

**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**

**Protocol Amendment Code Number: CTSUASCEND1-1**

**Version: 7**

**Date: 2004-05-19**

**Summary of Proposed Amendment:**

Addition of a request for an optional urine sample during the pre-randomisation Run-in period, and for urine to be assessed at least once during follow-up on a random sample of participants.

Measurement of urinary albumin to creatinine ratio will allow more precise stratification of participants by baseline cardiovascular risk, since urinary microalbuminuria is an important predictor of risk. Long-term storage of urine sample may allow future analyses of new or emerging biochemical risk factors for diabetes.