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22 June 2021

Dr Cheryl Battersby
Clinical Senior Lecturer and Honorary Consultant Neonatologist
Chelsea & Westminster Hospital
369 Fulham Road
Chelsea and Westminster Hospital Imperial College campus
SW10 9NH

Dear Dr Battersby,

Application title:	**neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies**
CAG reference:	**21/CAG/0081**
IRAS project ID:	**293603**
REC reference:	**21/EM/0130**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

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 application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 17 June 2021.

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:

The application, to allow;

1. Disclosure of confidential patient information (from NNRD) from The Neonatal Data Analysis Unit (NDAU) at Chelsea & Westminster Hospital NHS Foundation trust to Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, NWIS) in File 1 (as Trusted third party for purposes of linkage with Welsh data in SAIL databank),

2. Disclosure of confidential patient information (from NNRD) from The Neonatal Data Analysis Unit (NDAU) at Chelsea & Westminster Hospital NHS Foundation trust, Universities of Leeds and Leicester (PICAnet), and Kings College London (SLaM-CRIS) to NHS Digital (in file 1) as trusted third party for purposes of linkage together, and to link to Hospital Episode Statistics (HES), Office for National Statistics (ONS) mortality data, and the Mental Health Services Dataset (MHSDS) **(**The MHSDS also contains its predecessor, the Mental Health and Learning Disabilities Data Set and the Mental Health Minimum Data Set), in order to disclose a pseudonymised dataset back to the NDAU,

3. NHS Digital to link confidential patient information (from NNRD) with the personal demographics service (PDS), and for NHS Digital to disclose confidential patient information alongside unique ID to ONS SRS in order to link to National Pupil Database (NPD),

4. NHS Digital and Department for Education (DfE) to retain linkage keys for possible future applications,

is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

The applicant has stated that the following processes are outside the scope of this application and do not require support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002:

1. Linkage with SAIL database undertaken by DHCW (formerly NWIS) is undertaken without identifiers and this does not require CAG support.

2. Linkage with Small Area Health Statistics Unit (SAHSU) - NDAU analysts will link the postcodes at neonatal unit discharge held in the NNRD Chelsea and Westminster servers to environmental datasets provided by the SAHSU. No identifiers will be sent to SAHSU.

3. Support not required for disclosure of File 2 (clinical info only) from NNRD to SAIL, or from CRIS and PICANet to send file 2 to NNRD.

4. Support not required to link NNRD, PICAnet, CRIS, HES, ONS, MHSDS linked clinical data back to NNRD clinical data, as this is undertaken with pseudonymous ID, or for the onwards disclosure of this dataset from NNRD to ONS-SRS for linkage with pseudonymous NPD data.

Context

Purpose of application

This application from the Neonatal Data Analysis Unit (NDAU) at Imperial College London sets out the purpose of medical research that aims to improve the lifelong health and wellbeing of babies born preterm and/or with surgical conditions by linking existing data from the National Neonatal Research Database (NNRD) with routine health, educational and environmental datasets in England and Wales to evaluate the long-term impact of neonatal interventions. A pseudonymous linked dataset will be crated for analysis, and the applicant is specifically researching long-term health and educational outcomes, the effect of air pollution or other environmental and socio-economic factors, and the impact of neonatal interventions, for example donor breast milk, on health and educational outcomes.

Medical and surgical interventions in babies born preterm and/or with surgical conditions influence health and educational outcomes. Survivors are at risk of long-term neurological impairment and ongoing health, educational and social care needs, however due to the cost and complexity of obtaining long-term outcome data mean that longer term outcomes for the 90,000 babies born very preterm in the UK over the last decade is not yet known. This research will benefit children born preterm and/or with surgical conditions by identifying modifiable factors that influence long-term health and developmental outcomes, with the aim of improving outcomes for this patient group. Information on long-term outcomes will support counselling of families, decision-making, and inform future research and public policies to benefit patients and families.

Support is requested to use confidential patient information held in the NNRD for the purpose of linkage, by three trusted third parties – NHS Digital, Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, NWIS) and Office for National Statistics secure research service (ONS-SRS). These third parties will remove identifying information, and disclose only outcome data alongside an anonymised unique ID. The researchers will not have access to any confidential patient information and no individual patient will be able to be identified. A split file process will be used which will ensure that no organisation will hold identifiers along with clinical data together.

Four cohorts of babies born between 2007 and 2020 who are either preterm, and/or have a surgical condition, will be created from the NNRD. The NNRD is an established national database retaining confidential patient information which is collected with support under the Regulations as the legal basis (CAG ref: **ECC 8-05(f) / 2010**). These cohorts will be linked to other health and education databases. A unique ID will be applied by the NDAU.

Regarding Welsh data, NDAU will disclose identifiers from NNRD to DHCW (formerly NWIS) in a ‘File 1’, as Trusted third party for purposes of linkage with Welsh data in SAIL databank. Linkage with SAIL data is undertaken by DHCW without identifiers and this therefore does not require Regulation 5 support. ‘File 2’ of NNRD clinical data only, alongside the unique ID is disclosed to SAIL from the NDAU, and will be linked to Welsh health and education outcome data using only the anonymised unique ID.

For English data, PICANet, South London and Maudsley Clinical Record Interactive Search (SLaM-CRIS), and NDAU will send the identifiers (file 1 - NHS number, sex, postcode, date of birth, unique ID) for babies born in the study years to NHS digital as the trusted third party. Note that not all the NNRD records will have a match in the PICANet and CRIS datasets, and multiple PICANet or CRIS records may match with same record in the NNRD. NHS Digital will only retain PICANet and CRIS records that match with NNRD, non-matching identifiers will be discarded. (Note that NDAU will not be sending identifiers directly to PICANet / CRIS as a large proportion of these identifiers will not have matches).

NHS Digital will undertake linkage between the NNRD cohorts, PICANet, CRIS, HES, ONS mortality data, and MHSDS. Identifying information is then removed, except the unique ID, and the pseudonymous dataset is transferred back to the NDAU. File 2 from each source (clinical data, unique ID, no identifiers) is then linked back to the outcome dataset from NHS Digital using the unique ID only by the NDAU.

Regarding English education data, the Department for Education (DfE) holds the National Pupil Database (NPD) in the ONS-SRS and data from the NPD cannot leave the ONS SRS. The NNRD reliably captures data items such as date of birth, postcode, and infant NHS number, but it does not reliably hold the child's registered name. Additionally, the NNRD contains the infants' postcodes at birth, but does not capture postcode changes throughout childhood. Therefore NHS Digital will also link the identifiers from the NNRD cohorts to the Personal Demographics Service (PDS) to identify registered forename and surname and postcode changes, in order to undertake linkage with the NPD which does not contain NHS number. Forename, surname, date of birth, and postcodes alongside unique ID will be securely transferred to the ONS SRS to be used to link to educational data within the NPD. Identifying information is then removed. The NDAU send the clinical NNRD-HES/ONS/MSDS-PICANet-CRIS data and unique ID to ONS SRS and this is then linked to NPD using unique ID. The final de-identified NNRD-HES/ONS/MSDS-PICANet-CRIS-NPD linked dataset (without identifiers) will be accessed via researchers in the ONS-SRS safehaven, and the de-identified linked Welsh data will be accessed within the SAIL databank.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Approximately 120,000 babies born and received care in neonatal units in England and Wales between 1st Jan 2007 and 31st December 2020; recorded gestational age of less than 32 weeks **OR** Any gestational age AND recorded to have received surgery and diagnosis of one of 6 conditions: necrotising enterocolitis, Hirschsprung's disease, gastroschisis, oesophageal atresia, congenital diaphragmatic hernia and posterior urethral valves. 1. **Cohort 1 Born 2007-2020 in England: link to health data (HES,ONS, PICANet, MHSDS)** Preterm babies born less than 32 weeks and surgical babies (all gestations) 2. **Cohort 2 Born 2007-2016 in England: link to school age outcomes (NPD and CRIS)** Preterm babies born less than 32 weeks gestation 3. **Cohort 3 Born 2012-2016 in England: link to school-age outcomes (NPD and CRIS)** Surgical babies (all gestations) 4. **Cohort 4 Born 2012-2020 in Wales: link to SAIL databank (contains health, education, social data)** Preterm babies born less than 32 weeks (Inclusion

	criteria: Preterm babies born <32 weeks in neonatal units in Wales 2012-2019 (11 neonatal units in the Wales Neonatal Network))
Data sources	1. National Neonatal Research Database controlled by the Neonatal Data Analysis Unit (NDAU) (Chelsea and Westminster NHS Foundation Trust campus of Imperial College London) 2. NHS Digital • NHS Digital Personal Demographics Service (PDS) • Hospital Episode Statistics (HES) • Office for National Statistics (ONS) mortality data Identifiers include NHS number, date of birth, gender. • Mental Health Services Dataset (MHSDS) **(**The MHSDS also contains its predecessor, the Mental Health and Learning Disabilities Data Set and the Mental Health Minimum Data Set) 3. National Pupil Database (controlled by Department for Education DfE), retained in the ONS-SRS 4. Paediatric Intensive Care and Audit network, (PICANet) controlled by Healthcare Quality Improvement Partnership (HQIP) and is retained at the Universities of Leeds and Leicester 5. South London and Maudsley Clinical Record Interactive Search (SLaM-CRIS); held and controlled by South London and Maudsley NHS Foundation Trust (SLaM) at King's College London. 6. (SAIL) databank, also holds education data for Wales. (linkage is undertaken by using DHCW (formerly NWIS) as a trusted third party without using confidential patient information and support not required).
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Sex 4. Postcode 5. Unique ID
Identifiers required for analysis purposes	6. N/A no identifiable information for analysis
Additional information	**Date of death:** Note that date of death is modified to postnatal age at death by NHS Digital **Data access:** The de-identified linked dataset set containing education data will be accessed through the Office for National Statistics (ONS) Secure Research Service (SRS). A de-identified dataset without the education data will also be held on the Imperial College server. A de-identified linked

	Welsh dataset will be retained in SAIL databank.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members were very supportive of this application, noting the clear medical purpose and the strong public interest, acknowledging that this appeared to cover a major gap in current knowledge.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicant has reasoned that consent is not feasible for a number of reasons, including the further disclosure of address required in order to contact families to seek consent, the possibility of compromising the integrity, generalisability, validity and representativeness of the study, the potential distress it may cause to families of children with who may have severe disabilities or who may have died, and the large numbers of children involved would make consent prohibitive. The CAG agreed with the justification provided that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to undertake linkage. Linkage will be conducted using a split-file process. Identifiers will not be held alongside clinical or educational outcome data. The minimum number of personal identifiers will be used for linkage. These will associated with a unique anonymous identifier ID number. Upon confirmation of linkage, all personal identifiers will be removed, and the clinical and educational data pseudonymised - retaining the anonymous unique identifier. The Members agreed it would not be possible to undertake linkage in any less disclosive manner, and the proposed data flows appeared safe and comprehensive.

Justification for Slam-CRIS

Members commented that they were unclear why the applicant required SLaM-CRIS data, as this is a very small, distinct population in one area of London, and the applicant is already receiving data from the Mental Health Services Dataset (MHSDS) from NHS Digital. The applicant is requested to provide further justification for the inclusion of SLaM-CRIS data.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A patient notification has been provided for review. It will be disseminated through stakeholder groups including collaborator BLISS, a national charity for preterm and sick babies, networks of the neoWONDER parent/patient group (around 400 people), and social media platforms of other charities such as Smallest things, and Twins Trust. The applicant also states it will be disseminated to parent/patient preterm groups, out-patient clinics, community clinics, charities, and schools to raise awareness of the study and offer the chance to opt out. It will be also be displayed on the neoWONDER website as well as social media (Facebook, Instagram and twitter). Applicants are connecting with schools and SENCOs (Special Educational Needs Co-Ordinators), to raise awareness. They are also developing a 1 minute video for the the neoWONDER website and you tube.

A Letter has also been provided which is sent to neonatal units that participate in NNRD. To access data available in the NNRD, all neonatal units will be written to with information about the study and offered the opportunity to opt-out (as a whole unit). This is an established process managed by the Neonatal Data Analysis Unit (NDAU) based at Imperial College, and is a standard process for researchers who wish to use NNRD data.

A local opt out option is provided, for parents or carers to request their childs information is not used for this purpose by informing the clinical team at the unit they were treated in. This matches the method of opt out provided for the NNRD itself, however the applicants have confirmed that the opt out process will be specific for neoWONDER. The national data opt out will be applied, alongside separate additional opt outs applied by NNRD, CRIS and PICAnet.

The Committee commented that the planned display and dissemination of the patient notification was very good, and all outlets seemed appropriate.

The CAG however did require some changes to the content of this notification to ensure clarity. The CAG noted that it was quite a long document, and it would be preferable to develop a layered approach, of one short notification describing the linkages and how to opt out, which has a link to a longer more detailed notification document if people wish to read further information. This is in line with advice from the ICO on how best to present privacy information What methods can we use to provide privacy information? | ICO.

Members felt that the notification is not fully detailed, and contains some inaccuracies regarding flows and facts which will need to be amended (as described in the advice form). For example the *statement ‘They (TTPs) will not be given any new data not already held’* is factually correct, and of course can be left in the notification, as advised by the parents group. However, the TTP’s will be given confidential patient information, and it is important that this is communicated to participants, as the original statement alone implies that no data is flowing. The CAG identified other statements in the notification which they felt could also be misleading, such as ‘*no baby will ever be identified’.* It was noted that in some of the conditions studies, there may be relatively small numbers, and despite all safeguards and the removal of identifying information it is

a bold claim to make that may not hold true. Another example is the statement that '*taking part in the research is entirely voluntary'* as this implies the research is consent based, when in fact it is dissent based. The applicant is required to modify the notification materials to correct these inaccuracies.
Regarding the opt out approach, the Members agreed that the separate study specific opt out for neoWONDER needs to be made clear on the notification documents rather than referring to the NNRD opt out. It was commented that to ensure the opt out option was valid, the notifications should be displayed for at least 6 weeks before any data extraction, to allow participants time to opt out.

Members also commented on the 'whole unit' opt out option provided as part of conditions for using NNRD data. Noting that this is not within scope for CAG as part of this application, but it was felt that this may possibly mean that some people may want to be part of neoWONDER and are unable to if their unit has opted out. They would be interested in an update as to whether any units do decide to opt out of this linkage study. The applicant is asked to provide this at annual review.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have carried out an extensive patient and public engagement REC approved workstream (national survey, focus groups and interviews) which demonstrated support from over 500 parents and ex-patients for the use of routine data and linkage without consent. The applicant states that this was deemed acceptable as long as there is a notification strategy for opt-out processes and strong engagement workstreams. Within the survey undertaken, there was an explanation for the need to seek CAG support to link these data without explicit consent. The majority of people supported the use of confidential patient information without consent, and the negative responses were mostly based around requiring further information. A letter of support from BLISS has been provided, and one of the co-applicants is also a parent with experience.

The Committee commented that the applicant has clearly put in a lot of effort to communicate with patients and the public, and has made extensive changes to the application as a result. There is a lot of engagement with various stakeholders, and the CAG recognised the amount of work undertaken, and the efforts made to listen to the feedback and make changes as a result. It was commented that the only group that appeared to be missing from the patient and public involvement undertaken was teenagers who would potentially be part of the cohort. It is suggested that patient and public involvement should be undertaken with teenagers. The applicant should use these ongoing discussions as an opportunity to improve patient notification materials, and to explore the reasons why some people would not be happy to share their data for the described purposes, as the members commented that there were more negative responses than might have been expected. It is noted that the applicant had plans to undertake further in depth interviews with this specific group of people.

Exit strategy

The exit strategy is pseudonymising the data for analysis, which will be effectively anonymous to the applicant. Support is only required until linkage is complete, estimated to be March 2023. The Committee were content with this exit strategy.

Multiple pseudonymous datasets

It was commented by the Committee that there did not appear to be a reason for the applicant to require a pseudonymous linked English health dataset to be retained at the NDAU, in addition to the linked NPD and health data that is retained in the ONS-SRS. The applicant is asked to provide justification as to why multiple datasets for analysis are required to be held in two different locations.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Please provide further justification for the inclusion of SLaM-CRIS data, within one month from the date of this letter.

2. Please provide an updated patient notification document for CAG review, within one month from the date of this letter. This should incorporate the following changes;
    a. Incorporate a layered approach
    b. Remove inaccuracies, and ensure clarity, using the feedback in the advice form and the letter
    c. Ensure neoWONDER specific opt out is clearly provided

3. The patient notification should be displayed for at least 6 weeks prior to data extraction.

4. Please provide an update as to whether any individual units have opted out of neoWONDER at annual review.

5. Please undertake ongoing patient and public involvement with teenagers, to explore the acceptability of the use of confidential patient information without consent, and provide feedback to CAG within six months from the date of this letter.

6. Please provide justification as to why multiple datasets for analysis are required to be held in two different locations, within one month from the date of this letter.

7. Favourable opinion from a Research Ethics Committee. **Confirmed 02 June 2021**

8. 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. See section below titled 'security assurance requirements' for further information. **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **22 June 2022** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
20CAG0107 s251 Conditionally Supported Outcome		28 January 2021
ECC8-05 (f) 2010 NIGB Neonatal database outcome		27 January 2012
Appendix data flow		
Appendix Patient notification neoWONDER v 1.0 150421	1.0	15 April 2021
BLISS letter of support		20 May 2019
CAG cover letter		14 May 2021
CAG application form		14 May 2021
Caldicott Guardian support letter neoWONDER final		13 May 2021
Email of support from Department for Education		16 May 2019
Johnny Downs CRIS NPD support letter		27 July 2019
Letter to neonatal units neoWONDER v1.0	1.0	
neoWONDER REC Protocol060421	1.0	24 March 2021
NPD emails Linkage of NNRD to NPD		17 May 2019
ONS Data Access policy		
PICANET CRIS flow diagrams appendix 13.6		
SAIL support letter		
293603_21EM0130_SL05_Favourable_opinion_with_additional_conditions_sg020621		02 June 2021

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

CAG member Dr Katie Harron declared a conflict of interest, as she has been invited to sit on the advisory panel for the study. She therefore did not participate in the development of the recommendation provided by the CAG.

CAG member Professor Lorna Fraser declared that she knows the applicant as they both undertake research in a similar disease area. However she is not a colleague of the applicant, and has no conflict of interest with this application, and as such did participate in the development of the recommendation provided by the CAG.

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.

With the Group's best wishes for the success of this project.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included:	List of members who considered application Standard conditions of support
Copy to:	leicestersouth.rec@hra.nhs.uk

Confidentiality Advisory Group meeting attendance
17 June 2021

Members present:

Name	
Professor William Bernal	CAG alternative vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Mr. Myer Glickman OBE	CAG member
Dr Katie Harron	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Laura Gordon	HRA Confidentiality Advisory Group Assistant
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Observer

NHS
Health Research Authority

Standard conditions of support

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

The applicant and those processing the information under the terms of the support 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 and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and relevant 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 approved 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.