GBS3_Participant privacy notice v3.0 14 Nov 2023

Why we collect your personal data

We collect personal data under the terms of the University of Nottingham's Royal Charter in our capacity as a teaching and research body to advance education and learning. Specific purposes for data collection on this occasion are to conduct a randomised clinical trial to compare interventions in clinical practice. Particularly the trial will focus on assessing whether routine testing of women for Group B Streptococcus (GBS) colonisation either in late pregnancy or during labour reduce the occurrence of early-onset neonatal sepsis, compared to the current risk factor-based strategy.

What data are we collecting

Data will be obtained from different sources including UK Health Security Agency (UKHSA), NHS England, National Neonatal Research dataset, BadgerNet Paediatric intensive care unit dataset (and devolved nation equivalents) and NHS Wales. Maternal pregnancy and delivery characteristics will be considered together with the new-born health status, including microbiological test results, to assess the occurrence of confirmed and suspected sepsis in new-born babies, following different types of intervention in women prior delivery. Minimally identifiable data (NHS number, date of birth and full postcode) will be used to link all the relevant datasets before being removed to anonymise the final dataset used for the analysis. Pseudo-anonymised data (NHS number will be replaced with a GBS3 unique identifier) will be stored on secure servers accessible to only authorised individuals and will not be shared at a participant level outside of the trial team.

Approval for disclosure of confidential data without individual consent

This trial has received approval from the Health Research Authority (HRA), following guidance from the Confidentiality Advisory Group (CAG), to enable the common law duty of confidentiality to be temporarily lifted under section 251 of the NHS Act 2006. This means that confidential patient information can be disclosed by the person responsible for the information (data provider) without being in breach of the common law duty of confidentiality.

Legal basis for processing your personal data under GDPR

The legal basis for processing your personal data for this trial is under Article 6(1e) of the General Data Protection Regulations "processing is necessary for the performance of a task carried out in the public interest". Giving antibiotics in labour to high-risk women reduces the risk of their babies developing GBS infection. However, some babies born to low-risk mothers still develop an infection and many high-risk women do not carry GBS but receive antibiotics unnecessarily. Therefore, this research focussed on the effectiveness of the "routine testing" is carried out in the public interest.

Special category personal data

In addition to the legal basis for processing your personal data, the University must demonstrate a further basis when processing any special category data, including: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

The basis for processing your sensitive personal data for this trial is under Article 9(2j) "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes".

Storage and retention periods for the personal data

All electronic databases will be encrypted and hosted on a University of Nottingham secure server or the Health Informatic Centre (HIC) Trusted Research Environment (TRE) located at University of Dundee. All data is accessed by authorised research staff only using individual usernames and passwords to access the secure platforms.

The University may store your data for up to a period of no less than 7 years after the research project finishes and is published. The researchers who collected or processed your data may also store the final dataset ("research data") used for the analyses (that contains processed data, pseudoynmized, not raw data) indefinitely for use in future research. You will not be identifiable in any data used in this way. Measures to safeguard your identity in stored data include encryption, pseudo-anonymization and full anonymization, whichever is applicable to the particular research study. Identifiers such as NHS numbers, date of births and postcodes will be safely stored in a separate location.

The University of Nottingham also works with suppliers and partners who may make use of Cloud and/or hosted technologies. We undertake data security due diligence on our partners, ensure that suitable contracts are in place and that these partners conform to appropriate accreditations.

Wherever these transfers take place, the University of Nottingham will have an appropriate contract in place and there are strict rules regarding the confidentiality and security of your information in place to safeguard it.

Who we share your data with

The HIC team in Dundee will be managing the data transfer between the TRE and each data provider therefore University of Dundee is one of the data processor for this trial.

Economic analysis on the anonymised dataset will be carried out by Oxford University (data processor) researchers appropriately GDPR trained, through safe access of the data. Results from each trial analysis will be published in aggregate format (not at individual level), for use by the scientific community. Your anonymised data may also be stored indefinitely (as explained above) on external data repositories (for example, the UK Data Archive) and be further processed for archiving purposes in the public interest, or for historical, scientific or statistical purposes, following further ethical approvals.

Transfers of your data outside Europe

Data will not be shared outside the European Economic Area (EEA).

Right to withdraw

You are not under a statutory or contractual obligation to provide personal data. As the trial will use routine hospital data, obtained for all women delivering during the study period, you can request that your data is removed via the national data opt-out process. If you use the national data opt-out process, this will not affect your future care, but it will be applicable for all future research and not solely for the GBS3 trial.

The withdrawal request will be applicable if the request is received before your routine data has been transferred to NCTU from the national routine data sources. Once your routine data has been received and processed at NCTU, data will be anonymised, and it will not be possible to withdraw the data from the analysis.

You have the right to lodge a complaint with the Information Commissioner's Office at University of Nottingham on the ICO's website(https://ico.org.uk/).

You can also find the University of Nottingham and NCTUs research privacy notices for all research conducted by such parties on the NCTU website http://www.nctu.ac.uk/data-protection/data-protection.aspx

Data Controller and Data Protection Officer

The University of Nottingham (University Park, Nottingham, NG7 2RD (0115 951 5151)) is the Data Controller for the trial (legally responsible for the data security)and is registered as a Data Controller under the Data Protection act 2018 (registration No.Z5654762).The University of Nottingham has appointed a Data Protection Officer. Their postal address, email address and telephone number can be found here: https://www.nottingham.ac.uk/utilities/privacy.aspx

Notice Review

We will keep this privacy notice under regular review and will place any updates on this web page. This privacy notice was last updated on 14 November 2023.