Reviewer's report

Title: Randomised Prospective Study for the Effect of Therapy on Residual Beta Cell Function in Type-1 Diabetes Mellitus

Version: 3 Date: 2 October 2003

Reviewer: Anders Green

Reviewer's report:

Concerning point B1 (ethical issue) I have no further comments, leaving any conclusions and opinions to be made by other parties based on the argumentation presented.

Concerning the remaining points I suggest that the replies from the authors should be incorporated into the text, based on the fact that this paper represents a description of a protocol.

Definitions of neuropathy and retinopathy (point B4) should be specified or, at least, be given appropriate references.

The section on statistical methods should include the account of the complex methods needed to be applied in the analysis of "change of C-peptide", with the redundancy of C-peptide levels (point B3).

The problem of potential bias due to diagnostic misclassification (point B2) remains unsolved by the mere inclusion of autoantibodies for a relatively small fraction of the patients. How will this information be managed to address the problem? And, how will the potential confounders BMI, age and sex be managed statistically?

It remains unclear what is meant by the term "familywise" frequently used particularly in conjunction with statistical aspects (point B8).