NHS
Health Research Authority

**Minutes of the meeting of the Confidentiality Advisory Group**

**11 December 2014 at 9.30am at Skipton House, SE1 6LH**

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**Present:**

| Name | Capacity |
|---|---|
| Dr Mark Taylor (Chair) | Lay |
| Dr Patrick Coyle | |
| Dr Tony Calland MBE | |
| Mr Anthony Kane | Lay |
| Mr C Marc Taylor | |
| Dr Robert Carr | |
| Professor Julia Hippisley-Cox | |
| Professor Barry Evans | |
| Dr Miranda Wolpert | |
| Dr Murat Soncul | |
| Ms 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 |
| Mr John Robinson | Confidentiality Advisor, HRA (Item 2d to 7) |
| Mr Stephen Robinson | Corporate Secretary, HRA (observing; Items 5a and 5b) |
| Mr Tommy Denning | Department of Health (observer, item 2a) |
| Serena Box | HRA (observer, item 2a) |
| Tracy Papiccio | HRA (observer, item 2a) |
| Phil Walker | Information Governance Alliance (by phone; item 2a) |

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| Ming Tang | NHS England (by phone; item 2a) |
| Sadie Parker | Southend Clinical Commissioning Group (item 2a) |
| Dr Peter Long | Southend Clinical Commissioning Group (item 2a) |
| Emma Branch | Southend Clinical Commissioning Group (by phone; item 2a) |
| Martin Winkle | Southend-on-Sea Borough Council (item 2a) |
| Michael Barrett | Southend-on-Sea Borough Council SBC (item 2a) |
| Mike Bennett | Southend-on-Sea Borough Council (by phone; item 2a) |
| Darren Sugg | Department of Health (item 2a) |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

### Introduction

Members were welcomed to the meeting.

### Apologies

Apologies were received from Dr Kambiz Boomla, Ms Gillian Wells, Professor Jennifer Kurinczuk and Ms Clare Sanderson

### Declarations of Interest

Professor Barry Evans declared that item 5a was partially funded by his employer, Public Health England, however the involvement in the activity was not affiliated within his department and had no relevance to his role within PHE. It was agreed that this should be recorded but that no further action was required and Professor Evans could contribute to discussions.

### Relationship with the Information Commissioner's Office

As representatives from the Information Commissioners Office would no longer attend CAG meetings on an ongoing basis members discussed the remit of CAG in relation to advising applicants on meeting the requirements of the Data Protection Act 1998. It was agreed that applicants should continue to be asked to consider DPA requirements as those requirements were not affected by support under the Regulations. It was advised that where necessary applicants should be referred to published ICO guidance in order to ensure that the requirements were understood but all should be clear that CAG's remit did not extend to advising on DPA aspects specifically. It was noted that work was also being undertaken on the IRAS form which would clarify the DPA requirements for applicants.

Members noted that as well as being a requirement of the DPA under the first principle, providing information in relation to the processing of confidential patient information was also a key consideration for CAG in the interest of maintaining public confidence and transparency. It was agreed that CAG should form its own view whether applicants had taken reasonable steps to meet this requirement, which was separate from the DPA requirement.

Members suggested that if specific areas of concern were raised in relation to any application a formal letter could be provided to the ICO. It was agreed that consideration of which circumstances a letter to the ICO might be necessary should be set out and communicated with the ICO in order to formalise the position.

## 2. DEFERRED APPLICATIONS

### a) CAG 5-05 (a)/2014 Southend on Sea Integrated Care Pioneer: disclosure of commissioning datasets from clinical commissioning group and social care datasets from Local Authorities to a local data processor(s), for the purposes of linking patient-level data in order to improve health and care services for the local population

This non-research application from the Department of Health, supported by NHS England, sought approval to extend and build upon the NHS England risk stratification application (reference CAG 7-04(a)/2013) in terms of identifiers and purposes. The overarching purpose was to enable the linkage of social care data with risk stratified commissioning data sets as part of integrated care, although 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. This application had been assessed twice previously and advice provided via letters dated 05 August 2014 and 08 October 2014.

**Confidentiality Advisory Group advice recommendation**

Members welcomed and thanked the following attendees for having expressed an interest in attending, and in giving their time to respond to queries: Mr Phil Walker (by phone, Information Governance Alliance, Health & Social Care Information Centre, , Ms Ming Tang (by phone, NHS England), Ms Emma Branch (by phone, Southend CCG), Mike Bennett (by phone, Southend Council), Darren Suggs (Department of Health), Sadie Parker (Southend CCG), Dr Peter Long (Southend CCG), Michael Barratt (Southend Council) and Martin Winkle (Southend Council).

Members agreed that the application documentation was much improved since the previous iteration and more usefully focused to enable more ready assessment of the relevant issues. It was acknowledged that papers received the day beforehand had not been considered within the assessment due to the short notice.

The following provides a summary of the issues discussed and taken into account within the CAG advice recommendation. Attendees were asked if they wished to respond at the time to certain questions or to await the formal outcome and respond in writing; the latter option was selected.

Future Pioneer applications

Members queried the intent of the Department of Health (DH) for this application to form a template for other Pioneer organisations, questioned what responsibility DH would have for supporting other Pioneer applications and who would be responsible for enabling this activity to become a template for others.

The applicants confirmed this was an iterative process and the intent was to develop an overarching template to help others following the system. The current application outline had been shared with the other Pioneers and they were actively following up on previous questions on local fair processing. The intent was to work with the Pioneers and Local Government Association to seek to identify a streamlined approach. Members noted their understanding that a different Pioneer had submitted to the CAG meeting in January 2015, prior to a formal approval outcome being issued to the current applicants.

Public interest

Members recognised and reiterated, as per previous advice, that this was an important activity with potential to benefit patient management and planning, albeit currently untested, therefore commitment by the applicants to test efficacy was welcomed. Members also recognised that this was a significant data collection and the importance of maintaining public trust and confidence was critical and should be embedded throughout the governance and communication of the activity. It would therefore be extremely important to undertake this whilst maintaining the highest of standards so as to ensure public confidence, particularly as this pilot could be used as a baseline for future applications.

Scope

The refined documentation and cover letter helped clarify the scope and included the following points arising from discussion. It was confirmed that social care staff would never see health records of a patient without consent. If others were to ask for the information this would be a disciplinary matter within social care. Social care workers could never access Care Trak. Members questioned the limits of this consent as would help refine the scope of what CAG was asked to advise against and asked that this and the other aspects provided in the cover letter be clarified within the application form itself. It was also confirmed that the application scope related to adults only.

The CAG also emphasised that use of the term ‘weakly pseudonymised’ was not appropriate to use as its meaning is neither clear nor standardised. Members questioned whether references were the same as the term ‘DEID4LA’ as specified in

the ‘Caldicott2’ Review report and in any event, clarified that any such reference should be removed from all documentation produced to support the application, and precise detail provided on the relevant data e.g. clinical data plus NHS number. There was also variation within the documentation and lack of clarity of what was meant by pseudonymised so member advised rectification within a revised iteration.

Practicable alternatives

It was accepted that pseudonymisation at source was not feasible, with pseudonymisation on landing the specified and agreed approach. However, it was noted that the pseudonymisation key and information would both be held by PI Benchmark, which would technically render the information identifiable. It was acknowledged that no one at PI Benchmark would view the data as it would be within a ‘black box’ closed system designed to ensure there could be no physical access and any testing would be carried out on test data. Noting that the key would still be retained by PI Benchmark, members advised there should be a separation of the key from the information and requested clarification on the feasibility and options for managing this as it was clarified that where the pseudonymisation key was held and the controls in place would be important to specify and manage, so as to maintain high governance controls.

Purposes and corresponding access to identifiers

In reviewing the specified purposes, it was clear that risk stratification for commissioning and case finding was a key component and this purpose had already received support under reference CAG 7-04 (a)/2013, therefore no issues were raised over this aspect, provided it followed precisely the conditions set out in CAG 7-04 (a)/2013. The applicants must liaise with Ming Tang, NHS England, to ensure these conditions are adhered to; these conditions were appended to the end of the provisional approval letter for convenience.

In relation to the other purposes specified in section (l), members welcomed the updated list of examples provided but remained unclear where the boundaries lay and what would be excluded. Members unanimously agreed that purposes should be specific and not open-ended, although appreciating some efforts had been made in follow-up to seek to refine these.

It was indicated that there was currently insufficient evidence to demonstrate that all ten of the remaining purposes required identifiable information. For example, in section (l) it stated the joint needs assessment was a purpose for which identifiable information was required, but later stated this purpose required anonymised data only. It was clear to members that support could not be recommended for those purposes where the need for identifiable information was not required or evidenced, so members advised that only the following purposes should currently remain within scope on the grounds that the others were too broad and/or had not yet provided a clear justification for access to identifiable information:

Approved purposes

1. Analysing the health of a population ("risk stratification for commissioning")
2. Targeting additional preventive care interventions, [for example the support of a community matron], to high-risk patients ("risk stratification for case finding").
   **Purpose 1 and 2 above are subject to the conditions set out in CAG 7-04 (a)/2013**
3. Identify high cost individuals whose care may need to be reviewed by the multidisciplinary team with whom they have a legitimate relationship
4. Identify those with abnormal or perceived abnormal outcomes (for example emergency admissions) for alternative interventions
5. Commission new services in an affordable manner by identifying populations of clients with certain constellations of features
6. Assess whether new services are having the desired effects

In relation to the purpose '*map the density of one or more pathologies, impairments, functions, services and events within health and care services across the locality for example by [political] ward'*, members noted that this may require access to postcode but this had not been justified so if necessary, this justification should be provided. Members also questioned why full date of birth was necessary, whether year would be sufficient and whether analysis could be undertaken with less identifiers.

Should there be an evidenced need for full identifiers then the CAG would welcome this information being provided when available. Members also identified that transfer of information for "innovation" purposes was too open-ended and advised that should the appropriate innovative activities be identified, these should be submitted individually back to the CAG for review via a separate full application. It was also unclear to members who would onwardly receive information, and requested that this be specified.

Communication and public confidence

It was acknowledged that the upload of data from GP practices to Care Trak was greater than 'care.data', and intended to extract data from the previous three years. In its previous considerations, members had indicated that on average, 30% patients would not have attended their GP in the previous 12 months, thus equating to approximately 40,000 patients, and would generally receive no benefit arising from the data extraction. Members did not receive a clear response on how the significant amount of patients, who would not have been to a GP surgery, would know of the proposed data flow based on the current communication plan, noting this was a point that had previously been raised for clarification.

Members referenced the approach undertaken by the care.data pathfinders where individual letters would be sent. Views were therefore sought on why the intent for communication for this application should be any less than the approach applying to care.data as this would be critical to developing public confidence. Applicant feedback stated that the communications plan had been refined based on a Nuffield Trust study, communication would be undertaken via GP Surgeries and the Council with additional media on the websites. It was confirmed that individual letters had not

been considered and the intent was not to follow care.data model as this was more local than national. The CAG emphasised the need to carry out best possible attempts to make information available to those who would be included within the potential upload, considering the significant numbers involved.

The feedback provided by the Information Commissioner's Office (ICO) confirmed that the ICO did not check nor 'rubber stamp' the privacy notices associated with any data sharing initiatives and that they expect any data controller to ensure they are compliant with the Data Protection Act 1998 whether or not they are applying for approval under Regulation 5. Members noted the ICO view in relation to Data Protection Act 1998 and welcomed this.

The issue for CAG, separate to that of Data Protection compliance, was ensuring that there was appropriate information provided so as to increase public confidence in uses of data where this takes place without consent. This appropriately differs from the ICO role. The fact a significant proportion may never be aware of the data extraction, based on the current communication plan, was not considered acceptable in the context of the application and the CAG could not advise provisional support while proceeding on this basis. In the absence of a compelling reason being provided to members when discussing this aspect it was unanimously agreed that the applicants should go beyond the requirements of the Data Protection Act 1998 and the activity should follow the approach of individual communication as being trialled within the care.data pathfinder programme. Members advised of real world cost-effective examples where GPs could use text messaging facilities, therefore the CAG requested information on how this could be implemented, taking into account the differing communication mediums. It was agreed that without an overwhelming evidenced reason then individual communication must be the default standard.

Member conclusion on this aspect was as this was meant to set a standard for other Pioneers then it should act as a beacon to others in setting out acceptable approaches and if accepted, could transform how the public is effectively informed and given opportunities to understand the benefits to which data could effectively support.

Patient objection

Members questioned how patients could opt out of data flowing to Care Trak and it was confirmed the patient could contact their GP and the GP could add a read code so that information would not leave the practice. Patients would be asked to do this in writing. It was confirmed this would relate only to data being shared from primary care. The applicants acknowledged that the application was asking to extend the GP data flows and the issue in addition to allowing opt out from Care Trak was there would also be a need to share GP objections with the HSCIC as access was also sought to SUS data from the HSCIC into the Data Services for Commissioners (DSCRO).

Ms Tang acknowledged that there was a need to explain Care Trak better and also to evidence how patient objection would be managed in the broader contexts of care.data, the summary care record and Care Trak and a diagram would be provided to illustrate this in the next application iteration. It was explained that work was being

undertaken to harmonise this but had not yet been completed. Members advised that this must be resolved before any data flows.

Data controller arrangements

Members questioned the data controller arrangements and Mr Walker confirmed that the GP would not be a data controller in common as there would be no data controller relationship for GPs once data had flowed. Questions were raised that if GPs are responsible for ensuring patient objection is communicated and managed then how realistic would this be if the GP had no control over future uses of data. Applicant feedback was requested on this aspect as it appeared to conflict with the agreement made between NHS England, following advice from the ICO, in relation to risk stratification where GPs were data controllers in common. Members requested that there be a clearly aligned position to avoid future confusion, noting the purpose of risk stratification must follow the conditions set out in CAG 7-04 (a)/2013 that specify the data controller relationships.

Letter to General Practitioners (GP)

It was agreed this was much improved and more factually correct, however it was noted that the purposes listed in the application had not been set out in the letter so inconsistencies between documentation would need to be rectified. Members expressed the view that the issue of the letter was more what it did not say than what it did, and was relatively limited on the governance controls that would be applied, along with ambiguity on the nature of the information that would be transferred. Dr Calland offered to work with the applicants to support development of the letter in line with CAG request for absolute clarity and this offer was accepted.

Additional discussion points

In reviewing the social service leaflet it was noted there was a phrase where data could also be used for tax and other non-health purposes, and members advised they had not seen this phrasing before in this context. Members were advised that the wording had been sugested by Mr Walker however it was agreed that this was not necessary and would be removed from all documentation.

It was agreed that the patient factsheet was much improved and provided a succinct summary in plain English. Members offered a view that the applicants may wish to use another example of sensitive data items apart from sexual health that may be more readily pertinent to the cohort.

In relation to the Clinical Data Sharing and Engagement Strategy, it was identified that it incorrectly referred to obtaining implied consent. Attendees agreed at the meeting that this phrasing and approach was incorrect and would be removed

Members noted that the following information was outstanding as referred to within the applicant responses:

1. Limited patient and user engagement and request for this to be strengthened
2. Positive engagement with the LMC and evidence that they are supportive of this activity. It was understood from applicant discussion that further engagement had been sought and the LMC had raised a series of questions similar to those raised by the CAG; this discussion was ongoing at time of CAG consideration.

In reviewing the time period for which support was requested, the applicant responses had referred to an end state but it was clear that this had not yet been established. Members therefore advised that support should be provided for a period of 12 months from date of final approval, at which point the end state should be articulated and need for any further support more closely defined.

**Confidentiality Advisory Group conclusion**

Noting the high public interest to this activity, and acknowledging that the applicants had a number of concrete actions to progress, the CAG advised recommending provisional support to this activity, subject to the exclusions listed above and subject to satisfactory responses provided to the actions listed below. The CAG advised that all actions must be satisfactorily completed prior to issuing a final approval letter. Support does not come into effect until this final approval letter is issued.

Applicant actions:

1. A revised application, sufficiently comprehensive and accurate to provide the baseline for any further similar activities, to be provided back to the CAG. This should include rectification of all points covered in the CAG advice letter, with a summary as set out below:

    a. Clarify the scope specified in discussion and documentation for incorporation within the main application form including removal of excluded purposes. The limits of the consent obtained should be made explicit in the application so that scope for which support is sought and exclusions are specified.
    b. Review of application for consistency in terms of data referred to, with clarity on what is meant by pseudonymised and removal of ‘weakly pseudonymised’. Data should be clearly described.
    c. Consideration of separation of the pseudonymisation key from the information held by PI Benchmark with feedback to be provided on revised approach.
    d. Should applicants wish to provide further evidence to support the need for the excluded purposes to process identifiable information, these should be submitted as separate applications to the CAG
    e. Further justification of full date of birth and consideration of access to less identifiers for analysis to be provided.
    f. Clarification of the GP role as data controller or data controller in common and resolution of how this conflicts or aligns with the approach previously approved under CAG 7-04 (a)/2013 (see Appendix A)

g. Dr Calland to provide advice on the letter to GPs; applicants to contact the advice team when at the appropriate stage to progress.
h. Clearer information on how patient objection will be managed in line with discussion.
i. Clinical Data Sharing and Engagement Strategy and references to implied consent to be removed.
j. References to sharing data for tax and other non-health related purposes to be excluded from consent form and any other documentation
k. Clarification and specificity on who would receive onwardly disclosed information
l. Develop plan & timetable for reporting and learning to inform future Pioneers
m. Plan to provide individual communications to affected patients to be provided to the CAG, in addition to the communication materials. An overwhelming reason would need to be evidenced should this approach not be deemed suitable.
n. Provision of acceptance by LMC through providing suitable information. It is understood this is currently in progress
o. Provision of final version of council fair processing booklet
p. Improved information on patient and user engagement

Once all actions are completed these should be provided, in one tranche, back to the CAG for final review. Piecemeal submission of information will not be accepted, however once all information is received the intent is for this to be considered outside the CAG formal meeting schedule by all member virtual review.

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, with detail of the checks and balances to be put in place to be provided as part of revised application.

4. Individually targeted communication to be provided to each relevant patient with information on how to register patient objection. Communications to be provided to CAG in advance of sending to patients.

5. 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.

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

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

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

9. Confirmation from the HSCIC IG Delivery team that those processing data have achieved a satisfactory IG toolkit level. This confirmation should be sent directly to the Confidentiality Advice Team before any approval comes into effect.

## 3. RESUBMITTED APPLICATIONS

### a) 14/CAG/1040 UCL Infection DNA Bank

This application was for the establishment of a new tissue bank to undertake research to analyse the genetic basis for infections and potentially the interactions with non-communicable diseases at a later point. It was intended that both a microbial and human DNA would be analysed. The tissue bank would include residual diagnostic samples, held anonymised for retrospective samples and linked with hospital numbers for prospective samples. The disclosure of confidential patient information would be limited to instances where further collection or investigation of patient records is requested by researchers, having identified samples of interest. Consent would be sought to complete any such further analysis and support was requested for project researchers to be given patient details to seek consent for further analysis and samples to be collected, after the patient had been first approached about this by their clinician.

A recommendation for class 3 and 6 support was requested to cover access to for an authorised user to select and contact patients to seek their consent.

Confidential patient information requested

Access was requested to clinical data, name, address, date of birth, gender and hospital number.

**Confidentiality Advisory Group Advice**

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 that within the application documentation there continued to be references to pseudonymisation and anonymisation, however these terms appeared to have been used inconsistently.

It was understood that unique sample identifiers would be used and provided to researchers who if interested in particular samples would then contact the DNA Bank with the selection of sample identifiers. The Bank Co-ordinator would then request clinicians contact their patients to provide an opportunity to opt-out of being contacted by the researchers, who otherwise would seek to request consent for further analysis or collection of samples. After a two week period after which the clinician had approached their patient and where a response had not been received, the researchers would be provided with the patient's details so that they could then approach the patients for their consent to further analysis and/or for further samples to be collected.

Justification of identifiers

The confidential patient information requested was felt to be appropriate for the activities described within this application.

Researcher contact

Members discussed the two week period between clinicians contacting patients and it was felt that this period should be extended by a further week, to three weeks in total. It was suggested that individuals may be away from their home for two weeks, for example if they were on holiday, to return to find that their information was being used within research projects where they may have otherwise potentially objected to this.

Deceased patients

It was stated that this application for support did not include retention and use of identifiers for the purposes outlined within this application for deceased patients. The Applicant was advised that should they wish to include deceased patient data that they should seek advice from the Confidentiality Advisory Group.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research 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. Patients should be approached by a member of their care team in clinic and not directly by researchers.
2. Researchers should only have access to patient details three weeks after the patient's clinician has sent the letter to enable the patient to opt-out of being further contacted.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

## 4. NEW APPLICATIONS – NON RESEARCH

### a) CAG 9-04(a)/2014 National Clinical Coding Audit

This application from Monitor set out the purpose of the annual National Clinical Coding Audit, forming part of the Payment by Results (PbR) Data Assurance Framework, which audits the quality of the recording of coded data in relation to the diagnosis and procedures carried out on individual patients. The overarching aim of programme was to improve the quality of data underpinning PbR payments, planning & provision of healthcare services.

A recommendation for class 1, 5 and 6 support was requested to allow Capita to access medical records as data processor on behalf of Monitor, in order to carry out a review of the quality of recording of coded data.

**Confidentiality Advisory Group advice**

Public Interest

Members agreed that the audit aims were important and reiterated their support for the activity taking place. It was noted that support had been recommended for the last annual audit.

Practicable Alternatives

Members are required to consider 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. Where a practicable alternative does exist support under the Regulations should not be provided.

Members discussed whether existing statutory powers provided to Monitor under the Health and Social Care Act 2012 would provide a legal basis to allow access to medical records to take place. It was noted that the activity appeared to be clearly within Monitor's functions, noting Schedule 8 which extended the functions which Monitor inherited, and in particular paragraphs 14, 15 and 17. There was no indication that audit activities would be excluded from the use of confidential patient information. The application asserted that the access to data could not fall within S104 of the Act and members queried whether any formal legal advice had been obtained to this effect. Members also agreed it was unclear why the activity would not fall within other sections of the Act such as S70 and S108.

In addition to the above, members also noted that the December 2014 revision of the statutory guidelines "Audit Code for NHS foundation trusts" continued to include the following statement in Appendix B:

Access to patient records

*As set out above, under Schedule 10, paragraph 2 of the 2006 Act, auditors of NHS foundation trusts have the right to access patient identifiable information where necessary. However, auditors are also required to observe a statutory duty of confidentiality as set out above (paragraph 8 of Schedule 10 to the 2006 Act) and are required to be mindful of the confidentiality, security and data protection requirements in relation to patient identifiable information that the NHS foundation trust maintains."*

Members were mindful that support under the Regulations should not be recommended where there was an alternative legal basis, which in this instance had undergone parliamentary scrutiny, and that the application form referred to support being additional to Monitor's own powers. It was agreed that formal legal advice should be provided to clearly address why Monitor could not use the statutory provisions within the Act, without this further information members could not identify why the Health and Social Act 2012 did not provide a practicable alternative in this instance.

**Confidentiality Advisory Group Advice Conclusion**

In line with the considerations above, the CAG agreed that they were unable to recommend support formal legal advice had not been obtained in relation to whether Monitor's own statutory powers would be applicable in this instance and therefore could not determine if there was a practicable alternative.

**b) CAG 9-04(b)/2014 Troubled Families Evaluation**

This application from the National Institute of Economic and Social Research (NIESR) described the evaluation of the Troubled Families programme, commissioned by the Department for Communities and Local Government. The programme began in April 2012 and involved 120,000 families in England. 59 local authorities would take part in the evaluation. A recommendation for class 1, 4, 5 and 6 support was requested to cover access to Hospital Episode Statistics data from the Health and Social Care Information Centre. Name, postcode, NHS number and date of birth would be used to carry out linkages to HES data.

**Confidentiality Advisory Group advice**

Medical Purpose

It is a requirement that any application for support has a clear medical purpose. Members queried what the specific medical purpose had been identified and confirmed that without further information they would be unable to recommend support. They requested specific details of the medical purpose and public interest in the activity taking place.

User Involvement

Members advised that where identifiable patient information is to be accessed without an individual's consent it is important that views are obtained from the patient population to demonstrate the public interest in the activity taking place and to raise awareness. Members noted that the application specified that no user involvement had taken place and agreed that it was important that participants and potential participants in the Troubled Families programme were consulted, both to determine their views in relation to their information being used without consent and to raise awareness of the activity.

Pseudonymised Method

Members considered whether an alternative existed and noted that the applicant had had limited discussions with the Health and Social Care Information Centre about the linkage activity. It was agreed that further information in relation to the potential alternatives such as adopting a method which used pseudonymised or anonymised information would be required as it was not possible to assess if these has been considered in full. Members also queried why it would be necessary for the NIESR to retain the key to identifiable information and advised that this should be reconsidered and further justification provided as to why this was required.

Consent

Members also considered whether consent could be obtained as another potential alternative and noted that it could be possible for the HSCIC to write to individuals on the applicants behalf in order to seek consent. It was noted that whilst the cohort was large, the dataset requested was extensive and the potential for consent should be considered in detail.

Transparency and patient information materials

Members were pleased to note that the applicant had consulted with the Information Commissioners Office in relation to the requirement to inform patients under the first principle of the Data Protection Act 1998. Members discussed that the patient information materials provided were lengthy and could be more informative about the uses of data and in confirming that identifiable data would be used. Members advised that these should be tested and feedback sought as part of the user involvement activity.

Members advised that if support under the Regulations was recommended in future, further efforts to inform the participants would need to be made to ensure that the processing was as transparent as possible and to ensure that public confidence was maintained. For example, if consent proved not to be possible, whether the HSCIC could write to inform families about the processing of information and provide them with an opportunity to opt out.

Research or Service Evaluation

Members noted that the application had been confirmed not to be research by a REC, however they queried whether, given the extent of linkages, research elements and potentially vulnerable data subjects, whether the REC should be asked to review the application on a discretionary basis. It was confirmed that if the application was to be resubmitted this should be considered and the Confidentiality Advice Team informed in order to liaise with the National Research Ethics Service.

**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.

## 5. NEW APPLICATIONS – RESEARCH

### a) 14/CAG/1039 Small Area Health Statistics Unit (SAHSU)

This application from Imperial College London set out a request for continued support for a research database covering England and Wales, the database would be mainly used by studies focusing on environmental health risks. The original application specified that support would be required for the funding period of 5 years, as the funding period had been extended the application requested an extension to the initial support provided.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to the following datasets:

- ONS Births and Still births
- ONS Cancer Incidence
- Welsh Cancer Intelligence and Surveillance Unit.
- ONS Mortality
- National Congenital Anomaly Register (NCAR from ONS)
- Local Congenital Anomaly registries affiliated with BINOCAR [CARIS (Wales), Glasgow Register of Congenital Anomalies, Merseyside and Cheshire Congenital Anomaly Survey, North Thames (West) Congenital Malformation Register, Northern Congenital Abnormality Survey (NORCAS), Oxfordshire Congenital Anomaly Register (OXCAR), Scottish Congenital Anomaly Register (SCAR), East Midlands & South Yorkshire Congenital Anomaly Register (formerly Trent), West Midlands Congenital Anomaly Register, Wessex Antenatally Detected Anomalies Register (WANDA), National Downs Syndrome Cytogenetic Register (NDSCR)
- Terminations grounds “E” (that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped)
- NN4B – currently expecting data for 20062011 (data arrival expected November 2014).

- HES Inpatients
- HES A+E – current holdings
- HES ONS mortality link – current holdings
- NCCHD (National Community Child Health Database)

Confidential patient information requested

Access was requested to address, postcode, NHS number, date of birth and date of death.

**Confidentiality Advisory Group advice**

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 consent would not be feasible due to the large (300 million records) and retrospective nature of the database and lack of contact between researchers and patients. It was noted that obtaining pseudonymised information only would not be possible at this stage. The applicant had previously been advised by the CAG's predecessor, the Ethics and Confidentiality Committee (ECC), to consider whether the HSCIC could undertake linkages on their behalf. A number of reasons why it would not currently be feasible for the HSCIC to undertake this work on the applicant's behalf were detailed within the application. In particular, the need for high accuracy in exposure assessment and the requirement to ensure the highest quality in data linkages was asserted.

Members noted that there was currently no alternative to the use of confidential patient information without consent; however they encouraged the applicant to explore alternatives with others, such as the HSCIC, on an ongoing basis to ensure that an exit strategy could be adopted in future if one became available.

Justification of identifiers

Members noted that patient address would be required in order to work out precise proximity in cases where this was required.

The application specified that it may be feasible to replace the NHS number with a pseudonym once all data providers had implemented a secure mechanism to use the same key for each research dataset using NHS numbers. Members requested that the applicant document NHS number ascertainment where possible and provide further information in relation to the anticipated issues and timescales in adopting this approach at annual review stage.

Informing Patients and Transparency

When reviewing an application to access confidential patient information without consent the CAG will consider efforts made to inform the patient population that the

processing of confidential patient information is being undertaken for the specified purposes with a view to maintaining transparency and public confidence. Members reviewed the information provided on the SAHSU website and advised that further efforts could be made to make the information more accessible, for example by creating a section specifically for patients and the public. It was advised that this section should also inform patients how to opt out if they wanted to.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, 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 the Health Research Authority to provide a recommendation of support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

**Health Research Authority recommendation**

Following advice from the CAG, the Health Research Authority agreed to recommend support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

**Specific conditions of support**

1. Continued consideration with others the feasibility of an exit strategy from and reduction of the use of confidential patient information without consent. This should be reported on at the next annual review stage.
2. The creation of a patients and public section of the SAHSU website, which includes information in relation to the data being processed and methods to enable patient objection.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

**b) 14/CAG/1032 Investigating the association between IQ and self-harm**

This application from the University of Bristol set out the purpose of linking HES and GP record data in order to conduct a study to determine a more accurate estimate of the association between IQ and self-harm among adolescent and to investigate how non-response and under-reporting in questionnaires affects estimates of this association.

A recommendation for class 1, 4 and 6 support was requested to cover disclosure of confidential patient information including NHS number and date of birth from GP records and Health and Social Care Information Centre to the NHS Wales Informatics Service. Linkage would then be undertaken to ALSPAC data using the methodology approved within the overarching ALSPAC application (ECC 1-05(b)/2012).

**Confidentiality Advisory Group advice**

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 that the methodology detailed within the application was identical to the approved overarching ALSPAC application, that identifiable data would be required in order to identify relevant HES and GP records and that linkage would be carried out using a pseudonymised methodology.

Members noted that all ALSPAC participants had been written to in order to inform them that their data was included within the study and provided with an opportunity to object.

Justification of identifiers

Members noted that the applicant had detailed using postcode in order to calculate deprivation score and that the HSCIC had confirmed that it would be possible to calculate this prior to disclosure. Members therefore advised that postcode data should not be provided to the applicant.

Retention of dataset

Members agreed that the linked dataset created for this specific study purpose should only be retained for as long as necessary for the specific study.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, 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 the Health Research Authority to provide conditional support, subject to compliance with the specific and standard conditions of support as set out below.

**Specific conditions of support**

1. Postcode should not be disclosed and deprivation score should be used instead.
2. The linked dataset should only be retained for the duration of the specific project.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission. Confirmed

## 6. MINUTES OF THE MEETING HELD ON 6 NOVEMBER 2014

There was a minor correction to page 22 where “March 3015” rather than March 2015 had been recorded.

The minutes were otherwise agreed as an accurate record.

## 7. CHAIR'S REPORT

### Confidentiality Advisory Group new role

The Chair provided a brief written and verbal report in relation to the planning that had been undertaken with the Health and Social Care Information Centre (HSCIC) in relation to CAG's new advisory role. It was noted that further information had been requested from the HSCIC and that once received preparations could continue. Members were advised that some input from members would be required in relation to the developments of the new role and were asked to confirm to the CAT if they would be interested in giving additional time.

**Action: Members to confirm to CAT if interested in assisting in development of new role.**

## 8. CONFIDENTIALITY ADVICE TEAM REPORT

### Public Health England and Regulation

Ms Dunkley provided an update on the issue discussed in relation to Public Health England and seemingly different approval arrangements for a sub-set of requests processed under Regulation 2. Members had sought clarity on these arrangements and requested advice on how CAG could discharge its responsibilities when not advising against a disclosure carried out under Regulation 2. It was confirmed that a response had not yet been received from the SofS representative, however PHE had provided a copy of their standard operating procedures that set out the process. The document was clearly draft with tracked changes and additional information speciied by the legal advice had not been supplied. During discussions with the Department of Health on a separate matter, advice had been sought on whether these arrangements were known and the contact within the Department of Health would be following up on this query.

### Change to Health Research Authority legal status – 01 January 2015

Members were informed that the Health Research Authority (HRA) was currently a Special Health Authority and from 01 January 2015 the Commencement Order, issued in October 2014, will come into force so that the HRA legal status will change to become a Non-Departmental Public Body (NDPB).

The primary role of the HRA will continue to be to protect and promote the interests of patients and the public in health research and to streamline the regulation of research with the addition of important new roles to assume responsibility for the Research Governance Framework from the Department of Health and to promote transparency in research.

A number of roles were strengthened, including a duty to work collaboratively and cooperate, in relation to functions related to health and social care research, with

different bodies with a view to coordinating and standardising practice relating to the regulation of such research. These bodies include the Secretary of State, Health & Social Care Information Centre, Chief Medical Officer of the Department of Health, Care Quality Commission, Human Tissue Authority and Human Fertilisation & Embryology Authority. The HRA must also publish guidance on principles of good practice in the management and conduct of health and social care research and requirements, whether imposed by enactments or otherwise, to which persons conducting health or social care research are subject. The HRA must also promote the co-ordination and standardisation of practice in the UK related to the regulation of research and ensures that such standards are proportionate.

Current arrangements with committee members, Chairs and Vice Chairs would continue unchanged once the HRA becomes a NDPB.

**Dame Fiona Caldicott appointed as National Data Guardian**

Members were informed that Dame Fiona Caldicott had been appointed as National Data Guardian as reported by the Secretary of State for Health on 13 November 2014.

**Integrated Research Application System**

Following queries raised by members at the November meeting in relation to updating the IRAS form to detail CAG, rather than NIGB, CAT confirmed that they had been in contact with the HRA systems team and that the change to CAG will be included on the next release of IRAS. CAT would work with the IRAS Delivery Manager to confirm requirements.

**Standard Operating Procedures (SOPs) update**

Version 1.0 of the CAG SOPs was approved at the Operational Management Group on 5th November subject to changes and clarification in response to comments raised. Members were informed that version 1.1 would go to the OMG meeting on 11th December for approval. It was anticipated that the SOPs will be amended where necessary and reviewed by OMG every 6 months with a CAT review to identify changes every 3 months.

**Application updates**

**CAG 8-02(d)/2014 PEDW**

Following the provisional approval provided after the November meeting, members are advised that the amended documentation will be provided to the January CAG meeting. If possible documents will be reviewed prior to the meeting by a sub-committee of members.

**PIAG 2-07(d)/2007 Research to identify and publish measures of quality delivery of health by provided or by area and also to provide management information for the NHS**

The original application from Imperial College London received support in 2007 in order to process hospital administrative data (Secondary Uses Service data supplied through commissioning datasets from the Health and Social Care Information Centre (HSCIC) to provide measures of quality of delivery of healthcare by provider or in some instances by area and to support a management information function for the NHS. Anonymised data would be provided to Dr Foster Intelligence for analysis purposes.

Access was requested to date of birth, date of death, postcode and NHS number. The following conditions were specified within the original approval:

1. Appropriate contractual arrangements being established with organisation providing data.

2. That sensitive information such as sexual health information is filtered out prior to disclosure to Imperial College London.

3. That the Imperial Unit undertakes its own user involvement rather than relying on that of DFI.

4. That data is pseudonymised on rolling 3 year programme.

5. Clarification of precisely what data is disclosed to DFI and assurance that it is effectively anonymised.

<u>Response to request for clarification and Confidentiality Advice Group advice</u>

The applicant explained within their response that the HSCIC had confirmed that sexual health data was fully anonymised prior to disclosure based on the procedure and diagnosis codes documents within Data Set Change Notice (DSCN) 41/1998 around sensitive data and the list of treatments provided under the licence of the Human Fertilisation and Embryology Authority. A stricter set of anonymisation rules were applied in relation to disclosures from the applicant.

The response in relation to this issue was referred to a sub-group of members. There was some discussion in relation to whether the list of sensitive conditions for anonymisation provided to PIAG within the original application referred to the dataset provided to the applicant or whether this referred to the information disclosed by the applicant. It was noted that sexual health data disclosed from the HSCIC had been anonymised using the DSCN standard as detailed above, which did not include four of the codes specified within the list provided to PIAG with the original application; I98.0 Cardiovascular syphilis, N74.2 Female syphilitic pelvic inflammatory disease, N74.3 Female gonococcal pelvic inflammatory disease and N74.4 Female chlamydial pelvic inflammatory disease.

Members noted that a response had been submitted to the original application in 2008 and in subsequent annual reviews which had consistently confirmed that “it is the NHS trust responsibility to ensure that data relating to sexually transmitted infections were not submitted in an identifiable format and that appropriate safeguards were in place to ensure that where sexual health data was received, it was automatically anonymised." Members were therefore mindful that the current practice had been confirmed consistently since 2008.

It was agreed that, given PIAG/ ECC previous responses, the assurance that the applicant was presently acting in accordance with previously agreed practice was affirmed. It was advised that the question of pseudonymisation of data prior to disclosure to the applicant would be one of the issues that would be considered following the submission of the new application for the January CAG meeting and at that stage a distinction may be drawn between sensitive data items that are currently disclosed to Imperial and non-sensitive items.

### 14/CAG/1012 – previous reference 14/CAG/1001 Critical Care Health Informatics Collaborative

This application detailed the establishment of a research database including clinical, laboratory and demographic data in relation to all patients admitted to Adult Critical Care Units across 5 NHS Trusts.

An application for support under class 1, 2, 4 and 6 was received to allow access to data from hospital systems and Hospital Episode Statistics (HES) data from the Health and Social Care Information Centre (HSCIC). NHS number, date of birth, postcode and gender were requested in order to carry out linkages to HES data.

**Confidentiality Advisory Group advice**

At the meeting on the 28 August it was agreed that further information would be required prior to confirming that the minimum criteria under the Regulations appeared to have been met. Members requested that the applicant provide further information in relation to the following points. Members advised that if useful a meeting could be arranged with the applicant as they were supportive of the application in principle and were keen to engage with the applicant on the points raised.

A meeting between the applicant and members, Mr C. Marc Taylor, Dr Patrick Coyle and Ms Clare Sanderson, took place on 1 October and further information was submitted following this meeting on 28 October 2014.

This information was forwarded to a sub-group of members who noted that the applicant had explored the feasibility of using a pseudonymised approach and this had proved not to be feasible due to capacity. Members agreed that this should be explored further when an application was submitted for the full activity.

Members reviewed the data sharing agreement (DSA) provided and noted that this specified - *Each party is jointly a data controller until the data is de-identified and no longer personal data as defined by the Data Protection Act 1998.* Members highlighted to the applicant the need to assign appropriate terms and conditions through the DSA in order to constrain the chance of re-identification and the applicant confirmed that this could be undertaken.

**Confidentiality Advisory Group advice**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

1. Confirmation of a favourable Research Ethics Committee opinion

2. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

**Secondment report**

The Chair provided a written update on activities undertaken so far in his secondment capacity as Data Policy Advisor to the Health Research Authority (HRA). This item was noted by members.

## 9. ANY OTHER BUSINESS

There was no other business.