Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
March 2018

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1. Applications

Application title: **An evaluation of the impact of the MedEye System in one U.K. Hospital Trust**
CAG reference: **17/CAG/0173**
IRAS project ID: **232954**
REC reference: **17/NE/0342**

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay
Mr Anthony Kane	Yes	Lay
Dr Rachel L Knowles	Yes	
Mr Andrew Melville	Yes	Lay
Mrs Diana Robbins	Yes	Lay
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from Newcastle University sets out the purpose of medical research into the use of MedEye, a bedside tool used to prevent medication administration errors. The system scans medication at the bedside and verifies whether the correct medication is being administered. The combination of MedEye technology with an electronic health record (EHR) and prescribing system holds a great deal of promise to reduce medication errors at the administration stage for hospitalised patients. However,

without evidence on safety, effectiveness and efficiency, it is difficult for health care organisations to prioritize this technology among many other potential safety interventions.

The study contains a number of elements; however, the CAG consideration is only in relation to the first aim of the project, which is to evaluate what effect the MedEye system has on the incidence of serious medication administration errors. Two research observers will undertake observation of medication administration in the wards 2-4 weeks prior to the roll out of MedEye and then 4-8 weeks afterwards. The observers will be clinically experienced healthcare professionals who hold an honorary contract with the Trust. They will be blinded to the clinician's prescribing instructions. Support is requested to allow the researcher observers to access the medical records of the patients whose medication administrations were observed to check the accuracy of drugs administered against those prescribed.

A recommendation for class 1, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All patients aged over 18 years admitted to adult wards during the study period will be eligible to be indirectly involved in the study. 16 wards will be included in the study which will be half surgical and half medical.

Each single tablet administration which is observed is classed as one observation. It is intended that 16,000 medication administrations will be observed in total. Intravenously administered and solution based medications are excluded from the project.

The following items of confidential patient information will be accessed and utilised for the purposes described:

- Patient name – validation,
- NHS ID Number – validation,
- Date of Birth – accessed to enable patient age to be recorded – analysis.

Further clinical details in relation to the patient's prescription will also be required.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG considered the applicants response to the request for further information, as set out in the previous provisionally supported outcome in correspondence.

1. **Further information is required to explain why seeking consent from patients for the use of their data within the project is not feasible.**

The applicants advised that there were a number of reasons why consent was not feasible for this project. The first was that patients may be prompted to remind staff that they are due certain medications by way of assistance. Secondly, patients who notice an error in their medication may not raise this point in case this should have an impact on the research. The applicants explained that both of these scenarios had the potential to bias the study findings. It was also explained that the additional time, expense and resource required to consent all patients to the trial was potentially inhibitive of the study proceeding due to the large volume of medication administrations to be observed. Finally, the applicants did not want to place any further burden on patients who were unwell.

The Sub-Committee received the response and no further issues were raised.

2. **Justification is required to explain why gender and ethnicity are required for the study analysis.**

The applicants responded to confirm that gender and ethnicity would no longer be collected in order to reduce the identifiability of the dataset retained about patients.

The Sub-Committee received the response and no further issues were raised in this area.

3. **Patient and Public Involvement and Engagement – activity should be undertaken in this area and feedback provided to the CAG for consideration. The following points should be addressed:**

a. **The acceptability of using confidential patient information without consent for the proposed application activity should be tested. If the responses provided are negative, the CAG will take this into account when considering whether a recommendation of support under the Regulations should be made.**

b. **Patients and the public should also be engaged with around the communications strategy for the project to seek views on how it could be best promoted together with review of any materials.**

It was explained that the project manager had presented an overview of the project and discussed the use of using confidential patient information without consent with Newcastle upon Tyne NHS Foundation Trust's Community Advisory Panel (CAP), at a meeting held on the 5th December 2017. The CAP is formed of eight patient and/or public members together with a coordinator. It was explained that a short power point was used to describe the project, which were provided for information purposes, which was followed by questions and discussion with the panel related to: (a) study and methodology (b) the use of confidential patient information without consent and (c) the poster and consent/ assent process. The applicants also distributed a copy of the study poster for members to look at. It was explained that there was a great deal of interest and discussion about both the system and the project.

An overview of the outcomes of the meeting was provided and attendees were supportive of the project. A request was made for an information leaflet to supplement the study poster, which the applicants had compiled and submitted for review. It was further noted that the engagement with the CAP had been useful and further engagement was planned in the future, including provision of the study findings.

The Sub-Committee received the response and no further issues were raised.

4. **Patient Notifications and Dissent – the information materials used to inform patients and the public of the application activity and offer a means objection require revision. The following points should be considered:**

a. **The poster requires revision to address the following points:**

i. **Include clear information around what the project involves, explaining how and why data will be accessed,**

ii. **It should be explained that patients have the right to raise an objection to the use of their data and explain how this can be done,**

iii. **Alternate means of contact should be provided to supplement the email addresses which are detailed within the document,**

iv. **It was noted that one of the email addresses detailed within the text included a typographical error.**

b. **Additional communication strategies to promote the project are required to supplement the poster. A detailed overview should be provided, together with copies of any documentation for consideration by the CAG.**

The applicants explained that, based on the feedback from both the CAG and CAP, the study poster had been revised so that it advised patients about how researchers may access their hospital electronic medical record in order to review medications prescribed. The study poster also included detailed around how a patient could raise an objection together with relevant contact details. The study poster would be

more widely displayed throughout the hospital e.g., on notice boards, to supplement the information within the wards. It was noted that an information leaflet had also been produced.

The Sub-Committee received the response and supporting documentation and no further issues were raised in this area.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Newcastle upon Tyne Hospitals NHS Foundation Trust shows a reviewed grade of 92% satisfactory on Version 14, 2016-17).**

Application title: **UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)**

CAG reference: **17/CAG/0184**

Group Members:

Name	*Present*	*Notes*
Dr Kambiz Boomla	Yes	
Dr Tony Calland	Yes	Chair
Ms Hannah Chambers	Yes	Lay
Mr Anthony Kane	Yes	Lay
Dr Murat Soncul	Yes	Alternate Vice Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the Royal College of Paediatrics and Child Health sets out the purpose of clinical audit into the healthcare provided to children and young people with suspected epileptic seizures. This application is for the third round of the audit which has been commissioned by HQIP from 01 April 2017 to 31 March 2021. The audit will run in England, Wales and Scotland and aims to build on current high levels of engagement established during the previous two rounds to provide a high value audit leading to ongoing significant improvements and equality in clinical outcomes, practice and patient experience.

The audit has three main domains:

1. Service Descriptors – An annual census approach will continue to detail the components of the services that each Health Board/Trust provides to children and young people (CYP) with seizures and epilepsies. This will also be mapped to best practice tariff criteria.
2. Clinical Performance Indicators – These will continue to be applied to CYP presenting to a paediatric service with a paroxysmal episode or episodes and particularly focus on those with epileptic episodes.
3. Patient Reported Experience Measures – The audit will capture, via anonymised questionnaires, the experience of both young people and parents on their experience of the care that they have received from the point of their first paediatric assessment for epilepsy and the following 12 month period.

The Royal College of Paediatrics and Child Health delivered rounds one and two of the audit between 2009 and 2014; however, the previous rounds of the audit had been delivered without the requirement for support under the Regulations.

The methodology of the prospective audit differs from that employed by the historic rounds in that the applicants are proposing linkage via NHS Digital and NHS Wales Informatics Services to enable linkage with HES/PEDW and ONS mortality data.

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

Confidential Patient Information Requested

Cohort

All children and young people (aged 0 to 16 years 364 days) under NHS paediatric care with suspected epilepsy with a first paediatric assessment from "day 0" (proposed as 1 April 2018) with ongoing audit of those diagnosed with epilepsy.

The data will be provided by participating Trusts and Health Boards and will be cross-referenced with information held by NHS Digital as part of the HES/ONS datasets and NHS Wales Informatics for data within PEDW.

The following items of confidential patient information are required for the purposes outlined:

- First name/surname – only viewable by the treating Trust/Health Board – captured to aid local provider patient monitoring and clinical improvement activity,
- Gender – analysis,
- Ethnicity – analysis,
- Date of birth – analysis,
- Date of death – linkage and analysis,
- NHS/CHI/ number – validation and linkage,
- Home postcode – translated into LSOA for analysis,
- Details of individual patient care – analysis.

Confidentiality Advisory Group Advice

A Sub-Committee considered the applicants response to the request for further information included within the provisionally supported outcome in correspondence.

1. Clarify the start date for the 'Epilepsy12' audit.

The applicants confirmed that data entry by participating Health Boards and Trusts would commence week commencing 23 April 2018.

The response was received and no further issues were raised in this area.

2. Contact should be made with NHS Digital and NHS Wales Informatics Services to clarify what patient identifiers are required to facilitate the linkage with HES/PEDW and ONS – provide confirmation of the outcome of these discussions.

The applicants provided copies of email correspondence, which clarified that NWIS had confirmed that they only required the NHS number as they do not use any other personal identifiers for data linkage.

It was also confirmed in email correspondence with NHS Digital, that they follow an 8-step deterministic linkage algorithm to link a variety of data sets to one another which required the following fields: NHS number, date of birth, postcode and sex. NHS Digital, as standard, request that these identifiers, together with a pseudonymised patient identifier, are sent for the patients in the cohort to facilitate linkage.

The Sub-Committee received the response and no further issues were raised in this area.

3. **Provide copies of all patient notification materials which are developed for the project for consideration. An overview of how the patient objection mechanism will be managed should also be provided.**

The applicants provided a draft patient information leaflet for consideration. It was explained that the overall appearance and some of the language in the leaflet would be edited in conjunction with the RCPCH Children and Young People engagement team to make it more accessible but the main points that are covered in the draft text would be retained. In terms of the patient objection mechanism, as the patient information leaflet describes children and/or their parents are given direction on how to express their desire to opt out of the audit.

It was further explained that a related patient/parent opt out function would be incorporated into the Epilepsy12 system itself which will allow the Health Board/Trust team to indicate that a patient/parent had notified them that they do not wish for their data to be used for the purpose of the Epilepsy12 audit. This function will block the ability to extract data for the particular patient from the secure Epilepsy12 system for analysis by the RCPCH-based data analysis team for the purposes of Epilepsy12. This function will not block the local provider Health Board/Trust from still viewing the patient's details locally for the purpose of patient care and local service improvement. It was explained that the opt-out function would also always appear via a prominent button on each patient's management page on the Epilepsy12 data system so that it can be easily accessed should the patient indicate their desire to opt at any given point in time, not just at the point of their initial entry into the audit.

The Sub-Committee received the response, together with the revised draft of the patient information leaflet. Members commented that the document was quite complex and would not be easily accessible to the general public and particularly not children. It was queried whether the final documentation had been finalised as yet. The applicants explained that the team was currently liaising with key stakeholder groups including CYP via contacts within Epilepsy Action, Epilepsy Scotland and Young Epilepsy on the information materials to support the audit.

It was further explained that the team was preparing different ways of presenting information on Epilepsy12 which can appeal to different audiences in different formats, with different reading levels, but always point towards (a fully RCPCH-house style version) the drafted full document for anyone who wishes to access more complete information. The applicants explained that this would include a range of materials that were currently being tested such as posters, powerpoint slide sets, a short film, scribe videos, animated infographics, all of which will appeal to a different audience and will always reference where more detailed information can be found. The applicants confirmed that they would also be providing guidance to the registered participating Health Boards and Trusts and suggest how to introduce these materials to their patients as well as providing them with hard copies of the full information leaflet.

The response was received and it was acknowledged that the applicants were still working with relevant stakeholders in order to prepare appropriate information materials to support the audit programme. It was agreed that support would be recommended for the proposal; however, feedback would be required at the time of first annual review around the outcome of this further engagement activity, together with copies of the finalised information materials to support the proposal.

<u>Scope of Support – Clarification</u>

A reference had been made in the initial application to the project dataset being used for 'audit, service evaluation or research'. The applicants had clarified in response to a query raised in connection with this point that the RCPCH was not applying to use Epilepsy12 data for research; however, as per the NCAPOP procurement process and the agreed deliverables with HQIP as the commissioning body and Data Controller for the audit, Epilepsy12 data would also be made available for research purposes subject to HQIP's strict data access and sharing processes. It was clarified that the recommendation of support being provided under the Regulations for this application was for non-research purposes only to support the national audit programme and did not extend to the use of the data collated with support for any wider purposes, for example research.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

3. Support extends to England and Wales only.
4. Support is in place for a non-research purpose only to support the audit programme and does not extend to any use of the data collected via this application for research purposes.
5. Provide a report at the time of first annual review of actual patient and public involvement and engagement activity which has been undertaken. This should explain how children and young people were involved in the project. If the responses given are negative, the CAG will take these into account when considering whether support should continue, or whether further actions are required.
6. Provide an overview of further engagement work which had been undertaken in relation to patient notification materials to support the audit programme, together with copies of the finalised documentation, at the time of first annual review.
7. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Net Solving Ltd shows a reviewed satisfactory grade at 97% on Version 14, 2016/17. Royal College of Paediatrics and Child Health shows a reviewed satisfactory grade at 82% on Version 14, 2016/17).**

Application title: **Understanding homicide against family carers: Expanding the focus from individual- to contextual-relational factors-A Phase II Analysis**
CAG reference: **17/CAG/0114**
IRAS project ID: **223746**
REC reference: **17/NW/0234**

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland	Yes	Vice Chair
Dr Rachel L Knowles	Yes	
Mr Andrew Melville	Yes	Lay
Ms Clare Sanderson	Yes	
Dr Murat Soncul	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from Mersey Care NHS Trust set out the purpose of undertaking qualitative research to gain a wider understanding of circumstances and processes under which homicide against a caregiver by an individual with a mental health diagnosis occurs. The applicants have devised a multi-level framework which will be utilised to analyse the clinical records of six patients currently detained in secure services with a conviction of murder or manslaughter against a family carer. The purpose of the study is to identify risk and protective factors in these cases to inform prevention or reduction of violence by patients with a mental health diagnosis against caregivers and to inform future research directions. The overarching aim is to inform the development of carer safety guide for use in routine clinical practice.

A recommendation for class 2, 4 and 6 support was requested to cover activity as described in the application.

Confidential Patient Information Requested

Cohort

The cohort will involve the records of six patients within the Mersey Care Trust region detained in High Secure Services with a conviction of murder or manslaughter between 2002 and 2015, of their Mother,

Father, sibling or current or ex -spouse/partner, where the victim was over 16. Patients will have a range of diagnoses from psychosis, depression.

The applicants will have access to the full clinical record of the patients involved in the study; however, identifiable data will not be extracted as this is not required for analysis.

The applicants will, if possible, collate the following items to support analysis:

- Age at time of event,
- Sex,
- Ethnicity.

Confidentiality Advisory Group Advice

A Sub-Committee of the original reviewing Members considered a written response from the applicants to the request for further information issued as part of the provisionally supported outcome, issued on 09 September 2017.

1. **Confirm whether postcode will be extracted from patient records. If so, clarify whether this would be in a complete format or reduced to be less-identifiable.**

The applicants confirmed that postcode would be extracted a reduced format, which would be the first three digits only.

The Sub-Committee received the response and no further issues were raised in this area.

2. **Provide an updated GANT chart detailing the timeframe for the project.**

A revised GANT chart was provided with updated study timeframes.

The applicants provided a revised GANT chart proposing an updated study timeframe which was received by the Sub-Committee.

3. **Clarify the duration of support requested under the Regulations, taking account of the discussion referenced around the potential risk if re-identification of patients from the anonymised data set.**

The applicants confirmed that they were seeking support under the Regulations for 12 months, to cover the period of data extraction and report writing.

The Sub-Committee considered the response together with detail provided below in response to point four to the provisional outcome.

4. **Confirm how long study data will be retained and in what format following the end of the project.**

The applicants advised that an anonymised study dataset would be retained for 10 years in an encrypted excel spreadsheet stored on the secure password-protected server of the University of Liverpool.

The Sub-Committee considered the response provided and whilst it was acknowledged that the applicants were not extracting confidential patient information in a complete format from medical records, concerns were raised around the risk of re-identification from the retained data. Members stated that due to the small sample size and the high-profile nature of patients to be included in the cohort, there was a significant risk that an individual would still be identifiable from the anonymised dataset.

The applicants were asked to reconsider the duration of support requested under the Regulations, or provide further assurances around the anonymisation of the dataset which was to be retained.

The applicants considered the request and advised that, following analysis and prior to archiving, specific sections of the dataset would be deleted and destroyed, which would contained detail which put an individual at potential risk of being identified. It was confirmed that the sections of the dataset entitled 'Perpetrator Socio-Demographics' and 'Perpetrator Professional Contacts' would be deleted prior to archiving. This would include the following key data items: region, incident and incident date, age at time of incident and care coordinator contacts as well as further less specific points.

The Sub-Committee received the response and was assured by the proposed reduction in data retained. No further issues were raised in this area.

5. **Clarification is requested around the data sources to be included – it was acknowledged that some of the data sources referenced as forming part of the patient's health care record were generated outside of the health environment, e.g. Ministry of Justice reports, Tribunal reports. Confirmation was required around who is the current data controller for these data sources in order to determine whether these items are to be considered within the scope of the Regulations support (i.e. if the data controllership responsibility for these records has formally transferred to the Trust) or outside of the scope of the Regulations support (i.e. the external non-health organisation continues to be data controller for these records).**

The applicants confirmed that they would only have access to health reports, which may include reports to the Ministry of Justice or Mental Health Review Tribunals. It was confirmed that Mersey Care NHS Foundation Trust was the data controller for these reports. It was further advised that, were there any replies from the Ministry of Justice or Tribunals regarding these reports, the applicants would not include these within the study.

The Sub-Committee was assured that access would be limited to health data only for the project. No further issues were raised in this area.

6. **Provide a more detailed overview of the publication intentions for the research findings.**

The applicants confirmed that the purpose of the project was to produce a clinical guide, with the potential to be published within a revision of Mersey Care NHS Foundation Trust policy and procedure. In addition, the applicants anticipated that 1-2 papers would be published in peer reviewed journals or conference proceedings.

The response was received an no further issues were raised in this area.

7. **Confirm who the 'not-for-profit' organisation is that will be undertaking data processing, as referenced in the previously completed advice form.**

The applicants clarified that the data extraction and anonymisation processing would be undertaken by the Mersey Care NHS Foundation Trust and data analysis and reporting would be undertaken by the University of Liverpool.

The response was received by the Sub-Committee and no further issues were raised.

8. **Public and Patient Involvement – provide response in relation the following points:**

a. **Provide an overview of the individuals who have been consulted around the project in the preliminary phase, to provide further understanding of their association with the research topic.**

It was explained that representatives of the Service User Research Evaluation (SURE) group were involved in the consultation. This was made up of four service users and one carer. The consultation was chaired by the lead from the SURE group and the focus was to consider alternatives to applying for CAG and consequences for and against asking for consent from participants. The applicants provided background information around the SURE group, explained that all members either experience mental health difficulties or care for someone who does.

The response was received and no further issues were raised in this area.

b. Provide further information around the intentions to continue this public and patient involvement and engagement activity as the project progresses, advising how it is intended that these individuals would be approached and the role they will take in the project.

The following overview was provided around the plans for patient and public involvement to continue throughout the project:

- Direct contact and consultation with the Mersey Care SURE group,
- The tabling of the study at the Research Facilitation Forum (RFF) , which is a forum of service representatives from across Mersey Care NHS Foundation Trust meeting by-monthly,
- Inclusion of the study on the agenda for ARISE (Applied Research Innovation and Service Evaluation) meetings.

The Sub-Committee received the plan for ongoing patient and public involvement.

9. Patient Notifications and Dissent – provide response on the following issues:

a. Confirm whether the Trust currently operates a generic notification system which would include the secure unit at which participants for this project would be detained, which informs patients and staff that research may be undertaken in the unit on occasion. If so – provide a copy of any information materials which are utilised to inform individuals about this.

It was confirmed that the Mersey Care NHS Foundation Trust did not currently operate a generic system to notify patients that the Trust was involved in research.

The response was noted.

b. If a generic system (as described in point 'a' above) is not currently operated within the Trust and/or specifically within the patient unit, it is requested that generic information materials are developed for display within the unit. These materials should inform the patients that research may be undertaken and provide a means for objection to be raised. As detailed above – this does not need to include specifics about the project.

The applicants advised that they had raised this point onto the Chair of the Mersey Care Research Facilitation Forum (RFF) to explore if this system could be operationalised at the site (medium secure and high secure hospitals).

The Sub-Committee received the response and it was agreed that feedback would be required at the time of first annual review around the progress which has been made in this area.

c. It was acknowledged that patients may previously have registered a generic dissent against being included or approached about research – any historic objections should be respected within the project. Confirm agreement to this point and confirm how this would be managed.

Confirmation was provided that should the clinical notes indicate that a patient had recorded an objection against all research involvement, that individual would be excluded from the study.

The Sub-Committee was assured that historic dissent would be respected and no further issues were raised in this area.

10. Recommendation only – the applicants were advised to seek assurance that the proposed data transfer method was compliant with the local IG policies.

The applicants confirmed that this was compliant.

The Sub-Committee received the response and no further issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Patient and Public Involvement and Engagement – provide ongoing reports, at annual review stage, of the activity which has been undertaken with the patient and public group which is associated with the project. If the response received from patient and public engagement and involvement is negative, the CAG will take this into account when considering whether continued support can be recommended.
2. Patient Notifications – provide an update at the time of first annual review around the progress which has been with the Research Facilitation Forum in providing generic notices within sites around the Trust being research active.
3. Favourable opinion from a Research Ethics Committee. **(Confirmed – 13 June 2017)**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Mersey Care NHS Foundation Trust, Version 14, 2016/17 – email received 02/03/2018).**

Application title: **The Street Triage Project V1**
CAG reference: **17/CAG/0187**
IRAS project ID: **225531**

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland	Yes	
Mr Anthony Kane	Yes	
Mr Andrew Melville	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of application

This research study from the University of Sheffield set out the purpose of exploring the experience of service users who have undergone 'Street Triage', and their understanding of its role, purpose and delivery. The research would include observations of practice in multi-disciplinary teams, and aimed to inform future practice in England and Wales.

Street Triage is a health and social care crisis intervention service, based on joint working between various agencies including the police, and designed to improve patient experiences during mental health crises.

The research aims to build an evidence base for the effectiveness of the intervention and will seek the views of NHS patients as well as staff employed by NHS Trusts who are involved with the scheme and Police Officers who work in collaboration with NHS staff on the scheme. The research is deemed important as this new model of care may be incorporated as part of the NHS 5-year Forward plan; joint working between the police and health and social care professionals is likely to become mandated by amendments to the Mental Health Act 1983 in the future.

Support was requested for two aspects of the study: recruitment, via a third party who would send out surveys to patients, and observations of staff working as part of Street Triage Schemes– the researcher would accompany staff on call-outs, and although they would not observe any interactions between patients and staff, there could be incidental disclosure of patient details during the period before and after the interaction.

A recommendation for class 3 and 6 support was requested to select and contact patients to seek their consent, and to allow an authorised user access for the above purpose.

Confidential patient information requested

Access was requested to:

1. Data from Sheffield triage Scheme in relation to patients who were subject to Sheffield Street Triage scheme over an 18-month period between 1st September 2016 and 1st March 2017 (estimated 1000)

   Name
   Date of birth
   Postcode

2. Incidental disclosures of patient details during observations undertaken by the researcher; no information relating to individual patients is to be recorded.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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.

Request for further information

1. Please clarify the time frame for processing of identifiable patient data, for which Section 251 support is required.

The applicant provided further clarification by email sent 11 December 2017; the maximum time period required in order to identify participants and to complete the mail-out, until deletion of identifiable data, would be 6 months.

Members reviewed the response and deemed it reasonable. It was therefore confirmed that support would be in place for a 6-month period.

Specific Conditions of Support

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 20/12/2017)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed for: UK Mail Ltd., Sheffield Health & Social Care NHS Trust and Derbyshire Healthcare NHS Trust – Version 14, 2016/17, Satisfactory reviewed grade.**

Application title: **CRIS Linkage wtih the Office for National Statistics Census Data**
CAG reference: **17/CAG/0204**
IRAS project ID: **235847**
REC reference: **18/SC/0003**

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE	Yes	Chair
Mrs Diana Robbins	Yes	Lay
Ms Clare Sanderson	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from Office for National Statistics and the South London and Maudsley NHS Foundation Trust (SLaM) sets out the purpose of medical research through the establishment of a research database linking mental health records from the South London and Maudsley NHS Foundation Trust (SLaM) with UK Census data and mortality data, held by the Office for National Statistics (ONS), to enable provision of an anonymised data resource for research purposes.

A cohort of people with relevant clinical diagnoses and clinical information will be linked to their data from the UK census from 2001 and 2011. SLaM is a large mental health trust covering a geographic catchment of four London boroughs (Lambeth, Southwark, Lewisham, and Croydon) and a population of around 1.2 million residents. SLaM also provides a range of national specialist services accessed across England. The ONS census runs every ten years and surveys all residents in England and Wales. The census asks after individual-level and household-level circumstances and includes questions around employment/ occupation and worklessness, education, tenure/ type of property, access to household vehicles and heating, number of persons resident in the household, carers, self-rated health and disability, migration, citizenship and ethnicity, language, and religion.

The resulting anonymised database will be used as a research tool to further explore the wider inequalities of patients with a mental health diagnosis. A control cohort will also be established within the database of people who are not known to SLaM services but who were resident within one of the four boroughs covered by SLaM at the time of the census which the applicant has confirmed is out of scope.

A recommendation for class 1, 4 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

The patient cohort is all patients registered in the SLaM CRIS database, which covers approximately 350,000 individuals.

Confidential patient information as detailed below will be provided by SLaM for the purposes outlined. This will be linked to wider sensitive data from the census dataset for analysis.

- Name – linkage,
- Date of birth – linkage and calculation of age for analysis dataset,
- Gender – linkage and analysis,
- Postcode – linkage and translated to borough/LSOA/MOSA for analysis
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG considered the applicant's written response to the request for further information in correspondence.

1. **Public Interest – further information is required to provide assurance of the public interest in the wider future uses of the database – the following points should be addressed:**
   a. **Provide further information around how applications to use the resulting database will be considered and what criteria will be used when providing approval,**

The applicants confirmed that applications to use the database for other projects would need to be lodged with the CRIS Oversight Committee, as well as with the ADRN approvals panel and the ONS Micro Release Panel (MRP). The applicants provided a detailed overview of the approval criteria for each of the review panels for information purposes and confirmed that no application would be approved unless explicitly approved by all panels.

The Sub-Committee received the response and considered the approval criteria for each of the review panels. Members were assured that the approval criteria appeared robust and raised no further queries.

   b. **Provide assurance that any applications to use the database would have, as an overarching aim, an improvement in the situation of and outcomes for people with mental health problems.**

The applicants provided confirmation that this was a criterion for approval from the CRIS Oversight Committee.

As stated in the CRIS Oversight Committee Terms of Reference, when reviewing applications relating to datasets that CRIS is linked to, the Oversight Committee will consider applications' alignment with the controls used by NHS Digital, such as in accordance with the Care Act 2014 section 122 (3) which states, '…the Information Centre may [disseminate information] only if it considers that disseminating the information would be for the purposes of (a) the provision of health care or adult social care, or (b) the promotion of health.' It was confirmed that the Oversight Committee would only approve applications to use data where applications demonstrate underlying value and potential benefits to the health and social care systems and excluding solely commercial uses of data.

The applicants further explained that when assessing and approving applications to use this database, the ADRN would adhere to any requirements specified by the data owner or the Confidentiality Advice Group (CAG). Should it be a requirement from the data owner or the CAG that applications to use this database would have, as an overarching aim, an improvement in the situation of, and outcomes for, people with mental health problems, the ADRN and the ADRN Independent Approvals Panel are committed to include this as a criteria used by the Approvals Panel when providing approval.

The Sub-Committee received the response and were satisfied that the internal approvals systems would assess applications to use the database to ensure that there was an overarching aim in making improvements for mental health care patients.

2. **It is unclear why the resulting anonymised dataset will be retained by the ONS. Provide further rationale to support these proposed data retention arrangements, or provide confirmation that this can be returned to SLaM for the ongoing retention within the NHS environment.**

It was clarified that the proposed data retention arrangements reflect that the identity of participants is protected under the Census Act and so currently ONS are unable to release their data to SLAM. However, the ONS only retains the linked anonymised dataset in the short term - while research is being conducted. Once the project is complete the linked anonymised dataset is destroyed. As an ADRN approved project there are a number of processes put in place to obtain ADRN approval and these protect the data by providing a secure environment and training for researchers.

ONS' role within the ADRC-E is to provide a secure environment where approved researchers can access the linked data for their project. ONS disseminate the linked data via a secure environment, our Secure Research Service (or Virtual Microdata Laboratory), where the relevant approved researchers can access only the linked data for their approved project.

The Administrative Data Research Centre for England (ADRC-E), and the other national Administrative Data Research Centres within the UK, are tasked with meeting the objectives of the Administrative Data Research Network (ADRN) by facilitating research projects approved by the network. ADRN projects require the legal and secure acquisition of individual-level administrative datasets which are securely linked creating a de-identified research dataset available to approved researchers in a secure environment. ONS may be involved in one or more of these steps but primarily we will provide secure data linkage, and a secure environment where approved researchers can access only the linked data relevant to their approved project.

ONS has a legal obligation to protect the confidentiality of all the information it holds, including datasets we handle during ADRN projects. We have designed systems, procedures and methods for our contribution to the ADRC-E that minimise the risk of inadvertent or deliberate disclosure of any personal information.

All processes for the storage and retention of data take account of obligations in the Data Protection Act 1998, the Statistics and Registration Service Act 2007, Government data security and handling standards and the requirements of individual data suppliers. Once the data have been imported to the linkage facility, the physical media on which the data arrived are either stored securely and separately in a locked safe accessible only to Security Managers, or returned to the data supplier. Once ONS has completed the linkage work all data are returned to the supplying organisation or destroyed using appropriate techniques.

Ultimate responsibility for safe transit is still held by the data owners, so ONS will adhere to any requirements specified by the data owners in making this transfer, and we will provide the CESG approved encrypted media for the data transfer. Where the linked dataset contains ONS data, all activities in transfer are governed by the Statistics and Registration Service Act, 2007. Authority to

transfer will be made by the ONS Microdata Release Panel (MRP) in accordance with instructions from the data owners whose data make up the linked dataset.

The Sub-Committee received the response and no further issues were raised in this area.

3. **Provide confirmation that the patient data from the CRIS database would only be linked to census data by ONS. If it is the intention to link to wider datasets, to collate mortality information and date of death, further information would be required around this proposed linkage.**

The applicants clarified that it was their intention to link CRIS with Census and Mortality data (date and cause of death) via the ONS. The mortality data would not be provided via the CRIS database (i.e. the applicants were not proposing to use the existing CRIS-ONS Mortality linkage). The mortality data would be derived from death registration data held by the ONS. The identifier file would be encrypted and matched to census data before linking the census-mortality data to the CRIS dataset. The applicants provided a revised data flow diagram which clearly reflected this.

The Sub-Committee received the clarification and the revised dataflow chart and no further issues were raised in this area.

4. **Confirm the duration of support which is being requested under the Regulations to cover the application activity.**

The applicants confirmed that they were requesting six months support under the Regulations, in order to allow time for the linkage to be carried out and checked by ONS before confidential patient information was deleted.

The Sub-Committee received the response and advised that notification should be provided when this has been achieved so the application of support can be expired.

5. **Clarification is required around the roles (data controller/processor) which each organisation involved in the project is responsible for.**

It was clarified that within the current project the data was being provided by the South London and Maudsley NHS Foundation Trust (SLaM) and the Office for National Statistics (ONS). It was confirmed thaT SLaM and the ONS would act as data controllers in common with regards to the linked CRIS-Census data. The ONS would also act as the data processor and would conduct the linkage using confidential patient information. The ONS would store and provide access to the anonymised linked dataset.

It was confirmed that the lead applicant (Dr Jayati Das-Munshi) is substantively employed by King's College London and holds a clinical academic contract which allows her to conduct her clinical and research work within SLaM. Within the current project, Dr Das- Munshi is representing SLaM; King's College London have no role in the project with regards to the data.

The Administrative Data Research Network (ADRN) are funding the data linkage and providing administrative and Information Governance support to the applicant. The ADRN have no role with regards to the data.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 19 February 2018).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – ONS – 70% satisfactory on Version 14, 2016/17 and South London and Maudsley – 91% satisfactory on Version 14, 2016/17).**

Application title: **Exploring collaborative working in adult intellectual (learning) disability services**
CAG reference: **18/CAG/0012**
IRAS project ID: **224902**
REC reference: **17/SW/0268**

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice Chair
Dr Harvey Marcovitch	Yes	
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the University of Plymouth sets out the purpose of medical research focusing on how the multi-disciplinary teams involved in the provision of specialised care and support to adults with intellectual learning difficulties (I(L)D) work collaboratively in the provision of this care.

In order to understand how I(L)D services are set up to support collaborative working, the applicant undertake an observation of three different adult I(L)D community teams for one week each. This will provide an understanding of how the services are set up to support collaboration, together with an understanding of what collaboration between professionals in these services looks like. Alongside, interviews will be held with three professionals with a range of roles from each team to understand how professionals themselves understand collaboration in these services. The applicant will also record and examine interactions between professionals in multidisciplinary already occurring meetings. These meetings are one area for which there is an expectation that collaboration occurs, for example to enable care planning for service users.

The focus of the project is on the medical professionals delivering care to patients, not the patients; however, it is acknowledged by the applicant that in shadowing the care professionals and examining the multi-disciplinary meetings, patient confidence may be in directly breached.

A recommendation for class 1 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The applicant will be observing health care professionals who provide care and support to adults living with an intellectual learning difficulty within England.

The applicant is not seeking access to any confidential patient information; however, it has been identified that this may be disclosed incidentally during the course of the observations with staff.

Confidentiality Advisory Group Advice

The Sub-Committee considered the applicants response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide further information around the intended benefits for patients and the wider public from the study, in order to establish a public interest in the activity proceeding.**

The applicants explained that there was a public need for the proposed research. It was explained that most research into service delivery focuses on patient interaction, which is a needed area of research and it is clear how this might impact directly on patient experience with NHS services. Yet, in the light of serious service failure, there is 'No decision about me, without me' imperative (DoH, 2012). This research will investigate how multi-disciplinary teams currently do collaborate. Understanding how I(L)D teams currently work together will help provide best practice guidance for teams to develop their collaborative working to provide the best care possible. Effective collaboration between professionals is in everyone's best interest, to prevent any more gaps in service that could lead to premature deaths and serious harm to members of our society.

The Sub-Committee received the response and were assured that there was a public interest in the research proceeding. No further issues were raised.

2. **Provide further information around which patient identifiers were likely to be revealed during the MDT sessions, and what steps (if any) are being made to minimise this disclosure.**

It was clarified that in the multidisciplinary team meetings minimal patient identifiers were referenced. It was noted that often the patient's name was referred to, and less often date of birth and geographical identifiers would be mentioned. The professionals in the meetings often have access to projected or printed full client information; however, the applicant confirmed that she would not have access or be exposed to these client records.

The response was received and no further issues were raised.

3. **Provide confirmation that no patient data, even in an anonymised form, will be used in analysis.**

The applicants clarified that the focus of the research project and analysis was on collaboration and team interactions, rather than patient data. Thus no patient information would be recorded when undertaking observations of the team, so this could not be used in analysis.

For the MDT meetings, it is likely that patient information would be referred to and recorded. This information will be anonymised on site, and is not the focus of analysis. The applicant confirmed that she would be looking specifically at how professionals talk to each other, and anonymised patient data would not form part of the analysis. Short extracts of recordings would be used in analysis to examine interactions between staff members. An example of the type of extract was provided for information purposes.

The response was received and no further issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 30/11/2017).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Devon Partnership Trust shows a self-assessed grade of 77% satisfactory on Version 14, 2016/17 – email confirmation received 23/01/18 from NHS Digital as satisfactory).**

2. NEW AMENDMENTS

Application title: **The Two Week Wait (2WW) study - an investigation of patient non-attendance at urgent referral appointments for suspected cancer.**
CAG reference: **16/CAG/0060**
IRAS project ID: **201398**
REC reference: **16/NE/0146**

Name	*Notes*
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the Department of Health Sciences at the University of York set out the purpose to investigate the reasons for non-attendance at clinical appointments as part of the two week wait process of referrals for suspected cancer as well as to identify interventions to improve timely access to urgent care. Since 2000, NHS patients with suspected cancer have been guaranteed to see a hospital specialist within two weeks of the GP requesting an urgent referral - a Two Week Wait (2WW) appointment. This policy intended to shorten time to diagnosis and treatment, and ultimately improve survival rates. However, a significant minority of patients are not seen within two weeks, largely due to patients not attending, cancelling or postponing the appointment. Despite audit data identifying the scope of the problem, reasons for patients not attending or cancelling are unknown and no current studies have been identified which are examining this issue.

This study will be completed in five phases:

Phase 1 - Categorisation of patients not seen within two weeks of referral drawing on Leeds NHS Hospital Trust data for approximately 6,000 patients in 2014 and 2015.
Phase 2 - Analyse variation in factors between patients who postpone or cancel their appointment, and those who do attend, to identify predictors of non-attendance. This will use cross-sectional analyses within the same data set as Phase 1.
Phase 3 - Compare rates of cancer diagnosis (and cancer stage at diagnosis) in attending patients with those who postpone, cancel or do not attend to assess the significance of non-attendance. Health outcome data for patients referred in 2009 will be analysed 1, 2,3,4,5 and 6 years later and 1 year later for patients referred in 2014. This data will be compared to similar data from attending patients.
Phase 4 – Explore the views of patients and GPs as to why patients do not attend 2WW appointments and interventions to improve attendance.
Phase 5 – Gain consensus from GP and patient stakeholder groups on the top 3 proposed interventions to improve attendance rates.

The quantitative research in phases 1-3 requires access to non-identifiable, routinely collected patient data via the Leeds Hospital Trusts' Patient Pathway Manager (PPM). The researcher will have access to a limited view of PPM which has been created by the PPM informatics team at the study hospital site using a previously agreed study template. Anonymised medical events and outcomes will be accessed. Consent will not be sought given that this is routinely collected and anonymised data as part of a patients care, and thus not patient identifiable. The quantitative researcher will be based at the study hospital site

under the supervision of the PPM informatics team at all times whilst accessing the study data set. The quantitative researcher (Rebecca Sheridan) will then work alongside these teams to pull the relevant data to a separate research database to conduct analysis from.

Potential patient participants for Phases 4 and 5 will also be identified via the PPM system by the data teams at SJUH following a non-attendance without reason for a 2WW referral for suspected cancer. The research team are the only holders of all the information and expertise to purposively sample the potentially eligible patient participants who should then be approached by their GP to take part in the interview. In addition, data on whether the GP practice with whom the individual eligible patient is registered, has been collected by the research team

Potentially eligible patients for Phase 4 interviews will be identified via their routine hospital records shortly after the patient's non-attendance at their urgent 2WW appointment for suspected cancer. This will be carried out by NHS staff that have the relevant permissions to routinely access and manage this data. Confidential, minimal identifiable patient data regarding eligible patients will be transferred to the research team at the University of York on a weekly basis to capture patients who have not attended their appointment within the last 7 days. On receipt of this information, each potential patient will be checked against study eligibility criteria by the research team who will then notify participating GP practices of a newly identified eligible patient.

Eligible patients will then be approached in the first instance by a personalised invitation letter and study recruitment pack from their GP. Due to the practical constraints to follow-up of non-responding eligible patients by their GP or GP practice, the GP invitation letter will inform the patient that a nominated, experienced researcher will contact the patient within 7-14 days to discuss the study in more detail (if a signed consent form has not already been received by the research team expressing the patient's wish to take part in the study or to not take part in the study). Eligible patients will also be made aware that, subject to their consent, the researchers would like to collect data on their cancer status toward the end of the study. Data linkage with the National Cancer Registration Service would be completed in collaboration with the informatics team at Leeds Hospital Trust to prevent unintended access to non-anonymised data. Eligible patient participants have the option to withhold consent for collection of their cancer outcome data on the consent form whilst still taking part in the study.

A recommendation for class 3 and 6 support was requested to select and contact patients to seek their consent and to allow access to an authorised user for one or more of the above purposes.

Confidential Patient Information Requested

Access was requested to NHS number, NI number, name, date of birth, gender, postcode at the unit level, contact telephone number, registered GP, GP practice and patient postal address.

Amendment Request

This amendment requested an extension in the duration of support up to 31 October 2018. The applicants had experienced issues with recruitment which had caused delays with the proposal.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the Vice Chair who agreed that the rationale provided to support the extension to the duration of support under the Regulations was legitimate and was content to recommend support to this.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Vice Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed – Version 13 (2015-16) reported at a reviewed grade of satisfactory (96%).**
1. Confirmation of a favourable opinion from a Research Ethics Committee. **No requirement for submission of an amendment to REC for a duration extension.**

Application title: **Personalised Risk assessment in Febrile illness to Optimise Real-life Management across the European Union (PERFORM)**
CAG reference: **16/CAG/0136**
IRAS project ID: **209035**
REC reference: **16/LO/1684**

Name	*Notes*
Dr Murat Soncul	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application, submitted by Imperial College Healthcare Trust, sets out the purpose of the establishment of a research database to assess the management and outcome of febrile children who seek medical treatment in hospital whilst providing data for comparative health evaluation and cost effectiveness modelling. The management and outcome of children who seek medical treatment in hospital MOFICHE component of the study will collect routine clinical data on patients presenting to emergency departments and the data will be used for a prevalence study of bacterial illness amongst febrile children in order to study the determinants of diversity between countries in hospital admission, antibiotic prescription and investigations related to clinical signs and symptoms in 50,000 febrile children, of which the UK is to recruit 15,000 children aged 0-18 years. It involves the creation of a large multicentre database holding routinely collected electronic patient information.

A recommendation for class 1, 5 and 6 support was requested to cover the activities specified in the application.

Confidential Patient Information Requested

Access was requested to patient data via hospital databases to allow for the bulk extraction of emergency department presentation data. Date of birth was specified to be the confidential patient data item to be extracted.

Support was requested to enable members of the research team to access patient data from UK hospital databases. It is at this initial stage that researchers will have access to confidential patient information. It was confirmed that the extracted dataset will not contain any identifiable information.

Amendment Request

The patient-facing materials which supported the elements of the study which have support under the Regulations had been revised by the applicants. Copies were submitted for consideration by the CAG.

Confidentiality Advisory Group Advice

The amendment request and revised documentation was considered by the Alternate Vice Chair who was content to recommend support to the revised information materials.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the Alternate Vice Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Imperial College Healthcare NHS Trust, Version 14, 2016/17 reviewed satisfactory grade).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 23/03/2018)**

Application title: **UK Women's Cohort Study - HES**
CAG reference: **17/CAG/0081**
IRAS project ID: **213210**
REC reference: **17/YH/0144**

Name	*Notes*
Dr Tony Calland	Chair
Ms Sophie Brannon	Lay
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from University of Leeds set out the purpose of research through the establishment of a database. The UK Women's Cohort Study was established in 1993 on a consented basis to explore links between diet, lifestyle and chronic disease, in particular cancer. Approval was granted at this from each local REC for the study to follow participants for cases of cancer and other diseases. Individual consent forms were not required by the REC's, therefore those women who returned questionnaires with a completed back page were considered to have provided consent for participation. The back page of the questionnaire informed participants that the purpose of the study was to examine "the occurrence of certain diseases such as cancer which are registered by the National Health Service" and participants were asked to provide their NHS number and GP address in order for their medical records to be accessed. The applicants hold name, date of birth and NHS number against a participant ID number from this historic consented study.

This application proposes the establishment of a new database, which will be generated from the existing cohort held by the applicants as part of the UK Women's Cohort Study. The new database will hold the existing dietary information collated as part of the UK Women's Cohort Study and will be linked with HES and ODR data held by NHS Digital. The applicants propose the disclosure of confidential patient identifiable data from the established cohort to the University of Leeds Integrated Research Campus (IRC). The IRC will then send this information to NHS Digital in order for the dataset to be linked with HES and ODR data for the cohort. This will be returned by NHS Digital to the IRC, whereby the research team will access the information via a Virtual Research Environment.

A recommendation for class 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The cohort is already established and will include all participants within the existing UK Women's Cohort Study, which amounts to 35,372 women.

Confidential patient identifiable information will be transferred from the University of Leeds Nutrition Epidemiology Group UK Women's Cohort data holding to the IRC platform within the University of Leeds to enable the set-up of this new proposed database. Data will then be shared with NHS Digital for linkage and returned to the University of Leeds.

The following items of confidential patient information will be required to facilitate the data linkage to be undertaken by NHS Digital:

- NHS number,
- Date of birth,
- Participant ID.

Amendment Request

The amendment requested approval to link the existing UK Women's Cohort Study (UKWCS) with National Cancer Registry and Analysis Services (NCRAS) data, held by Public Health England and ONS mortality data, held by NHS Digital.

The linkage with the ONS would be undertaken on an ongoing annual basis. Date (in DD/MM/YYYY format) and cause of death would be returned as part of this data request.

The linkage with NCRAS would be undertaken once only and would include return of Cancer Registration (Patient table, Tumour table, and Treatment table), which includes cancer subtype, diagnosis dates (used for survival analysis), site of cancer, and treatment information.

Confidentiality Advisory Group Advice

The amendment requested was considered by a Sub-Committee of the main CAG. It was acknowledged that these linkages were intended as part of the original application; however, the CAG did not have sufficient information around the data flows to recommend support to these wider linkages at that time. The Sub-Committee were satisfied that the amendment documentation clearly described the proposed linkages. Members were assured that there was a public interest in the wider linkages as this was an established patient cohort with value in maintaining ongoing follow-up. The Sub-Committee was content to provide a recommendation of support.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the Sub-Committee agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. (**Confirmed – received 21/06/2017**).
2. Confirmation of a favourable opinion from a Research Ethics Committee. (**Confirmed - University of Leeds Integrated Research Centre shows a reported published score of 88% satisfactory on Version 14, 2016/17).**

Application Reference: **PIAG 4-07(j)/2002**

Application Title: **Evaluation for screening for colorectal cancer**

Name	*Notes*
Dr Murat Soncul	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

Colorectal cancer is the second most frequent cause of death from cancer in the UK. Each year there are 33,000 new cases diagnosed and 19,000 deaths.

Colorectal cancer survival rates in the UK are amongst the lowest in Europe, and much lower than in the US, probably due to the late stage at which most UK cases are diagnosed. When diagnosed at an early, localised stage survival rates exceed 90%; however patients are usually asymptomatic at this stage, in which case cancer can be detected only by screening.

Colorectal cancer is a potentially preventable disease since most cancers develop from polyps, called adenomas, which take many years to become malignant. Polyps can be removed painlessly during an endoscopic examination of the colon.

This application from Imperial College London set out a study aiming to provide valid estimates of the number of colorectal cancers that could be prevented and the number of lives that could be saved by a method of screening, by linking data with cancer registries and the NHS Central Register.

Secondary aims were to examine acceptability, safety, costs and feasibility issues, including:

- The optimum age for the screening and the duration of effect
- Uptake, acceptability, and psychological and physical impact, particularly in disadvantaged subgroups.
- Quality control of all aspects of the procedure
- Feasibility and manpower issues
- Cost-effectiveness.

A recommendation for class 4 and 6 support was requested.

Confidential Patient Information Requested

Access was requested to data on name, address, date of birth, NHS number and GP.

Amendment Request

This amendment request sought support for the following two project changes:

1. Duration Amendment – the project has been extended by a further 10 years (01/04/2017 – 31/03/2027). This will enable ongoing data collection for those patients who received Flexible Sigmoidoscopy Screening as part of the trial to be followed up until they reach the age of 80.

2. Other – Additional Secondary Analyses of data collected – the applicants are proposing to undertake additional secondary analyses of the data which has been collected in order to answer further questions in relation to the trial.

Confidentiality Advisory Group Advice

The amendment requested was sent to the Alternate Vice-Chair for consideration. It was acknowledged that the application activity continued to be within the public interest, so the extension to the duration would enable additional follow-up. Undertaking further analysis on the dataset which had been established in the study ensured the optimum use of the data which had been collated. The Alternate Vice Chair was content to recommend support for the amendment.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the Alternate Vice Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2016/17, 94% Satisfactory)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 08/06/2017)**

Study title: National Confidential Inquiry into Suicide and Homicide by People with Mental Illness

CAG reference: PIAG 4-08(d)/2003

Name	*Notes*
Dr Tony Calland	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

The original application considered by PIAG in 2003 detailed a national study of adverse incidents within the NHS psychiatric services which aimed to improve the clinical care provided.

Amendment Request

The amendment requested changes to the homicide datasheet which is sent to NHS Trusts and Health Boards to identify cases for inclusion. This did not change the information which was requested as part of the datasheet. The amendment also sought approval to extend the duration of support to 31 March 2019 as the inquiry had been awarded further funding by the Healthcare Quality Improvement Partnership (HQIP).

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Chair who agreed that the proposed amendment was fully justified as this ongoing confidential enquiry was in the public interest as suicide prevention remains a high priority. Support was recommended for both elements of the amendment proposal.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2016-17, Satisfactory Reviewed Grade at 77%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(These amendments have been submitted as non-substantial amendments to REC/Assessment and do not require REC review).**