

ASCEND: Document Changes for Re-Submission to the North West MREC

Attachment 1

Amendments to B15-2: Participant Invitation Letter, Screening Questionnaire and Consent Form (version for participants identified from general practice) [V1_170903]

New Version File Name: Participant Invitation Letter, Screening Questionnaire and Consent Form (version for participants identified from general practice) [V3_140504]

Please note that the same changes to the questionnaire and consent form are applicable to B15-1 (version for participants identified from diabetes registers) and B15-3 (version for participants identified from trial database). There have however been no changes made to the participant invitation letter on the front cover of the questionnaire in any of these versions (B15-1, B15-2 and B15-3).

Attachment 2

Amendments to B17-1: Information Leaflet "ASCEND: Invitation to join a large medical project" [V6_201103]

New Version File Name: "ASCEND: Patient Info Leaflet" [V7_070504]

Please note that a detailed description of all the changes that have been made to the Patient Information Leaflet are contained in Attachment 8 (Amendments to ASCEND Protocol [V7_190504]).

Attachment 3

Amendments to B17-2: Supplementary Information Leaflet; "ASCEND: Information about blood sampling" [V4_201103]

New Version File Name: "ASCEND: Blood & Urine Sampling Information Leaflet" [V5_210504]

Attachment 4

Amendments to B17-3: Information about study medication [V1_170903]

New Version File Name: "ASCEND: Study Treatment Information Leaflet" [V2_210504]

Attachment 5

Amendments to B18-2: Consent form for blood sampling; "ASCEND: Consent for blood collection, storage and analysis" [V2_060803]

New Version File Name: "ASCEND: Blood & Urine Sample Consent Form" [V3_210504]

Attachment 6

Amendments to B22-1: Participant Letter and Randomisation Questionnaire [V1_170903]

New Version File Name: Participant Letter and Randomisation Questionnaire [V2_200504]

Attachment 7

Amendments to B22-2: Participant Letter and Follow-up Questionnaire [V1_170903]

New Version File Name: Participant Letter and Follow-up Questionnaire [V2_190504]

Attachment 8

Amendments to ASCEND Protocol [V6_201103]

New Version File Name: ASCEND Protocol [V7_190504]