Text for substantial amendment (IRAS V3.0 Notice of Amendment)

- Under 'Project filter' questions 1 – 11 are unchanged
- Under 'Notice of amendment' details of CI and study are unchanged
- Under 'Type of amendment'
    - QA – Yes
    - QB – No
    - QC – Yes
- **Is this a modified version of an amendment previously notified and not approved? –**No

Summary of changes

Under Summary of changes please use the following text to structure the section:

We are not proposing to make any changes to the main substance of the *[Host trial name]* trial: the objectives, sample, recruitment procedure, interventions and measures remain as approved by the REC on [*date of REC approval].* We are proposing to run an additional trial [and qualitative study] as a sub-study, entitled MRC START in *[Host trial name]*. This sub-study will focus on the written information provided to potential trial participants (participant information sheet). Data from the sub-study will contribute to a progamme of research funded by the MRC to expand the relatively small evidence base on an important issue concerning the recruitment of participants to trials [and informed consent – delete if not using decline forms, quality of informed consent measures or focus groups].

The main change is to the written participant information sheet that is given/posted out to potential participants in *[Host trial name]*.

For the sub-study, potential participants will receive one of two versions – the original version or a revised version, which has had both its language and its design modified. The content (i.e. the topics covered) remains the same in the two versions of the sheet. The allocation of sheet version to each participant will be decided randomly. The main outcome of interest here is the proportion of participants receiving each version of the sheet who go on to take part in the *[Host trial name]* trial.

The following paragraphs relate to additional/optional study elements – delete as appropriate and amend list of enclosed documents

Participants who have consented to take part in the *[Host trial name]* study, will be asked to complete an additional questionnaire to those already approved as part of the *[Host trial name]* study. This will be a scale measure looking at the quality of informed consent.

In patients who state that they would prefer not to take part in *[Host trial name]*, we have [amended] a 'decline' form including a response concerning the written information they have received.

We also wish to run a qualitative study on the written information participants received. We aim to recruit approximately XX participants who:

1. have consented to participate in the *[Host trial name]* study
2. have agreed to receive information about related studies in their original consent

Participants who agree to take part will attend a focus group discussion, lasting 60 – 90 minutes, and read two versions of the information sheet before the meeting. These qualitative data should be invaluable in helping us to understand the extent to which the written information they received about the *[Host trial name]* study impacted on their decision to take part.

Any other relevant information

We have enclosed a copy of the new MRC START in *[Host trial name]* protocol and associated documents for your information.

List of enclosed documents

Document	*Version*	*Date*
MRC START in *[Host trial name]* Protocol	*V*	
Revised *[Host trial name]* PIS	*V1*	
MRC START data sharing agreement	*V3*	*25-10-12*
MRC START Publication & Authorship Arrangements	*V3*	*25-10-12*
[Host trial name]'Decline Form' – delete as appropriate		
Quality of informed consent scale – delete as appropriate		
Focus group study information letter – delete as appropriate		
Focus group study participant information sheet – delete as appropriate		
Focus group study study consent form – delete as appropriate		