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To: West Midlands -
Heads of Midwifery; Directors of Nursing;
Clinical Directors of Obstetric & Neonatal Services;
Caldicott Guardians.

Cc: PCT - PEC Chairs; Directors of Public Health;
SHA Medical Directors and Children's Leads.

Dear Colleague,

Consent protocol for secondary use of perinatal data

Please find enclosed the Perinatal Institute's consent protocol for the secondary use of perinatal data. It concerns any identifiable data which are obtained from, or arise during, a patient's contact with health services and which are collected for audit and/or further analysis. This is of particular relevance for mothers and babies, as information surrounding pregnancy outcome can often not be completely anonymised.

It is essential that this protocol is implemented as soon as possible. It is required for the Perinatal Institute's remit to collect and handle denominator data about all West Midlands pregnancies, births and neonates - on behalf of PCTs, SHAs, Regional Levy Board, WM Specialised Services Agency, the WM Strategic Commissioning Group and several national audit programmes.

The consent protocol has been developed following a seminar we held last year with representatives of the NHS Information Authority to address this Region's needs. It has since also benefited from multidisciplinary consultation, and has been agreed by both Advisory Groups for the Maternal and Neonatal Electronic Recording System (MANNERS), which include professional and lay members. The protocol fits into the Institute's overall regional data strategy, which conforms to principles of data security, confidentiality and consent:

1. The Perinatal Institute is registered under the Data Protection Act (Z7666186) which guards against unauthorised or unlawful processing of personal data. Registration with DPA requires a solid information security protocol, physical security measures, controls on access to information and trained staff.

2. Handling patient identifiable information requires adherence to the Health and Social Care Act (2001), which essentially states that the information belongs to the patient, and that consent should be obtained wherever possible. The Patient Information Advisory Group (PIAG) considers applications for support under Section 60 of the Act to use identifiable data where obtaining consent is difficult or not yet feasible. PIAG scrutinises applications carefully, and where approval is given, it is usually for limited (usually 12 month) periods, with the proviso that the applying organisation proceeds with plans to implement policies for obtaining consent.

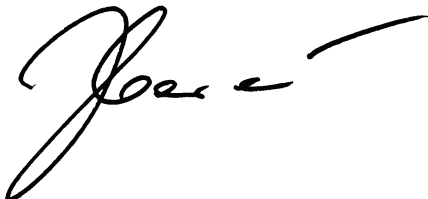
3. Currently, we have Section 60 support to collect patient identifiable information about adverse events (perinatal deaths, congenital anomalies, admissions to neonatal intensive care). Special information leaflets are being developed to cover such instances.

4. Our Protocol relies on providing information about data collection at the beginning of all pregnancies, and is in keeping with the national agenda for the NHS Care Record, for **consent by 'opt out'**. It has been reviewed by PIAG, who have advised that we should proceed with implementation.

I would be grateful if you could ensure that all your staff are familiarised and adhere to the protocol, and provide all mothers at booking with the relevant information as laid out on page 2 of the Pregnancy Notes. Please note that data recorded in the hand held notes should not be entered on electronic data systems for secondary use unless the care provider had signed in the notes to confirm that information has been provided about data, together with opportunity to ask questions or to decline. For non-English speaking mothers, interpreters should be available as part of standard good practice.

The Perinatal Institute protocol will also facilitate the development of local protocols to cover audits with patient identifiable data, many of which are currently being undertaken without consent and appropriate supporting measures. This may include data collection about anaesthetic services, SureStart programmes, infectious diseases, breastfeeding, smoking cessation, or teenage pregnancy.

With sincere regards,

A handwritten signature in black ink, appearing to read 'Jason O. Gardosi', with a long horizontal stroke extending to the right.

Professor Jason O. Gardosi
Director, Perinatal Institute

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