Abstract Template

Project title **Opting In versus Opting Out: Advancing knowledge of trial consent procedures**

Institution **National University of Ireland, Galway**

Project details (250/250 words)

Specifically include how this project will improve the design, conduct, analysis, reporting, dissemination or implementation of clinical trials.

Traditional informed consent for randomised controlled trials follows an Opt-In approach, where potential participants are provided with information about a trial and are only enrolled if they give voluntary written consent to take part. This process can be time-consuming, impact on recruitment reach and may not be an accurate reflection of real-world implementation of healthcare innovations.

Opt-Out consent has been suggested as an alternative, where potential participants are provided with information and automatically enrolled to take part unless they actively dissent. Following an Opt-Out approach offer potential benefits, but may also raise legal and ethical issues.

The aim of this project is to conduct a scoping literature review on the benefits and challenges of the use of Opt-Out consent, and to identify the key stakeholders to be consulted in exploring the feasibility and ethicality of alternative consent procedures.

The findings from this project will inform the development of the recruitment strategy for an implementation study as part of the Support through Mobile Messaging and digital health Technology for Diabetes (SuMMiT-D) study, a six year study funded by the UK National Institute for Health Research. The implementation study will run parallel to the main effectiveness trial, and aims to explore the potential reach of text-message support if implemented at scale in general practice.

Consent is a key aspect of trial recruitment and understanding the benefits, challenges and key stakeholders associated with alternative consent procedures will be beneficial to the trial methodology research community in the planning and conduct of trials.

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