MEMORANDUM OF UNDERSTANDING

The Royal College of Obstetricians and Gynaecologists and the Health Services Investigation Branch

Introduction

1. This Memorandum of Understanding (MoU) sets out the framework to support the working relationship between the Royal College of Obstetricians and Gynaecologists (RCOG) and the Healthcare Safety Investigation Branch (HSIB), to facilitate the reporting of incidents and productive themed learning of local investigation reports.
2. It is intended to inform members of staff about how the RCOG and the HSIB will work together, and to ensure that effective channels of communication are maintained.

3. The RCOG is a registered charity (no. 213280). It was granted a 'Royal' title in 1938 and the Royal Charter was awarded on 21 March 1947. RCOG works to improve health care for women everywhere, by setting standards for clinical practice, providing doctors with training and lifelong learning, and advocating for women's health care worldwide. The RCOG is the "Data processor".

4. HSIB is a safety investigation body established under the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 and the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. The HSIB was set up to discharge the Secretary of State (SoS) duties in relation to the promotion of a comprehensive health service and securing continuous improvement in the quality of services. HSIB is the "Data controller"

5. The functions of the RCOG and the HSIB are set out above. Both organisations seek to encourage and promote patient safety and quality within healthcare settings.

Principles of Co-operation

6. This MoU is a statement of principle which supports our focus on promoting patient and public safety and wellbeing. More detailed operational protocols and guidance can be developed as required.

7. The RCOG and the HSIB intend that their working relationship be characterised by the following principles:

    a. The need to collaborate to improve the quality of care for mothers and babies across England and support the workforce to deliver improved care.
    b. Respect for each organisation's independent status.
    c. The need to maintain public and professional confidence in the two organisations.
    d. Openness and transparency between the two organisations as to when co-operation is and is not considered necessary and/or appropriate.
    e. Promoting unified messages to the sector regarding emerging thematic trends
    f. Promoting mutually agreed recommendations drawn from the findings of the HSIB investigations

Areas of Co-operation

8. The working relationship between the RCOG and HSIB involves co-operation in the following areas:

Notification

    a. Both organisations will work together to develop a simplified system for Trusts who currently notify both RCOG and the HSIB of all cases fulfilling EBC criteria.

Investigation Reports

    a. The HSIB may share reports with the RCOG that do not include personal identifiable data but may include a referral number that can be used to identify the referral route and the reporting trust.

Theme development

    a. HSIB and the RCOG shall work together to understand the themes from investigations.

9. The RCOG and the HSIB recognise their responsibilities under the Freedom of Information Act 2000. Where either party receives a request under the Act for information received for the other organisation, each agrees to take reasonable steps to consult on the proposed disclosure and the application of exemptions but

recognise that the responsibility for disclosure lies with the organisation that received the request.

Duration and Review

10. This MoU commences on the date of the signatures below. The MOU will be reviewed every two years or when changes to either party's legislation of Directions. It will also be reviewed if the principles described above need to be altered and/or cease to be relevant for any other reason. Any alterations to the MoU will require both parties to agree.

11. For both organisations the Information Governance leads will be responsible for the management of this MoU and will liaise as required to ensure that:

    a. This MoU is kept up to date;
    b. They identify any emerging issues in the working relationship between the organisations;
    c. They resolve any questions that arise regarding the interpretation of this MoU.

Intellectual Property

12. The RCOG shall retain IPR (intellectual property rights) for all its products, including, but not limited to, Each Baby Counts data and outputs.

13. The HSIB shall retain IPR for all products it develops and manages, including, but not limited to its investigation reports, published recommendations from emerging thematic trends any systems or software designed and procured for facilitating information sharing and all information recorded on those systems.

Agreement

14. Each Party is responsible for its own administration.

15. Any costs associated with this collaboration shall be discussed between both Parties before any agreement is made.

Branding

16. All products and services developed in collaboration shall be branded as RCOG and HSIB products.

Data protection

17. Where the Parties share data, it will be on the understanding that data ownership is not changed.

18. Data will be used only for the specific purpose for which it has been provided.

19. Each Party shall comply always with applicable Data Protection legislation in respect of any personal data processed by it pursuant to this MoU. Such data sharing will be subject to a data sharing agreement between both organisations.

20. Data is not permitted to be copied onto non-secured personal devices.

21. No such data shall be passed on to any third party without the prior consent of the data owner.

Governing law

22. This MOU is not intended to be a contract in law and does not give rise to any contractual rights or liabilities. It does not override the signatories' statutory responsibilities or functions, nor does it infringe their autonomy or accountability.

23. Any legal agreements prepared in connection with this MoU, and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) shall be mutually resolved between the two parties, and if necessarily governed exclusively by and construed in accordance with the jurisdiction of the courts of England and Wales.

Entire Agreement

24. This MoU, in its present form, constitutes the entire agreement between the parties and supersedes and extinguishes all previous drafts, agreements, arrangements and understandings between them, whether written or oral, relating to this subject matter.

25. Each Party hereby confirms its agreement to the terms contained in this Memorandum of Understanding.

26. Either party may terminate this MOU with immediate effect and may request the prompt return of any information it has share with the other organisation.

Signed on behalf of ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS

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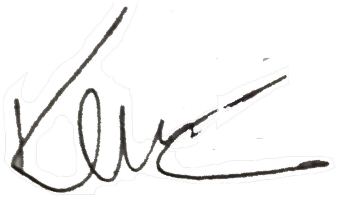
Name (Print): **Linda Burke**

Position: **Executive Director, Education & Quality**

Date: 22nd January 2019

Signed on behalf of the HEALTH SERVICES INVESTIGATION BRANCH (HSIB)



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Name (Print): **Keith Conradi**

Position: **Chief Investigator**

Date: 18th January 2019

Appendix 1 – Definition of an EBC eligible case

The Department of Health and Social Care (DHSC) publication *Safer Maternity Care* (2017)[1] made a commitment to fund the Healthcare Safety Investigation Branch to undertake investigations into eligible EBC babies. The Secretary of State report stated "The Department of Health is committed to improving the standards and quality of investigations and learning from serious incidents leading to stillbirth, early neonatal death or serious brain injury in term babies and all maternal deaths from direct or indirect causes related to pregnancy. The new Healthcare Safety Investigation Branch (HSIB) will be funded to develop investigation standards and conduct independent investigations into all cases that are in accordance with the criteria for notification to the RCOG's Each Baby Counts Programme and all maternal deaths from direct or indirect causes related to pregnancy. NHSE, working with NHS Improvement, the Department of Health and HSIB will publish, by Quarter 2 2018, information and guidance on the standards for maternity investigations to deliver the Morecambe Bay and Better Births recommendations."

Notifiable cases include term deliveries (≥37+0 completed weeks of gestation) following labour that resulted in one or more of the following three outcomes:
1. Intrapartum stillbirth: when the baby was thought to be alive* at the start of labour but was born with no signs of life†; this includes cases in which:

- Labour was diagnosed by a health professional; this includes the latent phase of labour, i.e. less than 4cm dilatation
- The woman called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes
- The baby was thought to be alive at induction of labour
- The baby was thought to be alive following suspected or confirmed premature rupture of membranes (PROM)

2. Early neonatal death: when the baby died within the first week of life (i.e. days 0–6) of any cause.
3. Severe brain injury diagnosed in the first seven days of life. These are any babies that fall into the following categories:

- Was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE) OR
- Was therapeutically cooled (active cooling only) OR
- Had decreased central tone AND was comatose AND had seizures of any kind

*As assessed by any means, including but not limited to: Pinard stethoscope, handheld Doppler, CTG, bedside ultrasound, assessment of fetal movements, or assumed to be alive without confirmation.
† Exclude macerated stillbirth if confirmed by post mortem.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf

Appendix 2 – Each Baby Counts methodology

Each Baby Counts is a UK-wide quality improvement programme led by the Royal College of Obstetricians and Gynaecologists (RCOG). Its aim is to reduce the incidence of intrapartum stillbirth, early neonatal death and severe brain injury as a result of events in labour by 50% between 2015 and 2020.

The Each Baby Counts team is made up of a project team, based at the RCOG, who have compiled this report; 316 local Lead Reporters, who have responsibility for completing an online registration form for all eligible babies born in their unit; and 60 Each Baby Counts reviewers, who complete an independent review of the local investigation reports submitted by Lead Reporters.A full list of Each Baby Counts Lead Reporters and reviewers is available on the RCOG website: https://www.rcog.org.uk/each-baby-counts-team.

Lead Reporters were nominated by the clinical director of each trust/board.Trusts/boards are able to nominate more than one Lead Reporter to help identify and report every eligible baby. Each Baby Counts reviewers (25 obstetricians; 24 midwives; 8 neonatologists; 3 anaesthetists) were recruited via the relevant professional bodies and were trained to carry out a structured review using the Each Baby Counts pro forma.The RCOG wishes to stress that the Each Baby Counts project would not function without the expertise and support of the reviewers and Lead Reporters, and the College is indebted to them for all their hard work in providing the information on which this report is based.

By April 2015, all (100%) NHS trusts/boards in the UK had agreed to participate in the Each Baby Count project and nominated Lead Reporter(s) to report all eligible babies born in their trust/board since 1 January 2015. Private maternity hospitals and independent midwives were also invited to participate in the project to ensure improvements in all aspects of intrapartum care can be identified.

Eligible babies include all term babies (at least 37+0 completed weeks of gestation) born following labour who have one of the following outcomes:

- Intrapartum stillbirth: when the baby was thought to be alive at the start of labour but was born with no signs of life.
- Early neonatal death: when the baby died within the first week of life (i.e. days 0–6) of any cause.
- Severe brain injury diagnosed in the first 7 days of life, when the baby:
    - was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE) OR
    - was therapeutically cooled (active cooling only) OR
    - had decreased central tone AND was comatose AND
    - had seizures of any kind.

Babies whose outcome was the result of congenital anomalies were excluded centrally by the project team.

The definition of labour for Each Baby Counts includes:

- any labour diagnosed by a health professional, including the latent phase of labour at less than 4 cm cervical dilatation
- when the woman called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes
- induction of labour
- when the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes.

The rationale for this is to have an inclusive definition of labour to include as many babies as possible and to identify babies who are affected in the latent phase of labour.

The severe brain injury definition is a pragmatic definition which is a composite of defined populations such as those entering the TOBY (Total Body HYpothermia) trial as well as data that can be captured from neonatal information systems. It is not yet known how many of these babies will have a significant long-term disability as a result of the injuries sustained during birth, but the fact that the majority of these infants require active therapeutic cooling – an intensive intervention requiring sedation and admission to the neonatal unit – reflects the serious clinical condition of these babies.

Lead Reporters are requested to complete basic information within 5 working days of the baby's birth or death via a secure online platform. This is used to confirm that the baby is eligible for Each Baby Counts. If a baby is confirmed as eligible by the local trust or health board, the Lead Reporter is required to upload an anonymised copy of the local review and complete a short form capturing details about the review process.The data include professionals involved in the review process, involvement of the parents and the specific review tool(s) used. Lead Reporters are requested to remove all patient identifiers from local investigation report files before these are uploaded.

The anonymised report from the local review is then sent to two independent Each Baby Counts reviewers, a midwife and an obstetrician.The reviewers do not have access to the case notes or statements from the staff involved; therefore the process is reliant upon the quality of the local reviews.The reviewers are required to answer the following questions:

- In your opinion, taking into account the information presented, is this review of sufficient quality to make a judgement about the care provided?
- According to the information presented, might different clinical care have resulted in a different outcome?
- What were the critical contributory factors that, if done differently, could have changed the outcome?

If there is a discrepancy between the reviewers' answers to the first question, the report is read by a member of the Each Baby Counts team and the consensus opinion is upheld. A report that contains insufficient information for a judgement about the care to be made is flagged as such and the Lead Reporter from the reporting unit is informed.

If the report is considered to contain sufficient information and it is felt that different care might have prevented the outcome, the reviewer is asked to identify the factors that

contributed to the outcome.The list of contributory factors was adapted from the framework previously used by the National Patient Safety Agency augmented by an analysis of the contributory factors that emerged from the review of the first 100 Each Baby Counts reports received in early 2015.

The reviewers are asked to indicate if they feel that the report requires the review of a neonatologist or anaesthetist. Reviewers are not asked to assess the care of babies who were born in their own or neighbouring regions to protect the confidentiality of both patients and staff involved.

Case ascertainment

Intrapartum stillbirths and early neonatal deaths are cross-checked against data from MBRRACE-UK. MBRRACE-UK conduct case ascertainment against Office for National Statistics and National Records of Scotland birth and death registration data and hospital data in Northern Ireland, to ensure that all perinatal deaths are recorded. In addition to the cross-checking undertaken by MBRRACE-UK against Each Baby Counts eligibility, the MBRRACE-UK system flags any babies potentially eligible for Each Baby Counts when they are entered.

Babies with a severe neonatal brain injury are cross-checked against the National Neonatal Research Database, which holds data on 98% of neonatal units in England,Wales and Scotland. Northern Irish neonatal units use the BadgerNet database and this is also used to check case ascertainment. A system is currently being developed to cross-check these cases of severe brain injury in Northern Ireland.

Lead Reporters are sent lists of potentially eligible babies identified from these data sources who have been born in their unit but have not been reported to Each Baby Counts.They are asked to confirm their eligibility via the online reporting system.The clinical director of obstetrics (chief of service) in each maternity unit has overall responsibility for ensuring that data are submitted in a timely fashion and that each eligible baby is reported.