



Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048285

03 August 2020

Professor Jane Daniels
Professor of Clinical Trials,
Nottingham Clinical Trials Unit,
University of Nottingham
Building 42, Room B04
University Park, Nottingham
NG7 2RD

Dear Professor Daniels

Study title: The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)
REC reference: 19/EM/0253
Protocol number: 19056
Amendment number: SA01 July 20
Amendment date: 11 June 2020
IRAS project ID: 263682

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|--|----------------|--------------|
| Completed Amendment Tool [GBS3_Amendment Tool_Locked] | N/A | 20 July 2020 |
| Copies of advertisement materials for research participants [GBS3_Poster_England] | 2.0 | 11 June 2020 |
| Copies of advertisement materials for research participants [GBS3_Poster_Scotland and Wales] | 2.0 | 11 June 2020 |
| Copies of advertisement materials for research participants [GBS3_Qualitative_Poster_HCP] | 1.0 | 11 June 2020 |

| | | |
|--|-----|------------------|
| Copies of advertisement materials for research participants [GBS3_Qualitative_Poster_Women] | 1.0 | 11 June 2020 |
| Covering letter on headed paper [GBS3_REC and CAG covering letter] | 2.0 | 17 July 2020 |
| Interview schedules or topic guides for participants [GBS3_Qualitative_Interview Guide_HCP C] | 2.0 | 11 June 2020 |
| Interview schedules or topic guides for participants [GBS3_Qualitative_Interview Guide_HCP C_Track changes] | 2.0 | 11 June 2020 |
| Interview schedules or topic guides for participants [GBS3_Qualitative_Interview Guide_Women AB] | 2.0 | 11 June 2020 |
| Interview schedules or topic guides for participants [GBS3_Qualitative_Interview Guide_Women AB_Track changes] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Follow up letter_HCP C] | 1.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Follow up letter_Women A] | 1.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Invitation Letter_Women A] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Invitation Letter_Women A_Track changes] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_InvitationLetter_HCP C] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_InvitationLetter_HCP C_Track Changes] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Invitation Letter Women B] | 2.0 | 11 June 2020 |
| Letters of invitation to participant [GBS3_Qualitative_Invitation Letter Women B_Track changes] | 2.0 | 11 June 2020 |
| Notice of Amendment (non-CTIMP) [GBS3_CAG Amendment Request Form] | N/A | 17 July 2020 |
| Other [GBS3_Participant privacy notice] | 1.0 | 11 June 2020 |
| Other [GBS3_Video Transcript] | 2.0 | 11 June 2020 |
| Other [GBS3_Video Transcript_Track Changes] | 2.0 | 11 June 2020 |
| Other [GBS3_Website Headers_Track Changes] | 2.0 | 11 June 2020 |
| Other [GBS3_Website Headers] | 2.0 | 11 June 2020 |
| Other [GBS3 PICANet meeting minutes] | N/A | 07 January 2020 |
| Other [GBS3_PICANet enquiry_Supporting email] | N/A | 09 January 2020 |
| Other [GBS3_RCOG PIS_Agreement in principle] | N/A | 09 March 2020 |
| Other [RCOG_GBS in pregnancy and newborn babies_Leaflet_Original_Approved] | 1.0 | 01 December 2017 |
| Participant consent form [GBS3_Qual_ConsentForm_Women_AB] | 2.0 | 11 June 2020 |
| Participant consent form [GBS3_Qualitative_ConsentForm_Women_AB_Track Changes] | 2.0 | 11 June 2020 |
| Participant consent form [GBS3_Qualitative_ConsentForm_HCP_Track Changes] | 2.0 | 11 June 2020 |
| Participant consent form [GBS3_Qual_ConsentForm_HCP] | 2.0 | 11 June 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Joint-RCOG-GBS3_Adapted] | 1.0 | 11 June 2020 |
| Participant information sheet (PIS) [GBS3_Qualitative_PIS_HCP C_Track changes] | 2.0 | 11 June 2020 |
| Participant information sheet (PIS) [GBS3_Qualitative_PIS_HCP C] | 2.0 | 11 June 2020 |
| Participant information sheet (PIS) [GBS3_Qualitative_PIS_Women_AB] | 2.0 | 11 June 2020 |
| Participant information sheet (PIS) [GBS3_Qualitative_PIS_Women_AB_Track Changes] | 2.0 | 11 June 2020 |

| | | |
|--|------------------------|--------------|
| Participant information sheet (PIS) [GBS3_PIS_ECM_Eng_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Qual_Eng_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Qual_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Scotland_Draft 1.0_Final 2.0_11Jun2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Scotland_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_ECM_Wales_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Eng_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Eng_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Qual_Eng_Draft 1.1_Final 2.0_30Jul20_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Qual_Eng_Draft 1.1_Final 2.0_30Jul20_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Scotland_Draft 1.1_Final 2.0_30Jul20_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Scotland_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Rapid Test_Wales_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Eng_Draft1.1_Final 2.0_30Jul2020_Clean] | Draft1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Eng_Draft1.1_Final 2.0_30Jul2020_TC] | Draft1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Scotland_Draft 1.1_Final 2.0_30Jul2020] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Scotland_Draft1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Wales_Draft 1.1_Final 2.0_30Jul2020_Clean] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Participant information sheet (PIS) [GBS3_PIS_Risk Based Strategy_Wales_Draft 1.1_Final 2.0_30Jul2020_TC] | Draft 1.1 Final 2.0 | 30 July 2020 |
| Research protocol or project proposal [GBS3_Protocol] | 2.0 | 17 July 2020 |
| Research protocol or project proposal [GBS3_Protocol_Track Changes] | 2.0 | 17 July 2020 |
| Sample diary card/patient card [GBS3_Participant Card] | 1.0 | 11 June 2020 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [GBS3_Outcomes Flowchart] | 2.0 | 11 June 2020 |

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

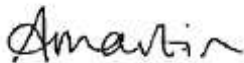
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

| | |
|----------------------------------|---|
| IRAS Project ID - 263682: | Please quote this number on all correspondence |
|----------------------------------|---|

Yours sincerely
p.p.



Dr John Fenlon
Chair

E-mail: derby.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Angela Shone Confidentiality Advise Team

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 31 July 2020

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-------------------|--------------------|----------------|---------------|
| Mrs Janet Mallett | Retired Nurse | Yes | Meeting Chair |
| Joe Walsh | Chartered Engineer | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|------------------|---|
| Miss Anna Martin | Approvals Administrator |