

# Could you help to improve future research involving adults who lack capacity to consent?

We have developed a decision aid to help families acting as consultees or legal representatives.

We are looking for 'host' studies to help evaluate it in a 'Study Within a Trial' (SWAT)



## 'PROXY CONSENT'

Families often find it hard to decide if their loved one should take part in a study, and would like help when making these decisions



## DECISION AID

We have developed a decision aid booklet to help them think it through and support them to make a more informed decision on the person's behalf



## EVALUATION

We now need to see whether it is an effective form of support by testing it within different studies that recruit adults who lack capacity

## WHAT IS THE PROJECT ABOUT?

Research involving adults who lack capacity to consent can be challenging. Many of the challenges arise from the need to involve alternative decision-makers at the time of recruitment. This is usually a family member acting as a consultee or legal representative. Previous research has shown that family members experience uncertainty when making what can be complex and challenging decisions, and some may experience decisional and emotional burden as a result. This can lead to a higher proportion of families declining participation, compared to people providing their own consent. A decision aid to help family members making a decision about research has been developed in collaboration with public involvement contributors and stakeholder groups. The CONSULT study is evaluating the decision aid as a 'Study Within a Trial' (SWAT) which is a self-contained research study that is embedded within a host study (or studies). We are looking for research teams to help us by embedding our SWAT in their study and contribute to the evidence-base for improving future research involving adults lacking capacity.

## WHAT IS INVOLVED?

Host study teams and sites will be fully supported to integrate the SWAT into their recruitment pathway. Full training will be provided, and SWAT materials (participant information, decision aid booklet, questionnaire) are included. Costs of up to £5K are available for host trials/sites to support SWAT-related activities, e.g trial manager time.

CONSULT SWAT is on the NIHR portfolio and already has REC and HRA/HCRW approvals in place. Host study sites are classed as PICs for the purpose of the SWAT. Each study seeks REC approval to embed the SWAT in that study, either from the start if it is in development, or as a substantial amendment if it already has approval. We can provide an example of text that has approval in other host studies.

## STUDY ELIGIBILITY?



Study team anticipates that a reasonable proportion of participants will lack capacity to consent



Recruitment involves family members acting as personal consultees or legal representatives



It is not emergency research using 'deferred consent' or a very narrow recruitment window

**For more information, or to express an interest in being a host study:**



<https://bit.ly/3Zye2vS>



[ShepherdVL1@cardiff.ac.uk](mailto:ShepherdVL1@cardiff.ac.uk)



[www.capacityconsentresearch.com](http://www.capacityconsentresearch.com)