Abstract Template

Project title **Evaluation of Implementation of TRUST clinical trial in Ireland**

Institution **UCC**

Project details (max 250 words)

Background

Clinical trialists in Ireland work within an international framework of Good Clinical Practice (GCP), and a regulatory structure based on the European Clinical Trials Directive. There has been some difference in interpretation and implementation of the current directive in different countries. In Ireland, implementation is based on a number of Statutory Instruments. Informed consent is an essential component of the safe and appropriate conduct of clinical trials. While EU law does not specify that informed consent must be obtained by a medical doctor, Irish law does. Also, unlike other European countries, it is illegal in Ireland to supply medicines by post. These country specific barriers require innovative approaches to conducting large-scale clinical trials in Ireland. In TRUST, an EU FP7 funded clinical trial with sites in Scotland, Netherlands, Switzerland and Ireland, local modifications to the study protocol were developed to address these challenges.

Aim

To gain insights using process evaluation into impact of local modifications on stakeholders in TRUST (i.e. participants, study personnel and health care providers) to inform future conduct of clinical trials in Ireland.

Methods

Semi-structured interviews with purposive sample of study nurses, doctors and participants will be undertaken. The topic guide will include questions on the informed consent process and the supply of study medications as well as more general questions on attitudes towards and experience of participation in clinical trials. Data will be transcribed verbatim and entered into NVivo for analysis. Thematic analysis will be undertaken using a framework approach to obtain insights into local process.

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