

INCLUDE Impaired Capacity to Consent Framework

Key questions to ensure your trial is designed for all who could benefit

Trial teams need to do everything possible to make their trial relevant to the people that the results are intended to apply to (often patients) and those who are expected to apply them (often healthcare professionals). The **four generic questions** below are intended to prompt trial teams to think about who should be involved in their trial as participants, and how to facilitate their involvement as much as possible. These questions should be considered by trial teams in partnership with patient and public partners, including individuals from, or representing, groups identified in Question 1. Note that:

* *‘Intervention*’ means the treatment, initiative or service being evaluated.
* ‘*Comparator*’ means what the intervention is being compared to.
* Diagram, timeline

  Description automatically generated‘*Effective*’ means the intervention provides important benefits for people with the disease or condition that is the focus of the trial.

We have developed a **series of worksheets** to help answer these with respect to adults with impaired capacity. We recommend that trial teams use these questions and worksheets (preferably at the design stage) to help them think through their answers to the four key questions identified below and then identify any considerations needed. See **Figure 1** for a diagram of the framework.

**1. Who should my trial results apply to?**

**Figure 1. Diagram of INCLUDE Impaired Capacity Consent Framework**

The underlying principle is that all groups should be offered the chance to participate in research. Consider whether there are reasons why any groups should be excluded from this study, and which groups in the population could benefit from the intervention if found to be effective (or benefit from not having it if found to be ineffective and/or harmful)? Consider whether the disease or condition you are studying is more prevalent in certain groups of the population (e. g people with particular conditions or disabilities) or if it would affect groups differently (e.g have a greater severity or impact on people with a particular condition or disability). As this framework relates to adult populations with impaired capacity to consent, think particularly about conditions or disabilities that can affect a person’s ability to provide consent but there may be other conditions or intersecting factors to consider.

**2. Are the groups identified in Question 1 likely to respond to the intervention and/or comparator in different ways?**

How might some groups in the population respond to, or engage with, the intervention(s) being tested in different ways?

**3. Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?**

How might the intervention and/or comparator, including how they are provided, make it harder for some groups in the population to take part in the trial?

**4. Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part and remain in the trial?**

How might elements of trial design, such as eligibility criteria, recruitment and consent process, or data collection methods, make it harder for some groups in the population to take part and remain in the trial?

Worksheets for thinking through factors that might limit the involvement of adults with a condition or disability that may impair their capacity to consent

The **worksheets A-F** are intended to be used by trial teams in partnership with patient and public partners (and other stakeholders) to ensure that the involvement of adults with a condition or disability that may impair their capacity to consent is considered at the trial design stage.This impaired capacity may be **due to the condition** or disability that is the focus of the trial or may be **co-existing** with the condition or disability that the trial is focused on. The impairment may be **long-term,** a **temporary or** **acute** impairment where the intervention being tested cannot wait for the person to recover capacity, or the person’s capacity may **fluctuate**. While the framework may cover issues that some trial teams already think about, the worksheets will help to highlight issues consistently across trials for all trial teams, as well as raising some questions that may not be considered at present.

The final **worksheet G** provides a space to summarise the actions you may need to take in order to address the issues you have identified, and any resources/costs needed to enable the participation of adults with impaired capacity to consent. You may wish to populate this summary with the actions/considerations you have identified as you go along.

While the worksheets ask trial teams to think about possible differences between groups who may experience impaired capacity, it is important to remember that there are also differences *within* groups. No group is homogenous, and there will be intersectionality between these and other factors or personal characteristics. Tailored support can help meet individuals’ information and decision support needs to maximize their ability to understand information and provide their own consent or contribute to decisions about participation.

See [**Appendix 1**](#Appendix1) for more on the legal definition of capacity and the legal arrangements for including adults with impaired capacity to consent. As the legal frameworks require researchers to justify the inclusion of adults who lack capacity to consent, the benefit and risks, and that appropriate consent arrangements are in place, working through the framework may enable researchers to explore and clarify these aspects. This might include **why** the intervention could not solely be evaluated with people who are able to provide their own consent, **how** consent arrangements will be tailored according to the needs of participants and aligned with the specific trial context, and **whether** processes for data collection and use of data may need to be flexible to account for changes in capacity over time. This could then inform the initial trial design, help justify any additional resources being requested in a funding application, and provide the information needed to support an application to include adults lacking capacity when seeking ethical approval.

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| **Who should my trial results apply to?** |
| The underlying principle is that all groups should have an opportunity to participate in research. Think about **who could benefit from the intervention** if effective, or not having it if found to be ineffective (e.g people with particular types/severity of conditions or disabilities that may affect their capacity to consent).  **Q1** |
| *[NB: The information in the framework is based on a sepsis management trial. It is intended to be illustrative and may not be a proper reflection of the trial. It was completed by Victoria Shepherd, Cardiff University who was not involved in the trial nor discussed the framework with the trial team. The worksheets were completed retrospectively rather than at the trial design stage.]*  This is a randomised controlled trial (RCT) investigating the management of adults with suspected sepsis presenting to the Emergency Department (ED). It compares standard clinical management plus a point-of-care test (POCT) compared with standard clinical management alone to see whether this approach reduces antibiotic prescribing without increasing mortality.  Sepsis is a life-threatening condition and is a medical emergency requiring prompt treatment (Sepsis-3 definition). The guidelines recommend administering antimicrobials immediately, ideally within 1 hour of recognition (Surviving Sepsis Campaign 2021). However, the clinical presentation of sepsis is often nonspecific, making early identification difficult, which may lead to delayed treatment and a worse prognosis [Olander et al 2019]. POCT testing may help guide antibiotic use in people with suspected sepsis.  In this trial, the requirement for rapid clinical assessment and treatment in the management of suspected sepsis impacts on the ability for participants to provide informed consent and it is not practicable to consult others on their behalf prior to recruitment. The trial intends to use a ‘research without prior consent’ approach (sometimes referred to as ‘deferred consent’). In England and Wales, the Mental Capacity Act 2005 allows the use of ‘deferred consent’ in emergency research situations where the time dependent nature of intervention would not allow fully informed consent to be obtained.  Risk factors for sepsis include older people (over 75 years of age), very frail, co-morbidities, indwelling lines or catheter. Adults presenting to ED with sepsis have an average age of 68 years [Daniels et al 2010], which rises to 78 for those with severe sepsis or septic shock [Majuran & Clancy 2006]. Dementia increased the risks of acute organ dysfunction, severe sepsis and hospital mortality. Sepsis-associated delirium (SAD) may also commonly occur in patients with sepsis. People with learning disabilities are more likely to be admitted to hospital with infections and sepsis than the general population. People with learning disabilities die over 25 years sooner than people without learning disabilities. Sepsis as a key contributor to premature mortality, with 11% of deaths being recorded as sepsis related [LeDer 2018].  **In summary:**  Sepsis is a medical emergency requiring prompt treatment and so sepsis trials may use a ‘deferred consent’ model where participants are recruited without prior consent, and consent to continue in the trial is later sought (or a consultee/legal representative consulted). However, many people with sepsis will also have co-morbid conditions or disabilities that affect their ability to provide consent. It is important to include (and retain) all these groups, and ensuring they are supported to be involved in consent decisions where possible. |

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| **Are the groups identified in Q 1 likely to respond to the**  **Q2**  **intervention and/or comparator in different ways?**  [**(VIEW WORKSHEET A)**](#WorksheetONE) |
| How might some groups in the population **respond to, or engage with, the intervention(s)** being tested in different ways (e.g if they have particular types/severity of capacity-affecting conditions or disabilities)? |
| **Summarised from Worksheet A:**   * All participants will be recruited without prior consent due to the emergency nature * It is unlikely that presence/severity of cognitive impairment (whether due to an acute or chronic condition) will affect a person’s ability to engage with the sepsis management intervention. * People who are older, more frail, or who have a concomitant capacity-affecting condition or disability may be more at risk of developing severe sepsis and septic shock, and may have worse outcomes * The trial should include people who lack capacity to consent due to pre-existing cognitive impairment, with reasonable adjustments to support their inclusion. * Consent and data collection processes need to take account of pre-existing cognitive impairment, acute development of delirium, and delirium superimposed on pre-existing cognitive impairment. * Consent and consultee process will need to take account of this, with corresponding PIS/ICF documents. If the participant does not regain capacity after the acute event they should remain in the trial with appropriate consent arrangements. * If the trial involves self-reported data at follow-up periods, may need to consider alternative methods of engagement and data collection such as options to involve family carer (or staff for people living in a care home), proxy-reported outcomes, or use of routine data. * The trial needs to be designed to be culturally sensitive and accessible to people with additional language and/or communication needs. This will include translation and interpretation provision and ensuring there is diverse public involvement throughout the trial. * Pre-trial public involvement activities and the embedded qualitative study will need to include the perspectives of diverse range of people, including people living with pre-existing cognitive impairment and their carers |

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| **Worksheet A** | | | | |
| Consider how any **FACTORS RELATED TO THE PERSON’S CONDITION OR DISABILITY** might influence their response to (or engagement with) the intervention/comparator. Please add details of any actions/considerations required to the summary [**Worksheet G**](#WorksheetG). | | | | |
| **Condition or disability related factors** | How might the **prevalence or severity** of the capacity-affecting condition or disability vary between groups who are able to consent and those who may not be able to consent? | Response:  As sepsis is a medical emergency, all participants will be recruited without prior consent. People with pre-existing cognitive impairment may be more at risk of sepsis, likely to present later and develop more severe sepsis, and experience poorer outcomes including mortality. Recruiting only those without pre-existing cognitive impairment will exclude those at highest risk of poorer outcomes. |
| Action/consideration required?  Trial should include people who lack capacity to provide consent to continue in the trial, including reasonable adjustments to support their inclusion. |
| How might the **presence of co-morbid conditions** vary between groups who are able to consent and those who may not be able to consent? | Response:  As above, people with pre-existing cognitive impairment may be more at risk of sepsis, likely to present later and develop more severe sepsis, and experience poorer outcomes including mortality. |
| Action/consideration required?  Consent to continue in the trial and data collection processes need to take account of pre-existing cognitive impairment, acute development of delirium, and delirium superimposed on pre-existing cognitive impairment |
| How might the **nature** of impaired capacity affect their response (e.g due to an acute condition, long-standing/chronic condition, or acute superimposed on long-standing/chronic)? Might capacity to consent **change** over time? What impact might that have? What are the relevant **legal arrangements** (see [**Appendix 1**](#Appendix1))? | Response:  May be due to delirium and/or dementia participants may lack capacity at outset, may lose or regain capacity during the trial, or have fluctuating capacity. |
| Action/consideration required?  Consent and consultee process will need to take account of this, with corresponding PIS/ICF documents. Consider option of seeking consent pre-operatively. If the participant does not regain capacity after the acute event, they should remain in the trial with appropriate consent arrangements. |
| How might the condition or disability **present** in people from each group (this may include symptoms, type or pattern or rate of disease progression) and how might that impact on capacity to consent? | Response:  Participants may have a formal diagnosis of a capacity-affecting condition or disability (e.g dementia or a learning disability) or may not. May affect reporting of sepsis symptoms and ability to provide self-reported data, as well as the ability to understand and retain information about trial and provide consent to continue in the trial. | |
| Action/consideration required?  If data collection includes via self-reported methods, may need to consider alternative methods of engagement and data collection such as options to involve family carer (or paid care staff if living in a care home for example), proxy-reported outcomes, use of routine data. | |
| Any other condition or disability related factors to consider:  No | | |
| **Other factors** | How might **perceptions** of the condition or disability and social stigma around it be different for people who may not be able to consent? Might any **cultural or language** factors influence the acceptability of, and adherence to, the treatment(s)? | Response:  Pre-existing cognitive impairment may be unrecognised, or not reported due to misconceptions or stigma. This may be the case for communities where misconceptions can be higher such as Black, Asian and minority ethnic populations. Additionally, language and cultural factors may also influence peoples’ ability to engage with consent process. | |
| Action/consideration required?  The trial needs to be designed to be culturally sensitive and accessible to people with additional language and/or communication needs. This will include translation and interpretation provision and ensuring there is diverse public involvement throughout the trial. | |
| How might **ways of describing** the condition or disability be different for people who may not be able to consent? | Response:  It is not clear whether sepsis symptoms etc are referred to using different terms by different communities. | |
| Action/consideration required?  Pre-trial public involvement activities the embedded qualitative study should include the perspectives of people from different communities and with co-morbid conditions and disabilities. | |
| How or when might people who may not be able to consent **access healthcare** (or other care) for this condition or disability differently? | Response:  People with pre-existing conditions or disabilities may access ED later than those without due to issues around communicating and identifying symptoms of sepsis. There may be a lack of awareness by healthcare professionals and carers about sepsis and the need to seek urgent medical attention. This may be particularly relevant for people living with dementia in care homes or people with a learning disability living in supported accommodation. | |
| Action/consideration required?  Pre-trial public involvement activities and the embedded qualitative study should include the perspectives of people with experience of living with and caring for people with co-morbid conditions and disabilities. | |
| Any other factors to consider:  In addition to cognitive impairment, cultural and language factors and socio-economic and geographical factors may need to be considered (e.g living in more rural areas, or areas of higher deprivation). This may need to be explored further (consider Ethnicity Framework and Socio-economically Disadvantaged Framework). | | |

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| **Will my trial intervention and/or comparator make it**  **Q3**  **harder for any of the groups identified in Q 1 to respond to or** **engage with?** [**(VIEW WORKSHEET B)**](#WorksheetTWO) |
| How might **the intervention and/or comparator**, including how they are provided, make it harder for some groups in the population to take part in the trial (e.g if they have particular types/severity of capacity-affecting conditions or disabilities)? |
| **Summarised from Worksheet B:**  The main aim of the intervention is to help guide antibiotic use in people with suspected sepsis without increasing mortality. As the intervention is delivered without prior consent, it is unlikely that the intervention or comparator will affect the inclusion of people with impaired capacity to consent, including those with pre-existing cognitive impairment.  Those who contributed to the development of the intervention (e.g public involvement contributors and other stakeholders) should include a diverse range of people, including those with experience of cognitive impairment and/or caring for someone who does. |

**Worksheet B**

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| Consider any factors related to the **INTERVENTION AND/OR COMPARATOR** that might affect how some groups respond or engage^. Please add details of any actions/considerations required to the summary in [**Worksheet G**](#WorksheetG). | | |
| **What** | How might the intervention(s) and comparator **limit participation** of people with the condition or disability who may not be able to consent? | Response:  The intervention is delivered without prior consent, it is unlikely that the intervention or comparator will affect the inclusion of people with impaired capacity to consent, including those with pre-existing cognitive impairment | |
| Action/consideration required?  None | |
| How, and in what way, were people with the condition or disability (and/or carers) and other stakeholders **involved** in selecting or designing the trial intervention/comparator? | Response:  The intervention a reliable biomarker that is used in other contexts and settings. A patient and public involvement representative. The trial protocol describes the extensive public involvement activities, and a member of the PPI group is a co-applicant. The PPI group supported the need for this trial recognising the potential for POCT measurement to improve outcomes for patients with suspected sepsis. However, it is not clear if the PPI group and other stakeholders considered issues around the inclusion of older, frailer people and those with pre-existing cognitive impairment | |
| Action/consideration required?  Those who contributed to the development of the intervention (public involvement contributors and other stakeholders) should include a diverse range of people, including those with experience of cognitive impairment and/or caring for someone who does. These perspectives should be included in public involvement throughout the trial. | |
| Other factors to consider:  None | | |
| **Who** | How might the **person(s)** delivering the intervention/comparator limit participation of people who may not be able to consent (e.g the person’s role, skills, experiences, or characteristics)? | Response:  The intervention is delivered without prior consent, it is unlikely that the person delivering the intervention or comparator will affect the inclusion of people with impaired capacity to consent, including those with pre-existing cognitive impairment | |
| Action/consideration required?  None | |
| Other factors to consider: | | |
| **How** | How might the **mode of delivery** of the intervention/comparator (e.g telephone, video-call, face-to-face, in groups, drug administration route) limit the participation of people who may not be able to consent? | Response:  The intervention is delivered without prior consent, it is unlikely that the mode of delivering the intervention or comparator will affect the inclusion of people with impaired capacity to consent, including those with pre-existing cognitive impairment | |
| Action/consideration required?  None | |
| Other factors to consider: | | |
| **Where** | How might **where** the intervention/comparator is being delivered (e.g hospital, general practice, local library, emergency setting) limit the participation of people who may not be able to consent? | Response:  See response to previous question. | |
| Action/consideration required?  None | |
| Other factors to consider: | | |
| **When** | How might **when** the intervention/comparator is delivered (e.g during working hours, requirement to deliver the intervention urgently and cannot wait until capacity is regained) or **the intensity** (e.g number of times it is delivered, over what period, time commitment for each session and overall) limit participation of people who may not be able to consent? | Response:  See response to previous question. | |
| Action/consideration required?  None | |
| Other factors to consider: | | |

^These factors are taken from TIDieR ([http://www.equator-network.org/reporting-guidelines/tidier/](about:blank)).

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| **Will the way I have planned and designed my trial make it harder for any of the groups identified in Q 1 to consider taking part and remain in the trial?\***  **Q4**  **(VIEW WORKSHEETS** [**C**](#WorksheetC)**,** [**D**](#WorksheetD)**,** [**E**](#WorksheetE) **and** [**F**](#WorksheetF)**)** |
| How might **elements of the trial design**, such as eligibility criteria, recruitment and consent process, or data collection methods, make it harder for some groups to take part and remain in the trial (e.g if they have particular types/severity of capacity-affecting conditions or disabilities)? |
| **Summarised from Worksheets C-F:**   * Participants lacking capacity should be supported to understand information about the trial and provide their own consent to remain in the trial where possible * Accessible and culturally sensitive participant information should be developed, in conjunction with diverse public involvement contributors with relevant experience, to support people with impaired capacity to make/participate in a decision about remaining in the trial, and to disseminate the findings in an accessible way * Consultee arrangements will need to take account of the availability of personal consultees and individuals’ circumstances e.g who can act as a nominated consultee if no family/friend able or willing, and the process for participants who live in a care home or supported accommodation on discharge * The use of translation/interpreter services should be considered. Recruiting staff and those involved in data collection should be trained in assessing and supporting communication needs and assessing capacity as required * Use of proxy versions should be considered, with data collection methods tailored to take account of any additional communication and/or capacity needs * Sub-group analyses should be planned for those with and without pre-existing cognitive impairment |

\*See <https://www.capacityconsentresearch.com/> for a range of resources and practical suggestions about how you can address factors that affect the involvement of adults with conditions or disabilities that may impair their capacity to consent.

**Worksheet C**

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| Consider which factors around **TRIAL ELIGIBILITY AND PARTICIPATION** might affect the inclusion of some groups. Please add details of any actions/considerations required to the summary in [**Worksheet G**](#WorksheetG). | | | | |
| **Eligibility criteria** | How might the **eligibility criteria** exclude people with the condition or disability for reasons other than their clinical eligibility for the trial (e.g ability to provide consent, availability of family member as consultee/legal representative, requirement to speak English, location, age, internet/mobile telephone access)? | | Response:  Exclusion criteria are clinical/risk-based e.g patients already receiving IV antibiotics, currently receiving myeloablative chemotherapy, patients with solid-organ transplantation, allogeneic bone marrow or stem cell transplantation within prior 3 months, and those requiring urgent surgical intervention. |
| Action/consideration required?  None |
| Other factors to consider:  None | | |
| **Opportunity to participate** | How might the way(s) potential participants are **made aware** of the trial (e.g posters in a clinic, written letter from a doctor, asked by a nurse) and by whom, limit the participation of people who may not be able to consent for themselves? | | Response:  Potential participants will be identified during their admission to ED and recruited without prior consent |
| Action/consideration required?  None |
| How might the **information** that tells potential participants about the trial (e.g format and content of participant information leaflet) limit the participation of people who may not be able to consent for themselves? What accessible information or format may be needed? | | Response:  Participants are recruited without prior consent. See ‘consent procedures’ below and ‘Retention’ section for more details about consent to continue in the trial. |
| Action/consideration required?  See ‘consent procedures’ below and ‘Retention’ section for more details about consent to continue in the trial. Accessible participant information should be developed, in conjunction with public involvement contributors with relevant experience. |
| How, and in what way, were people with the condition or disability (and/or carers) and other stakeholders **involved** in developing the information for potential participants? | | Response:  Participants are recruited without prior consent. See ‘consent procedures’ below and ‘Retention’ section for more details about consent to continue in the trial. Public involvement activities included input into developing the trial information, but it is not clear whether this included people with experience of pre-existing cognitive impairment. |
| Action/consideration required?  See ‘consent procedures’ below and ‘Retention’ section for more details about consent to continue in the trial. Accessible participant information should be developed, in conjunction with public involvement contributors with relevant experience. |
| How might **cultural or language factors** change the way people with the condition or disability (and/or carers) perceive the information they are given (e.g beliefs about consent, language proficiency)? What language(s) should information be provided in? | | Response:  See previous responses about additional language and cultural factors which may also influence peoples’ ability to engage with the trial |
| Action/consideration required?  See ‘consent procedures’ below and ‘Retention’ section for more details about consent to continue in the trial. As previously, the information needs to be culturally sensitive and accessible to people with additional language and/or communication needs. |
| Other factors to consider: | | |
| **Consent procedures** | How might the **way consent is sought** (i.e. when, where, by whom, written vs verbal vs electronic, availability of language/translation and access to interpreters) limit the participation of people who may not be able to consent? What alternative **consent documents** **and processes** (e.g recruitment without prior consent in an emergency) are needed? | | Response:  Participants are recruited without prior consent. Participants will be approached to provide informed consent to remain in the trial as soon as is practicably feasible after randomisation, ideally within 72 hours. After three approaches, or if the participant is not likely to regain mental capacity, a personal consultee will be approached. Where no personal consultee can be identified, a nominated consultee will be approached. | |
| Action/consideration required?  Consultee information sheets and declaration forms are needed for personal and nominated consultees, together with participant documents if capacity is regained. Accessible versions (e.g pictorial, Easy Read) of participant information for both regaining capacity for the trial and for the qualitative study should be developed to support people to understand the trial information and provide their own consent where possible. The use of translation/interpreter should be considered. | |
| How might the **consent arrangements** differ for people who are able to consent and those who may not be able to consent (e.g need for assessment of capacity, availability of personal consultees/legal representatives, involvement of professionals as consultees/legal representatives, deferred)? This may differ between acute and chronic conditions, and in emergency situations. | | Response:  If there are concerns about a person’s capacity to consent to remain in the trial then an assessment is required. There will need to be arrangements in place for who can act as a nominated consultee, and for situations where the participant lacks capacity but consultee declaration has not been sought prior to discharge - would a family member/friend be contacted after discharge, what if there is no family/friend to act as a personal consultee (e.g could a member of care home staff be involved as a nominated consultee)? | |
| Action/consideration required?  Research staff should be trained in assessing capacity as required. Consider guidance for nominated consultee process and creating a list of staff able/willing to act as nominated consultee. Consider enabling a nominated consultee to be involved following discharge if necessary, e.g member of care home staff. | |
| How might the ways in which the research team can check how well consent **information is understood** differ for people who may not be able to consent (e.g presence of communication disorders, use of communication aids)? | | Response:  Research staff will need to be aware of assessing and supporting additional communication needs, particularly for people with pre-existing cognitive impairment or communication disabilities | |
| Action/consideration required?  Consider the use of tools such as [Consent Support Tool](https://www.jr-press.co.uk/consent-support-tool.html) | |
| How might consent arrangements need to **change over time**? When might consent need to be revisited (e.g data collection points)? How might the ongoing consent arrangements limit the participation of people who may not be able to consent (e.g where capacity fluctuates, capacity is lost or regained during the trial)? What **consent** **documents and processes** are needed? | | Response:  Participants are recruited without prior consent. Participants will be approached to provide informed consent to remain in the trial (or a consultee involved). Trial data is collected from patients’ health records until 28-day follow-up which is conducted via telephone (or in person if the participant remains an inpatient) to collect EQ-5D and health resource use data. It is not clear how capacity will be assessed (where indicated) at this timepoint | |
| Action/consideration required?  Process for assessing capacity at follow-up might be needed, with relevant process for consent/consultation if capacity status has changed | |
| Other factors to consider:  There is [evidence](https://doi.org/10.1186/s13063-021-05568-z) that cultural and other factors may affect peoples’ views about the acceptability of the use of ‘research without prior consent’ models. Public involvement activities and the embedded qualitative study will need to include the perspectives of diverse range of people, including people from ethnic minority backgrounds. | | | |
| **Trial design** | How might the **design** of the trial (e.g cluster vs individual randomisation) limit the participation of people who may not be able to consent? | Response:  N/A | | |
| Action/consideration required? | | |
| Other factors to consider: | | | |

**Worksheet D**

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| Consider which factors around **DATA COLLECTION** might affect how some groups engage with the trial. Please summarise any actions/considerations required in [**Worksheet G**](#WorksheetG). | | |
| **What** | How, and in what way, were people with the condition or disability (and/or carers) in the target population **involved** in selecting the trial outcomes? Is there a relevant core outcome set? | Response:  It is not clear from the trial protocol whether the public involvement activities included input into selecting the trial outcomes, although acceptability to healthcare practitioners, patients and their family is one of the secondary outcomes. |
| Action/consideration required?  Public involvement activities and the embedded qualitative study should include the perspectives of diverse range of people. |
| How might the trial outcomes themselves, or other **data being collected** (e.g. where data is self-reported) limit the participation of people who may not be able to consent (and may not be able to self-report)? | Response:  Use of self-reported outcome measures at 28-day follow-up (with carers completing proxy versions) will enable participant with cognitive impairment to contribute follow-up data. It is not clear whether the Health Economics questionnaire can be proxy-completed -or how this might be conducted for people living in care homes or supported living. In the qualitative study, semi-structured interviews are conducted with patients after the 90-day follow-up, including a close family member where possible. It is not clear whether, if a participant lacks capacity at that point, the interview would be conducted with the family member only (otherwise it may not include perspectives of families of people with long-term cognitive impairment). |
| Action/consideration required?  Data collection processes should include proxy-reported data and carer perspectives where possible. |
| **Who** | How might the **people** who collect data limit the participation of people who may not be able to consent (e.g the person’s role, skills, experiences, or characteristics)? | Response:  Data collection at baseline and up to 28 days will be from patient notes. It is not clear who will be conducting follow-up phone calls or visits at 28 days, or who will be conducting the qualitative interviews. |
| Action/consideration required?  Research staff conducting the 28 day follow up and qualitative interviews should be trained in supporting people with cognitive impairment during data collection, both in person and remotely, and the processes for raising concerns about capacity if necessary. |
| **How** | How might data collection **methods** limit the participation of people who may not be able to consent (e.g method of data collection such as online)? Are arrangements to access confidential patient information **without consent** (e.g CAG approval) appropriate or required? | Response:  It is presumed that data collection at 28 days will primarily be verbal. In situations where the participant dies following the intervention, the trial will continue to use their data. |
| Action/consideration required?  Communication methods will need to be tailored to take account of any additional communication and/or capacity needs. |
| **Where** | How might **where** data are collected (e.g hospital, general practice, local library, emergency setting) limit the participation of people who may not be able to consent? | Response:  See previous response |
| Action/consideration required?  None |
| Other factors to consider: | |

**Worksheet E**

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| Consider which factors might affect the planned **ANALYSIS** of trial results. Please summarise any actions/considerations required in [**Worksheet G**](#WorksheetG). | | | |
| **Retention** | How might **follow up** differ between groups who are able to consent and those who may not be able to consent (e.g ability to remain in the trial if capacity is lost, use of data if unable to obtain retrospective/deferred consent or in event of death or withdrawal, whether consent survives any loss of capacity depending on different legal frameworks)? Might re-assessment of capacity be required? | Response:  Participants who regain capacity will be approached to provide consent to remain in the trial. Follow-up is at 28-days by phone or in person. It is not clear how capacity will be assessed at that point if required. | |
| Action/consideration required?  See previous sections about ensuring accessible information, assessment of capacity, consultee arrangements, and enabling proxy-reported outcomes to reduce any loss to follow up. | |
| Other factors to consider: | | |
| **Benefits** | How might the **benefits** of the trial intervention(s) differ between groups who are able to consent and those who may not be able to consent (or between other diagnostic groups)? | Response:  It is not clear whether there will be any difference in benefit between different groups | |
| Action/consideration required?  None | |
| Other factors to consider: | | |
| **Harms** | How might the possible **harms or burdens** of the trial intervention(s) differ between groups who are able to consent and those who may not be able to consent (or between other diagnostic groups)? | Response:  It is not clear whether there will be any difference in harms between different groups | |
| Action/consideration required?  None | |
| Other factors to consider: | | |
| **Subgroup analyses** | How should **variation** between groups who are able to consent and those who may not be able to consent in the target population be explored– should there be planned subgroup analyses? | Response:  It is not clear whether there are any differences in benefits and harms between different groups, including those with and without pre-existing cognitive impairment. | |
| Action/consideration required?  An *a priori* planned sub-group analysis should be considered, alongside those already planned. | |
| Other factors to consider: | | |
| **Interim analyses** | How should any **interim analysis** handle variation between groups who are able to consent and those who may not be able to consent in the target population? How might any variations or differences in experiences be explored or known (e.g through embedded qualitative research)? | | Response:  It is not clear whether there are any differences between groups, including those with and without pre-existing cognitive impairment. Any planned interim analysis should look for signals suggesting that benefits or harms were importantly different between these groups. |
| Action/consideration required? |
| Other factors to consider: | | |
| **Stopping triggers** | How should any **rules to stop** the trial early on safety or benefit grounds handle variation between groups who are able to consent and those who may not be able to consent? | | Response:  Any planned stopping triggers should look for signals suggesting that benefits or harms were importantly different between these groups. |
| Action/consideration required? |
| Other factors to consider: | | |

**Worksheet F**

|  |  |  |
| --- | --- | --- |
| Consider which factors might affect the planned**REPORTING AND DISSEMINATION** of trial results. Please summarise any actions/considerations required in [**Worksheet G**](#WorksheetG). | | |
| **What** | How, and in what way, were people with the condition or disability (and/or carers) and other stakeholders **involved** in planning the reporting and dissemination of the trial results? | Response:  The results will be disseminated through peer-reviewed journals and presented at scientific conferences and via the Sepsis Trust. Planned public involvement activities including input into lay summaries. |
| Action/consideration required?  Diverse public involvement contributors with relevant experience, will be needed to ensure that the dissemination routes, mode, and information shared are accessible to people with impaired capacity and carers. |
| Other factors to consider: | |
| **How** | How might planned **reporting and dissemination** methods limit engagement with people who may be unable to consent (e.g accessible versions available)? | Response:  See previous response |
| Action/consideration required? |
| Other factors to consider: | |
| **Where** | How might **where** trial results will be reported and disseminated limit engagement of people who may be unable to consent (e.g online only)? | Response:  See previous response |
| Action/consideration required? |
| Other factors to consider: | |

**Worksheet G**

|  |  |  |
| --- | --- | --- |
| **Summary of actions and resources needed\*** | | |
| **Lightbulb and gear with solid fill**Use this worksheet to summarise the **KEY FACTORS** you have identified that might affect the involvement of people with capacity-affecting conditions or disabilities in your trial, along with **ACTIONS OR CONSIDERATIONS** that are needed to support their inclusion, and the **COSTS OR RESOURCES** that might be required. Add extra rows as needed.  Please remember that there are also differences *within* groups who may experience impaired capacity. No group is homogenous, and there will be intersection between these and other factors such as ethnicity or language. | | |
| **Factors that may prevent the involvement of adults who have impaired capacity to consent** | **Proposed actions or considerations (several options may be needed)\*** | **Costs or resources required (if any)** |
| Accessibility of participant information sheets | Develop accessible or ‘easy read’ versions of participant information sheets | Obtain quote for accessible documents from [Thinklusive](https://thinklusive.org/) |
| Additional communication needs and assessment of capacity to consent | Resources to support assessment of communication needs and capacity to consent | Ensure training on assessing capacity and [Consent Support Tool](https://www.jr-press.co.uk/consent-support-tool.html) available for recruiting staff |
| Public involvement may not be designed to include perspective of people with cognitive impairment | Design public involvement activities to be accessible for people with cognitive impairment and their carers | Arrange smaller and more accessible meetings; include costs for creating accessible information prior to meetings; provide payment for more time to review information; and cover carer/supporter costs |
| More time needed to recruit participants (tailored information and support, assess capacity, contact consultees) | Ensure sufficient research nurse time available to support participants and consultees, to revisit capacity and consent as needed, and to support data collection | Include costs for additional research nurse time (e.g in Schedule of Events Cost Attribution Template) |
| Etc. |  |  |
|  |  |  |

\*See <https://www.capacityconsentresearch.com/> for a range of resources and practical suggestions about how you can address factors that affect the involvement of adults with conditions or disabilities that may impair their capacity to consent

Acknowledgements

This INCLUDE Impaired Capacity to Consent Framework builds on work by [NIHR INCLUDE](https://sites.google.com/nihr.ac.uk/include/home) and their [Ethnicity Framework](https://www.trialforge.org/trial-forge-centre/include/). It was developed by members of the [Trial Conduct Working Group](https://www.methodologyhubs.mrc.ac.uk/files/8815/8091/5879/NEW_TCWG_remit_300120_002.pdf) Inclusivity subgroup of the [MRC-NIHR Trials Methodology Research Partnership](https://www.methodologyhubs.mrc.ac.uk/about/tmrp/).

The development of the INCLUDE Impaired Capacity to Consent Framework was led by Victoria Shepherd (Centre for Trials Research, Cardiff University) and Katie Joyce (Bristol Trials Centre, University of Bristol) with Samantha Flynn (CEDAR, University of Warwick), Amanda Lewis (Bristol Trials Centre, University of Bristol) and Madeleine Clout (Bristol Trials Centre, University of Bristol). It was developed in collaboration with [Trial Forge](https://www.trialforge.org/).

A number of researchers and research teams kindly piloted and/or provided feedback on earlier versions of the framework, including Amy M Russell, Lindsay Mizen, Nicola Farrar, Julia Wade, Edward Carlton, Clare Clements, Holly McKeon, Liz Coulthard, Laura Goodwin, Sarah Voss, Anna Mulvihill, Jennifer McAnuff, Phillip Whitehead, Tim Rapley, Adwoa Parker, Alexandra Dean, Callum Kaye, Liz Cook, Joanne Laycock, Anne Cochrane, Ashley Scrimshire, Marian Brady, Donna C. Tippett, Jonathan Hewitt, Ceri Battle, Paul Dark, Matthew Costa, Khalid Ali.

The implementation activities were conducted as part of [a project](https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/implementation-of-the-include-impaired-capacity-to-consent-framework-for-researchers) funded by the Innovation for All programme at Cardiff University and led by Victoria Shepherd (Centre for Trials Research, Cardiff University) with Shaun Treweek (University of Aberdeen and Trial Forge), Brittany Nocivelli (Cardiff University), Jeremy Segrott (Centre for Trials Research, Cardiff University) and members of the development group. The Easy Read materials were developed by [Thinklusive](https://thinklusive.org/) and were co-produced by Maximilian Clark and the Thinklusive Advisory Group which includes people who are experts by experience.

The development of both the framework and the implementation materials have benefitted from the involvement of a lay advisory group consisting of people with experience of living with, and caring for, people with conditions or disabilities that may affect their capacity to consent. We are very grateful for their support.

**Appendix 1. Research involving adults who lack capacity to consent – legal summary**

***Background***

Research is an important way for us to understand illness and disabilities, and to improve the treatment, care and support people receive. Sometimes this research can only be carried out if it involves people who lack the mental capacity to provide informed consent to take part. Capacity can only be assessed in relation to a particular decision and a particular time – a person may have the capacity to make some decisions but not others, or their capacity to make a decision may vary over time. Adults are presumed to have capacity to make decisions about themselves unless proven otherwise through a formal assessment.

For those who are unable to provide informed consent for themselves, there are alternative legal provisions for their participation in research. The law allows such research to take place but sets out strict rules to protect people who lack capacity to consent to take part in research, and to make sure their wishes and preferences are taken into account.

***The legal frameworks***

There are separate laws governing research involving adults who lack capacity to consent in England and Wales. The Mental Capacity Act 2005 (MCA) governs how adults lacking capacity can be involved in research, although it excludes clinical trials of investigational medicinal products (CTIMPs) which are regulated separately by the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTR). The CTR also apply to CTIMPs in Scotland, with non-CTIMPs governed by the Adults with Incapacity (Scotland) Act 2001 (AWI).

Although there are many similarities between the regulations, there are important differences in who is involved in decisions about participation and the legal basis for their decision (e.g whether it constitutes consent or not). A summary of the main differences are shown in **Table 1** below. Other legal frameworks apply to non-CTIMPs in N Ireland and the Republic of Ireland.

***Who is involved in decisions about adults who lack capacity to consent?***

The researcher must consult a person who, by virtue of their relationship with the person who lacks capacity, is suitable to act as an advisor on their behalf and is available and willing to act. They are either termed a Personal Consultee under the MCA, or Personal Legal Representative under the CTR, or for non-CTIMPs under AWI in Scotland they are termed either a Guardian, Welfare Attorney or Nearest Relative. A number of people may be able to act as a Personal Consultee or Personal Legal Representative, but they should be someone whom the person who lacks capacity would trust with important decisions about their welfare (MCA (s32(2)) and CTR Part 5). Usually it will be someone with a close personal relationship with the person, for example their spouse/partner, adult child or parent, but it can be a close friend. They do not have to hold Power of Attorney. If a potential consultee does not feel able to take on the role, they may suggest that someone else takes on the role, or ask that a Nominated Consultee or Professional Legal Representative be appointed. In Scotland, the AWI outlines who can act as Guardian, Welfare Attorney or, if there is no such Guardian or Welfare Attorney, then the adult’s Nearest Relative defined in the Mental Health (Scotland) Act 1984.

A Nominated Consultee (MCA) or Professional Legal Representative (CTR) is required when no-one who knows the person in a personal capacity is either available or willing to act. This is usually a healthcare professional or another nominated individual involved in their care, but they cannot be connected with the research study.

In all cases, the person lacking capacity should be informed about the research and involved in the decision as much as possible, even if they are unable to provide informed consent. If they have fluctuating capacity or are likely to regain capacity, the decision should be delayed until they regain capacity where possible. The researcher must take into account the wishes of the person who lacks capacity about whom to consult (e.g. their partner, or a particular friend or carer) and to act in accordance with any relevant previous statement or wishes.

***How should the decision be made?***

Careful thought is needed before including in research projects any adults who lack the capacity to make their own decisions. In England and Wales, unlike other decisions covered by the MCA such as those about medical treatment and care, ‘best interests’ procedures do not apply to decisions about taking part in research (MCA Code of Practice). Instead, each individual decision is based on what the person would have decided if they had capacity to do so.

The Consultee must be given information about the project and gives advice as to whether the person should take part in the project, and what the person’s wishes and feelings about taking part in the project would be if they had capacity to decide (MCA s32(4)). The Consultee gives advice on what they think the participant would want to do, rather than give consent themselves. If the Consultee so advises, the participant must not take part and, if already taking part, must be withdrawn. The responsibility whether to include the participant lies with the researcher. If the person who lacks capacity indicates (in any way) that they wish to be withdrawn from the project, they must be withdrawn without delay.

Under the AWI in Scotland governing decisions made by Guardians, Welfare Attorneys, and Nearest Relatives, Principle 3 states that account must be taken of the present and past wishes and feelings of the person, as far as this may be ascertained.

For clinical trials of medicines, the Legal Representative is provided with information about the trial that includes the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted. They are then asked to provide informed consent that represents the person’s presumed will. The person who lacks capacity should also have received information (according to their capacity of understanding) about the trial, its risks and its benefits. If the person is capable of assessing the information and forming an opinion, any refusal to participate should be considered by the researcher.

The basis for a decision by a Nominated or Professional Legal Representative is the same as for someone acting in a personal capacity (i.e. advice under MCA, informed consent under CTR) based on what the person themselves would have decided.

***What if it is in an emergency situation?***

Research carried out in emergency situations pose unique challenges in terms of obtaining consent. Emergency research is when treatment needs to be given urgently, and it is necessary to take urgent action for the purposes of the study. In some emergency situations people may lack capacity to give consent themselves and obtaining consent from a legal representative/consulting others is not reasonably practicable.

In England and Wales, the law allows adults who lack capacity to take part in emergency research without prior consent from a legal representative or consulting others, if certain conditions are met (Medicines for Human Use (Clinical Trials) Amendment (No 2) Regulations SI 2006 2984, and MCA s32(8)). Following enrolment in the study, a consultee should be consulted as soon as possible to seek advice on the person’s likely views and feelings, and for a CTIMP consent should be sought from a Legal Representative as soon as possible. Informed consent should also be sought from the person themselves as soon as possible following any regaining of capacity. Consent may be required for the person to continue in the study, or for the continued use of data or samples obtained.

The CTR arrangements for emergency research apply to CTIMPs in Scotland. However, the AWI governing non-CTIMP studies in Scotland does not provide any 'exemptions' from the requirement for consent from a Welfare Attorney/Guardian or Nearest Relative for adults not able to consent for themselves, even in emergency situations.

**Table 1.** Summary of the provisions for adults lacking capacity under the Mental Capacity Act 2005 (MCA), Adults with Incapacity (Scotland) Act 2000 (AWI), and Medicines for Human Use (Clinical Trials) Regulations 2004 (CTR)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **MCA** | **AWI** | **CTR** |
| **Who is involved in decisions about participation** | ***Personal consultee*** - a person who is engaged in caring for the person or is interested in their welfare, except as a professional or for remuneration – friend, relative, unpaid carer, attorney acting under LPA, court appointed deputy (s32(2)).  ***Nominated consultee*** - a person who has no connection with the project - healthcare professional, nominated individual (s32(3)). | ***Guardian or welfare attorney*** *-* who has power to consent to the adult’s participation in research, or where there is no such guardian or welfare attorney, from the adult’s nearest relative (for both CTIMPs (AWI s51) and non-CTIMPs).  Guardianship is granted by the sheriff’s office upon application, can cover property and financial matters or personal welfare including health, or a combination of these.  Power of attorney is appointed by the individual whilst they have capacity, and grants someone they trust powers to act as their continuing (financial) and/or welfare attorney.  ***Nearest relative*** - the AWI uses the hierarchy of relationships defined in the Mental Health (Scotland) Act 1984 as the definition of nearest relative, | ***Personal legal representative*** – a person who, by virtue of their relationship, is suitable to act as their legal representative and is available and willing to act (Schedule 1 Part 5).  ***Professional legal representative*** – the doctor primarily responsible for their medical treatment or a person nominated by their health care provider. Must not be connected with the trial (Schedule 1 Part 5). |
| **Basis for the decision** | Consultee is asked for ***advice*** whether the participant should take part or would not have wished to participate (s32(4)). The responsibility whether to include the participant ***lies with the researcher.*** | Not stated - although general principle 3 is ***account must be taken*** of the present and past wishes and feelings of the person, as far as this may be ascertained. | ***Informed consent*** given by the legal representative represents their presumed will (Schedule 1 Part 5(12)). Representative to decide whether the participant would have wanted to participate had they capacity to do so. |
| **Requirement for provision of information** | MCA does not specify any provisions that the person has to be informed about the research once they have been assessed as lacking capacity. | Does not specify any provisions that the person has to be informed about the research once they have been assessed as lacking capacity. | Person lacking capacity must have received information about the trial, its risks and benefits, according to his or her capacity before they can be involved. |
| **Weight of any dissent/objection** | Weight is given to any refusal or dissent from the individual lacking capacity, even when the person has little or no ability to understand the situation. If the person indicates (in any way) that he wishes to be withdrawn from the project he ***must be* *withdrawn*** without delay (s33(4)). | The research ***must not be carried out*** if the adult indicates unwillingness. | The explicit wish of a subject who is capable of forming an opinion and assessing the information to refuse participation in, or to be withdrawn from, the clinical trial at any time ***must be* *considered*** by the investigator. |
| **Level of risk permitted** | Research must be connected with an impairing condition in the functioning of the mind or brain affecting the person, or its treatment. There must be reasonable grounds for believing that the risk to the person is ***negligible*** and that anything done in relation to the person will not interfere with their freedom of action or privacy in a significant way or be unduly invasive or restrictive (s31). | Purpose of research must be to gain knowledge of the causes, diagnosis, treatment and care of the adult’s incapacity or the effect of any treatment or care given to the adult while he or she is incapable. Research must be of ***real and direct benefit to the adult involved,*** or where it is not likely to but ***likely to improve the scientific understanding*** of the adult’s condition and in the long term contribute to the attainment of real and direct benefit to persons suffering from the same form of incapacity(s51(4)).  The research involves ***no foreseeable risk or only minimal risk*** to the adult and should impose ***no or only minimal discomfort***. These conditions should be seen in the context of the adult’s standard treatment, if that is appropriate. | The clinical trial must relate directly to a life-threatening or debilitating condition clinical condition from which the person suffers. There must be grounds for expecting that administering the product will ***produce a benefit* *to the person* *outweighing the risks or produce no risk at all*** (Schedule 1 Part 5(9)). |
| **Loss of capacity during research** | Unless the research started before the MCA came into force (1st October 2007), when a person loses capacity during a research project, the study must have approval under s30 of the MCA.  Consent given by a person with capacity is not considered to survive any loss of capacity during the study and the researcher must seek the views of a consultee (s34) (see also Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007, and Wales equivalent). | There is no specific provision for adults who lose capacity while taking part in non-CTIMPs in Scotland. Researchers and RECs might expect that in most circumstances the original consent should be respected.  However, a request by a legal representative to withdraw someone from a study after they have lost capacity, should be considered carefully to ensure that it reflects the wishes of the person before they lost capacity, and that their current situation is fully considered. | If a capable adult gives informed consent to take part in a CTIMP and subsequently becomes unable to give informed consent by virtue of physical or mental capacity, the consent previously given when capable remains legally valid, provided the trial is not significantly altered. It is good practice in such cases to consult with carers and take note of any signs of objections or distress from the participant. The researcher should consider withdrawing a participant if any objections are raised.  If a capable adult refuses informed consent, and subsequently becomes unable to give informed consent the refusal is legally binding. They cannot be entered into the trial by seeking consent from a legal representative. |
| **Emergency situations** | s32(8) of the Act allows exceptionally for a person lacking capacity to be entered into research prior to a consultee being consulted in emergency situations, if it is also necessary to take action for the purposes of the research as a matter of urgency, but it is not reasonably practicable to consult under the previous provisions of this section. | No emergency research provisions relating to surgical, medical, nursing, dental or psychological research under AWI in Scotland, only CTIMPs under CTR. | Inclusion without prior consent from the participant or a legal representative is possible under defined circumstances under the Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006. This includes that the treatment to be given as part of the trial needs to be given urgently. |

***Where can I find more information?***

**Health Research Authority (HRA)**

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/> and <http://www.hra-decisiontools.org.uk/consent/principles-ALC.html>

**Medical Research Council (MRC)**

[Guidance issued by the Medical Research Council](https://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/) on medical research involving adults who cannot consent

**Capacity to consent to research website**

<https://www.capacityconsentresearch.com/>

Collated resources and information created as part of the CONSULT project

**NIHR Learn Informed Consent with Adults Lacking Capacity (eLearning)**

<https://sites.google.com/a/nihr.ac.uk/crn-learn-help/accessing-nihr-learn> An introduction to informed consent with adults lacking capacity. It explores the requirements of the Mental Capacity Act and Medicines for Human Use (Clinical Trials) regulations when involving adults who lack capacity in non-CTIMP and CTIMP research.

***References***

[The Medicines for Human Use (Clinical Trials) Regulations 2004](http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf)

[Mental Capacity Act 2005](http://www.legislation.gov.uk/ukpga/2005/9/contents)

[Adults with Incapacity (Scotland) Act 2000](https://www.legislation.gov.uk/asp/2000/4/contents)

[Guidance on nominating a consultee for research involving adults](http://webarchive.nationalarchives.gov.uk/20130123193236/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131) who lack capacity to consent

[Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007](http://www.legislation.gov.uk/uksi/2007/679/contents/made)

[Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007](http://www.legislation.gov.uk/wsi/2007/837/contents/made)

[DH Mental Capacity Act 2005 guidance page](http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/MentalCapacity/MentalCapacityAct2005/DH_078789)

[Mental Capacity Act 2005 Questions and Answers](http://www.hra.nhs.uk/resources/questions-and-answers-mental-capacity-act-2005/)

[Mental Capacity Act Code of Practice](http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpgacop_20050009_en.pdf)

[Ethics Guidebook – a resource for Social Scientists](http://www.ethicsguidebook.ac.uk/Mental-Capacity-Act-118)

[NIHR Clinical Trials Toolkit](http://www.ct-toolkit.ac.uk/)

***About this summary***

This summary forms part of a project to explore the ethical, legal and methodological aspects of conducting research involving adults who lack capacity (CONSULT). It is being carried out as part of an NIHR Advanced Fellowship at Cardiff University and is funded by the Welsh Government through Health and Care Research Wales. For more information, please contact Dr Victoria Shepherd [ShepherdVL1@cardiff.ac.uk](file:///C:\Users\vicky\AppData\Local\Packages\Microsoft.MicrosoftEdge_8wekyb3d8bbwe\TempState\Downloads\ShepherdVL1@cardiff.ac.uk)

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