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

Summary and rationale of Proposed Amendment:

As specified in section 3.7.1 of the ASCEND Protocol [V9.0_140111], a randomly selected sub-set of randomised participants (5-10%) will be asked if they are willing to provide a blood and urine sample and mail these to us. Similar procedures were used during the pre-randomization run-in phase of the study and allowed blood or urine samples to be collected from about three quarters of the randomized participants. These baseline measurements will allow us to see whether the effects of the treatments being used in the study vary between different types of people taking part. We now wish to repeat those tests to assess the impact of the study treatments on these factors and use this as an objective measure of compliance. We have prepared the necessary documents (as listed below) to use during the process of sample collection.

List of new documents enclosed:

1. Additional Blood & Urine sampling consent form V1.0_2011-12-01
2. Additional Blood & Urine sampling Information leaflet V1.0_2011-12-01
3. Additional Blood & Urine sampling Instruction V1.0_2011-12-01
4. GP letter for additional blood and urine results V1.0_2011-12-01