Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

17 March 2016 at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Tony Calland	Chair; items 2a to 4a
Ms Gillian Wells	Chair; items 4b to 5d
Dr Mark Taylor	
Dr Patrick Coyle	
Dr William Bernal	
Dr Robert Carr	From 11am
Ms Clare Sanderson	
Dr Murat Soncul	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Diane Pryce	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA; item 5c
Mr Christopher Ward	Senior Confidentiality Advisor, HRA
Ms Ellen Lim	Head of Practice Quality Sussex Partnership NHS Foundation Trust; observer
Ms Rae Granville	HRA Guidance & Advice Support; observer; items 2a to 5a

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Professor Julia Hippisley-Cox.

The observers listed above were welcomed to the meeting.

2. ITEMS FOR CONSIDERATION

a) **NHS England amendments.**

i) CAG 2-03 (a)/2013; Application for transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH)

1) Duration amendment request (updated)

Confidentiality Advisory Group advice

In reviewing the updated paper, members wished to highlight two specific aspects as summarised below.

Additional matters:

1. Members noted that the anticipated 'business case' to set out the case for transmission of dual identifiers had not been submitted, and was therefore not considered further.

2. The paper contained a section on patient preference. It was advised that this was a substantial item and lacked sufficient detail and context to be clear on what was to be asked of the CAG. Any consequences had not been specified and it was unclear to which application or amendment this could be linked. In light of this, it was agreed that a view could not be taken and this aspect was not considered further.

Duration amendment

With regards to the amendment requests, updated information was provided following the meeting on 11 February 2016 where discussion had taken place regarding future amendments and discussion as to the proposed exit strategy, with the conclusion drawn that support until 31 March 2017 appeared appropriate for the reference CAG 2-03 (a)/2013. Following clarification by the Advice Team that the extension considered in February 2016 had not sought extended support for the additional references, the paper considered on 17 March 2016 set out a request to extend four other references linked to this application. Outcomes for the different references are provided in separate letters.

The February 2016 report had previously confirmed that this activity was taking place under the umbrella programme called the National Data Services Development programme. The DSfC programme will be the first users of this system and jointly they have developed a release roadmap. A draft version of the road map was provided to the CAG. The phased approach in the roadmap has been agreed with the DSfC Programme Board. Delivery of the national capability for de-identification and re-identification was anticipated to be available for testing during September 2016 and completely rolled out to all DSCROs by December 2016. The de-identification process combined with the contractual and data usage controls will mean that data disseminated by DSCROs will be in accordance to the ICO Code of practice for anonymised data in context. This will therefore form NHS England's exit strategy, and at that point support will not be required.

NHS England therefore requested an extension to the current s251 support to be extended to 31 March 2017 in line with the exit strategy above with a 3 month deployment timeframe to enable full transition of all commissioners to use the HSCIC de-identification solution.

In reviewing the updated information provided in March 2016, Members noted that the paper confirmed there were a significant number of internal and external fluid dependencies, set out in the paper and five attachments, including the outcome from the National Data Guardian review. In light of these dependencies, members advised that they thought it would be appropriate to receive progress updates at three month intervals as progress would determine the length of support, and to ensure that the CAG was fully informed when asked to provide recommendations.

In light of the paperwork, members agreed that support would be recommended to the Secretary of State for Health, and to include specific conditions that there would be reporting to advise of external changes that would impact on the exit strategy, and to ensure clear mutual understanding, across all linked NHS England applications (ASH commissioning, risk stratification and invoice validation). Members also advised that while the information presented was complex, it would be helpful if the applicant could provide clear guidance or highlight those aspects particularly relevant to the considerations of CAG within the paperwork

This positive recommendation was subject to the following:

Specific conditions of support

1. An executive summary to be provided to the June 2016 meeting, in accordance with published timescales, setting out the applicant understanding as to what support covered, purposes data could be used and to whom it applied for the following individual references, so as to confirm mutual understanding:
    a. CAG 2-03 (a)/2013
    b. CAG 7-04 (a)/2013
    c. CAG 7-07 (a)/2013
    d. CAG 7-07 (b)/2013
    e. CAG 7-07 (c)/2013
2. An update/presentation to be provided to the June 2016 meeting of the current status of the programme relevant to the exit strategy, including a clear articulation of what identifiers would be utilised within the definition of ‘anonymisation in context’.
3. Further reports to be provided, against all five references, to the September 2016 and December 2016 meetings providing updates against the timescales presented to CAG; to include:
    a. Status report showing the progress against the timelines described to CAG in February and March 2016

b. Consideration on how the future solution are impacted by emerging issues
c. In light of the dependencies described, and as these become clearer, how the plan has to evolve, and any impact on the solution.

This outcome supersedes the previous duration amendment outcome; the previous outcome is no longer an official record and should no longer be relied upon by data controllers.

ii) CAG 2-03 (a)/2013; Application for transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH)

1. Amendment for inclusion of additional datasets

Amendment request – inclusion of Mental Health Minimum Data set (MHMDS) and Mental Health Learning Disability (MHLDDS) and Maternity Services Data Set (MSDS data sets

This item was originally considered via sub-committee; an update paper was provided to the meeting on 17 March 2016 that sought to provide a response to the conditional support provided following this sub-committee meeting.

Confidentiality Advisory Group advice

Members had previously advised against this amendment request (see previous outcome); the conditional outcome had specified the following conditions of support, and the applicant asked to provide a satisfactory response to enable a final approval recommendation to be provided so that support could come into effect. The outstanding areas and applicant response are summarised below:

1. Applicant to provide clear information to provide assurance that relevant patient information materials are very easily available with information on how to object. This should be provided within 20 working days.

A document titled '*Privacy Notice update for CAG 2-03 (a)/2013 amendment March 2016 v1'* was submitted in response to these conditions.

The paper stated that NHS England had reviewed their approach to privacy notices and highlighted that under the Data Protection Act (DPA) 1998 that local data controllers were responsible for ensuring their compliance to the DPA. Reference was made to the IG toolkit and that NHS England is in the process of strengthening their assurance role. Figures stated that 79% of GP practices had submitted a satisfactory assessment to level 2. The paper confirmed that 100% of CCGs had submitted a satisfactory

assessment and that evaluation of these assessments would be undertaken by the corporate IG team "in due course".

Members noted that the importance of appropriate patient notification, under the terms of this support, was different to the responsibilities placed under the DPA. The Group also advised that they did not consider this response to be comprehensive nor did it address how the inclusion of these datasets would be made clear to the relevant population. Members queried what the status was in relation to those who had not achieved a satisfactory toolkit submission, and specifically in relation to appropriate patient notification. Members were also unclear as to what steps would be undertaken by NHS England to strengthen their assurance role, and were unclear as to timescales for the corporate IG team to undertake the evaluations mentioned.

In particular, members identified that details to enable a patient to object had not been specified within the paper; members therefore agreed that the response had not adequately addressed the requested clarification aspects.

2. **Confirmation as to how NHS England will ensure there are easily available, appropriate patient notification materials, for all those who will receive data under this support**

It was noted the supporting information in relation to the privacy notice from the HSCIC had not been submitted, and although there had been direct communication from the HSCIC to the HRA Advice Team, no formal information had been submitted for consideration in time for the meeting.

Members also identified that the report focused on the fair processing aspect of the Data Protection Act 1998, and had not addressed the concept of patient notification that is a condition of these applications. Members therefore expressed the view that the response provided had not addressed the question posed, and did not make clear how this potential inclusion would be made clear.

Confidentiality Advisory Group advice conclusion

Support to include the datasets specified in (i – iv) was conditional upon satisfactory responses to the further requests for assurance; the responses provided were <u>not</u> considered satisfactory therefore final approval has not yet come into effect.

i. Mental Health Minimum Data set (MHMDS)
ii. Mental Health Learning Disabilities Data set (MHLDDS)
iii. Mental Health Service Data set (MHSDS) (once available)
iv. Maternity Services Data Set (MSDS)

Satisfactory responses should be provided to a full meeting to enable further consideration and to enable a final recommendation to be provided.

Further action

1. Please review this outcome and respond accordingly to the specific conditions of support and issues raised in the letter and previous conditional outcome. The response will be reviewed and when confirmed as satisfactory, a final recommendation will be issued.

iii) CAG 7-04 (a)/2013; Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs)

1. Duration amendment request

Confidentiality Advisory Group advice

In reviewing the updated paper, members wished to highlight an additional aspect as summarised below.

Additional matters:

1. The paper contained a section on patient preference. It was advised that this was a substantial item and lacked sufficient detail and context to be clear on what was to be asked of the CAG. Any consequences had not been specified and it was unclear to which application or amendment this could be linked. In light of this, it was agreed that a view could not be taken at time of the meeting and this aspect was not considered further.

Duration amendment

Members advised that in light of the recommendation provided to CAG 2-03 (a)/2013 that support should also be recommended to this application until 31 March 2017. This was for the reason that the data flows were linked to this original reference and this would ensure alignment in terms of length of support.

In reviewing the updated information provided in March 2016, Members noted that the paper confirmed there were a significant number of internal and external fluid dependencies, set out in the paper and five attachments, including the outcome from the National Data Guardian review. In light of these dependencies, members advised that they thought it would be appropriate to receive progress updates at three-month intervals as progress would determine the length of support, and to ensure that the CAG was fully informed when asked to provide recommendations.

Confidentiality Advisory Group advice conclusion

In light of the paperwork, members agreed that support would be recommended to the Secretary of State for Health until 31 March 2017, and to include specific conditions that there would be reporting to advise of external changes that would impact on the exit strategy, and to ensure clear mutual understanding, across all linked NHS England applications (ASH commissioning, risk stratification and invoice validation). Members also advised that while the information presented was complex, it would be helpful if the applicant could provide clear guidance or highlight those aspects particularly relevant to the considerations of CAG within the paperwork

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1. **CAG 7-07 (a-c)/2013: CAG 7-07 (a)/2013, Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013; CAG 7-07 (b)/2013, Invoice validation within Clinical Commissioning Groups (CCGs) controlled environment for Finance; CAG 7-07 (c)/2013 Invoice validation within NHS England within the Commissioning Support Units controlled environment (for Finance) on behalf of Clinical Commissioning Groups**

1. **Duration amendment request**

Confidentiality Advisory Group advice

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Confidentiality Advisory Group advice conclusion

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    c. In light of the dependencies described, and as these become clearer, how the plan has to evolve, and any impact on the solution.

b) **PIAG 03(a)/2001: National Cancer Registration Databases – amendment to data controller for the National Radiotherapy Dataset.**

Public Health England (PHE) has Section 251 support under PIAG 03(a)/2001 to process confidential information without patient consent under the Health Service (Control of Patient Information) Regulations 2002.

As part of an ongoing process of rationalising and consolidating the management of the data processed to support improvements in the diagnosis and treatment of neoplasia in England, PHE wishes to add the National Radiotherapy Data Set (RTDS) to the existing data items it currently processes without patient consent under PIAG 03(a)/2001.

A recommendation for Class 2 and 4 support was requested to cover access to confidential patient information.

Amendment request

The RTDS collection is currently managed by NATCANSAT under contract to the PHE National Cancer Registration Service, Reference **PIAG 3-09(g)/2003**, Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002; PHE is responsible for paying for and directing the collection, with the support of NHS England and other partners in the Radiotherapy Information Strategy Group.

PHE proposes to assume direct responsibility for RTDS from 1st April 2016 by ending the current contract with NATCANSAT and bringing the management of the collection in-house to PHE.

Dr Peter Kirkbride, Medical Director at NATCANSAT, has been informed of and agreed to the transfer of RDTS to PHE.

Confidentiality Advisory Group advice

Members were in agreement that this request falls in-line with the responsibilities of PHE and were content with the proposal for PHE to take responsibility for the RTDS.

Confidentiality Advisory Group conclusion

In line with the considerations above, the members 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.

c) **CAG 10-02(d)/2015; NCARDRS: National Congenital Anomaly and Rare Disease Registration Service.**

This application from Public Health England set out the purpose of providing continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies for the populations of the North East of England and the West Midlands by means of two regional registers of congenital anomalies, the West Midlands Congenital Anomaly Register (WMCAR) and the Northern Congenital Abnormality Survey (NorCAS). .

A recommendation for class 1,3, 4, 5 and 6 support was requested to cover access to confidential patient information in relation to all deliveries in the geographical regions specified - NorCAS the Strategic Clinical Network area of North East and North Cumbria and WMCAR the former West Midlands (WM) health region or current WM ONS Statistical Region.

<u>Confidential patient information requested</u>

Access was requested to mother's name, address, postcode, hospital number, NHS number, date of birth, baby's name, address, postcode, hospital number, NHS number, date of birth, date of death and address at conception.

i) **Amendment request**.

As part of the ongoing development of NCARDRS, additional national data sources have been identified to help with the core registration functions of case ascertainment and completion. These are as follows:

- Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK)
- Newborn Blood Spot Screening programme
- National Hearing Screening Programme
- National Infant Physical Examination
- ONS births and deaths data
- Badger neonatal
- National Institute for Cardiovascular Outcomes Research (NICOR)
- Private healthcare providers of antenatal screening services
- Private maternity care services
- Private healthcare providers treating individuals with congenital anomalies and rare diseases

National data feeds would reduce the data collection burden on frontline clinical staff, who currently provide the majority of data to NCARDRS.

Additional data items were also requested:

- Consultant - obstetric, paediatric, neonatal
- GP name
- GP practice address
- Details of post mortem - type, results, location
- Cause of death
- Procedures - prenatal and postnatal & dates
- Mother's country of birth
- Place of death
- Referral hospital
- Date of admission/discharge
- Ethnicity of baby
- Rare diseases
- Prescription drugs
- Father’s DOB
- Father’s address, including postcode
- Father’s NHS number
- Morbidities
- Family history of congenital anomaly/rare disease

NCARDRS has reached an agreement with all of the new feeds, with the exception of Badger neonatal (work ongoing) and private services.

Confidentiality Advisory Group advice

The amendment requested was considered at the CAG meeting on 17 March 2016 in conjunction with the annual review for this study.

The Group agreed that the amendment was in the public interest and were generally supportive in principle, subject to the following points:

1. Members felt that, given the number and sensitivity of the additional data points requested, a more detailed justification of each should be provided; this should reference to the purposes set out in the original application to CAG.
2. Members sought reassurance that all of the additional data sources are established on a legal basis.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation that the all of the additional data sources have a legal basis.
2. Justification of the additional data items; this should be linked to the purposes set out in the original application.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Responses to points 1 and 2 above will be reviewed by the Chair and the reviewers who considered the amendment at the meeting.

ii) Annual review.

Security arrangements

A satisfactory Information Governance Toolkit score of 66% for version 12 (2014—15) was noted.

Study Progress

The members were satisfied with the progress reported against the conditions of approval.

Project changes

It was noted that an amendment had been received for this study; which was considered at the same meeting on the 17 March 2017 (above).

Access to identifiers

The applicant confirmed that complete ascertainment of all new cases is critical to the value of congenital anomaly and rare disease registration. The committee were satisfied that there was still a continued need to access confidential patient information as specified within the original application.

Practicable alternatives or exit strategies

The applicant noted that it was not possible to move towards anonymised or pseudonymised data. However they are undertaking a pilot to test the suitability of moving towards a consent based model. The members recognised that this was problematic and congratulated the applicants on this work, the outcomes of which they looked forward to reviewing in the next annual review.

Projected end date

The applicants confirmed that the rare nature of the conditions studied meant that there was no projected end date. It was agreed that this was reasonable and proportionate.

User feedback and involvement

The group were satisfied with the progress in user feedback and involvement reported.

Confidentiality Advice Group conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter.

3. RESUBMITTED APPLICATION

a. 16/CAG/0025 – Extension of the Partnerships in Care Research Database.

This application from Partnerships in Care detailed the creation of a research database to use for research studies to inform treatment and the planning of services.

The collection of data for the Partnerships in Care (PiC) research database commenced in 2001 and involved patient file information from four of the organisation's medium secure hospitals being abstracted to form the database. This comprised information from 935 patients.

Subsequently, information on an additional cohort of 859 patients from the four original and from two additional hospitals were added to the initial cohort so that the total number on the database is now 1794. This makes it one of the largest databases of detained patients within the UK.

A recommendation for class 4, 5 and 6 support was requested to cover access to link records collected in relation to 1794 patients from medium secure units to Hospital Episode Statistics (HES) and mortality data from the Health and Social Care Information Centre (HSCIC). The HSCIC are to replace the identifiers with a pseudonym before returning the linked data to the applicant organisation.

This application was a resubmission from the applicant in which they have sought to address questions previously raised by the CAG. Previous applications are: 14/CAG/1017 and CAG 10-08(a)/2014

Confidential patient information requested

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

Confidentiality Advisory Group advice

Public interest

Members agreed that projects of this type could be in the public interest.

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.

- Feasibility of consent

Members accepted that because this was an historic database consent was not practicable.

Justification of identifiers

Members agreed that for the purpose of linking identifiable data was required. However, it was noted that once linkage has taken place the identifiers are to be removed by the HSCIC and the information returned to the applicant will then be held in a pseudonymised format.

Patient objections

Members agreed that the information available to patients on the PIC website and via the PIC patient newsletter was an improvement to the information previously provided. However, they were not convinced that this fully informed patients about how they could opt out to the further use of their information. Members requested that patients are advised how they can opt out, and requested to know who is to be notified when someone has opted out and how this process would be managed.

The applicant was advised to make information available in the organisation's Fair Processing notice.

Additional points

Governance; members agreed that there was limited information about how access to the research database was to be managed. They were of the opinion that this should be managed through a properly constituted committee, which should have user and lay member involvement.

Small Numbers; members noted that it was still intended to use a count of 3 when releasing data to third parties. Members would remind the applicant that the requirement for small number suppression was a count of 5, and would refer the applicant to the ICO Anonymisation Code of Practice and the ONS codes relating to publication and anonymisation standards. It was further noted that this information also forms part of the contract which the applicant has advised was in place with the HSCIC.

For further information the applicant is advised to refer to:

- The anonymization code of Practice;
- ONS Guidance for Health Statistics; and
- ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore recommended 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.

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. Updated patient information must be made available to patients about how they can opt out of the further processing of their information. The researchers must include details of who will know that patients have opted out and how this process is to be managed. This should information must be provided tot eh committee to review.
2. The researchers should provide details of a governance process to manage applications for access to the PIC database.

Once received the information will be reviewed by a sub-committee,via correspondence in the first instance, and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific conditions of support

1. Information to be made available to patients about how they can opt out of the further use of their information
2. Confirmation that small numbers will not be released under a count of 5
3. A suitable governance process in place to manage requests for access to the PIC database
4. Favourable opinion from a Research Ethics Committee.
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. NEW APPLICATIONS – Research

a. 16/CAG/0031 – The Effectiveness and cost-effectiveness of Mother and Baby Units versus general psychiatric Inpatient wards and Crisis Resolution Team services.

This application from the Institute of Psychiatry, Psychology and Neuroscience, King's College London set out the overall purpose of the application as follows: Psychiatric Mother and Baby Units (MBUs) are specialist psychiatric services that aim to care not only for the mother's psychiatric needs but also the mother and baby relationship, which may be at risk in this group. However, there has been little research on the effectiveness of MBUs and no data comparing MBUs with other services for acutely ill women in the postnatal period.

Support was intended to cover the following aspects:

1. Trust staff to identify all eligible women that **had not consented** to take part and will access (without consent) clinical and demographic information from women's case notes.
2. Support is requested for the collection of a minimum dataset for women who had not taken part in the study.
3. The applicant will proceed with the consent-based approach consent as per original 2014 REC application.

A recommendation for class 1, 2, 5 and 6 support was requested to cover these activities.

Confidential patient information requested

Access was requested to the following:

- Baseline (i.e. details of index admission): age, ethnicity, clinical diagnosis, Health of the Nation Outcome Scale (HONOS) score at admission; postcode; severity of illness (as measured by number of general psychiatric ward and CRT days, and Mental Health Act (MHA) status in the two years prior to the index admission), length and date of index admission and MHA status
- Outcome measures: re-admission rates, number of inpatient and CRT days, and Mental Health Act status

This data was requested to enable the application to identify the exact location in each sector where women reside and allow accurate assessment of ease of accessibility by geographical distance within the district, and those in surrounding districts, from access to Mother and Baby Units.

Confidentiality Advisory Group advice

Public Interest

It was agreed that there was a public interest in the overarching purpose of the application, the research question was relevant and it could be answered more accurately with the missing data. The overall purpose of the activity was an important one and could lead to potential improvement.

Members noted the assertion that those women who are asked to participate and positively respond are not representative of the cohort as a whole, and this application sought to address the issue of non-representation in order to inform development of future pathways of care. It was indicated that without this data there would be a risk of bias.

However, it was agreed that a sufficiently strong public interest case had not been made to justify the breach of privacy; specifically in relation to override an actual expressed dissent for those who had actively chosen not to provide consent.

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.

- Feasibility of consent

The application asserted that seeking consent would lead to bias and there was a need to maximise validity of the outcomes. It was indicated that it would be distressing to seek consent.

Scope of activity and issues raised

Member understanding of the cohort impacted by this activity, and the issues considered for each are summarised below:

1. **Women who had been asked by the treating clinician for their details to be passed to the research team, and had not provided consent for this transfer of data.**

It was noted that these women had clearly not provided consent; therefore the applicant was seeking a CAG recommendation and final decision to override a previously expressed dissent. As indicated in the advice form, it is generally a principle of support that dissent be respected, therefore, this application sought to override this general principle. It was agreed that such an approach would require a much stronger rationale and demonstrate how the public interest would be best served by overriding a previously expressed dissent.

2. **Women who had been asked by the treating clinician for their details to be passed to the research team, they had discussed the activity with the research team, and the woman subsequently did not provide consent. This was indicated to cover 8% of the women.**

The CAG unanimously agreed that they would be unable to recommend support to the decision-maker for the specific 8% of women who had dissented in (2). The reason for this was in light of the general principle of support, and that these women had initially responded positively to the invitation from the treating clinician but following discussion with the research team had taken a clear step to refuse consent. This indicated that following this discussion a choice had been clearly made and CAG did not agree that this choice or the common law duty of confidentiality should be overridden for this purpose.

3. Women who had not been asked by the treating clinician for their details to be passed to the research team

It was not clear to members from the application why these women had not been asked or had been missed. Questions were raised as to whether this was due to any capacity issues and how this possibility could be identified. Members advised that if a proportion of these could be identified or disaggregated, where reasons were not due to capacity issues, then they would consider an application for this sub-group. This would only be on the proviso that there were reasonable steps taken to provide suitable patient notification materials, and to respect any expressed objection.

Members were not supportive of the research team accessing patient notes and would consider a resubmission if the Trust staff extracted relevant information and the research team would receive a reduced proforma, so steps should be taken to reduce the identifiability of the data received by the research team. A question had been raised in the queries as to whether full postcode was necessary, and the response indicated that advice was welcome from the CAG, however, it is advised that it is the applicant responsibility to assess the necessity of data items in light of this feedback and to make the case for full or reduced items to achieve the purposes.

Patient notification and objection.

The intent of the applicant not to provide fair processing material under the Data Protection Act (DPA) 1998 was noted.

Members noted that, separate to the DPA, it is a general principle of any support provided under Regulation 5 that appropriate information is made available to the affected cohort, along with a mechanism to facilitate patient dissent that is respected. It appeared that there was limited intention to provide this facility when seeking support, and this had been previously flagged within the advice queries. Members agreed that if seeking support under Regulation 5 that any resubmission should provide information on how the applicant intended to provide greater transparency in light of this outcome.

Application form

Members noted that the original application submitted to the Research Ethics Committee in 2014 had undertaken a consent-based approach where women were asked by the treating clinician at point of discharge whether their details could be transferred to the research team and if the woman agreed, they would be approached by the research team who would seek consent for researcher access to their clinical notes.

The form submitted to the CAG appeared to have amended certain aspects of this original consent-based application but not others, so there were inconsistencies within the application; members advised it would have been more appropriate to submit a new

form covering the intended non-consented aspect of the activity and that any future application must be a new form and consistent throughout the documentation.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

Resubmission

If the applicant considers that the issues raised by the CAG can be addressed, a resubmission can be made.

A new full application, covering the submission to the CAG that does not amend the original application submitted to the REC, should be submitted with a covering letter detailing any amendments made to the application currently considered and how the issues raised are addressed. The normal submission process should be followed when submitting the application for review.

Should the applicant wish to resubmit an application to cover this specific cohort then considerations within this outcome should be addressed, and a stronger argument provided as to why the public interest would be best served in obtaining this information, taking into account the fact it appeared unknown as to why the sub-cohort in (3) were missed. Members noted that support cannot be provided where consent has not been sought due to capacity issues as this would be addressed separately under the research provisions of the Mental Capacity Act.

b. 16/CAG/0029 – Cancer Diagnosis via Emergency Presentation Study (Empress).

This application from University of Hull set out the purpose of a case-control study into colorectal and lung cancer. This involves an investigation of the emergency presentation pathway in order to identify and understand the reasons for this type of presentation. In particular the researchers are asking:

- Are there differences in the pathway to diagnosis between patients who are diagnosed during an emergency presentation compared to those who are referred to hospital by their GP through the usual UK fast track system – the two-week-wait pathway (2WW)?
- What are the characteristics and primary health care experiences of patients with colorectal and lung cancers who are diagnosed as a result of emergency presentation, compared to those diagnosed through the 2WW referral system?

The research will also consider patients' socio-economic status.

Some patients will have died quite quickly after presentation. The researchers therefore sought support to include the medical records data (hospital and general practice) for the patients who have died.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover to cover the activity specified in the application.

Confidential patient information requested

Access was requested to Name, NHS number, Hospital ID number, GP registration, Date of birth, Date of death, Gender, Occupation, Ethnicity, and Postcode (unit level).

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type had potential medical benefit and were in the public interest.

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.

- Feasibility of consent

The group was content that it was impracticable to seek consent for access to the data used in this study given the potential distress this might cause and the difficulty of identifying the correct individual to approach for consent in order to guard against a common law claim of breach of confidentiality. It was noted that pre-mortum dissent would be respected.

- Use of anonymised/pseudonymised data

Members agreed that the importance of consistency of information meant that it was impracticable to ask members of the care teams to collect and de-identify data.

Justification of identifiers

The members concluded that the identifiers requested were necessary and appropriate to achieve the purposes of the study

Exit strategy

The group noted that date of birth and date of death will be converted to age and time from symptoms to death. The identifiable data will be retained for the purpose of linking the hospital and primary care data only. Anonymous data-items will be used thereafter. All identifiable data will be destroyed not less than twelve months after the study had ended. The members confirmed that they considered this to be satisfactory.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection. Members were content that no notification was, in this specific instance, acceptable as a means of avoiding distress.

As such, it was agreed in this specific instance that the usual condition to provide patient notification materials would go against the public interest for the reasons cited above.

Additional points

The group felt that greater efforts could have been made with regards to patient and public involvement – specifically with reference to bereavement and cancer. These are important and should be pursued more vigorously in future. An update on this should be included in the first annual report to the 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

1. An update on patient and public involvement to be included in the first annual review submitted to CAG.
2. CAG receipt of a favourable opinion from a Research Ethics Committee. **Received, letter dated 03 June 2015**
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

The applicant should provide confirmation that the above conditions have been accepted and/or met within ten working days of receipt of this letter. Once provided, the response will be reviewed by the Confidentiality Advice Team and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

7. NEW APPLICATIONS – Non-research

a. 16/CAG/0044 – National Bariatric Surgery Registry (NBSR).

This application from set out the purpose of recording data on a national scale for patient outcomes after Bariatric Surgery (weight loss surgery).

From April 2013 data entry into NBSR became mandatory for all NHS providers. Currently they are mandated to collect data for 2 years, which is the standard follow up period recommended by NHS for all patients who have undergone bariatric surgery. At every visit to the bariatric team, data are regularly logged into the database, which includes comorbidities associated with bariatric surgery, mobility, weight changes, revision surgery and complications.

The data currently recorded is identified by date of birth, local hospital number, date of operation, and gender. However with moving populations it is difficult to track the patients for their long term outcomes looking at weight reduction –changes in comorbidities, complication rates, mortality, and revision surgery during this period –as the initial entry is specific to the unit and cannot reliably be traced to other units. Therefore support for the addition of name and NHS number was requested

A recommendation for class 4, 5 and 6 support was requested to cover the activity specified in the application.

Confidential patient information requested

Access was requested to data in relation to patient outcomes after Bariatric Surgery from clinical care teams to the NBSR, and from the NBST to the care teams. The following data would be included: name, date of birth, NHS number, local hospital number, date of operation, and gender.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

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.

- Feasibility of consent

The group was content that it was impracticable to seek consent for access to the data for patients who had already undergone bariatric surgery.

- Use of anonymised/pseudonymised data

Members were content that the nature of the information they are seeking from the notes may make de-identification impracticable. However the applicant was requested to explore whether, were an objection raised, a limited de-identified dataset could be used. The applicant should justify whether using this more limited dataset would be practicable or not.

Justification of identifiers

Whilst the members concluded that the addition of NHS number was appropriate to ensure that the registry was able to achieve its purpose, they were unconvinced that the redundancy offered by the addition of patient name was justified. The applicant was requested to provide a justification for the collection of name in addition to NHS number.

Exit strategy

The group noted that, as surgery of this type was elective, it may be possible to move toward a consent model prospectively. This should be explored by the applicant in the resubmission. In order to ensure that bias was excluded, consent to inclusion on the registry could be a condition of consent to surgery and be included in this consent.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection. The committee noted that there was precedent from other surgery registries for not offering opt-out for clinical safety reasons and in order to avoid bias. As such, subject to the response on using a limited anonymous dataset (above), the committee were content that in this instance patient opt-out should not be offered.

The group were concerned that the information sheet was misleading. The statement that ‘Each patient is allocated a unique anonymous number, but the database includes your date of birth, operation date, and gender‘ should be modified. Date of birth is an identifier.

The members noted that the information sheet offers the opportunity to raise concerns with the NBSR committee, however there are no contact details in the link provided.

Members also noted that it was intended to put in a separate application for support in order to utilise this dataset for research. The applicant was commended for including an opt-out mechanism for this future work in the present patient information. These objections to the use of data in research must be respected in every instance.

Patient and public involvement

The group felt that greater efforts could have been made to include the views of patients and the public in setting up this study.

Whilst the applicant had provided a survey which showed 86.9% of respondents were happy to for their anonymised details to be added to a national database for the purpose of research and quality control of surgery, the group thought that a 13.1% dissatisfaction/unsure response was high enough to raise concerns. They further felt that the questions were misleading: it would be better to separate the research & non-research components; moreover the registry does not store anonymised data.

The applicant was advised to consider making use of greater patient and public involvement especially before submitting any future applications for research.

Additional points

The group expressed concern that date of birth was already being collected and requested that the applicant clarify under what legal basis this was taking place.

The committee sought clarification as to whether the data controller was Dendrite or the Royal College of Surgeons. If it was the latter their Data Protection Registration should be provided.

Concern was also expressed that data was potentially being accessed from the homes of Dendrite employees. Clarification should be provided on this.

Clarification should also be provided as to whether the data is appropriately encrypted.

The Group noted that there appeared to be some confusion within the Royal College of Surgeons (RCS) about their roles and responsibilities in relation to confidential data. This was agreed to be something that CAG might proactively offer to help with. It was agreed that the Chair team should investigate this.

ACTION: Chair Team to investigate whether help should be offered to the Royal College of Surgeons.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, no recommendation was provided as the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided in a new application to allow the CAG to continue their consideration of the application:

1. Justification as to why patient name is needed in addition to NHS number.
2. Consideration as to whether, were an objection raised, a limited de-identified dataset could be used. The applicant should justify whether using this more limited dataset would be practicable or not.
3. Consideration as to whether it would be possible to move toward a consent model prospectively.
4. Corrections to the patient information provided, including contact details for concerns and clear information as to the data held and its identifiability.
5. Confirmation that a separate application for any research components would be made and that any patient opt-out of the research components would be respected.
6. A response to the groups concerns re patient and public involvement.
7. Confirmation that the Royal College of Surgeons was the data controller and (if so) provision of their Data Protection Registration.
8. Clarification as to whether home access to the data was possible for any Dendrite employee.
9. Clarification as to the encryption to which the data was subjected.
10. The applicant should clarify under what legal basis the collection of date of birth was presently taking place.
11. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once received the information will be reviewed at the next available CAG meeting.

b. 16/CAG/0034 – Islington Transition Evaluation Study: Young Person's Experience of Transition.

This application from set out the purpose of evaluating the transition from a Child and Adolescent Mental Health Service (CAMHS) to an Adult Mental Health Service (AMHS), considered by many as a particularly risky time.

The study looks to provide robust information on the number and success of transitions from CAMHS services into AMHS in the borough of Islington, and young people's experience of them. Information on transition histories will be gained in the first instance through evaluating the electronic notes of young people of transition age within the borough. This will allow the study team to gain an overall picture of transition over a

specific time period. Gaining information on transitions within the borough will highlight a) transition pathways that are poorly coordinated, missing, or poorly resourced; b) areas in which current policies are difficult to follow within current service structures; and c) areas in which the Islington Transitions Team should work to best support mental health transitions within the borough.

A subset of the cohort will later be contacted via their clinician and asked if they would be willing to consent to an interview asking more detailed questions about their transition experience. Separate information sheets and consent forms will be provided for this part of the evaluation study for which support was not requested.

A recommendation for class 1, 4, 5 and 6 support was requested to cover the activity specified in the application.

Confidential patient information requested

Access was requested to data in relation to the transition from child and adolescent to adult mental health care from:

- Young people aged 17 to 19 between April and September 2015 attending Islington Child and Adolescent Mental Health Services (Whittington Health NHS Trust)
- Young people aged 17 to 19 between April and September 2015 attending Islington Adult Mental Health Services (Camden & Islington NHS Foundation Trust)

The following information will be extracted from the notes: name, age, ethnicity, date of birth, address, postcode, date of referral, reason for referral, and name of primary worker/care coordinator.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

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.

- Feasibility of consent

The group were content that it was impracticable to seek consent for access to the data used in this study as this might introduce bias.

- Use of anonymised/pseudonymised data

Members were content that the nature of the information the applicant was seeking from the notes makes de-identification impracticable.

Justification of identifiers

The members concluded that the identifiers requested were necessary and appropriate in order to achieve the purposes.

Exit strategy

The group noted that if future work of this kind were envisaged steps should be put in place to seek consent for this work now.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection. The members felt that greater efforts should be made to notify individuals, as many of them are likely to be presently accessing Islington Adult Mental Health Services. Information sheets should be provided for this cohort, and sufficient time provided for them to opt out before commencing data-collection.

The group also questioned whether the section of the privacy notice which read 'anyone who receives any personal information from us is also under a legal duty to keep it confidential' was correct. Members recommended that this section be revisited and revised.

Additional points

The group felt that greater efforts could have been made to include the views of patients and the public in setting up this study. The applicants are advised to make greater efforts in this respect in any future applications.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Information sheets should be provided explaining the study to any patient presently accessing Islington Adult Mental Health Services. The applicant should:

- Provide copies of this patient information for the committee to review.
- Explain how these will be disseminated.
- Clarify the length of time patients would have to opt-out before data-collection commences.

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

The applicant should provide the above within ten working days of receipt of this . Once provided, the response will be reviewed by the chair and original reviewers.

c. 16/CAG/0030 – HES data on sepsis for Christie Chemotherapy patients.

This application from The Christie NHS Foundation Trust set out the purpose to identify risk factors for neutropenic sepsis amongst people receiving chemotherapy at the Christie Hospital.

Patient's undergoing chemotherapy that have a fever are encouraged to contact the Christie's patient hotline, and any cases of suspected neutropenic sepsis are referred to their nearest A&E. Around 2/3 of patients are referred to other hospitals. Because The Christie does not have routine access to these hospital's data, they do not have a good understanding of what happens to those patients and are requesting access to HES data to get this information.

NHS numbers of the cohort will be sent to HSCIC and HES data will be sent back. These data will be combined with data on patients admitted to the Christie with diagnosis of febrile neutropenia or sepsis together with other data related to risk of sepsis for all Christie patients, all these datasets are already held by the Christie. The combined Christie held data and HES data will only be used to build and validate a model and decision making tool for predicting emergency admissions due to febrile neutropenia or sepsis amongst chemotherapy patients being treated at the Christie Hospital. The use of this model in clinical practice to identify high risk patient will allow several interventions to take place amongst those patient.

A recommendation for class 4, 5, and 6 support was requested to link patient identifiable information form more than one source, for auditing monitoring and analysing patient care and treatment and to cover access to an authorised user for one or more of the above purposes.

<u>Confidential patient information requested</u>

Access was requested to NHS number, date of treatment, IC10 code, Hospital of treatment

Confidentiality Advisory Group advice

<u>Public interest</u>

Members agreed this was a worthwhile project with a clear public interest and medical benefit. Members were in agreement that this was a useful area of study into the factors underlying a misunderstood condition.

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.

- Feasibility of consent

Members accepted the arguments about ascertainment bias and agreed that as the Christie did not have an A and E department they could see the need for data collected from other sites.

- Use of anonymised/pseudonymised data

Members queried whether the NHS number could be replaced by a project number and only pseudonymised data returned from HSCIC. It was agreed that this depended on who would access to the data returned from HSCIC.

Justification of identifiers

Disclosure was limited to NHS number to HSCIC for linking purposes. However members noted that if identifiable data was being returned by the HSCIC to someone outside the direct care team the S251 support would also be required for this element.

Additional points

Members queried whether this should actually be classed as a research project.

It was noted that the links provided by the applicant to the privacy notice on the website did not seem to be working. On searching the website for the information only general information on the work of the Christie was available rather than details of the specific study. Reference was also made to NIGB which was out of date having been replaced by the Confidentiality Advisory Group.

It was noted that the project would be reviewed by the PPI group at the Christie. Members agreed that patients were likely to be supportive over the uses of their data for this type of project.

Members felt that as most patients would be coming back that fair processing notices provided at the hospital were likely to be viewed by most participants.

Confidentiality Advisory Group advice conclusion

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

and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The researcher should provide further detail on who will analyse the data on receipt from HSCIC – will this be a member of the care team? If someone outside the care team then only pseudonymised data should be received from HSCIC to prevent disclosure.
2. The privacy notice should be updated on the website to avoid reference to NIGB and the method of opt-out for potential participants should be provided.
3. Fair processing notices should be displayed at the relevant hospitals.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.. **This was confirmed by the applicant 14 March 2016**

d. 16/CAG/0028 – Use of administrative data for the evaluation of gynaecological cancer care services in England.

This application from Clinical Effectiveness Unit set out the purpose of this service evaluation to develop valid, clinically relevant, methodologically rigorous and technically robust performance indicators to access the quality of gynaecological cancer care in England.

The applicant wishes to examine the potential of using linked Cancer Registry (CR), Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data to describe the pattern of care on women diagnosed with gynaecological cancer in England, including the treatments they receive and their outcomes in terms of complications, readmissions and mortality. With this linked dataset the applicant will be able to determine how successfully these performance indicators could be used to compare quality between different levels of care including;

- Regional level/Cancer networks
- Hospital provider
- Individual consultant (e.g. surgeon level)

A recommendation for class 4, 5 and 6 support was requested to cover access to an extract of linked patient level cancer data from the Public Health England (PHE) Office of Data Release (ODR).

<u>Confidential patient information requested</u>

The applicant is requesting an extract of linked patient level cancer data from the Public Health England (PHE) Office of Data Release (ODR) which would include the date of death.

Confidentiality Advisory Group advice

Public interest

Members agreed that this type of application was in the public interest.

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.

- Feasibility of consent

Members were of the opinion that consent was not practicable for this request.

- Use of anonymised/pseudonymised data

Members noted that this project primarily used pseudonymised data with the exception of date of death, which was the reason this application was submitted.

Justification of identifiers

Members agreed that date of death was required for this application.

Additional points

Members discussed whether consultants would be aware of this project; they were of the opinion that it would be good practice to inform them.

Members further discussed what Fair Processing information was available to patients and, in particular, whether the Fair Processing information available from the Cancer Registry made clear to patients that their data may be used for this purpose.

Members also noted that there has been no direct Patient and Public Involvement (PPI) carried out and that participants were not informed as to how they could opt out.

Members also reminded the applicant that it was necessary to have the required approval in place from the Office for National Statistics for the death information they are to receive from the ODR.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Recommendations

Members recommend that project information should be made available to patients via the Cancer Registry which informs them about the use of their data, and that the applicant needs to be clear to patients as to how they can opt out of the further use of their data.

Specific conditions of support

1. Please confirm that consultants will be made aware of this project and advise how this will be done.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

6. MINUTES OF THE MEETING HELD ON 14 January 2016 and 11 February 2016

A correction was noted for the minutes of the 11 February 2016. Other than this, the minutes were agreed to be an accurate record.

A member who was not present had provided written comments on the minutes for the 14 January 2016.. It was noted that the minutes had already been published, but members agreed that this clarification should be included and the minutes relaced with the corrected version.

7. CAG CHAIR REPORT

The report dated February 2016 was provided to the group for information.

Discussion was had as to how best to ensure consistency of advice. It was agreed that relevant precedents should be used in the summing ups and included in the Chair's Report (under the 'policy' section).

The group recognised that the last training day had been very successful and expressed their gratitude to the organisers. Whilst future events of this type would be very welcome, it was important that at least four months' notice is given, to ensure that all members can attend. There was a mixed response to the possibility of adding educational items to meetings as some members felt that this, on occasion, meant trying to fit too much into a single day. Any suggestions as to future topic for training would be welcomed.

It was noted that CRUK and Macmillan were undertaking a review of communications with cancer patients about registrations. Following communication with the Chair, CAG offered to seek a volunteer member to participate in this review if it was considered helpful.

There are a number of streams of Patient and Public Involvement (PPI) work which bear relation to CAGs work being conducted at present, including the forthcoming workshops which CAG has commissioned to be run in conjunction with the University of Sheffield. Work is ongoing with the HRA to develop the PPI plan. Members were encouraged to feedback any further work to the CAG when they become aware of it.

8. CAG OFFICE REPORT

The report dated February 2016 was provided to the group for information.

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 22 October, 05 and 26 November 2015, 14 and 28 January 2016 and 11 and 25 February 2016 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 22 October, 05 and 26 November 2015, 14 and 28 January 2016 and 11 and 25 February 2016 meeting applications.

Operational and CAT advice updates

Recruitment

Recruitment for new members is currently ongoing with interviews taking place mid-end March 2016.

Information Governance Toolkit equivalence in Wales

A copy of the Memorandum of Understanding between the Welsh Assembly Government and NHS England was received as part of the measures to ensure that the Welsh equivalent of the Information Governance Toolkit, Caldicott Principles into Practice (C-PiP) could be accepted as providing equivalent security assurance. The CAG had previously written to the approver over a period of nearly 18 months to highlight the delays and was supportive of a resolution being achieved.

Recently, there has been misunderstanding that the signing of the MoU was sufficient to enable CAG to recommend final support and a number of queries were received from applicants, citing CAG as the cause of delays. Following correspondence with NHS Wales Information Services, both the HRA and SofS approvers were written to on behalf of CAG to set out the current position; CAG did not have capacity or skillset to recommend how and whether an assurance mechanism would be provided to the CAG on individual C-PiP assessments, similar to the process currently in place where the HSCIC provides independent assurance to CAG. The approvers have discussed and the final decision on approach was with the Department of Health policy team.

A proposal was provided on 15 February 2016. This was reviewed and queries returned to DH on 29 February 2016. The proposal was that any self assessed score of 91% or above would be considered to be equivalent to the current English IGT level 2. DH has been asked to clarify whether CAG should recognise that the score is self-assessed and whether there will be any independent verification of the score. If not, clarity was sought on who would bear liability for any errors in self-reporting. Additionally, should the score be under 91% to whom should the applicant be directed. A recent example to be addressed involves Public Health Wales that currently has a published score of 86% but is expecting an updated assessment to be provided at end of March that is anticipated to be above 91%. At present this score is not considered satisfactory therefore clarification on how this situation can be resolved for the applicant without incurring a time delay has been requested.

Meetings:

Two meetings have taken place with the newly appointed HSCIC IG Information Sharing Assurance Manager to seek to establish better operational workings. Issues that have arisen have been unilateral issuing of guidance and interpretations of CAG advice that have subsequently significantly impacted on the operational business of the Advice Team. This was a productive meeting and the intent is to continue this on a monthly basis to develop better practical working relationships. An offer to observe a CAG meeting was extended and is expected to be taken up in due course; an information session was also offered to assist those HSCIC reviewers when undertaking their local governance checks

A meeting took place with UCL National Institute of Cardiovascular Outcomes Research (NICOR) to discuss anticipated changes to applications and a revised application is expected in due course. A query was also raised in relation to the classes of support, namely class 4 that states: "*The processing of confidential patient information for medical purposes from more than one source with a view to (a) linking information from more than one of those sources;…).* It was confirmed that this class of support does not allow for unspecified and broad-brush approval for linkage purposes, and that any linkages would have been described within the application.

IRAS issues with Research Databases

It has been identified that for at least some Research Database studies, the full CAG IRAS form does not generate. This is a functionality issue, the applicants filling in the form incorrectly. The office has created a stopgap form which can be e-mailed to applicants, containing the missing sections, and is seeking a resolution with the HRA IRAS team.

Register of approved applications

Due to technical issues with the Macro system used to update the register of approved applications to the website, it has recently not been possible to update the register.

Guidance from the provider of IRAS, BGO, through the HRA has identified the issue and work is being completed on the technical solution which is imminent.

HARP Minimum Data Standards

Discussions have been initiated with the HRA to consolidate and unify the types of information that must be uploaded to HARP. Work on these minimum data standards has begun with a meeting between CAT and the Audit team to understand which documents would be required by CAG as a mandatory upload to HARP in line with SOPs and audit requirements.

CAG member portal

This facility has recently been released. A training session will be scheduled with the Cat and CAG members. In brief, it will allow for the review of documents online and has been positively received when rolled out throughout the RECs.

9. ANY OTHER BUSINESS

An update was provided against the Arnold Lodge (15/CAG/0199) application from the University of Nottingham. The applicant had indicated that the study had been put on hold, however, the applicant had taken this to mean that responding to their conditions of support was also on hold e.g. provision of an annual review. This had been identified at a previous CAG meeting where a new applicant sought to use the data collected under this original reference, however, discussions after this meeting with the applicant showed there to be a lack of understanding of the terms of support and the general principles of the Data Protection Act 1998. For example, the applicant did not understand that holding identifiable information was considered to be a form of processing under the DPA, which raised questions as to how the application was compliant with their support.

It has also been identified that the same applicant from the University of Nottingham is responsible for a separate application (reference CAG 1-06 (c)/2014) that had been approved in September 2014. Support had been specifically provided for a period of 12 months until 11 September 2015, and specified that “continuing support after this point would be dependent upon receipt of a satisfactory annual review report, to be received no later than 10 August 2015”. An annual report had not been received. Correspondence with the applicant had indicated they had submitted an annual review however there was no evidence of this being received, and the applicant has been advised that support was clearly provided for a time limited period; at present, there are questions as to whether support is in place. A colleague of the applicant has requested a meeting and an update will be provided once this meeting takes place, however, it is disappointing to note that despite flagging the issues, the applicant has yet to provide an annual review as an interim measure. It is also noted that the purpose of the case

register was for service evaluation, and there is a question as to whether the applicant intends to use the data for research purposes.

Reliance upon letters issued by the National Information Governance Board (NIGB) Ethics and Confidentiality Committee (ECC).

A steer was requested from members on the situation where applicants who had employed a pseudonymisation methodology that had been reviewed by the NIGB ECC and where the ECC had indicated that it appeared that confidential patient information was not being processed. These applicants were providing the NIGB ECC outcome letter to data controllers as evidence that support under Regulation 5 was not required as the data was de-identified and there was no processing of confidential patient information. The assessment undertaken by the NIGB ECC will have taken place prior to 01 April 2013 and the instances that had triggered this steer were from approximately 2012. This date is significant as there have been a number of broader changes in legislation and policy guidance since this date e.g. the Health & Social Care Act 2012, new guidance issued by the Information Commissioner's Office, guidance issued by the Health & Social Care Information Centre etc. It was agreed that how applicants chose to represent an outcome letter was their decision as they would bear responsibility in the event of action by data controllers relying upon this letter, however, it was agreed that the CAG would not be able to confirm that these types of letters, in this specific context, were accurate as it would represent a snapshot in time; these letters were also likely to be approximately 4 years old.

A recent example where this situation had arisen was ResearchOne who had contacted the CAT seeking confirmation that the previous NIGB ECC advice that support was not required (on behalf of the Secretary of State for Health at the time) was still current. The applicant had been informed that if seeking a view that a previous pseudonymisation approach meant that data was genuinely de-identified in accordance with the ICO Anonymisation Code of Practice, that CAG would be unable to review or formally confirm this without benefit of an up to date application. Members agreed with this approach and accepted that this may mean new applications will need to be considered.

CAG Membership

Members noted that Dr Robert Carr and Professor Julia Hippisley-Cox would both be leaving the group on the 31 March 2016 due to their terms of office expiring. The chair highlighted their contribution and indicated that he would be writing to express his appreciation of Professor Julia Hippisley-Cox's input (as she had been unable to attend the meeting). The members thanked Dr Robert Carr for having contributed so much to the Group.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date