Minutes of the meeting of the Confidentiality Advisory Group

08 July 2021 – held via Zoom

Present:

Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice-Chair
Dr Sandra Duggan	CAG member
Professor Barry Evans	CAG member
Dr Rachel Knowles	CAG member
Dr Simon Kolstoe	CAG member
Professor Jenny Kurinczuk	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **03 June 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **03 June 2021** meeting applications.

3. New applications

a. 21/CAG/0091 – Ambulance Data Set – Returning linked patient outcome to Ambulance Services

Context

Purpose of application

This application from NHS England set out the purpose of a non-research application, to develop and implement a nationally standardised minimum data set within

Ambulance Services, capturing patient level operational and clinical information across all Ambulance Services.

Following the successful implementation of the new Ambulance Response Programme in late 2017, it became clear that further understanding on how and why people use Ambulance Services needed to be developed in order to improve the way in which patient care is delivered. The need to develop an equivalent ambulance data set that will, for the first time, bring together data from all ambulance services nationally in order to follow and understand patient journeys from the ambulance service into other urgent and emergency healthcare settings was recognised in the NHS Long Term plan, published in 2019. The Ambulance Data Set (ADS) Project is a three-year project to develop and implement a nationally standardised minimum data set within Ambulance Services, capturing patient level operational and clinical information across all Ambulance Services. This application is being made by NHS England on behalf of the eleven English ambulance services.

On a daily basis, completed patient records for the previous calendar day will flow to NHS Digital via a secured Application Programme Interface (API) connection using FHIR (Fast Healthcare Interoperability Resources) messaging. This data will then flow through a secure 'pipeline' of Data Services and the Data Management within the NHS Digital environment to be adapted into a format that can be curated for analysis and extraction. This data can then be used within the agreed NHS Digital scope of data analytics and reporting, and flow to the NHS England and NHS Improvement National Commissioning Data Repository (NCDR) via the Arden and Greater East Midlands CSU DSCRO. Within the secure DSCRO environment, the appropriate information from the ECDS Data set can be linked and sent back to the originating ambulance trust with identifying keys via a secure MESH API. This data can then be imported into the Ambulance Service data warehouse to match with the full ADS Record for that event to be used for onward internal audit and analytics.

Patient incident data from Ambulance Services will flow to NHS Digital, with joint controllership of this data being held with NHS Digital and NHS England and Improvement. NHS England and Improvement will be the 'asset owners' of the information. Once implemented, the collection of the data will transfer into 'business as usual' operations and the data flow will continue as routine. Ambulance Services will only receive data that pertains to records that were initially generated within their service, where patients have been transported (conveyed) to a provider destination where an Emergency Care Record is generated (primarily Emergency Departments and Urgent Treatment Centres) and where the onward care record has been successfully linked to the ADS record. It is not proposed that ambulance services receive any and all ECDS Records; neither is it anticipated that patient details will be included in the data flow back to services. It is proposed that a limited number of internal identifiers from the ADS specification will be sufficient to enable linking within Ambulance Services to the original Ambulance Case Record, rather than the full ADS

record flowing back to services. Data received into ambulance services will come under the same data safeguarding and retention protocols that are in place and under individual Ambulance Service governance arrangements.

The implementation of the Ambulance Data Set into live services is to be completed on a phased approach, with approximately 50 data items due to be reported across all services in live service from September 2021. The remainder of the data items is scheduled to report from January 2022 onwards, with all services planned to be reporting a complete data set by May 2022. An Information Standard will accompany the data set publication.

The legal basis for the confidential patient information to flow to NHS Digital from Ambulance Services will be covered by a legal direction and data provision notice (currently in final stage draft).

A Data Sharing Agreement (DSA) is in place for the data to flow from NHS Digital to NHS England's data warehouse via the Data Services for Commissioners Regional Offices (DSCRO) data safe haven.

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 in contact with any of the 11 English Ambulance Services listed below, who go on to receive care through an NHS Provider that completes an Emergency Care Record through the Emergency Care Data Set (ECDS) and flows to NHS Digital.
Data sources	1. Data collected from the following 11 Ambulance Services: a. East Midlands Ambulance Service b. East of England Ambulance Service c. Isle of Wight Ambulance Service

	d. London Ambulance Service e. North East Ambulance Service f. North West Ambulance Service g. South Central Ambulance Service h. South East Coast Ambulance Service i. South Western Ambulance Service j. West Midlands Ambulance Service k. Yorkshire Ambulance Service 2. The Emergency Care Dataset at NHS Digital 3. Data from treating hospital trusts.
Identifiers required for linkage purposes	1. NHS Number 2. Name 3. DOB 4. Address 5. CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) 6. Call sign (Unique vehicle reference of ambulance service)
Identifiers required for analysis purposes	1. NHS Number 2. Name 3. DOB 4. Address 5. CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) 6. Call sign (Unique vehicle reference of ambulance service)

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services 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 agreed that the application had a medical purpose and was in the public interest. The need for creating the Ambulance Data Set had also been well-explained in the application. However, further work needed to be undertaken before a recommendation of support could be made. Further information was also needed on the Government's intention to legislate in this area, so that the CAG can better understand the proposal.

The CAG agreed that there was a lack of clarity over what the data collected would be used for. Further information needed to be provided on what was planned for the dataset.

Scope

The return of confidential patient information to the ambulance trusts needed further clarification. It is unclear why confidential patient information is being returned and whether support under the Regulations is required for this.

Practicable alternatives

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

- Feasibility of consent

Nationally, Ambulance Services manage approximately 25,000 – 40,000 incidents per day, treating patients in a variety of settings and circumstances. Due to the patient presentation, it will not always be possible to establish patient consent for onward record sharing and there is a risk that manually collecting this information for each patient could lead to unintentional errors in the recording of consent.

The applicants explained that, where patients are able to give consent, the Ambulance Dataset Project will be explained to patients by the treating ambulance staff and patient consent sought. A screenshot of the electronic consent (21CAG0091 Section 251 Application - EPR Consent Screenshot) was provided. The applicants expected that the majority of patients would be unable to consent when receiving treatment due to lack of capacity at that time. The applicants also noted the need for complete case ascertainment, particularly for those who are acutely unwell.

The CAG noted the reasons given for not seeking consent. However, the applicants had stated that they would seek consent where possible and included a screenshot with the question that would be asked of patients. The consent sought was broad, stating that clinical information would be shared electronically with the Ambulance Trust and NHS, but is not explicit that this will be confidential patient information. The consent also advises that the ambulance personnel will explain the use of data, but no details are given on what patients will be told. The CAG also noted that most patients would not have capacity to consent to use of their confidential patient information when they were receiving care from the ambulance personnel.

Members agreed that the applicants needed to consider the issue of seeking consent further. This included considering whether consent should be sought from any patients or whether all patients should be recruited under Regulation 5 support.

- Use of anonymised/pseudonymised data

The applicants advised that confidential patient information is required to link data from the ambulance services to datasets held by NHS Digital and the trusts where patients were treated.

'Patient Notification' and mechanism for managing dissent

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

The applicants noted the difficulty in informing the entire patient population, as the 11 Ambulance Services involved do not have a defined patient population, other than the regional population covered by the services. All the involved Ambulance Services will have a published Privacy Notice. NHS England and NHS Improvement will work with the services to ensure that updated Privacy Notices, including the agreed data sharing activity required to undertake the implementation of the Ambulance Data Set, are made available on the services websites. A sample of the Privacy Notice was provided. It was noted that this was a screenshot, showing only brief information. At the request of the CAT, a more detailed example of the Privacy Notice was provided.

The applicant noted that the application is not for a one-off study, but an ongoing consistent approach to sharing data to allow ambulance services to develop operational and clinical behaviours in the interest of improving patient outcomes. Specific models of feedback will be recommended for implementation in services for internal use, however it will be for local determination how the information is disseminated to the population covered by ambulance services. Standard message communications as outlined in the S251 application have been developed for initial adoption within services and the applicants will work with the National Ambulance Communications Group (with all services representatives as constituent members) to further develop communication tools for local populations around ADS development, notification and dissent.

The applicants clarified that patients can register dissent by telephone, and post. Local services will be able to advise on the next steps according to local procedures. The participating Ambulance Services are able to flag records where consent has been withdrawn, so that these records are not disclosed to NHS Digital. If the patient records at the trusts where patients were conveyed to indicate that patients do not consent to use of their data, then the data linkage to the Ambulance records will not take place. The National Data Opt-Out will be applied.

The CAG noted that privacy notices had been created for each trust. Members agreed that work should be undertaken to standardise information across all participating trusts, such as by use of agreed wording. The further patient and public involvement requested below should cover the creation of revised, standardised privacy notices.

Patient and Public Involvement and Engagement

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

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The applicants advised that in early 2021, engagement had commenced with the leads of the Sheffield Emergency Care Forum, a patient and public involvement group representing patients involved in multi-site centres across the UK. A project briefing and Survey Monkey questionnaire was developed and shared with the leads for dissemination to groups, including the Sheffield Emergency Care Forum, Lay Advice for Diabetes and Endocrine Research Panel, Online Advisory Panel, the Independent Cancer Patient's Voice, the Yorkshire and Humber Consumer Research Panel, Stroke

and Aphasia PPI panel and the Across the Care Group Panel for Combined Community Acute Care Group.

The majority of the responses agreed that sharing data and providing consistent data was a positive thing to do, however concerns were raised around patient privacy and the accessibility of information. The applicants advised that these concerns had been addressed by creating a robust information governance process to allow data to flow securely from Ambulance Services into the central NHS Digital data repository before it is linked and returned securely to the Ambulance Services. The ADS Project Team at NHS England have also worked with the Ambulance Service to develop models of feedback to ensure a consistent approach is taken within services around the protection of information and the governing of data access.

The initial briefing and response to the groups were provided (Section 3 (s) ADS Patient Request and Section 3 (s) Response to Patients Survey FV).

Additionally, as part of the Ambulance Data Set Project, a pilot in two ambulance services around changes to the way data is collected by clinicians is due to commence in July. As part of this pilot, clinicians who are involved in patient care, where appropriate, will be asked to gather views from patients and feedback to the ADS Project Team this will include asking for views of patients on the information that is given to patients around consent (a screenshot of the consent was provided in 21CAG0091 Section 251 Application - EPR Consent Screenshot), and to seek views on the acceptability of sharing information without consent. The applicants will also look to engage with additional patient groups to gather additional feedback and will share the outcomes of this with the CAG in writing at the earliest opportunity.

The CAG noted the patient and public involvement that had been carried out. Members observed that 11 ambulance trusts were included in this application and considered whether further patient and public involvement needed to be conducted. Members agreed that patient and public involvement should be undertaken within each participating trust and feedback from this provided in the resubmitted application. The feedback should include the number of patients and members of the public who took part and their demographics. The Group noted that those already consulted had raised concerns, but the concerns had not been described. Details on any concerns raised would also need to be included in the feedback to the CAG.

Exit strategy

The applicants explained that there is currently no legal statute or legal basis for the provision of this data via any other method than a Section 251 application, and therefore there is no known exit strategy. They are exploring options with their legal

and information governance teams to understand where they may be able to influence development around data sharing.

The CAG noted the reasons given for no exit strategy currently, however the Group agreed that further justification needed to be given on why an exit strategy is currently unfeasible. Further details on the potential options for data sharing in future also need to be provided. Other potential exit strategies also need to be explored, such as data minimisation or the separation of patient identifiers from their clinical data.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Further details on the what the data collected would be used for and future plans for the dataset need to be provided.

2. Provide information on the Government's intention to legislate in this area, so that the CAG can better understand the proposal.

3. Provide further details on the return of confidential patient information to the ambulance trusts, including why this information will be returned and whether support under the Regulations is required for this.

4. Further consideration needs to be given to the issue of seeking consent. This included considering whether consent should be sought from any patients or whether all patients should be recruited under Regulation 5 support.

5. The privacy notices need to be standardised across all participating trusts. The further patient and public involvement requested below should cover the creation of revised, standardised privacy notices.

6. Further patient and public involvement needs to be carried out:

    a. Patient and public involvement should be undertaken within each participating trust and feedback from this provided in the resubmitted application,
    b. The feedback should include the number of patients and members of the public who took part and their demographics,
    c. The number of participants who raised concerns and the concerns raised also need to be detailed,
    d. Input on the creation of revised, standardised privacy notices should be sought during patient and public involvement.

7. Further justification needs to be provided on why an exit strategy is currently not feasible.

8. Further details on the potential options for data sharing in future also need to be provided. Other potential exit strategies also need to be explored, such as data minimisation or the separation of patient identifiers from their clinical data.

b. 21/CAG/0092 – PARAMEDIC 3 – Pre-HospitAL Randomised trial of MEDICation route in out-of-hospital cardiac arrest

Context

Purpose of application

This application from the University of Warwick sets out the purpose of medical research that seeks to determine whether giving drugs through a vein or into the bone improves survival at 30-days in adults that have an out-of-hospital cardiac arrest.

Cardiac arrest is an important health condition. Each year NHS ambulance services treat 30,000 patients who have experienced an out-of-hospital cardiac arrest (OHCA).

Survival is poor, with less than 10% of patients surviving to hospital discharge. The main treatments for cardiac arrest are chest compressions, defibrillation, artificial ventilations and drug treatments. The results of the previous PARAMEDIC-2 trial, conducted by the same applicants, had shown that drug treatments are effective at restarting the heart. However, in the PARAMEDIC-2 trial, the drug treatments were given 21 minutes after the cardiac arrest, on average. This delay likely influenced the effectiveness of the treatment. The statistical analysis from that study showed that, for every one-minute reduction in the time taken to give treatment, survival increased by 0.7%. Currently, guidelines advise that paramedics administer drugs into a vein, referred to as intravenous (IV) route. It can take several minutes to insert a drip into a vein. If paramedics are unable to insert the drip after two attempts, then an alternative form of vascular access, intraosseous route (IO) may be used. IO is a faster way of giving drugs, which involves the insertion of a small needed into an arm or leg bone, and allows drugs to be injected directly into the rich blood supply found in the bone marrow. It is currently unknown whether use of IO access, rather than IV access, as a first attempt would allow vascular access to be obtained more quickly and, consequently, improve survival. Data from research audits has found that use of the IO route has doubled between 2014 and 2018 and the London Ambulance Service reported that the amount of money spend on IO equipment has doubled over a two-year period, which provides evidence of a change in clinical practice in the absence of evidence. The International Liaison Committee on Resuscitation (ILCOR) have conducted a systematic route in which they evaluated the current studies on IO and IV routes for administering drugs, and concluded that there is insufficient evidence to support the routine use of IO access and highlighted the need for a randomised controlled trial to determine the most effective approach.

Patients that sustain an out-of-hospital cardiac arrest will be enrolled into the trial by the treating ambulance clinician. On arrival at the scene, the treating ambulance clinician will assess patient eligibility and, where appropriate, randomise the patient to receive either IO (the intervention arm) or IV (the control arm) as a first strategy. For patients randomised to the intervention group, initial vascular access attempts will be via the IO route and two attempts at vascular access will be made. Once IO vascular access has been successfully achieved, cardiac arrest drugs (including fluid) will be administered through the IO cannula. If the treating clinician has made two attempts at vascular access via the IO route and been unsuccessful at both attempts, then further attempts at vascular access may be made via the IO or IV route at the clinician's discretion. In patients randomised to the control group, initial vascular access attempts will be via the intravenous route and the usual NHS guidelines will be followed. The treating paramedics will inform the treating hospital that the patient has been recruited into PARAMEDIC-3 on the patient report form, routinely used by ambulance services to record the treatment received from the ambulance service. The ambulance service NHS trust research team will also be informed via the patient report form or other secure communication method, such as telephone call or secure email.

Once the research paramedic is aware of the recruitment, they will enter the patient's information on to the secure Warwick CTU database.

Information about patients' cardiac arrest and hospital stay will be collected from patients' records by research paramedics and from other data linkage sources. Long-term follow up will be conducted at 3 and 6 months following randomisation, to investigate how patients recover from their cardiac arrest. Survival status will be obtained from NHS Digital or other electronic data sources. Quality of life questionnaires will be posted by the research paramedics to the patient for completion at 3 and 6 months, and patients will be asked to return these to the Warwick CTU. Alternatively, if the research paramedic completed the follow up questionnaire with the patient over the telephone or in person, the research paramedic will enter the participant's responses directly on to the CTU database. These questionnaires may be completed on the participant's behalf by someone that has a good awareness of their health state.

All patients will be unconscious at the time of treatment, therefore patients will be recruited under a deferred consent model, in accordance with the Mental Capacity Act 2005. The applicants are seeking support to process confidential patient information for all patients from the end of the emergency event until patient death or until either patient consent or a consultee opinion is obtained. For non-survivors, support is needed for the collection of confidential patient information from the treating hospital and linkage to other data sources. For surviving patients, confidential patient information will be collected until either the patient or a consultee explicitly refuses agreement to the processing of their confidential patient information. If the patient survives but the researchers are unable to contact the patient or a consultee to seek consent, support will also be needed to continue to collect confidential patient information and link to other data sources.

Confidential patient information will also be disclosed from the Warwick CTU to NHS Digital, the Out-of-hospital cardiac arrest outcome registry, the Intensive Care National Audit and Research Centre (ICNARC), the Patient Episode Database for Wales (PEDW), the National Institute for Cardiovascular Outcomes Research (NICOR), ONS mortality data, GP records, the UK Transplant Registry (UKTR) and Health Data Research UK (HDR UK).

A recommendation for class 1, 2, 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	Male and female patients aged 18 years and over who have experienced an out of hospital cardiac arrest. 15,000 patients will be included, recruited on a 1:1 ratio between control and intervention.
Data sources	1. Participating NHS hospital trusts – to be confirmed 2. Participating NHS ambulance trusts: a. North East Ambulance Service NHS Foundation Trust b. North West Ambulance Service NHS Trust c. West Midlands Ambulance Service University NHS Foundation Trust d. East Midlands Ambulance Service NHS Trust e. South Western Ambulance Service NHS Foundation Trust f. South Central Ambulance Service NHS Foundation Trust g. South East Coast Ambulance Service NHS Foundation Trust h. London Ambulance Service NHS Trust i. East of England Ambulance Service NHS Trust j. Welsh Ambulance Services NHS Trust k. Potentially the Yorkshire Ambulance Service NHS Trust (participation to be confirmed). 3. HES and Mortality datasets at NHS Digital 4. Out-of-hospital cardiac arrest outcome registry, held by the University of Warwick 5. Intensive Care National Audit and Research Centre (ICNARC) 6. Patient Episode Database for Wales (PEDW) 7. National Institute for Cardiovascular Outcomes Research (NICOR) 8. ONS mortality data 9. GP records 10. UK Transplant Registry (UKTR) 11. Health Data Research UK (HDR UK)

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode – unit level 6. Ethnicity
Identifiers required for analysis purposes	7. Date of birth 8. Date of death 9. Postcode – unit level 10. Gender 11. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- Feasibility of consent

The applicants noted the difficulty in consenting patients prior to enrolment or at enrolment, due to the nature of OHCA. Patients are likely to be unconscious or otherwise unable to consent and it is likely that, should a potential consultee be in attendance, they will be too distressed to be approached for consent. Also, patients must receive treatment as soon as possible. Consent, or a consultee opinion, will be sought as soon as practical. The CAG noted that an emergency research model under the Mental Capacity Act 2005 will be used. Under this process, treatment under this study may be started prior to either consent from the participant or a consultee declaration under the Mental Capacity Act given the emergency nature. REC have a specific remit to approve studies using this design and, at the time of the CAG review, the REC had issued a Provisional Opinion.

- Use of anonymised/pseudonymised data

Confidential patient information is needed to conduct patient-level data linkage of data collected from participating ambulance services to NHS Digital, the Out-of-hospital cardiac arrest outcome registry, the Intensive Care National Audit and Research Centre (ICNARC), the Patient Episode Database for Wales (PEDW), the National Institute for Cardiovascular Outcomes Research (NICOR), ONS mortality data, GP records, the UK Transplant Registry (UKTR) and Health Data Research UK (HDR UK), and the return of linked datasets to the Warwick CTU. The CAG accepted that the research could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

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

The applicants refer to "passive methods" of making relatives aware of this trial, but the materials were not provided with the initial application. Following queries from the CAT, the applicant explained that a patient notification strategy had been devised in collaboration with the study's Patient and Public Involvement panel. Information about the study would be made available in the public domain. This would include posters,

NHS communications, and a trial website, which was in development. The poster was provided for review.

For survivors, ambulance service researchers will, wherever possible, approach the participant and invite them to participate in the follow-up part of the trial. The participant information sheet details the activities being undertaken, the purpose of these activities, and how the individual might opt-out.

In the case of cardiac arrest non-survivors, the passive information strategy relies on placing information in the public domain, as outlined above. This strategy will provide relatives with the opportunity to seek further information at a time when they are ready if this is desired. The applicants will place information in locations where individuals may visit following the death of a relative, including, where possible, emergency department waiting rooms and register offices.

The applicants advised that the National Data Opt-Out will be applied.

Patient and Public Involvement and Engagement

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

The applicant explained that they had worked closely with patients and members of the public when designing the trial, including discussions with their PPI co-applicant and presentation. The trial has also been presented to the Clinical Research Ambassador Group at University Hospitals Birmingham NHS Foundation Trust. The applicants will follow the INVOLVE best practice guidance to embed meaningful patient and public involvement throughout the project. A PPI group, with membership chosen to reflect the diversity of people at risk of cardiac arrest, will be convened at the start of the trial. This group will meet regularly throughout the trial. Two PPI members will also be included as independent members of the Trial Steering Committee, who will be responsible for oversight of the trial and advising the Sponsor and Funder in accordance with the NIHR terms of reference.

The applicants will adopt the same approach as used in the PARAMEDIC-2 study model. Significant input and agreement from patient, public and service user representatives had been included in the design of this model. For this new trial, the applicants have explored the acceptability of the approach at the first meeting of the Patient Public Involvement panel. This panel is comprised of six members, who have a range of back grounds and experiences, including those who have survived cardiac

arrest, those with experience of critical illness and others with experience through family members. The panel were supportive of the approach. The panel cautioned against the use of leaflets as their recent experience was that few places allow leaflets to be left out due to COVID restrictions, and that the poster was adequate to provide the relevant information.

The CAG noted the patient and public involvement undertaken and recommended that the scope was broadened to include families of those who had suffered cardiac arrest and to explore their views on the issue.

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. Further patient and public involvement is to be undertaken while the study is ongoing. This further involvement is to include the families of those who had suffered cardiac arrest and to explore their views on the issue. Feedback is to be provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 12 July 2021**

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.

- **The NHS Digital DSPT review for University of Warwick Clinical Trials Unit for 2019/20 was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 12 July 2021).**

c. 21/CAG/0089 - ReSPECT in primary care

Context

Purpose of application

This application from the University of Warwick sets out the purpose of medical research to evaluate the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process for adults in primary care, to determine how, when and why it is used, and what effect it has on patient treatment and care.

The ReSPECT plan is a type of emergency care treatment plan, used in hospitals and intended to help patients (or their families) and doctors or senior nurses talk about and record advice about emergency treatments that they may need or want, should they become seriously ill and unable to be involved in decisions about their care. The applicants have recently completed an evaluation of ReSPECT in NHS Acute Trusts, but the ReSPECT process may be more effective if discussed in primary care. The applicants noted the important of evaluating how this process works in primary care, and what impact it has for patients and their families. GPs were encouraged to use ReSPECT prior to COVID, and this has accelerated during the pandemic. However, rapid implementation under pressure of the pandemic risks inappropriate use, which may have implications for future implementation. There is therefore a pressing need to explore how the ReSPECT plan currently does or does not work in primary care, the impact of the pandemic on its implementation, and implications for patients, their families and health care professionals. If the plan is effective, then patient care should be improved and NHS resources used more effectively.

The project involves a number of work packages; however, only work packages WP1 and WP3 are within the scope of support sought under s251. Support is required as members of the research team, who are not part of the direct care team, may be required to view patients medical records, as it will not always be possible for GP staff to undertake these tasks.

In Work Package 1, the applicants will undertake consented interviews with patients with a ReSPECT form, their families and GPs or senior nurses involved in the ReSPECT process, and staff in care homes. GP staff will identify eligible patients, and contact them via letter in order to consent for interview, however it may be necessary for researchers who are not part of the direct care team to view confidential patient information when extracting a pseudonymised dataset for analysis regarding all patients in participating GP practices who have had a ReSPECT form completed in the last 12 months. They will record basic demographic data, eFrailty index, and type of residence (residential care or own home). These data will not contain any items of identifiable information, but researchers may be required to access medical records to extract this dataset, which therefore requires support under ‘s251’. Patient contact details are required in order to invite participants for interview, however this is undertaken via the GP practice.

Work Package 3 involves a review of ReSPECT forms and patient GP records to map ReSPECT recommendations to subsequent treatment decisions. Researchers at the Univresity of Warwick will review the anonymised records of patients who have a

ReSPECT form completed in the last 12 months. Support under 's251' is requested in order to allow the research team to access the patients' medical records to extract a pseudonymised dataset for analysis, and collect pseudonymised copies of the ReSPECT form, and discharge summaries or appointment letters.

A pseudonymised dataset is disclosed to the University of Warwick for analysis, however this will be effectively anonymous to researchers as the key will be retained at GP practices. 24 care homes will also be taking part in this research study, however support is not required for this element as only care home staff, who are providing direct care, will be processing confidential patient information in order to extract a pseudonymised dataset.

A recommendation for class 1, 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	WP1: all adults (18 and over) in the practice with a ReSPECT form completed in the previous 6 months - will have data accessed in order to screen for eligibility. Up to 100 patient records per practice will be accessed and 48 will be invited for interview. WP3: all adults (18 and over) in the practice with a ReSPECT form completed in the previous 12 months - will have data accessed in order to screen for eligibility and extract an anonymised dataset for analysis (not required if direct care team). 40 patient records per practice will be accessed in order to achieve the estimated sample size for analysis.
Data sources	4. 12 GP practices from across three Clinical Commissioning Groups (CCGs)

	5. 24 Care homes (outside the scope of support)
Identifiers required for extracting a pseudonymised dataset	**For WP1;** Clinical patient records will be viewed in order to extract the pseudonymous dataset for analysis **For WP3**; Clinical patient records will be viewed in order to extract the pseudonymous dataset for analysis Copies of ResPECT form and entire GP record (hospital discharge letters) for 6 months following form completion. These records will be copied, but pseudonymised before being disclosed to the research team.
Identifiers required for analysis purposes	Pseudonymous participant identification number Age Sex Ethnicity eFRailty index This can be considered anonymous to researchers.
Additional information	The participant identification number will be assigned by practice staff at the original identification of patients who have had a ReSPECT form completed. Patient NHS number only will be retained with participant identification number as the key at GP practices.

	The pseudonymisation key will be retained until the end of data collection and analysis.

Confidentiality Advisory Group advice

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

Public interest

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

The Members agreed that this application had a clear medical purpose and was in the public interest.

Practicable alternatives

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

- Feasibility of consent

The applicants have considered the feasibility of obtaining written informed consent and believe it would not be reasonably practical due to the costs and the risk of bias that an incomplete sample would bring to the research questions under consideration. They state the following rationale to support this assessment:

- The study requirement is for a comprehensive overview of ReSPECT decisions and therefore the design requires full and proportionate representation of all groups of patients within the eligible population.
- The most vulnerable patients (such as those with communication difficulties, learning difficulties and those that lack capacity) would be most difficult to consent and therefore most likely to be excluded due to the challenges of obtaining consent leading to a biased sample, that would differentially exclude a group of significant interest because they are particularly likely to benefit from a ReSPECT process.

- Pilot work has shown that over 50% of patients with a do not attempt resuscitation decision lack mental capacity. Moreover those with DNACPR decisions were more likely to be frail (less independent with activities of daily living) and more likely to be very unwell (McCabe scale).
- In the pilot work for the previous CAG application, of those who lacked capacity, the clinical team had been unable to inform the relatives of the presence of a DNACPR decision in one in five cases which would likely be the minimum rate of failure to obtain informed consent for research purposes. Only recruiting 20% of eligible participants in this group, would introduce bias.

Whilst the Members acknowledged that support under the Regulations cannot be used to bypass the Mental Capacity Act, it is noted that the research proposed here would not be considered intrusive, i.e. data extraction from patient records, so the activity would be suitable for a recommendation of support under the Regulations. The CAG agreed that consent would not be a practicable alternative for this application, due to the bias that would be introduced.

- Use of anonymised/pseudonymised data

Confidential patient information is required to be viewed in order to extract a pseudonymised dataset for analysis. This could not be otherwise achieved without viewing confidential patient information.

- Direct care team

The applicant originally requested additional support for members of the research team who were not part of the direct care team to undertake screening of medical notes in order to identify eligible patients, however has confirmed as part of a response to queries that the direct care team will now be able to undertake screening for eligibility. It was briefly discussed by Members that if the direct care team were now able to undertake screening, would it be a practicable alternative for the direct care team to also undertake the data extraction, and thereby removing the need for ‘s251’ support. However the Committee accepted the justification provided as a response to queries, that this burden of work may not be possible for the direct care team to undertake, as data extraction is more time consuming that screening for eligibility. The applicant will ensure that where possible the direct care team will undertake any work involving processing confidential patient information, and where it is not possible, the research team will undertake these tasks and ‘s251’ is in place for those occasions.

‘Patient Notification’ and mechanism for managing dissent

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

The applicants provided a poster to be used on the GP surgery and website (ReSPECT-PC_WP3 Poster v1.0 29.06.21).

The applicants plan to send out patient invitation letters to all eligible patients in order to then take consent for interviews. This will include information on how the data will be collected and anonymised, and contact details for the study team and information on how to dissent from inclusion. At the request of CAT, the applicants provided revised materials that explained the role of the CAG and that members of the research team may access confidential patient information. The materials were also revised to make it clearer that patients information will not be processed if they opt-out.

The study specific opt-out approach was developed with patient and public partners and implemented successfully in the previous CAG supported study evaluating ReSPECT in acute NHS Trusts. A key of the participant identification numbers will be retained at the research sites in order to enable withdrawal of participants who opt out. The key will be retained until the end of data collection and analysis. No data will be collected from medical records for four weeks after the information letters have been posted to enable time for patients to opt out. They can do this via the pseudonymous participant identification number. Additionally, as part of the screening process for eligibility carried out by practice staff, if a patient record is flagged as the patient having opted out of their data being used for purposes other than direct clinical care the patient will be excluded. A sentence has been added to the protocol describing this.

The Members were broadly content with most of the patient notification materials, and how the opt out option will work. However the Committee commented that the poster and corresponding website text for GP practices was quite short, and as such did not contain enough information. Members felt that the text should explain what ReSPECT is. They also noted that only an email address contact was offered, and that a telephone number and postal address should also be provided. The opt out offered on the poster was not immediately clear, as it refers to filling in a box on a form, which will be provided via post at a later date to anyone who is eligible. The poster and corresponding text for the GP website should be updated according to the advice above, and provided to the Confidentiality Advice team (CAT) for review.

Patient and Public Involvement and Engagement

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

The application was developed with the Patient and Public Involvement group from the current ReSPECT evaluation study (17/CAG/0060). The group have agreed to continue their role for this application. The application also has a Patient and Public Involvement co-investigator, and two patient representatives are on the Study Steering Committee. The Patient and Public Involvement advisory group will be involved at all stages of the study, advising on patient and public facing documentation, contributing to analysis and interpretation of findings and active engagement in a stakeholder conference.

A Patient and Public Involvement advisory group meeting was held specifically to seek opinions on the acceptability of this use of confidential patient information without consent. The panel included patients and carers who have experience of emergency care and end of life decisions. The group were supportive of using confidential patient information without consent in this manner, and further information is in the application form.

The CAG were impressed with the Patient and Public Involvement undertaken, commenting that it was well established and included people from different faiths.

Exit strategy

The proposed exit strategy from support is the extraction of a pseudonymised dataset for analysis. Support is only required until this timepoint. Analysis of results from Work package 1 and 3 is expected to take approximately 18 months from the time of support.

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 poster and corresponding website text for GP practices should be updated to explain what ReSPECT is, provide a telephone number and postal address alongside the email address, and provide a clear opt out option. Updated versions should be provided to the CAT for review, within one month from the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 June 2021.**

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. **Confirmed:**

   Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

d. 21/CAG/0097 - PARADISE: Predicting AF after Cardiac Surgery - A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to develop and validate two prognostic models to predict post-operative atrial fibrillation after cardiac surgery.

Atrial Fibrillation (AF) after cardiac surgery (AFACS) is the most common complication following cardiac surgery, with an incidence between 30% and 50%. Around 35,000

patients undergoing cardiac surgery in the UK every year. AFACS is strongly associated with adverse patient outcomes, longer hospital and ICU stays, increased risk of stroke, increased risk of developing long-term AF, with associated complications and need for anticoagulation, and increased all-cause 30-day and 6-month mortality. Interventions that reduce the incidence of AFACS would have a substantial impact both on patient outcomes and cost. Current evidence therefore indicates that AFACS itself contributes to poor patient outcomes following cardiac surgery, and that tools to predict, prevent and guide treatment of AFACS are needed. There is no widely accepted prediction model currently, that reliably allows clinicians to determine the risk of a patient developing AFACS, despite multiple efforts over the past 15 years to develop one. The lack of effective pre and immediate post-operative prediction models for estimating AFACS risk has prevented the implementation of AF prophylaxis protocols. Interventions to prevent AFACS lead to decreased hospital length of stay, lower costs of hospital treatment, and decreased risk of postoperative stroke.

This is an international, multi-centre retrospective cohort study of patients who have undergone cardiac surgery. Two prognostic models will be developed, PARADISE-1 and PARADISE-2. PARADISE-1 will be conducted in the pre-operative assessment clinic and PARADISE-2 in the post-operative care unit. Both models will then be externally validated on prospectively collected data from two large UK centres and one UK clinical trial. The predictive models will be developed using data from the CALIBER and PARTNERS research databases, for which existing ethical approvals are in place. The models will be externally validated on data collected as part of the Tight-K study and the Brigham and Women's CABG Genomics Database in the United States. Consent from participants in the Tight-K study has already been sought to use their data for related research. The applicants will apply for separate ethical approvals to use Brigham and Women's CABG (Coronary Artery Bypass Grafting) Genomics Database. The applicants will also use prospective data collected at The Liverpool Heart & Chest Hospital (LHCH) and Barts Heart Centre (BHC) to carry out validation. Data from all study databases/sites will be de-identified prior to secure transfer to Oxford.

The applicants are seeking support to allow staff outside the direct care teams at LHCH and Barts Health NHS Trust to process confidential patient information in order to identify the study cohort and to compile a dataset containing information from multiple routinely-collected data sources. Confidential patient information will also be disclosed from LHCH and Barts Health NHS Trust to NHS Digital in order for the National Data Opt-Out to be applied. Pseudonymised data only will be disclosed from LHCH and Barts Health to the research team at the Nuffield Department of Clinical Neurosciences. Pseudonymised information will also be shared from the Tight-K trial, and the Brigham and Women's CABG Genomics Database and PARTNERS study in the United States to the Nuffield Department of Clinical Neurosciences.

A recommendation for class 1, 2, 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	Male and female patients aged 18 years and over who were admitted to hospital for any cardiac surgery. The scope of support extends to 12,000 patients treated at LHCH and BHC, treated between 1st January 1998 to 31st December 2020, for the retrospective cohort and the 1st July 2021 to 31st July 2023 for the prospective cohort.
Data sources	6. Electronic patient records held at the Liverpool Heart and Chest NHS Foundation Trust 7. Electronic patient records at Barts Health Centre at Barts Heath NHS Trust. 8. Pseudonymised data from: a. The Tight-K study at Barts Health NHS Trust, b. The CALIBER study at University College London, c. The Brigham and Women's CABG Genomics Database, Brigham and Women's Hospital, USA, d. The Partners Research Database (PRD), USA.
Identifiers required for linkage purposes	12. Name 13. NHS Number 14. Hospital ID number 15. Date of birth 16. Postcode – unit level

Identifiers required for analysis purposes	12. Postcode – district level 13. Age 14. Gender 15. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- Feasibility of consent

The applicants cited the number of patients involved, as 12,000 patients are included in the scope of support. Seeking consent from patients in the prospective cohort had been considered, however it is important that the dataset is representative of all patients undergoing cardiac surgery, so that the models did not disadvantage certain groups. The applicants were concerned that a consent process would mean that those who are at a higher risk of developing peri-operative atrial fibrillation, which would include those who require emergency surgery and those who lost capacity around the time of surgery, and consequently less able to participate. Mortality in these groups is

also likely to be high, which may further bias against these vulnerable patients. The CAG accepted the reasons given for not seeking consent.

- Use of anonymised/pseudonymised data

The applicants explained that the study research team will work with the local hospital IT team to create the dataset in order to ensure that reliable research-quality data extraction is carried out. Support is needed so that research nurses within the study team can retrieve missing variables from confidential patient records. The direct care team will not have time to undertake this process. The CAG agreed that confidential patient information was required to undertake the activity.

'Patient Notification' and mechanism for managing dissent

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

A patient notification document and a Privacy Statement were provided with the application. These both contained contact telephone and email contacts for the study team at the University of Oxford, as well as information on the National Data Opt-Out. For data collected from Liverpool Heart and Chest Hospital and Barts Heart Centre, the National Data Opt-Out will be applied. Records held at the two sites will also be checked and records flagged as requesting opt-out will be removed.

The CAG noted that online information only was provided. Members asked that the applicants consider making hard copies of information available at participating sites and to report on their decision in the response to the provisional outcome.

Patient and Public Involvement and Engagement

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

The applicants explained that two Patient and Public representatives, one patient and one member of the public, are included in the study oversight group. The two representatives have been actively involved in previous projects undertaken by the research team.

Two patient advocacy groups for heart rhythm problems, StopAfib.org and the Arrythmia Alliance, and the Atrial Fibrillation (AF) Association have also assisted with the funding application and have committed to assist in dissemination. The founder and CEO of the AF Association is also a member of the Project Oversight Group. The applicants will also seek input from the Oxford Critical Care Forum, who are a group of patients treated in an ICU and their families, as well as other lay members. The chief investigator will attend a meeting of the Oxford Critical Care Forum and specifically survey their views on the use of confidential patient information without consent for the purposes of this study.

The applicants will involve the two key patient advocates in the literature review and Delphi process of risk factors to assist in ensuring that the results are reported in language suitable for a lay audience. They will also liaise with the local NIHR Biomedical Research Centre (BRC) Patient and Public Involvement oversight group. The applicants will also host a workshop, in collaboration with the Oxford BRC PPI management team, to understand how patients might be affected by the used of the algorithm to assign patients a risk, and the different ways in which risk can be interpreted and communicated to both patients and clinicians. Also, StopAfib.org and the AF Association and Arrhythmia Alliance, the two largest patient advocacy groups in the field of AF, provided formal letters of support for our funding application. The applicants will continue to work with both organisations to publicise study progress and to share their findings.

The CAG noted that it was unclear whether the specific issue of the use of confidential patient information without consent had been discussed during the patient and public involvement and engagement carried out. Members asked that this issue was discussed with a patient and public involvement group. Feedback from this discussion, including the number of those consulted and their demographics, needed to be provided.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The specific issue of the use of confidential patient information without consent needs to be discussed with a patient and public involvement group. Feedback from this discussion, including the number of those consulted and their demographics, needed to be provided.

2. Consider whether hard copies of information about the study can be made available at participating sites and provide the outcome of these considerations.

e. 21/CAG/0090 (previously PIAG 4-07(c)/2002- PICANet

Context

Purpose of application

This non-research application from University of Leeds (on behalf of Healthcare Quality Improvement Partnership (HQIP), NHS England & Improvement (NHSE&I) and University of Leicester), set out the purpose of collecting data on all infants, children and young people accepted for referral, transported or admitted to designated paediatric intensive care units (PICUs) in the UK, to establish PICANet - the national clinical audit of the Paediatric Intensive Care services. PICANet is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

The commissioning body for data collected from English NHS PICUs and transport teams is HQIP. They are data controller for this part of the dataset alongside NHSE&I. The University of Leeds is data controller for all other personal data alongside University of Leicester. The database is held at the University of Leeds. PICANet is a collaboration between the Universities of Leeds and Leicester, both of whom are considered data processors.

PICANet currently has ‘s251’ support under application reference **PIAG 4-07 (c)/ 2002.** This non-research application has been submitted alongside a research application (**21/CAG/0098),** in order to split out the research and non-research functions of PICANet into separate applications, and to refresh the support required, as the original application was supported in 2002. **PIAG 4-07 (c)/ 2002** will be expired and replaced with **21/CAG/0090** and **21/CAG/0098**.

The aim of PICANet is to audit the quality of care delivered against the Paediatric Intensive Care Society (PICS) standards and key quality metrics adopted by the Care Quality Commission (CQC), including the whole patient pathway from the initial referral to paediatric intensive care, specialist transport and inpatient care. Data is also used to support healthcare planning and undertake service evaluations. Audit data is used continuously to develop anonymised outputs, including an annual report on data.gov and PICANet websites, CQC reports, and published papers**.**

Data collection started in 2002 and is currently ongoing under PIAG 4-07 (c)/ 2002. Data is collected from PICUs and Specialist Paediatric Critical Care Transport Services throughout the UK and Republic of Ireland via a secure web based application, however this ‘s251’ application only covers English and Welsh data. Confidential patient information is collected to allow identification of multiple admissions, referrals, and transports for the same individual. Data is also collected regarding demographics, referral, transport and admission details, diagnosis, interventions received and outcomes. Customised data collections are occasionally undertaken, which collect additional clinical data items specific to an area of care or in response to local or national policy requirements. However, no additional identifiers are required to support these customised data collections. Current customised data collections include NET-PACK 3, Renal Summary, Renal Daily and COVID-19/PIMS-TS.

Identifiable patient data collected as part of PICANet dataset is stored at the University of Leeds on the Secure Electronic Environment for Data (SEED) system. Identifiers are retained in the same database as clinical data but are stored in a separate table using column-level AES-256 encryption. During Summer 2021, the SEED architecture is being replaced by a new system called LASER. Patient identifiable data will be stored in a secured project area on the LASER platform.

Data requests from third parties that are outside scope of the purposes of this application will be requested to submit a separate ‘s251’ application. PICANet has a Clinical Advisory Group (CAG), whose members review requests for access to PICANet data to ensure feasibility, prevent duplication of service evaluation and audit, and to encourage collaboration.

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 infants, children and young people accepted for referral, transported or admitted to designated paediatric intensive care units (PICUs) providing paediatric Level 3 Critical Care (as defined by the Royal College of Paediatrics and Child Health) in the UK and Republic of Ireland. ('s251' support covers England and Wales only). There are on average around 20,000 new admissions per year in total, approximating 16,500 for England and Wales. (relevant to 's251' support) Data collection started in 2002 and is ongoing.
Data sources	Medical records from the below sources; 9. English NHS Paediatric Intensive Care Units (PICU)s 10. English private/non-NHS PICU 11. Welsh NHS PICU 12. English NHS Transport teams 13. Welsh NHS Transport teams
Identifiers collected in PICANet database	Name Address Postcode (unit level) NHS number Case note number/Hospital number GP registration Date of birth

	Date and time of death Sex Ethnicity
Identifiers required for linkage purposes within PICANet database	NHS number Case note number/Hospital number Postcode (with address used to validate postcode) Name Date of Birth Sex
Identifiers required for analysis purposes	Identifiers required for analysis within PICANet 16. Date of birth 17. Postcode 18. Date of death 19. Sex 20. Ethnicity No identifiers released to external third parties for analysis.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The Confidentiality Advisory Group noted that this activity fell within the definition of the management of health and social care services 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 Committee agreed that this application had an appropriate medical purpose, and is clearly in the public interest, noting that PICANet had demonstrated itself to be a valuable and important resource during the pandemic.

Scope of support

Within the application, linkages with datasets held by NHS Digital are mentioned. However the applicant has confirmed that support is not requested for linkages with Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality datasets at this time, and any future linkages will be processed as an amendment.

Practicable alternatives

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

- Feasibility of consent

The applicants provide multiple justifications for why consent is not a practicable alternative. These include but are not limited to the following; There are over 15,000 PICU admissions a year in England and Wales, and consent would represent a significant burden on the clinical team. If parents/carers were approached for consent, it could be considered that the timing of these discussions would be inappropriate during this highly stressful period, and additionally they might not be available. If consent were not obtained at the time of referral, transport or on admission or during a PIC unit stay, it could lead to long delays in data collection, validation, and analysis. The success of PICANet has depended on full ascertainment of every PIC episode. Additionally, the applicant has investigated the feasibility of obtaining consent from all admissions to PICU. The feasibility study demonstrated that practical implementation of consent for data collection in this setting was extremely challenging -the most successful hospital at gaining consent within the feasibility study 'missed' 15.8% of admissions; this level of incompleteness would severely compromise the effective functioning of PICANet. The feasibility study also demonstrated the rate of acceptability for sharing of data with PICANet: of those parents / children approached, refusal rates were extremely low with only one parent known to refuse.

The Members agreed with the justifications provided, although noted that the feasibility study was undertaken many years ago. The Group were content that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is used to ensure multiple re-admissions and other PIC events for the same individual are assigned to that individual. The applicant reasons that the use of a pseudo-identifier to enable event assignment to an individual patient is not feasible or practical in the paediatric intensive care setting as the care pathway is highly complex with patients transferred between district general hospitals, specialist transport and retrieval teams and PICUs across the country (and across national borders) often in circumstances of emergency or urgent care need. As such the consistent and accurate communication of a PICANet identifier between all these different care teams would be unworkable and would not provide robust linkage.

The Group agreed with the justification provided and felt there was no alternative less disclosive method of undertaking the processing described.

Justification of identifiers

The members were content that most of the identifiers requested were justified appropriately. However, GP registration was listed in the identifiers collected, but was not listed as having a purpose for either linkage or analysis. The applicant is requested to justify the purpose of collecting GP registration.

'Patient Notification' and mechanism for managing dissent

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

The applicant has provided multiple notification options and is using a layered approach. A privacy notice which includes an opt out option is available on PICANet website. A poster is provided in English and Welsh, with an opt out option, for participating units to display. There is no mention of 's251' on the poster, but a link is provided for the privacy notice which does try to explain the legal basis for processing. A leaflet for adults and a leaflet for children is provided in English and Welsh, for participating units to display.

Members commented that the poster appeared simple and clear. However the Group did request some changes to the privacy notice. The applicant is advised to bear in mind the additional feedback from the research application (21/CAG/0098) when altering the privacy notice. It was commented that the term 'PICANet' had not actually been defined on the privacy notice, and this terminology should be explained. Confusing references are made to Latvia, which are not explained, and are potentially not relevant to any privacy notice displayed in England and Wales. The PIAG reference has been provided, and this should be updated to reflect the updated CAG references. References are made to permission from the Health Research Authority (HRA) regarding the collection of identifiers, and these are not quite accurate. A clearer explanation should be provided explaining the legal basis for processing confidential patient information under the common law duty of confidentiality, and the statement should be amended to include the correct reference to the decision-making element. For example, *'The Health Research Authority, on advice from the Confidentiality Advisory Group, an advisory body which provides independent expert advice on the use of confidential patient information without consent in England and Wales, has provided support regarding research purposes, and The Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group, has provided support regarding non-research purposes, etc. etc.'* The Group also commented that the privacy notice alongside other patient notifications, should be reviewed by a Patient and Public Involvement group to ensure clarity.

Two specific options to opt out of PICANet have been provided. Participants can either contact the PICU that the child was treated in, or contact the PICANet team. The National data opt out will be applied by the providing data processors where applicable.

If a subject (or their parent / carer) requests that personal identifiers are no longer processed, their record within the PICANet database will be de-identified using the 'Remove all identifiers' functionality available within the database. This functionality performs the following actions:

- sets name, address, NHS number & ethnic category to blank

- truncates the postcode to first 5 characters, e.g. BT1 1LT becomes BT1 1**

- replaces the date part of date of birth with 01, e.g. 17 May 2018 becomes 1 May 2018 (and indicates that this is an anonymised DOB).

This allows the record to be identified in any follow-up procedures with the participating organisation but not the individual and it is no longer classed as personal data. Full date of death was planned to be retained, however as a response to queries, the applicant has agreed that full date of death could be modified in line with date of birth.

The Members noted that if a person requests to opt out of PICANet for non-research purposes, it was not clear if that person understood that only their identifiable information would be removed, and other anonymised information would remain. It was commented that this is common practice for clinical audits, and the committee understood the justification for doing so (however, it is noted that this is different to the advice given as part of the feedback for the research application 21/CAG/0098). The Group accepted that anonymous information would remain within the audit. They requested an explanation of how the retention of anonymous data is discussed with those opting out. For example, is there a telephone script that explains the process?

Patient and Public Involvement and Engagement

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

PICANet has parent representation on the PICANet Steering Group which oversees the project and meets on average twice per annum. The design and early stages of PICANet also involved a PIC Families group who were advocates for ensuring PIC children and parents / carers were considered in the establishment of the project. The PIC Families group (containing 8 parents) have indicated their support for the collection of data without consent over many years, but this has not been formally recorded. Attendance is declining, and the applicants are looking into ways to increase this, and to formally discuss the use of confidential patient data without consent, with a more representative group of people. In addition, applicants work with key stakeholder groups for children who have been treated in PIC including those associated with specific PICUs.

The Committee commented that although the applicants have a longstanding Patient and Public Involvement group, this does not appear to be functioning as it used to. It is noted that the applicants have undertaken some discussions surrounding the use of confidential patient information without consent, although these discussions have not been formally recorded. It is also noted that some work has been undertaken with local specific groups. As this application has been ongoing since 2002, the Members did not wish to hold up the ongoing activities of PICANet, but they commented that this was an

opportunity to improve the Patient and Public Involvement input into the application. In this case a condition has been applied to provide a Patient and Public Involvement plan to the Confidentiality Advisory Group within three months, to detail how the Patient and Public Involvement will be strengthened, including formal discussions surrounding the use of confidential patient information without consent, with a larger, more representative group of people. The Group requested the applicant consider recruiting adults who have previously been patients in PICUs to take part in Patient and Public Involvement in order to provide representation of the children themselves rather than just parents and carers.

Members also commented that it appeared the PICANet Clinical Advisory Group did not contain any lay representation.

Exit strategy

Personal identifiers are automatically removed from the PICANet database once an individual is older than 18 years and has not been in PICU for the past five years. Full date of death was planned to be retained, however as a response to queries, the applicant has agreed that full date of death could be modified in line with date of birth, representing an exit from ‘s251’ support.

Support is requested on an ongoing basis, as data collection is continuous. The sponsor, HQIP, request that data is retained indefinitely as long as the project is running. ‘s251’ support will be provided for five years in the first instance, and a duration amendment will be required at that time to extend support. This is to account for any developments in information governance and relevant legislation.

Confidentiality Advisory Group advice conclusion

The Confidentiality Advisory Group 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. Support for PIAG 4-07 (c)/ 2002 is expired from the date of this letter.

2. Support extends to data collected in England and Wales only.

3. Support is provided for five years, at which time point a duration amendment is required.

4. Please provide justification as to why GP registration is required, and feedback to the Confidentiality Advisory Group within three months from the date of this letter.

5. Please review the privacy notice in line with the advice given in the text of this letter, and provide an updated version to the Confidentiality Advisory Group within three months from the date of this letter.

6. Please provide a description of the communications and processes used surrounding the opt out process, specifically regarding the data that remains in PICANet, within three months from the date of this letter.

7. Please provide a Patient and Public Involvement plan to the Confidentiality Advisory Group within three months from the date of this letter.

8. Please consider lay representation on the PICANet Clinical Advisory Group.

9. Confirmation provided from the IG Delivery Team at NHS Digital to the Confidentiality Advisory Group 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:**

   The NHS Digital **19/20** DSPT reviews for **University of Leeds - Secure Electronic Environment for Data (SEED)** (8E218 – SEED) and **University of Leicester College of Life Sciences** (EE133832-CMBSP) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 26 July 2021)

   The NHS Digital **20/21** DSPT review for **University of Leeds - LASER** (8KM29) was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 26 July 2021) - will be required once migration from SEED to LASER is complete later this year.

Due to the number of participating PICUs/transport providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

f. 21/CAG/0098 - PICANet

Context

Purpose of application

This application from University of Leeds and University of Leicester, set out the purpose of creating a research database collecting data on all infants, children and young people accepted for referral, transported or admitted to designated PICUs providing paediatric Level 3 Critical Care.

The University of Leeds and the University of Leicester are joint data controllers for this research application and the database is held at the University of Leeds. In addition to the two universities, Healthcare Quality Improvement Partnership (HQIP) & NHS England & Improvement are also joint data controllers for English NHS PICUs and transport teams only. PICANet is a collaboration between the Universities of Leeds and Leicester who are both also data processors and considered part of the Research Database Team.

PICANet currently has 's251' support under application reference **PIAG 4-07 (c)/ 2002.** This research application has been submitted alongside a non-research application (**21/CAG/0090),** in order to split out the research and non-research functions of PICANet into separate applications, and to refresh the support required, as the original application was supported in 2002. 's251' support for **PIAG 4-07 (c)/ 2002** will be expired and replaced with **21/CAG/0090** and **21/CAG/0098**.

The aim of the research database is to support high quality research into: paediatric intensive care; specific conditions affecting children and young people accessing paediatric intensive care services; public health, including the impact of Covid-19; and other research areas listed in the application. Data collection started in 2002 and is ongoing under **PIAG 4-07 (c)/ 2002**. Data is collected from PICUs and Specialist Paediatric Critical Care Transport Services throughout the UK and Republic of Ireland via a secure web-based application, however, this application only covers English and Welsh data. Confidential patient information is collected to allow identification of

multiple admissions, referrals, and transports for the same individual. Data is also collected regarding demographics, referral, transport and admission details, diagnosis, interventions received and outcomes. Customised data collections are occasionally undertaken, which collect additional clinical data items specific to an area of care or in response to local or national policy requirements.

Identifiable patient data collected as part of PICANet dataset is stored at the University of Leeds on the Secure Electronic Environment for Data (SEED) system. Identifiers are retained in the same database as clinical data but are stored in a separate table using column-level AES-256 encryption. During Summer 2021, the SEED architecture is being replaced by a new system called LASER. Patient identifiable data will be stored in a secured project area on the LASER platform.

The REC Favourable Opinion allows research to be carried out by the PICANet Database Research Team or by sharing de-identified data with other researchers. Data may also be shared for the purposes of research if the recipient has their own project specific-research ethics approval in place and an appropriate legal basis for data sharing. PICANet has a Clinical Advisory Group (CAG), whose members review requests for access to PICANet data to ensure feasibility, prevent duplication of research activity and to encourage collaboration. Requests are also reviewed by the PICANet team and, where requests involve data from English providers, will be subject to approval by the HQIP Data Access Review Group (DARG). Only anonymous data is released to external third parties, or pseudonymous data which cannot be re-identified by the third party.

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	All infants, children and young people accepted for referral, transported or admitted to designated PICUs providing paediatric Level 3 Critical Care (as defined by the Royal College of Paediatrics and Child Health) in the UK and Republic of Ireland. (‘s251’ support covers England and Wales only).

	There are on average around 20,000 new admissions per year in total, approximating 16,500 for England and Wales. (relevant to 's251' support) Data collection started in 2002 and is ongoing.
Data sources	Medical records from the below sources; 14. English NHS PICUs 15. English private/non-NHS PICU 16. Welsh NHS PICU 17. English NHS Transport teams 18. Welsh NHS Transport teams
Identifiers collected in PICANet database	Name Address Postcode (unit level) NHS number Case note number/Hospital number GP registration Date of birth Date and time of death Sex Ethnicity
Identifiers required for linkage purposes within PICANet database	NHS number Case note number/Hospital number Postcode (with address used to validate postcode) Name Date of Birth

	Sex
Identifiers required for analysis purposes	Identifiers required for analysis within PICANet 21. Date of birth 22. Postcode 23. Date of death 24. Sex 25. Ethnicity No identifiers released to external third parties for analysis.

Confidentiality Advisory Group advice

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

Public interest

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

The Members agreed that building a research database was an appropriate medical purpose but felt that there was not enough clarity regarding how PICANet review research applications to be assured that the activities are definitely in the public interest. This is explained in more detail in the sections of this letter concerning the 'process for reviewing data requests' and the 'website'.

Scope of support

Within the application, linkages with datasets held by NHS Digital are mentioned. However, the applicant has confirmed that support is not requested for linkages with Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality datasets at this time, and any future linkages will be processed as an amendment.

Process for reviewing data requests

It is noted that PICANet has a Clinical Advisory Group, whose members review requests for access to PICANet data to ensure feasibility, prevent duplication of research activity and to encourage collaboration. However, the Committee were not clear if the PICANet CAG are also assessing whether these requests are in the public interest, and were also unclear on the detail of any decision making process. The Group would therefore like more information on how research proposals will be reviewed and approved, for example, a 'terms of reference' document for the data access committee. The Group wanted clarity on the process for internal research requests as well as external research requests. This should include details of how the applicant is assured that the data released to external parties is not identifiable.

Website

The Group discussed the website in the context of evidencing the public interest in the research database activity. It is stated in the protocol provided to the Members that all data requests are published, however, members of the Group were unable to find any lists of previous requests, or types of research undertaken, or any results or benefits from any of the research undertaken. The Committee commented that the website should be reviewed to provide a separation between non-research uses, and research use. The Group stated that currently it is difficult to establish the public interest in allowing research to be undertaken with information collected without consent, as the website does not include a complete list of the research activities undertaken, and the benefits are not clearly stated.

Practicable alternatives

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

- Feasibility of consent

The applicants provide multiple justifications for why consent is not a practicable alternative. These include but are not limited to the following; There are over 15,000 PICU admissions a year in England and Wales, and consent would represent a significant burden on the clinical team. If parents/carers were approached for consent,

it could be considered that the timing of these discussions would be inappropriate during this highly stressful period, and additionally they might not be available. If consent were not obtained at the time of referral, transport or on admission or during a PIC unit stay, it could lead to long delays in data collection, validation, and analysis. The success of PICANet has depended on full ascertainment of every PIC episode. Additionally, the applicant has investigated the feasibility of obtaining consent from all admissions to PICU. The feasibility study demonstrated that practical implementation of consent for data collection in this setting was extremely challenging - the most successful hospital at gaining consent within the feasibility study 'missed' 15.8% of admissions; this level of incompleteness would severely compromise the effective functioning of PICANet. The feasibility study also demonstrated the rate of acceptability for sharing of data with PICANet for those parents / children approached; refusal rates were extremely low with only one parent known to refuse.

The Members agreed with the justifications provided, although noted that the feasibility study was undertaken many years ago. The Group were content that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is used to ensure multiple re-admissions and other PIC events for the same individual are assigned to that individual. The applicant reasons that the use of a pseudo-identifier to enable event assignment to an individual patient is not feasible or practical in the paediatric intensive care setting as the care pathway is highly complex with patients transferred between district general hospitals, specialist transport and retrieval teams and PICUs across the country (and across national borders) often in circumstances of emergency or urgent care need. As such the consistent and accurate communication of a PICANet identifier between all these different care teams would be unworkable and would not provide robust linkage.

The Group agreed with the justification provided and felt there was no alternative less disclosive method of undertaking the processing described.

Justification of identifiers

The members were content that most of the identifiers requested were justified appropriately. However, GP registration was listed in the identifiers collected, but was not listed as having a purpose for either linkage or analysis. The applicant is requested to justify the purpose of collecting GP registration.

‘Patient Notification’ and mechanism for managing dissent

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

The applicant has provided multiple notification options and is using a layered approach. A privacy notice which includes an opt-out option is available on PICANet website. A poster is provided in English and Welsh, with an opt-out option, for participating units to display. There is no mention of ‘s251’ on the poster, but a link is provided for the privacy notice which does try to explain the legal basis for processing. A leaflet for adults and a leaflet for children is provided in English and Welsh, for participating units to display.

Members commented that the poster appeared simple and clear. However, the Group did request changes to the privacy notice. The applicant is advised to bear in mind the feedback from the non-research application (21/CAG/0090) when altering the privacy notice, noting that all changes will need to be encompassed. It was commented that the term ‘PICANet’ had not actually been defined on the privacy notice, and this terminology should be explained. Confusing references are made to Latvia, which are not explained, and are potentially not relevant to any privacy notice displayed in England and Wales. The PIAG reference has been provided, and this should be updated to reflect the updated CAG references. References are made to permission from the Health Research Authority (HRA) regarding the collection of identifiers, and these are not quite accurate. A clearer explanation should be provided explaining the legal basis for processing confidential patient information under the common law duty of confidentiality, and the statement should be amended to include the correct reference to the decision-making element. For example, *‘The Health Research Authority, on advice from the Confidentiality Advisory Group, an advisory body which provides independent expert advice on the use of confidential patient information without consent in England and Wales, has provided support regarding research purposes, and The Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group, has provided support regarding non-research purposes, etc. etc.’* The Group also commented that the privacy notice alongside other patient notifications, should be reviewed by a Patient and Public Involvement group to ensure clarity.

The Committee commented that the research database purposes are not clearly explained on any of the patient notification materials, and felt that the research uses of

peoples' data needed to be explained in all patient notification material, including the benefits of the research.

Two specific options to opt-out of PICANet have been provided. Participants (or their parent / carer) can either contact the PICU that the child was treated in, or contact the PICANet team. The National data opt-out will be applied by the providing data processors where applicable.

If a subject (or their parent / carer) requests that personal identifiers are no longer processed, their record within the PICANet database will be de-identified using the 'Remove all identifiers' functionality available within the database. This functionality performs the following actions:

- sets name, address, NHS number & ethnic category to blank

- truncates the postcode to first 5 characters, e.g. BT1 1LT becomes BT1 1**

- replaces the date part of date of birth with 01, e.g. 17 May 2018 becomes 1 May 2018 (and indicates that this is an anonymised DOB).

This allows the record to be identified in any follow-up procedures with the participating organisation but not the individual and it is no longer classed as personal data. Full date of death was planned to be retained, however, as a response to queries, the applicant has agreed that full date of death could be modified in line with date of birth.

The Members noted that if a person (or their parent / carer) requests to opt-out of PICANet for research purposes, an option should be offered to be able to opt-out of all of their data being used for research purposes, rather than only their identifiable information being removed. The Committee felt that this option should be available on the database, if people still wish for all their data to be removed after an opt-out discussion. This advice is only for 21/CAG/0098.

Patient and Public Involvement and Engagement

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

PICANet has parent representation on the PICANet Steering Group which oversees the project and meets on average twice per annum. The design and early stages of PICANet also involved a PIC Families group who were advocates for ensuring PIC children and parents / carers were considered in the establishment of the project. The PIC Families group (containing 8 parents) have indicated their support for the collection of data without consent over many years, but this has not been formally recorded.

Attendance is declining, and the applicants are looking into ways to increase this, and to formally discuss the use of confidential patient data without consent, with a more representative group of people. In addition, applicants work with key stakeholder groups for children who have been treated in PIC including those associated with specific PICUs.

The Committee commented that although the applicants have a longstanding Patient and Public Involvement group, this does not appear to be functioning as it used to. It is noted that the applicants have undertaken some discussions surrounding the use of confidential patient information without consent, although these discussions have not been formally recorded. It is also noted that some work has been undertaken with local specific groups. As this application has been ongoing since 2002, the Members did not wish to hold up the ongoing activities of PICANet, but they commented that this was an opportunity to improve the Patient and Public Involvement input into the application. In this case a condition has been applied to provide a Patient and Public Involvement plan to the Confidentiality Advisory Group within three months, to detail how the Patient and Public Involvement will be strengthened, including formal discussions surrounding the use of confidential patient information without consent, with a larger, more representative group of people. The applicant is also requested to ensure that research specific discussions take place as part of ongoing Patient and Public Involvement, to ensure that there is public interest in the uses of confidential patient information for the purposes of this research database. The Group requested the applicant consider recruiting adults who have previously been patients in PICU's to take part in Patient and Public Involvement in order to provide representation of the children themselves rather than just parents and carers.

Members also commented that it appeared the PICANet Clinical Advisory Group did not contain any lay representation.

Exit strategy

Personal identifiers are automatically removed from the PICANet database once an individual is older than 18 years and has not been in PICU for the past five years. Full date of death was planned to be retained, however, as a response to queries, the applicant has agreed that full date of death could be modified in line with date of birth, representing an exit from 's251' support.

Support is requested on an ongoing basis, as data collection is continuous. The sponsor, HQIP, request that data is retained indefinitely as long as the project is running. 's251' support will be provided for five years in the first instance, and a duration amendment will be required at that time to extend support. This is to account for any developments in information governance and relevant legislation.

Contacting patients

The Committee did not think the applicant was requesting support for any types of research study that required individuals to be contacted, however, they wished to make it clear in the letter that this support for the PICANet research database does not also support direct contact with patients for individual research studies, and any application of this type would require a separate ‘s251’ support in place.

Overseas patients

It was noted by the Group that there may be a high proportion of overseas private patients in this cohort, and Members were interested if this affected epidemiological analyses. No condition of support is applied regarding this, as this is likely to be easily separated out if required, as the applicants retain postcode for analysis, however this point is included for completeness of the Groups discussions.

Confidentiality Advisory Group advice conclusion

The Confidentiality Advisory Group 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 for PIAG 4-07 (c)/ 2002 is expired from the date of this letter.

2. Support extends to data collected in England and Wales only.

3. Support is provided for five years, at which time point a duration amendment is required.

4. Please provide evidence of how PICANet reach conclusions about the appropriateness of research which is undertaken both internally and externally. The

Group would like clarity on what the process is in deciding which research projects will be undertaken, and this should be evidenced by a 'terms of reference' document for a data access committee, and any other relevant evidence. Please feed back to the Confidentiality Advisory Group within three months from the date of this letter.

5. The website should be edited in order to clearly define the research function of the database. There should be clear information regarding the previous and current activities, and benefits should be presented in order to help evidence that the PICANet research database is in the public interest. Please provide feedback to the Confidentiality Advisory Group within three months from the date of this letter.

6. Please provide justification as to why GP registration is required, and feedback to the Confidentiality Advisory Group within three months from the date of this letter.

7. Please review the privacy notice, and other patient notification materials in line with the advice given in the text of this letter, ensuring the research database purposes are clearly described, and provide updated versions to the Confidentiality Advisory Group within three months from the date of this letter.

8. Objections should be available to remove all data fields for research purposes, not just identifiable fields. Please confirm if this can be implemented, within three months from the date of this letter.

9. Please provide a Patient and Public Involvement plan, which includes discussions surrounding research activity to the Confidentiality Advisory Group within three months from the date of this letter.

10. Please consider lay representation on the PICANet Clinical Advisory Group, and report back to the Confidentiality Advisory Group within three months from the date of this letter.

11. Please confirm your understanding that this application does not support direct contact with patients for the purposes of research.

12. Favourable opinion from a Research Ethics Committee. **Confirmed 18 October 2018, originally approved 2005 (05/MRE04/17)**

13. Confirmation provided from the IG Delivery Team at NHS Digital to the Confidentiality Advisory Group 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:**

The NHS Digital **19/20** DSPT reviews for **University of Leeds - Secure Electronic Environment for Data (SEED)** (8E218 – SEED) and **University of Leicester College of Life Sciences** (EE133832-CMBSP) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 26 July 2021)

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Due to the number of participating PICUs/transport providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

Specific conditions of support

The following sets out the specific conditions of support.

10. Text

4. Minutes of the meeting held on XXXX

The minutes of the meeting held on XXXX were not reviewed as an outcome is pending.

5. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Minutes signed off as accurate via correspondence by Chair Dr Tony Calland MBE and Vice Chair Dr Patrick Coyle	12/10/2021

Signed – Confidentiality Advice Team	Date
KM Cassidy	12/10/2021