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

JUNE 2019

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1. NEW APPLICATIONS

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

Application title: **Using Health Informatics to Improve Neurological Services**

CAG reference: **19/CAG/0056**

IRAS project ID: **255676**

REC reference: **19/NW/0178**

Context

Purpose of application

This application from Lancashire Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to assess neurological services in the Trust area. Areas which will be explored include an analysis of diagnosis by geographical area and GP, an investigation of appointment types and patient pathways and an exploration of appointment attendance, non-attendance and cancellation. This will provide evidence for future service redesign and the provision of more efficient care.

The applicant will collate routinely collected information from outpatient neurology appointments linked with data extracted from the wider business intelligence data at Lancashire Teaching Hospitals NHS Foundation Trust to create a pseudonymised dataset to be used for analysis. The clinical data would also be linked to publicly available Census information using Lower Super Output Areas (LSOA) for population-based analysis.

Attention was brought to the state of neurological services in 2011 by a National Audit Office (NAO) report entitled ‘Services for people with neurological conditions’. The issues highlighted by this report include delays in diagnoses, incorrect GP referrals, geographical inequalities in access to consultant neurological care, and the lack of good quality data on neurological conditions. Previous studies in other areas such as cardiology have demonstrated that routinely

collected patient data can be used to investigate issues like these. Research has been conducted into areas including re-visit patterns in outpatient clinics, and the effect that diagnosis has on appointment attendance.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover the disclosure of specified confidential patient information from Lancashire Teaching Hospitals NHS Foundation Trust to the student investigator in order to facilitate linkage with wider hospital data sources in order to create a pseudonymised data set for analysis.

Confidential patient information requested

Cohort

All patients who were offered an appointment with neurological services in Lancashire Teaching Hospitals NHS Foundation Trust between the 18 September 2015 and 15 January 2019. There were 5,800 appointments offered within this study period.

The following items of confidential patient information are requested for the purposes set out below:

- NHS number – sample validation and linkage,
- Hospital Number – sample validation and linkage,
- GP registration – analysis,
- Date of birth – accessed to calculate age for analysis,
- Postcode – accessed to calculate Lower Super Output Area (LSOA) for analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

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

1. **Provide further justification to support the requirement to retain GP practice name for analysis. If this is required in its current format, explain why this would be required, or alternatively, clarify how this would be coded within the analysis dataset.**

The applicant explained that GP practice information was necessary for the purposes of analysis to identify whether it is a significant factor in referral rates. This would also enable recommendations for targeted interventions to be made in certain locations (if the statistical analysis supports this). It was recognised that retaining the actual GP practice name could represent a risk for identification, especially in small populations. As such the applicant confirmed that GP Practice name would be replaced in the analysis information with a linked code (the key to which the researcher will not have access to).

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

2. **Provide details of the communications strategy which will raise the profile of the proposed activity within the public arena and offer a mechanism by which patients can object to the use of their data within the study. Copies of any documentation which would be used to facilitate this strategy should be provided for review.**

A poster document was provided which would be displayed in the neurology outpatient clinics at the Royal Preston Hospital (RPH). The document provided details of how objection could be raised. Further details were also provided around the wider patient and public involvement and engagement activity which was planned.

The Sub-Committee received the documentation and supplementary information and raised no further queries 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 - Lancashire Teaching Hospitals NHS Foundation Trust has a satisfactory grade on V14.1, 2017/18).**

Name	*Notes*
Ms Sophie Brannan	Lay Member
Dr Tony Calland MBE	Chair
Dr. Liliane Field	
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Deciphering AMD by deep phenotyping and machine learning - PINNACLE retrospective study**

CAG reference: **19/CAG/0046**

REC Reference: **19/WA/0079**

IRAS Project ID: **259360**

Context

Purpose of application

This application from the University of Southampton set out the purpose of medical research which aims to use retrospective medical imaging and clinical data understand whether machine learning computer algorithms can be used to discover imaging markers of retinal aging and to predict individual progression and conversion to late Age-Related Macular Degeneration. This is a collaborative project which involves sites in Vienna and Switzerland combining anonymised patient images and information to test computer software.

University Hospital Southampton Foundation Trust and Moorfields Eye Hospital will be providing patient images and data in England. Optical Coherent imaging tomograms (OCT) images will be extracted from clinical databases on site the company which created the imaging software. The images will include confidential patient information which cannot be removed prior to extraction. The research team will use the confidential patient information present on the OCT images to wider clinical information within the patient's hospital record. Once linked, all items of confidential patient information will be removed from the dataset which will be used in the study analysis. A linkage file will be created and held onsite by a member of the clinical care team.

The study will also request supplementary information and samples from the UK Biobank; however, this information will be released to the applicant in an anonymised format and is out of scope of the CAG application.

Support is requested to allow the extraction of confidential patient information from patient records at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital by the software company which designed the OCT imaging software. Support is also required to enable the research team to use specified items of confidential patient information to facilitate the linkage of OCT images and wider clinical data held within patient's medical records.

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

Confidential patient information requested

Cohort

Patients aged over 50 years who underwent OCT imaging at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital. It is estimated that 72,000 scans will be included from these sites. The time frame for patient inclusion is 01/01/08-31/12/18.

The following items of confidential patient information are requested for the purposes described:

- Name – present on extracted OCT images,
- Hospital ID – to facilitate linkage,
- Sex – 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 detailed in the provisionally supported outcome in correspondence.

1. Confirm the start and end date of the patient inclusion timeframe.

The time frame for patient inclusion was confirmed as 01/01/08-31/12/18.

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

2. Provide further information around the cohort size to explain how many patients would be included in the overarching sample of 13,000 scans.

The applicant responded to explained that when checking through the practicalities of extracting the data, it had been discovered that the initial estimations provide in this area were extremely conservative. From Moorfields the number of patients will equate to about 25,000. From Southampton this figure is around 47,000.

The Sub-Committee acknowledged that the scope of support had been extended considerably from the initial estimation. Members recognised the identified public interest in the proposal and were content to provide a recommendation of support.

3. **Clarify discrepancies between the items of confidential patient information cited as required for linkage between the CAG application form, the protocol and the data sharing plan. Confirmation is required of the specific data items which would be used to facilitate linkage within the English sites.**

The applicant confirmed that patient ID would be used. This will be changed to a study ID as the point of linkage of image data (OCT scans) and electronic medical information.

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

4. **Confirm who would facilitate the linkage between OCT scans and wider clinical information which would be used for analysis.**

It was clarified that this would be facilitated by the local NHS IT department who will provide access to the OCT scans and wider clinical information. The data manager from Vienna would link the records, using their software, while being overseen by a member of the local research team.

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

5. **Provide finalised drafts of website text which would be displayed on the Southampton University and Hospitals Trust websites for consideration. It is noted a telephone number and postal address should be provided to facilitate dissent.**

The applicant provided a draft of the website text for review.

The Sub-Committee considered the document which was provided. Members commented, from the detail presented, a member of the public may struggle to understand that confidential patient information would be processed to enable the creation of the dataset to be used in analysis. It was also noted that the document did not explain that a legal basis had been established, via seeking support under Section 251 of the NHS Act 2006 and its Regulations to legitimise the processing which would be undertaken without consent.

It was also noted that the text made reference to the Information Commissioner's Office but did not provide explanation of what the entity was. It was also noted that the ordering of the text could be changed to provide the project specific objection mechanism prior to informing patients that future research would be carried out on an anonymised dataset.

The Group agreed that further work was required on the drafted website text to make this more accessible to a lay audience. It was agreed that support under the Regulations would be recommended on the basis that this revised text was provided within two months of this outcome letter.

6. **Confirm that patient notification information would also be displayed on the Moorfields Eye Hospital website.**

This was confirmed.

No issues were raised by the Sub-Committee.

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)

3. The website notification text should be revised to address the following points. A copy of the final draft should be provided within two months of the date of this letter for review.
    a. Provide a clearer explanation that confidential patient information would be processed in order to create the analysis dataset,
    b. Explain that a legal basis in relation to the common law duty of confidentiality had been established to legitimise this processing without seeking direct consent from patients,
    c. Information around the patient's right to object to the inclusion of their data in this study should be relocated to an earlier point in the text,
    d. It is recommended that the reference to the Information Commissioner's Office is explained.
4. Favourable opinion from a Research Ethics Committee **(Confirmed 20 March 2019)**
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: University Hospital Southampton Foundation Trust and Moorfields Eye Hospital both have published satisfactory reviewed grades on V14.1, 2018/18.)**

Name	*Notes*
Ms Sophie Brannan	CAG Lay Member
Dr Lorna Fraser	CAG Member
Dr Murat Soncul	Alternate Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis: Mascot Registry**

CAG reference: **19/CAG/0053**

IRAS project ID: **261989**

REC reference: **19/LO/0495**

Context

Purpose of application

This application from the University College Hospitals London NHS Trust set out the purpose of medical research which aims to establish a research database of patients with Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT) to use this to investigate demographics, clinical features, co-morbidities, outcomes & UK treatment practices for MPN-SVT enable future clinical trial design and facilitate regulatory approval decision-making. MPN-SVT is rare. It is life-long, affects young people, especially women and comprises three separate but connected set of problems occurring more or less simultaneously: bone marrow cancer, severe thrombosis, liver plus intestinal damage. The database will enable documentation of the prevailing situation and prospective information in UK and can help improve care pathways in UK for these patients.

Data will be collected from participating sites in England and Wales and entered directly into an online data platform hosted by Dendrite Clinical Systems Ltd. Information from the research database would only be released in an anonymised format to any applying researchers.

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

Confidential patient information requested

Cohort

Patients, aged 18 years and over, treated at participating Trusts throughout England and Wales, who have the relevant clinical characteristics to confirm a Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT) diagnosis. Patients will be included both retrospectively and prospectively for newly diagnosed patients.

The following items of confidential patient information will be disclosed by treating clinicians to Dendrite Clinical Systems Ltd for inclusion in the research database. The items of information are required for the purposes set out below:

- NHS Number – sample validation and linkage,
- Hospital ID – sample validation and linkage,
- Date of birth – sample validation, linkage and analysis,
- Date of death – analysis,
- Postcode (District Level) – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A sub-committee of the CAG considered the applicant's response to the request for further information detailed within the provisionally supported outcome in correspondence.

1. **Provide further information around the pilot exercise which was undertaken in 2018, clarifying what basis, in relation to the common law duty of confidentiality had been relied upon to support the disclosure of confidential patient information.**

The applicant explained that this was a service evaluation exercise carried out across six hospital Trusts, which provided pseudonymised data linked by unique centre-specific identifier. It was confirmed that confidential patient information was not provided by local centres. Each centre provided data collected under the supervision of the Haematology Consultant responsible for the patient's care.

It was explained that the 2018 exercise differed from the proposed registry in that the registry plans to collect NHS number of patients to avoid duplication between sites (eg. chemotherapy in Liverpool and liver transplant in Birmingham) and to facilitate cross-linking with wider NHS datasets as patients suffer multiple co-morbidities. The applicant advised that this was of value of the registry in terms of quality of information, contribution to other national datasets and contribution to service developments for these patients across UK is enhanced by collecting the NHS number, date of birth and stem postal code.

The response was received, and further queries were raised by the Sub-Committee.

2. **Provide a stronger justification to support why consent is not feasible for the retrospective living cohort and those patients who are prospectively included. Clear articulation is required to explain why consent cannot be taken for each sub-cohort of patients.**

The applicant provided a detailed overview of the reasoning to support the establishment of the registry proceeding on an unconsented basis. This included the complexities of identifying patients due to rarity of these conditions which are not reportable to wider registries, the difficulties for clinicians who identified and reported conditions outside of clinic and the purpose of the registry to understand service provision and facilitate wider research, which had specifically been identified as an unmet need by patients.

Option to reduce the identifiability of the dataset were also considered together with alterative consenting options. Specific patient was provided from patient members of the Registry Review Committee, which supported the project proceeding with support under the Regulations.

The rationale was received by the Sub-Committee which was assured that consent was not feasible. No further queries were raised in this area.

3. **A clear overview of the data flows to support the creation of the research database is required, including clarification of the items of confidential patient information which would be stored locally at Trust sites and those which would be transferred to the centralised database held by Dendrite.**

A data flow diagram was provided together with an overview of the items of confidential patient information which would be stored locally by Trusts and centrally by Dendrite in the registry dataset.

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

4. **Patient-facing information materials should be revised to address the following points:**

    a. **A postal address and telephone number should be added for the purposes of patient objection,**
    b. **Reference to the review by the CAG should be amended to read: 'The Health Research Authority has supported the application to process confidential patient information without consent for the purposes of the project, following guidance from the Confidentiality Advisory Group'.**
    c. **It is recommended that the formatting and style of the documents be reconsidered to ensure this is readable and accessible to a wider audience.**

Revised materials were provided which addressed the points raised by the CAG.

The Sub-Committee received the documentation and raised no further queries.

5. **The protocol for applications to access the database and subsequent review and approval process should be finalised and submitted for consideration.**

This document was provided for review.

The Sub-Committee received the document and raised no further queries.

6. Confirm that the legal basis being relied upon for processing special category data in relation to the GDPR was Article 9(1)(J) – research purposes.

This was confirmed by the applicant.

No queries 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)

6. Support extends to data generated in England and Wales only.
7. Favourable opinion from a Research Ethics Committee (**Confirmed 21 May 2019**).
8. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – Dendrite Clinical Systems Ltd. has a published satisfactory reviewed grade on V14.1, 2017/18)**

Name	*Notes*
Dr Tony Calland MBE	CAG Chair
Dr. Liliane Field	CAG Member
Dr. Simon Kolstoe	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Salford Kidney Study**

CAG reference: **19/CAG/0061**

IRAS project ID: **191925**

REC reference: **15/NW/0818**

Context

Purpose of application

This application from Salford Royal NHS Foundation Trust set out the purpose of medical research which aims to follow-up historic deceased participants of the CRISIS study to establish a cause of death.

The CRISIS study was a consented longitudinal study which merged, along with other kidney-based research projects, into the Salford Kidney Study. At this stage, patients were re-consented to their ongoing involvement in the refreshed project. However, there were a small number of patients who were originally recruited to the CRISIS study that were deceased at this stage for whom cause of death has not been recorded. This application has been submitted to seek support under the Regulations to legitimise the disclosure of confidential patient information from the Salford Royal NHS Foundation Trust to NHS Digital to facilitate linkage with ONS Mortality information to establish cause of death.

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

Confidential patient information requested

500 patients identified as part of the CRISIS study who were diagnosed with chronic kidney disease who died between 1 January 2012 and 31 January 2016.

The following items of confidential patient information will be disclosed from Salford Royal NHS Foundation Trust to NHS Digital to facilitate linkage with ONS Mortality information:

- Study ID,
- NHS Number,
- Date of birth,
- Date of death,
- Cause of death.

Confidentiality Advisory Group advice

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

1. Clarify how long NHS Digital would retain the items of confidential patient information disclosed to facilitate linkage, to provide an overview of the duration of support required under the Regulations for this activity.

The applicant explained that the request to NHS Digital for information on cause of death would be made once. There would be no need for NHS Digital to retain the confidential patient information once the applicant had confirmed to NHS Digital that the required information had been received. The confidential patient information sent to NHS Digital for the purposes of data linkage could then be deleted. The applicant anticipated that the confidential patient information would need to be retained by NHS Digital for a maximum of seven days, after the request had been fulfilled.

The Sub-Committee received this response and raised no further queries in this area.

2. Patient and public involvement and engagement activity should be undertaken specifically to test the acceptability of the use of confidential patient information to collate information on deceased patients without their consent. Provide details of the activity undertaken, the demographics of those involved together with an overview of the feedback provided, If the responses given are negative, the CAG would take this into account when considering whether support can be recommended, or whether any further action is required.

Professor Kalra explained that he had met with members of the Hope Kidney Patients Association, a group who are actively engaged in research and support patient engagement activities across Salford, to discuss the application. Professor Kalra provided feedback from this meeting. He explained that the Association had recognised that the sharing of confidential patient information with NHS Digital was a one-off request and applied to a limited group of patients. Any future requests for cause of death information would be supported by the written consent of the patient. The Association accepted that this data was essential to the completion of the longitudinal dataset on those patients who have now died, and that it would be the wish of patients participating in this type of research that their information is made available.

A letter confirming that the Association were supportive of the application was provided. This also included the names of Association members who attended the meeting.

The Sub-Committee received this response and raised no further queries 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

1. Favourable opinion from a Research Ethics Committee. **(Confirmed: 11 February 2019).**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **(Confirmed - the NHS Digital has a confirmed 'Standards Met' grade on its DSPT submission).**

Name	*Notes*
Ms Clare Sanderson	Alternate Vice-Chair
Mr Marc Taylor	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Anti-thyroid Drug (ATD) Study**

CAG reference: **19/CAG/0042**

IRAS project ID: **250064**

REC reference: **19/WM/0019**

Context

Purpose of application

This application from Royal Devon and Exeter NHS Trust set out the purpose of medical research which aims to follow-up patients who have suffered a reaction to anti-thyroid drugs which led to a very low white blood cell count or liver injury. The study will recruit across a two year window, in which time participating sites will be asked to report eligible patient details for a retrospective cohort across the previous ten years. Patients will also be recruited prospectively from clinic.

The application has been submitted to the CAG to facilitate the recruitment of retrospective patients and patients who are found to be deceased. The applicant has stated that the retrospective patient cohort would no longer be considered to be under the direct care of the hospital clinicians and thus support under the Regulations would be required to enable the patient recruitment process. For historical patients who are deceased, support under the Regulations is requested to access patient records to extract information to be included in the study analysis.

A recommendation for class 1, 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All patients treated at the 11 participating sites in England and Wales who were treated with anti-thyroid drugs and suffered a severe reaction which led to a very low white blood count or

liver. A two year recruiting period would be established where prospectively diagnosed patients would be recruited. A retrospective patient cohort will also be included comprising of eligible patients treated across the previous ten years.

The following items of confidential patient information are requested to facilitate the postal invitation process for the retrospective patient cohort. Wider items of clinical information would also be extracted in relation to the deceased patient cohort for analysis:

- Full name and title – facilitate invitation process,
- Full address and postcode – facilitate invitation process,
- Date of birth – accessed to confirm age eligibility and retained for analysis,
- Date of death – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

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

1. **Provide a copy of the electronic CRF form which would be used in the study, together with an overview of the wider clinical dataset which would be collated for analysis.**

The applicant provided a draft of the CRF form which would be utilised in the study for information purposes. It was explained that this included all data to be collected for analysis. The applicant confirmed that only pages one – nine would be sent to the Society for Endocrinology, with page E being retained by the site.

It was confirmed that only information allowing the initial contact and confirmation of patient eligibility would be collected with support under the Regulations. The remaining data set would only be collected after a patient has provided their consent to the study.

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

2. **Clarify when confidential patient information held in relation to living patients who are approached for consent and either decline participation or do not respond to the request, and deceased patients would be destroyed in order to establish an exit strategy from support under the Regulations.**

The applicant confirmed that this information would be destroyed after the follow-up attempt to contact a patient, which would be made two weeks after the initial documentation had been sent to the patient's home address.

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

3. **A communication strategy should be established to promote the study in the public arena prior to data being extracted for the recruitment process, to allow patients the**

right to object to this approach. Provide details of how this mechanism would be operated together with copies of any documents being used to facilitate it.

The applicant provided a patient poster, which would be displayed in clinics and also via the Society of Endocrinology website alongside further information about the study and the fair processing notice.

The Sub-Committee received the document and wider communications strategy and raised no further queries in this area.

4. **The invitation letter should be revised to include some supplementary introductory information about the project and to explain why patients have been invited to participate. Provide a revised copy of the document for review.**

The applicant provided a revised information sheet which addressed the points raised.

The Sub-Committee received the revised invitation letter and raised no further queries 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 (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission for sites in England (**Not checked – the study will be carried out across nine Trusts in England– security assurance would not be checked for all participating sites. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place**).
3. Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the two Health Board sites in Wales via the Caldicott Principles into Practice report (**Confirmed – CPIP Assurance received by direct email from NHS Wales Informatics Service 15 April 2019**).

Name	*Notes*
Dr William Bernal	CAG Member
Dr Malcolm Booth	CAG Member
Mr. David Evans	CAG Member
Mrs Diana Robbins	CAG Lay Member
Dr Murat Soncul	CAG Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The 'OxMIV' violence risk assessment tool: an external validation study in patients referred to Early Intervention in Psychosis services using routine documentation in Electronic Patient Records.**

CAG reference: **19/CAG/0092**

IRAS project ID: **257332**

REC reference: **19/LO/0498**

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to assess the accuracy of a tool which is used to assess the risk of patients, who are under the care of the community mental health teams as part of the Early Intervention in Psychosis program, turning violent.

The OxMIV tool has previously been trialled in Sweden and the applicant wishes to test its efficacy in England. It utilises data which is routinely collected by clinicians to predict the likelihood of patients turning violent. This study aims to test the accuracy of the tool's estimations on a historic patient cohort. To achieve this, routine information from electronic healthcare records for patients who were previously treated under the Oxford Health NHS Foundation Trust's Early Intervention in Psychosis (EIP) services will be accessed in order to calculate the OxMIV score. Police and health care records will then be checked for evidence of subsequent violence which will be utilised to evaluate the accuracy of the tool.

The applicant will require access to patient's medical records for the 12-month period following the EIP referral to examine for incidents of violence. Access to police records for the same duration would also be required to establish a complete picture of patient violence following the intervention.

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

Confidential patient information requested

Cohort

1300 consecutive referrals EIP referrals, up to May 2018, within the Oxford Health NHS Foundation Trust will be accessed in order to identify approximately 1000 eligible patients for inclusion.

Access to the complete patient record will be required in order to identify eligible patients for inclusion in the study and to enable wider data required for analysis to be extracted. The following items of confidential patient information are specifically required for the purposes set out below:

- Name – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date of Early Intervention Service referral – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

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

1. **Confirm whether the OxMIV tool will be applied to all 1000 patients included in the study.**

The applicant explained that in order calculate the predictive accuracy of the OxMIV tool, information on the ratings made by the tool for both the individuals who went on to develop the outcome of interest, and those who did not is required. It was confirmed that it was not possible to establish the accuracy of the tool without both types of information. Therefore, the tool would be applied to all 1000 individuals included within the study, regardless of whether or not they developed a violent outcome.

The Sub-Committee was assured by the clarification provided.

2. **Clarify the source of third-party data, in relation to the parents and siblings of the patient cohort, and the extent of information to be included in the analysis dataset.**

It was explained that there were three pieces of information required to complete the OxMIV tool that relate to family information. These were parental drug/alcohol use (yes/no), parental violent crime (yes/no) and sibling violent crime (yes/no). This information would be extracted from the

electronic health record in the same manner as the other items for OxMIV, and if present would likely be located within the family or personal history sections of the assessment.

The applicant confirmed that no identifiable information about these family members was required i.e. the information is not triangulated with any sources of information relating to that family member themselves. It was further confirmed that these three parameters would be treated in exactly the same manner as all the other parameters within the OxMIV tool for the purposes of analysis, i.e. any link to the identifiable index individual will be deleted prior to data analysis.

The Sub-Committee received the clarification and raised no further queries.

3. **Provide assurance that the laptop computer to be used in data transfer will be appropriately encrypted.**

The applicant confirmed that the laptop used in all data collection activities would be protected by Whole Disc Encryption.

Confirmation was received by the Sub-Committee.

4. **Feedback from the initial meeting of the project-specific patient and public involvement group is required. Provide details around the demographics of the group and the format of the initial meeting, together with an overview of discussions held and the views expressed by the group around the project and proposed methodology.**

A detailed overview was provided by the applicant around the initial patient and public group, which was held on 11 June 2019. The group consisted of five individuals (three females >40 years of age, and two males <30 years of age). Of these, two have personal experience of recent engagement with Early Intervention in Psychosis (EIP) services, one is currently engaged with EIP services, one is a carer for someone with a severe mental illness, and one has lived experience of a relevant disorder and engagement with non-EIP mental health services.

Following the meeting, which was supplemented by further written information about the specific issues, feedback regarding the use of confidential information was collated.

Of the individuals with personal lived experience, none raised concern about the approaches employed by the study and the use of data without consent. A common comment was noting the potential value to patients of the overall work to develop a tool that was particularly strong at assigning low risk status. One individual commented that they thought the reasons for not contacting 1000 people to gain consent were well explained. Another individual commented on the potential benefits to patients, families and the wider community of the work, as well as for health services, and felt that this made the ‘sacrifice’ of using data without consent worthwhile, and that the safeguards in place to minimise the risks of this seemed appropriate and the overall approach was acceptable.

One individual group member who is a carer did raise some issues. These were that they were unsure whether the ‘ends justified the means’, and it was reported that they felt that effort should be made to contact the 1000 people to both inform them of the study activity and

consent them. This individual was concerned at how statistical methods to account for missing predictor data could be reliable and felt that it was unfair to 'label' people based on this data, and group violent offences together when there was a spectrum of severity.

The Sub-Committee received the feedback from the patient and public involvement activity. It was recognised that the feedback which had been provided was detailed and covered both positive and negative views from attendees. Members commented that the negative views expressed around the project were quite significant and agreed that it would be beneficial for the applicants to undertake further patient and public involvement and engagement activity to ensure that these concerns were not shared more widely. It was agreed that support would be recommended on the basis that further patient and public engagement activity was carried out to explore views about the project. Feedback would be required at the time of first annual review.

5. **Provide copies of the additional information which would be provided to patients in the patient packs for consideration.**
6. **Provide copies of the text to be displayed on the University and Trust websites for consideration.**

The applicant confirmed that the poster document which had been provided in the initial submission would be made available at base sites, in patient information packs and online. It was also confirmed that a privacy notice, in order to meet the GDPR requirements would be displayed on the University of Oxford website. This document was provided for information.

The Sub-Committee received the clarification and supplementary document.

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. Support extends to the processing of confidential patient information from records at the Oxford Health NHS Foundation Trust only. An alternative legal basis has been established to legitimise access to and extraction from the Thames Valley Police database.

2. Support extends to the use of confidential patient information and supporting clinical information extracted from medical records at Oxford Health NHS Foundation Trust within the scope of this project only. Data cannot be used by the applicant or the Thames Valley Police for any wider purposes.

3. Wider patient and public involvement and engagement activity should be carried out to test the acceptability of the project and its methodology with a wider group. Feedback about the activity undertaken and the views expressed is required at the time of first annual review. If the views provided were negative, the CAG would take this into account when considering whether support can continue or whether further work is required.

4. Favourable opinion from a Research Ethics Committee (**Confirmed**).

5. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission (**Confirmed – University of Oxford Medical Sciences Division, Standards Met confirmed 21/06/2019 and Oxford Health NHS Foundation Trust, Standards Met confirmed 01/07/2019**).

2. NEW AMENDMENTS

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

Application title: **Pregnancy Outcome Prediction Study: Transgenerational and Adult Review**

CAG reference: **18/CAG/0024**

IRAS project ID: **228733**

REC reference: **18/EE/0036**

Amendment request

The amendment request is seeking support to link the study's patient cohort to education data within the National Pupil Database from the Department for Education.

Due to ongoing issues around confirmation of the necessary security assurance for the Department for Education, which was originally intended to facilitate linkage, the applicant submitted an amendment to remove this data flow from the overall application activity in December 2018, to enable the wider activity to be undertaken.

The Department for Education has now made educational data available via the Office for National Statistics, acting as trusted third party, for linkage. The amendment is seeking support under the Regulations include the Department for Education datasets as an additional data source for the study and to update the data flows to include the Office for National Statistics as an additional processor. Linkage will be undertaken on name and date of birth.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The CAG recognised that it had been supportive of the proposed data linkage at the initial application review; however, support could not be extended at that time due to the wider issue of security assurance.

The Group was content to provide a recommendation of support to inclusion of the National Pupil Database as an additional data source for the study. It was recognised that utilising the Office for National Statistics as a trusted third for linkage was an accepted secure mechanism.

It was recognised that there was no requirement to revise the patient-facing documentation as the previously supported amendment to remove data linkage with the Department for Education was temporary and patients had been accurately informed of the overall study intentions.

The CAG was content to provide a recommendation of support to the amendment, which was in line with scope of support considered under the initial application.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed: NHS Digital and Office for National Statistics have a published satisfactory reviewed grade on Version 14.1, 2017/18**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed 07/06/2019**)

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

Amendment Request

The amendment is seeking support under the Regulations for the updated supporting study protocol. The following changes had been made at the request of Public Health England, as data provider, to ensure this accurately reflected the scope of the project:

- The application title has been updated,
- Further background information has been added which reflects recent evidence around the origins of inequalities in cancer survival,
- The aims of the project remain unchanged; however, the wording has been revised to make this more accessible,
- References to specific timescales for linkage datasets have been removed from the document. This has been updated to state that linkage will be carried out with the most recent completed dataset to account for available annual updates.

Confidentiality Advisory Group Advice

The amendment requested was considered by Chair's Action. It was acknowledged that the revisions to the protocol were administrative, implemented to ensure the document clearly reflected the project scope.

It was noted that the amendment had also described wider data linkages with national clinical audit datasets; however, the applicant had provided confirmation that these would no longer proceed. The Group acknowledged the revised scope of the amendment and confirmed that the wider linkages were not considered or supported.

No queries were raised with the revised protocol document and the CAG was content to provide a recommendation of support.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

3. Confirmation of suitable security arrangements via DSP Toolkit submission **(Confirmed – Cancer Survival Group, London School of Hygiene and Tropical Medicine, DSPT Standards Met, by NHS Digital email on 11 June 2019).**
4. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed)**