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30<sup>th</sup> September 2008

Dear Mr Feinmann,

**Appraisal of machine (pulsatile) perfusion versus cold (static) storage solutions for the preservation of donated kidneys – Comments on the Appraisal Consultation Document for consideration by the Appraisal Committee**

**Please note all academic in confidence information is in red and underlined**

Thank you for the opportunity to provide comments on the Appraisal Consultation Document (ACD) for the above appraisal.

Organ Recovery Systems is supportive of the recommendations contained within the ACD. In particular we are encouraged by the decision to recommend both cold storage and machine perfusion options while directing *'The choice of storage method should take into account clinical and logistical factors within both the retrieval teams and transplant centres'*.

While we consider that all the currently available and relevant information has been taken into account we have the following clarification points

- Section 4.1.6

This section is currently incorrect referring to the Machine Preservation Trial but then presenting, within the same paragraph the results of a separate retrospective record review published by Moustafellos et al.<sup>1</sup> For accuracy this section should be divided into two separate points as follows:

*'4.1.6 The results of the Machine Preservation Trial study were provided as academic-in-confidence and are not included in this document*

*'4.1.7 A retrospective review reported.....'*

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<sup>1</sup> Moustafellos P, Hadjianastassiou V, Roy D, Mukhtadir A, Contractor H, Vaidya A et al. The influence of pulsatile preservation in kidney transplantation from non-heart-beating donors. *Transplant Proc* 2007; 39(5):1323-1325

- Section 4.3.6

Within this section we have three points we would like to comment on:

1. The current statement on the Machine Preservation Trial *'The Committee was aware that this study included mainly kidneys from deceased heart beating donors....'* excludes the information which is available on kidneys on DCD donors which demonstrates the effectiveness of LifePort over static storage in preserving these kidneys.
2. The statement; *'The Committee considered that this study suggested a small benefit in terms of graft survival favouring the use of machine perfusion'* is misleading and does not highlight to the reader the statistically significant results observed at 12-months post transplantation. In the first year post transplantation compared with cold static storage machine perfusion significantly:
  - [AIC information removed](#)
  - [AIC information removed](#)

We would recommend that the Committee consider revising the current text as follows; *'The Committee considered that this study suggested a ~~small~~ statistically significant benefit in terms of graft survival favouring the use of machine perfusion'*

3. The ACD makes the statement; *'The Committee heard clinical specialists express concern about the exclusion of a large number of kidneys from the statistical analysis in the Machine Preservation Trial, and the effect that these exclusions may have had on results'*. While we agree that the number of exclusions may seem rather large this is primarily due to the requirement for achieving successful randomisation. Within the trial the acceptance criteria used required randomisation to be performed at an early stage when there was merely the possibility of a potential kidney donor. Only after both kidneys had actually been transplanted could it be determined whether this kidney pair would meet the inclusion criteria. In addition all combined organ transplants were excluded according to the study protocol.

In addition to these main comments further comments from Organ Recovery Systems are documented in the attached table.

Yours sincerely



**Organ Recovery Systems**



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**Organ Recovery Systems: Additional Comments on the Appraisal Consultation Document - Appraisal of machine (pulsatile) perfusion versus cold (static) storage solutions for the preservation of donated kidneys**

| Page | Section    | Comment  |
|------|------------|--|
| 17   | 4.3.4      | In order to reflect the pending Machine Preservation Trial data on viability testing we would suggest the following underlined text is added:<br><br><i>‘...The Committee concluded that although viability testing is potentially important, there was insufficient evidence <u>at this point in time</u> to make this a deciding factor in choice of storage methods.’</i> |
| 19   | 4.3.7      | Again to reflect pending results from the Machine Preservation Trial we would recommend the addition of the following sentence to the end of this recommendation:<br><br><i>‘Additional 12-month outcomes data will be available from the Machine Preservation Trial’</i>  |
| 28   | Appendix B | Ken Tupling, nominated by BODY is a transplant recipient and Secretary of British Organ Donor Society not a clinical specialist  |