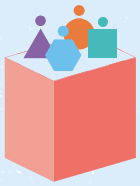
INCLUDE
Impaired Capacity to Consent Framework

Why has this framework been developed?



Participants in clinical trials should be representative of the anticipated population who are likely to receive the treatment in practice.

However, **some groups are frequently excluded from trials**, including people who **may not be able to provide consent**.
For example, they are excluded from 8 out of 10 hip fracture trials.

Researchers often describe the challenges of designing and conducting trials involving adults with impaired capacity to consent.

This includes:

- ethical concerns about including people not able to consent
- practical issues such as who gives consent on their behalf
- methodological issues such as data collection

Addressing the exclusion of under-served groups is essential in order to develop effective interventions for these populations.

How will this framework help?

The INCLUDE Impaired Capacity to Consent Framework will help researchers who are designing trials to identify the ethical, methodological, and practical issues that their trial will encounter, and to minimise the barriers to inclusion.

1

It will ensure that **people with conditions or disabilities** that affect their capacity to consent **can participate in**, and **benefit from**, research – and so make research better.

2

It will **reassure research ethics committees** that the trial has been appropriately designed to include adults with impaired capacity.

3

It will also **benefit researchers** by improving the quality of their trial and demonstrate to funders that the proposed trial is inclusive of the population who are likely to need the intervention.

CARDIFF UNIVERSITY
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Trials Methodology TMRP Research Partnership

TRIAL FORGE

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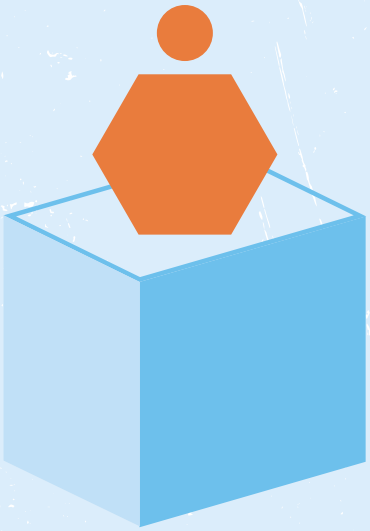
What does framework contain?

The Framework consists of **4 key questions** for researchers to think about. For each question there are **worksheets** to **help researchers answer the questions and identify what actions and resources are needed**, with signposting to information and resources on capacity and consent. Researchers can then summarise the actions to be taken to ensure their trial is inclusive of populations who may have impaired capacity, and identify any resources needed.

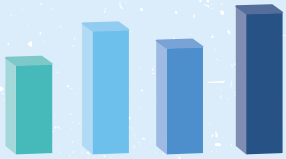
Q1 Who should my trial results apply to?	People with particular types or severity of conditions or disabilities that may impair their capacity to consent
Q2 Are they likely to respond to the intervention in a different way?	**Worksheet A** - condition/disability related factors, other factors
Q3 Will 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

Not all questions/sections will be relevant and can be left out if they are not helpful. **Some will require interpretation** to apply to the particular trial context or population.

It is **intended to be used for clinical trials**, but it may be useful for designing other types of studies – particularly Q4 and Worksheets C-G.



How is the framework used?



The framework should ideally **be used at the earliest stage of trial design**, prior to a funding application. It should be **used collaboratively across the research team** and, most importantly, **including public contributors**.

The framework can be completed iteratively. **The questions and worksheets can form the basis of discussions about the trial design**, with the framework document used to record the outcome of the discussions and actions required.

Using the framework will increase the time and work needed at the initial trial design stage as it **supports researchers to fully consider issues** and **collaborate on design solutions**. However, it will **enhance the quality of the funding application** and can facilitate later stages such as informing the design of the protocol and ethics application.

It may also increase the overall costs being requested but it will help justify how inclusion of these 'missing costs' will ensure that the inclusive design is appropriately resourced and funders are supportive of the INCLUDE frameworks.

To download the INCLUDE Impaired Capacity to Consent Framework and access other resources:
www.capacityconsentresearch.com

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