1 PURPOSE OF AGREEMENT

1.1 This agreement authorises the release of the neonatal data listed in appendix 1 (termed the “National Neonatal Dataset”) held on the Badger.net/Neonatal.net server by Clevermed Ltd (www.clevermed.com), to the Neonatal Data Analysis Unit (NDAU), to form the “National Neonatal Database”.

1.2 The Badger.net platform is a neonatal patient data management system in wide use in the UK; identifiable patient data are held on a dedicated NHS.net server in a secure NHS approved hosting site; these data are owned by the contributing NHS Trust.

1.3 The National Neonatal Database has been established to enable data captured by NHS Trusts to be held securely as a national resource in a central repository for use for multiple purposes; it is held on the NHS server of Chelsea & Westminster NHS Foundation Trust and managed by the Neonatal Data Analysis Unit; data items added to the National Neonatal Database will be provided as an updated appendix annually.

1.4 Contributing NHS Trusts are known as the UK Neonatal Collaborative.

1.5 The Neonatal Data Analysis Unit Steering Board includes representation from neonatal network managers, commissioners, clinicians, academics, Bliss, and the National Neonatal Audit Programme; details may be found at www.imperial.ac.uk/ndau.

1.6 The National Research Ethics Service (ref 10/H0803/151) and the Ethics & Confidentiality Committee of the National Information Governance Board (ref ECC8-05(f)/2010) have approved the use of the National Neonatal Database to support NHS services and research.

2 SUPPORT FOR NHS SERVICES

2.1 Non-research purposes include the Royal College of Paediatrics & Child Health National Neonatal Audit Programme (NNAP), support for quality improvement programmes, surveys and service evaluations including neonatal dashboard analyses, carried out by the Neonatal Data Analysis Unit.

2.2 In accordance with current expectations regarding transparency, Neonatal Trusts and Networks will be identifiable in NHS service support reports; patients will not be identified.

2.3 Contributing NHS Trusts/Neonatal Networks/Lead Clinicians will be acknowledged and listed in all NHS service support outputs; examples include National Neonatal Audit Programme reports, web-reports, peer-reviewed publications, professional and lay publications, conference presentations and commissioned reports.
3 SUPPORT FOR RESEARCH

3.1 The regulatory approvals governing the creation of the National Neonatal Database are distinct from those required for each individual research study involving the Database.

3.2 Under the Research Governance Framework there is no requirement for Research & Development Office approval from each individual NHS Trust supplying data to the National Neonatal Database; however NHS Trusts supplying data must be made aware of their role and must agree to release the data (also see 3.4).

3.3 Separate approval by the National Research Ethics Service is required for each research study carried out involving the National Neonatal Database. The Neonatal Data Analysis Unit is willing to advise on study design and obtaining approvals if desired.

3.4 The agreement of each contributing Trust will be sought by the investigators for all research projects employing data held in the National Neonatal Database.

3.5 NHS Trusts, Networks and patients will not be identifiable in any research outputs.

3.6 NHS Trusts contributing data for research studies that are adopted onto the National Institute for Health Research portfolio may list participation in their Research Quality Account returns, register their involvement through the Central System for Processing, and may be eligible for support through the appropriate Research Network.

4 PARENT INFORMATION

4.1 The Ethics & Confidentiality Committee of the National Information Governance Board has approved the use of data held in the National Neonatal Database under Section 251 that permits access to patient identifiable information without consent; with the National Research Ethics Service they have also approved the “National Neonatal Audit Programme/Neonatal Data Analysis Unit Parent Information Leaflet” (appendix 2) that explains the purposes for which these data may be used; it is recommended that all parents of babies admitted to NHS Neonatal Units are given a copy.

5 USING THE NATIONAL NEONATAL DATABASE

5.1 The National Neonatal Database is a national resource; full details of the regulatory approvals that govern access and guidelines on the process for individuals or organisations wishing to utilise the Database can be obtained from the Neonatal Data Analysis Unit.

5.2 Individuals or organisations utilising the National Neonatal Database will be asked to confirm that contributing members of the UK Neonatal Collaborative will be acknowledged and listed, that authorship of research outputs will take the form “[Named authors] and members of the UK Neonatal Collaborative” and that the standard criteria of the International Committee of Medical Journal Editors will be followed.
(www.icmje.org); named authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) all named authors should meet conditions 1, 2, and 3.

6 AGREEMENT

- We have read and understand this information
- We agree to the release of neonatal data listed in appendix 1 (the “National Neonatal Dataset”) held by Clevermed Ltd to the Neonatal Data Analysis Unit
- We understand that these data will be held securely as a national resource and will be used to support NHS services including the National Neonatal Audit Programme and other non-research service evaluations
- We understand that data may also be used for approved research and that separate NHS trust agreement, distinct from this, will be sought by the investigators for all research-related use
- This agreement supersedes all previous agreements between NHS Trusts and the Neonatal Data Analysis Unit and is valid to July 31st 2017

Name of NHS Trust _______________________________

Name of Caldicott Guardian _______________________________

Signature of Caldicott Guardian _______________________________ Date _______________

Lead Neonatal Clinician _______________________________

Signature of Lead Neonatal Clinician _______________________________ Date _______________

Please return this form by post or scanned email to: Mr Richard Colquhoun, Neonatal Data Analysis Unit Manager, Imperial College London, 4th Floor, Neonatal Medicine, Chelsea & Westminster NHS Foundation Trust, 369 Fulham Road, London SW10 9NH

Email: r.colquhoun@imperial.ac.uk; Tel: 0208 746 5841