## J2: Summary of Proposed Amendment:

## ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and of omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes.

Reference: MREC 03/8/087

Substantial Amendment Code Number: CTSUASCEND4
Version: 8
Date: 2008-06-12

**Amendment to update Study Treatment Information Leaflet.**

All participants in the ASCEND trial are sent a Study Treatment Information Leaflet (STIL) if they are willing and eligible to participate in the study, based on the answers they give to the Screening questionnaire. The STIL is sent with a letter informing them that they have entered the “run-in” phase of the study, prior to them receiving their “run-in” pack of study medication.

All participants who complete this “run-in” phase and are still willing and eligible are then randomised into the study. They are sent another copy of the STIL with the letter informing them that they have been randomised.

We wish to update the STIL to clarify some of the information given, and to provide further information about how participants might manage minor symptoms which they believe might be due to the study treatment. We also wish to provide some pictorial information on the simplest method of removing study treatment from the calendar blister packs in which it is provided, as this is a common reason for participants contacting the coordinating centre.

There is also an important list on the final page of the STIL which indicates which proprietary medicines contain aspirin (and therefore should not be taken with ASCEND study treatment), and this has been updated to reflect what is currently available.

The STIL provides valuable information for study participants, and it is recommended that they keep it for future reference. It is therefore important that it is clear and up to date. We therefore intend to send an updated version of the STIL to all randomised participants, as well as to all new participants entering the study as above.

A copy of the previous version of the STIL is enclosed [V2.0_210504] as well as copies of the new version [V3.0_160508] (one copy with changes highlighted and one plain copy).