NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

23 March 2017, Meeting Room 2, HRA Manchester, Barlow House

Present:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr William Bernal	Yes	
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	
Ms Kim Kingan	Yes	
Dr Rachel Knowles	Yes	
Mr Andrew Melville	Yes	
Mrs Diana Robbins	Yes	
Dr Murat Soncul	Yes	Alternate Vice Chair
Dr Mark Taylor	Yes	Chair
Ms Gillian Wells	Yes	

In Attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies or declarations of interest were noted.

2. APPROVAL DECISIONS

It was noted that the minutes of the previous meeting from Thursday 23 February were not yet available.

3. ITEMS FOR CONSIDERATION

a) NHS Privacy Notices

The Chair provided a verbal update around the request for guidance around privacy notices.

b) NHS Digital Correspondence (Dated 15 March 2017)

The Chair tabled correspondence received from NHS Digital around a request for guidance.

The document also included a revision request to previously agreed guidance around how to deal with requests for advice from NHS Digital. The Group considered the proposed revision to the text and a further minor agreement was suggested. The Chair agreed that would be proposed to NHS Digital in order to agree the final draft of this document.

Members considered the formal request for guidance and it was agreed that Mr Martin Severs should be formally invited to attend the next CAG meeting on Thursday 06 April to discuss this in line with route B of the previously referenced guidance framework.

c) CAG Away Day

An informal discussion was held about the forthcoming away day and the proposed agenda for the event.

d) Application CR17/2014 – Data Breach

Context

This application from the University of Cambridge requested support in order to access mortality and cancer data from the Data Access Request Service (DARS) NHS Digital.

The study aims to follow-up a cohort of BRCA1 and BRCA2 mutation carriers with associated epidemiological, clinical, pathological and genetic data to study cancer epidemiology in mutation carriers was flagged at the HSCIC for mortality and cancer updates.

The applicant confirmed that the retrospective cohort had previously consented to accessing their medical records and any stored samples from previous operations being used for this research. The applicant also confirmed that confidential patient information would not be held once analysis had been completed.

<u>Identifiers</u>

Confidential patient information was requested to permit access to NHS number, name, date of birth and address including postcode.

Breach Identified

The application was given a conditional approval in 2015. The conditions set were as follows:

1. Support was approved for the retrospective cohort only
2. Support only applies to data generated in England and Wales.

3. Prospective cohort consent model must be submitted to the Health and Social Care Information Centre (HSCIC) for consultation and approval.
4. Provide fair processing/patient notification materials
5. Follow the anonymised method as detailed within your application form as an appropriate mechanism to exit from using confidential patient information.
6. A current REC Favourable opinion letter.
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.
8. Provide confirmation of how you are intending to proceed with IGT/REC approval to the Confidentiality Advice Team by 1st May 2015.

A response was provided to all conditions apart from Condition 4, which was never met.

Data linkage via NHS Digital proceeded although final support was not in place. This was only picked up when the Data Sharing Agreement was renewed, and was then reported to CAG.

Actions requested and applicant response

The following information was requested by the CAT in an email sent on 25 January 2017:

1. Patient notification materials to be provided.

The following information was provided on 7 February 2017:

- Draft Consent Form that now explicitly requested consent to use NHS Digital and ONS records
- A Patient Information Sheet with additional details. This also referred the recruit to the EMBRACE website for more detailed information if they wished to know more.
- A Fair Processing of Data document, to be posted on the EMBRACE website.

These documents were reviewed by the CAG.

The Participant information and consent forms were to be reviewed and approved by the REC.

The CAG did not consider the fair processing of data document to fit the intended purpose of patient notification. The document appeared to describe the entire study, including aspects of the study which were consented and therefore were not relevant to CAG considerations or to the purpose of the notice.

It was a general principle of CAG support that reasonable attempts were made to inform the relevant population of the activity and to provide a right and mechanism to respect objection. This was known as patient notification, and was separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG requested that the applicant provide patient notification materials referring solely to access to patient identifiable information by persons outside the care team without consent. These should provide a description of the activity to be undertaken without consent, listing the purpose of the activity and who was carrying out the activity. They should explain how service users could opt out or dissent to the use of their information for this purpose.

2. An explanation to the CAG as to how Condition 4 was omitted before proceeding with the activity, along with any remedial action taken. This explanation should relate to the CAG application only, rather than steps relating to the DSA application.

The following response was provided by the applicant via email on 7 February 2017:

'*The problem, as we stated previously, came about through staffing issues, miscommunications and lack of communication both internally and externally. Our previous database manager, who was the addressee in your email Jun 2015, had left and we did not have a trained designated person in place and it is our understanding, from investigating this, that the emails that you refer to did not reach the right person to action or query them, as to what was required.*

Since the alert to this breach we have had an internal meeting with the PI on the study and we have implemented a procedure so that email communication of this type be cc'd to include Professor Easton, Professor Easton's PA, Debra Frost and Daniel Barrowdale. We will also create an electronic file and a hard copy file to store communications that take place and highlight actions where appropriate.

All patients were consented to take part in the study and we have been flagged for many years without any problems. We understand that the CAG requires us to change the wording of the consent and we are committed to fulfilling this. Unfortunately the process of developing a new consent process has inevitably taken some time, partly as a result of uncertainties in funding. We now enclose drafts of the material, that have been provisionally approved by David Cronin (Data Approvals Owner at NHS Digital's DARS) and which we will submit to the ethics committee. Once we have full approval from NHS Digital, CAG and Ethics we will then use the new documentation'.

This response was reviewed by the CAG who noted that email procedures had been updated to avoid problems arising due to miscommunications; also that storage of communications would be improved. The CAG was satisfied with this aspect of the response but made a recommendation that further review of internal procedures take place to ensure that approvals were in place prior to commencing an activity.

3. In response to a request for an extension of the time period of support, it was clarified that an extension to the time period of support could only be provided once support was actually in place.

4. The applicant had raised an additional issue regarding consent:

'We will also be addressing the issues of re consenting through our participants' next scheduled follow up for those that have been recruited and submitted to NHS digital since 2015, and potentially a means of re consenting, should this apply, for those that will not be followed up. The latter will require some thought since they would not normally be contacted further. Any individuals responding that they do not consent will be removed from the study. S251 support would be required to cover participants that cannot be contacted or do not respond'.

The following advice was given by the CAT:

Please read the information under Managing Non-Response on the following link: http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/ as once you have requested consent you cannot rely on Section 251 to provide a legal basis for accessing the data, if a patient does not respond.

The CAG requested a response to this point.

5. The REC letter we have on file does state that REC approval is until January 2017 – I would advise contacting the REC for their advice on whether any further actions are required in relation to REC approval.

A substantial amendment approval letter from the REC, following review of the revised PIS and consent forms, was submitted on 24 March 2017.

Outstanding Actions

1. Patient notification materials to be provided.
2. The CAG recommends that further review of internal procedures takes place to ensure that approvals are in place prior to commencing an activity (please note that this is a recommendation and a response is not mandated on this point).
3. The CAG requests a response from the applicant to point 4, above, to answer the question how will the applicant address ICO guidance on non-response?

4. NEW APPLICATIONS – Non-research

a. 17CAG0041 - Feasibility study to evaluate the potential cost-effectiveness of a new drug in people with high cardiovascular risk in Salford

Context

Purpose of Application

This application from North West E-Health set out the purpose of service evaluation around cardiovascular disease in Salford. A client of North West E Health (NWEH) is interested in understanding the overall health resource utilisation of patients in Salford who have an increased risk of or documented atherosclerotic cardiovascular disease (ASCVD). The client wants to examine how costs differ between subgroups of patients and gain a deeper insight into the patients that pose the biggest financial and healthcare burden to the economy of Greater Manchester.

Salford Royal Hospitals NHS Trust (SRHT) will use the Salford Integrated Record (SIR) to identify people with ASCVD or at high risk of Cardiovascular Disease (CVD) and their healthcare resource utilisation (HRU) costs. Identification of all HRU costs will involve linking the SIR cohort data to data from regional hospitals to which these patients are likely to be referred. This data may be derived from the Secondary Uses Service (SUS) or directly from the hospitals concerned. The application will involve linkage to Office of National Statistics (ONS) mortality data. NWEH will model potential cost savings for these patients if they were treated with a new drug which could lower their LDL cholesterol considerably more than conventional treatments.

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

Confidential Patient Information Requested

Cohort

Salford Royal Hospitals NHS Trust will use the SIR database to identify patients alive in Salford on 01.01.2006 (ensuring that archives pre-2008 are included in all searches) who meet specified clinical indications of cardiovascular illness/risk. The dataset will be a one-off snapshot of this cohort on the day that the extract is performed.

Access was requested to the following items of confidential patient identifiable information for the purposes described:

- NHS number – used for linkage but not provided to the applicant in the final dataset,
- Age – for analysis,
- Gender – for analysis,
- Year and month of death – for analysis,
- Ethnicity – for analysis.

The following additional items of confidential patient information will be collated from patient records:
From SUS Payment by Results: where available:

1. Haematology data,
2. Biochemistry data,
3. Comorbidities – All comorbidities in the data (with onset date, not entry)
4. Medicines – All medicines prescribed during that episode and dose,
5. Procedures – All procedures during admission including Percutaneous Angioplasty and any imaging along with date and cost
6. Demographics

a. NHS number (used to link data but returned in anonymised form)
b. Age
c. Gender
d. Date of death (month and year only)
e. Ethnicity
f. Lower Super Output Area (for deprivation score)

7. Healthcare Resource Utilisation (HRU)

a. Inpatient
i. Admission date
ii. Discharge date
iii. Reasons for admission
iv. Cost of admission

b. Outpatient
i. Outpatient visit date
ii. Outpatient type (i.e. new or follow-up)
iii. Outpatient speciality
iv. Cost of outpatient visit

From ONS mortality data: where available, the following data should be provided for each patient:

8. Demographics

a. NHS number (used to link data but returned in anonymised form)
b. Date of death (month and year only)
c. Cause of death

Rationale for the data items:

- Data in points 1, 2, 4, 5, 7 and 8 will allow the calculation of HRU costs.
- Data in points 3 and 6 will allow categorization of patients to gain a deeper insight into the patients that pose the biggest financial burden. The applicants have submitted evidence that discussions have been had with NHS Digital regarding what data are available from SUS.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the potential public interest had not been clearly articulated within the application. Members commented that information provided identified possible public benefit from future projects which may be undertaken following this proposal; however, it was argued that analysis of the findings may identify the proposed new cholesterol drug as too expensive, which would remove the potential for any future trials.

Members queried what the publication arrangements were for the project, as it was suggested that the public benefit may be strengthened if the analysis findings were made more widely available to the public and research community. It was noted that publication of both positive and negative findings was considered good practice.

The CAG further commented that the public benefit from the project could be strengthened through better public and patient engagement in the project.

It was noted that the only document which referenced the external client as a pharmaceutical company was the letter of support from the Caldicott Guardian. Members commented that the main application form could have been more transparent about the purpose of the project. The CAG further commented that it was unclear from the information provided what the pharmaceutical client intended to do with the study findings and it was agreed the detail here needed to be more explicit to enable public confidence in the activity and ensure a clear public benefit can be identified in the project.

Members also queried whether the Salford Integrated Record Board included lay representation as it was noted that they had provided approval for access to information within the database. The CAG commented that lay representation within the SIR Board review process would also help to strengthen the public interest in the application.

Practicable Alternatives

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

- Feasibility of consent

The applicants estimated there would be approximately 150,000 patients within the cohort to be studied. The CAG were satisfied that consent was not feasible for these proposed numbers.

- Use of anonymised/pseudonymised data

The CAG understood that the analysis would be undertaken on a pseudonymised dataset; however, it was acknowledged that there had been some confusion around the terminology used within the application and queries had been raised with the applicant by the CAT ahead of the meeting around the classification of anonymised and pseudonymised data. Members recommended that the applicants refer to the ICO guidance around pseudonymisation to assist with the classification of the data types in use within the project.

Justification of Identifiers

The CAG noted that the identifiers requested appeared to be justified to undertake the data linkage described within the application.

Data Flows

Members advised that a clearer narrative was required to describe the data flows within the application together with a complete data flow diagram, which clearly depicts the flow of the various classifications of data during the project and identified which organisations had access at each stage. Clearer information was also required around how linkage with other hospitals would be carried out. It was suggested that the previously referenced ICO guidance around anonymization could be taken on board when preparing this information.

Data Source

The CAG requested clarification around the legal basis under which data was currently held within the Salford Integrated Record database.

Exit Strategy

The CAG noted that the internal application within Salford Royal Hospitals NHS Foundation Trust stated that data would be retained for two years; however, the CAG application form stated only 12 months. It was agreed that clarification around this point was required.

Classification of Project

The CAT had raised queries with the applicants ahead of the meeting around the classification of the project and response had been provided from the applicant that the proposal was more accurately deemed as service evaluation. Members considered the information and queried how this determination had been made. It was agreed that further clarification was required from the applicant around how this classification had been reached and whether external guidance from the Trust R&D Office had been sought around this point. The CAG referenced the HRA decision tools which were available via the website and it was recommended that the applicant undertake the algorithm in relation to the project, as Members were of the opinion that this was a research feasibility study.

Patient Involvement and Engagement

The applicants had advised that a patient telephone survey would be undertaken to test the acceptability of utilising patient data without consent as described within the application. This task remained incomplete at the time of the CAG meeting; however, the interim report provided by the applicant suggested that patient perception was positive. The Committee received the interim findings with interest; however, it was agreed review of the overall report was required to support the application.

Members discussed the potential for further patient engagement and involvement with the application process as it was noted that the applying organisation appeared to be well-placed and networked to achieve additional meaningful interaction with the target cohort.

The CAG was supportive of the wider use of the Salford Integrated Record beyond patient care; however, it was agreed that further evidence of how these additional uses were publicised within the local area was required.

It was noted that the Citizen Science newsletter was a useful tool to engage with the patient population within the Greater Manchester area. Whilst this document had been submitted as evidence of healthcare engagement with the population in the area, the applicant had not detailed any plans to publish within the newsletter.

The CAG agreed that a detailed overview of patient and public engagement plans moving forward would also be required for consideration. It was further recommended that the applicants consider the merits of patient involvement and engagement being impartially facilitated or through increasing the transparency of the questions put to patients.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG considered the information which had been provided by the applicant in relation to patient notification and it was agreed that this was too heavily reliant on information which had previously been circulated as part of standard health care communications within the area. Members considered the information booklet around the Salford Integrated Care record which was referenced within the application and it was noted that this stated that patients would be approached for consent in

connection with the release of their identifiable data for research purposes, which was not consistent with the application being considered as consent would not be sought. It was suggested that if the SIR database would continue to be utilised in the manner described in the application, it may be pertinent to update the information literature around its uses.

Members agreed that the applicant needed to establish an enhanced plan for project-specific patient notification which provided an opt-out mechanism for patients and was separate to information around the standard care uses of the SIR database. The CAG agreed that consideration of these plans was required to ensure that they were appropriate to the activities being undertaken.

Principles of the Data Protection Act 1998

The CAG advised that it was the responsibility of the applicant to provide confirmation of how the project adheres to the principles of the DPA. This cannot be determined during the consideration of the project.

Additional Points

There was a reference within the application to a Health Economist at the University of York being involved within the application and further information was required around the involvement of this individual and organisation, together with clarification around access to confidential patient information.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required

The following information should be provided to allow the CAG to continue their consideration of the application. Response should be provided in the form of a revised CAG application form, together with a detailed covering letter addressing the below points and identifying where revisions have been made to the main application. Any additional supporting documentation would also need to be submitted for consideration alongside the new application.

1. Clarify the process followed to determine the service evaluation classification of the application. It is recommended that the HRA decision tools are referenced to provide further evidence to support the categorisation as service evaluation, rather than research. If the application has been incorrectly categorised, the resubmission should be made via the IRAS system (which managed research applications) together with a submission for HRA Approval (REC and Assessment review).
2. Clearly define the public interest in the project taking account of all comments raised by the CAG within this section above.
3. Provide details of the intended publication arrangements for the project findings.
4. Confirm the legal basis under which data is currently held within the Salford Integrated Record database.
5. Clearer narrative is required around the data flow within the application, together with submission of a revised data flow diagram. It is recommended that the ICO guidance around anonymization is referenced here.
6. Patient and Public Involvement and Engagement:

a. Provide a report on the overall findings of the telephone survey which had been undertaken to test the acceptability of using patient data with consent for the activities described,
b. Provide details of planned public and patient engagement activities which would be undertaken moving forward.

7. Patient Notification and Objection:

a. Establish an enhanced plan for project-specific patient notifications, detailing how and where the project would be publicised and providing copies of any notification materials for review,

b. Devise a project-specific opt-out mechanism and advise how this would be managed moving forward in the project.
8. Clarify how long study data would be retained to address the contradiction identified between study documents.
9. Provide further information around the Health Economist and the University of York's relationship to the project and clarify whether they would have access to confidential patient identifiable information.
10. It was noted that compliance with the principles of the Data Protection Act was to be determined by the applicant.

b. 17CAG0042 - Feasibility study to better understand the patient journey for Chronic Heart Failure amongst Salford patients

Context

Purpose of Application

This application from North West E-Health set out the purpose of service evaluation to better understand the patient journey for Chronic Heart Failure amongst Salford patients. A client of North West E Health (NWEH) wants to use linked and pseudonymised NHS data from primary and secondary care in Salford, Greater Manchester. The project aimed to better understand the patient journey for Chronic Heart Failure from two years pre until five years post diagnosis, enabling a longitudinal assessment of patient characteristics, management and healthcare resource utilisation (HRU). The cohort will be identified from the Salford Integrated Record System (SIR) which is hosted by Salford Royal Hospitals NHS Trust. Data linkage to ONS mortality data will be undertaken by NHS Digital.

The primary purposes of this project are detailed below which will help understand the patient journey:

- Establish population split between preserved Ejection Fraction (pEF) and reduced Ejection Fraction (rEF).
- Establish Heart Failure and Cardiovascular related treatments and triggers for therapy review / dose level adjustments pre and post diagnosis.
- Calculate resource utilisation pre and post diagnosis,
- Calculate 5 year mortality
- Evaluate comorbidities.

The secondary purposes for the project are:

- Establish real world adherence to NICE guidelines such as whether are all patients receiving echo, BNP (B-type natriuretic peptide) measurement and specialist referral
- Assess ejection fraction and BNP levels as indicators of disease progression,
- Determine size of population in primary care with symptomatic chronic heart failure with reduced ejection fraction.

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

Confidential Patient Information Requested

Access was requested to the following data items from the Salford Integrated Record for each patient:

1. NHS number
2. Age
3. Gender
4. Date of Death (year and month only)

5. GP Code
6. GP Practice Code
7. All journal data

Access was requested to the following data items from ONS the following data for each patient:

1. NHS number
2. Date of Death (year and month only)
3. Cause of death

Confidential patient identifiable data was required for the following purposes:

- NHS number is used to link SIR and ONS mortality data. Once linked, the NHS number will be replaced with anonymised study ID before the combined data set is made available to NWEH.
- Date and cause of death are used to determine 5 year mortality.
- Date of death is requested from both data sets as an extra check quality check (increased confidence that patients have been matched successfully).
- Age, gender, GP code, practice code and journal data will allow analysis of resource usage for different categories of patients.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the potential public interest had not been clearly articulated within the application. Members commented that information provided identified possible public benefit from future projects which may be undertaken following this proposal; however, it was argued the analysis may produce findings that are not conducive to undertaking further clinical trials, which would see no public benefit realised from the work which had been carried out here.

Members queried what the publication arrangements were for the project, as it was suggested that the public benefit may be strengthened if the analysis findings were made more widely available to the public and research community. It was noted that publication of both positive and negative findings was considered good practice.

The CAG further commented that the public benefit from the project could be strengthened through better public and patient engagement in the project.

It was noted that the only document which referenced the external client as a pharmaceutical company was the letter of support from the Caldicott Guardian. Members commented that the main application form could have been more transparent about the purpose of the project. The CAG further commented that it was unclear from the information provided what the pharmaceutical client intended to do with the study findings and it was agreed the detail here needed to be more explicit to enable public confidence in the activity and ensure a clear public benefit can be identified in the project.

Members also queried whether the Salford Integrated Record Board included lay representation as it was noted that they had provided approval for access to information within the database. The CAG commented that lay representation within the SIR Board review process would also help to strengthen the public interest in the application.

Practicable Alternatives

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

- Feasibility of consent

The applicants estimated there would be approximately 7,000 patients within this cohort; however, it was not clear how this cohort would be established and what the duration for the sample was. The CAG agreed that this would need to be clarified. Members discussed the potential for consent for these proposed numbers and it was agreed that this was not practicable; however, there was the requirement for appropriate patient notification and opt-out mechanism to be put in place.

- Use of anonymised/pseudonymised data

The CAG understood that the analysis would be undertaken on a pseudonymised dataset; however, it was acknowledged that there had been some confusion around the terminology used within the application and queries had been raised with the applicant by the CAT team ahead of the meeting around the classification of anonymised and pseudonymised data. Members recommended that the applicants refer to the ICO guidance around pseudonymisation to assist with the classification of the data types in use within the project.

Justification of Identifiers

Members discussed the identifiers which were requested for the project and whilst it was agreed that these were justified to enable the activities described to achieved, there was some concern around weaknesses in the level of pseudonymisation within the data set.

The Committee acknowledged that there was substantial information provided around the data held within the SIR database; however, this did not explain what the applicant meant by the term journal data or what this would include. It was acknowledged that GP's were prone to include confidential and identifiable information within the free text of patient medical records and clarification around this point was required. It was recommended that if the intention was to receive free text, this point should be specifically tested amongst the public for acceptability.

The CAG noted that date of death truncated to month and year, together with age at and cause of death was potentially identifiable, particularly if reported against a GP code. Members agreed that the applicant needed to consider these implications and provide further clarifications around the identifiers required to undertake the proposal and clarify whether the resulting data set was pseudonymised.

It was noted that the applicants were requesting GP and practice code for analysis to enable resource evaluation; however, it was noted that this information could be potentially commercially valuable if held together with prescribing information. Members expressed unease at the retention of the GP code and it was agreed that the applicant would be asked to remove this, or provide a stronger rationale for its retention, together with assurances around the reporting of information.

Data Flows

Members advised that a clearer narrative was required to describe the data flows within the application together with a complete data flow diagram, which clearly depicts the flow of the various classifications of data during the project and identified which organisations had access at each stage. Clearer information was also required around how linkage with other hospitals would be carried out. It was suggested that the previously referenced ICO guidance around anonymization could be taken on board when preparing this information.

Data Source

The CAG requested clarification around the legal basis under which data was currently held within the Salford Integrated Record database.

Exit Strategy

The CAG noted that the internal application within Salford Royal Hospitals NHS Foundation Trust stated that data would be retained for two years; however, the CAG application form stated only 12 months. It was agreed that clarification around this point was required.

Classification of Project

The CAT had raised queries with the applicants ahead of the meeting around the classification of the project and response had been provided from the applicant that the proposal was more accurately deemed as service evaluation. Members considered the information and queried how this determination had been made. It was agreed that further clarification was required from the applicant around how this classification had been reached and whether external guidance from the Trust R&D Office had been sought around this point. The CAG referenced the HRA decision tools which were available via the website and it was recommended that the applicant undertake the algorithm in relation to the project, as Members were of the opinion that this was a research feasibility study.

Patient Involvement and Engagement

The applicants had advised that a patient telephone survey would be undertaken to test the acceptability of utilising patient data without consent as described within the application. This task remained incomplete at the time of the CAG meeting; however, the interim report provided by the applicant suggested that patient perception was positive. The Committee received the interim findings with interest; however, it was agreed review of the overall report was required to support the application.

Members discussed the potential for further patient engagement and involvement with the application process as it was noted that the applying organisation appeared to be well-placed and networked to achieve additional meaningful interaction with the target cohort.

The CAG was supportive of the wider use of the Salford Integrated Record beyond patient care; however, it was agreed that further evidence of how these additional uses were publicised within the local area was required.

It was noted that the Citizen Science newsletter was a useful tool to engage with the patient population within the Greater Manchester area. Whilst this document had been submitted as evidence of healthcare engagement with the population in the area, the applicant had not detailed any plans to publish within the newsletter.

The CAG agreed that a detailed overview of patient and public engagement plans moving forward would also be required for consideration. It was further recommended that the applicants consider the merits of patient involvement and engagement being impartially facilitated or through increasing the transparency of the questions put to patients.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG considered the information which had been provided by the applicant in relation to patient notification and it was agreed that this was too heavily reliant on information which had previously been circulated as part of standard health care communications within the area. Members considered the information booklet around the Salford Integrated Care record which was referenced within the application and it was noted that this stated that patients would be approached for consent in connection with the release of their identifiable data for research purposes, which was not consistent with the

application being considered as consent would not be sought. It was suggested that if the SIR database would continue to be utilised in the manner described in the application, it may be pertinent to update the information literature around its uses.

Members agreed that the applicant needed to establish an enhanced plan for project-specific patient notification which provided an opt-out mechanism for patients and was separate to information around the standard care uses of the SIR database. The CAG agreed that consideration of these plans was required to ensure that they were appropriate to the activities being undertaken.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required

The following information should be provided to allow the CAG to continue their consideration of the application. Response should be provided in the form of a revised CAG application form, together with a detailed covering letter addressing the below points and identifying where revisions have been made to the main application. Any additional supporting documentation would also need to be submitted for consideration alongside the new application.

1. Clarify the process followed to determine the service evaluation classification of the application. It is recommended that the HRA decision tools are referenced to provide further evidence to support the categorisation as service evaluation, rather than research. If the application has been incorrectly categorised, the resubmission should be made via the IRAS system (which managed research applications) together with a submission for HRA Approval (REC and Assessment review).
2. Clearly define the public interest in the project taking account of all comments raised by the CAG within this section above.
3. Provide details of the intended publication arrangements for the project findings.
4. Confirm the legal basis under which data is currently held within the Salford Integrated Record database.
5. Provide clarification around how an estimated sample size had been reached, advising how the cohort would be established and what the proposed sample duration was.
6. Clearer narrative is required around the data flow within the application, together with submission of a revised data flow diagram. It is recommended that the ICO guidance around anonymization is referenced here.
7. Address the concerns raised around the retention of GP codes for the project:

a. Either provide agreement that these can be removed,
b. Or if required for analysis, provide a stronger rationale for its retention together with further reassurances around how this data will be reported to the client and how they intend to use this.

8. Consider the information included within the analysis dataset, particularly if GP code is to remain within this, and the potential risk around identification of patients due to the variety and extent of information held. Provide further comment and assurances in this area.
9. Confirm whether free text information from GP medical records will be transferred as part of the journal information for the project.
10. Patient and Public Involvement and Engagement:

a. Provide a report on the overall findings of the telephone survey which had been undertaken to test the acceptability of using patient data with consent for the activities described,
b. Provide details of planned public and patient engagement activities which would be undertaken moving forward,
c. If utilising the free text information from GP records, this point should be specifically tested with the public for acceptability.

11. Patient Notification and Objection:

a. Establish an enhanced plan for project-specific patient notifications, detailing how and where the project would be publicised and providing copies of any notification materials for review,

b. Devise a project-specific opt-out mechanism and advise how this would be managed moving forward in the project.

12. Clarify how long study data would be retained to address the contradiction identified between study documents.

5. NEW APPLICATIONS – Research

a. 17CAG0038 – ECCI Congenital Cytomegalovirus Database Version 2

Context

Purpose of application

This application from St George's University London set out the purpose of establishment of a research database. This database aimed to provide further information on prognosis, treatment, side effects and outcomes in babies born with congenital cytomegalovirus (CMV). Since individual centres see only a few babies a year with this condition national data collection is necessary to be able to fully evaluate the spectrum of problems encountered by these children and the beneficial (or harmful) effect of any interventions. Data will be entered by individual centres that care for babies and children born with a diagnosis of confirmed congenital cytomegalovirus (CMV) infection in a standardised way onto this centralised database. Data will be electronically entered from clinical notes, correspondence, and investigation results accessible to clinicians as part of conducting standard clinical care. Data will be entered by the clinicians themselves or appropriately qualified, designated, members of their clinical (or research) teams. Individual clinicians will only be able to access data entered for cases entered by their own local team. The central study team will have access to all data entered electronically but will not directly be able to identify individuals entered onto the database since the only identifiable information held electronically will be date of birth. Information will be recorded on baseline clinical features, results of any measures of virus in blood, urine or other fluids (where recorded), treatment received, results of neuroimaging (any scans of the brain) and clinical, hearing and developmental progress over time. The aim will be to monitor progress and development of these children and any interventions or support received.

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

Confidential Patient Information Requested

Access was requested to the following items of confidential identifiable patient information for purposes identified:

- Date of birth – validation, remove duplicates, check eligibility and analysis,
- Date of death – analysis,
- Gender,
- Ethnicity – currently only being recorded at local site level, whilst applicants agree a standardised recording mechanism. Applicants state it may be 1-2 years before this field is opened up in the database.

Children eligible for inclusion would have born on or after 01/04/2007 and entry into the database will be ongoing for the five years of requested support.

Confidentiality Advisory Group Advice

Public Interest

Members agreed that the application defined a medical purpose which was in the public interest as this was a rare and harmful disease which currently did not have a screening programme as no defined treatment pathway exists. The CAG acknowledged that clearer understanding of the patient cohort was required to inform future prevention and treatment mechanisms. It was identified that the application was part of a wider programme which intended to bring together EU localised registries to provide a larger cohort to be studied, which strengthened the potential benefit in the project.

Identification of Cohort

The CAG was unclear around the scope of the project and data collections. It was understood that the cohort to be included was children born on or after 01 April 2007 through to 2022, which included both retrospective and prospective data collection. Members commented that further clarification was required around how the patient cohort would be identified when the focus was on the asymptomatic group and further clarification would be required. It was agreed that further information was required around the potential bias effect in connection with the retrospective cohort as it was acknowledged that the applicants would not capture all cases of CMV, which contravened the rationale provided to seek support under the Regulations to access this data without consent, which was the requirement for complete ascertainment to prevent bias. It was further noted that the applicant did not explain how they anticipated complete coverage with support under the Regulations.

Data Extraction

Members further noted at question 9 (page 16) of the CAG application form no response had been provided around the frequency of data extraction; however, it appeared that the database would be updated at 12 and 24 months following the initial entry so further clarification around this point was required. The CAG noted that identifiers would be retained for five years which supported the intentions to follow-up the entries within the database.

Research Sites

The CAG was not clear from the application which sites would be involved in the project to provide data and it was agreed that clarification around which centres were treating CMV in infants. It was further that the applicant had stated that they wanted to gather information from all clinicians who were treating this patient group; however, it was not articulated within the application how these clinicians would be identified and how the data flow would be established. Members also commented that a clear indication of data flows was required in the form of a dataflow chart together with the definitive list of research sites.

Practicable Alternatives

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

- Feasibility of Consent

The applicant explained within the application that the establishment of the database had previously been trialled on a consented basis; however, recruitment rates had been low and the project had failed to progress. The applicant explained that the issues which faced the previous project had been delays to and inability to complete the site approval process, parents' not returning informed consent after providing verbal consent and lack of approach to eligible participants.

Members considered the rationale which had been provided and noted that a recommendation for support under the Regulations would not remove the requirement for completion of the site approval process. Whilst it was acknowledged that the HRA Approval system had gone live in the interim from the approval of the previous project, there was still requirement to seek local agreement for the project to run at the sites to be included. The CAG agreed that this rationale was not supportive of the proposal to bypass patient consent.

The applicants further argued that the informed consent process was time consuming and was not a good use of clinician's time. The applicants state that a verbal process of informing the parents was more efficient and this had also been proposed as the patient notification method for the project. The CAG stated that if there was sufficient time for the clinician to raise the database verbally with parents, then informed consent was feasible and was a practicable alternative to seeking support to access patient identifiable data without consent. Members commented that the evidence that some eligible patients were being overlooked due to difficulties in the clinical relationships or due to lack of response to correspondence were not supportive of the application to bypass patient consent as it was stated by the applicants that patient notifications would be undertaken verbally by clinicians. It was also noted that lack of response to correspondence would be determined as lack of interest in the project.

It was further noted that the requirement for complete ascertainment of the cohort was not supported by Members as it was acknowledged that there would be cases missed due to the asymptomatic nature of the focussed patient cohort.

The CAG also noted that the applicant intended to seek consent from the parents if there was the requirement to access data held with external organisations and it was agreed that this strengthened the argument that consent was feasible for this proposal.

- Use of Anonymised/Pseudonymised Data

The CAG acknowledged that access to patient identifiable data was required to enable validation of the cohort and remove any duplicated entries and also to undertake analysis calculations; however, further clarifications around the project were required to support the retention of these data items.

Justification of Identifiers

Members acknowledged that the identifiers requested were justified to achieve the outcomes of the proposal.

Patient Involvement and Engagement

The CAG acknowledge that an online survey had been undertaken with sub-group of parents around the use of the patient data without consent; however, it was queried whether those who completed the survey were representative of the population whose child's data would be used in the project. It was also unclear what questions had been asked in the survey. Members agreed that a full report around the survey would need to be provided to support the project.

The Committee considered the relationship which the applicant had established with the CMV Action and it was agreed this organisation would be a useful resource to undertake additional more meaningful patient and public engagement in the project.

Patient Notification and Objection

Members considered the patient notification plans and the earlier point was reiterated that if parents could be verbally approached about the inclusion of their child within the database to satisfy the patient notification requirement, there was feasibility to take informed consent.

The CAG further commented that, within the patient notification model proposed for the project did not account for those patients who would be retrospectively added to the database as it assumed that the clinician would be treating the child. It also did not allow parents time for consideration and reflection, and there was no meaningful dissent mechanism.

Discussions took place around the 'Missed Subjection Data Collection' form which would be utilised when an objection was raised around the data collection. It was noted that this document collated considerable information and whilst only month and year of birth were recorded in terms of potential patient identifiers, the extensive information was being recorded against the express wishes of the parent and could potentially be identifiable for the rare disease. Members agreed that if an objection to inclusion was lodged, this should be fully respected and no information about the child should be recorded.

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.

b. 17CAG0044 – S-AVANT Observational Study Follow-Up

Context

Purpose of application

This application from Bristol Oncology Centre set out the purpose of a medical research project which was a follow-up study of participants previously randomised in the AVANT study at 8 and 10 years median follow-up. No visits to the study site, and no assessments or clinical examinations are required as data will be obtained from the medical notes of those participants who were randomised into the previous AVANT study. It is an opportunity to evaluate overall survival and therapy after relapse and to perform analysis on survival, second cancers and treatment after relapse, if any of those patients involved in the trial. It is explained in the application that the previous trial did not show prolongation of disease free survival at three years and adverse events were consistent with the safety profile for the drug being trialled (Bevacizumab in combination with FOLFOX-4 or XELOX); however, more relapses and deaths due to disease progression were observed in both bevacizumab arms which necessitates a more prolonged follow-up to assess the overall survival and to evaluate long-term results and safety.

Treating teams at the investigational sites will identify participants from the previous trial from the records. Living patients will be contacted by a member of the investigator's healthcare team or a member of the clinical research team at the site and approached for consent for the use of their data. Data from deceased patients and those patients lost to follow-up will the collated with support under the Regulations if approved.

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

Confidential Patient Information Requested

Access was requested to the following items of confidential patient identifiable information from the investigational sites in relation to participants in the previous AVANT trial for the purposes stated:

- Name – for verification against source data (initials only) – previously collected and held by sponsor,
- Date of birth – for verification against source data – previously collected and held by sponsor,
- Gender – for verification against source data,
- Date of last contact/follow-up (routine follow up visit or phone contact),
- First relapse

- Date and site of relapse if applicable,
- If relapsed, how the relapse was diagnosed,
- Date and type of first relapse,
- Treatment after relapse for metastatic disease,
- First treatment of metastatic disease (chemotherapy and local treatment),
- Date and type of other cancer, biomarkers and adverse events occurred after AVANT database lock (31 Aug 2012) and related to bevacizumab or capecitabine administered in the AVANT study,
- Surgery,
- Survival Status - alive or deceased including date and cause of death,
- The presence of one or more additional diseases occurring alongside the primary disease (co-morbidity). These will include cardiomyopathy and/or congestive heart failure; arterial hypertension; pulmonary embolism; stroke; kidney disorders and any other disease or disorders that are recorded during the follow up period.

The cohort includes all patients who were previously consented into the AVANT study, who have not subsequently withdrawn their consent from the trial and/or who opposed additional data collection. There are approximately 252 patients within the UK.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application defined a medical purpose which was in the public interest as the overall survival data which was reported from the historic trial suggested that that there was a detrimental effect on participants. Then importance of following on these findings was acknowledged and strengthened the public benefit in the application.

Members queried how the findings of the project would be published as it commented that the outcomes could have significant implications for the wider health care community and it was agreed that clarification would be sought.

Practicable Alternatives

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

- Feasibility of Consent

The applicants were only seeking support to access information from the records of those participants in the original project who were now deceased or lost to follow-up. It was noted that living participants would be approached for consent by their direct care team.

- Use of anonymised/pseudonymised data

Members acknowledged that the applying organisation already had access to confidential patient information in relation to the previous cohort; however, processing of these identifiers was required to re-identify the cohort and collect additional information.

The applicants had confirmed that data of death could be truncated to month and year format for analysis and the CAG agreed that this was appropriate to reduce the identifiability of the dataset utilised for analysis.

Justification of Identifiers

The identifiers were deemed to be appropriate and justified to undertake the relevant data linkage.

Identification of the Cohort

The CAG was unclear how the applicants would establish which patients were deceased and it was agreed that clarification of this process was required. This was to ensure that letters and telephone calls of invitation were not directed to the relatives of a deceased patient.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members commented that further work could be undertaken by the applicants in respect of patient notifications in an attempt to reach those patients who are lost to follow-up. It was recommended that information could be displayed on the study or participating sites websites to advise the follow-up is being undertaken. Information could be provided around the follow-up telephones calls and also to provide a mechanism for dissent.

The CAG noticed at question 31-2 of the CAG application form that patient dissent would be recorded in the patient's notes in the investigator deemed this appropriate. The meaning of this comment was unclear and further clarification was required on this.

Sharing Data outside the EU

The CAG commented that confidential patient identifiable data could not be transferred outside the EU unless assurance was provided that the relevant safeguards were in place. Further information was required from the applicant's in respect of this point together with confirmation as to whether this data is identifiable.

IG Toolkit

It was noted that the accepted assurance level for information governance procedures which was accepted by the CAG in connection with the organisations processing confidential identifiable patient data was a satisfactory reviewed grade on the NHS IG Toolkit. It was noted that the toolkit could be completed by organisations external to the NHS where appropriate and clarification that this was in place would be required before final support could be recommended to the decision maker.

Confidentiality Advisory Group Advice Conclusion

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

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

Request for Further Information

1. Clarify how the research findings will be published.
2. Provide further information to explain how deceased patients would be identified to ensure that recruitment materials and telephone calls were not directed to the relatives of a deceased patient.
3. Patient Notification and Objection:

a. Plan further patient notifications in line with the comments of the CAG and provide an overview of how these would be achieved,
b. Clarify how and when patient dissent will be recorded in medical records to explain the previously referenced comment at question 31-2 of the application form.
4. Provide further information around the arrangements which are in place around sharing data outside the EU, acknowledging that this cannot be undertaken where relevant safeguards are not in place. Provide confirmation whether the data to be shared would be identifiable.
5. Provide evidence of the completion of an NHS IG Toolkit.

c. 17CAG0048 – East London Sickle Cell Disease Neonatal Cohort

Context

Purpose of Application

This application from the Royal London Hospital sets out a purpose to follow-up patients previously entered into the Sickle Cell Disease database which was established in East London in 1983. This cohort, referred to as the East London Newborn cohort, is a unique cohort of patients diagnosed with universal newborn screening in the London Boroughs of Hackney since 1983. The cohort is under continuous clinical follow up at The Royal London Hospital, although a minority have transferred care to other clinics or become lost to follow-up. The first report on the cohort was published in 2007. After a further decade of follow-up, an analysis of outcomes and risk factors will provide important data to inform health service planning and treatment decisions for Sickle Cell Disease in the UK and elsewhere. The current study will require collecting and validating clinical, laboratory and radiological data on all cohort patients, and undertaking a number of statistical analyses on the dataset. Data on patients under current follow-up at Royal London Hospital is maintained on a secure clinical database at site. Information on patients in other clinics will need to be sought from their GP or specialist. Attempts will be made to trace those lost to follow-up. In order to avoid bias and to enable an accurate assessment of overall outcomes, the applicants wish to use data from all patients within the cohort, if they have been lost to follow-up.

The request for support is designed to cover a further 10 year follow up on patients from the East London newborn cohort. This will include clinicians updating in respect of patients who are still under the care of the Royal London Hospital (out of scope of the support request), requesting information from clinicians for those patients who have moved to other hospitals for their treatment (support to cover the processing of the information) and attempts to locate patients who are lost to follow-up through contacting GP surgeries.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities defined within the application.

Confidential Patient Information Requested

Access was requested to the following items of confidential patient identifiable information for the purposes advised:

- Name – identification/verification,
- NHS Number – identification/verification,
- Hospital ID No- identification/verification,,
- GP Registration – identification/verification,
- Date of birth – identification/verification and analysis (applicant advised that this can be converted to MM/YY format if CAG require),
- Date of death – identification/verification and analysis (applicant advised that this can be converted to MM/YY format if CAG require),
- Postcode – analysis,

- Gender – analysis,
- Ethnicity – analysis.

The cohort is all patients added to the East London newborn cohort with sickle cell disease, found during the universal newborn screening, from its establishment in 1983. The established cohort is 396 patients; however, there will be additional patients who were added from 2007 (date of last analysis) onwards, who will also be followed up.

Confidentiality Advisory Group Advice

Public Interest

The CAG were satisfied that the application described a clear medical purpose through undertaking follow-up on an established and rich data resource which was in the public interest due to this being a poorly defined gene disorder.

Practicable Alternatives

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

- Feasibility of consent

The CAG considered the rationale which had been put forward by the applicants around the feasibility of consent and whilst it was acknowledged that consent was not possible for those patients who were lost to follow-up or deceased, the rationale was not supportive of those patients who were still under the care of the applying organisation. Members appreciated that complete ascertainment of the cohort was important to ensure the reliability of the data resource and to remove any bias. The CAG agreed that further information was required from the applicants to support the rationale for not consenting the patients within their care and it was commented that this could be achieved via a meaningful patient engagement programme, notification and objection mechanism, which is picked up later within the application.

- Use of anonymised/pseudonymised data

Members were satisfied that access to confidential patient identifiable data was required to enable the data linkage required to achieve the project aims.

Reduction of Identifiers

The CAG acknowledged that the applicants were anonymising data received from other sources at the first available point, which was at transcription. In response to queries which were raised by the CAT ahead of the meeting, the applicants had confirmed that it would be possible to truncate date of birth and death to month and year format for analysis to reduce the identifiability of the research dataset. Members agreed that this was an appropriate measure and this would be added as a condition of support.

Members also requested that the postcode be redacted in the research dataset to the lower-layer super output area (LSOA) to further reduce the identifiability of the dataset.

Exit Strategy

Members noted that the application form stated that study data would be retained for 10 years; however, the protocol stated 20 years and it was agreed that clarification was required around this contradicting information.

Patient and Public Engagement and Involvement

The CAG commented that this was likely to be vocal patient group that would appreciate involvement and engagement around their disease. It was commented that there was an established cohort, the majority of whom remained under the care of the applicants who could be readily approached about the project. Members requested that meaningful patient engagement be undertaken to test the acceptability of using patient data without consent as described in the project and a report provided to support the project.

The CAG further suggested that the Sickle Cell Disease charities could be utilised to further support the project.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was noted at question 15-2 of the application form that the applicants had reported that there was no dissent from the patient cohort received at the point of the previous follow-up study; however, Members commented that the information provided did not articulate whether a meaningful dissenting process had been offered during this project. Members agreed that a meaningful dissent mechanism must be provided for this proposal and it was agreed that feedback would be required on how this would be managed ahead of any recommendation of support.

The CAG acknowledged the proposal made by the application around the publication of a newsletter in which the project cohort would be a standing item and it was agreed that this appeared to be a useful tool to promote the project. It was agreed that feedback was required around the scope of the newsletter following the network meeting which the applicant had referenced in correspondence.

The Committee understood from the application that the majority of the cohort to be included were still attending follow-up at the Royal London Hospital so there was potential for study posters to be displayed in clinics to promote the project.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

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

Request for Further Information

1. Clarify how long study data will be retained for to address the contradictory information between the application (10 years) and the protocol (20 years).
2. Undertake patient involvement and engagement around the proposal and provide evidence of the outcomes of this activity to provide support for the application.
3. Patient Notification and Objection:
4. Provide further information around the proposed newsletter together with feedback from the recent network meeting,

5. Plan wider patient notification mechanisms and provide detail of what additional activities will be undertaken in this area,
6. Plan a meaningful dissenting system and provide information around how this would be operated and any objections respected.

Specific Conditions of Support

1. Reduction of Identifiers – the date of birth and death should be truncated to month and year format, and postcode should translated to lower-layer super output area within the research dataset.
2. Favourable opinion from a Research Ethics Committee. (Received – 08 March 2017)
3. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (Confirmed – Version 13, 2015-16, reviewed satisfactory grade at 76%).

6. MINUTES OF THE MEETING HELD ON 23 FEBRUARY 2017

It was noted that the minutes of the last meeting held on the 23 February 2017 were not yet available for consideration.

7. CAH CHAIR REPORT

A report from the Chair was received and noted.

8. CAG OFFICE REPORT

Processing information in Northern Ireland – security assurance gap

A recent issue has arisen via precedent set review where the applying organisation was based in Northern Ireland and intending to process information under support at this location. Entities processing confidential patient information under support are required to provide evidence of satisfactory security assurance. In England this is via Information Governance Toolkit submission. In Wales, a process has been developed where NHS Wales Information Services (NWIS) will provide assurance to CAG for those entities that follow the Caldicott Principles into Practice (CPiP) toolkit. This is the Welsh equivalent of the English IG Toolkit. It took approximately two years for this Welsh equivalency to be established through assessment, a formal memorandum of understanding and the results moving into practice. This issue regarding Northern Ireland was flagged with DH at the time but there has been a change of staffing and it is not anticipated this will be the highest priority for some time. The applicant has been strongly advised to seek to move the processing to an English site as the data will be collected at Moorfields, or to discuss further with the NI equivalent to DH.

National Data Guardian recommendation to HRA

In September 2016, the HRA published its formal response to the National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs Public Consultation. This report set out the following under recommendation 17:

"The Health Research Authority should provide the public with an easily digestible explanation of the projects that use personal confidential data and have been approved following advice from the Confidentiality Advisory Group".

As part of its Transparency agenda, the HRA ensures that all research applications have a research summary published within 3 months on the HRA website.

The Register of Approved applications is a statutory requirement and currently lists all those applications that have received a positive decision to process confidential information without consent from the relevant body. It consists of four separate Excel spreadsheets (advice provided by PIAG, advice provided by NIGB ECC, CAG advice for research, CAG advice for non-research). The current fields cover:

- Title and reference(s)
- Full contact details of the applicant
- Summary of the overall project
- The cohort the processing of information without consent relates to
- The confidential patient information to be processed
- Any specific conditions of support that restrict the scope of the processing
- Status.

In comparison to other existing approval bodies (e.g. ISAC, DAAG, PHE), while there are limitations using excel the Register provides more comprehensive detail than all of the other approval bodies where it relates to decisions to disclose and receives approximately 800 views per month. There have been no operational issues raised in feedback from applicants in relation to the current Register.

While there are always opportunities to improve what is presented on the website, these decisions are taken in a broader organisational context. Previous feedback from members in 2016 indicated a wish to include a section on public benefit, and the majority view was that the Register was broadly sufficient for its purpose. The HRA will be assessing where the Register is sited with a view to making it easier to locate, and will provide greater clarity on the Register and how it should be used through supporting text. This will be discussed with DH as part of the early sight of the response to the Report.

<u>CAG PPI event feedback</u>

Feedback will be gained from the recent CAG PPI event through issuing a survey via Survey Monkey to those patient representatives and stakeholders. Those members who attended have been asked for their views on what they would like to be included in the feedback questionnaire. Once collated, this will be fed to the QA team and results will be shared with CAG via the office report once received and synthesised.

<u>HRA - Service Improvement Update.</u>

Our Acting Chief Executive, Teresa Allen, has a new Service Improvement Programme (SIP) to create an even more effective HRA. The programme will be shaped and delivered by colleagues across the HRA, looking at our performance, our culture and our leadership, including:

- the service we provide to stakeholders
- the kind of workplace we want
- how we work across teams and with partners.

Part of this is a major programme of work to move HRA Approval from a programme to be integrated as part of business as usual. The initial focus of this detailed work will engage the Research Ethics Service and HRA Approval teams to move towards a more integrated service for applicants, taking into account the complexities of working across four nations. As the number of applications considered by the CAG is significantly smaller than the thousands considered by RECs and HRA Approval, the CAT is involved to ensure key changes take positively into account any implications for the CAT and CAG processes, with the understanding that the CAT will be involved as the project moves into its phases and work streams.

Business functions attended a four-day workshop to look at the various business areas of the HRA to identify duplicated steps and to establish where 'waste' took place and those steps that added genuine value. This workshop was also attended by researchers who provided valuable perspective and challenge to proposed projects, and helped to ensure focus remained on what was important to the HRA biggest customers; applicants. The website is undergoing a detailed project review and new platform to ensure it is tailored to its key customers as the HRA moves forwards.

Planning for potential social care work

Members are aware that the remit of the CAG was amended to include social care information. There has been an organisational concern that the demand for this type of information is unknown and to advise on this areas may require the CAG function to be provided with more resource. In accordance with standard bidding process, a bid was developed for potential budget and resources that may be required in light of the inclusion of social care information within the CAG remit. The estimation was based upon the costs considered when the need for the second CAG meeting (Manchester) was developed, in light of the predicted volume of work anticipated to arise from NHS Digital in relation to the CAG role to advice under the Care Act 2014.

Development of Register within HARP

A recent meeting took place to discuss integrating the Register within the internal HARP system. The HARP system is a system developed through the Research Ethics Service to manage their research applications. An initial platform in HARP was developed for CAG purposes however it comes with limitations such as not catering to non-research applications, CAG-specific amendments and annual reviews. The specification originally developed is over a year old and a review was undertaken to assess the utility of the original specification as there planning for technical updates is handled through a managed and stringent process. It was noted that as all CAG application activity is not on HARP that even if the existing Register transferred to HARP, updates would require a two tier system. There has been a suggestion that the Register should follow the existing HRA Research Summaries however, this has been pushed back as the research summaries require an enquirer to know what they are looking for, and the results cannot be downloaded or taken away for further review. The perspective is that while the existing Register is 'clunky' that its current format provides clear access to all applications considered by the CAG and its predecessor bodies and reversion to a different format, viewable solely via web-based format, would make the current accessibility more opaque. The initial steer is to ensure the current HARP system meets the CAG-specific requirements and to work to ensure these are all integrated onto HARP first.

Operational update

Precedent set review

1. Update on progress and work

The purpose of the review is to clarify and update the Precedent Set Review Process in line with recent trends and developments, reflecting member feedback and responding to common themes and issues which have manifested in the applications recently submitted via the Precedent Set Process. The full review will be complete by the end of March and will be presented at the Away day in April, for member feedback. Any CAG comments will be added and the documents taken to the Confidentiality advice Management Board for final approval before being published.

The review will comprise the following 3 documents:

1. Precedent Set Review Process for Members (internal document)
2. Precedent Set Review Process for Staff (internal document)
3. Precedent Set Review Process (external document).

The first document has been completed and circulated amongst the Chair team, and further changes made in line with Chair comments.

Once Chair review of this document is complete it will be circulated amongst Members for further feedback and the finalised document should be approved and implemented in early April.

The Precedent Set Review Process for Staff is in progress and will be discussed within the CAT in the first instance.

The Precedent Set Review Process document is being produced to replace the document which is currently on the external HRA website. This document will be presented to the CAG for feedback at the Away Day on the 5 April.

9. ANY OTHER BUSINESS

No further business was noted.

The meeting was closed.