Reviewer’s report

Title: Design and rationale for the 6S - Scandinavian Starch for Severe Sepsis/Septic Shock trial - A double-blinded, randomised clinical trial comparing the effect of hydroxyethyl starch 130/0.4 with balanced crystalloid solution on mortality and kidney failure in patients with severe sepsis

Version: 3 Date: 29 September 2010

Reviewer: Charlie Goldsmith

Reviewer’s report:

The revision and comments have now been reviewed. The answers provided to the reviewer comments were reasonable. However, I still think that the use of [and/or] is incorrect around consent. If a next of kin is available then consent should be sought; however, if not, then investigator consent should suffice given that these patients usually cannot give their consent.

Further suggestions for improvement:

1. P(age) 3, p(aragraph) 2, l(ine) 5. Suggest deleting [only] and the use of [single] later in the line should be adequate.

2. P 5, p 1, l 2. This reviewer still thinks that [and/or] should not be used but the phrase [including next of kin consent if possible, otherwise the investigator consent if not possible]. Logically one could still have both next of kin and investigator when the two are connected with [or]. Also P 11, p 7, l 7,8.

3. P 8, p 2, l 5. While it is okay to add a patient if one dropped out before completion of the study recruiting, it should not be described as [replacing the patient]. After the patient is randomized, CONSORT guidelines suggest reporting the patient numbers even if there are no data because the patients subsequently refused to let you use their data. Also, any data available with consent should be used in your analyses, even, if the impact on the conclusions is small.