Health Research Authority

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18 September 2020

Professor Jane Daniels
Professor of Clinical Trials, University of Nottingham
Nottingham Clinical Trials, Building 42, Room
University Park, University of Nottingham,
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Dear Professor Daniels

Application title:	**The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)**
CAG reference:	**19/CAG/0139**
IRAS project ID:	**263682**
REC reference:	**19/EM/0253**

Thank you for your amendment request to the above research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be supported, and if so, any relevant conditions.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment, to include the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal) as data sources and to include additional sensitive data items, is supported, subject to compliance with the standard conditions of support.

Amendment request

The applicants have existing support to process data from; electronic health records from participating maternity units in England and Wales, the National Neonatal Research Database, Patient Episodes Dataset Wales held by the NHS Wales Informatics Service, Group Strep B Infant Sepsis reports held by Public Health England, Group Strep B Infant Sepsis reports held by Health Protection Wales, and the English Maternity Services Dataset and HES data held by NHS Digital. Data from these sources will be processed in order to create an analysis dataset.

In this amendment, the applicants are seeking support to include the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal) as data sources.

Support is also sought to include the following sensitive data items:

- Neonatal Secondary Outcomes:
- Baby death before discharge
- Late onset culture-positive (blood or cerebrospinal fluid taken from 7 days to ≤ 28 days of birth) neonatal sepsis including clearly pathogenic organisms and excluding skin organisms (e.g. coagulase-negative staphylococci).
- Maternal Secondary Outcome:
- Intrapartum or postnatal sepsis within 42 days
- Duration of ruptured membranes to delivery

Process Outcome:

- Number of women receiving antibiotics for any other reason (except prophylaxis for Caesarean delivery)
- The proportion of failed tests
- Number of women with a test result available at least 2 hours before childbirth
- Collecting reasons why women decline IAP or swab when offered

Additional Descriptors:

- Number of fetuses
- Birth order
- Smoking at booking

An updated data flowchart and protocol were provided with the amendment submission.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG requested the below further information:

1. **The CAG noted that the Privacy Notice did not refer to s251 support and asked that this was revised.**

An updated Privacy Notice was provided. This was reviewed and accepted by the CAG.

2. **You are now seeking support to collect data from Badgernet and have existing support to include data from the National Neonatal Research Database (NNRD). The Group noted that all data from the NNRD came from Badgernet, and queried whether the data linkage to the NNRD could be removed and their data provided by Badgernet.**

The applicant advised that the NNRD no longer derives all of its data from BadgerNet, as a very small number of neonatal units have moved their electronic health record provider. Units do still submit data to the NNRD. The applicants therefore seek to continue to receive information from NNRD. The advantage of BadgerNet is that it also contains data on clinically suspected cases of early onset sepsis in babies who were not admitted to the neonatal unit. The CAG noted this information and raised no further questions.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed: Nottingham Clinical Trials Unit at the University of Nottingham has a confirmed 'Standards Met' grade on DSPT 2018/19 via NHS Digital email dated 04 August 2019. NHS Digital has a confirmed 'Standards Met' grade on DSPT 2018/19.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 03 August 2020**

Reviewed documents

Document	*Version*	*Date*
Amendment request form		17 July 2020
263682_SA01 July 20_11Jun2020_Locked20Jul20_161544 (1)		20 July 2020
19EM0253AM02 IRAS Project ID 263682 Confirmation of favourable opinion for substantial amendment		03 August 2020
GBS3 PICANet meeting minutes 07 Jan 2020		07 January 2020
GBS3_Outcome Flowchart_Final 2.0_11Jun2020	2.0	11 June 2020
GBS3_Participant Card_Draft 1.0_Final 1.0_11Jun20_Clean (1)	1.0	11 June 2020
GBS3_Participant privacy notice_Draft 1.0_Final 1.0_11Jun20 (2)	1.0	11 June 2020
GBS3_PIS_ECM_Eng_Draft 1.1_Final 2.0_30Jul2020	2.0	03 July 2020
GBS3_PIS_ECM_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_ECM_Qual_Eng_Draft 1.1 _Final 2.0_30Jul2020	2.0	30 July 2020
GBS3_PIS_ECM_Qual_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_ECM_Scotland_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 July 2020
GBS3_PIS_ECM_Scotland_Draft 1.1 _Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_PIS_ECM_Scotland_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_ECM_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_ECM_Wales_Draft 1.1_Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_PIS_Joint-RCOG-GBS3_Adapted_Draft 1.0_Final 1.0_11Jun2020_Clean	1.0	11 June 2020
GBS3_PIS_Joint-RCOG-GBS3_Adapted_Draft 1.0_Final 1.0_11Jun2020_TC	1.0	11 June 2020
GBS3_PIS_Rapid Test_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_Rapid Test_Eng_Draft 1.1_Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_PIS_Rapid Test_Qual_Eng_Draft 1.1_Final 2.0_30Jul20_Clean	2.0	30 July 2020
GBS3_PIS_Rapid Test_Qual_Eng_Draft 1.1_Final 2.0_30Jul20_TC	2.0	30 July 2020
GBS3_PIS_Rapid Test_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_Rapid Test_Wales_Draft 1.1_Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_PIS_Risk Based Strategy_Eng_Draft1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_Risk Based Strategy_Eng_Draft1.1_Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_PIS_Risk Based Strategy_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean	2.0	30 July 2020
GBS3_PIS_Risk Based Strategy_Wales_Draft 1.1_Final 2.0_30Jul2020_TC	2.0	30 July 2020
GBS3_Poster_England_Draft 1.0_Final 2.0_11Jun20	2.0	11 June 2020
GBS3_Protocol_Draft 1.0_Final 2.0_17Jul20_Clean	2.0	17 July 2020

GBS3_Protocol_Draft 1.0_Final 2.0_17Jul20_TC		
GBS3_Qual_ConsentForm_HCP_Draft 1.0_Final2.0_11Jun20_Clean	2.0	11 June 2020
GBS3_Qual_ConsentForm_Women_AB_Draft 1.0_Final2.0_11Jun20_Clean	2.0	11 June 2020
GBS3_Qualitative_Follow up letter_HCP C_Draft 1.0_Final 1.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Qualitative_Follow up letter_Women A_Draft 1.0_Final 1.0_11Jun20_Clean	2.0	11 June 2020
GBS3_Qualitative_Interview Guide_HCP C_Draft 1.0_Final 2.0_11Jun2020_Clean (1)	2.0	11 June 2020
GBS3_Qualitative_Interview Guide_Women AB_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Qualitative_Invitation Letter Women B_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Qualitative_Invitation Letter_Women A_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Qualitative_InvitationLetter_HCP C_Draft 1.0_Final 2.0_11Jun20_Clean	2.0	11 June 2020
GBS3_Qualitative_PIS_ HCP C_Draft 1.0_Final 2.0_11Jun20_Clean	2.0	11 June 2020
GBS3_Qualitative_PIS_Women_AB_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Qualitative_Poster_HCP_Draft 1.0_Final 1.0_11Jun2020	1.0	11 June 2020
GBS3_Qualitative_Poster_Women_Draft 1.0_Final 1.0_11Jun20	1.0	11 June 2020
GBS3_REC and CAG covering letter_Final 2.0_17Jul2020	2.0	17 July 2020
GBS3_Video Transcript_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
GBS3_Website Headers_Draft 1.0_Final 2.0_11Jun2020_Clean	2.0	11 June 2020
RCOG_GBS in pregnancy and newborn babies_Leaflet_Original_Approved_December 2017		December 2017

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

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Enclosures: Standard conditions of Support

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Health Research Authority

Standard conditions of support

Support to process confidential patient information without consent, given by the Health Research Authority, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be supported via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.