NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

6 November 2014 at 10:15 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Kambiz Boomla	
Dr Patrick Coyle (Chair for items 1 to 2c and 3a to 7)	
Dr Tony Calland MBE (Chair for items 1 to 2c and 3a to 7)	
Mr Anthony Kane (Chair for item 2d)	Lay
Mr C Marc Taylor	
Ms Clare Sanderson	
Professor Jennifer Kurinczuk	
Professor Barry Evans (Items 1-2d and 4-7)	
Dr Miranda Wolpert (Items 1 to 3d)	
Dr Mark Taylor (Item 2d)	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager (Items 2d to 7)
Mr John Robinson	Confidentiality Advisor, HRA (Item 2d)
Mr Hayden Thomas	NHS England (Items 2a to 2c)
Ms Hazel Watson	NHS England (Items 2a to 2c)
Ms Florence Starr	NHS England (Items 2a to 2c)
Mr Richard Sewart	NHS England (Items 2a to 2c)
Mr Andy Tookey	NHS England (Items 2a to 2c)
Mr Darren Lloyd	NHS Wales Informatics Service (Item 2d)
Mr Gareth Jones	NHS Wales Informatics Service (Item 2d)

Dr Robert Kyffin	Public Health England (Items 3a to 3d)
Dr Jen Rashbass	Public Health England (Items 3a to 3d)
Professor Barry Evans	Public Health England (Items 3a to 3d)
Mr Mat Johnson	Public Health England (Items 3a to 3d)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introduction

Members were welcomed to the meeting by Dr Tony Calland and Dr Patrick Coyle, who had agreed to undertake role of Chair for the meeting. It was agreed that Dr Coyle would act as Chair for agenda items 1 to 2c and Dr Calland for items 3a to 7. Mr Anthony Kane agreed to Chair for item 2d due to other conflicts of interest.

Members were notified that Professor Ann Jacoby had tendered her resignation in October 2014. The Group extended its thanks to Professor Jacoby for her contribution to the work of the CAG.

Apologies

Apologies were received from Dr Robert Carr, Ms Hannah Chambers, Professor Julia Hippisley-Cox, Dr Murat Soncul, Dr Mark Taylor, Ms Gillian Wells.

Declarations of Interest

The following interests were declared:

<u>Dr Patrick Coyle and Dr Tony Calland - Item 2d CAG 8-02 (d)/2014 (Patient Episode Database Wales)</u>

Dr Patrick Coyle and Dr Tony Calland advised that as members of the Welsh Information Governance Board and Privacy Advisory Committee that they would not participate in the discussion of this item and would leave the meeting during the discussion. It was agreed that Mr Anthony Kane would chair this item (2d).

<u>Professor Barry Evans - Items 3a to 3d Public Health England Annual Reviews – follow-up report</u>

Professor Barry Evans advised that he had been supporting Public Health England on their report to be considered by the CAG. He therefore joined the applicants in the discussion with CAG and did not participate nor was present for the CAG deliberations and recommendation.

Ms Clare Sanderson confirmed that she had been advising Ms Ming Tang on information governance issues but had had no involvement in item 2a-c. This was noted and agreed there was no conflict.

Professor Jennifer Kurinczuk noted that in future that she may have an arising conflict with Public Health England in relation to congenital anomalies due to her work on this aspect. This was noted, agreed there was not a conflict at present and any conflicts should be declared when known.

2. NEW APPLICATIONS – NON RESEARCH

a) Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting [CAG 8-02(a)/2014]

b) Assuring Transformation: Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient registers and reporting [CAG 8-02(b)/2014]

c) Assuring Transformation: Enhanced Quality Assurance Process Data Flow (Disclosure by HSCIC to NHS England) [CAG 8-02(c)/2014]

A suite of three applications were presented by NHS England to reflect the different data flows; this clarity was particularly welcomed and aided in clarity of the review. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management was defined in this context to mean ensuring the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided.

Confidentiality Advisory Group advice

Members welcomed the attendance of Mr Hayden Thomas and colleagues and found the discussion to be succinct, focused and very useful in clarifying the arising questions. The clarity of the application and engagement with the pre-meeting advice was also noted. Members confirmed that they were very supportive of this system being established and there was a significant public interest in these data flows continuing.

<u>Scope</u>

Discussions clarified that the majority of these data flows were in effect and the current legal basis rested upon reliance of the public interest; legal advice had been submitted that confirmed support was sought to manage any potential breach of confidentiality. It was confirmed that legacy or retrospective data already collected would not be within the scope of requested support and the processing of retrospective data would be addressed via an alternative legal basis through new Direction establishment. This position of legacy data was noted and agreed this would not be included within the scope of the application.

Support was therefore requested to enable the ongoing collection of data and facilitate the move to a more long-term solution of data collection from commissioners direct to the audit platform provided by the Health and Social Care Information Centre (HSCIC), and to support a broader change programme of standardisation. Support was requested until

end March 2016. Members queried whether this was a realistic time period for the seeking of support however the applicants confirmed that this was believed to be a reasonable timescale at the present time.

Public Interest

Members unanimously agreed that there was a high public interest in these data flows receiving a clear legal basis to remove any potential breach of confidentiality, and for an effective system to be embedded. The public interest, in seeking to identify NHS patients remaining in long-stay NHS beds in order to more appropriately manage care and to ensure that no patient was overlooked within the system, was considered to comprise an extremely strong public interest. The point was also noted that a key challenge faced was that commissioners of care were by constitution arms-length bodies. Members queried how it was known that the approach would provide the anticipated benefits and agreed that the realisation of these benefits should be articulated at annual review stage.

Practicable alternatives

Members noted the assertion that pseudonymised information would be insufficient as there was a clear need to identify specific patients in certain circumstances. The need to identify specific patients was acknowledged.

The application also asserted that consent would not be feasible due to large numbers and need to obtain 100% ascertainment; in particular, issues of provider conflict of interest that may arise should a consent-based approach be pursued was highlighted. Members agreed that reliance upon a consent-based mechanism would mean that those patients most in need may not receive the support required, and therefore agreed this was likely not to be a practicable alternative to seeking support. As a whole, members were unable to identify an alternative method by which this activity could be carried out, other than pursuant to seeking support under Regulation 5.

Patient objection under confidentiality

The application clarified that there was a need to achieve 100% patient ascertainment on public interest grounds. Noting that there was a lack of clear detail within the application on this specific aspect, the discussion around the patient leaflet clarified that a mechanism to manage patient objection would remain and was likely to follow the ‘section 10 notice’ mechanism established under the Data Protection Act 1998. It was confirmed that if an objection was made, any intent not to respect the objection would not be legitimised under Regulation 5 of the 2002 regulations; instead it would be considered under a public interest test. In addition, it was confirmed that any such objection would be managed on a case by case basis, involving the patient and/or representatives. Members noted that the provisions of the Mental Capacity Act, where applicable, must be adhered to. It was noted that it was difficult to be precise on the actual handling as there was no previous examples to cite; therefore members agreed that this detail, as currently known, should be clearly written into the application and an update on the practical application of patient objection provided at an early review stage and at annual review stage.

Security arrangements

Members noted reference to the NHS England 'safe haven' and commented that this was an unhelpful phrase with no clear definition that may not be an accurate reflection of what the arrangements are. Members questioned the level of specificity e.g., who would have access to the systems and sought clarity on whether NHS England had achieved a satisfactory IG toolkit score as the original security measures established under CAG 6-07 (a)/2013 were meant to be an interim measure while NHS England reached a satisfactory level. Members also sought clarity that each CCG would be expected to attain a satisfactory IG Toolkit score of level 2 as a minimum due to some ambiguity within the application.

Fair processing under the Data Protection Act 1998

It was noted that any approval cannot be inconsistent with the Data Protection Act (DPA) 1998, and that any relevant entity or person processing personal data must be compliant with this Act.. Members sought clarity on how this aspect would be addressed within the application and by the 221 Clinical Commissioning Groups (CCGs). It was confirmed that centralised information would be published/provided by the HSCIC with posters and pamphlets to be distributed locally. Discussions confirmed that for those CCGs unable to comply with requirements that measures would be taken e.g. Area Teams could go on-site to check and/or a detailed action plan would need to be in place.

Members agreed that this fair processing plan should be more clearly specified within the application. In reviewing the 16-page patient leaflet, members commented that the leaflet talked generically about information, but did not make explicit what the information was nor where it had derived from and it would be of benefit to make this more explicit. Members also advised that there should be appropriate leaflets for carers and relatives and questioned whether objection would be provided for this group; feedback should be provided on this. Members appreciated that a significant amount of engagement appeared to have taken place when developing the leaflet; a view was expressed that in not clearly making right of patient objection apparent there was a perceptual risk of appearing to treat this vulnerable group differently. Members therefore urged there to be a clear articulation on how patient objection was intended to be managed as discussion confirmed that

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health until end March 2016, subject to satisfactory resolution of the clarification requests, and compliance with the specific and standard conditions of support as set out below.

Clarification request

1. Review of patient leaflet to make more explicit the nature of the information being processed.
2. Review/development of leaflet for carer/relatives and how any objections may be managed.
3. Update to application to include explicit detail on how patient objection is intended to be managed.

4. Update to application to include greater detail on how fair processing compliance and the plan for implementation will be managed within the CCGs, including the compliance standards.

Specific conditions of support

1. Where a patient seeks to object to the data processing, any intent not to respect the objection must be legitimised under a different legal basis; this support cannot be relied upon in those instances.
2. Written confirmation to be received directly from the HSCIC IG Toolkit team that the updated security and processing arrangements specified for bodies receiving data are satisfactory, and that NHS England have achieved a satisfactory IG toolkit score.
3. Legacy data collected prior to the date of final approval in this letter is excluded from the scope of support and an alternative legal basis to be identified by the applicant to continue processing this data.
4. Data related to third parties, not considered to be that of the patient, is excluded from the scope of this support.
5. An annual review should be submitted no later than 11 months from date of final approval. Detail of any patient objections and how these have been handled to be included at annual review stage. Additionally, benefits arising from the activity should be articulated.
6. Short written update report to be provided in six months for consideration at the June 2015 meeting, this should include:
    a. Practical application of patient objection – guidance, process, experience, handling and outcomes
    b. Updated patient and carer leaflet
    c. Progression towards exit strategy – plan, any potential issues.

d. CAG 8-02(d)/2014 Patient Episode Database Wales

This application from NHS Wales Informatics Service (NWIS) detailed the definitive statistical database on NHS hospital activity in Wales, the Secondary Care National Database for Wales (SCNDW), used to support the NHS Wales Department and the Health Statistics Division of the Welsh Government, other Government functions and organisations in NHS Wales. A number of key purposes were set out within the application form.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information from a range of Welsh and English NHS organisations in relation to treatment of patients resident in Wales. Access was requested to NHS Number, Name, Date of Birth, Gender, Address and Postcode.

Background

Members were informed that the application had previously been submitted to both the Patient Information Advisory Group (PIAG) (in 2007) and the Ethics and Confidentiality Committee (in 2009) who had advised that the purposes of the application appeared to be too broad for class support under Regulation 5 and had recommended that the

applicant pursue specific support provisions, similar to Regulation 2 or 3, under the Health Service (Control of Patient Information) Regulations 2002.

Confidentiality Advisory Group advice

Members thanked Mr Darren Lloyd and Mr Gareth Johns from NHS Wales Informatics Service (NWIS) for attending the CAG meeting in order to discuss their application. It was agreed that the discussion was beneficial and provided further detail and context in relation to the submission.

Exit strategy

The exit strategy detailed within the application form and supporting documents was confirmed as the establishment of Regulations to allow the processing of confidential patient information to be undertaken by NWIS for specified purposes. NWIS would require similar statutory powers to that of the Health and Social Care Information Centre within England to enable this permanent legal basis to be in in place. Members raised concerns that this application from Wales had been received at this time when similar processing within England, which had previously relied on interim support under Regulation 5, had been provided with a statutory basis under the Health and Social Care Act 2012. The applicant explained the complexities of the situation involved in establishing a permanent statutory basis for the processing and progression towards this had not been as hoped. In this absence, it was therefore recognised that interim support under Regulation 5 would be required to provide a legal basis for processing in the short term.

Members reiterated that any support was a temporary measure only and, given the recent developments in England, recognised the importance of the appropriate bodies working together to seek a permanent legal basis to allow this important data collection to take place on a more long-term basis. The complexity of the situation was recognised, however, members recommended that this should be pursued as a matter of urgency. An update in relation to progress should be provided in relation to this specific issue within 12 months.

Scope of application

Members noted that both the PIAG and ECC considered that the application had been too broad in terms of purposes for class support. However, the discussion with the applicant at the meeting indicated that the request for support was for a limited amount of processing which would allow the data to be pseudonymised for secondary uses and that the initial processing by NWIS was undertaken on behalf of the Health Boards, for whom NWIS acted as a data processor. Members agreed that the application did not appear to accurately reflect that support was requested only for the purpose of undertaking pseudonymisation of data for secondary uses. In order to ensure that an accurate record of the request was retained, members asked that the applicant amend the application form and supporting documents to ensure that the scope of the requirement for support was clear.

Information governance controls

Members agreed that the controls explained to them by the applicant at the meeting provided reassurances that access to identifiable data would be restricted to limited individuals for specific purposes and that there were controls in place to prevent unauthorised access. The applicant had explained that these were system based controls which allowed techniques such as role based access controls to be implemented but that the identifiable data would not be physically separated from the identifiable data within the system. Member requested that the applicant ensure that these controls were detailed within the application form and supporting documents. Members did query whether physical separation of identifiable and clinical data could be achieved but recognised that this would not be possible in the short term.

Patient objection

The applicant explained that there were a number of difficulties in registering and respecting patient objections given the dual purposes of processing by NWIS and the capability of local systems to record objections. Members advised that patient objection for secondary uses would be required. The applicant confirmed that it would be possible for patients to register objection to processing directly with NWIS. Members requested that the patient information leaflet be updated to include this information and that it was ensured that objection was permitted and respected.

Confirmation of satisfactory security arrangements

Members were advised that an equivalence assessment had been undertaken in June 2013 by the Health & Social Care Information Centre (HSCIC) in relation to the Welsh Caldicott Principles into Practice (C-PiP) and the English Information Governance Toolkit. The report had recommended that C-PiP provided an acceptable equivalence level in terms of providing security assurance. To enable C-PiP to be accepted as an appropriate security assurance mechanism for the purpose of seeking support under these Regulations would require the Department of Health and NHS England to develop a memorandum of understanding (MoU) with the Welsh Government. No evidence was provided to demonstrate that this aspect had progressed. Once the MoU was in place, the HSCIC could confirm satisfactory security assurance for the purposes of this application. The applicant was advised that without confirmation of appropriate security assurance from the HSCIC, there would be likely to be a delay to any potential support coming into effect as evidence of appropriate security arrangements are a minimum requirement for final approval. Members were advised that completion of the Information Governance Toolkit as an alternative was being considered.

Confidentiality Advisory Group advice conclusion

Given the importance of the data collection, and in line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support and further satisfactory information being submitted as soon as possible and by the January 2015 CAG meeting at the latest.

Request for further information

Amended application documents that include the following information should be submitted:

a. Specific and clear reference to those aspects of data processing which require support under this application.
b. Details of controls in place to ensure limited access to identifiable data and prevent unauthorised access.

Specific conditions of support

1. An exit strategy via Regulations should be pursued and significant progress should be made within 12 months. A report on progress made should be submitted with the annual review report.
2. Confirmation of suitable security arrangements. This would need to be confirmed following the establishment of a MoU between DH and NWIS if C-PIP was to be relied upon, or via the completion of the IG Toolkit.
3. Fair processing information should be amended to include information in relation to how a patient can register an objection to processing by NWIS and this should be respected.

Security assurance for Welsh applicants

Noting the significant amount of time that had passed since the HSCIC equivalency report had been provided to the Department of Health, and the potential delay and impact to affected activities seeking support under Regulation 5, it was agreed that a letter should be sent to the Secretary of State Representative in order to draw their attention to this issue and impact to applicants.

Action: CAT to draft letter to SofS representative highlighting the potential impact of the lack of MoU on Welsh applicants.

3. ANNUAL REVIEWS

Public Health England had been invited to attend the meeting to discuss the annual review submission for items 3a-d below and answer any queries and members welcomed Professor Barry Evans, Mr Matthew Jordan, Dr Robert Kyffin, and Dr Jem Rashbass to the meeting. Members found the specific attendees to be particularly helpful in describing the current status and when discussing the arising issues, and wished to pass on their thanks to the representatives.

All annual review submissions had been submitted for review at the June and August 2014 CAG meetings and the CAG had recommended that the provision of advice be deferred to allow further information, requested at the August 2014 CAG meeting, to be provided and considered. Due to length of time members had previously advised of the potential for a recommendation of no support to be provided should suitable engagement with the points not be subsequently evidenced. It was noted that two separate positive meetings had taken place with CAG representatives and it was clear that significant engagement with the requirements of the applications had been made.

a. PIAG 03(a)/2001 - National Cancer Registries Database

Confidentiality Advisory Group advice

Information Governance Toolkit improvement plan

Members noted the detail of the update report and it was confirmed that the information governance toolkit for the discrete cancer registration service had achieved a satisfactory level. No further comments were made on this aspect. In reviewing the updates against the specific actions listed against this reference, members were pleased to note the progress that had been made.

In reviewing the timetable of actions, members queried whether these were realistic and were informed that these were seen to be realistic at the present time.

Application to be consistent with the provisions of the Data Protection Act

It is a requirement under section 251 (7) of the National Health Service Act 2006 that the processing of prescribed patient information cannot be inconsistent with the any provision made by or under the Data Protection Act 1998. The first principle of the Data Protection Act 1998 encapsulates the requirement for provision of fair processing information. At the August meeting members had asked that the applicant resolve the issue of fair processing in conjunction with the Information Commissioners Office (ICO) and develop a programme plan to manage establishment on an interim and long-term basis. In particular members had commented at the August meeting that the 28 page information booklet made no reference to recipients of data.

An update report in relation to patient information and objection was provided for review at the November meeting. It was confirmed that a consultation process had been undertaken by NCRS and Cancer Research UK in order to secure the endorsement of a large number of national cancer charities and patient representative groups to a revised cancer registration patient information leaflet and a simplified objection process. The revised information would be published at multiple online locations and print copies sent to all oncology departments and cancer charities. It was confirmed that PHE intended to audit the effectiveness of the dissemination strategy. The feedback from the ICO was also noted.

Patient objection under confidentiality

The patient objection policy was provided in relation to the NCRS at the August meeting and members had commented that the language used in the policy was abrupt, did not refer to the benefits and suggested that it would benefit from revision. PHE confirmed that changes had been made to the NCRS objection policy in response to these comments and provided an updated copy of the policy to the November meeting.

Clarification of legal basis for international transfers

Members noted the information provided that confirmed that overseas disclosures under Regulation 2 were being assessed and approved by a named senior civil servant within Public Health England. Members had not previously been aware of this approval

mechanism and reviewed the information provided by PHE from a DH lawyer. In discussing this management, members sought clarity on how recipient identity was checked and how approval was managed as part of the current approval mechanisms under the Regulations. Members requested a copy of the standard operating procedures that set out this approach and agreed to raise with the Secretary of State for Health approval representative to identify what, if any, impact, this would have on the CAG in terms of discharging its function to provide advice to the relevant approval bodies under Regulation 2.

Action: CAT to write to SofS approver to flag issue

Confidentiality Advisory Group recommendation

Members agreed that significant engagement had appeared to take place with the previous outcomes and welcomed this. It was clear that positive steps had been evidenced and there was a clear plan of action in place and members therefore agreed that a continuing recommendation of support should be provided for a further twelve months, subject to the specific and standard conditions of support.

Specific conditions of support

1. Provision of standard operating procedures and any other relevant documentation supporting the decision-making for the transfer of identifiable information overseas, to be provided no later than 05 December 2014.

2. Provision of short update report on progression against timetabled actions to be submitted no later than 13 May 2015 to enable consideration at the CAG June 2015 meeting.

b. PIAG 2-08(e)/2002 Congenital Abnormality Survey (NorCAS) and West Midlands Congenital Anomaly Register (WMCAR)

Confidentiality Advisory Group advice

<u>Submission of a new application form</u>

A new application had been received in relation to the two registers on 3 November 2014 and it was noted that the current approval under the above reference number would cease on 28 November 2014. The new application would be processed separately via the precedent set process.

A further submission was anticipated for the January 2015 meeting for the national data collection, Public Health England Congenital Anomaly and Rare Disease Registration Service. This would require consideration at a CAG meeting and the applicant was advised to review the submission process to ensure relevant timescales were met. Members advised that it would be useful for a privacy impact assessment to be submitted in the supporting documentation.

<u>Information Governance Toolkit improvement plan</u>

Members had requested that a final update be provided in relation to the attaining level 2 status in high-risk areas. It was confirmed that the PHE 2014/2015 mid-year IG Toolkit assessment update would be submitted to the Health and Social Care Information Centre (HSCIC) at the end of October and an update report on the outstanding improvement actions needed to ensure that all PHE applications satisfactorily complied with the IG Toolkit arrangements was provided. It was noted that improvements were reported to the IG Toolkit scores in August. It was noted that there was an outstanding action to ensure that appropriate confidentiality audit procedures to monitor access to confidential patient information were in place, which would be addressed by 30 November 2014, and to implement processes to ensure that information is protected through use of pseudonymisation and anonymisation techniques where appropriate. An update in relation to this was requested once complete and should be provided in the context of the new application submitted on 3 November 2014.

Confidentiality Advisory Group recommendation

Based upon the current progress in relation to the Information Governance Toolkit improvement plan and noting that a new application had been received; members recommended that the current support should continue in the interim whilst the new application which included NorCAS and WMCAR specifically was processed.

c. PIAG 1-08(a)/2003 Contacting National Health Applications and Infrastructure Services (NHAIS) Data Subjects for Cancer Screening Programmes in England

Confidentiality Advisory Group advice

Information Governance Toolkit improvement plan

Members had requested that a final update be provided in relation to the attaining level 2 status in high-risk areas. It was confirmed that the PHE 2014/2015 mid-year IG Toolkit assessment update would be submitted to the Health and Social Care Information Centre (HSCIC) at the end of October and an update report on the outstanding improvement actions needed to ensure that all PHE applications satisfactorily complied with the IG Toolkit arrangements was provided. It was confirmed that improvements had been made to the internal management of IG assurance for the National Office and regional Quality Assurance Reference Centres (QARCs) that comprise the Cancer Screening Programmes. The remaining improvement action was to implement appropriate physical access controls for the National Office and the action deadline for this was reported as 31 November 2014. Members agreed that an update in relation to the outstanding actions should be provided in 6 months' time.

Consistent approach to assessing the need and extent of confidential patient information

Confirmation that the detail within the report submitted to the August meeting applied to all novated application was requested as the report specified arrangements in relation to activities under Regulation 2 only. It was asserted that

the Cancer Screening Programmes had a fundamental operational requirement to process information from the National Health Applications and Infrastructure Services (NHAIS) system in order to identify eligible patients and invite for screening. It was noted that, as part of the IG Toolkit assessment, a review was underway in relation to the wider quality assurance function across PHE and a report would be provided at the end of 2014 which was expected to recommend new management arrangements and procedures to increase the level of standardisation in the delivery of the quality function. This would include addressing the lack of consistent use of pseudonymisation and anonymisation techniques.

Patient objection

Further information was requested in relation to how patient objection would be managed across all PHE activities or, if this differed, in relation to specific applications. It was confirmed within the patient information and objection update report that the advice of the Information Commissioners Office had been sought in relation to a clear objection process for those patients who did not wish to have their confidential patient information processed for purposes other than the direct provision and quality assurance. It was confirmed that discussions had taken place with the Confidentiality Advice Team in relation to a possible new application which would entail a review of the fair processing and objection arrangements for each of the three programmes. Members encouraged the applicant to pursue a new application as soon as possible.

Members queried whether the applicant could be clearer about the process for registering patient objection and the applicant explained the complexities in relation to opt out for screening programmes as data was derived directly from the NHAIS system.

Application to be consistent with the provisions of the Data Protection Act

It is a requirement under section 251 (7) of the National Health Service Act 2006 that the processing of prescribed patient information cannot be inconsistent with the any provision made by or under the Data Protection Act 1998. The first principle of the Data Protection Act 1998 encapsulates the requirement for provision of fair processing information. At the August meeting members had asked that the applicant resolve the issue of fair processing in conjunction with the Information Commissioners Office (ICO) and develop a programme plan to manage establishment on an interim and long-term basis.

An update report in relation to patient information and objection was provided for review at the November meeting. This confirmed that a revised fair processing notice had been drafted by PHE and would be published shortly, a copy was provided within the report. The advice of the ICO on how the current patient information leaflets for the screening programmes could be adopted had been sought and it was confirmed that the ICO had advised some amendments to the patient information sheets.

Onwards transfer of identifiable information

Members requested that the applicant provide documented recognition that support was not in place to allow the onwards transfer of identifiable information. PHE confirmed that there were no internal or external third party transfers of information taking place outside the conditions for any of the application. It was asserted that very clear managerial and operational controls were in place to ensure that it complied with all legal and contractual conditions in relation to the processing of confidential patient information.

Confidentiality Advisory Group recommendation

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, to the date specified above. An update report in relation to the outstanding issues must be submitted in time for the June 2015 CAG meeting and should include progress in relation to:

1. The implementation of appropriate physical access controls for the National Office.
2. The review of the wider quality assurance function across PHE and a report would be provided at the end of 2014 which is expected to recommend new management arrangements and procedures to increase the level of standardisation in the delivery of the quality function.
3. The submission of a new application form.
4. The amendments to the patient information sheets suggested by the ICO.

d. ECC 5-05 (e)/2012 National Drug Treatment Monitoring System (NDTMS)

Confidentiality Advisory Group advice

<u>Information Governance Toolkit improvement plan</u>

Members had requested that a final update be provided in relation to the attaining level 2 status in high-risk areas. It was confirmed that the PHE 2014/2015 mid-year IG Toolkit assessment update would be submitted to the Health and Social Care Information Centre (HSCIC) at the end of October and an update report on the outstanding improvement actions needed to ensure that all PHE applications satisfactorily complied with the IG Toolkit arrangements was provided. It was noted that the remaining action in relation to the NDTMS was to ensure that the confidential information of patients was further protected by increasing the use of pseudonymisation and anonymisation through the re-procurement of the data and analytical contract held by the University of Manchester. It was confirmed that this would be addressed once the re-procurement process had been completed at the end of the year.

<u>Consistent approach to assessing the need and extent of confidential patient information</u>

Confirmation that the detail within the report submitted to the August meeting applied to all novated application was requested as the report specified arrangements in relation to activities under Regulation 2 only. It was confirmed that the range of personal identifiers had been determined to be the minimum required to enable the linkage of treatment

episodes over time to support both the analysis of trends in drug addiction and to monitor the effectiveness of services.

Patient objection

Further information was requested in relation to how patient objection would be managed across all PHE activities or, if this differed, in relation to specific applications. It was confirmed that data within the NDTMS was collected with consent but that the arrangements for managing the records of non-current service users who object was being clarified.

Onwards transfer of identifiable information

Members requested that the applicant provide documented recognition that support was not in place to allow the onwards transfer of identifiable information. PHE confirmed that there were no internal or external third party transfers of information taking place outside the conditions for any of the application. PHE asserted that very clear managerial and operational controls were in place to ensure that it complied with all legal and contractual conditions in relation to the processing of confidential patient information.

Application to be consistent with the provisions of the Data Protection Act

It is a requirement under section 251 (7) of the National Health Service Act 2006 that the processing of prescribed patient information cannot be inconsistent with the any provision made by or under the Data Protection Act 1998. The first principle of the Data Protection Act 1998 specifies the requirement for provision of fair processing information. At the August meeting members had asked that the applicant resolve the issue of fair processing in conjunction with the Information Commissioners Office (ICO) and develop a programme plan to manage establishment on an interim and long-term basis.

An update report in relation to patient information and objection was provided for review at the November meeting, this confirmed that a revised fair processing notice to inform current and past drug treatment service users about how their information would be processed by the NDTMS was being prepared and would be forwarded to the Information Commissioners Office (ICO) and CAG in due course. Copies of the fair processing information currently available to patients were provided within the report.

The fifth principle of the DPA states that personal information must not be kept for longer than is necessary. Members advised at the August meeting that the case for ongoing retention in an identifiable format had not been made and requested a separate formal written amendment and justification to be submitted if the terms of the original approval were to be changed.

The update report confirmed that the retention requirements for NDTMS had been misstated in the original application and that the feasibility of deleting identifiers from records that had been held beyond a number of years had been reviewed by the NDTMS management team and it had been confirmed that deleting these would limit the time period over which treatment episodes could be linked. It was asserted that the would have a substantial negative impact on the ability of PHE to monitor and report on

longitudinal drug use patterns and assess the effectiveness of treatment programme in reducing drug dependency.

A separate amendment request was submitted in relation to this aspect on 3 November 2014 and tabled at the CAG meeting. Members reviewed the submission and queried whether the applicant considered there to be any exit strategy from the use of confidential patient information for this purpose. Members requested that the applicant provide further information in relation to whether they considered that there was a viable exit strategy to the use of confidential patient information without consent and progress made towards this at the next annual review.

Confidentiality Advisory Group recommendation

Based upon the current progress in relation to the Information Governance Toolkit improvement plan; members 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, to the date specified above. In addition to the original conditions of support, this was subject to the following conditions of support:

1. Further information in relation to whether there was an exit strategy from support under the Regulations. If an exit strategy was identified, progress in relation to the movement towards this exit strategy should be provided at the next annual review submission.
2. An update in relation to outstanding actions arising from the Information Governance Toolkit submission should be provided at the next annual review stage.

4. MINUTES OF THE MEETING HELD ON 02 OCTOBER 2014

The minutes were agreed as an accurate record.

5. CHAIR'S REPORT

Following on from the discussion at the August 2014 meeting, 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.

6. OFFICE REPORT

For information

Secretary of State approval decisions

The Department of Health 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 October 2014 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the October 2014 meeting applications.

Applications considered via precedent set review

14/CAG/1023 PRISM-TIMI Score - A Medical Record Review (v.1)

This application from St George's, University of London set out the purpose of determining whether using a novel prehospital risk stratification tool (The Modified Thrombolysis in Myocardial Infarction Risk Score) is better than the current methods used by paramedics in the London Ambulance Service at assessing the severity of a heart attack that a patient is suffering.

A recommendation for 1, 4, 5 and 6 support is being requested to perform a data linkage between ambulance and hospital records.

Confidential patient information requested

Access was requested to name, date of birth, gender and date of admission.

Confidentiality Advisory Group advice

Public interest

Members agreed that there was public interest in testing the use of the Modified Thrombolysis in Myocardial Infarction Risk Score risk stratification tool for paramedics to better assess the severity of a heart attack.

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 recognised that distress could be caused by approaching relatives. It was noted that there was a need to include every potential non ST Elevation Acute Coronary Syndrome patient in this research and that the Applicant would struggle to identify all patients living abroad.

Justification of identifiers

Members agreed that name, date of birth and gender was required for linking ambulance and hospital records.

Additional points

Members were unclear as to the retention period of the confidential patient information, as they noted that in response to question 57 of the application form it stated that

personal data would be stored for over 3 years whilst in another part of the form 6 months has been specified.

CAG 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 provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

Specific conditions of support

1. Favourable opinion from REC.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation that the retention period of confidential patient information is 6 months.

14/CAG/1024 Late aneurysm-related mortality up to 15 years, secondary endovascular repair late sac rupture risk and costs and cost-effectiveness implications in the United Kingdom Endo-Vascular Aneurysm Repair randomised controlled trial (EVAR 1)

This application from Imperial College London was submitted in order to access Hospital Episode Statistics (HES) data. The applicant requested HES data in relation to hospital admissions and procedures for patients who were participants in the EVAR 1 trial at hospitals in England and who had been lost to aneurysm related follow-up and fell into one of the following categories:

1. Patients who had been unable to attend an aneurysm specific follow-up visit after 2009 but were still known to be alive or lost to aneurysm related follow-up.

2. Patients who have had no aneurysm specific follow-up after 2009 and were known to have died since.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to Hospital Episode Statistics data in relation to the cohort continued receipt of mortality data from the Health and Social Care Information Centre (HSCIC) in relation to date and cause of death. This application was reviewed under the precedent set process by Dr Mark Taylor (Chair), Dr Tony Calland, Mr C Marc Taylor.

<u>Confidential patient information requested</u>

Access was requested to NHS number, hospital number, date of birth, date of death and gender.

Confidentiality Advisory Group advice

<u>Practicable alternatives</u>

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. It was noted that all patients participating in the EVAR trials gave written informed consent prior to randomisation, however the consent provided did not contain explicit reference to national databases.

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 conditional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

Specific conditions of support

1. Favourable opinion from Research Ethics Committee

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

14/CAG/1025 Cognitive Function and Ageing Study (CFAS) - Death notification of participants at HSCIC

This application from the University of Cambridge set out the purpose of the Cognitive Function and Ageing Study (CFAS) which was a large population based epidemiological study which began in 1990 involving people aged over 65 in six centres of Britain including Liverpool, Newcastle, Nottingham, Oxford, Cambridge and Gwynedd. Over 18,000 people were initially recruited to the study and conducted over 48,000 computer based interviews over a 20+ year period that has increased knowledge on the onset, course and risk factors for dementia and related conditions in the older population as well as healthy and frail ageing.

A recommendation for class 4 and 6 support was requested to cover access to mortality data from the Health and Social Care Information Centre (HSCIC). This application was reviewed under the precedent set process by Dr Mark Taylor (Chair), Mr Anthony Kane and Ms Clare Sanderson.

Confidential patient information requested

Access was requested to requested to name, NHS number, date of birth, date of death, postcode, place of death, cause of death, ICD10 codes, gender and occupation.

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. It was noted that consent

would not be practicable in this instance due to the retrospective nature of the cohort but that all participants had given consent to their data being used in a similar way, but using a different data source. Identifiable data would be required in order to link mortality data with cohort data currently held by the applicant in relation to interviews.

Retention of confidential patient information

It was noted that identifiable data would be retained until the death of a subject and would then be destroyed; however elsewhere the application form suggested that confidential patient information would be retained indefinitely. Confirmation was requested whether the intention was to hold identifiable data indefinitely and whether data had been de-identified where patients had already died.

Fair processing

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. Members discussed that fair processing would be difficult given the retrospective nature of the cohort. However, they advised that the applicant make some efforts to inform the cohort such as updating the University website to ensure that the data collected for the purposes of the study was clear.

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 provisional 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 provisional support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Specific conditions of support

1. Please ensure the deletion of identifiable data in relation to deceased patients or confirm why it is important or more appropriate to retain identifiable data in relation to the deceased at this time.

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

3. Confirmation of favourable Research Ethics Committee opinion.

Amendments to approved applications

CAG 6-07 (a)/2013 Enhanced quality assurance process of the provision of NHS- funded care for people with a learning disability or autistic spectrum disorder – duration amendment

This amendment, considered by the Chair and the Advice Team, related to a non-research, commissioning application from NHS England. Support had originally been provided to enable the quarterly data collection as specified in the approved application ('Triangulation of data') until August 2014. A subsequent contingency amendment was approved to enable NHS England to carry out the September 2014 data collection. This had been approved due to delays in the establishment of suitable Directions.

Subsequent correspondence between the Advice Team, Mr Ray Avery and Mr Hayden Thomas had clarified that there was a need to further extend the duration period for NHS England to carry out the data collection due to further delays in establishment of suitable Directions to enable the Health & Social Care Information Centre (HSCIC) to undertake the data processing and thus remove the need for reliance upon this support.

The amendment requested the following:

1. The existing support to be extended to enable NHS England to undertake the December 2014 data collection. The rationale cited was that this should allow sufficient scope and time for Directions to be issued to the HSCIC.

2. While the plan was for the initial data collection to be undertaken by the HSCIC to planned timescales and to required quality; it would be prudent to plan for a contingency arrangement. In line with this, the amendment also requested contingency support to cover the March 2015 data collection by NHS England and subsequent processing until 31 May 2015, in the event that Directions were not in place to enable the HSCIC to undertake the March 2015 data collection.

Confidentiality Advisory Group advice

It was noted that this activity had previously received support due to its stated high public interest to help ensure the appropriate safeguarding of adults. In noting the public interest in this activity proceeding, it was recommended that the duration amendment to enable the December 2014 data collection by NHS England to take place should be supported as there was a persuasive argument on the timeliness of Directions being in place for this time.

In relation to the justification for NHS England to carry out the March 2015 data collection, it was noted that sufficient time would have passed to allow Directions to be in place by this time so as to enable the HSCIC to undertake this data collection and it was strongly advised that the expectation would be for these to be in place so support should not be required. However, it was noted that progress on Directions appeared to be slower than expected and it was emphasised that having support in place should not be understood to reduce momentum nor the expectation for the HSCIC to undertake the March 2015 data collection. It was therefore advised that contingency support should be recommended. This was on the basis that NHS England would confirm by 30 January 2015 whether support would be needed and if so, a clear plan showing the exit strategy

for Directions should be provided to evidence the request and allow the support to come into effect.

Specific conditions of support

1. NHS England to maintain suitable security arrangements as agreed by the HSCIC in line with the original application detail.

2. The contingency arrangement to allow NHS England to carry out the March 2015 data collection to remain dormant until confirmation and evidence of need is provided by 30 January 2015 in addition to provision of a plan showing timescales for establishment of Directions as an exit strategy.

CAG 8-03(PR9)/2013 National Prostate Cancer Audit

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

Amendment request

The amendment requested the inclusion of the latest year that data was currently available, which was 2012.

Confidentiality Advisory Team advice

This amendment was considered by the Confidentiality Advice Team (CAT) who noted that this was a time extension to the original approval and did not increase the extent of data collection or purposes. As the arrangements for processing confidential patient information would remain the same as detailed within the application it was agreed that support should be recommended.

It was noted that an annual review for the application was due on 24 October 2013 and the applicant was advised to submit an annual review as soon as possible. I

Confidentiality Advice Team conclusion

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

1. An annual review for the application should be submitted as soon as possible.

ECC 1-03(d)/2012 National Bowel Cancer Audit

This application from the Health and Social Care Information Centre set out the purpose of collecting data in relation to bowel cancer patients in order to assess the effectiveness and appropriateness of treatment received by this patient group from NHS services. A recommendation for class 1, 4, 5 and 6 support was requested.

Amendment request

An amendment request was submitted which confirmed that the HSCIC would need to collect GP Practice Code from the Personal Demographics Service to enable reporting at Clinical Commissioning Group level, this will be linked to the Audit data by the data linkage team within the HSCIC.

Confidentiality Advice Team advice

It was noted that this request had been included within an amendment letters submitted earlier in the year and considered by the Vice Chair and that a similar request had been submitted in relation to other national audits, including the National Audit of Cardiac Rehabilitation (NACR) (ECC 3-04 (a)/2012). The requirement for this data item has been recognised and supported in these instances.

Confidentiality Advice Team conclusion

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

ECC 4-15 (h)/2009 All Wales Perinatal Survey

This surveillance study of perinatal and infant mortality in Wales sought section 251 approval to access the National Community Child Health Database (NCCHD) to identify deaths in babies aged 20 weeks gestation - one year old.

The survey aims to improve the understanding of the ways in which the risk of death in late foetal life and infancy may be reduced through:

- a continuous survey of perinatal and infant mortality in Wales
- collecting timely, accurate, complete and comparable data
- describing important inter-regional variations in death rates
- describing unrecognised variations in the cause of death
- disseminating this data to assist reviews aimed at reducing excess mortality
- benchmarking delivery unit performance.

Amendment request

The Applicant requested a five year extension to this research project as work remains ongoing, has been well established and continues to be funded by the Welsh Government.

It was confirmed that there had been no changes to the purpose, design or security and confidentiality arrangements for this project.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Vice Chair who noted that there had not been any change the methodology or purpose of the research. The Vice Chair was content with the request to extend this study subject to the continued submission of annual reviews and notification of any further changes for this application.

Health Research Authority recommendation

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Information Governance Toolkit submission.

2. Confirmation of a favourable opinion from a Research Ethics Committee.

CAG 2-03(PR3)/2014 COPD audit programme - pulmonary rehabilitation clinical audit pilot

This application from the Royal College of Physicians set out the purpose of a pilot for the pulmonary rehabilitation audit, commissioned by the Healthcare Quality Improvement Partnership, which would provide a snapshot audit of service delivery and quality. The audit aimed to enable providers of pulmonary rehabilitation for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.

A recommendation for class 1, 5 and 6 support was requested to cover access to data including NHS number, date of birth and postcode, no data linkages would take place at pilot stage.

Confidentiality Advisory Group advice

<u>Practicable alternatives</u>

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.

It was noted that the application depended on obtaining data from a multiplicity of public and some private service providers, and therefore members were of the view that pseudonymisation at source could not be considered as an alternative for this aspect of the audit at present.

Members highlighted that whilst pseudonymisation was not deemed to be feasible at this stage for this aspect and this option should be continued to be explored as part of an exit

strategy from the use of confidential patient information without consent. It was advised that provider organisations were encouraged to ensure NHS numbers were at the highest possible levels to facilitate this.

Members discussed whether consent would be feasible. Some views were raised that consent appeared to be difficult and may be too onerous in terms of resources and time and therefore have a detrimental effect on the pilot project. Members did note that the inclusion criteria meant that patients would attend an appointment during the pilot phase and recommended that the applicant pilot consent at this stage in order to provide evidence to inform any further application. Members agreed that this should be a condition of support and that the expectation would be that the applicant could collect sufficient information in the pilot stage to determine whether consent could be pursued as a potential exit strategy from support and how long it may take to establish this.

Extent of identifiers requested

Members noted that NHS number, postcode and date of birth had all been requested as these would be data items required to carry out linkages within the full audit application. Members requested that the applicant test the requirement for all these identifiable data items prior to submission an amendment to the full application. For example, it was queried whether linkages could be undertaken using NHS number alone. If linkages could be undertaken using NHS number only members queried why date of birth and postcode were required.

Data retention

It was noted that identifiable data items would be destroyed within 2 months of completion of the pilot. Members agreed that this was reasonable.

Patient information poster

It was advised that the final statement ‘For more information please ask a member of the hospital COPD team for a leaflet’ include a reference to opt out, for example ‘or ‘if you want to opt out’ or ‘chose not to participate’. In addition, members commented that the poster should include further information about the potential benefits of the audit.

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Information Governance Toolkit submission.
2. Please amend the patient information poster to make opt out more explicit in line with comments above.

3. A consent based approach should be piloted so further information can be provided in any future submission about the feasibility of consent and whether this could be adopted as an exit strategy.
4. Please consider whether linkages could be undertaken using NHS number only and provide evidence of the requirement for postcode and date of birth within any future application, this should include results of a pilot to determine whether linkage on NHS number alone has proved to be feasible.

For information

Confidentiality Advisory Group Away day actions

A CAG away day was held on 27 August 2014. A summary of the actions corresponding to each agenda item were summarised to members.

Future role of CAG

The presentation used by the Chair was to be circulated to members.

Annual review working group report and handling

All available members agreed to take part in annual review backlog processing commencing in October. It was agreed that further annual review sub-group would be scheduled once the legal advice had been assessed.

Precedent set – review of criteria

Members reviewed the precedent set review criteria. An updated version of the document would be reviewed and approved by the Operational Management Group in December 2014. Following approval, the document would be shared with members and published on the HRA website.

CAG processes

Following members comments at the away day, an amended version of the Standard Operating Procedures would be completed for approval at the November 2014 Operational Management Group meeting.

Transparency

The issue of transparency had been raised on a number of occasions and it was recognised that it was for the HRA, rather than CAG, to determine the correct route for ensuring maximum transparency of applications. The issue was considered at length at the Away Day with the Director of Operations and Approval present. At a practical level, it was noted that it would place a significant burden on CAT to ensure that applications were published, which it was not resourced to manage. In relation to the HRA publishing applications, it was recognised that the application forms may be subject to exemptions under the Freedom of Information Act 2000 which would require consultation on a case by case basis by the CAT with each individual. In addition, it was noted that whilst CAG could recommend conditions, it would be for the relevant approver to require publication

to be a condition of approval; and that this would need to be aligned across both. It was noted that previous informal consultation undertaken with the Secretary of State representative had previously raised concerns in adopting this approach for a number of reasons and in particular in relation to implementing additional barriers which might delay activities proceeding.

It was recognised that the ideal solution would be to ensure that the CAG register was fit for purpose and ensured maximum transparency. A new register would be established as part of the CAG transition into the HARP database (the database for managing HRA applications), which would eventually also allow more detailed information to be extracted from the application for publication within the Register. This would then enable publishing in a similar format to http://www.hra.nhs.uk/news/research-summaries/.

It was agreed that the following actions would be undertaken in the short term:

- Update the website to provide clear guidance to data controllers about what they would be advised to do if seeking further information about an approval and whether they could disclose data.
- Ensure that the applicant was aware that it was their responsibility to share details of the outcome letter and application form if requested and amend outcome letter to reflect this.
- Consider the amending outcome letter to be more specific in relation to the datasets and data items requested.

Business Improvement Programme – identified themes

Business Improvement Programme actions would be identified in a number of ways, for example comments from members at meetings regarding applications or process and identified improvements from the Confidentiality Advice Team (CAT) in line with wider HRA objectives. Member suggestions for actions to be included within the Business Improvement Programme could be made at any time.

The Chair team should discuss the identified actions monthly with the CAT and identify resource requirements and feasibility of each action point – this should be implemented from December 2014 CAG meeting. A report in relation to all suggestions, feasibility and an update on progress should be provided to CAG at least every other meeting.

6 ANY OTHER BUSINESS

Members expressed concern that the current IRAS form still retained references to NIGB considering length of time since abolishment. Ms Edgeworth provided an explanation as to the current status and would provide an update in relation to the status of changes at the next meeting.