Author’s response to reviews

Title: Saving Babies’ Lives Project Impact and Results Evaluation (SPIRE): a mixed methodology study

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Author’s response to reviews:

Dear Ms Boodhun and Dr Khalil,

Re – PRCH-D-17-00613- Study Protocol – Saving Babies’ Lives Project Impact and Results Evaluation (SPIRE): a mixed methodology study

Thank you for considering this protocol for publication in BMC Pregnancy and Childbirth. In response to your queries in the email dated 8th August.

With regard to the queries raised, this study is funded by NHS England and was peer-reviewed prior to funding by NHS England and adoption on to the Clinical Research Network. This study has not received any funding from a commercial organisation.

The study is currently ongoing, it is recruiting participants from the 12 sites, with 8 further sites due to commence recruitment in September 2017. The study will be completed in December 2017.

There have not been any other publications relating to this study. Statistical analysis will not commence until late Autumn/Winter 2017 so there are no published results at this stage.

The declarations section has now been completed according to the submission guidelines for BMC Pregnancy and Childbirth.

The project has been registered on ClinicalTrials.gov NCT03231007, the registration of 26th July has been added to the relevant line of the abstract.
The study is currently open for recruitment so should be regarded as an ongoing study. Completion of recruitment will not be complete until December 2017. As yet there have been no publications containing the results of this study.

This manuscript is not being considered for publication elsewhere. The authors do not have any competing financial or personal interests. All authors fulfil the requirements for authorship status. Thank you for considering this revised protocol for publication in BMC Pregnancy and Childbirth.

Yours sincerely,

Professor Alexander Heazell, Chief Investigator, SPiRE Study