Record of Reported Changes in HTA Project Protocol

Project Number: *99/33/51*

Project Title: *Psychological interventions for postnatal depression - randomised controlled trial and economic evaluation (The PoNDER Trial).*

Project Lead: *Dr Jane Morrell*

Project Contact: *Dr Jane Morrell*

In order for your final payments to be released, we need to ensure your report fulfils the requirements as set out in the finalised protocol and agreed during the commissioning of your project. You were requested to inform us of any changes to protocol in your six-monthly progress reports. The following table lists the changes to protocol you advised have been made since your project was commissioned.

Change to Protocol	Progress Report	Approved by
1. Inclusion of HV assessment, in addition to EPDS scores of 12+, to offer treatment to patients.	1	HB
2. EPDS + CORE replace BDI as assessments at the six month evaluation	2	SPL
3. (May 2005. A conscious violation of the protocol did not take place when HVs did not offer an intervention to all women 'Eligible for the intervention' by virtue of two scores of 12 or more on the EPDS, but a problem arose because insufficient detail was given in the original protocol)		
4.		
5.		
6.		

Please tick one of the following:

£ No changes have been made to the project protocol.

£ I agree that the Protocol changes listed above are accurate.

£ I have amended the list to include additional changes or to modify the changes listed.

I confirm that all changes to protocol are reported in the Methods section of the draft final report.

Signed: ..... (Principal Investigator)

Print Name: .**Carol Jane Morrell**
.....

Date: .....

If your project is a randomised controlled trial please confirm that you have followed the CONSORT guidelines in the preparation of your draft final report.

o YES **o** NO **o** N/A

Please enter the date of the most recent literature search undertaken: ..... **o** N/A

If it is more appropriate, the Project Co-ordinator/Trial Manager may sign this form.