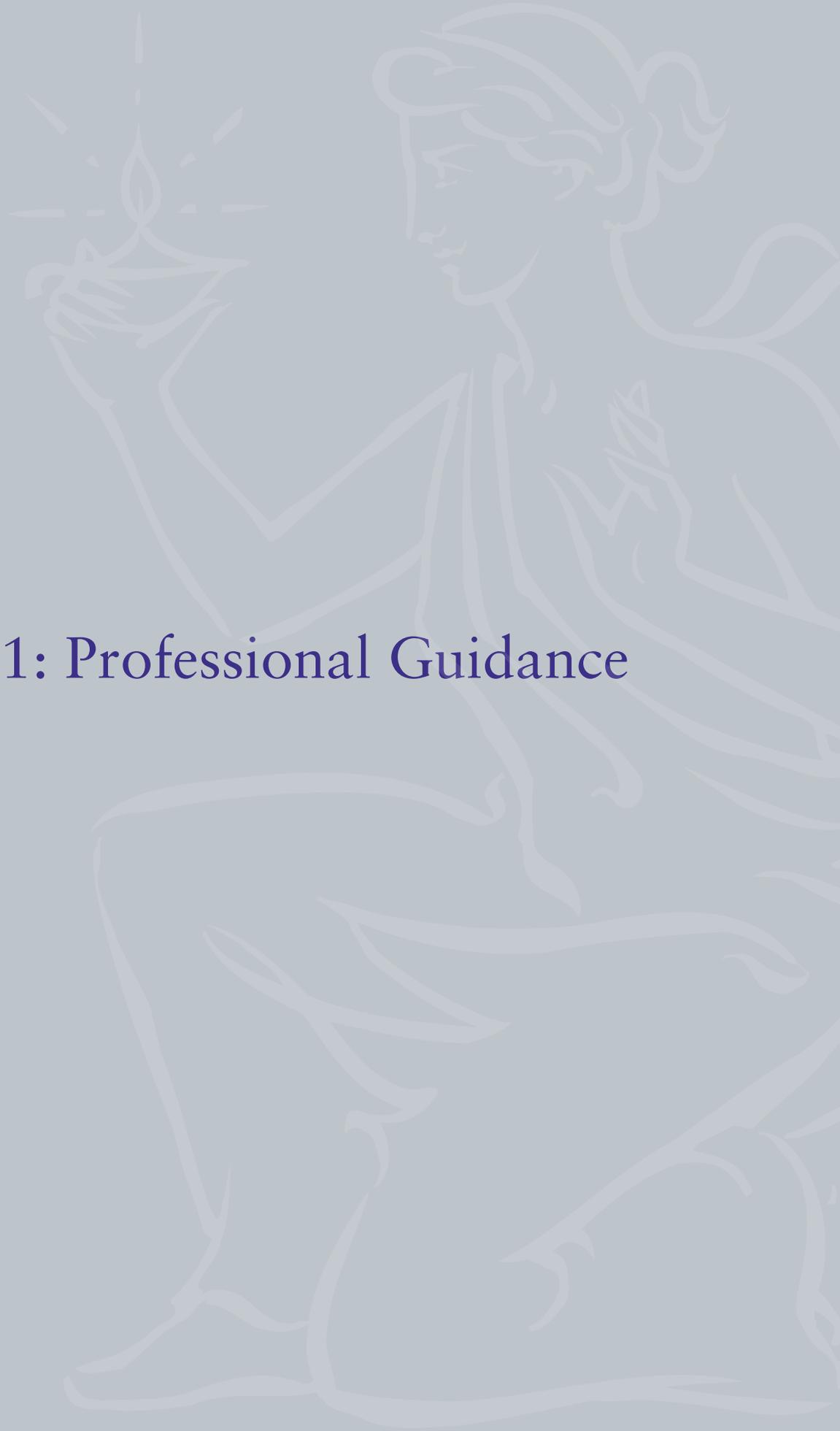
- Modifications to the research process in order that a project can comply with MCA;
- Procedures for ethical scrutiny;
- Application of the principles of the MCA to assess whether a participant can consent to their participation; and
- Safeguards afforded by the MCA, in particular the process of consultation 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.

Part 1: Professional Guidance



1. 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 new UK Policy Framework for Health and Social Care Research¹ provides a broad definition of research ‘as the

attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound 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

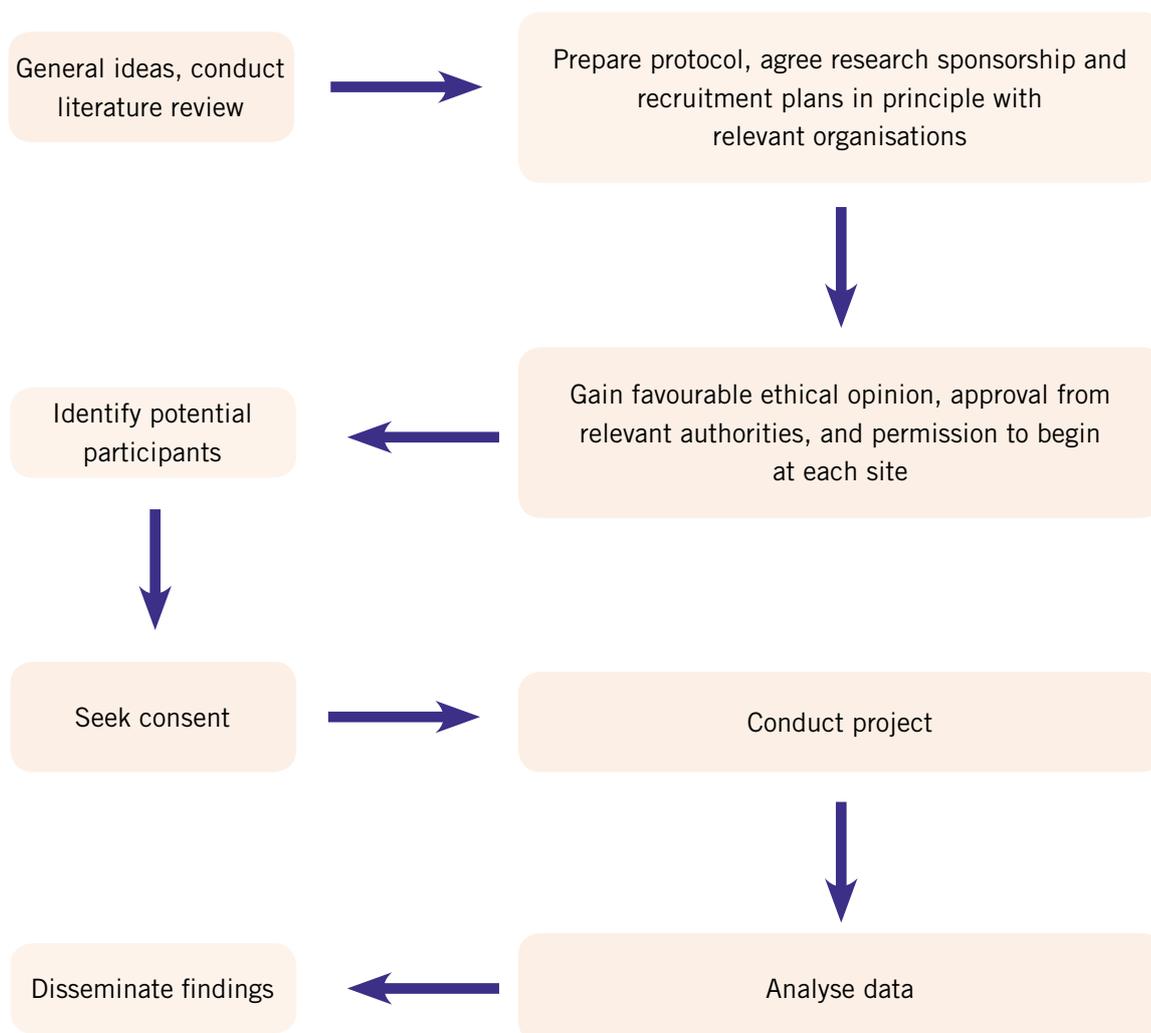


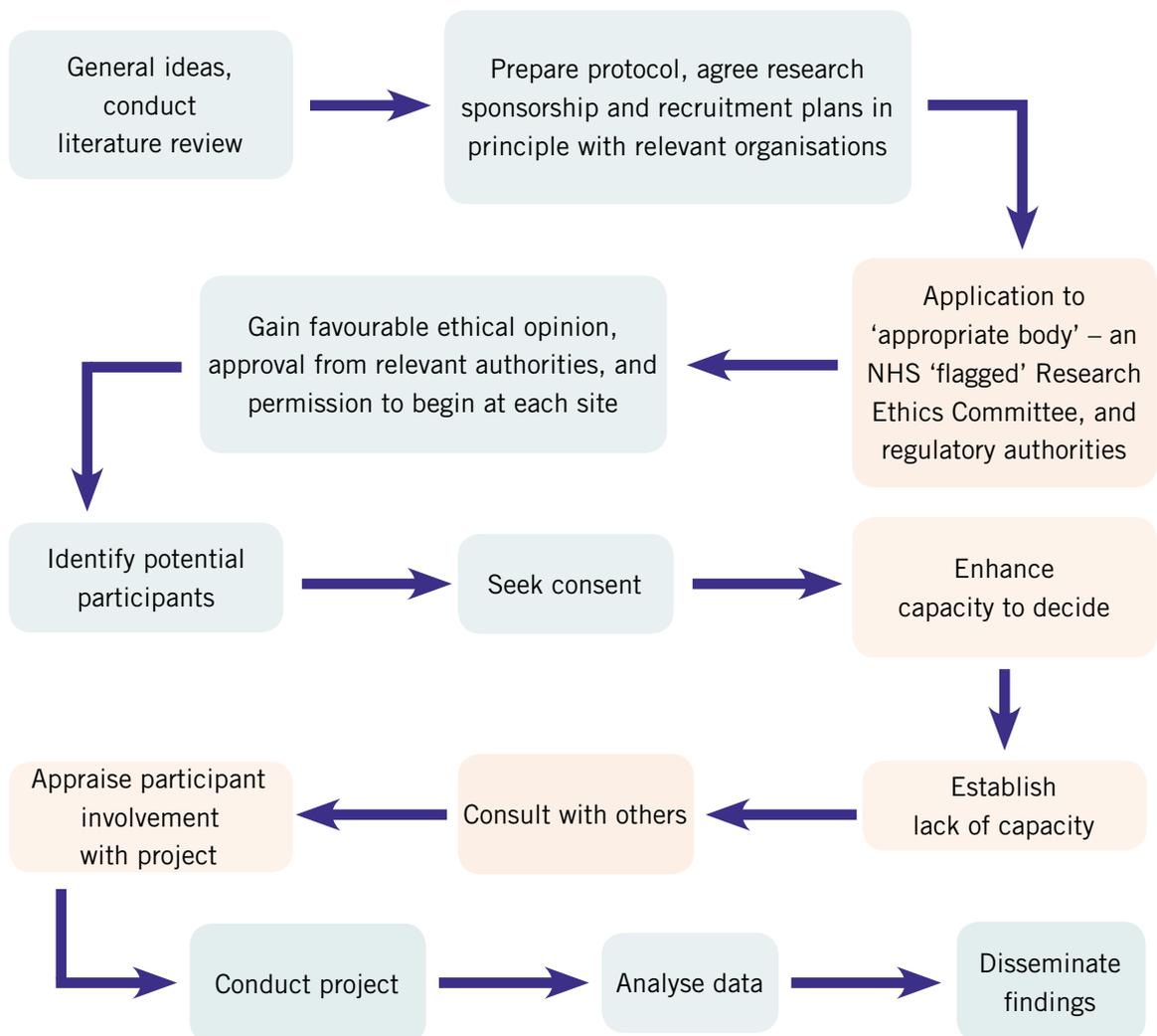
Figure 1 depicts a schematic representation of the ‘research process’ whilst Figure 2 indicates key modifications to that process so that the study meets legal requirements of the

MCA (2005) when conducting research with participants not having the capacity to consent to their participation.

KEY MODIFICATIONS TO THE RESEARCH PROCESS ENTAIL:

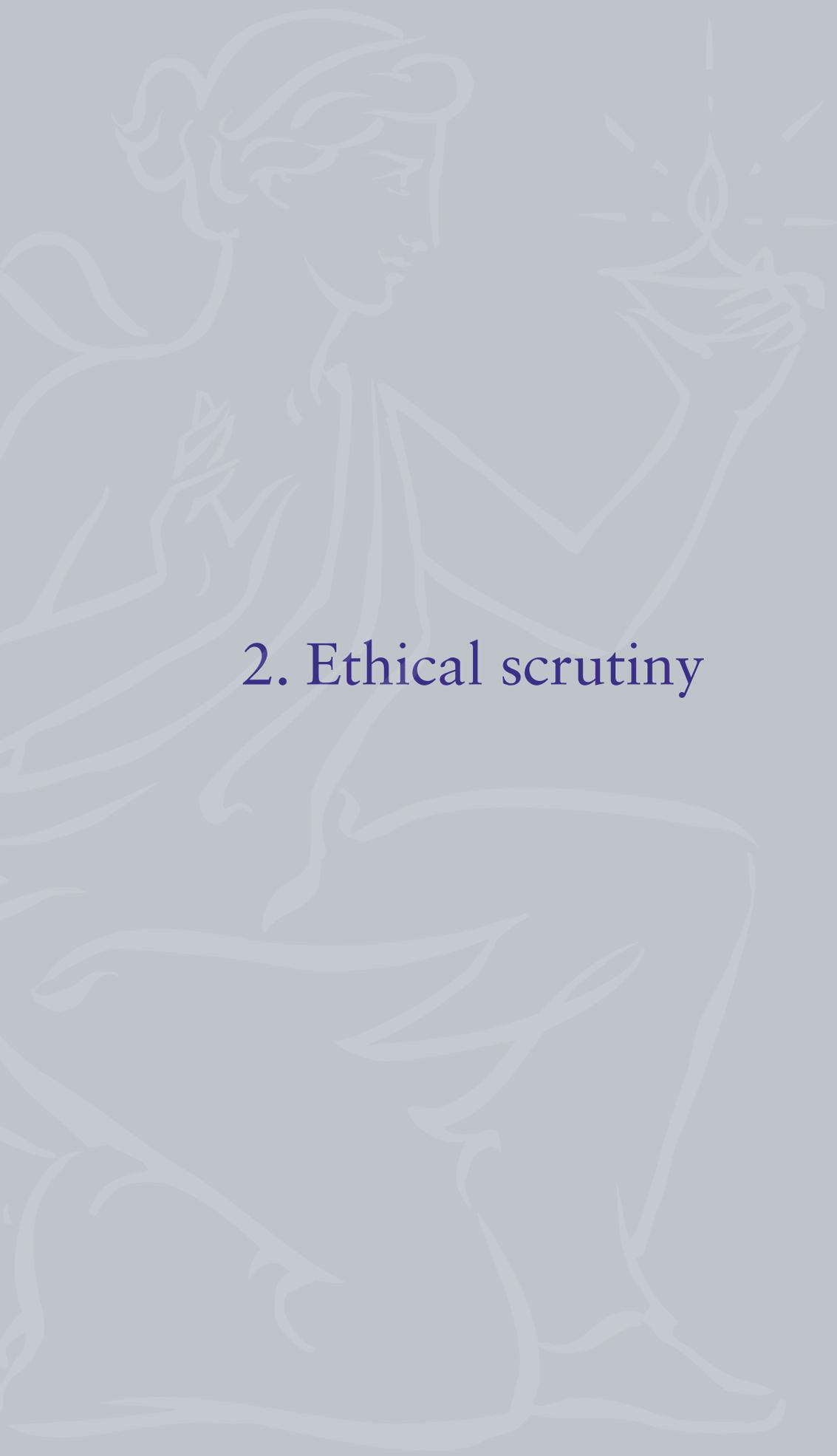
- Changes to the process of gaining ethical approval, by the submission of research for review by an ‘appropriate body’ this being one of the ‘flagged’ NHS Research Ethics Committees (see 2.2). University ethical review is not sufficient for research with people who lack capacity;
- Explicit assessment of the capacity to consent (see 3.1–3.9);
- Procedures for ensuring consultation with others (see 4.1–4.6 inclusive);
- Thorough consideration of benefit and risk to the participant;
- 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 MCA



N.B. Pink boxes 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.

2. Ethical scrutiny



2. Ethical scrutiny

2.1 PRINCIPLES OF ETHICAL SCRUTINY

Guidance and standards for the ethical conduct of research within medical, health care, and social care settings have developed significantly over the past 10 to 25 years. Currently and in response to the Care Act 2014, the Health Research Authority (HRA) coordinates research regulatory processes for health and social care research. The HRA supports Research Ethics Committees (REC) across the UK to scrutinise ethics of research applications, and conducts independent checks to ensure researchers follow good practice in the conduct and management of their work (see www.hra.nhs.uk). Similar standards of ethical review and governance now apply to 'student research' conducted as part of educational or professional training.²

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 Code³ and the subsequent World Medical Association Declaration of Helsinki⁴ 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;
- Scientifically-valid research design that could produce fruitful results for the good of society.^{2,5,6,7}

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. Herring⁸ 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 must be submitted to one of a number of 'flagged' NHS Research Ethics Committees (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' REC would be in addition to ethical scrutiny internal to the university or research organisation. Submissions of research applications in the UK to REC and relevant Regulatory Authorities are streamlined through the Integrated Research Application System

(IRAS). Specific questions about compliance with the Mental Capacity Act are found on the IRAS application form Part B Section 6. Research conducted at sites in England, Wales and Northern Ireland can be approved by a single flagged REC in England/Wales/Northern Ireland. Research conducted at sites in Scotland must have REC approval from ‘Scotland A’ Research Ethics Committee. This means that research seeking to cover sites in both Scotland and other UK countries must apply to two RECs, and may receive different responses from each.

THE KEY QUESTIONS TO ADDRESS ARE:

- 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?
- Is the research of potential benefit to the participant and is the risk proportionate? OR does the research potentially benefit others with the same or similar condition and involve negligible risk?

2.3 INTRUSIVE RESEARCH

The MCA (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 to clinical trials of investigational medicinal products (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 procedures for recruiting participants who may lack capacity, and the arrangements for accessing and consulting consultees must be also be outlined in the research protocol. If participants might regain capacity during the course of the study, consent procedures in this event should also be described in the protocol.

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. The Act makes provision for this via the Loss of Capacity During Research Project Regulations (see MCA, Section 34) and researchers are asked about this in their IRAS application form. If research conduct for managing this potential occurrence has not been detailed then the usual research process would need to be halted, the procedures revised and ethical opinion re-sought before these participants could again participate.

the Act cannot be carried out lawfully in relation to people who lack capacity.

The definition of ‘intrusive research’ in the MCA 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 (DCA, 2006), but omitted from the published Code of Practice (the primary focus for the Code not being research):

- 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;
- 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.

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 also recognises this and lists the following types of research as research that does not require consent:

- 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 where anonymised information will not suffice and consent is not practicable covered by section 251 of the NHS Act 2006 and the Data Protection Act 2018, which is approved by an NHS Research Ethics Committee and the Health Research Authority⁹.

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:

- The participant makes a decision about whether to take part or to refuse to be involved in a research project.

- 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.

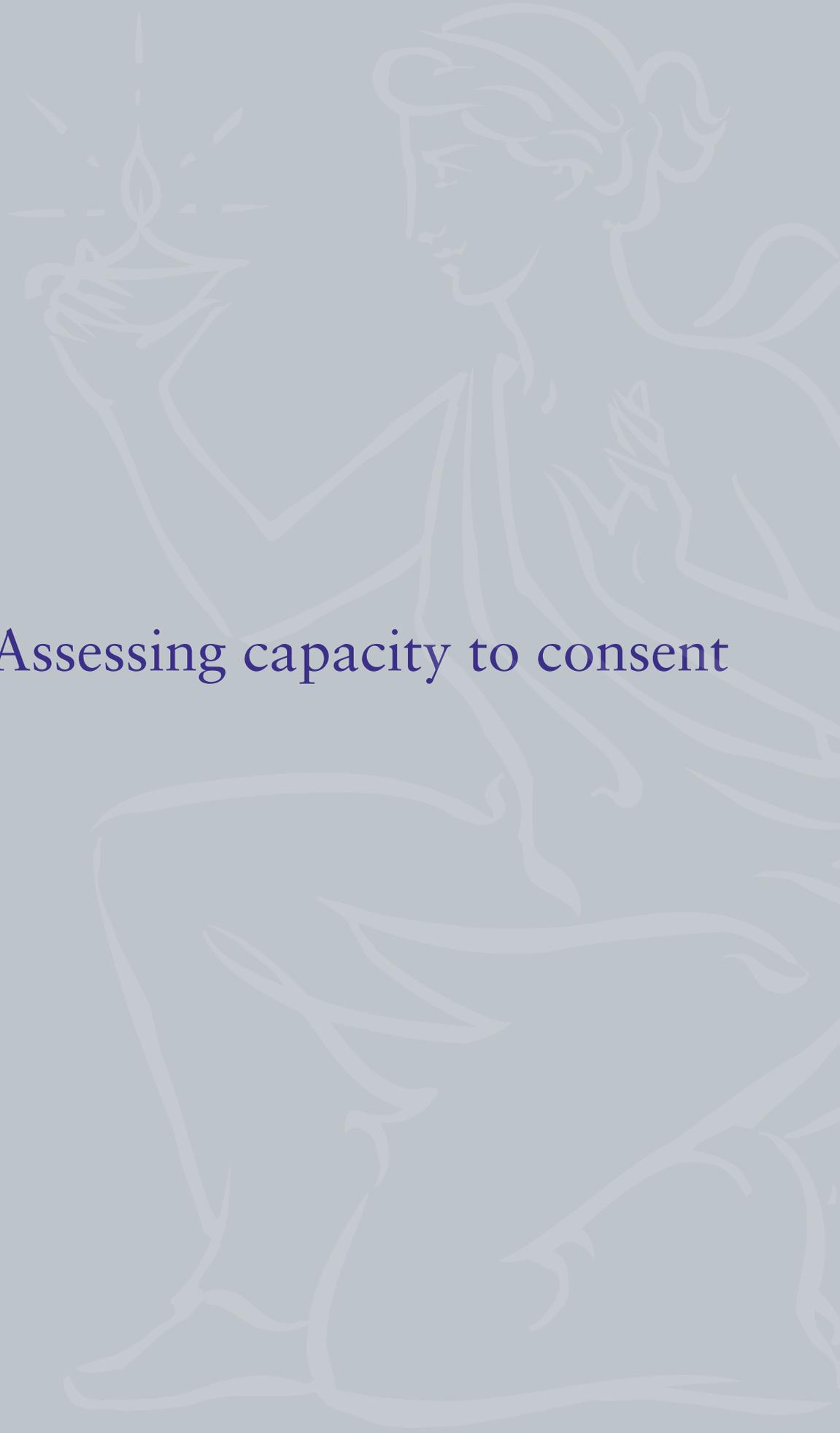
In terms of decision-making under the MCA, the key question for the researcher is, does the person have the capacity to consent (or refuse) at the time the decision needs to be made?

The Health Research Authority (HRA) adds that a proportionate approach to the process

of seeking consent 'in which the time allowed to make a decision is adapted to the needs of the specific person being approached to take part'¹⁰. When providing information about a project and seeking consent or making capacity judgements, the researcher will need to take heed of the nature of the project and the particular requirements of the project participants.

ASSESSING CAPACITY TO CONSENT

3. Assessing capacity to consent



3. Assessing capacity to consent

3.1 RECRUITMENT OF PARTICIPANTS

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

In the course of preparing 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 may 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 (Mental Capacity Act, 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) MCA 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.

The MCA 2005, the MCA (Northern Ireland) 2016, and the Adults with Incapacity (Scotland) Act 2000 apply to persons aged 16 and over.

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;

- 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.

For more detailed information about assessing capacity, please refer to the British Psychological Society’s document: What makes a good assessment of capacity?¹¹

3.3 APPLYING THE FIVE STATUTORY PRINCIPLES OF THE MCA TO JUDGE WHETHER A (PROSPECTIVE) PARTICIPANT HAS THE CAPACITY TO CONSENT

The MCA 2005 provides a decision-making framework that researchers could adopt to enable them to have a ‘reasonable belief’ that a person, aged 16 or over, 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, (3.4–3.9) 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 participant is given the project information and consent is sought.
3. The prospective participant decides whether to participate or to refuse.

4. 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.
5. 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.
6. If not certain, the researcher can use the following steps (Sections 3.4–3.9) 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.

3.4 PRINCIPLE 1 OF THE MCA

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

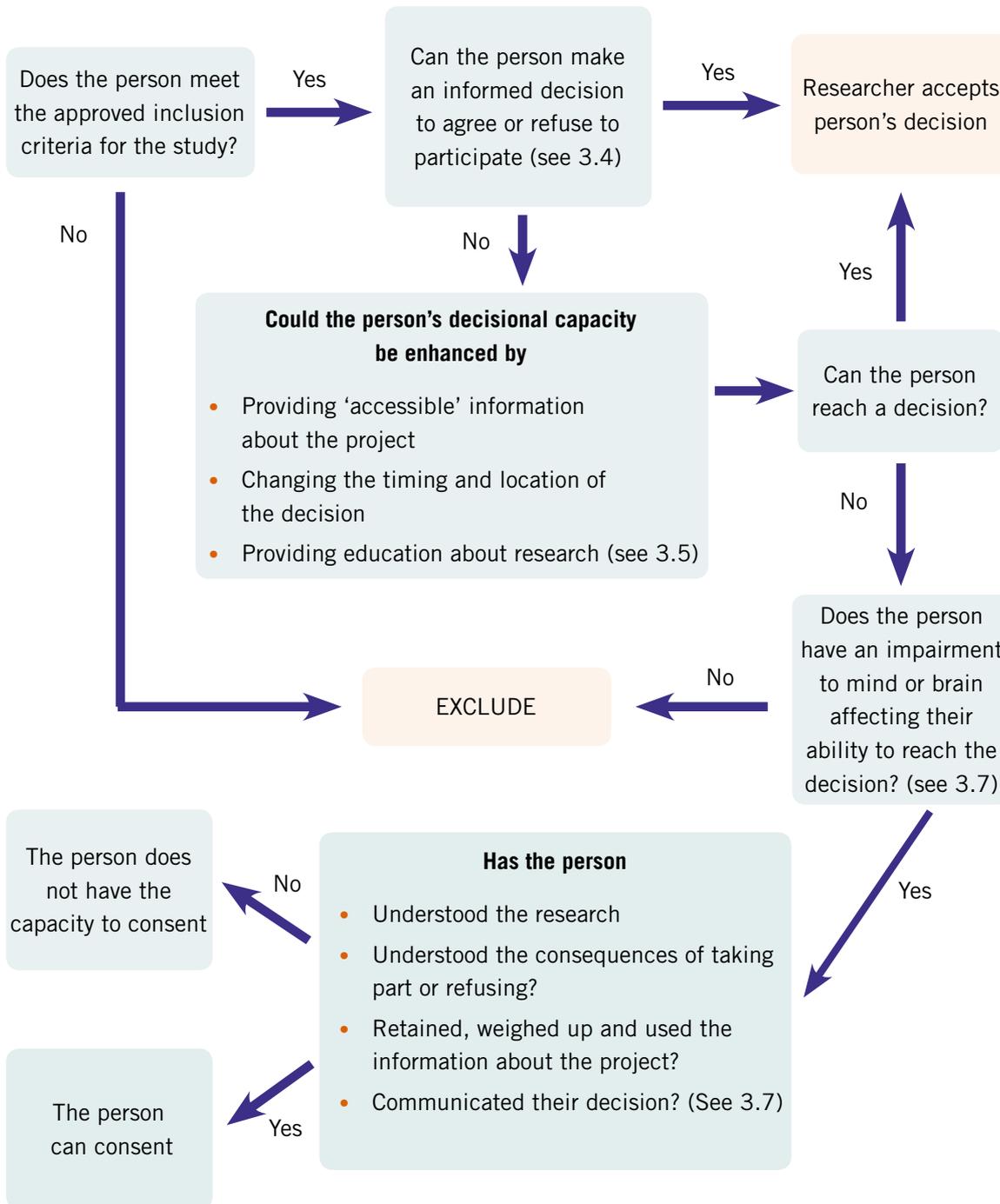
A researcher must assume that prospective participants for a research study have the capacity to consent, even when they may have a condition that may question that capacity.

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 for detail of how this judgement is reached.

Figure 3: Decision-tree for researchers in assessing capacity to consent to participate in research by persons aged 16 or over who meet the approved inclusion criteria of a study



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.
- Providing information in alternative formats, such as using multimedia, or presenting aurally for people with visual disabilities, as well as providing written portable formats. Consider conveying information with diagrams and use of colour.
- Breaking down complicated information into smaller points. Using a ‘layered’ approach to information provision⁹.
- 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.

CONSIDERING SYSTEMS FOR COMMUNICATING WITH THE PROSPECTIVE PARTICIPANT:

- Use of augmented communication or symbols or ‘talking mats’¹².
- Use of demonstration or ‘social stories’¹³ to show what practically happens when taking part.
- Can others assist the person in communicating, whilst at the same time not influencing the person in reaching a decision?

The Health Research Authority 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 www.hra-decisiontools.org.uk/consent/).

Organisations such as Connect and Medicines for Children Research Network have also produced suggestions about format and structure of information sheets.

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 some research projects may be viewed by many as bizarre or unusual.

Potential examples could include studies involving sleep deprivation, or extreme cold. Such research would be subject to ethical scrutiny. The greater the degree of risk, the higher the level of scrutiny. In assessing capacity, perceiving unwise decision making is not itself an indication of lacking capacity.

3.7 PRINCIPLE 4 OF THE MCA

States that decisions made for or on behalf of the person (are) to be made in the

person's best interests. This does not directly apply to research

3.8 PRINCIPLE 5 OF THE MCA

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 least restrictive to the person's rights and freedom of action. This principle also does not directly apply in research. However variations of Principles 4 and 5 can be seen in research ethics, which examines the risks and benefits of research. In all research the needs of the individual outweigh the needs of science or society

In contrast with many decisions under the remit of the MCA, the decision to participate in research is not an area where consideration

of an individual's 'best interests' applies as described by the MCA (see 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.

3.9 REACHING A JUDGEMENT ABOUT WHETHER A PARTICIPANT LACKS THE CAPACITY TO CONSENT TO RESEARCH

Where a judgement of lack of capacity is made, the researcher would need to prove that, on the balance of probabilities, the individual lacks the capacity to consent to participation in the research at the time that consent is required.

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;
- 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 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 themselves not been successful?

- **Retain the information 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.
2. **Use or weigh up the information**
- Can the person consider the benefits and risks of taking part in the research?
 - Can the person identify any consequences of participating or refusing to take part?
3. **Communicate their decision**
- Is the person able 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 answer is NO 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 judgement and consider whether to exclude the person from the study or to include them by taking account of the safeguards provided in the MCA.

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

3.10 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.

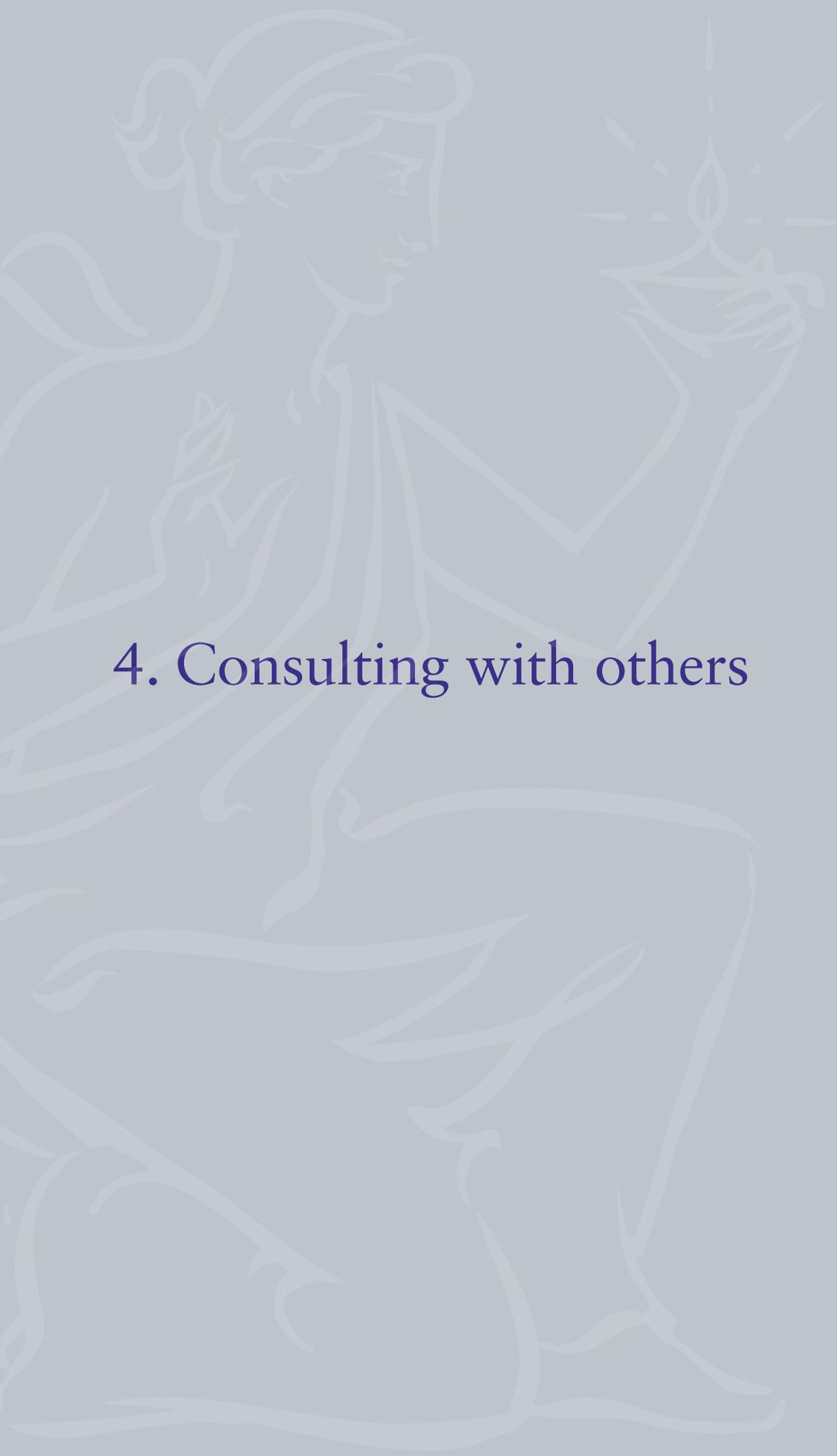
In general, under the MCA 2005 (Loss of Capacity During Research Project) (England) Regulations 2007 and The MCA 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007, if a person had given consent at some time in the past and that loss of capacity had not been anticipated, the researcher 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.
- The researcher may need to re-apply for approval from a 'flagged' Research Ethics Committee.

Studies designed since the MCA came into effect should anticipate the possibility of loss of capacity to consent and describe in their protocol and IRAS application how participants who lose capacity to consent are managed.

4. Consulting with others



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

The MCA 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 (see Section 5).

Consulting with others ensures that a person independent of the research can consider the potential participant’s presumed will about taking part when that person lacks capacity to give fully informed consent.

The term ‘consultee’ specifically relates to the Mental Capacity Act 2005 and Mental Capacity Act (Northern Ireland) 2016 legislation.

This section gives focus to how to work with Consultees in accordance with these Acts. The Adults with Incapacity (Scotland) Act 2000 (as amended) does not provide for Consultees in research but instead requires consent from the person’s guardian or welfare attorney, or where this does not exist, their nearest relative. Researchers undertaking research in Scotland need to be aware of this difference and provide separate information sheets and consent forms for this kind of consent (see AWI section 51 for

further details. The MCA requires a researcher to identify others who could be consulted about a prospective participant’s involvement in research (MCA para 32 (2)). This person must be consulted with about what the prospective participant’s wishes and feelings about participation in the project would be if the person had capacity. The Consultee could be either a relative or friend, and may be the prospective participant’s attorney or deputy if they have made a Lasting Power of Attorney (LPA). 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 who has no direct involvement with the project.

Guidance produced by the Department of Health and Welsh Assembly Government¹⁴ (2008) to accompany the MCA creates roles for ‘Personal’ and ‘Nominated’ consultees for research. 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 and research	<p>The Personal Consultee is someone the person knows and trusts with important decisions about their welfare and who:</p> <ul style="list-style-type: none"> • 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. 	<p>The Nominated Consultee is someone who:</p> <ul style="list-style-type: none"> • 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. <p>The Nominated Consultee must also be free from conflicts of interest, for example they:</p> <ul style="list-style-type: none"> • Must have no connection to the research project. • Cannot be employed by the research sponsor organisation.
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.	The researcher contacts the Nominated Consultee.
What information does the consultee receive?	<p>The researcher provides information about the project and about the role of a Personal Consultee.</p> <p>See suggested information sheet in Part 2.</p>	<p>The researcher provides information about the project and about the role of a Nominated Consultee.</p> <p>See suggested information sheet in Part 2.</p>

	Personal Consultee	Nominated Consultee
What advice does the researcher seek from the consultee?	<p>Consultee's general understanding of the project.</p> <p>Whether the participant may be interested in taking part in the project or whether they would object.</p> <p>Whether the person may benefit in any way by taking part.</p> <p>Whether the person has previously expressed views about involvement in research, assuming they had such capacity in the past.</p> <p>Whether the person has made any advance statements or has a written advance decision for refusal of life-sustaining treatment.</p> <p>Whether participation would cause any inconvenience or any other difficulty for the person.</p> <p>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.</p> <p>Whether the consultee would wish to be approached again for their views.</p> <p>Whether the consultee could suggest an alternative consultee.</p> <p>Whether, from their understanding of the person and the project, on balance the person should or should not take part.</p>	<p>Consultee's general understanding of the project.</p> <p>Whether the consultee has any personal or professional connections with the project or an interest in its outcome.</p> <p>What knowledge of the person, and if so, in what capacity.</p> <p>Whether the consultee has discussed involvement in the project with the person.</p> <p>Consultee's views about whether the participant may benefit from taking part.</p> <p>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.</p> <p>Consultee's views about whether participation may cause any problems or inconvenience.</p> <p>Whether, from their understanding of the person and the project, on balance the person should or should not take part.</p>

4.2 CONSULTING WITH A RESEARCH CONSULTTEE

The process of consultation starts with the clinical/care team contacting someone known to the prospective participant who cares about their welfare, to invite them to be consulted about their relative's or friend's involvement in the project (see Figure 4). If the relative or friend accepts the invitation to be a Personal Consultee, arrangements to discuss the project with the researcher. The process of identifying a Consultee requires the researcher to seek

a Personal Consultee first. Only if a Personal Consultee cannot practicably be found then the researcher may identify a Nominated Consultee, that is someone who knows the person in a professional capacity (see below).

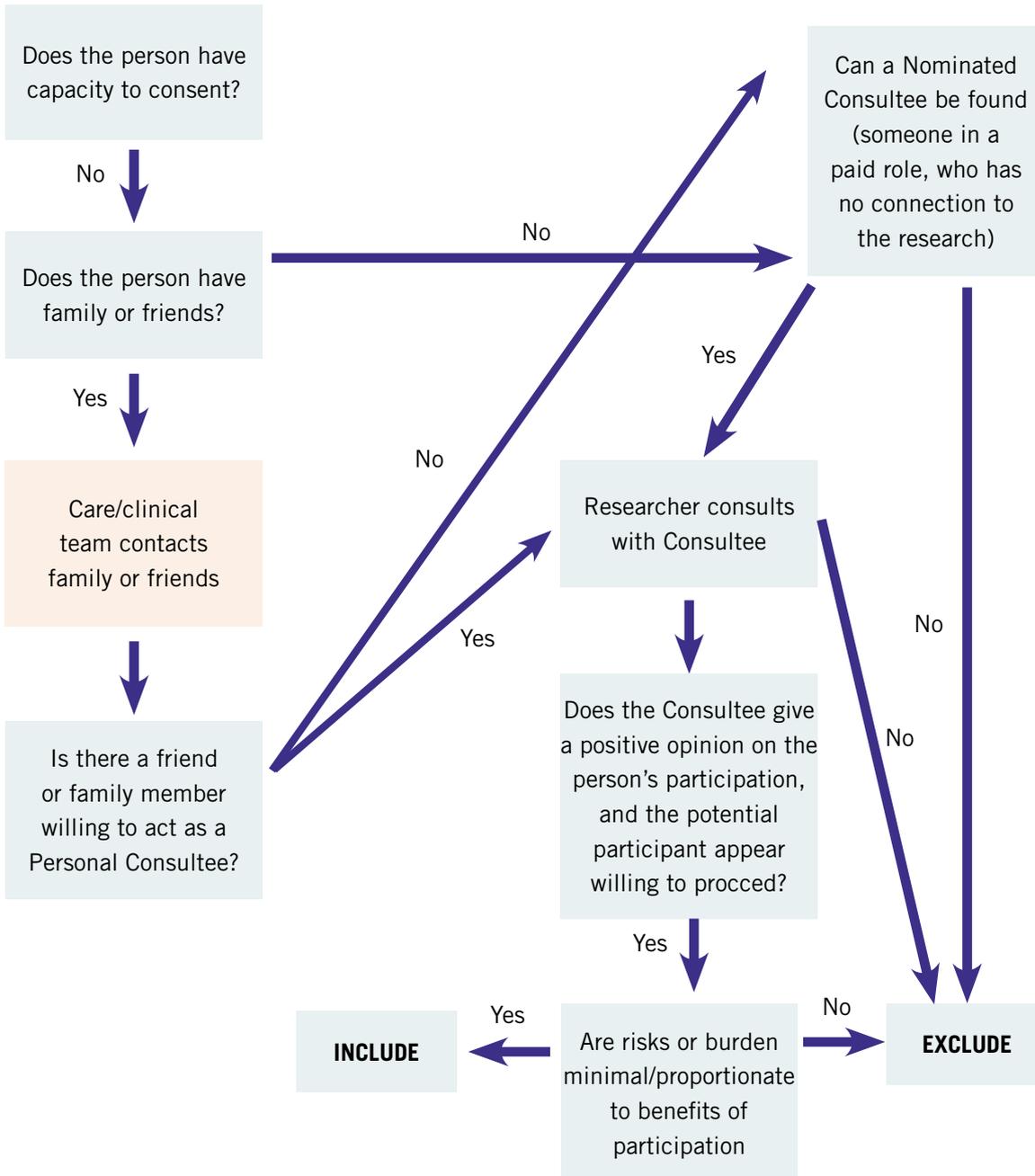
The researcher needs to make clear that they are seeking the Consultee's views about whether or not the prospective participant may wish to take part, not their own views about the project. The views and opinion of the Consultee

will need to be documented by the researcher for later reference. Suggested proformas are provided in Part 2.

process to confirm whether the participant would wish to continue with or to decline taking part in the project.

The researcher may also need to approach the Consultee at later stages in the research

Figure 4: Seeking advice from a consultee



4.3 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

The researcher is required to seek consultation with a Personal Consultee first, before considering speaking to a Nominated Consultee. 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.

4.4 NOMINATED CONSULTEE

Where the person has no family or friends who are able or feel willing to be Consultees for the research, then section 32(3) of the MCA provides provision for the researcher then to nominate a 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. They cannot be employed by the research sponsor organisation, be a member of the research team, or be in a position where they are unduly influenced by the research team.

Guidance prepared by the Department of Health and the Welsh Assembly Government¹⁴ 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.

4.5 CONSULTING WITH OTHERS IN EMERGENCY CARE RESEARCH

The Guidance produced by the Department of Health and Welsh Assembly Government¹⁴, to accompany the MCA also details how to plan for research in urgent care settings. In these situations where Consultees cannot be consulted with in adequate time for decisions to be made, the research protocol may include provisions such as agreement by independent doctor who has no connection

with the research, or alternative procedures agreed by the Research Ethics Committee. These provisions act as a temporary measure and the researcher must continue to make arrangements for seeking consent from the participant after they have regained capacity, or for consulting with a Consultee as soon as is reasonably practical.



5. Appraising participant involvement

5. Appraising participant involvement

5.1 APPRAISING WHETHER TO INCLUDE OR EXCLUDE A PARTICIPANT WHO LACKS CAPACITY TO GIVE CONSENT

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 judgements the researcher needs to make about including people who lack capacity to consent.

The requirements listed above can be debated in principle in the study protocol and in the application for ethical approval. The fifth point about the impact of involvement in the project for the individual participant, consultation with others.

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.

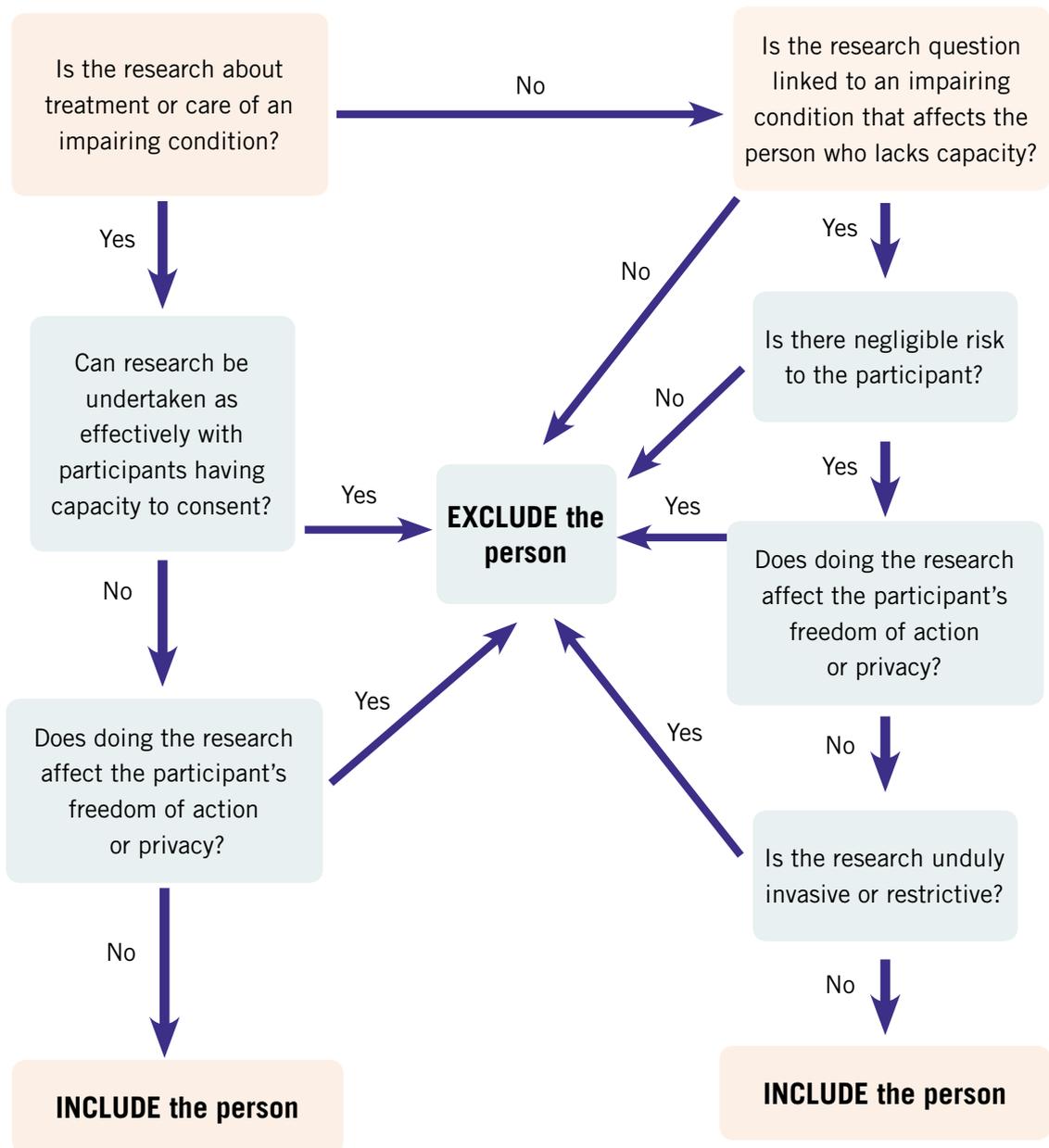
Participants who lack capacity to give fully informed consent for research still need to be willing to take part. If they are no longer willing then the researcher must withdraw them from the research. The only exception to this is if the unwillingness or resistance shown is in relation to a procedure designed to keep them from harm or eliminate pain or discomfort. In assessing willingness across the course of the

research, the researcher needs to consider the environment that the participant is in. The participant may be susceptible to influence as a result of pressure from researcher or carer or by merely being in the research environment. Researchers need to be aware of potential behaviour, both verbal and non-verbal which indicates that the person may wish to withdraw. Examples may be that the person pushes the equipment away or takes themselves away from the researcher, and respond to these signs and withdraw the participant if it is safe to do so.

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. These considerations need attention throughout the person's involvement and 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.

Figure 5: Appraising an individual's involvement in a project when they lack capacity

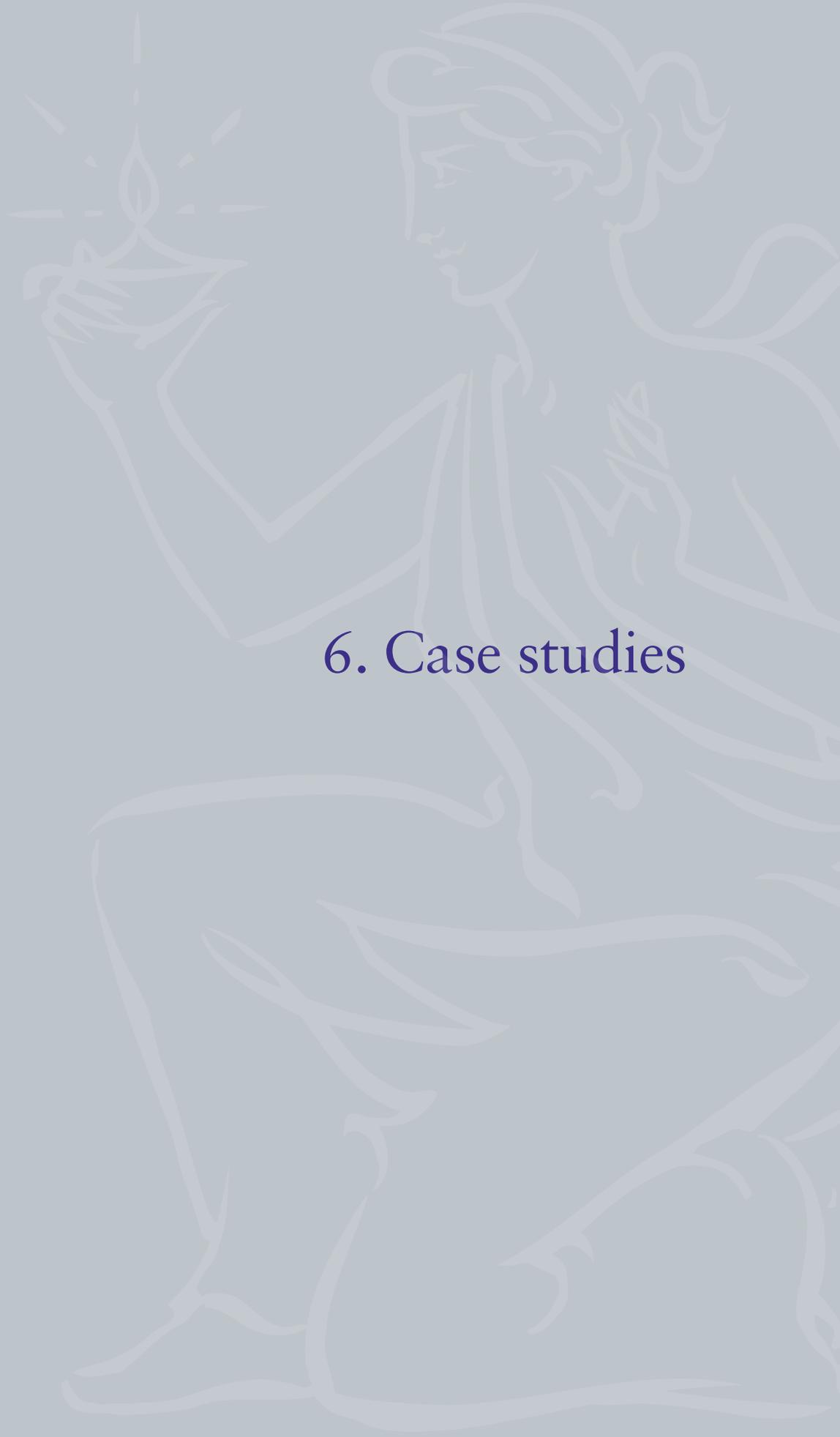


5.3 RECOMMENDATIONS FOR GOOD PRACTICE

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, monitored and audited.
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.

CASE STUDIES

6. Case studies



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: 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; and
- 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.

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.

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 Consultee.

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?
- b) Affect Susan's freedom of action or privacy?
- c) Be unduly invasive or restrictive?

A:

- 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) 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) 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.

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.

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'.

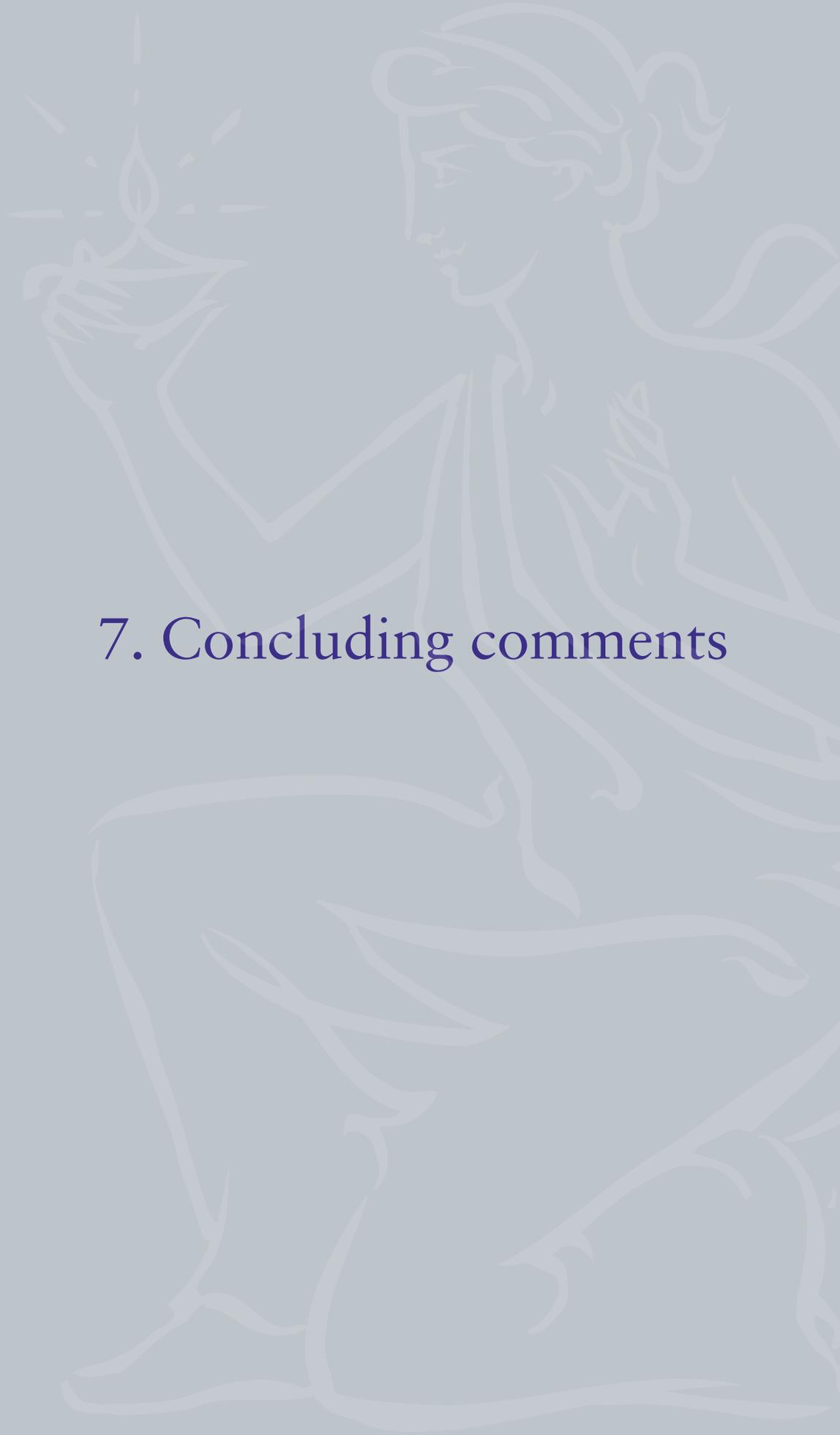
Consideration of whether research is unduly invasive or restrictive may also be different for different people. The MCA Code of Practice suggests that 'unduly invasive' research is that which does not go beyond 'the experience of daily life. Routine medical examination or psychological assessment is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

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 Guide¹⁷, 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.

7. Concluding comments



7. Concluding comments

The Mental Capacity Act (MCA) 2005 in England and Wales, the Mental Capacity Act (Northern Ireland) 2016 and the Adults with Incapacity (Scotland) Act (AWI) 2000 allow for the inclusion of people not able to consent in research, enabling access to experiences and potential treatments and care for which they may not hitherto have been considered. The legislation has sought to balance such access with safeguards applying at different stages of the research process.

Integral to working with vulnerable people who have an impairment is the need to offer support for capacity. Support is equally valuable for people who are judged to lack capacity, so that their wishes and feelings are understood and respected as much as possible. Lacking capacity is not a one-time decision, and can vary for different decisions or at different points of time. It is therefore important for researchers to be proactive in offering support and attention to research participants – whatever their level of mental capacity.

Preparation of this 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.

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

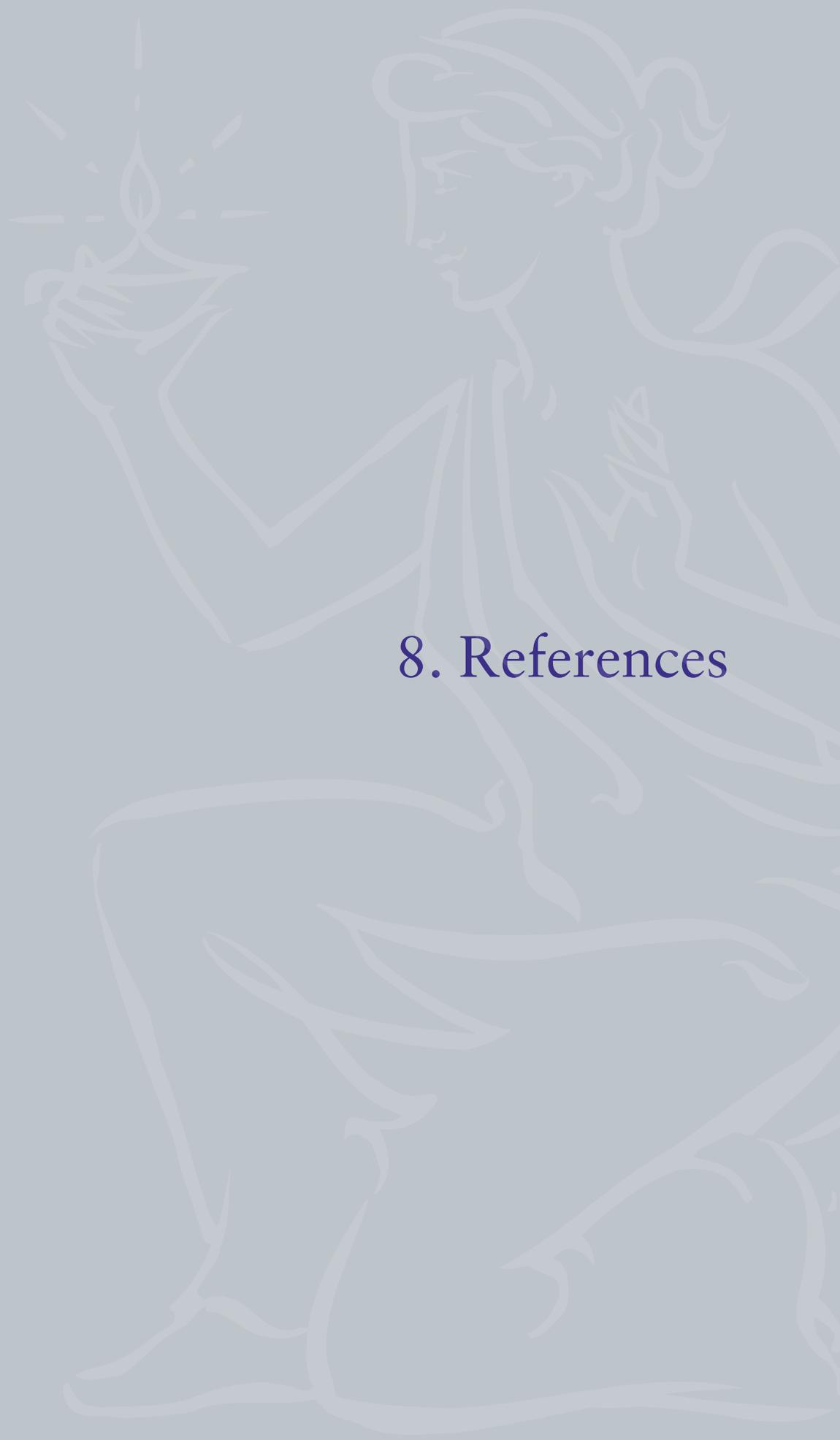
process. After much deliberation, the author considered that taking a systemic view of the research process would provide a meaningful structure for materials that a researcher may find useful.

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.

In addition, future research questions relating to key elements of the MCA in practice are being highlighted in both the research literature and in health and social care practice guidelines^{18,19}. Currently there exists a need to develop and examine resources and interventions that have potential to support capacity and decision-making processes. There is also a need to explore mental capacity assessment tools that may assist in specific decisions of capacity, and to examine the effectiveness of different training programmes to improve practice. These research questions demonstrate that there is still much to be done to develop best practice, and we look forward to seeing improvements in this field over the coming years.

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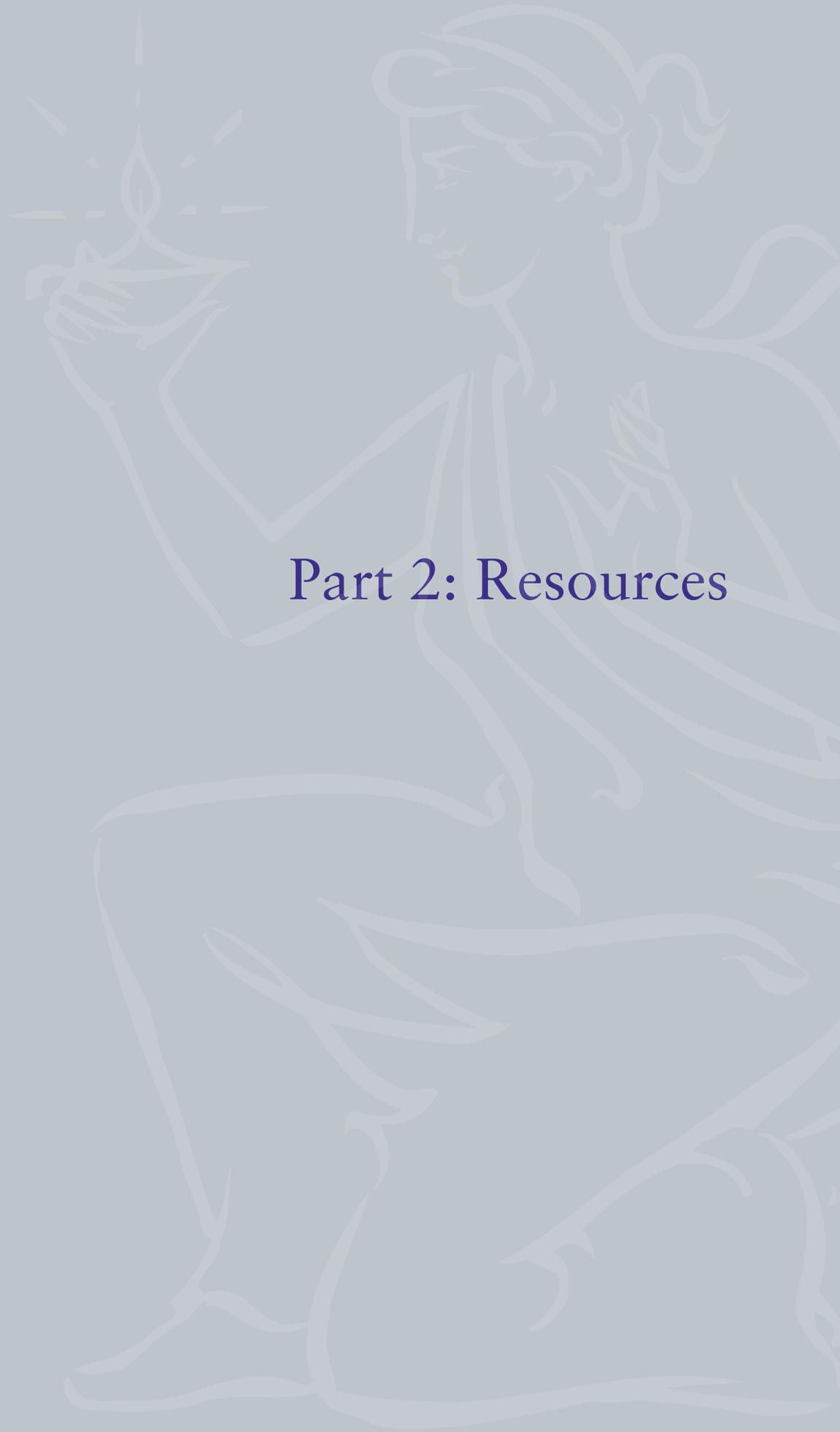


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APPENDIX

Part 2: Resources



9. Appendix 1 – 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 is listed on the Health Research Authority website

(see www.hra.nhs.uk/about-us/committees-and-services/res-and-recs).

FLAGGED RECS FOR RESEARCH INVOLVING ADULTS UNABLE TO CONSENT FOR THEMSELVES

Social Care

Social Care Research Ethics Committee

England

East of England – Essex

East of England – Cambridge Central

Health and Social Care Research Ethics Committee A (HSC REC A)

Health and Social Care Research Ethics Committee B (HSC REC B)

London – Camden and Kings Cross

London – Brighton and Sussex

London – Bromley

London – Camberwell St Giles

London – Harrow

London – Queen Square

London – South East

Social Care Research Ethics Committee

North East – Newcastle and North Tyneside 1

North East – Newcastle and North Tyneside 2

North West – GM South

North West – Haydock

South Central – Hampshire A

South Central – Berkshire

South Central – Oxford C

West Midlands – Coventry and Warwickshire

Yorkshire and the Humber – Bradford Leeds

Yorkshire and the Humber – Leeds East

Yorkshire and the Humber – Leeds West

Wales

Wales Research Ethics Committee 1

Wales Research Ethics Committee 2

Wales Research Ethics Committee 3

Wales Research Ethics Committee 4

Wales Research Ethics Committee 5

Wales Research Ethics Committee 6

Wales Research Ethics Committee 7

Scotland

Scotland A Research Ethics Committee

Northern Ireland

Health and Social Care Research Ethics Committee A (HSC REC A)

Health and Social Care Research Ethics Committee B (HSC REC B)

10. Appendix 2 – Roles and responsibilities in the research process

The definitions of roles and responsibilities in the research process are outlined in the new UK Policy Framework for Health and Social Care Research¹.

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 Bold in Table 2.

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

Chief Investigator, Principal Investigators, and other Researchers	<ul style="list-style-type: none"> • Developing proposals that are scientifically sound and ethical. • Seeking NHS Research Ethics Committee and HRA 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. • Communicating with Consultees. • Deciding if individual prospective participants can take part.
Research Ethics Committee	<ul style="list-style-type: none"> • Providing an independent expert opinion on whether the proposed research is ethical and respects the dignity, rights, safety and wellbeing of participants. • Assessing research protocol and materials in accordance with lacking capacity legislation
Sponsor	<ul style="list-style-type: none"> • Taking overall responsibility for confirming that everything is ready for the research to begin, including: <ul style="list-style-type: none"> • 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. • Appropriately support patient, service user and public involvement.
Main funder	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Providing training for researchers. • Supporting research set-up at sites. • Supporting research delivery in health and social care settings.

11. Appendix 3 – Checklists, sample letters and proformae

1. CHECKLIST ASSESSING CAPACITY TO CONSENT AND PARTICIPATION IN RESEARCH

<p>Diagnosis</p> <p>The Mental Capacity Act applies to persons whose ability to make a capacitous decision is affected by <i>‘an impairment of, or a disturbance in the functioning of, the mind or brain’</i> (MCA 2005, pg.2)</p> <p>1. Is there evidence to demonstrate impairment or disturbance of the mind or brain?</p> <p>If the answer is NO then the person does not meet criteria for a lacking capacity judgement.</p> <p>If the answer is YES continue to the next section.</p>	
<p>Enabling Capacity</p> <p>2. Have you made every effort to enable the prospective participant to make the decision themselves to participate or refuse?</p> <p>3. Have you used language or methods of communication that the person is most likely to understand?</p> <p>4. Have you given sufficient time for the person to think about the project?</p> <p>If the answer is NO to any of these items revisit steps that can be implemented to potentially enable capacity.</p> <p>If the answer is YES continue to the next section.</p>	
<p>Involving others</p> <p>Involving others as Consultees is essential in the event of a lacking capacity decision, however it may be that involving others can support capacitous decision-making.</p> <p>5. Have you supported the prospective participant to discuss the study with people they trust?</p> <p>If the answer is NO revisit options for involving others to support capacity.</p> <p>If the answer is YES continue to the next section.</p>	
<p>Capacity Assessment:</p> <p>When the information is presented appropriately to the prospective participant’s circumstances:</p> <p>6. Does the person understand that they can consent to or refuse to participate in research?</p> <p>7. Does the person understand what the research is about?</p> <p>8. Has the person retained the relevant information, even for a short period of time, as required to make a decision?</p> <p>9. Does the person understand and weigh-up benefits and risks/inconveniences of agreeing or refusing to take part?</p>	

10. Has the person been able to communicate their decision in any way?

If the answer is YES to all of these items (6–10) the prospective participant has capacity to provide their consent or refuse to take part in the research.

If the answer is NO to any of the items (6–10), the person DOES NOT have the capacity to consent to, or refuse to, take part in the research project.

Continue to the next section.

Lacking Capacity Decisions and Timing:

11. Is it likely that the person's capacity to make the decision will improve in the near future?

12. Can the prospective participant be approached at another time when they may have capacity to consent?

If the answer is YES to both these items, approach at another time when capacity is regained.

If the answer is NO continue to the next section.

Section 2: Assessing participation in research for individuals who lack capacity

Advance Decisions by people who lack capacity:

13. Does the research go against any wishes stated on an advance decision or decision stated by the potential participant?

If the answer is YES they cannot take part in the research.

If the answer is NO continue to the next section.

Inclusion of Adults who Lack Capacity in Research:

For research that does not involve medicinal products, the inclusion of adults who lack capacity depends upon opinion from a 'Personal Consultee', or a 'Nominated Consultee' where no Personal Consultee is possible.

14. Does the Research Protocol include adults who lack capacity in research?

15. Does this participant meet the Protocol Eligibility Criteria?

16. **In the case of emergency research:** Have the REC and HRA approved the Research Protocol to include participants in an emergency, and have the agreed processes been followed?

17. Is the participant likely to incur any burden by participating? Does the benefit outweigh the burden of participation?

18. Are any risks proportionate, or negligible for this individual participant?

19. Is there a Consultee who can be consulted with about the person's involvement in research?*

20. Does the person lacking capacity show willingness to participate in the research?*

If the answer is YES to all of these items the adult who lacks capacity to consent may be included in the research, providing that the Consultee agrees and is able to fulfil the requirements of the protocol.

If the answer is NO to any of these items then the potential participant is not eligible to be a participant in the research study.

** In the case of emergency research, the researcher must continue to make arrangements for seeking consent from the participant after they have regained capacity, or for consulting with a Consultee as soon as is reasonably practical.*

2. CONSULTING WITH A PERSONAL OR NOMINATED CONSULTEE

2.1 Checklist for communication with a Consultee

Project title: IRAS ID:	Participant code
The inclusion of adults who lack capacity depends upon opinion from a <i>'Personal Consultee'</i> , or a <i>'Nominated Consultee'</i> who has no connection to the research where no Personal Consultee is possible.	
Does the potential participant have a consultee who meets these requirements?	
First communication with their consultee is usually the care home or clinical team (unless stated otherwise in the protocol) – has this occurred?	
Has the Consultee received their REC approved Consultee Information sheet, and had the opportunity to ask questions?	
Has the Consultee completed their REC approved consultee declaration form?	

2.2 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 whethermay 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

2.3. 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 this 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 wellbeing 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).

2.4. Invitation to act as a Personal Consultee

<p>Invitation to act as a Personal Consultee</p>		<div style="border: 1px solid black; padding: 5px; width: fit-content;">Participant code:</div>
<p>Project title: IRAS ID:</p>		
<p>I think that my partner, friend or relative may NOT like to take part in the project.</p>	<p>Signed.....</p>	
<p>I think that my partner friend or relative may be interested in taking part and I would like to discuss this with the researcher.</p>	<p>I agree to being contacted further about the project</p> <p>Signed</p>	
<p>I think that my partner, friend or relative may like to take part in the project – but I do not wish to be consulted.</p>	<p>I do not agree to being contacted further about the project</p> <p>Signed.....</p>	
<p>Thank you for completing the form. Please send in the stamped addressed envelope to XXX care team/care home/clinical team.</p>		

2.5. Sample Personal Consultee Declaration

Research centre/sponsor headed paper

Personal Consultee declaration

(Version Date.....)

Participant code:

Project title:

IRAS ID:

<p>I confirm that I have read and understood the Information for Consultees (version ... dated....) for the study.</p> <p>I confirm that I have had time and opportunity to ask questions about the study or my role as a Personal Consultee.</p> <p>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.</p> <p>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.</p> <p>I understand that if my partner, friend or relative were withdrawn from the project, this would not affect in any way the care or treatment they receive, or affect their legal rights.</p> <p>I understand.....(<i>other features relevant to the project, such as what data is collected, who has access to person identifiable data, how it is stored and transferred, that my partner, friend, relative's GP will be informed about their involvement in the study</i>)</p>	<p>Please initial your confirmation/understanding below.</p>
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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.

2.6. 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 this 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.

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.

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).

Invitation to act as a Nominated Consultee

Research centre/sponsor headed paper

Invitation to act as a Nominated Consultee

Participant code:

Project title:

IRAS ID:

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

2.8. Nominated Consultee declaration

Research centre/sponsor headed paper

Invitation to act as a Nominated Consultee

Participant code:

(Version Date.....)

Project title:

IRAS ID:

<p>I confirm that I have read and understood the Information for Consultees (version ... dated....) for the study.</p> <p>I confirm that I have had time and opportunity to ask questions about the study or my role as a Personal Consultee.</p> <p>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.</p> <p>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.</p> <p>I understand that if my partner, friend or relative were withdrawn from the project, this would not affect in any way the care or treatment they receive, or affect their legal rights.</p> <p>I understand.....(other features relevant to the project, such as what data is collected, who has access to person identifiable data, how it is stored and transferred, that my partner, friend, relative's GP will be informed about their involvement in the study)</p>	<p>Please initial your confirmation/understanding below.</p>
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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.



the british
psychological society
promoting excellence in psychology

St Andrews House,
48 Princess Road East,
Leicester LE1 7DR, UK

☎ 0116 254 9568 📠 0116 227 1314 ✉ info@bps.org.uk

www.bps.org.uk

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REP135/03.2020