**Confidentiality Advisory Group**

Minutes of the meeting of the Confidentiality Advisory Group held on 24 August 2023 via video conference.

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**Present:**

| Name | Capacity |
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| Dr Tony Calland MBE | CAG Chair |
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Dr Martin Andrew | CAG Expert Member |
| Mr Thomas Boby | CAG Expert Member |
| Dr Malcolm Booth | CAG Expert Member |
| Professor Lorna Fraser | CAG Expert Member |
| Dr Pauline Lyseight-Jones | CAG Lay Member |
| Mrs Diana Robbins | CAG Lay Member |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |
| Mr William Lyse | HRA Approvals Administrator |
| Mrs Emma Marshall | HRA Confidentiality Specialist |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Anna Martin | Observer – HRA Approvals Specialist (Internal) |
| Neelam Patel | Observer – HRA Non-executive director (Internal) |

## 1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Mr Umar Sabat, Dr Rachel Knowles and Dr Sandra Duggan.

## 2. DECLARATIONS OF INTEREST

There were no declarations of interest.

## 3. SUPPORT DECISIONS

### Secretary of State for Health & Social Care Decisions

There were no applications requiring a decision by the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care in relation to the **13 July 2023** meeting.

### Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **13 July 2023** meeting applications.

### Minutes:

The minutes of the following meetings have been ratified and published on the website:

- **June Sub-Committee Meeting**
- **July Sub-Committee Meeting**

## 4. CONSIDERATION ITEMS

There were no items for consideration.

## 5. NEW APPLICATIONS FOR CAG CONSIDERATION

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| **5a.** | **23/CAG/0096** | **Clinical and cost-effectiveness of a maternity quality improvement programme to reduce excess bleeding and need for transfusion after childbirth: the Obstetric Bleeding Study UK (OBS UK) Stepped Wedge Cluster Randomised Trial** |
| | **Chief Investigator:** | **Dr Sarah Bell** |
| | **Sponsor:** | **Cardiff University** |
| | **Application type:** | **Research** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

## Summary of application

This application from Cardiff and Vale Health Board and Cardiff University set out the purpose of medical research that seeks to test the effectiveness of the Obstetric Bleeding Strategy intervention in treating excess bleeding during childbirth.

Excess bleeding is the most common complication of childbirth. Every year about 50,000 women in the UK lose 1L (2 pints) of blood or more. Many women need a blood transfusion or are admitted to intensive care and find the experience of bleeding traumatic, developing mental health issues after having their baby. There is a lack of knowledge about how best to treat the excess bleeding and, despite comprehensive national guidelines being in place, outcomes have not improved over the last 10 years.

The applicants have developed the Obstetric Bleeding Strategy (OBS). The strategy includes an assessment of every woman's bleeding risk, the real-time measurement of blood lost after all births, a consistent approach to managing excess bleeding and bedside tests to rapidly identify and treat abnormal blood clotting. This would be a change to current UK guidelines, which recommend measuring blood loss only after excess bleeding is identified. Confidential patient information will be extracted from patient records at participating NHS trusts and health boards by members of the local research team. The confidential patient information will be disclosed to Cardiff University and collated into the OBS UK database. Confidential patient information will then be disclosed to NHS England and Digital Health and Care Wales for linkage to national datasets, and the return of the linked dataset to Cardiff University. A pseudonymised dataset will be held within SAIL.

## Confidential information requested

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| **Cohort** | 189,000 Total international sample size (including UK).<br><br>Patients will be recruited from 32 NHS maternity units in England. All women giving birth in these units will be included. The applicants estimate that 235,200 patients in England will be included. |
| **Data sources** | 1. Hospital Episode Statistics, Maternity Services Dataset, Children and Young People's Health Services Dataset, Child Health Surveillance System<br><br>2. Data provided from participating maternity units, disclosed to Cardiff University and collated in the OBS study dataset. |
| **Identifiers required for** | 1. NHS Number<br>2. Date of birth |

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| **linkage purposes** | 3. Postcode – unit level |
| **Identifiers required for analysis purposes** | 1. Postcode – unit level<br>2. Ethnicity |

**Main issues considered, discussed and outcomes**

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

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG members requested clarity on how the research team would manage the overlap of cross border postcodes between England and Scotland. Furthermore, whether the postcode would be retained and used within analysis. [Action 1]

The CAG requested clarification as to why the identifiers must pass through Cardiff University instead of being sent directly to the relevant national processing organisation. [Action 2]

Furthermore, the CAG requested clarity as to the process for confidential patient information generated within Wales. The members noted references to Welsh data being used within the study and requested further details on how this would be used. [Action 3]

The CAG requested that continued patient and public engagement and involvement was undertaken. Specifically, the CAG needs to be provided with feedback on discussions regarding the use of confidential patient information without consent. [Action 4]

The CAG requested clarification on whether data would be obtained from the Hospital Episode Statistics (HES) database. If HES data would be collected, clarification on why should be provided. [Action 5]

The CAG requested for several revisions to be made within the patient poster. Firstly, the members highlighted a clash of colour and structure, which made the poster difficult to read. [Action 6a]

Furthermore, the CAG requested for the researchers to promote use of the local opt-out whilst still respecting the NDO. [Action 6b]

The CAG encouraged the participation of those under 16 years of age, however, requested the applicant to clarify whether special provisions were in place, especially in regard to accessing knowledge to their legal rights. [Action

7]

The CAG requested clarity as to why the participants post code was sought, and at what point this would be removed from the data. [Action 8]

The CAG sought clarification as to why the patient's name was retained. [Action 9]

Lastly, the CAG considered whether consent was to be captured during the observation. The CAG concluded that the use of verbal consent was sufficient under common law.

**Confidentiality Advisory Group advice: Provisionally supported**

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

| Number | Action required | Response from the applicant |
|---|---|---|
| 1. | Clarify how you would manage the overlap of cross border postcodes between England and Scotland. Furthermore, explain whether the postcode would be retained and used within analysis. | |
| 2. | Clarify why the identifiers must initially pass through Cardiff University instead of being sent directly to the national process organisation. | |
| 3. | Clarify the use of Welsh data within the study and how the research team intend to use it. | |
| 4. | Continue engagement with the patient and public engagement and involvement group, and provide feedback to the CAG on their discussions regarding the use of confidential patient information without consent. | |
| 5. | Clarify the intention to access the Hospital Episode Statistics (HES) database. Furthermore, clarify what the research team would be investigating. | |

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| 6. | Please amend the following within the patient poster:<br><br>a. Amend the colour and structure of the poster.<br><br>b. Promote the use of the local opt-out whilst still respecting the NDO. | |
| 7. | Clarify whether special provisions are in place for those participating under the age of 16. | |
| 8. | Clarify why the participants post code was sought, and at what point this would be removed from the data. | |
| 9. | Clarify why the patient's name was retained. | |
| 10. | Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. **Pending** (checked 25/08/2023) | |

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

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| **5b.** | **23/CAG/0091** | **CAG Overarching Application for Oxford Vaccine Group** |
| | **Chief Investigator:** | **Professor Sir Andrew John Pollard** |
| | **Sponsor:** | **Oxford Vaccine Group - University of Oxford** |
| | **Application type:** | **Research** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

**Summary of application**

This application from the University of Oxford set out the purpose of recruitment of patients to research studies, requiring the identification of patients from NHS England held datasets and the sending of invitations via CFH Docmail Limited.

The Oxford Vaccine Group (OVG), based in the Department of Paediatrics at the University of Oxford, conducts studies of new and improved vaccines for children and adults. Over the last 5 years, just under 8000 participants have been recruited into almost 30 clinical trials and studies. Various methods are used to recruit participants, including, but not limited to; email, telephone, SMS

messaging, posters, leaflets, websites, advertisements in newspaper, radio, social media and in public places, and mail-outs. Although in the past these methods of recruitment have been sufficient to meet target recruitment numbers, as the portfolio of studies has grown over recent years, the applicants have begun to explore different ways of recruiting patients.

The applicants intend to use the electoral open register or NHS England databases to identify and contact eligible patients, using a centrally arranged mailout. Consideration was given to submitting individual applications for each of the current OVG studies, however given all studies will be using the same approach, a single overarching application encompassing all current studies has been submitted. NHS England will be asked to identify those living in specific postcodes and/or who are within appropriate age ranges, and to run an extract of those patients' details. This extract will be transferred to CFH Docmail Ltd which will facilitate the sending of study invitations to potential participants. Those interested in taking part can then contact the study sites directly. Processes for eligibility assessment, informed consent and enrolment to the studies will follow the specific study protocol and informed consent taken before any study-related procedures. Patients will be sent a single reminder following the initial mailout. Patients contacted about different studies will be sent no more than 3 mailouts in any given year, with at least a three-month period between mailouts.

**Confidential information requested**

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| **Cohort** | Patients meeting the inclusion criteria for the below studies:<br><br>• Development of a Live Attenuated Vaccine against Salmonella Paratyphi A (VASP) IRAS Project<br>• A single-blind, randomised, phase II multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules in adolescents (COMCOV-3)<br>• A phase I study to determine the safety and immunogenicity of a new vaccine against Middle East Respiratory Syndrome Coronavirus in Adults aged 50 to 70 (MERS)<br>• A phase 1 safety and immunogenicity study of a Crimean-Congo haemorrhagic fever virus vaccine, ChAdOx2 CCHF, in healthy adult volunteers in the UK (CCHF)<br>• An open label Phase I/IIa clinical trial to assess the safety, immunogenicity and efficacy of the malaria vaccine candidate RH5.2-virus-like particle (VLP) in Matrix-MTM, and to compare the safety and immunogenicity of the malaria vaccine candidates RH5.2-VLP in Matrix-MTM and RH5.1 |

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| | soluble protein in Matrix-MTM used in various regimens (BIO-001)<br>• Phase I clinical trial to assess the safety and immunogenicity of the malaria vaccine candidate RH5.1 soluble protein in Matrix-MTM using two dosing regimens (BIO-002)<br>• Heterologous Boosting for Hexavalent Paediatric Vaccines in the UK Schedule (6in1 Part 2)<br>• Safety and Immunogenicity of a Shigella tetravalent bioconjugate vaccine in adults (SIS4V) |
| **Data sources** | 1. The Personal Demographics Service (PDS) held by NHS England |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of birth<br>3. Postcode – this may be district, sector or unit level, as required |
| **Identifiers required for analysis purposes** | The only identifiers retained by the Oxford Vaccine Group will be held under patient consent. |

**Main issues considered, discussed and outcomes**

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

The CAG recognised the potential importance of the trials that would be included under support for the overarching recruitment methodology. The CAG noted that although support has been recommended for other applications to access large numbers of patient records to identify and recruit participants via mailout, this application differed in that there were varying levels of risk involved across the trials proposed under the overarching methodology. As an example, members noted that Phase 1 trials and Phase 1 trials in healthy volunteers had a higher level of potential risk compared to other trials. Members expressed concern that they were unable to fully consider the risks and benefits for each trial based on the information in the overarching application and were therefore unable to consider if the use of confidential patient information for each trial was in the public interest.

The CAG agreed that insufficient justification had been provided to demonstrate that the proposed methodology was essential to meet recruitment targets for each trial and that all other methods of recruitment had been exhausted.

The CAG noted that the applicants sought to identify and recruit vaccine naïve

patients, some of whom may have not been vaccinated due to personal beliefs. The CAG expressed concern around the potential sensitives of identifying and approaching these patients. Members also expressed concern that these patients may not be supportive of having their vaccine status assessed either by those outside of the direct care team or without consent. Members also noted that NHS vaccine records may be incomplete, for example, if vaccinations have been given via private healthcare. Members agreed that this should be tested as part of patient and public involvement.

The CAG also noted that there was potential for confidential patient information to be processed by commercial entities, and that patients may express concerns over this.

The CAG noted that although patient and public involvement work had been undertaken with a favourable response to the proposed general research it was unclear whether the overarching methodology and the proposed use of confidential patient information without consent for identification and recruitment had been specifically discussed. Furthermore, members agreed that the overarching application approach did not enable them to fully consider what level of patient and public support there was for the use of confidential patient information without consent for each trial, and therefore whether each trial was in the public interest. Members agreed that patient and public involvement should also specifically include views on the use of data by commercial entities and consideration of the views of those who may have objections to vaccinations.

The CAG agreed that the proposed overarching application approach should not proceed. Members agreed that each trial should be submitted as a separate application to CAG to allow for proper scrutiny by members. Members also noted that owing to the varying degrees of risk and difference in inclusion criteria for each trial there may be different areas to address following CAG review to meet CAG conditions of support. Therefore, having a separate application approach would enable conditions to be tailored accordingly.
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**Confidentiality Advisory Group advice: Rejected**

In line with the considerations above, the CAG agreed that the application should be rejected.

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| **5c** | **23/CAG/0090** | **King's College London Cardiovascular Diseases Database** |
| | **Chief Investigator:** | **Dr Nilesh Pareek** |
| | **Sponsor:** | **King's College Hospital NHS Trust** |
| | **Application type:** | **Research Database** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

**Summary of application**

This application from King's College Hospital NHS Trust set out the purpose of medical research, of aiming to create a research database collecting data on all patients admitted with cardiovascular disease (CVD), or seen in cardiology outpatient clinic at King's College Hospital NHS Trust (KCH) and Guy's & St Thomas' NHS Trust (GStT). The database aims to advance prevention, early diagnosis and treatment of cardiovascular disease in the locality, and will support research into 4 cardiovascular disease research themes; acute & chronic coronary syndromes, structural and valvular heart disease, arrhythmia and complex electrophysiology, and heart failure & cardiomyopathy.

Structured and unstructured data collected during routine delivery of cardiology care will be extracted from electronic patient notes (EHR) by machine-learning artificial intelligence software (Cogstack), into 2 site-specific research databases: King's Electronic Records Research Interface (KERRI), and Guy's & St Thomas' Electronic Records Research Interface (GERRI). This will involve free text data such as patient appointment systems, pathology results, imaging and diagnostics, and letters and scanned documents for the purposes of research. The data will be extracted and structured to facilitate analysis and research. The applicant is not requesting 's251' support for this process. During the extraction process, identifiable information will be removed from the clinical datasets (i.e, name, hospital and NHS ID) or weakened (i.e., date of birth and address). However NHS number and full date of birth will still be retained in 2 separate files at each Trust, alongside assigned registry specific IDs, to create the GStT and KCH linkage files held separate from the pseudonymised clinical data. The GStT Linkage File and the pseudonymised GStT clinical data file are both transferred to KCH, and the GStT linkage file will be linked to the KCH linkage file, for the purposes of de-duplication, and to create a single KCL-CVD Registry Linkage File (containing identifiers), that is accessible only to CI & database manager. Pseudonymised clinical data from KCH is then combined with clinical data from GStT in a single pseudonymised KCL-CVD Disease Registry retained by KCH.

The KCL-CVD Registry Linkage File containing NHS number, full Date of Birth, and registry ID is shared with NHS England to enable linkage with Hospital Episode Statistics (HES) & ONS Mortality Data. NHS England will disclose a dataset back to the applicant containing full date of death amongst other outcome data. The data will be linked to the clinical data within the registry, and the full date of death will then be modified for analysis. After completion of the database, it will be stored for 10 years.

Researchers who have a substantive contract with KCH or GStT, or a substantive contract with KCL and honorary contract with KCH/GStT, will be able to request datasets for specific research questions. All proposed research projects require approval by an Oversight Committee. The Oversight Committee will review the proposal in respect to the scientific validity, the skill-mix of the research team, the potential benefit to patients and the risk for potential patient reidentification. At present, there are no plans for a lay person to sit on the Oversight Committee, however the Oversight Committee will meet on a six-

monthly basis with the PPI Oversight Group to review research priorities and ongoing governance. If approval is issued, the researchers will receive the minimal required dataset for their analysis. Data will remain within the Trust firewall at all times and can only be removed in the form of graphs and scientific reports.

**Confidential information requested**

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| **Cohort** | All patients admitted with cardiovascular disease (CVD), or seen in cardiology outpatient clinic at KCH or GSsT, between April 2012 to March 2022<br><br>Approximately 150,000 individuals |
| **Data sources** | 1. Participating Trusts Electronic patient Records;<br>• King's College Hospital NHS Trust (KCH)<br>• Guy's & St Thomas' NHS Trust (GStT)<br><br>2. NHS England:<br>• Hospital Episode statistics<br>• ONS mortality data |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Date of birth<br>3. Registry specific ID |
| **Identifiers required for analysis purposes** | 1. Date of death – received form NHS England, and modified for analysis<br>2. Month and year of birth<br>3. Sector level postcode in order to calculate deprivation score<br>4. Gender<br>5. Ethnicity<br>6. Registry specific ID |
| **Additional information** | Linkage file with NHS number, D.o.B. & Registry ID held separately from the pseudonymised clinical data, that is only accessible to the applicant and the Clinical Informatics lead, who share leadership of the resource.<br><br>KCL-CVD Registry Database locked following NHS Digital linkage – the linkage key to NHS number is deleted after 5 years. |

**Main issues considered, discussed and outcomes**

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

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the applicant appeared to have discussed the database with 5 patients who represent the cohort, and have created a Public and Patient Oversight Group consisting of potentially the same 5 people. The applicant states that the use of confidential patient information without consent was discussed and supported during previous conversations with patient and public involvement (PPI) representatives, however there are lots of references in the PPI feedback about being supportive as long as the data was anonymised – so it is unclear if the applicant has specifically discussed the use of identifiable data without consent. Therefore the CAG requested for continued ongoing PPI to be undertaken, and requested an overall plan to be provided regarding ongoing PPI. [Action 1]

The ongoing PPI should specifically focus on the use of confidential patient information without consent, being clear and explicit that identifiers are used for linkage. [Action 2]

The ongoing PPI should be undertaken with considerably more individuals, to be more proportionate to the size of the cohort, and should include a more diverse mix of individuals, to more closely reflect the diversity of the South London population. [Action 3]

All proposed research projects require approval by an Oversight Committee. At present, there are no plans for a lay person to sit on the committee. The CAG requested for lay membership on the Oversight Committee (which assesses data access requests). [Action 4]

The CAG requested for terms of reference for the Oversight Committee, and confirmation of how applications to use the data are reviewed with regards to public benefit and medical purpose. [Action 5]

The CAG noted several changes to be made to the patient notification material. The Members noted that there were certain terms which patients might find difficult to understand, for example ‘retrospective registry study’. The applicant should therefore improve the accessibility of the notifications, and provide updated patient notification documents to CAG, which are written in more lay friendly language. [Action 6]

The updated notification should be clearer about the role of CAG and the legal bases under common law being ‘section 251’ Support. [Action 7]

The updated notification should be clearer about the use of confidential patient information being used for the purposes of linkage. [Action 8]

The updated notification should remove the link to the National Data Opt-Out (NDOO). The CAG requested for the researchers to promote use of the local opt-out, by putting this first on the notification document, and merely state that the NDOO will be respected if one has been registered. [Action 9]

Furthermore, the CAG requested to review the text that was to be displayed on the website. [Action 10]

With regards to the exit strategy, the CAG requested clarification as to why the applicant intended to retain the key for 5 years, as it seemed that no further linkages were intended to be undertaken. [Action 11]

**Confidentiality Advisory Group advice: Provisionally supported**

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

| Number | Action required | Response from the applicant |
|---|---|---|
| 1. | Continued ongoing PPI is to be undertaken, and the applicant should provide an overall plan to CAG regarding ongoing PPI. | |
| 2. | The ongoing PPI should specifically focus on the use of confidential patient information without consent. | |
| 3. | The ongoing PPI should be undertaken with considerably more individuals, and should include a more diverse mix of individuals. | |
| 4. | The CAG requested that there be lay membership on the Oversight Committee (which assesses data access requests). | |
| 5. | Provide terms of reference for the Oversight Committee, and confirmation of how applications' intentions to use the data are reviewed with regards to public benefit and medical purpose. | |
| 6. | Provide updated patient notification materials, which are written in lay language which is more accessible to the lay reader. | |
| 7. | The updated patient notification materials should be clearer about the role of CAG and 'section 251' being the common law legal basis for the application. | |

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| 8. | The updated patient notification materials should be clearer about use of confidential patient information being used for the purposes of linkage. | |
| 9. | The updated notification should remove the link to the NDOO. The application specific opt out option should be described first on the notification document, and then merely state that the NDOO will be respected if one has been registered. | |
| 10. | Provide the draft website text. | |
| 11. | Clarify why key is to be retained for 5 years. | |

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

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| **5d** | **23/CAG/0110** | **Royal Hospital for Neuro-disability (RHN) patients Database** |
| | **Chief Investigator:** | **Sanome Limited** |
| | **Sponsor:** | **Sanome Limited** |
| | **Application type:** | **Research Database** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

**Summary of application**

This application from Sanome Limited sets out the purpose of medical research.

The RHN is a specialised hospital and medical charity treating adults with complex neuro-disabilities from both the NHS and private sector. This application proposes to collect patient data from all past patients who have been treated at the RHN into a research database for the purposes of conducting medical research. The database will be used to develop an early warning detection system to detect early signs of health deterioration or improvement in patients. The database will also be used to develop tools to identify potential links between variables and patient outcomes.

Support is requested for the flow of confidential patient information from the electronic patient record (EPR) system (Patient Source) at RHN for Sanome Limited to pseudonymise the data and create a research database held within the Patient Source cloud environment. Support is also requested for Sanome Limited and researchers at RHN to access the database.

**Confidential information requested**

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| **Cohort** | All past patients who have been treated since implementation of electronic patient records at the Royal Hospital for Neuro-Disability* |
| **Data sources** | Electronic patient records held at the Royal Hospital for Neuro-Disability |
| **Identifiers required for validation purposes** | 1.Year of birth<br>2.Date of death<br>3.Postcode (sector level)<br>4.Gender<br>5.Ethnicity<br>6.Free text and attachments forming part of a patient's medical record:<br>• Nursing daily progress notes<br>• HCA personal care record<br>• Summary of nursing care<br>• National Early Warning System 2 (NEWS2) actions<br>• Notes from other role types within the hospital e.g. physiotherapy notes |
| **Identifiers required for analysis purposes** | 1.Year of birth<br>2.Date of death<br>3.Postcode (sector level)<br>4.Gender<br>5.Ethnicity<br>6.Free text and attachments forming part of a patient's medical record:<br>• Nursing daily progress notes<br>• HCA personal care record<br>• Summary of nursing care<br>• National Early Warning System 2 (NEWS2) actions<br>• Notes from other role types within the hospital e.g. physiotherapy notes |
| **Additional information** | *Number of past patients is 606 |

**Main issues considered, discussed and outcomes**

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

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted confusion upon review of the data flow diagram. The CAG requested for a revised data flow diagram, which clearly reflects the flow of retrospective data and anonymisation. [Action 1]

The CAG requested for the applicant to capture within the revised data flow diagram, whether they are taking a copy of the electric patient record or working of a live version. [Action 2]

The members requested for the applicant to clarify the size of the retrospective cohort. [Action 3]

The CAG requested clarification on the de-identification process and why the date of death was required. [Action 4]

The CAG requested for the applicant to explain who will view the free text data. [Action 5]

The CAG requested the applicant to clarify processes in place to help limit identifiers through free text. [Action 6]

The CAG requested the applicant to clarify the opt-out processors and for it to not remain on one individual's responsibility. [Action 7]

The CAG requested to view the text to be uploaded upon the Royal Hospital for Neuro-Disability website. [Action 8]

The CAG also requested for the researchers to promote use of the local opt-out whilst still respecting the National Data Opt-Out [Action 9]

Lastly, the CAG requested for the applicant to provide further information on the discussion held with the patient and public involvement and engagement (PPIE) group. The applicant should also clarify to the PPIE group whether the dataset used was would be anonymous or pseudonymous. [Action 10]

**<u>Confidentiality Advisory Group advice:</u> Provisionally supported**

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

| Number | Action required | Response from the applicant |
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| 1. | Provide a revised data flow diagram, which clearly reflects the flow of retrospective data and anonymisation. | |
| 2. | Capture within the revised data flow diagram, whether they are taking a copy of the electric patient record or working from a live version. | |

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| 3. | Clarify the size of the retrospective cohort. | |
| 4. | Clarify the de-identification process as well as why the date of death was required. | |
| 5. | Clarify who will have access to the free text data. | |
| 6. | Explain the processes in place to help limit identifiers through free text. | |
| 7. | Provide an alternative method regarding the opt-out mechanism, ensuring the process is not burdensome upon one individual. | |
| 8. | Provide CAG with the text to be uploaded upon the Royal Hospital for Neuro-Disability website. | |
| 9. | Promote use of the local opt-out whilst still respecting the National Data Opt-Out | |
| 10. | Provide further details on the discussion with the patient and public involvement and engagement (PPIE) group. As well as clarify to the PPIE group whether the dataset would be anonymous or pseudonymised. | |
| 11. | Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. Pending (Checked 25/08/2023) | |

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

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| **5e** | **23/CAG/0100** | **GP Management After Transition Events (GP-MATE) - Developing an intervention to assist older patients' communication with their GP practice after discharge from hospital in order to improve patient safety** |
| | **Chief Investigator:** | **Dr Rachel A Spencer** |
| | **Sponsor:** | **University of Warwick** |
| | **Application type:** | **Research** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

**Summary of application**

This application from the University of Warwick set out the purpose of medical research to produce an intervention to aid older patients in communication with their GP practice after discharge from hospital.

Discharge from hospital is a potentially risky stage of the patient journey, particularly for older patients who may have multiple morbidity and poly pharmacy. Communication at the interface of secondary and primary care has been identified by the James Lind Alliance as one of the top three priorities for primary care patient safety. Clear communication via discharge summaries is essential in providing a safer discharge experience. Currently discharge summaries are designed for inter-professional communication, but patients have indicated their preference for receiving a copy of the discharge summary and want to be involved in conversations about their post-discharge care. The applicants seek to produce a tool, GP-MATE, to be used by older patients and their carers to aid communication with their GP practice about their care after discharge.

The study will take place over a four-year period. During the first year, a film will be made of patients experiences following discharge from hospital. In year two, three groups of patients and GP staff will create the GP-MATE tool. In the third year, the GP-MATE tool will be used at eight GP practices. Patients and staff will also be interviewed and surveyed. The records of around 300 patients will also be reviewed. In year 4, the findings will be drawn on to finalise the tool. Support under s251 is required to allow the research team to access the notes of all patients at the GP practices who are over 65 and have been admitted to hospital in the previous year. For the retrospective cohort, rates of readmission to hospital and links between the index admission and subsequent admissions will be investigated. For the prospective cohort, a weekly rolling search will be undertaken to identify all patients aged 65 or over admitted to hospital during the study period. The GP-MATE pack will be mailed out to suitable patients, and the research team will assist with the mail-out. Patients will complete and return the questionnaires, which will not be identifiable to the research team. The research team will collect data from the GP records of all patients in the prospective cohort from baseline (discharge) to 3 months after the GP-MATE consultation to determine: uptake, length and mode of appointment, and participating clinician’s roles.

**Confidential information requested**

| | |
|---|---|
| **Cohort** | PQDC - 300 retrospective cohort, 300 prospective cohort, anticipated 150 questionnaire cohort (50% response rate) 24 patient/carer interviewees (100% overlaps with PQDC prospective cohort).<br><br>Retrospective cohort: patients treated between 01 July 2022 and 30 September 2023.<br><br>Prospective cohort: patients treated for a 9-month period from 01 November 2023 to 31 July 2024. |

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|---|---|
| **Data sources** | 1.The electronic healthcare records and appointment systems at participating GP practices. |
| **Identifiers required for linkage purposes** | 1.Name<br>2.Date of birth<br>3.Date of death |
| **Identifiers required for analysis purposes** | 1.GP practice<br>2.Gender<br>3.Ethnicity |

**Main issues considered, discussed and outcomes**

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

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG requested clarity as to why collecting prospective patient consent was not practicable. [Action 1]

The CAG requested for the applicant to ensure that the local opt out was clearly displayed amongst the patient notification materials. [Action 2]

The CAG stated that the wording within the signposted website was not lay friendly and targeted more towards health care professionals. The CAG requested the applicant to create a second page where the information displayed is in a lay friendly language. [Action 3]

Furthermore, the new website page must clearly clarify where confidential patient information is coming from, the process of how they are being sampled as well as clarification on how to opt-out via the local opt-out. [Action 4]

The CAG requested the applicant to confirm the age limit of the cohort. [Action 5]

The CAG requested clarification on how and when the research team would exit from section 251 support. [Action 6]

**Confidentiality Advisory Group advice: Provisionally supported**

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

| Number | Action required | Response from the applicant |
|---|---|---|
| 1. | Clarify why collecting prospective patient consent is not practicable. | |
| 2. | Ensure that the local opt out is clearly explained amongst the patient notification materials. | |
| 3. | Create a second website page where the information displayed is in a lay friendly language which is more accessible to the lay reader. | |
| 4. | Ensure that the new website page clearly explains where confidential patient information is coming from, the process of how the information is being sampled as well as clarification on how people might opt-out via the local opt-out. | |
| 5. | Confirm the age limit for the cohort. | |
| 6. | Clarify how and when the research team will exit from section 251 support. | |

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

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|---|---|---|
| **5f** | **23/CAG/0101** | **Where is all the heart failure? A community study** |
| | **Chief Investigator:** | **Professor Andrew L Clark** |
| | **Sponsor:** | **Hull University Teaching Hospitals NHS Trust** |
| | **Application type:** | **Research** |
| | **Submission type:** | **New application** |

The Group reviewed the above application in line with the CAG considerations.

**Summary of application**

This application from Hull University Teaching Hospitals NHS Trust set out the purpose of medical research to determine the true prevalence of heart failure in primary care by assessing all patients with a marker of heart failure.

The applicants advised that they suspect that a significant proportion of patients diagnosed as having heart failure with normal ejection fraction may have a

cardiomyopathy due to deposition of an abnormal protein called transthyretin cardiomyopathy (ATTR). Epidemiological data on ATTR cardiomyopathy is scarce and estimates of prevalence come from populations of patients with known heart disease. The applicants aim to define the prevalence of ATTR cardiomyopathy in a primary care population, many of whom will not have a diagnosis of heart failure but have an indicator of heart failure on electronic care records.

Identifiable data will be collected from different GP surgeries within the Beverley Primary Care Network and disclosed to Hull University Teaching Hospitals NHS Trust for linkage to datasets held by the Trust. The electronic records of all patients on a practice's heart failure register will be scanned by the research team to find whether each patient is appropriately on the list, whether the appropriate investigations (echocardiogram, NTproBNP) and whether the appropriate treatment and up-titration of treatment has been performed. Where tests are missing and where appropriate medication has not been started, patients will be invited for review in a face-to-face consultation. At this stage, the clinical research team, who are cardiologists in secondary care, will be acting as the direct care team. They will then be offered the appropriate tests and/or treatment. SystemOne, a software used for electronic health records in the primary care, will then be used to identify all patients not on the heart failure register but who may have the disease by performing a series of hierarchical searches on the practice electronic record. Two datasets will be created. The first dataset will contain confidential patient information. This will be used in different GP practices and secondary care to obtain and link primary and secondary care data. The second dataset will contain fully anonymised information.

**Confidential information requested**

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|---|---|
| **Cohort** | Patients aged 16 and over who are under the care of the Beverley Primary Care Network, and are diagnosed with either:<br>• Heart failure<br>• Amyloidosis |
| **Data sources** | 1. Electronic health records from GP practices<br>2. Summary Care Records (SCR) from NHS England<br>3. Electronic health records from Secondary Care |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Date of birth |
| **Identifiers required for analysis purposes** | 1. Date of birth<br>2. Gender |

**Main issues considered, discussed and outcomes**

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.
Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG agreed that the data controllership arrangements needed to be clarified. Members noted that GPs could be in jeopardy if the data they control is used for a purpose outside of support by the Trust or other people and questioned how they control the data once a copy has left their servers and lies on the Trust servers. Members queried whether the Trusts and GPs would have joint controllership or would data controllership be transferred from the GPs to the Trusts. [Action 1a].

For patients who receive an intervention, the applicants have advised that the research team will then become part of the direct care team and support under s251 will no longer be required. The CAG queried whether the consent sought from patients would cover their involvement in research as well as consent for direct care. [Action 1b].

Members queried whether the Beverley Primary Care Network was the only Primary Care Network involved. [Action 1c].

Patients' name, NHS number and gender were retained. Members requested clarification on why patients' names were retained, as this data item was not necessary for linkage to datasets held by NHS England. [Action 2a].

For patients who do not receive any intervention, the applicant advised that their anonymised data would remain in Hull University Teaching Hospitals NHS Trust. Members noted that patients' dates of birth would be retained, which meant that the dataset was not truly anonymised. [Action 2b].

Patients date of birth would be retained, but not their date of death. The CAG queried whether date of death was needed or whether deceased patients would be excluded. [Action 2c].

The CAG agreed that the patient notification materials and patient facing materials needed to be rewritten. Members agreed that it was also not clear who the intended audience for these documents was and where and when the information would be made available. [Action 3].

Members noted that patients were given an opportunity to opt-out after the breach in the common law had already occurred, i.e., after their patient records had been accessed. The CAG queried whether there were other methods by which patients could opt-out before their confidential records were accessed. [Action 4].

The CAG agreed that patient and public involvement should be undertaken. This should include discussion of the specific issue of use of confidential patient information without consent. Views should also be sought around who makes

up the direct care team and whether this is who the patients would expect. It should also include a review of the patient notification and patient facing materials [Action 5a-5c].

The CAG noted that the application made for REC approval had been invalidated before REC review.

**Confidentiality Advisory Group advice: Deferred**

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

| **Number** | **Issue:** |
|---|---|
| 1. | Clarification on the scope of the support sought needs to be provided.<br><br>This includes clarification on:<br><br>a. The data controllership arrangements: whether the trusts and GPs would have joint controllership or would data controllership be transferred from the GPs to the trusts.<br>b. Whether the consent sought from patients who receive an intervention covers their involvement in research as well as consent for direct care.<br>c. Whether the Beverley Primary Care Network is the only Primary Care Network involved. |
| 2. | Clarification on the data items to be retained needs to be provided.<br><br>This includes clarification on:<br><br>a. Why patients' names need to be retained.<br>b. Whether the dates of birth for patients who do not receive an intervention would be retained in the dataset held in Hull University Teaching Hospitals NHS Trust. If the dates of birth are retained, the dataset cannot be considered to be anonymised.<br>c. Whether patients' dates of death will be retained. |
| 3. | The patient notification materials and patient facing materials need to be rewritten and ensure it is clear who the intended audience is. Additionally, clarification should be provided on where and when the notification materials would be made available. |

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| 4. | Consider whether it is feasible for patients to register opt-out of use of their data in this application specifically before their records are accessed. |
| 5. | Patient and public involvement needs to be undertaken.<br><br>This needs to include:<br><br>a. Discussion of the specific issue of use of confidential patient information without consent.<br>b. Views need to be sought on who makes up the direct care team and whether this is who the patients would expect.<br>c. Review of the patient notification materials and other patient facing documentation. |
| 6. | A Favourable REC Opinion needs to be in place before the CAG can make a recommendation of support. |

## 6. ANY OTHER BUSINESS

The Chair thanked CAG member Mrs Diana Robbins for her commitment and service to CAG.

The Chair thanked members and observers for attending and closed the meeting.

Insert name of member that chaired the meeting

*Dr Tony Calland, MBE, CAG Chair,* *14 September 2023*
*Dr Murat Soncul, CAG Alternate Vice-Chair*

……. ……..
*Signed – Chair* *Date*

Insert name of minute taker(s)

*Ms Kathleen Cassidy – HRA Confidentiality Advisor*
*Mrs Emma Marshall – HRA Confidentiality Specialist*
*Mr William Lyse – HRA Application Administrator*

*14 September 2023*

……. ……..
*Signed – Insert job title* *Date*