NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

26 March 2015 at 10am – 5pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	Chair for AOB
Dr Robert Carr	
Dr Tony Calland MBE (Vice Chair)	
Mr Anthony Kane	Lay
Professor Barry Evans	
Professor Julia Hippisley-Cox	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms. Amy Ford	Senior Confidentiality Advisor, HRA
Ben Redclift	Observer, HRA
Ms Liz Hunt	University of Sheffield
Ms Ashley Totenhoefer	Observer, HRA
Ms Naomi Masunari	Faculty of Nursing and Human Nutrition Yamaguchi Prefectural University
Mr Phil Walker	CAG 5-05(a) 2014 Southend Pioneer response-item 2a
Mr Darren Sugg	CAG 5-05(a) 2014 Southend Pioneer response-item 2a

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Professor Jennifer Kurinczuk, Ms Clare Sanderson, Dr Murat Soncul, Mr Marc Taylor, Ms Gillian Wells and Dr Miranda Wolpert.

Submission of expense claims

Members were reminded to ensure that expenses were submitted as soon as possible after the meeting due to financial year end.

Action: Members asked for clarification regarding expenses procedures and claim allowances.

2. FOR CONSIDERATION

a) Southend Integrated Care Pioneer [CAG 5-05 (a)/2014]

This non-research application led by the Department of Health in conjunction with Southend Council and Southend Clinical Commissioning Group, sought approval to extend and build upon the NHS England-led risk stratification application (reference CAG 7-04(a)/2013) in terms of identifiers and purposes. The overarching purpose was to enable the linkage of (consented) social care data with risk stratified commissioning data sets as part of integrated care. Access to social care data was excluded from CAG consideration as this was stated to be undertaken on the basis of consent. The application also set out the purpose of planning and assessing care interventions across health and social care needs for individual service users. Provisional approval was provided by the Secretary of State for Health (see minutes dated 11 December 2014) subject to satisfying the outstanding clarifications to enable full approval to come into effect.

Confidentiality Advisory Group advice recommendation

Members welcomed and thanked the representatives that attended by telephone and in person in giving their time to discuss the follow-up responses.

The purpose of the item was to discuss the clarification responses and as a whole, members agreed that the responses and documentation had satisfactorily addressed the clarifications. This included the removal of references to sharing data for non-health purposes, consistency rectification, clarification of the data controller and processor relationships (stated to be confirmed with the ICO) and improved patient notification plan. The recently commenced work to develop clarity of approach to managing patient objection at a national level was noted.

It was noted that separation of the pseudonymisation key from the data processor had been considered but not considered feasible due to contractual constraints. Members advised that as it was understood that the contract will be subject to a tendering process in the near future that any new contract should enable this separation of the pseudonymisation key from the body processing the data.

In reviewing the patient notification plan, members advised that the plan for notifying patients of the proposed activity had been improved and it appeared that reasonable efforts were being made to reach the relevant population, on the understanding that all actions would take place as specified. In considering whether this plan could be seen to be setting a precedent, the Group advised that they considered neither the specific documentation nor approach to set a definitive precedent in terms of the CAG considerations. It was advised that should the applicants wish to seek to establish a precedent in terms of the material and adequacy of the approach, that this should be discussed with the National Data Guardian in her new capacity before seeking to roll out further similar activities.

Members noted that the some documents made reference to the HRA CAG approving or agreeing and noted that in light of the comment above, these should be removed prior to any dissemination. Examples included the media release but related to any such instance in information intended for dissemination. It was advised that any approval or agreement should refer to the Secretary of State for Health (as the legal entity responsible for approving non-research applications) or future engagement with the National Data Guardian as considered appropriate.

Members advised that guidance should be sought on the patient information leaflet in terms of its style and referred to the HRA guidance on suitable style and layout to ensure suitability. As agreed, the CAG had reviewed the letter to be provided to GPs and a reviewed copy was provided as part of the outcome. It was noted that this review had been carried out on an exceptional basis as members considered it critical for GPs to be provided with complete and accurate information to enable them to satisfy their obligations.

Based upon the follow-up documentation and responses, the CAG agreed to recommend to the Secretary of State for Health that support should come into effect for a period of 12 months, subject to the specific conditions of support.

Specific conditions of support

1. In addition to the purpose of linking data to enable risk stratification for commissioning and case finding, four other specified purposes (page 4) are approved. All other purposes are removed from scope.

2. Approval for the purpose of risk stratification will be subject to the existing conditions set out in relation to the risk stratification application CAG 7-04 (a)/2013. There can be no deviations from these conditions.

3. Effective design, harmonisation and implementation of handling and respecting patient objections to be in place prior to any data flows taking place.

4. Removal of any text from all documentation (now and future) stating that approval or agreement has derived from the HRA Confidentiality Advisory Group. Correct approval/agreement must be factually correct to reflect the Secretary of State for Health.

5. The applicants to make available to any person who requests it the full application documentation (subject to any other existing legal constraints)

6. Age to be used for the purposes of analysis instead of full date of birth

7. Any purposes relating to innovation should be submitted as an individual application on a case by case basis as these develop as currently the scope is unknown and it would be unclear what would be supported.

8. Evaluation of benefits realised through new approach to be provided at annual review stage (no later than 12 months following date of final approval)

9. Any new contract should contain provision to ensure separation of the pseudonymisation key from the data processor

10. The communication plan as specified to be implemented.

11. Following final approval, a report to be provided to CAG at a six-month interval on progress, issues, patient objections and communications

12. GP letter to be revised in line with advice from Dr Calland.

13. Confirmation from the HSCIC IG Delivery team that those processing data have achieved a satisfactory IG toolkit level.

Action: Chair to escalate CAG advice in relation to establishing precedent for patient notification plans for activities of this nature to the National Data Guardian.

3. NEW APPLICATIONS – Non-research

a) MBRRACE-UK – Delivering the national Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) [15CAG0119]

This application from University of Oxford set out the purpose of the Maternal, Newborn and Infant Review Programme (MNI-CORP) which is a national programme which aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events.

A recommendation for class 2, 4 and 6 support was requested to cover access to confidential patient information from ONS and NHS Trusts. Patients treated between 1 Jan 2009 and 31 March 2017 would be included.

Access was requested to name, postcode, NHS number, date of birth and date of death in relation to maternal deaths, maternal morbidity, late fetal losses, late terminations of pregnancy, stillbirths, neonatal deaths and perinatal morbidity and mortality.

Confidentiality Advisory Group Advice

Members agreed that the information submitted was comprehensive and thanked the applicant for providing a detailed submission. It was noted that this was a result of several amendments being submitted to an existing application and the submission incorporated all of these and detailed the ongoing work following an extension to the contract until 2017.

Public interest

Members agreed that the specified outcome were of significant public benefit and agreed that they were supportive of the application in principle.

Practicable alternatives

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

Members agreed that the applicant had fully evidenced why consent would not be feasible within the application form.

Members queried whether the applicant had considered receiving information from the Neonatal Data Analysis Unit at Imperial College rather than collecting this directly from Trusts. Members queried whether this would contain the information required and be an alternative to receiving identifiable data in some circumstances. It was noted that support would still be required for some elements and members agreed that they were supportive where it did not prove possible to use anonymised data from another source. Members requested that the applicant provide further information in relation to the feasibility of utilising a secondary data source in an anonymised format as specified above.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for further information

1. Members requested that the applicant provide further information in relation to the feasibility of utilising a secondary data source in an anonymised format as specified above.

Specific conditions of support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

4. NEW APPLICATIONS – Research

a) Decision-making for intensive care unit admissions [15CAG0116]

Purpose of application

This application from University Hospitals Coventry and Warwickshire NHS Trust set out the purpose of investigating how clinical decisions are made in the best interests of the patient to determine admission into ICU or palliative care and how the process of assessment can be improved. The applicant would be observing the process across six hospitals to establish current practice and evaluation through interviews with ICU doctors, referral activity to ICU and family views on how the decisions should be made. For part of this study, consent would be obtained.

A recommendation for class 1 and 6 support was requested to cover access to allow an authorised user for the purpose of extracting and anonymising the information.

Confidential patient information requested

Access was requested to allow disclosure of confidential patient information for the purpose of anonymisation. This would include work package 3 where access to health records will be required in order to extract anonymised data within 3 NHS Trusts. Work package 4 would require a research nurse to identify the health records of a consecutive series of patients where a referral to ICU was received and to extract information for anonymisation within 5 NHS Trusts.

Confidentiality Advisory Group Advice

Practicable Alternatives

Members commented that for part of this study, consent will be sought. Members noted that the request for support was necessary in order for the research team to access health records to extract data for the purpose of anonymisation, and that the activity would take place within hospital sites.

Patient Notification

Members noted that patient materials were to be made available at hospital sites providing information regarding the research study. The members agreed that specific materials regarding the opportunity for patient opt-out was not required as it was deemed unnecessary and may be intrusive at that point of the patient's treatment.

Public interest

Overall, the members were enthusiastic and satisfied with the application and information submitted. The members highlighted that this study was a high public benefit with a limited access to number of patient's health records as consent would form a large part of the study.

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.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) Life after prostate cancer diagnosis [15CAG0110]

This application from the University of Leeds set out the purpose of conducting a survey to assess the health-related quality of life in men, twelve months after prostate cancer diagnosis. Support had been requested to permit the disclosure of confidential patient information from the National Cancer Registration Service (NCRS) to the survey provider (Picker) in order to carry out the patient survey. This will require the survey provider to carry out address tracing and mortality checks prior to sending the surveys to the identified individuals. The research team will also utilise qualitative methods with consent to assess health-related quality outcomes to inform healthcare policy and service delivery.

A recommendation for class 3, 5 and 6 support was requested to cover access to allow an authorised user to select and contact patients to seek their consent and for the purposes of auditing, monitoring and analysing patient care and treatment.

Access was requested to obtain name and address for the purpose of sending the surveys to the identified patients. Prior to sending out the survey, the survey provider, study team and funder, will write directly to Chief Executives and the Prostate Multi – disciplinary leads for permission to survey the men who had received treatment within local NHS Trusts. Confirmation will also need to be sought to ensure that the patient had prostate cancer and to filter any patients where it is thought that contact would not be appropriate.

Confidentiality Advisory Group Advice

Feasibility of consent

Members highlighted that the methodology applied to this survey was similar to surveys which had been carried out nationally and agreed that consent would not be feasible as the application had been submitted to obtain support in order to trace and contact participants. The members noted that consent would be obtained for telephone interviews and this falls out of scope of the regulations.

Patient Notification and Opportunity to Dissent

Members commented that the only option for participant opt-out was through the survey provider study centre and questioned the extent to which participants would be able to review the patient notification and the associated study information. Members questioned as to whether any of the cohort is currently receiving treatment, if so, further efforts should be made at a local level to inform participants of the disclosure of data and the mechanisms established to enable opt-out of the survey. It was noted that if the cohort was entirely retrospective, there would be limited opportunities for the access and review of patient notifications.

Justification of identifiers

Members agreed that the identifiers were necessary for the purpose of tracing and contacting patients to participate in the survey, however, the members had highlighted that the identifiers should only be retained to enable this purpose and should be deleted by the survey provider once this activity had been completed. The members requested clarification regarding the purpose for retaining the identifiers for fifteen years.

Extraction of Disease and Treatment Information

Members requested confirmation as to whether the disease and treatment information will only be extracted from the NCRS and sent to the analysis centres, for patients who had returned the questionnaires and registered their consent. The data in relation to non-responders would have demographic details only.

Contact Details for Telephone Interviews

Members noted that on page 30, the application requested support for access to participant contact details that had consented for the research team to contact them for telephone interviews. Members advised that this was not included as part of the recommendation of support, as prior consent had been in place.

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. Confirmation as to whether it is a retrospective study only, if any of the cohort was still receiving treatment, members had advised that further efforts should be made at a local level to inform participants of the disclosure of data and the mechanisms established to enable opt-out of the survey.

2. Telephone interviews were not included as part of this support, as prior consent would be in place.

3. Confirmation regarding what data and identifiers would be retained, for what purpose and duration of retention.

4. Confirmation that disease and treatment information will only be extracted from the NCRS to send to the analysis centres, for the patients who had returned the questionnaires and registered their consent. The data in relation to non-responders would have demographic details only.

5. Favourable opinion from a Research Ethics Committee.

6. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

c) Validation of Risk Assessment tools in CFCAMHS [15CAG0118]

This application from University of Manchester set out the purpose of a research study which aims to contribute to the knowledge about risk assessment in children and young people in contact with forensic community mental health services. It will also promote the development of a standard risk assessment schedule to improve the communication of information about risk, and to provide cohesion and consistency among disjointed services with a potentially high risk population.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information from Community Forensic Child and Adolescent Mental Health Teams in relation to patients treated over a one year period

Access was requested to name, NHS number and date of birth in order to link NHS data to data held on the Police National Computer.

Confidentiality Advisory Group advice

Public interest

Members agreed that the study outcomes would be of significant public interest and agreed that they were supportive of the activity in principle.

Practicable alternatives

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

Members noted the assertions within the application that consent would not be feasible due to potential bias and agreed that in this instance it appeared to be difficult to obtain consent and also maintain the validity of data collected. However, members were pleased to note that the applicant intended to test whether consent could be obtained at some sites and requested that the results of this pilot were provided to the committee for information and would welcome the opportunity to discuss with the applicant in person.

Patient information leaflet

Members reviewed the information leaflet provided and noted that there were some inconsistencies in the assurances provided. In one section, What will my child have to do if they take part, it stated that if the recipient was happy for the researcher to talk to the young person they would not need to do anything. In another, Do I have to give permission, it was suggested that if the recipient did not want the young person to be included they should not send back the consent sheet and they would then not be included. Members requested that the applicant ensure that the repercussions of not returning the consent form were clear.

In addition the information sheet referenced the National Information Governance Board and it was advised that this should be amended to reflect that CAG had reviewed this.

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

a) Applicant to ensure that consent form is consistent and submit the final version.

b) Favourable opinion from a Research Ethics Committee.

c) Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

d) Avoidable mortality from in-hospital cardiac arrest study [15CAG0113]

This application from London School of Hygiene and Tropical Medicine set out the purpose of study which aimed to determine the association between different services aimed at identification of patients at risk of deterioration and their subsequent management and ward-based cardiac arrest rates and outcomes. The applicant will investigate on the implementation and effectiveness of services and the differentiation of arrests and outcomes within hospitals as new services had been introduced. It is the objective of the study to improve outcomes for all patients and to reduce avoidable mortality. This study will also involve carrying out a staff survey with consent.

The application of support was requested to permit the disclosure of confidential personal information from Intensive Care National Audit and Research Centre (ICNARC) to the Health and Social Care Information Centre (HSCIC) in order to carry out linkage with Hospital Episode Statistics (HES) and Office for National Statistics (ONS) Mortality and outcome data.

A recommendation for class 4 and 6 support was requested to cover access to allow access to an authorised user for the purpose of linking patient identifiable information obtained from one or more source.

Access was requested to link NHS number, date of death and postcode in order to carry out the linkages specified above.

Confidentiality Advisory Group advice

<u>Patient and Staff Notification</u>

Members commented that there had been no attempts to provide patients and staff with information regarding the study, the disclosure of data and how to opt-out. Members highlighted that prior to disclosure; efforts should be made to provide patient notification materials and to inform patients of the mechanisms in place to opt-out.

Research Ethic Committee Favourable Opinion

Members agreed that it is necessary for the applicant to consult with the NHS Research Ethics Committee (NRES) and to submit an application for favourable opinion. Members requested that once favourable opinion had been received; the applicant will be required to submit it to CAG. Members highlighted that due to the small number of staff who is to be surveyed within each hospital, there is potential for staff to be re-identified.

Justification of identifiers

Members agreed that the identifiers were necessary for the purpose of linking ICNARC, HES and ONS data, however, the members had highlighted that the identifiers should only be retained to enable this purpose and should be deleted by the research organisation once this activity had been completed. The members requested clarification regarding which organisation will be retaining date of death, the retention period and for what purpose is it to be retained.

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. The members requested clarification regarding which organisation will be retaining date of death, the retention period and for what purpose is it to be retained.

2. Provide patient information materials.

3. Favourable opinion from a Research Ethics Committee.

4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

e) National investigation into suicide in children and young people [15CAG0120]

This application from University of Manchester set out the purpose of a multi-agency designed study combining available sources of information on cases of suicide and probable suicides in those aged 20 and under to provide a range of information at individual patient level that is currently not available. The study aims to identify the

characteristics and antecedents of young person suicide and use these findings to help inform policy and safer practices with a view to reducing suicide rate in this age group.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover researcher access to confidential patient information from ONS, NHS Trusts Serious Untoward Incident reports and data held on the National Confidential Inquiry's database on individuals under the contract of mental health services prior to death. Scanned documents would be requested from participating organisations.

Access was requested to name, postcode, date of birth, date of death and place of death.

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a clear public benefit to the proposed study outcome and agreed that they were supportive of the activity in principle.

Practicable alternatives

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

Members agreed with the assertions made within the application that consent would not be feasible because patients would be deceased, seeking consent from next of kin would cause unnecessary distress and further information in relation to contact details would be required to allow this to happen.

It was confirmed that data would be pseudonymised upon receipt with limited individuals having access to identifiable information.

Data retention

The Regulations require an applicant to review the requirement for continued processing of confidential patient information annually. In addition, the fifth principle of the DPA specifies that personal data must not be kept for longer than is necessary. With this in mind members queried why the applicant proposed keeping the confidential patient information in identifiable form for 6 years.

Scope of datasets requested

Members noted that a number of health and non-health datasets were specified within the application and advise that support under the Regulations could only apply to those datasets which contained patient information.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised

recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Applicant to confirm why identifiable data needed to be retained for 6 years.

Once received the information would be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible.

Specific conditions of support

1. Support applies only to those datasets containing patient information.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

4. MINUTES OF THE MEETING HELD ON 19 FEBRUARY 2015

The minutes of the meeting held on 19 February 2015 were approved subject to minor changes.

5. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the February 2015 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the February 2015 meeting applications.

Meetings and events

Meeting with HQIP

Dr Tony Calland and Ms Claire Edgeworth attended a meeting with Healthcare Quality Improvement Partnership and NHS England in relation to national audit applications and pursuit of an exit strategy from support. It was confirmed that HQIP would return to CAG in June to clarify options for national audits, confirm results of the information governance review and explain the model being piloted moving forwards.

HRA Social Care Listening event 24th February

Dr Tony Calland and Ms Claire Edgeworth attended a Social Care Listening event hosted by the HRA with the aim of obtaining views from the social care research community about issues faced given the HRA's new remit in relation to adult social care research. It was noted that a follow-up meeting had subsequently taken place between Dr Mark Taylor, Janet Wisely and Ms Deborah Rutter.

Amendments considered by Confidentiality Advice Team

National Paediatric Diabetes Audit - NPDA [ECC 2-03 (c)/2012]

The applicant advised that since the split of the provision of the National Diabetes Audit into Adult NDA led by HSCIC and NPDA at RCPCH a piece of work had been identified by both organisations. This work was a joint enterprise linking datasets from both the adult and paediatric national diabetes audits. The work would be designed to audit diabetes transition care from paediatric diabetes services to adult diabetes services, as stipulated by the National Service Framework (NSF) for Diabetes. The HSCIC working together with the clinical leads and specialists for NDA Adults (NDAA), the NPDA of RCPCH and Diabetes UK would design, develop and deliver the work. The methodology would explore whether the standards of care changed when there was a transition from paediatric to adult care. It was expected that those results would drive improvements by identifying specific changes in glycaemic control and care provision.

The work would involve the RCPCH sending HSCIC the historical paediatric audit data from 2003/4 to 2011/12; this data would need to be retained in identifiable format by the HSCIC for a period of 12 months to allow for the analysis to take place and in line with the NDAA governance controls. HSCIC had already previously sought and received approval from the Secretary of State to amend the current support to cover this piece of work. However, as this project had not started, s251 support had lapsed. A subsequent amendment request had been submitted to the Confidentiality Advice Team to review and recommend support to extend s251 support to cover this project.

Confidentiality Advice Team advice

The amendment was reviewed by the Confidentiality Advice Team who was content to support an extension of the previous amendment on the basis that the HSCIC had already sought and received approval from the Confidentiality Advisory Group to amend the Section 251 approval to cover this piece of work.

Confidentiality Advice Team conclusion

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

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness [PIAG 4-08(d)/2003]

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. This amendment request detailed that the University of Manchester had been awarded a contract to deliver the inquiry for a further three years from 1 April 2015 until 31 March 2018. Dr Alyson Williams, the former lead contact submitted a notification of new end date and lead contact for the inquiry.

Confidentiality Advice Team advice

The Confidentiality Advice Team reviewed the amendment and noted that this was a repeat notification of the application submitted and was therefore the only change was duration extension; there were no changes to the purpose, data flows and data items. This was therefore considered under the precedent set review criteria 8 – Validity of Consent. The Confidentiality Advice team therefore advised the Secretary of State for Health that support should be provided for a further period of 12 months, subject to provision of an annual review.

Confidentiality Advice Team conclusion

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

National Prostate Cancer Audit [CAG 8 – 03(PR9)/2013]

This application refers to a collaborative prostate cancer audit which is part of the Healthcare Quality Improvement Partnership programme looking at treatment and outcomes for all patients. The application detailed the linkage of the HES dataset already held by the Royal College of Surgeons (PIAG 2-07(i)/2004) Audit of outcomes after surgical procedures using linked HES data and ONS mortality data) to cancer registry data held by Public Health England using the Health and Social Care Information Centre's date linkage service.

The amendment request submitted was to extend the timeframe of the patient cohort to include the latest year, which is 2013. This would enable the applicant to carry out an up to date analysis of the process of care of men with prostate cancer and to provide the most current and relevant baseline data for the prospective audit. The aim, purpose and methodology remained the same as the original application.

Confidentiality Advice Team advice

The Confidentiality Advice Team reviewed the amendment and noted that this is a repeat notification of the application submitted and it was therefore considered under precedent set criteria 4: Time limited access to undertake record linkage and to pseudonymise the data. The Confidentiality Advice team advised to continue the submission of annual reviews.

Confidentiality Advice Team Conclusion

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

5. ANY OTHER BUSINESS

a) Research to identify measures of quality and safety of healthcare [15CAG0005]

This application from Imperial College London set out the purpose of the establishment of two databases. The first database would include a monthly and annual pseudonymised extract of Hospital Episode Statistics (HES) from the Health and Social Care Information Centre (HSCIC) on English NHS hospitals for the purpose of research. Data from this database would be provided to the Dr Foster Unit at Imperial College in a pseudonymised format.

The second database would hold a limited set of identifiable fields including NHS number and local patient ID to allow acute provider trusts to identify their own patients contributing to mortality alerts or other quality and safety alerts for the purpose of case note audits and mortality reviews.

A recommendation for class 4 and 6 support was requested to cover disclosure of confidential patient information from the Health and Social Care Information Centre (HSCIC) to Imperial College London.

Access was requested to monthly and annual extracts of HES, including Hospital Consultant Code, General Practitioner Code and Referring Practitioner Code and NHS number, Local Patient ID (LOPATID) and date of death (these three data items would be included on the second database only)

Confidentiality Advisory Group advice

<u>Identifiers to provide re-identification service for all trusts</u>

It was noted that information in relation to the anticipated difficulties and timescales in pursuing this alternative had not been provided from the HSCIC and members advised at the meeting on 26 March that they would require this information prior to recommending support for this aspect as it was currently not clear that this was not a practicable alternative that could be utilised within an acceptable timeframe. It was agreed that the CAT should contact the HSCIC to request this information.

<u>Transfer of data outside the EEA</u>

Members noted that DFI had recently been bought by Telstra Health. It was noted that the application form specified that “All our data are held on a Private Network which exists only within the Dr Foster Unit at Imperial Office on the Ground Floor, 3 Dorset Rise, London, EC4Y 8EN. No data are ever disclosed outside the EU or elsewhere”. It

was confirmed by the applicant that no data would leave the EEA and that data would be processed in line with the original application.

Appendix G

Members thanked the applicant for providing an amended version of appendix G. It was advised that it would be beneficial to amend the DFI email address for lost usercodes to a DFU one to avoid any confusion. In particular as NHS Trusts were informed that inadvertent disclosure to the company would "trigger a security event which may result in access to the service being withdrawn".

Confidentiality Advisory Group advice conclusion

Research database and identifiers to provide re-identification service to DFI customers

CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending conditional support to the Secretary of State and Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below. The recommendation covers the disclosure of the dataset for non-research purposes with two identifiers (NHS number and local patient ID) for patients admitted to hospitals by the HSCIC to Imperial College to support the re-identification service for DFI customers only.

Specific conditions of support

Prior to final support

1. An amended version of appendix G should be provided.

2. The research database must be used for medical research purposes only.

3. It should be ensured that historical data processed under PIAG 2-07(d)/2007 is irreversibly pseudonymised in line with this application. This should be carried out as soon as possible, please confirm when this is complete. New identifiable data processed under CAG [15/CAG/0005] should be retained for a maximum of three years after which it should be destroyed or irreversibly pseudonymised on a rolling basis.

4. It should be ensured that all patient information is as coherent as possible with clear instructions to allow patient objection.

5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

6. Confirmation of a favourable research ethics committee opinion.

As the above conditions have been accepted and met this letter provides confirmation of final approval to receive confidential patient information for the research database and

identifiers to provide re-identification service to DFI customers. Please note the following reporting requirements.

To report on in 6 months (please submit by 29 September 2015 for 22 October 2015 meeting)

7. Appropriate contractual arrangements should be established with trusts who are not customers of DFI; progress towards this should be reported within 6 months.

8. Further information in relation to the discussions with HSCIC around the filtering of datasets and feasibility of them offering the re-identification service for DFI customers should be reported within 6 months.

To report on at annual review stage

9. Consultation with the patient group on the governance and monitoring of the databases should be explored on an ongoing basis and reported at annual review stage.

10. Further possibilities to inform patients should be explored in conjunction with the patient group and further information provided at annual review stage.

Identifiers to provide re-identification service for all trusts

In line with the considerations above, the CAG agreed that further information would be required from the HSCIC in order for a recommendation under the Regulations to be provided. It was noted that information in relation to the anticipated difficulties and timescales in pursuing this alternative had not been provided from the HSCIC and members advised that they would require this information prior to recommending support for this aspect as it was currently not clear that this was not a practicable alternative that could be utilised within an acceptable timeframe. It was agreed that the CAT should contact the HSCIC to request this information as soon as possible.

b) Membership definitions

Members discussed the current lay; lay plus and expert definitions that were currently applied when defining membership capacity. Members were asked to consider whether these remained appropriate. Members raised some concerns about the method of defining member categories in general, however, it was agreed that the current HRA NRES definition provided would be satisfactory. Members asserted that the best method to maintain public confidence in the relevance of skills and experience of members was from ensuring that the biographies included on the HRA website were up to date and comprehensive.

Action: CAT to reference agreed definitions within relevant Standard Operating Procedures.