Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

September 2020

1. New Applications

a. 20/CAG/0063 - A population-based comprehensive lymphoma registry

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr William Bernal	CAG Alternative Vice-Chair
Ms Sophie Brannan	CAG Member
Dr Lorna Fraser	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Gillian Wells	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from Nottingham University Hospitals NHS Trust set out the purpose of medical research with the aim of creating and managing a lymphoma registry.

The incidence of lymphoma is rising faster than any other common cancer in the Western world and there is increasing awareness of the complex abnormalities driving these diseases, permitting rapid therapeutic advances. However, the paucity of large, high-quality population-based datasets remains a clear area of unmet research need within the UK. The applicants envisage this database as a pioneering effort in the UK to better catalogue and understand lymphomas on a very large scale. Large volume, population-based, 'real world' data will allow accurate descriptions of natural history and clinical outcomes, with sufficient follow-up duration to allow identification of unmet clinical need and thus inform therapeutic options for clinicians worldwide. National bodies (such as the Public Health England National Cancer Registration and Analysis Service) already require individual hospitals to collect data on individual patients with lymphoma. However, there are significant issues with the granularity and accuracy of data collected. Diagnostics are not well recorded, in particular the many (>60) subtypes of lymphoma as well as response and outcome data being incomplete. Our definitive database, also able to constantly collect new prognostic indices, as they are reported in the literature, as well as report outcomes for specific patient groups, diseases and therapies, will significantly enhance the quality of data available for research.

This registry is being developed by Nottingham University Hospitals NHS Trust to collect data on all new lymphoma cases from January 2020. This database would start with patients from Nottingham University Hospitals NHS Trust (for which support is not requested for) and extend to other Trusts in the East Midlands region. This would begin with University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust (for which support is being requested) and extend thereafter. At each external Trust, an employee from Nottingham University Hospitals NHS Trust, would access confidential information of patients to identify eligible patients and record the required information into the database. The database would contain age at diagnosis and gender only, as well as a pseudonymised identifier. The key to link the patients (accessible by only the database manager) would be stored securely at Nottingham University Hospitals NHS Trust. The applicants expect to access and upload the

data from each Trust to the central database on a yearly basis, with no determined end date. External parties would be able to access the pseudonymised database, subject to the access processes the applicants have put in place.

A recommendation for class 1, 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	All patients newly diagnosed with lymphoma from 01 January 2020 at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust.
Data sources	1. Patient medical records at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust
Identifiers required for linkage purposes	1. Hospital Number 2. NHS Number 3. Name
Identifiers required for analysis purposes	1. Age at diagnosis 2. Gender

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Confirm the legal basis under which the Database Manager will process confidential patient information at Nottingham University Hospitals NHS Trust.**

The applicant clarified that the database manager was part of the direct care team. The CAG accepted this and raised no further queries.

2. **Clarify whether the pharmaceutical company that provided funding for the database will be allowed access to the database.**

The applicant explained that Pharma will be able to apply to the access committee for data. Should the request be considered appropriate, data from REDcap Cloud will only be accessed directly by either the database manager or members of NUH R&I, and only fully anonymised data will be released. The CAG accepted this and raised no further queries.

3. **Confirm that the key database will be held separately and accessed only by the Data Manager.**

The applicant confirmed that this was correct. The CAG accepted this and raised no further queries.

4. **Clarify the identifiers that will be used for data linkage and retained for analysis purposes.**

The applicant explained that each individual hospital would hold individual patient lists, holding the key for the unique identifier e.g. NUH1, NUH2, NUH3 etc. The unique identifier would only be used to identify patients when inside the relevant hospital. The list will be retained in the participating Trust and also by the Database manager. The CAG accepted this and raised no further queries.

5. **Clarify whether any free text will be accessed. If so, provide further information on how this will be accessed and if any data will be extracted from free text.**

The applicant explained that each Trust will have several IT systems holding specific data required for the database. It is likely that at least some free text will be accessed, for example the results of scans and histology results by the database manager. Free text will not be uploaded, and data extrapolated from free text into database fields will be anonymised. The CAG accepted this and raised no further queries.

6. **The poster needs to be revised to explain that confidential patient information will be processed by those outside of the direct care team and remove the statement that it won't be possible to trace data back to individuals.**

The revised poster was submitted. The Group reviewed this and asked that a telephone number was included for patients who wanted to opt-out. CAG also needs to be referred to as 'HRA Confidentiality Advisory Group'. A revised poster was submitted, which was reviewed and accepted by the CAG.

7. **Relevant charities are to be approached and asked that information about the project is displayed on their websites.**

The applicant advised that the NUH lymphoma charity and the Director of Operations and External Affairs of the charity Lymphoma Association (LA). The LA intend to publish a news article about the database as well as an interview with the applicant about the registry. The CAG accepted this and raised no further queries.

8. **Further details on how the dissent process will work at a local level needs to be provided.**

The applicant explained that, should any patient object to the inclusion of their anonymised details in the database then, regardless of which Trust leads the patients care, they can contact either the database manager or the Database lead via email. The response from the research team will answer any particular questions submitted as well as offer a discussion via telephone or teleconferencing. If after this, should any patient still wish for their details to be removed in part or in whole, then this will be done, and the patient list at the corresponding Trust will note that there is a redacted patient. The CAG accepted this and raised no further queries.

9. **Confirmation needs to be provided on whether the National Data Opt-Out will be applied, once this comes into place in September 2020.**

The applicant confirmed that the database manager will check the National Data Opt-Out register at each visit to a site, once this is available. The patient list at the corresponding Trust will note that there is a redacted patient. The CAG accepted this and raised no further queries.

10. **Clarification needs to be provided on whether the specific issue of processing of confidential patient information outside of the direct care team, without**

consent being sought from individual patients, has been discussed during patient and public involvement and engagement. Feedback from these discussions needs to be provided.

The applicant provided email feedback from the Director of Operations and External Affairs of the charity Lymphoma Association. The CAG queried whether this specific issue had been discussed with any patients. The applicant confirmed that the specific issue of the use of confidential patient information without consent was discussed with the relevant patient group and was specifically mentioned on the original letter of support included with the IRAS application. The CAG noted this and raised no further queries.

11. Confirm that lay representation will be included on the Access Committee.

The applicant advised that a retired nurse had agreed to provide lay representation on the Access Committee.

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. Favourable opinion from a Research Ethics Committee. **01 May 2020**

2. 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.

    - **University Hospitals Leicester NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 21 May 2020.**

    - **Nottingham University Hospitals NHS Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training. As a result, the following specific condition of support has**

been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.

- **Sherwood Forest Hospitals NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 02 September 2020.**

b. 20/CAG/0044 – Revision Hip and Knee Replacement: Evaluation of Clinical, Psychological and Surgical Outcomes

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Dr Katie Harron	CAG Member
Dr Simon Kolstoe	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Gillian Wells	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford set out the purpose of medical research that seeks to investigate how satisfied patients are following revision hip or knee replacement, and whether the reason for surgery affected this.

Hip and knee replacement implants are designed to last a long time, but they do not last forever. A revision joint replacement is a procedure to replace an implant that is no longer functioning correctly. These procedures are major surgery because performing a joint replacement can be much more complicated the second or third time. This may be due to the presence of infection or formation of scar tissue and loss of bone over time. Around 13,000 revision operations are performed each year in the United Kingdom at a cost of up to £200 million. The majority of these procedures are successful and many cannot be avoided. Other revision procedures are discretional and depend on a discussion of risks versus benefits between a patient and their surgeon. In the discretional group, up to one-in-three patients who undergo revision surgery do not experience any benefit and the reasons for this are not well understood.

In this application, anonymised data will be obtained from several sources in the NHS that routinely collect information related to revision joint replacement. Data on Patient Reported Outcome Measures and from the National Joint Registry, alongside HES and ONS data from NHS Digital, will be collected and analysed in order to describe patient satisfaction and function following revision surgery, medical risks, and the need for further surgery and identify the factors that underpin each of these. Confidential patient information will be disclosed from the National Joint Registry (NJR) to NHS Digital for data linkage to HES, ONS and Patient Reported Outcome Measures (PROMS).

A recommendation for class 1, 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	150,000 patients, who have undergone revision hip or knee replacement from April 2003 to the present and the procedure recorded on either HES or the National Joint Registry.
Data sources	1. The National Joint Registry, held by Northgate Public Services 2. PROMs, HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Provide further details on the patient and public involvement carried out, specifically whether the acceptability of processing confidential patient information without consent had been tested.**

The applicant advised that there was strong patient and public representation on the National Joint Registry Research Steering Committee. The data flows for this study had been highlighted to lay members during the approval process and were considered to be acceptable. The Chief Investigator had also been involved with the James Lind Alliance PPI work, determining key priorities for patients before and after revision knee replacement.

The CAG requested further information on how many lay members of the Research Steering Committee had taken part in the patient and public involvement.

The applicant advised that two patient representatives were included in the NJR Research Sub-Committee. Five patient representatives and eighteen clinical representatives were included in the involvement undertaken with the James Lind Alliance Priority Setting Partnership for Revision Knee Replacement. The applicants confirmed that they had plans for ongoing engagement with a PPI group.

Following a request for further details, the applicant provided feedback from the Nuffield Orthopaedic Centre Revision Knee Patient Group, the James Lind Alliance Priority Setting Partnership, the NJR Approval Panel and the NHS REC that reviewed the application. Open days will also be held at the Nuffield Orthopaedic Centre as soon as possible.

The applicants were also recruiting a PPI group of 8-12 patients, who will have undergone or are awaiting revision knee replacement. A website for the Revision arthroplasty study will also be set up, which include the Privacy Notice and lay summaries.

2. **Patient notification needs to be carried out. A dissent mechanism also needs to be created and information on how patients can dissent included in the patient notification.**

The applicant provided the Privacy Notice, to be displayed on Price Knee Group webpage and the NJR will also be asked to include on their website.

The CAG noted that the National Data Opt-Out will be applied. This meant that patients who dissented to their inclusion in this project specifically would need to dissent to their inclusion in all research. The Group asked if a project specific dissent mechanism could be created.

The applicant explained that patients will be able to opt-out of all NHS Digital or NJR research, but that it was not possible to create an opt-out mechanism for this project specifically. The study team at the University of Oxford will be supplied with de-identified, linked data from the NJR and NHS Digital. This is a one-off, single point in time data linkage project. The applicants do not have a system or permission to create a register of personal details for patients who wish to opt out of this particular study nor a system to be able to securely transfer those details to the NJR and NHS Digital prior to data linkage. After data linkage, no patients will not be identifiable to the study team. As such, the applicants had determined that it was more appropriate for patients to contact with NHS Digital or the NJR directly if they wish not to participate. For NHS Digital, the National Data Opt-Out will be applied. For the NJR, contact details have been added to the Privacy Notice which patients can use to opt out of NJR research altogether.

The CAG noted this information and raised no further queries.

3. **Clarify if age at death or year and month of death could be retained for analysis purposes.**

The applicant clarified that the year and month of death for analysis, rather than the exact date of death, will be retained. The CAG noted this information and raised no further queries.

4. **Clarify the start and end date of the data collection period.**

The start date for data collection is 1st April 2003. The end date for data collection is 1st August 2020. The linked NJR data from 1st January 2007 only will be analysed. The CAG noted this information and raised no further queries.

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. Favourable opinion from REC. **Confirmed 01 April 2020.**

2. 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: Northgate Public Services (by NHS Digital email dated 07 February 2020) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

c. 20/CAG/0069 - C&I CRIS Linkage with HES and Mortality

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr William Bernal	CAG Alternative Vice-Chair
Ms Sophie Brannan	CAG Member
Dr Lorna Fraser	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Gillian Wells	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from University College London (with the controller for the activity confirmed to be Camden and Islington NHS Foundation Trust) set out the purpose of medical research which aims to establish a research database linking the mental health records of patients treated within the Camden and Islington (C&I) NHS Foundation Trust area with data from NHS Digital.

The Camden and Islington Research Database is already established and contains mental health data generated within the boroughs of Camden and Islington. This database was established using the South London and Maudsley NHS Foundation Trust (SLaM) Clinical Records Interactive Search (CRIS) methodology in 2012. South London and Maudsley NHS Foundation Trust acts as processor for the Camden and Islington Research Database.

Confidential patient information in relation to patients treated by mental health services in the Camden and Islington boroughs will be disclosed by South London and Maudsley NHS Foundation Trust (SLaM) Clinical Data Linkage Service (CLDS) to NHS Digital in order to facilitate linkage with Hospital Episodes Database and ONS mortality data. This information will be supplemented by anonymised information from HES and ONS relating to patients within the named London boroughs who were not detailed within the existing mental health database.

A recommendation for class 1, 4 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	The cohort in the proposed study linkage will include patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 to 31 December 2018. It is estimated that 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database.
Data sources	1. Camden and Islington NHS Foundation Trust C&I Database records.

Identifiers required for linkage purposes	1. Full name 2. NHS number 3. Date of birth 4. Sex 5. Postcode,
Identifiers required for analysis purposes	1. Sex 2. Postcode 3. Date of death 4. Ethnicity

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Two new data flow diagrams are required, one showing the structure and the other showing the data flows within the structure.**

The applicants advised that the data flow had been amended to include a colour legend, providing further clarification on which parties have access to which data. The applicant also clarified that all references to SLaM referred to SLaM CLDS, and not the South London and Maudsley NHS Foundation Trust, and confirmed that the Trust do not have access to the confidential patient information within the C&I CRIS research database.

The CAG noted these further clarifications and the revised data flow diagram, and raised no further queries.

2. **Provide clarification over who will have access to the database, including whether IT staff from SLaM NHS Foundation Trust will have access.**

The applicant clarified that staff within SLaM CLDS will not have access to the C&I research database. C&I Trust have contracted with the SLaM Trust's CLDS to carry out certain necessary duties for the processing, supply and hosting of the distinct C&I CRIS research database. SLaM CDLS will, as Data Processor, process C&I clinical data on behalf of, and under contractual to, to C&I. C&I will maintain exclusive control over access to the C&I CRIS research database as the Data Controller. SLaM CDLS has no ability or permission to access C&I data.

The contractual relationship between SLaM CLDS and C&I is analogous to that of an NHS Foundation Trust and any third-party data processor and host, insofar as the NHS Foundation Trust is the Data Controller while the third-party vendor acts of a Data Processor. SLaM CLDS will process the data, governed by the Data Processing Agreement, in order to fulfil the terms of its contractual obligation to C&I. Access to the C&I CRIS research database is limited to the C&I research database administrator and approved research users at C&I only for research projects which are approved by the C&I research database oversight committee. Access can only be gained via the C&I network. This includes all data validation and quality checks for pseudonymisation which are conducted by C&I staff following data processing by SLaM CDLS.

The CAG noted the information provided and raised no further queries.

3. **Provide clarification that the relationship between Camden and Islington NHS Foundation Trust and SLaM NHS Foundation Trust is analogous to a data controller contracting with an IT system supplier to undertake processing of data on their behalf. If this is the case then information about the contract between the two organisations needs to be provided.**

The applicant clarified that relationship between C&I and SLaM CDLS is analogous to that of a Data Controller contracting with an IT system supplier to undertake processing of data on their behalf. For context, C&I also contracts with Advanced, a third-party data vendor, to manage its CareNotes electronic health records system in an analogous way to C&I's relationship with SLaM CDLS. The current Service Agreement and Data Processing Agreement between C&I and SLaM CDLS are attached. If this data linkage is approved by the CAG, the Service Agreement and Data Processing Agreement will be amended to reflect SLaM CDLS's work to support this data linkage.

The CAG noted the information provided and raised no further queries.

4. **Provide clarification that the disclosures of confidential patient information will be made by the Camden and Islington NHS Foundation Trust, as Data Controller for the Research Database.**

For the proposed linkage in this application, SLaM CDLS, as part of its contractual obligation to C&I as a Data Processor and under C&I's direction, will create the C&I CRIS Identifier Tables to send to NHS Digital on C&I's behalf with C&I's consent. SLaM CDLS is not authorized to involve any other third parties in the processing of data without C&I's written prior consent as per the §2.2.6 of the Data Processing Agreement between SLaM CDLS and C&I.

The CAG noted the information provided and raised no further queries.

5. **Confirm that data from the Research Database will not leave the Camden and Islington NHS Foundation Trust data warehouse, and that the CRIS processing system will be used within the data warehouse to undertake the pseudonymisation and anonymisation process.**

The applicant confirmed that data from the C&I research database will not leave the C&I data infrastructure. C&I will transfer confidential patient information into C&I CRIS secure infrastructure whereupon the service provider (SLaM CDLS) and then apply automated architecture/processing to the source C&I data for the purpose of deidentification, resulting in the C&I CRIS Research Database. The deidentified C&I CRIS Research Database is hosted by the service provider within the dedicated C&I secure infrastructure.

The C&I CRIS Research Database is administered directly by local C&I staff (i.e. C&I retain full control over access to and use of the data). The CAG noted the information provided and raised no further queries.

6. **The items to be used in both the data linkage and the comparator cohort need to be clarified.**

The applicant clarified that the following variable were necessary to facilitate the linkage;

• First and Last Names

• Gender

• Date of Birth

• NHS Number

• Post Code

• BrcId (a unique identifier for each patient)

This C&I CRIS Identifiers Table will be sent securely to NHS Digital. Using the variables in this Identifiers Table, NHS Digital will create the tables containing HES/Mortality C&I CRIS Cases and HES Controls, removing all patient identifiers and using only BrcIds for HES/Mortality C&I CRIS Cases and encrypted HES IDs for all HES C&I CRIS Cases and Controls. This is the minimum set of variables necessary for accurate record linkage.

The CAG noted the information provided and raised no further queries.

7. **Provide confirmation that no sensitive data items would be included in the dataset, particularly for the comparator cohort.**

NHS Digital will categorise HES data as General, Sensitive, and Identifiable variables. The application includes all General variables and no Sensitive or Identifiable variables (for both cases and controls). The CAG noted the information provided and raised no further queries.

8. **Confirm that patient and public involvement will continue while the project is ongoing.**

The applicant confirmed that patient and public involvement (PPI) is central to the operation and ethical approval for the C&I CRIS research database. Three service users were included on the C&I CRIS research database oversight committee. All applications for projects to access the C&I research database are reviewed by a service user.

A separate Data Science PPI group had also been created to comment on and contribute to the design and conduct of studies using the C&I CRIS research database. This PPI group continues to meet regularly. The next Data Science PPI meeting is scheduled for September/October 2020. The CAG noted the information provided and raised no further queries.

9. **The patient and public involvement needs to be strengthened by ensuring that both lay members and professional members from within Camden and Islington NHS Foundation Trust are included.**

The applicant advised that the PPI group is attended by two consultants and academics from Camden and Islington NGS Foundation Trust.

The C&I research database oversight committee meets quarterly. The composition of the committee has been approved by the ethics approval for the C&I CRIS Research Database. This application to the CAG, and the CAG feedback, was discussed at this committee. The committee includes three service users (lay members), four consultant psychiatrists, clinical academics, C&I Head of Information Governance, the Director of Information, and the medical Director and Caldicott Guardian, plus an external consultant from a separate NHS Trust. The CAG was satisfied by this further information.

10. **Further steps need to be undertaken to disseminate information about the project more widely, including use of social media.**

The applicant agreed with the CAG and advised that this had been discussed with the C&I CRIS oversight committee. Upon approval of the data linkage, the applicants will disseminate information about this project more widely with C&I Communications using the website, social media (with both clinical and lay audiences), and print materials. The CAG was satisfied by this further information.

11. **The patient facing materials need to be amended as follows:**

    a. **A statement assuring patients that dissenting from the study will not affect the care they receive needs to be included.**

    b. **The documents need to be revised to ensure that the involvement of South London and Maudsley NHS Foundation Trust and the dissent process are explained consistently across all documents.**

The applicant clarified that the patient information leaflet and frequently asked questions, which had been approved by the NHS REC, already highlighted the role of SLaM and the appropriate opt-out procedure. The applicant provided the text available on the C&I Trust website.

The CAG reviewed this information and raised no further queries.

12. **Provide confirmation that an amendment or new application will be submitted should the applicants intend to undertake linkages to data sets other than those included in this application.**

The applicant agreed that amendments or new applications will be submitted, should the applicants undertake future data linkages involving other data sets. The CAG was satisfied by this assurance.

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. **The applicants are to consider whether an address for patients to register dissent could be included in the patient notification materials, and to provide feedback on this at the time of the first annual review.**

The applicant explained that opt-out was already possible via email, telephone and via discussion with a clinician. The patient-facing materials had been amended to include an address for patients to register dissent as reflected in the attached documents. The CAG reviewed this information and raised no further queries.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 25 August 2020.**

3. 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. **Camden and Islington NHS Foundation Trust (by check of the NHS Digital DSPT tracker on 25 August 2020), South London and Maudsley NHS Foundation Trust (by check of the NHS Digital DSPT tracker on 21 May 2020), and NHS Digital (by check of the NHS Digital DSPT tracker on 21 May 2020), have a confirmed 'Standards Met' grade on DSPT submission 2018/19.**

d. 20/CAG/0071 - Birmingham and Lambeth Liver Evaluation Testing Strategies - 10 Year Follow Up

Name	Capacity
Dr Rachel Knowles	CAG Member
Mr Andrew Melville	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

The application from University Hospitals Birmingham NHS Foundation Trust sets out the purpose of medical research to determine the extent to which a 'fatty liver' leads to serious liver disease later in life.

Non-alcoholic fatty liver disease (NAFLD) is the most common liver condition in high-income countries, affecting 25% to 30% adults. There is no doubt that NAFLD can progress to more severe diseases; first to a condition called ‘steatosis’ and then to established cirrhosis. While the possibility of such progression is not in doubt, the risk of progression is unclear and disputed. It is important to provide scientific evidence regarding the magnitude of the risk of progression since the recommendation has been made that all people with NAFLD should be investigated by means of serial blood tests and scans of the liver. Such a policy would have massive implications in terms of costs and harms resulting from serial investigation of a fruitless ‘treadmill’ of investigations for about one third of the entire adult population. The BALLETS study provides a population of patients typical of those that might be identified in the course of routine primary care practice. To our knowledge, our proposed study would be much the largest cohort study of people with NAFLD.

The BALLETS study consented participants in 2005-2008 to participate and have been characterised into one of four groups. The group represents a ideal opportunity to determine the risk of progression. Whilst applicants consented to future follow up, the researchers at the time did not know what form that follow up would take, and the original consent is not deemed sufficient for the proposed study. This study wishes to link the original study data (held by University of Birmingham and passed to University Hospitals Birmingham NHS Foundation Trust) with ONS and HES data from NHS Digital to create a pseudonymised dataset for analysis.

A recommendation for class 1, 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	All participants that consented to participate in the original BALLETS study. (1290 participants)
Data sources	1. University of Birmingham – Trial Data 2. NHS Digital – ONS and HES datasets
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of Birth 4. Hospital Number
Identifiers required for analysis purposes	1. Date of Birth 2. Date of Death 3. Gender

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

Describe exactly the flows of data between organisations in this study, including detail on:

a. What identifiable data items will be transferred between which organisation?
b. Where the linkage between datasets will be undertaken.

The applicants provided an updated flowchart that detailed the flows of information, showing:

- University of Birmingham will share NHS number and Date of Birth for each participant with University Hospitals Birmingham NHS Foundation Trust

- University Hospitals Birmingham NHS Foundation Trust will share NHS number with NHS Digital, who will return the HES/ONS data with NHS number to University Hospitals Birmingham NHS Foundation Trust

- University Hospitals Birmingham NHS Foundation Trust will link the data together and remove identifiers.

The group were content with this clarity in data flows.

Provide clarity on how the research will move away from using confidential patient information.

The applicants confirmed that, once the linkage is complete, no further data will be collected. Data will be linked, and the identifiers removed. Members were content with the response.

Please clarify for how long is support is anticipated.

Support was requested by the applicants for approximately 18 months from the date of receipt of the data from NHS Digital, to allow data to be analysed. The group raised no issues in this area.

Provide confirmation on the size of cohort for which support is requested.

The group noted that the applicants wish to use the whole cohort, which totals 1290 patients. Members were content with this.

Clarify whether this is a one-off linkage, or whether it is anticipated that further linkages are planned in the future.

The applicants clarified that this is a one-off linkage, and no further linkage is planned. No issues were raised by the group.

Detail a local mechanism for the patient cohort to opt out of this study

The applicants state there will be an opt out mechanism through contacting the study team. Whilst the original study was undertaken in a number of practices, the applicants argue that it is not practicable to place notification in these practices given that many doctors will have moved from the practice over the intervening period, it is expected that over one in five participants in the study will have died, patients visit practices episodically and a very small

proportion are likely to visit the practice and observe the notice at the relevant time, and patients may have moved practices.

The CAG noted these points and were content with the study team being the point of contact for the opt out mechanism.

Provide the patient notification materials to be used in this study, which should detail the local opt out mechanism.

The applicants provided the patient notification materials, including opt out details, that will be displayed on the University of Birmingham website.

No issues were raised on the patient notification materials.

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. Favourable opinion from REC **Confirmed 26 March 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 June 2020).**

   The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 15 September 2020).

e. 20/CAG/0073 - Assessing the cancer risks due to occupational exposure to styrene

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This is an application from the Institute of Occupational Medicine (IOM) which sets out the medical purposes to determine whether workers in the British glass reinforced plastic manufacturing industry are at an increased cancer incidence or mortality risk from their occupational exposure to styrene. Whilst this is a UK study, the resultant pseudonymised dataset will be transferred to Denmark to feed into a wider international study.

Styrene is a high-production high-volume chemical with about 18 thousand tonnes produced annually in the manufacture of plastic and synthetic rubber products worldwide. The general population is exposed to very low levels of styrene while occupationally exposed workers may encounter much higher levels of exposure. High exposures to styrene occur in the reinforced plastics industry, and co-exposures to other known and suspected carcinogens are limited, making this industry ideal for studying the carcinogenicity of styrene. The Health and Safety Executive (HSE) styrene cohort has previously been included in an international pooled cohort study coordinated by the International Agency for Research on Cancer (IARC) but has never separately been analysed. This study will use the HSE styrene cohort data and link this with cancer and mortality data held by NHS Digital to determine whether these workers are at an increased risk of cancer incidence.

The HSE will transfer the study dataset (including name, date of birth, gender and address) to IOM. IOM will then request cancer and mortality data from NHS Digital, using their name, NHS number and date of birth, which will be transferred back to IOM. The data from NHS Digital will be linked to the HSE dataset to produce the final pseudonymised dataset.

A recommendation for class 1 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	Workers at a glass reinforced plastics manufacturer, aged 18 and over (1807 workers)
Data sources	1. Health & Safety Executive 2. NHS Digital (cancer registration data and mortality data)
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Gender 4. Address
Identifiers required for analysis purposes	1. Date of birth (month and year) 2. Date of Death (month and year) 3. Gender
Additional information	The data used in analyses will consist of month and year of birth, details of work carried out in the industry (for the assessment of exposure to styrene) the timing of this work and any mortality or cancer registration data

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

Detail the data items to be transferred from the HSE, including whether or not this will include clinical information

The applicant clarified that the information will be transferred in the form of paper 'study cards', with each card containing information about each worker in the study. In addition, part of the information on the study cards is in the form of a computer file. Both the study cards and computer file need to be shared in order for IOM to produce a study data set with the fields needed for tracing with NHS Digital.

Some of the information on the study cards would be regarded as clinical as these workers were previously traced. The study cards will contain surname; forenames; maiden name; date of birth; sex; address; country of birth; NI number; company name; date starting and ending employment at the company, NHS number and (if applicable), date and cause of death code, date of cancer registration and cancer site and type codes. The computer file contains all the above fields except name and address.

The members were content with this response.

Provide justification why identifiable information cannot be passed directly to NHS Digital from the HSE in order to minimise the flows of identifiable information.

The applicant stated that IOM is coordinating this study, and that the information from the study cards and computer file need to be combined prior to requesting data from NHS Digital. HSE do not have the resource to do this currently, hence why IOM are undertaking this function, and why data needs to be passed to IOM.

The group raised no issues with this response.

Undertake Patient and Public Involvement and Engagement activities with a group of industry users and provide the outcomes to the CAG. This should specifically discuss the use of confidential patient information without consent.

The applicant, at the request of CAG, provided a considered response from a representative of the Union of Shop, Distributive and Allied Workers. This response was supportive in the use of confidential information without consent and raised no issues.

The CAG were content to accept this evidence of support for the use of confidential information without consent.

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. Favourable opinion from REC **Confirmed 05 May 2020.**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Institute of Occupational Medicine and NHS Digital (checked on DSPT tracker 11 June 2020) have been confirmed as 'Standards Met' by NHS Digital.**

f. 20/CAG/0051 - Exploring the impact of mental health services in reducing suicide risk for those accused of online sexual offences against children within the Cleveland area

Name	Capacity
Ms Sophie Brannan	CAG Member
Dr Liliane Field	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair

Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV) sets out the purpose of medical research which aims to compare the outcomes of people arrested on child sex offences between those who accepted or declined the involvement of mental health services, following their initial arrest.

Suicide prevention is seen as a national priority within the United Kingdom, with reduction in the numbers of suicides being part of Government policy and subject to regular report. Within the group accused of online child sexual offences, known as child sex offenders (CSO), the rate of suicide is higher. Estimates of increased risk of suicide in the CSO group range from 183 to 230 times higher when compared to the general population, with the greatest risk of suicide between 48 hours and one month of disclosure or discovery of the crime. Public benefit is highlighted as the National Police Chiefs' Council (NPCC) report regards increased suicide risk in this group, indicating the need to understand what measures may improve this outcome and understand whether the intervention carried out in TEWV is having a positive impact on suicide.

CSO cases matching the inclusion criteria will be identified using the Cleveland Police Database (approval obtained). The investigators will record name, date of birth and date of death (where applicable), as well as any other key demographic data available (e.g. yes/no answer to whether the individual is a professional) on an NHS laptop (or the police will send this data using an encrypted email). The researchers, who are not part of the direct care team and potentially from external organisations, will link this with data on Tees, Esk and Wear Valleys NHS Foundation Trust PARIS IT system, in order to collect the data required for the research. Identifiable data will be stored on a separate spreadsheet to the study data, which will be identified purely by a study code. The resultant dataset will be used to highlight key factors that may make individuals arrested by the Cleveland Police more vulnerable to committing suicide and also highlight whether involvement of mental health services at an early stage is of benefit in this particular group. There is also the potential for service improvement, dependent on the outcomes of the research.

A recommendation for class 1 and 4 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	Any individual that was arrested by the Cleveland Police Paedophile and Online Investigation Team (POLIT) between 2015-2018. The sample size is estimated at 700-800 people.
Data sources	1. Tees, Esk and Wear Valleys NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of Death (where applicable)
Identifiers required for analysis purposes	1. date of arrest, 2. ethnicity 3. gender 4. aged between 40 and 60 years of age (yes/no) 5. married or residing with a partner (yes/no) 6. a parent (yes/no) 7. employed (yes/no) 8. not previously known to the police (yes/no) 9. suffering from a mental health issue (yes/no) 10. previously known to attempt suicide(yes/no) 11. participants live in the Cleveland area
Additional information	Due to the relatively small population size and the sensitivity of the work, the above may potentially be identifiable.

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

The applicant to speak with The Lucy Faithfull Foundation for comments on the proposed research.

The applicants discussed the proposed research with The Lucy Faithfull Foundation who thought it to be a valuable area of research, and provided a letter of support.

The group were content with this feedback.

Request comments on the poster by The Lucy Faithfull Foundation.

The Lucy Faithfull Foundation reviewed the poster and were supportive of it, with the suggestion of adding information for offenders as to services which may support them and reduce the risk of reoffending, which the applicant undertook.

The CAG raised no issues, understanding the poster is to be formatted without change the content.

Include a contact name on the poster.

A contact name was added, which was noted by members.

Provide a data flow diagram, detailing the flow of identifiable data in the research.

A data flow diagram was provided, detailing the flow of identifiable data. The group were content with this.

Confirm that identifiable information from Cleveland Police will be used to access information on the Tees, Esk and Wear Valleys NHS Foundation Trust IT system, not the other way around.

This was confirmed by the applicant, and no issues were raised by members.

Provide a complete list of the data items being collected from Tees, Esk and Wear Valleys NHS Foundation Trust.

A complete list of data items was provided by the applicant, which the group were content with.

Confirm what data is being maintained by the applicant for the duration of the study.

The applicant confirmed that during data collection name, date of birth, NHS number and date of first police involvement will be retained to allow for subject identification and linking. The data maintained following completion of data collection and verification of the non-identifiable binary data as complete will be only the non-identifiable binary data.

The CAG raised no issues.

Provide clarification on what will happen if the data custodian moves Trusts.

The applicant explained that this happened in August 2020 when the moved organisations. It was confirmed that the applicant will be contracted to Tees, Esk and Wear Valleys NHS Foundation Trust on an honorary basis, and provided with an NHS laptop and secure access to the Trust systems for the duration of the research. It was also confirmed that no identifiable data will leave Trust systems, and that David Minchella is be the data custodian.

The CAG raised no issues with this, and clarified that the support extended to the applicant when their substantive employment is with another organisation.

Confirm who will be accessing/collecting data at the Tees, Esk and Wear Valleys NHS Foundation Trust.

It was confirmed that Dr Paul Cooper and Mr David Minchella will access the data, which the CAG noted.

Confirm that all accessing data at Tees, Esk and Wear Valleys NHS Foundation Trust have a duty of confidentiality.

This was confirmed by the applicant, which the CAG were content with.

Confirm the security arrangements of the laptop to be used, including confirmation that it will be encrypted.

An email from Tees, Esk and Wear Valleys NHS Foundation Trust IT department to confirm the IT arrangements.

No issues were raised by the CAG.

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. Favourable opinion from REC **Confirmed 20 May 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for Tees, Esk and Wear Valleys NHS Foundation Trust was confirmed as 'Standards Met'. Email from NHS Digital received on 04 May 2020.**

g. 20/CAG/0056 - PEARL s251 Sensitive Health Records Template (Maternal smoking during pregnancy and intellectual disability)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Mr Tony Kane	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Mr Marc Taylor	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Laura Gordon	HRA CAG Assistant
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from University of Bristol set out the purpose of medical research that seeks to investigate whether maternal smoking during pregnancy is associated with intellectual disability in children.

Tobacco use during pregnancy has been shown to influence foetal brain development and has also been associated with intellectual disability. It is unclear whether this link is causal or not. The applicants will use a variety of statistical techniques with the aim of improving understanding of linkage between tobacco use in pregnancy and intellectual disability in children. The smoking behaviour of mothers and fathers will be compared, and genetic methods used to determine causality. These analyses will be undertaken in several large population-based birth cohorts, including the Avon Longitudinal Study of Parents and Children (ALSPAC) and sibling designs in other cohorts, to seek better understanding of the non-genetic causes of intellectual disability.

The applicants seek support to process confidential patient information from GP records, NHS Digital (HES data, the Mental Health Services Data Set) and data from the Avon and Wiltshire Mental Health Partnership, in line with ALSPAC's existing approval.

ALSPAC wish to:

- If the required sensitive data has already been collected through a previous project specific s251 support, repurpose the data for this purpose, in order to reduce flow of confidential information.
- For data not already collected though a previous project specific s251 support, request data from GP providers, NHS Digital and Avon and Wiltshire Mental Health Partnership using existing processes.

The data will then combined/anonymised by the ALSPAC team within UKSeRP (hosted by the University of Swansea but managed by ALSPAC staff). ALSPAC staff will then make the anonymised combined data available to the research team for this project.

A recommendation for class 1 and 4 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	All people enrolled in ALSPAC, excluding those who have explicitly withdrawn from the study, declined consent to linkage to their health record, have not received ALSPAC fair processing information or have consented to data linkage.
Data sources	1. NHS Digital (HES and MHSDS data) 2. GP software providers 3. Avon and Wiltshire Mental Health Partnership NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	1. Gender 2. Date of Birth will be used (by ALSPAC) to derive 'Age at Event' (expressed in days, minutes, seconds) and time intervals. This allows ALSPAC to provide information to researchers in event sequence order without disclosing Date of Birth or event date.
Additional information	Of the 15,000 ALSPAC participants, around 5500 have consented to data linkage and are not part of this request for support.

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by the CAG.

1. **Provide a dataflow diagram which indicates the flow of confidential patient information and pseudonymised data, indicating which identifiers are used within which flow.**

The applicant provided a revised data-flow diagram for NHS Digital data and a data-flow diagram for GP data. These were reviewed by the CAG, who raised no further queries.

2. **In the web notification, add a link to the ALSPAC opt out page.**

The applicants confirmed that a link to the ALSPAC opt-out page had been added to the web notification. The text and a link to the notification was provided. The CAG reviewed this and raised no further queries.

3. **Explain in the web notification that a participant can opt out of this specific project, without opting out of ALSPAC as a whole.**

The applicants provided the text of the web notification and a link, which described that patients could opt-out of inclusion in this project specifically. The CAG reviewed this and raised no further queries.

4. **Clarify and update the project start date in the web notification.**

The applicant clarified that the start date for the project was listed as May 2019 as ALSPAC collected data was being used in the analyses. In October 2019, data was linked to electronic health records for patients who had consented. The applicants noted that it was common in these types of projects for data to be provided to the researchers in stages and linked data may not be included until some time after the project start date, with the consenting sample being made available first if support under s251 is required. The CAG noted this clarification and raised no further queries.

5. **Change the web notification to make clear that it is preferred for participants to opt out prior to the start date, but they can opt out at any time.**

The applicant advised that participants were able to change their mind at any point, however consent updates were not fed into the live in-use dataset. The CAG noted this clarification and raised no further queries.

6. **Define what the term community records mean, with respect to where data is collected from.**

The applicant advised that "community records" is defined in the ALSPAC section of the University of Bristol website. The records used are "1. Health records (from your GP, hospital visits and community care) about mental health conditions, treatments and care. 2. Department for Education and local authority records on children who had a statement of special educational needs." The CAG noted this clarification and raised no further queries.

7. **Clarify whether, in advance of the National Data Opt-Out applying, whether the GP Type 1 opt out will be applied.**

The applicant explained that if the Type 1 Opt-Out was applied, then data cannot leave the practice, as this is classed as sharing information for non-care purposes, which this flag stops. Type 1 Opt-Out will be applied to the extract of GP records, as the GP system providers can see it, but the applicants will not see flows of this to implement it later. NHS Digital were aware

of this and the applicants were attempting to establish a mechanism to resolve this. The CAG noted this information and raised no further queries.

8. **Confirm that the applicants are not collecting free text data.**

The applicant clarified that no free-text data will be accessed or collected. The CAG noted this clarification and raised no further queries.

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. Favourable opinion from a Research Ethics Committee. **Confirmed February 2011**

2. 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. **The NHS Digital DSPT review for University of Bristol, The Phoenix Partnership and the EMIS Group was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 May 2020).**

h. 20/CAG/0085 - 2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Ms Diana Robbins	CAG Member

Ms Clare Sanderson	CAG Alternative Vice-Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2020 NHS Adult Inpatient Survey.

The Adult Inpatient Survey is the most established survey within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The 2020 Adult Inpatient survey will be the eighteenth carried out to date, and the first mainstage to be completed using a mixed method approach, following a pilot of the approach during 2019.

Following a pilot in the 2019 survey, the survey will use a mixed methods approach for conducting the surveys. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI) and one of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe). The contractors will distribute questionnaires to patients using the approach detailed below, as successfully piloted:

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online
Contact 1.1	SMS reminder timed to arrive with the initial letter including a link to the survey
Contact 2	Postal reminder inviting the patient to take part online
Contact 2.2	SMS reminder timed to arrive with the second letter including a link to the survey

Contact 3	Postal reminder along with a paper questionnaire

Whilst the survey remains similar to previous years, COVID status has been added to the data requested for analysis so the applicants can distinguish between these patients for reporting purposes.

A recommendation for class 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	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital. Exclusions: • deceased patients • children or young persons aged under 16 years at the time of sampling • obstetrics/maternity service users, including spontaneous miscarriages • patients admitted for planned termination of pregnancy • psychiatry patients • day cases • private patients (non-NHS) • any patients who are known to be current inpatients patients • patients without a UK postal address or patients whose address was unusable because it was incomplete • any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey

	instructions request that all responses to posters are logged and used for this purpose).
Data sources	1. Electronic patient records within acute and specialist Trusts in England
Identifiers required for linkage purposes	1. Title 2. Initials or first name 3. Surname 4. Address Fields including postcode 5. Mobile phone number 6. Patient unique identifier
Identifiers required for analysis purposes	1. Trust code 2. Patient unique identifier 3. Postcode 4. Year of Birth 5. Gender 6. Ethnic Category 7. Mobile phone indicator 8. Day of the month of admission 9. Month of admission 10. Year of admission 11. Day of the month of discharge 12. Month of discharge 13. Year of discharge 14. Length of stay 15. Treatment Function Code 16. ICD-10 or ICD-11 (Chapter Code) 17. Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified) 18. Treated as a suspected or confirmed covid-19 case 19. CCG code 20. Treatment Centre Admission 21. Admission Method 22. Hospital Site Code on Admission 23. Hospital Site Code on Discharge

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

Provide detail on how use of confidential patient information without consent for the purposes of the survey has been explored as part of planned patient engagement activities, providing an overview of the feedback.

The applicant provided information on this aspect. Patient views were sought on their information being used for research purposes without consent. The majority of patients were comfortable with this approach and cited it as being similar to customer experience surveys they are sent from their banks and dentists. A key consideration was reassurance about who was conducting the survey and there being a need for transparency. The letters were reviewed in detail for the pilots and the text updated to ensure that it was explicit to patient who was conducting the survey on their trust behalf and who to contact with any queries or how to opt out

The CAG was content with this explanation.

Consider using other notification methods of the survey to raise further publicity among patients

The applicants noted the original document sent to the CAG for consideration on publicising the study was corrupted and provided the full document for review. It was also explained that other methods, such as social media, can be used by participating Trusts for notifying patients. Further, as a result of patient feedback, instructions to Trusts have been amended to ensure that notification will be placed in a position that patients are most likely to see. We have attached an updated document for publicising the survey. Trusts are being asked to consider whether any COVID-19 arrangements in may impact patients' opportunities to see the poster and ensure the posters are widely visible.

The group were content with this explanation and raised no issues.

Provide detail on the flow on information related to COVID-19 status, including:

a. **Whether the mailing contractors receive this information.**
b. **If mailing contractors will receive this information, provide a justification why these organisations receive the COVID-19 status.**

The applicants provided a specific data flow diagram for the flow of COVID-19 status information. It was confirmed that mailing contractors will not be receiving COVID-19 status, and they only receive the minimum contact details to send out the postal or SMS mailings.

COVID-19 status linked to patient contact details will be limited to approved contractors only. Patient contact details, along with the sample information including COVID-19 status, will be

securely transferred by trusts to the approved contractor they have commissioned to conduct the survey on their behalf. The approved contractors will send the pseudonymised sample information (with the exception of postcode which has been discussed previously) to the Coordination Centre. At the end of the survey approved contractors will send the survey dataset to the Coordination Centre, where it will be combined with the pseudonymised sample information (including COVID-19 status) for analysis purposes.

Members were content with this explanation.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT submission for Ipsos MORI, Patient Perspective, Quality Health and Picker Institute Europe were confirmed as 'Standards Met' by NHS Digital by check of DSPT tracker (03 August 2020)**

i. 20/CAG/0084 - PIONEER: The UK Health Data Research Hub for Acute Care

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Professor Barry Evans	CAG Member

Mr David Evans	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternate Vice-Chair
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University Hospitals Birmingham NHS Foundation Trust set out the purpose of medical research which aims to create and manage the PIONEER database, which will be used to understand and inform acute healthcare processes and long-term consequences for patients admitted to hospital which can inform current and future patient health care and health processes.

Acute care traditionally has not been the subject of research or innovation, despite its scale and the costs involved, and acute care records are traditionally siloed within individual NHS organisations. Linking records at a population level and allowing use of this data for research purposes could provide significant benefits. PIONEER will gather and link data from across acute care providers to become the first such research database to combine routine acute care provision. Using linked organisation level data, rather than national level data will provide a greater granularity of data and greater utility.

The PIONEER database will be managed within University Hospitals Birmingham NHS Foundation Trust. Initially, routinely collected acute care data from University Hospitals Birmingham NHS Foundation Trust data will be linked with routinely collected data from West Midlands Ambulance Service NHS Foundation Trust. It is expected that the database will expand the number of NHS organisations submitting routine clinical care data over time, although future unspecified organisations were not considered within this application.

Processing elements requiring support

The application indicated that, in most instances, the data to be transferred from participating organisations to University Hospitals Birmingham NHS Foundation Trust will be in a pseudonymised format. Upon receipt University Hospitals Birmingham NHS Foundation Trust will process this data through briefly reidentifying three identifiable fields (NHS number, postcode and date of birth) in order to link the data to that of other organisations. This element of processing for the purpose of linkage would require a lawful basis.

Where participating organisations do not have the capacity to pseudonymise the data prior to transfer, they would send the data in an identifiable format to University Hospitals Birmingham NHS Foundation Trust to undertake the pseudonymisation. A lawful basis would be required for this sub-set of organisations to disclose this identifiable information to University Hospitals Birmingham NHS Foundation Trust for this purpose.

Researchers can apply for data extracts for specific research projects, which will undergo a defined application process, including scrutiny by lay members, before released in an anonymised form (for example, only age will be provided, not date of birth). Support would be required to process and render relevant information fully anonymous prior to disclosure.

A recommendation for class 1, 2, 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	Patients who have undergone an acute care contact, within University Hospitals Birmingham NHS Foundation Trust or West Midlands Ambulance NHS Trust. Data will be collected retrospectively (from 01 January 2000 at the earliest) and prospectively.
Data sources	1. University Hospitals Birmingham NHS Foundation Trust 2. West Midlands Ambulance NHS Trust

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Postcode 2. Date of birth 3. Gender 4. Ethnicity 5. Diagnosis information (including rare diseases)
Additional information	Postcode is not provided to researchers. Instead, a less specific geographical unit such as the Lower layer Super Output Area (LSOA), or the associated data of interest such as the Index of Multiple Deprivation score will be provided. Date of birth is not provided to researchers. It will be used to calculate the age of the patient at the time of interest to the researcher.

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by the CAG.

Provide a letter from West Midlands Ambulance NHS Foundation Trust, as data controller, to confirm their support for this application and to confirm that 'section 251' support is required to enable this transfer for this purpose.

A letter of support from West Midlands Ambulance NHS Foundation Trust was provided to confirm that support was required for the transfer of information to University Hospitals Birmingham NHS Foundation Trust.

Members were content with this letter.

Provide firm examples of the research questions that the database will initially be used to answer.

The applicants provided three examples of initial uses of the data in the fields of sepsis, diabetes and cancer therapy, with full details of the research question and how PIONEER will be used to address the question.

The group noted these examples and raised no issue.

Provide considerations as to why, if a common pseudonymisation process was used, the linkage could not be undertaken on pseudonyms.

The applicants provided detail that is as become standard practice at University Hospitals Birmingham NHS Foundation Trust to quality check data by re-identifying the NHS number, postcode and date of birth of patient to quality check linkage. Using three identifiers to do this gives a negligible error rate, compare to a 1% error rate when only using one identifier. This is undertaken using a code applied to the data and checked automatically and is not a manual process.

The group considered this point, and concerns remained about the need to undertake this reidentification, whilst noting this is automated, and felt that the justification for pseudonymisation at source with a common pseudonym (which would remove the need for reidentification) had not been fully explained. There were also concerns that, whilst it may be justifiable to undertake on a small scale with West Midlands Ambulance NHS Foundation Trust, reidentification on a larger scale across the country has not been justified in the response

As such, a meeting between the CAG chair team and the applicant was arranged to fully discuss the remaining concerns, with the applicants providing an options appraisal paper to supplement the conversation. The applicants fully detailed their approach to this, and the methodology used to automatically reidentify patient data to match across datasets. Where there are discrepancies the match will be rejected. The advantage for this method over using a common pseudonym is the ability to be able to quality control the data.

Following this meeting the CAG chair team agreed to support the use of reidentification of NHS number, postcode and data of birth of data provided by West Midlands Ambulance NHS Foundation Trust to link to University Hospitals Birmingham NHS Foundation Trust data, on the following conditions:

a. The applicants, alongside this, pilot the use of a common pseudonym to link data between the West Midlands Ambulance NHS Foundation Trust and University Hospitals Birmingham NHS Foundation Trust.

b. The applicants explore returning rejected pseudonymised linkages back to West Midlands Ambulance NHS Foundation Trust, in order for the Trust to identify and correct the error, before returning back to University Hospitals Birmingham NHS Foundation Trust.

c. The applicants record the percentages of mismatch from linkage through reidentification, linkage through a common pseudonym, and the impact of returning pseudonymised rejected linkages to the original Trust. A report on the effectiveness of each method, and as well as a summary of the benefits and challenges encountered with each should be provided to the CAG prior to any request to add further organisations.

Clarify the understanding of pseudonymisation within the application in terms of what is transferred to Birmingham and the Pioneer database.

The applicants detailed that pseudonymisation is the form of deidentification which will be used within PIONEER, to replace or remove information in any data set that identifies an individual. The data that will be transferred to Birmingham and the PIONEER database that will need pseudonymisation are personal data, for example NHS number, date of birth and postcode. The applicants further explained how this will be undertaken.

Whilst noting the previous point, the CAG raised no issues on this description.

Specify, in absolute clarity, the exact relationship between the four hospitals of University Hospitals Birmingham NHS Foundation Trust and the PIONEER database team who may access confidential patient information of these hospitals, providing confirmation where 'section 251' support is or is not required.

c. On what common law duty of confidentiality basis are the PIONEER team accessing this data, for research purposes, considering the processing relates to a different purpose.
d. Detail the medical system infrastructure within University Hospitals Birmingham NHS Foundation Trust. Are the systems of each hospital linked, or separate?

The applicants confirmed that the four hospitals that make up University Hospitals Birmingham NHS Foundation Trust are one legal entity, and that health data from all four hospitals is held and processed for its primary purpose under a single and joint UHB informatics service, using a linked system. This team have access to patient data from University Hospitals Birmingham NHS Foundation Trust as part of the provision of

healthcare. Given the team have access as part of clinical care ‘section 251’ support is not required for this element.

This was confirmed in an email from the Data Protection Officer dated 29 June 2020

Members were content with this response.

Detail the ultimate ambition, in terms of geographical scope, of the PIONEER database.

It was clarified that the intention is to initially expand PIONEER across the West Midlands, and then nationally, to enable PIONEER to address important research questions arising from differing geographical areas and populations.

Members raised concerns about providing blanket support for this expansion without further oversight to ensure that the systems in place were secure, and ensuring that, when expanding to areas outside the West Midlands that appropriate patient notification is undertaken to ensure that patients are made aware of the uses of their data in PIONEER. Whilst this does not need to be addressed immediately, the CAG will expect this to be addressed when submitting any future amendment to widen the geographical scope of PIONEER.

Provide, separate to the privacy notice, further patient notification materials. This should include:

a. **Information, in Plain English, for service users to understand the work of PIONEER**
b. **Details of how service users may use the local opt out for PIONEER, including contact details.**
c. **Supplementary information on where the provided patient notification materials will be used.**

The applicants provided template text for the PIONEER website (the website is currently under construction). As well, two ethically approved blogs for CAG to see and a series of “frequently asked questions” were provided that will be used on the PIONEER website.

It was explained that patient opt out information will be included in all patient facing material, with the template text provided. Patient materials will be displayed in a number of ways:

- The University Hospitals Birmingham NHS Foundation Trust privacy notice will contain a link to the PIONEER website
- The PIONEER website itself
- Facebook and twitter, using the text provided
- At public facing events, webinars and public "You ask and we answer" sessions
- The PIONEER specific text within the UHB privacy notice will be incorporated into the West Midlands Ambulance NHS Foundation Trust privacy notice.

The group noted these and no issues were raised, though noting the provisional support letter condition of support to provide the CAG with a comprehensive media and communications strategy.

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. Support is limited to the involvement of West Midland Ambulance Trust initially. Prior to the addition of subsequent external organisations, a report should be sent to the CAG for consideration on the success of the processes with this Trust, detailing any issues that have arisen in the initiation of the database, and how these have been resolved.
    a. This report should include details of the percentages of mismatch using linkage through reidentification, linkage through a common pseudonym, and the impact of returning pseudonymised rejected linkages to the original Trust. The effectiveness of each method, and as well as a summary of the benefits and challenges encountered with each should be included.

2. Support is limited to the use of structured data and unstructured medical image data only.

3. Support is not provided for the use of unstructured free text data. Where the applicants wish to use this form of data in the future, a detailed amendment/paper should be submitted to the CAG, providing information on how the applicants have considered the pseudonymisation methods of free text data at source, and how they demonstrate its effectiveness in deidentification.

4. Support is not currently provided for participating organisations to transfer identifiable information to University Hospitals Birmingham NHS Foundation Trust to undertake the

pseudonymisation process. Where this situation is expected to occur, an amendment should be submitted to the CAG, providing assurances on the minimisation of identifiable information and the further detail on the processes that will be used.

5. Within three months of the final outcome letter date, provide the CAG with a comprehensive media and communications strategy. This should include details on how the applicants will maintain patient notification to the wider public throughout the lifetime of this project, and how the applicants will handle media enquiries.

6. Support is given for the use of data for medical research purposes only.

7. Favourable opinion from REC **Confirmed 21 August 2020.**

8. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for West Midlands Ambulance Service NHS Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 29 June 2020).**

   The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS DSPT Tracker (checked 29 June 2020). Support is conditional upon organisation meeting the action plan, as agreed with NHS Digital, and maintaining the agreed standard for the duration of support. All University Hospitals Birmingham staff handling information under this support must act in accordance with all details specified in the application.

j. 20/CAG/0078 - Accuracy of using crown rump length measurements in dating pregnancies

Name	Capacity
Dr Martin Andrew	CAG Member
Mr Andrew Melville	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from University Hospital Southampton NHS Foundation Trust sets out the purpose of medical research to whether the due date of an IVF pregnancy is better determined by measuring crown-rump length on ultrasound or using the conception dates from IVF (known as 'dating' a pregnancy), and to if the measurements of unborn babies at 12-weeks of pregnancy which generates a due date from population data from the 1970s, are still accurate.

Calculating an accurate estimated due date (EDD) is paramount in providing optimal maternity care. For example, for making decisions at the extremes of viability, legalities for terminating the pregnancy, as well as many other aspects of antenatal care. Crown-rump length (CRL) measurements are undertaken before 14 weeks of pregnancy to determine an EDD for the baby. However, the charts used to determine the EDD from the CRL are based on data from the 1970s, which likely used less accurate technology than today. Further, IVF conceived embryos may develop at a different rate in pregnancy compared with natural conceptions. If this rate effects the size of the fetus at 12 weeks, then the calculated EDD will be inaccurate using naturally conceived pregnancy data. In IVF pregnancies, the exact date of conception is known. This is because the date of collection of the egg from a woman, the fertilisation and growth stages of the early embryo are witnessed. Using CRL to calculate an EDD is more accurate than relying on a menstrual history, but whether it is more accurate than using the IVF conception dates is not known. This study hopes to demonstrate whether IVF pregnancies have equivalent growth to spontaneous conceptions by 12-weeks, how to calculate the EDD for women who undergo IVF and hopes to claim that the currently used methods for calculating EDDs for spontaneous conceptions, is still relevant and accurate.

This study has three cohorts, of which only the first two require support. The first cohort will look at pregnancy data from all IVF pregnancies delivered in University Hospital Southampton NHS Foundation Trust between 2011-2018. The second cohort will look at the pregnancy data from all pregnancies that had a dating scan and were delivered spontaneously in University Hospital Southampton NHS Foundation Trust in the past 20 years. This data is held within a number of separate databases within University Hospital Southampton NHS Foundation Trust and a member of staff, who is not a member of the direct care team and does not have a legal basis, will access the confidential information of patients in order to link the data together to create a dataset to be used for analysis in this study. Additional confidential patient information is requested from Portsmouth Hospitals NHS Trust and Complete Fertility Southampton, which will be linked with data collected from University Hospital Southampton NHS Foundation Trust.

A recommendation for class 1, 4 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	Cohort 1: All IVF pregnancies conceived at Complete Fertility, having a 12-week USS and delivered in University Hospital Southampton NHS Foundation Trust (2011-2020). (n=1000) Cohort 2: All babies of women who had a dating ultrasound scan in University Hospital Southampton NHS Foundation Trust between 2006-2020 who underwent spontaneous labour and delivered in University Hospital Southampton NHS Foundation Trust. (n=100,000)
Data sources	1. University Hospital Southampton NHS Foundation Trust 2. Portsmouth Hospitals NHS Trust 3. Complete Fertility Southampton
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital Number 4. Date of Birth
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity 4. Other demographic data (including date of birth of child?)

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

Provide explicit detail on the identifiable data items collected, which organisations will be providing confidential patient information, the data flows and how the linkages will happen. This should include:

e. **A list of organisations that will be providing confidential patient information**
f. **For each organisation, list the identifiable information that will be collected**
g. **For University Hospital Southampton NHS Foundation Trust, state which databases will be used to collect information from**
h. **Detail on where and how the linkage between datasets will occur**

The applicant clarified that:

- Portsmouth Hospitals NHS Trust and Complete Fertility Southampton will provide confidential patient information to University Hospital Southampton NHS Foundation Trust.
- These data will be identified by NHS number, hospital number and date of birth.
- For University Hospital Southampton NHS Foundation Trust , data will be collected from HICCS (or the maternity system that exists at the time - currently being considered for upgrade), Viewpoint, PACS and Equest.
- Data will be transferred from Portsmouth Hospitals NHS Trust and Complete Fertility Southampton to University Hospital Southampton NHS Foundation Trust by staff at those organisations. Data from University Hospital Southampton NHS Foundation Trust will be extracted by the Clinical Informatics Research Unit (CIRU), or the CI. Data from all sources will be linked at University Hospital Southampton NHS Foundation Trust.

Members were content with the descriptions and noted the clear information provided by the applicant.

Detail why the use of hospital ID is required for linkage when data from several hospitals appears to be occurring.

It was reasoned that hospital number is requested as all organisations involved will use the University Hospital Southampton NHS Foundation Trust hospital number. However, the applicant also stated that NHS number will only be used where possible.

The CAG was content with this description.

Provide clarity on the size of the cohort

It was clarified that cohort 1 will contain approximately 1000 patients, with cohort 2 containing approximately 100,000 patients.

No issues were raised by the CAG.

Detail the timeframes between which data will be collected

The applicant stated that data will be collected from 2020 backwards, until records began. For cohort 1 this is approximately 2011, with cohort 2 being approximately 2006.

The CAG was content with this description

Provide written confirmation from the Human Fertilisation and Embryology Authority (HFEA) that IVF clinics are able to provide confidential patient information without consent, under 'section 251' support.

The applicant attempted to contact HFEA to discuss this point but was unsuccessful. The Confidentiality Advice Service Manager was able to discuss this issue with the Head of Research and Intelligence at HFEA, who confirmed that there was no legal barrier for IVF clinics to provide the requested data under 'section 251' support.

The CAG noted this clarification and accepted this position.

Update the poster to provide details of how patients can opt out of their data being used in this study.

The applicant updated the poster to make explicit that patients can opt out of their data being used. No issues were raised by members.

Clarify that the use of confidential patient information without consent was discussed in the Patient and Public Involvement and Engagement activities.

The applicant explained that, in the PPI sessions, it was explicitly explained that data would be used in a confidential manner. The participants said they would not object to any of their data being used (including identifiers) so long as only the research team had access to this information.

The CAG were content with this explanation.

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. Favourable opinion from REC **Confirmed 11 May 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for University Hospitals Southampton NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 June 2020).**

2. New Amendments

a. CAG 7-04(a)/2013 - Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of Secondary Use Services (SUS), commissioning data sets, which have support under s251 under application CAG 2-03(a)/2013, and GP data for risk stratification purposes to data processors working on behalf of GPs and CCGs.

In this amendment, the applicants are seeking support to extend the duration of support for a further 24 months. The new end date will be 30 September 2022.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the amendment to extend the duration of support was in the public interest.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

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.

   Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

b. 15/CAG/0207 - NHS Cancer Screening Programmes: National Coordination and Quality Assurance

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The NHS Cancer Screening Programmes run by Public Health England (PHE) enable cases of bowel, breast and cervical cancer to be identified and treated at the earliest possible stage in order to improve patient outcomes. There is currently support under the Regulations to enable PHE to process confidential patient information for those components of the programmes (for which it is responsible and accountable to the Secretary of State for Health for as part of its core remit) that depend on the processing of confidential patient information without consent.

This amendment seeks to change the data processor for the cervical cancer screening programme from Capita to NHS England via their team in the North of England Commissioning Support Unit

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who were content to recommend support for this change in data processor.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

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**

    - **The NHS Digital DSPT 2018/19 review for Public Health England was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS Digital DSPT Tracker (checked 18 August 2020).** Please note the updated specific condition of support below.

      Support is conditional upon **Public Health England** achieving the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

    - **NHS Digital and Hitachi Consulting have confirmed 'Standards met' 2018/19 by check of the NHS Digital DSPT tracker (28 August 2020)**

    - **NHS North of England Commissioning Support Unit has confirmed 'Standards met' 2019/20 by check of the NHS Digital DSPT tracker (18 August 2020)**

c. PIAG 4-08(b)/2003 - National Confidentiality Enquiry into Patient Outcome and Death

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

Extension to project timetable - Dysphagia in Parkinson's Disease and Physical Health in Mental Health Hospitals

The applicants also seek support to extend the time-scale of support for 12 months in relation to two specific studies: Dysphagia in Parkinson's Disease and Physical Health in Mental Health Hospitals. Current NCEPOD studies have been suspended by NHS England as the applicants are unable to contact clinicians to complete questionnaires, review cases or write the reports. This extension to allow the applicants time to write the report for dysphagia, the data collection for which has already taken place, and to complete the data collection for the Physical Health in Mental Health Hospitals. The amendment requested for support to be extended to retain the identifiable information for up to 12 months in relation to these two studies.

Change to viewing arrangements for anonymised case notes

NCEPOD hosts peer review meetings, where clinicians review copies of anonymised patient case notes. These meetings have always been hosted at the NCEPOD office, with typically 10-12 people in attendance. In response to the Covid-19 pandemic, the applicants are seeking support to hold meetings remotely. This will allow the work program to continue whilst Covid-19 related restrictions are in place. The amendment set out that access would be managed by Teams or a secure desktop connection.

Members noted this change and advised that the applicant should ensure that any access takes place in line with local security policies and procedures, using security controls proportionate to the sensitivity of the accessed information.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the changes requested were in the public interest.

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 Secretary of State for Health and Social Care.

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 – National Confidential Enquiry into Patient Outcome and Death (NCEPOD) has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 11 December 2019).**

d. 16/CAG/0064 - The UK Renal Registry: A Research Database

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

This amendment set out a request for support to process COVID-19 data, currently collected under the audit permissions for the UK Renal Registry (UKRR) audit, for the purposes of research.

An amendment to the UK Renal Registry audit, under reference 16/CAG/0153, was given support in May 2020 to make changes in order to investigate the effect of COVID-19 infections impact on the health, treatment and outcomes of patients with kidney disease. The data was used to create timely reports supporting the work already carried out by the Renal Association and the UK Renal Registry and to provide renal centres, renal regional working structures, commissioners and NHS England with high quality data to assist them in more effectively handling the COVID-19 pandemic.

In the amendment to 16/CAG/0153, the applicants sought support to make the below changes.

1. To include patients diagnosed with Chronic Kidney Disease (CKD) Stage 1. This means the core patient cohort included in the research database would consist of patients diagnosed CKD stages I-V, patients with Acute Kidney Injury (AKI), or any patient receiving renal replacement therapy (RRT).

2. To include the following real time data flows from renal centres:

    a. Patientview - an online portal where patients can view their test results and manage medication. The UKRR are seeking support to process this data flow to augment the data already collected from renal centres and allow for more timely research on factors that affect the treatment and outcomes of renal patients who are infected with COVID-19.

    b. The National Registry of Rare Kidney Diseases - a research database which enables research into rare kidney diseases. The UKRR sought support to process the data held in RaDaR to identify patients who have rare underlying renal conditions which mean they are at higher risk of developing severe complications should they be infected with COVID-19.

3. To increase the frequency of its existing linkages with Public Health England from annual to monthly, and expand the linkage to include reported cases of COVID-19 alongside the data collected on other Healthcare acquired infections (HCAIs). The change in frequency and extra data does not require the use of any additional identifiers and the data flow is the same, only more regular and including tests and results for COVID-19.

4. To establish a linkage between the UKRR and the Intensive Care National Audit and Research Centre (ICNARC), to allow the applicants to understand which renal patients were admitted to intensive care as a result of a COVID-19 infection and the length of their stay.

5. To collaborate with the Getting It Right First Time (GIRFT) programme, supported by NHS England and NHS Improvement, to analyse the Covid-19 data in a timely manner. This collaboration will be subject to a data sharing agreement.

6. To collect additional data from the renal centres in order to support regional efforts to manage cases of COVID-19 while continuing to deliver the renal services that are needed. The UKRR will ask renal centres to report positive cases of COVID-19 via NHS.net, providing the registry with patient identifiers, and the date of the positive test. In addition, the UKRR requires renal centres to provide data on symptoms and centre policies so the registry can compare the approaches used to handle the pandemic. The UKRR will then aggregate this data and feed the number of cases back to renal centres to allow them to work together to manage resources across a region.

In this amendment, the applicants sought support to process the data collected via the above linkages for research purposes, as well as for the UKRR audit. The applicants aim to explore the changes that the Covid-19 pandemic has presented to renal centres, who need to facilitate patients' need to attend regular dialysis appointments while also limiting the spread of a virus amongst a population that are at a higher risk of developing severe symptoms. The applicants also aim to develop understanding of the risk factors of Covid-19 related mortality in dialysis patients and assist in the advance care decision making, if patients opt for maximum conservative care and not attend a high risk setting for dialysis. The amendments are also requested to enable the UKRR in ensuring that it can produce timely and relevant reports to provide high quality data to clinicians, renal centres and commissioners.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group asked the applicant to provide the following further information and clarifications:

1. **The CAG requested further clarification on who will be undertaking the research and whether anyone other than the entities described in the data flow will be able to access the data for research.**

The applicant advised that the Renal Association (RA) hosts the UK Renal Registry (UKRR), to which both internal (RA employees) and external researchers (NHS researchers and academic institutions) can apply to receive pseudonymised or aggregated data. Details of the data application process and associated documents were submitted in an amendment to CAG in November 2019, which was approved on 22 January 2020. As such, research using UKRR held data is conducted by researchers with an interest in renal medicine who are based in UK health or academic institutions. External researchers sign a fixed length data sharing agreement with the Renal Association that states that the data can only be used for the approved project and that they are not allowed to onwardly share the data.

The CAG noted this information and raised no further queries.

2. **The Group requested further clarification on the additional data that the applicants would obtain from Patientview and how this assist in meeting the aims of the study.**

The applicants explained that Patienview is patient viewing platform, where patients can see their test results and current medications. Including the daily Patientview data feed would mean that researchers who applied to access the UKRR data would be able to access timely data. Many studies, clinical trials, audit or quality improvement initiatives want to look at the impact of interventions or quality improvements on markers of care, but this is currently not possible, as the UKRR only provides access to the data collected by renal centres, which has a delay of at least a year.

The CAG noted this information and raised no further queries.

3. **Patients consented to the inclusion of their data in Patientview. Members queried why it was no possible to seek consent from patients for the use of their data as described in this amendment.**

The applicant advised that the RA did not hold valid email addresses for approximately 65% of patients using Patientview in order to re-contact patients for consent. The RA also did not have permission to contact all patients using Patientview, as it was also used by patients who are not cared for by kidney doctors. The RA had just completed a postal re-consenting process for the National Registry of Rare Kidney Diseases (RaDaR) registry, which is consented, and the return rate of re-consent letters was about 30%. Many of the patients would have died – about 15% of people starting RRT die within a year making retrospective consent a further issue.

The CAG noted this information and raised no further queries.

4. **Clarify whether, should other researchers apply to use data from the UKRR in their own research, there is a mechanism in place for anonymising data prior to release?**

The applicant advised that the data released for research would be de-identified. The CAG noted that support under s251 would need to be sought should any data containing confidential patient information be released to third parties.

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. If data is released to third parties, no confidential patient information should be released without further support under s251 being sought for that release.

2. 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 – The Renal Association has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 14 October 2019).**

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 29 April 2020.**

e. 17/CAG/0011 - Genetic mechanisms in polyposis of the bowel

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants had initially applied for support under ‘Section 251’ and its Regulations to include a cohort of up to 20 deceased patients, alongside a cohort of consented participants, which is outside the scope of this support. The applicants have received support in a recent CAG amendment to extend the end date of the study until 31 August 2021 to allow more time to meet the recruitment target of 375 participants. However during the processing of the previous amendment it was noted that our records show a recruitment target of around 350 patients, and that we had a different Chief Investigator name on record. Applicants confirmed that these changes were given REC favourable opinion in February 2020, alongside many other changes which are not relevant to CAG support. A further amendment was requested for the change in Chief Investigator.

In this amendment, applicants sought support to change the Chief investigator from Professor Julian Roy Sampson to Dr Hannah Deborah West. This is because Professor Sampson is now semi-retired. Applicants also sought support for the increased recruitment target of 375 patients. However the applicants have confirmed that there is no increase in the number of deceased patients to be included in this study, as this was a condition of support – the recruitment target of 20 deceased patients will not be exceeded. Therefore this change in total recruitment target does not need support under the Regulations, as the number of deceased patients recruited remains the same.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The change of Chief Investigator is justified.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT 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: Cardiff University confirmed ‘Standards Met’ on DSPT 2018/19 (by check of DSPT Tracker 09 September 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee:
   Confirmed 26 February 2020

f. 17/CAG/0050 - Educational Outcomes in Children Born after ART

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University College London Institute of Child Health is researching whether children born after assisted reproductive technology (ART) are at a higher risk of developing learning or behavioural problems. This project proposed combining and analysing data from two existing large research databases: the Human Fertilisation and Embryology Authority (HFEA) Register and the National Pupil Database (NPD), and was given provisional support in 2017. However it proved difficult to meet a condition surrounding appropriate data security assurances, which was required to enable the linkage to be performed at the Department for Education (DfE). This led to a change in proposed data flows and data processors, which was then given conditional support in July 2019. The study currently has support in place for the disclosure of confidential patient information from NHS Digital to the Office for National Statistics (ONS) to facilitate linkage with the NPD. The flow of data from DfE to ONS was out of scope of support under the Regulations because the data is not defined as patient information. The applicants have not yet started work on the project.

This amendment request sought support to revert to the study flow originally requested, of NHS Digital sending confidential patient information from the ART database to DfE for linkage with the NPD, and therefore include DfE as an additional data processor. The linked data is pseudonymised and transferred to the ONS Secure Research Service (SRS) for access by the UCL research team. The data flow for the unrelated school-matched control group is unchanged from the already supported application and is not part of the amendment request.

In summary, the data flows now requiring support under the Regulations are;

- The disclosure of confidential patient data from NHS Digital to DfE for the purposes of linkage with NPD,
- The linkage of the control group created by DfE with birth records by ONS.

All other data flows are either pseudonymised or not classed as patient data.

The reason for the amendment request is a change in circumstances regarding DfE, who now have NHS Data Security and Protection Toolkit assurance from NHS Digital in place. As a result of this, the DfE will only proceed with the study on the basis that the data linkage to the NPD is undertaken by the DfE team. The amendment requested will also significantly reduce the amount of identifiable data that will need to be transferred between organisations.

The amendment sought support to add postcode as an additional data linkage variable, in order to optimise the data linkage, following discussions with NHS digital.

The amendment sought to extend the duration of support required until 31 December 2021. This is due to the delays experienced in setting up the data processors for the study.

The amendment provides an updated flowchart and protocol in order to reflect the described changes.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group were supportive of the proposed change, and commented that this would reduce the amount of identifiable data flowing between organisations.

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) submissions has achieved the 'Standards Met' threshold
   Confirmed –

   University College London School of Life and Medical Sciences and NHS Digital have confirmed 'standards met' grades on 2018/19 DSPT (by check of the DSPT tracker 7 September 2020).

   The Office for National Statistics has confirmed 'standards met' grades on 2019/20 DSPT (by check of the DSPT tracker 7 September 2020).

   The Department for Education has confirmed equivalent security assurances for 2019/20. (by check of the DSPT tracker 7 September 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Favourable opinion confirmed 21 July 2020

g. 19/CAG/0139 - The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

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 foetuses
- 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**

h. 18/CAG/0100 - HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to process confidential patient information supplied by acute hospitals trusts and NHS Digital to the Clinical Trial Service Unit at the University of Oxford in order to contact patients to seek consent to include their data on a pre-screening database.

The applicants initially intended to contact patients by letter once. In this amendment, the applicants are seeking support to send a second invitation letter to patients who did not respond to the first contact. Prior to the beginning of the Covid-19 pandemic, the ORION-4 senior management team reviewed the response to invitations.

Approximately 1 in 20 of the potentially eligible patients approached had expressed interest in taking part, however less than 1.2% of these patients were randomised. The main reason for this was that many did not meet the requirement of having a point-of-care total cholesterol of at least 4 mmol/l at the screening visit. Sites may have exhausted their pool of potentially eligible patients. Recruitment has also been affected by the Covid-19 pandemic. In previous studies using similar invitation methods, a significant number of potentially eligible patients who did not reply to an initial mailed invitation, did volunteer to take part after receiving a second invitation. As is in place for the initial invitation letters, a regular check will be undertaken with NHS Digital to ensure that these re-invitation letters are not mailed to those who are known to have died or who have expressed a national opt out of secondary uses of their health care data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group noted the reasons for the amendment and determined that the proposed change was in the public interest.

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 – University of Oxford – Medical Sciences Division – Nuffield Department of Population Health – Clinical Trial Service Unit, have confirmed 'Standards Met' grade on DSPT 2018/19 by NHS Digital DSPT Tracker checked 14 August 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 07 September 2020.**

i. 19/CAG/0228 - Impact & acceptability of 10-year risk at breast cancer screening v1

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University of Manchester aims to test the effect of communicating personalised estimates of breast cancer risk (BC-Predict) on acceptability, informed choices and possible harms to women offered personalised risk estimates. Support under the Regulations is currently in place to allow access to confidential patient information within the NHS Breast Screening Programme database to be accessed remotely by a member of the research team within the Manchester University NHS Foundation Trust to enable an eligible patient cohort to be identified and approached to participate in the study.

This amendment sought support to extend the duration of study support until 31 December 2021, due to delays experienced by Covid-19.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT 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 has achieved the 'Standards Met' threshold
   Confirmed –

   The NHS Digital DSPT review for Manchester University NHS Foundation Trust was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 11 August 2020). Please note the updated specific condition of support below.

   All staff at Manchester University NHS Foundation Trust that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed – REC Favourable opinion 10 September 2020

j. CAG 7-07(a-c)/2013 - Invoice validation within NHS England within the Commissioning Support Units/Clinical Commissioning Groups controlled environment (for Finance) on behalf of Clinical Commissioning Groups

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

In this amendment, the applicants requested an extension to the duration of support to continue the legal basis permitting Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs) to process confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for invoice validation purposes. Support is currently in place until 30 September 2020 and the applicants sought to extend this by a further 24 months until 30 September 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair and Confidentiality Advice Team. The amendment set out that the extension would allow a continuation in ensuring that organisations receive the correct funding for the NHS services they provide which is essential to maintain the NHS. The request stated that extending support would maintain essential business continuity and healthcare services to patients. Invoice validation is part of the effective management of health and social care services, ensuring that providers are appropriately reimbursed for the care and treatment they deliver to patients. The process confirms that providers receive the correct amounts by checking that the correct patient received the correct treatment and that the correct commissioner has been identified. Invoice validation allows prompt payments to healthcare providers to be made and fulfils the commissioners' duties for fiscal probity and scrutiny.

The CAG advised that the importance of continuing support would provide a clear public benefit in terms of the management of health and care services.

New legislation as an exit strategy

In particular, the amendment specified that the original predicted exit strategy was new legislation that would remove the need for Regulation 5 support by 30 September 2020. It was stated that that due to the current focus on COVID-19 that this had not been progressed. Support was requested for a further 24 months to enable new legislation to be progressed. The need for new regulations in this area will need to be considered by officials in the Department for Health and Social Care.

The CAG agreed that the reasons cited for the duration extension were valid at the current time and therefore the duration was considered reasonable.

Annual review

It was noted that an annual review had not been provided for some time and reminded the applicants that provision of an annual review was a standard condition of support for all applications and was expected to be proactively submitted every 12 months to avoid jeopardising the future status of support.

Please note that the annual review submission date for these references is 30 September each year; an annual review should be submitted 4 weeks in advance of this date.

Security assurances – outstanding action

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved activities seeking support to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). In England, security is considered satisfactory once NHS Digital confirm (via internal tracker or direct email) that the relevant entity has achieved ‘standards met’ or ‘standards met – improvement plan in place’. This process applies to all supported activities.

Following review of the information submitted in the amendment, at time of submission, and following recent review of NHS Digital’s internal tracker, there are a significant number of entities that have not achieved the appropriate level of security assurances necessary to process confidential patient information under support. It is important to recognise that those

entities that do not meet the standard security assurance level are not covered by the legal support as the conditions of support are not being met.

The CAG understands the importance of the activity proceeding, however noted that it is important for public confidence that those operating under support maintain an appropriate level of security assurance in line with all other supported application activities. An appendix is set out in this letter that lists the current status of the entities specified as intended to be covered by support. The applicant is advised to closely review and mobilise the relevant information governance teams to complete the submissions to enable NHS Digital to complete their review and provide confirmation to CAG.

CAG advised that, on an exceptional basis, a clear update report should be provided in 3 months from date of this letter, that demonstrates clear progression of the relevant entities to achieve the required security standard. The expectation would be that the vast majority will have submitted all relevant information to enable NHS Digital to complete their DSPT reviews and confirm these as satisfactory. For any that remain a clear plan with timescales to manage their transition to the security standards would be necessary. It should be noted that a potential recommendation following the report will be that those that have not met the standards will be updated as not being included within support. The CAG therefore strongly encouraged NHS England to work with these entities to achieve this and avoid any future restriction of support. If there are any questions over this aspect, please do not hesitate to get in contact with the Confidentiality Advice Team.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care to extend the duration for a further 24 months. However, this was subject to the applicants providing a detailed report on the security status of outstanding DSPT confirmations in line with the details of the Appendix.

Specific conditions of support

1. Report to be provided in 3 months providing clear update status on entities that have not yet achieved satisfactory security assurances, with expectation the majority will have achieved the standards.

k. 18/CAG/0146 (Replacement of PIAG 2-05(j)/2006) – National Joint Registry (NJR)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

The National Joint Registry (NJR) collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. There is support in place to record confidential patient information in the NJR database when the consent status is 'unknown'.

Support is also in place to allow the flow of confidential patient identifiable information in relation to all patients with the relevant OPSC4 codes from NHS Digital and NHS Wales Informatics Service to Northgate Public Services in order to be able to identify procedures missing from the NJR dataset. This includes Hospital Episodes Statistics (HES), PROMs, Civil Registry (formerly ONS) and Patient Episode Database Wales (PEDW) data. Support under the Regulations is in place for all patients including those with a consent status of 'unknown' or 'no'. Linkage with the NJR database would then only be undertaken for those patients whose consent status was confirmed as 'yes' and 'unknown'.

Support under the Regulations also includes the disclosure of confidential patient information from the local PAS (Patient Administration Systems) at participating Trusts and Health Boards to Northgate Public Services as processor for the NJR, in relation to all patients who have undergone a specified joint replacement, to facilitate auditing of the data submitted to the NJR. Again, linkage with the NJR database would then only be undertaken for those patients whose consent status was confirmed as 'yes' and 'unknown'

This amendment sought support to reverse the direction of flow for PROMs data only, so that NHS number, DOB, Gender and Postcode from within the NJR database and the corresponding unique NJR identifier would flow from Northgate Public Services (on behalf of the NJR) to NHS Digital. NHS Digital would then link the NJR records directly to PROMs data at the patient level, remove the identifiers and send the PROMs data linked to NJR ID

back to Northgate Public Services in pseudonymised form. Only patients with a consent status of 'yes' or 'unknown' would have identifiers sent from NJR to NHS Digital for linkage. NJR would not receive any PROMs data regarding the patients with a consent status of 'no'.

Flows for both HES, Civil registry and PEDW data would remain as described in the current support.

This amendment has been requested because the applicants have become aware of issues around the coding of some unicompartmental (partial) knee replacements which means that using the current model will fail to link NJR to National PROMs data for this population. It is estimated that the records for over 30% of all unicompartmental knees are missing from the data currently provided by NHS Digital.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group commented that the amendment request was to resolve a specific issue which the NJR has become aware of surrounding coding of some unicompartmental knee replacements. It was noted that PROMs data is particularly useful for this group of patients. The Group noted that the implementation of this amendment would further limit the flow of confidential patient information, and were supportive of this amendment.

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 Secretary of State for Health and Social Care.

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 –

   The NHS Digital 2018/19 DSPT review for **Northgate Public Services** was confirmed as 'Standards Exceeded' on the NHS DSPT Tracker (checked 18 August 2020).

The NHS Digital 2018/19 DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 August 2020).

I. 18/CAG/0207 - Defining delirium and its impact in Parkinson's Disease(DELIRIUM-PD)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

This study from Newcastle University aims to understand the incidence of delirium in Parkinson's disease. Support is currently in place to disclose confidential patient information relating to patients with Parkinson's treated at Newcastle upon Tyne Hospitals Foundation Trust, to the DELERIUM-PD research team, to facilitate the recruitment process.

This amendment is seeking to extend the duration of support under the Regulations until 1 June 2021 for the purposes of screening and recruitment. This is due to study recruitment being temporarily paused due to Covid-19.

This amendment also sought support for the DELERIUM-PD research team to perform a Covid-19 medical note review, to understand the impact of Covid-19 in inpatients with Parkinson's disease and to identify all cases of delirium. This will consist of a review of all medical notes of people with Parkinson's disease who were admitted to Newcastle upon Tyne Hospitals Foundation Trust during the time of Covid-19, specifically 1 March 2020 until 1 August 2020. Anonymous data only will be extracted. The research team will compare this data to 2018 and 2019 data to assess the impact of Covid-19 on the Parkinson's disease with delirium population. Applicants are seeking to perform the medical note review as more research is needed into the presentation of Covid-19 in this patient group, as recent evidence suggests that people with Parkinson's disease may be at increased risk of Covid-19 and of developing associated delirium.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group on 25 August 2020, and a provisional outcome was issued. This fully supported outcome letter should be read in conjunction with provisional outcome letter dated 1 September 2020.

Further information was requested form the applicant as detailed below. The applicant responded to these requests as detailed below.

Request for further information

1. **Please ensure appropriate patient notification is in place for the study changes, and feedback to the CAG within 1 month of the date of this letter.**

   The applicant responded with a document detailing the information to be displayed on a website notifying patients about the study change.. This will be displayed on the research group website and the applicants staff page. Information will be displayed for one month prior to commencing the activity. The CAG were happy with this response.

2. **Please develop an opt-out mechanism which is displayed with the patient notification, and feedback to the CAG within 1 month of the date of this letter.**

   The website patient notification now includes information for patients and/or their relative/friend/carer to contact the research team to opt out of the additional medical notes review. Contact telephone numbers and email address of the research team are now included for this purpose, and the CAG were content with this dissenting method.

3. **Please confirm the acceptability of the amendment with the study PPI group, and feedback to the CAG within 1 month of the date of this letter.**

   The applicants confirmed that the PPI advisory panel has reviewed and supported the amendment. A summary of the PPI panel's feedback on the medical notes review, the website patient notification and the extension to the study recruitment period was provided, and the CAG were satisfied with this response.

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:

   The NHS Digital 2018/19 DSPT review for **Newcastle Upon Tyne Hospitals NHS Foundation Trust** was confirmed as **'Standards Not Fully Met (Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 17 August 2020). Please note the updated specific condition of support below.

   Newcastle Upon Tyne Hospitals NHS Foundation Trust should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 14 August 2020

m. 20/CAG/0067 - Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was

previously given support under reference 16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

The applicants are seeking support to link data from the LeDeR programme to the National Cancer Registry in order to provide surveillance about the types of cancer and specific aspects of their diagnosis and treatment in patients with learning disabilities. The NHS numbers and dates of birth of patients with learning disabilities, who also have a diagnosis of cancer mentioned on LeDeR documentation pertaining to the review of their death, and who died between 2017-2019, will be sent to Public Health England (PHE). PHE will then link the NHS numbers and dates of birth to any entries for these patients on the National Cancer Registry. PHE will return to the LeDeR programme team the following details; patient age at diagnosis, days from diagnosis to death, basis of diagnosis, site of the neoplasm, behaviour of tumour, grade of tumour, Dukes stage, type of treatment received, treatment within 6 months of diagnosis and the summary of 'route to diagnosis'.

It is known that patients with learning disabilities live, on average, approximately twenty years less than those in the general population and are less likely to access screening. The NHS Long-Term plan states the intention to take action on prevention and health inequalities, and to aid those with learning disabilities to live longer, healthier lives. No baseline data exists on the diagnosis and treatment of cancer in those with learning disabilities. In work proposed in this amendment will be undertaken with the intention of providing this data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment request was in the public interest.

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 Secretary of State for Health and Social Care.

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. **NHS England (Controller), University of Bristol (Processor), North of England CSU (Processor), South Central and West Commissioning Support Unit (Processor). Confirmed via DSPT tracker, checked 04 May 2020.**

n. 17/CAG/0011 - Genetic mechanisms in polyposis of the bowel

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants had initially applied for support under 'Section 251' and its Regulations to include a cohort of up to 20 deceased patients, alongside a cohort of consented participants, which is outside the scope of this support. The applicants have received support in a recent CAG amendment to extend the end date of the study until 31 August 2021 to allow more time to meet the recruitment target of 375 participants. However during the processing of the previous amendment it was noted that our records show a recruitment target of around 350 patients, and that we had a different Chief Investigator name on record. Applicants confirmed that these changes were given REC favourable opinion in February 2020, alongside many other changes which are not relevant to CAG support. A further amendment was requested for the change in Chief Investigator.

In this amendment, applicants sought support to change the Chief investigator from Professor Julian Roy Sampson to Dr Hannah Deborah West. This is because Professor Sampson is now semi-retired. Applicants also sought support for the increased recruitment target of 375 patients. However the applicants have confirmed that there is no increase in the number of deceased patients to be included in this study, as this was a condition of support – the recruitment target of 20 deceased patients will not be exceeded. Therefore this change in total recruitment target does not need support under the Regulations, as the number of deceased patients recruited remains the same.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The change of Chief Investigator is justified.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT 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: Cardiff University confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 09 September 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 26 February 2020

3. Annual Review Approvals

CAG Reference	Application Title
15/CAG/0119	MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)
18/CAG/0008	Sight-threatening chemical injury study in association with the British Ophthalmological Surveillance Unit
15/CAG/0207	NHS Cancer Screening Programmes: National Coordination and Quality Assurance
ECC 3-04(i)/2011	Global surveillance of cancer survival (CONCORD programme)
18/CAG/0207	Defining delirium and its impact in Parkinson's Disease (DELIRIUM PD)
ECC 3-03(c)/2012	Manchester Cancer Research Centre Biobank - collection of tissue, blood and urine for cancer research
18/CAG/0091	Connected Bradford - Linked Education and Health Research Database
ECC 7-05(h)/2011	CRANE Database – Epidemiology Register
18/CAG/0100	ORION-4
PIAG 4-07(c)/2002	Audit database of Paediatric Intensive Care (PICANet)
19/CAG/0097	2019 NHS Adult Inpatient Survey
ECC 3-06(m)/2009	Prognostic Factors in Prostate Cancer for Patients Treated By Watchful Waiting
CAG 2-03(PR2)/2014	Mental Disorder & Cancer Care: A Data Linkage Study in South London II
CAG 1-03(PR2)/2014	1958 National Child Development Study (NCDS)
CAG 10-08(c)/2014	Intergenerational and lifecourse influences on health and mortality
CAG 2-03(PR4)/2014	1970 British Cohort Study
14/CAG/1006	Millennium Cohort Study (MCS)

CAG 1-03(PR3)/2014	Next Steps previously known as Longitudinal Study of Young People in England (LSYPE)
19/CAG/0035	Updating cancer survival index trends for England and Wales to 2016

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date