INCLUDE

Impaired Capacity to Consent Framework Webinar

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Trials Methodology TMRP Research Partnership

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Importance of including adults with impaired capacity in trials:

- Over 2 million people in UK have significantly impaired decision-making
- Associated with a number of long-term conditions or disabilities, or may follow an acute event
- Particular ethical and legal considerations in studies including adults lacking capacity
- Challenging to conduct - leading to their exclusion
- Excluding populations from trials raises concerns about:
    - unrepresentative populations – lack of generalisability
    - inequitable opportunity to participate in research
    - under-representation of their experiences - voices unheard
- Exclusion leads to *evidence-biased* care and widens health inequalities

Adults with impaired capacity – an under-served group:

- Exclusion of people with cognitive impairment from trials is widespread - even in conditions/areas with high levels of cognitive impairment in target population (Shepherd et al 2019)
- Increasing focus on ensuring research is inclusive of under-served groups (NIHR INCLUDE)
- Key strategic priority for DHSC e.g Best Research for Best Health, and funders e.g NIHR, NIH
- To date, little attention has been paid to how to improve the inclusion of adults with impaired capacity (Shepherd 2020)

1 in 3 patients with a hip fracture also have a cognitive impairment, yet this population is **excluded or ignored** in 8 out of 10 hip fracture trials

90% of RCTs are **designed in a way that excludes** people with a learning disability

Stroke patients unable to consent are more severely affected, older and more likely to develop fever and infections .. trials are **affected by this selection bias**

Trials involving adults with impaired capacity are challenging:

CONSULT-ENABLE Study explored researchers' and healthcare professionals' views about the barriers and facilitators to research involving adults lacking capacity to consent and identified 3 main themes (Shepherd 2022)

Complexity of trials involving adults with impaired capacity	Importance of having access to appropriate support and resources	Need for greater knowledge and expertise to support future trials
"It feels like an **insurmountable black box of horrendousness** that I dare not go. It feels very much [that] if you get this wrong you will be **illegal** ….. and the **ethics police** will come for you!	"I've been stabbing in the dark like '**where should I look for reliable information**'? A lot of it was potluck Googling …. it still took the thrashing at the REC meeting for them to go **you've not interpreted that correctly** or not thought about this	"I think [the framework] is a fantastic idea. Patients lacking capacity are excluded from studies. A lot of people get to that box [in IRAS] and just say 'no'. If we have equipoise and there may be benefits to the patients, then not having capacity should never be a barrier

INCLUDE
Impaired Capacity
to Consent Framework

Development of NIHR INCLUDE Impaired Capacity to Consent Framework:

01 Concept
Established scope and content; drafted initial framework

02 Scoping
Scoped proof of concept; research teams pilot framework (n=9)

03 Consultation
Public involvement to review and refine the framework

04 Completion
Finalised version created; start of implementation planning

05 Implementation
Stakeholder consultation; creation of theory informed toolkit

INCLUDE Impaired Capacity to Consent Framework:

Questions and worksheets

Q1	Who should my trial results apply to?	People with particular types or severity of conditions or disabilities that may impair their capacity to consent
Q2	Are they likely to respond to the intervention in a different way?	**Worksheet A** - condition/disability related factors, other factors
Q3	Will my intervention make it harder for them to respond?	**Worksheet B** – intervention/comparator related factors (who, what, how, where, when)
Q4	Will my trial design make it harder for them to take part in or remain in the trial?	**Worksheet C** – eligibility, recruitment **Worksheet D** – data collection **Worksheet E** – analysis (subgroup etc) **Worksheet F** – reporting, dissemination
	Summary of actions and resources needed	**Worksheet G** – key factors, actions, costs/resources

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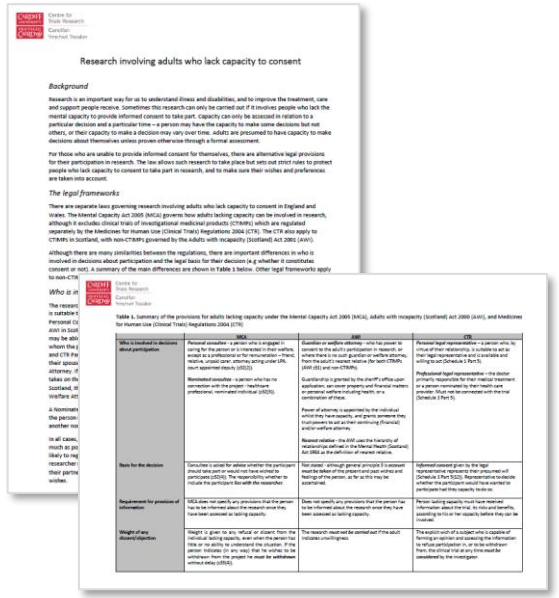
Summary of legal frameworks


Research involving adults who lack capacity to consent

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Links to guidance and info

https://www.capacityconsentresearch.com

Key messages for the INCLUDE Impaired Capacity to Consent Framework:

- **Generic tool** for use with any population with capacity-affecting condition or disability – interpretation, context
- **Intended for trials** – but may be useful for other study designs (especially Q4 and worksheets C-G)
- **Preferably used at earliest stage** (pre-funding trial design) and iteratively - useful at all stages e.g protocol, ethics
- **Involve the whole team** – public involvement that reflects the relevant population(s) is essential
- **Forms the basis of discussions** - questions/worksheets, record in document with outcomes and actions
- **Benefits researchers** as it improves quality of application/trial and helps justify costs (funders supportive), provides **reassurance to RECs**, and ensures research is **accessible to people** living with capacity-affecting conditions

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Toolkit to help when using the Framework:

1

Introduction

2

Accessible information

3

User guide

4

Library of examples

Video: Introduction to INCLUDE Impaired Capacity to Consent Framework

https://www.youtube.com/watch?v=bJt84ZjqMjc&t=6s

How to access the INCLUDE Impaired Capacity to Consent Framework:

https://www.capacityconsentresearch.com/include-impaired-capacity-to-consent-framework.html

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NIHR INCLUDE Guidance

Acknowledgements for INCLUDE Impaired Capacity to Consent Framework:

Development team:

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Consultation and piloting:

A number of researchers and research teams listed in the Framework kindly piloted and/or provided feedback on previous versions.

Implementation team:

Victoria Shepherd (Cardiff University), Shaun Treweek (University of Aberdeen and Trial Forge), Brittany Nocivelli (Cardiff University), Jeremy Segrott (Cardiff University) and members of the development group. The Easy Read materials were developed by Thinklusive and co-produced with the Thinklusive Advisory Group which includes people who are experts by experience.

Public involvement contributors:

The project has benefitted from the involvement of a lay advisory group of people with experience of living with, and caring for, people with conditions or disabilities that may affect capacity.

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Next steps:

- Download the Framework, toolkit materials, and a recording of the webinar available at:

  https://www.capacityconsentresearch.com/include-impaired-capacity-to-consent-framework.html

- We will be sending a brief **post-webinar survey** to capture your feedback and reflections
- Will collate the Q&A into a '**Frequently asked questions**' guide to accompany the toolkit
- An **opportunity to receive help to use the Framework** – contact us to arrange an online individual discussion
- **Further work** to support researchers and evaluation of the Framework
- Other **work on inclusivity** ongoing - INCLUDE Socio-economic Disadvantage Framework (webinar 24th Jan), LGBTQ+ groups, care home residents, focus on intersectionality and bringing INCLUDE Frameworks together

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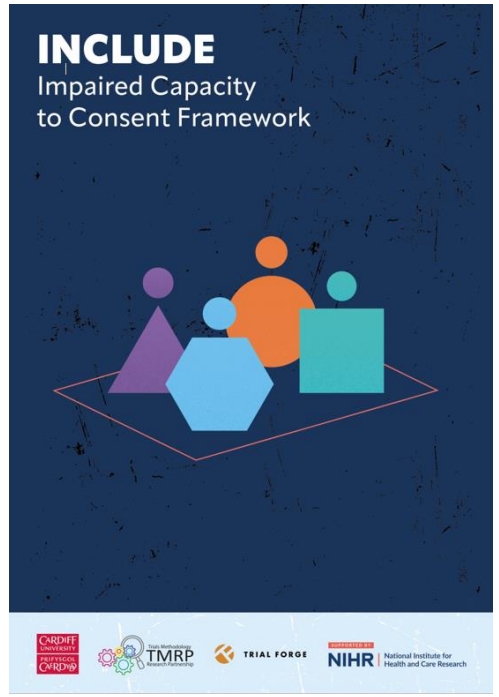
https://www.capacityconsentresearch.com



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