



## Abstract Template

### Project title

An Investigation into the Factors Affecting Investigator Initiated Trial Start Up and Completion in Ireland

### Institution

UCD

### Project details (max 250 words)

Clinical research is the critical way to gather in-situ evidence on the efficacy of therapeutic interventions, develop effective clinical management strategies, decide on best practices, and to inform the development of the healthcare system. Clinical Trials initiated by investigators are particularly important in this context. Despite this starting up clinical trials is recognised as extremely time-consuming and resource intensive. There are various structural and administrative factors that can delay the initiation of clinical trials. Structural factors may include fixed meeting dates of ethics boards, lack of parallel review, or requirement of approvals from multiple agencies. Administrative factors may include the time and effort involved in adequate preparation of the complex application process, issues in finalising various contracts and agreements, and budget and funding.

The focus of this study, a collaboration with CRDi and its Clinical Research partners,, is to understand the contractual, ethical, administrative, regulatory, and logistical bottlenecks to the initiation of investigator initiated clinical trials in Ireland. To achieve this goal, we propose to comprehensively profile the impediments to implementation and running clinical research in all the recent DIFA awards. Given the complexity of the variables affecting study start up, we will achieve this goal using a mixed methods approach. In contrast to the qualitative and the quantitative approaches, which solely rely on a specific type of data and method, the mixed methods approach uses both qualitative and quantitative data and integrates them to get a more complete picture of the research question. Using this approach we will identify both

quantitative (for example timelines) and qualitative (for example process description) factors influencing study start up and completion.

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